



The Digital Institute for Cancer Outcomes Research
participation to the Horizon Europe Research
and Innovation Action:

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

DIGICORE leads the WP5: Digital tools for data collection

Objectives

In order to allow digital collection, storage and sharing of QoL data, the WP aims at providing:

- A web-based platform for data collection of the pilot survey, including PROMs.
- A web based App (WebAPP) integrated with the web-based platform, for the collection patient reported data, including the EUonQoL-Kit, through mobile devices of in all the languages of participating countries.
- An open access module of the digital platform for customizable data visualization and download to allow widespread dissemination of the pilot survey results to stakeholder, including patients and citizens.
- Module of the web-based platform for spontaneous data HRQoL data by patients, subsequent the pilot survey.

Participants involved in the WP5

Digital Institute for Cancer Outcomes Research - Leader

Region Hovedstaden - Hillerød

Fondazione IRCCS Istituto Nazionale dei Tumori - Milan

European Institute of Oncology - Milan

European Cancer Organisation - Brussels

Istituto Nazionale Tumori G. Pascale - Naples

Alleanza Contro il Cancro - Italy

Istituto Tumori Regina Elena - Rome

Stichting Nederlands Instituut voor Onderzoek van de Gezondheidszorg - Utrecht

Description of work

A digital platform will be made available to host the collection of patients reported and clinician reported data. The EUonQoL-Kit will be administered to patients in the pilot study through the use of mobile devices through a web application (webAPP) allowing a direct patient-to-database collection of data. Data governance will address data ownership and responsibility throughout the life cycle, and consider the design, operation and monitoring of processes/systems to comply with the principles of data integrity including control over intentional and unintentional changes to data. A detailed diagram and description of the transmission of electronic data will be available. It will be described which data will be transferred and in which format, the origin and destination of the data, the parties with access to the transferred data, the timing of the transfer and any actions that may be applied to the data, for example, data validation, reconciliation, verification and review.

Task 5.1 ICT platform for QoL data collection and data sharing

The ICT platform for QOL data collection in this WP will interact with the National Cancer Institute of Naples/Alleanza Contro il Cancro platform for collection and storage of clinical reported data through electronic CRFs and possibility of remote data management according to quality standards required by regulatory authorities. All the process will be accessible in all participating countries. Privacy and cyber-security will be guaranteed. The platform uses open-source technologies and made available to the community.

The work will be planned as follows:

- 1) choice of the main technologies for the development of the platform, languages, databases and operating systems;
- 2) choice of infrastructure (e.g., hardware, server, backup and restore systems, security systems, connectivity);
- 3) planning of the modules and steps of the development;
- 4) development of the modules including user interface;
- 5) testing;
- 6) production of ready-to-use version.

The platform language is English, which means that investigators will receive an English user manual and will have an English interface. Data collected at national level will be automatically integrated in a unique database for storage and analysis. The platform will have a module to export collected data in processable files, by both automatic report operations (for frequent reports) or by a software of database interrogation (for complex and specific report). Data export will be available in English.

Methodology of data analysis will be defined in the study protocol and files for analyses will be provided as required according to what planned.

Task 5.2 Development of a webApp for the collection of patient reported data

Using a co-design approach as indicated by WP1 and including end users (patients) as co-researchers, a web-app for mobiles will be developed to collect the EUonQoL-Kit data as well as any other patient reported data to be collected during the pilot survey carried out in WP6.

Patients will perform the data collection in the hospital through tablets dedicated to the study. The webApp will have a secure access for the investigator that in turn will give access to the patient by an individual study code that will the data linked to the patient electronic file in the study platform. The App will be available in each national language and will have a user-friendly interface.

The WebApp will also be integrated with the CAT software for the administration of questionnaires based on live CAT. A user manual including plain language use instructions will be provided.

Task 5.3 Implementation of CAT

CAT based short-forms (based on the work in WP3), will be integrated into the web-based PRO collection flow, within the pilot study. A 'live CAT' will be integrated in the web-app operating and will be implemented as test in 10% of patients involved in the pilot survey after the 'ordinary assessment'

for validation purposes. Live CAT will take place by establishing a connection of the web app to an outside server, through a data retrieve session that acting as interface for the CAT engine, pass it the information needed to elaborate the next patient question.

Task 5.4 Visual graphic of results

Computing tools will turn QoL data into visual graphics. To ensure such tools and techniques are effective and appropriate for use, they will be developed through close collaboration between multidisciplinary scientists and computer scientists as well as other stakeholders including patients in collaboration with WP1.

A set of algorithms will be incorporated in the developed digital technologies and infrastructures, to process and analyze the datasets generated according to a number of different requests, to extract information on realworld monitoring of patient QoL and transform them into visual graphics. These tools will be accessible to investigators through the web platform in this WP, and an open access web platform will be also implemented.

Task 5.5 Web-based platform module for spontaneous HRQoL data collection by patients using the EUonQoL-Kit

To allow the collection of QoL data based on voluntary participation of patients across EU27, a version of the webApp open to anonymous participation and compatible with several devices (mobile, desktop, public totems) will be provided.

All the principles and technologies reported above will be applied. The app will be GDPR compliant.