

# EUonQoL: measuring what matters for cancer patients and survivors in Europe

## Project overview

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# Conflict of Interest disclosure

I do not have any actual or potential conflict of interest in relation to this presentation.

# Talk outline

- The «origins» of the project
- Project overview
- The pan-European pilot survey

# Patient quality of life and cancer care

- Survival, recurrence as well as other clinical and process indicator are relevant cancer care outcomes
- However patient-centred outcomes, such as health-related quality of life (HRQoL-PROMs), functional impairment, pain, psycho-social aspects, experience of care, are factors of great significance for patients.

# Patient quality of life and cancer care

Clinical trials and real-world data have shown the positive effects of routine PROMs assessment on patient wellbeing, use of health care resources and on survival.

Kotronoulas 2016 - Basch 2016, Denis 2017 - Lizée 2019  
BarberaL JOP 2020, BarberaL Cancer med 2020, BarberaL BMJ SUPP Pall Care 2020  
Fjell 2020, Absolom 2021, Maguire 2021 Mir 2022, Basch 2022

## ....but

- full implementation of **QoL assessment** in routine oncology practice **is not yet part of standard of care.**
- health care systems and cancer control programs **do not take into consideration QoL outcomes** when devising clinical, societal, and healthcare policymaking systems.

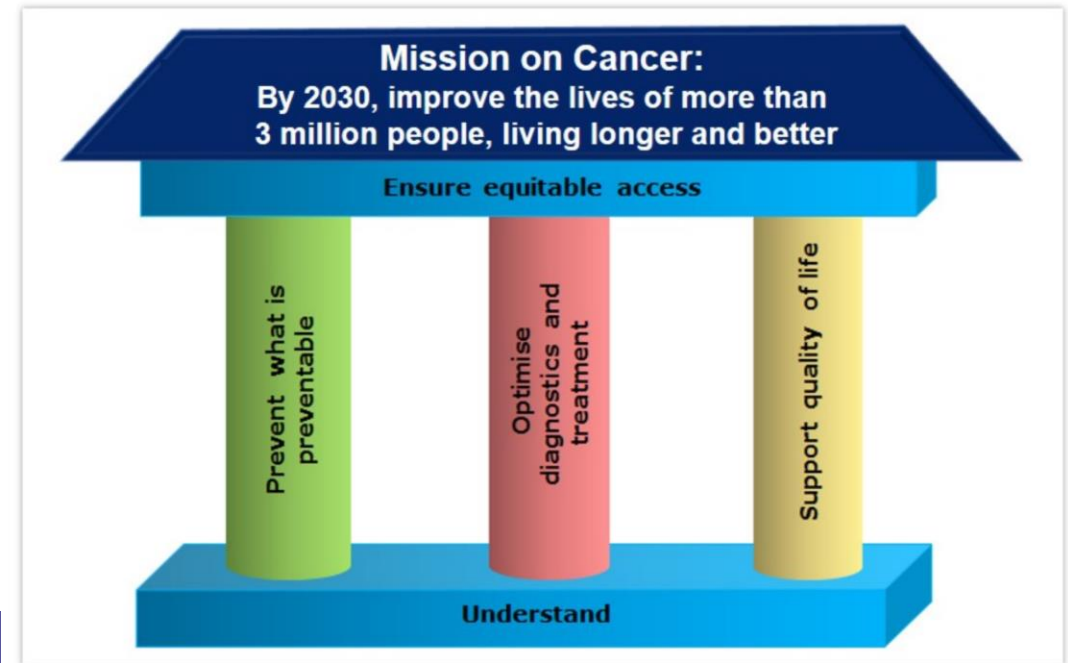
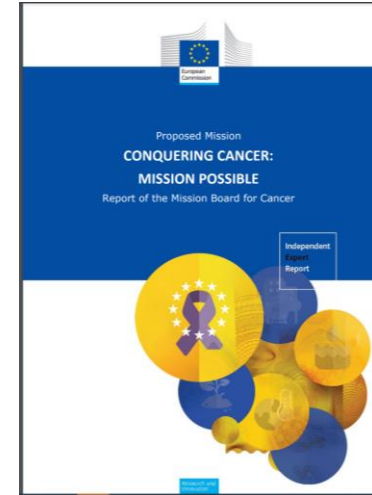
# OEI Cancer Outcome Research Working Group

The main aim of the COR-WG is to respond to this need and establish and coordinate a network of clinical cancer centers adopting common procedures for the routine collection and sharing of PROM data.

**EUonQoL project constitutes the first step in this direction**

# Mission on cancer & QoL

In parallel with prevention and treatment of cancer, the **improvement or preservation of patients quality of life** is one of the three pillars of the EC Mission on Cancer.





# OEI Cancer Outcome Research Working Group

OEI Working Groups

**OEI One-Shot Project**  
**OEI initiative on strategies of implementation of PROMs and PREMs in oncology clinical practice, research & benchmarking**

**Giovanni Apolone<sup>1,2</sup>, Cinzia Brunelli<sup>1</sup>, Alice Gallivanone<sup>1</sup>, and Augusto Caraceni<sup>1</sup>**  
1. Fondazione IRCCS Istituto Nazionale Tumori- Milano  
2. Organisation of European Cancer Institutes



Chairperson

**Cinzia Brunelli**

Outcome research has been defined as the study of the final results of health care interventions, and is aimed at providing all stakeholders the scientific evidence to base their decisions. Clinicians have to select effective and non-harmful treatments for their patients, policy-makers are interested in identifying cost-ineffective interventions/services, while patients need to make informed treatment choices.

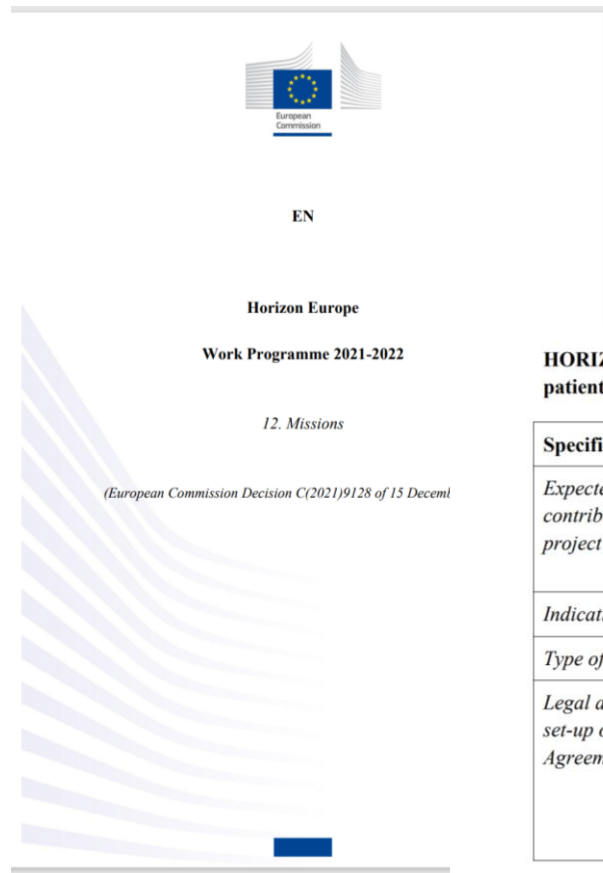
## A step forward PROmics

**Cinzia Brunelli<sup>1</sup>, Giovanni Apolone<sup>1</sup> and Augusto Caraceni<sup>1</sup>**  
1. Fondazione IRCCS Istituto Nazionale dei Tumori di Milano



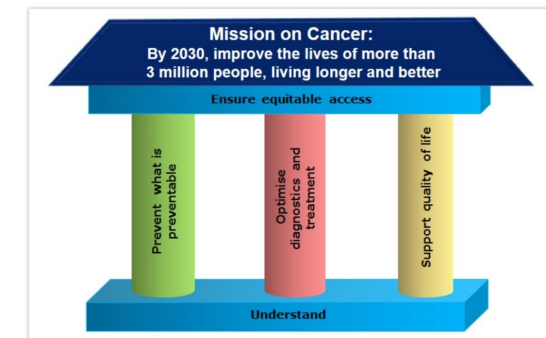
# HORIZON-MISS-2021-CANCER-02-02

Develop and validate a set of quality of life and patient preference measures for cancer patients and survivors



## HORIZON-MISS-2021-CANCER-02-02: Develop and validate a set of quality of life and patient preference measures for cancer patients and survivors

Specific conditions	
<i>Expected EU contribution per project</i>	The Commission estimates that an EU contribution of around EUR 11.00 million would allow these outcomes to be addressed appropriately. Nonetheless, this does not preclude submission and selection of a proposal requesting different amounts.
<i>Indicative budget</i>	The total indicative budget for the topic is EUR 11.00 million.
<i>Type of Action</i>	Research and Innovation Actions
<i>Legal and financial set-up of the Grant Agreements</i>	The rules are described in General Annex G. The following exceptions apply: Beneficiaries will be subject to the additional access rights: The selected beneficiaries must provide the results from the survey, including validation of the metrics, within two years from the start of the project for the purpose of developing EU policies and



<sup>97</sup> Especially through the 'European Guidelines and Quality Assurance Schemes for Breast, Colorectal and Cervical Cancer Screening and Diagnosis', and the 'European Cancer Information System (ECIS)', see [https://knowledge4policy.ec.europa.eu/cancer\\_en](https://knowledge4policy.ec.europa.eu/cancer_en)  
<sup>98</sup> <https://eithealth.eu/who-we-are/>  
<sup>99</sup> <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32021R0694&qid=1623079930214>

# EUonQoL project

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

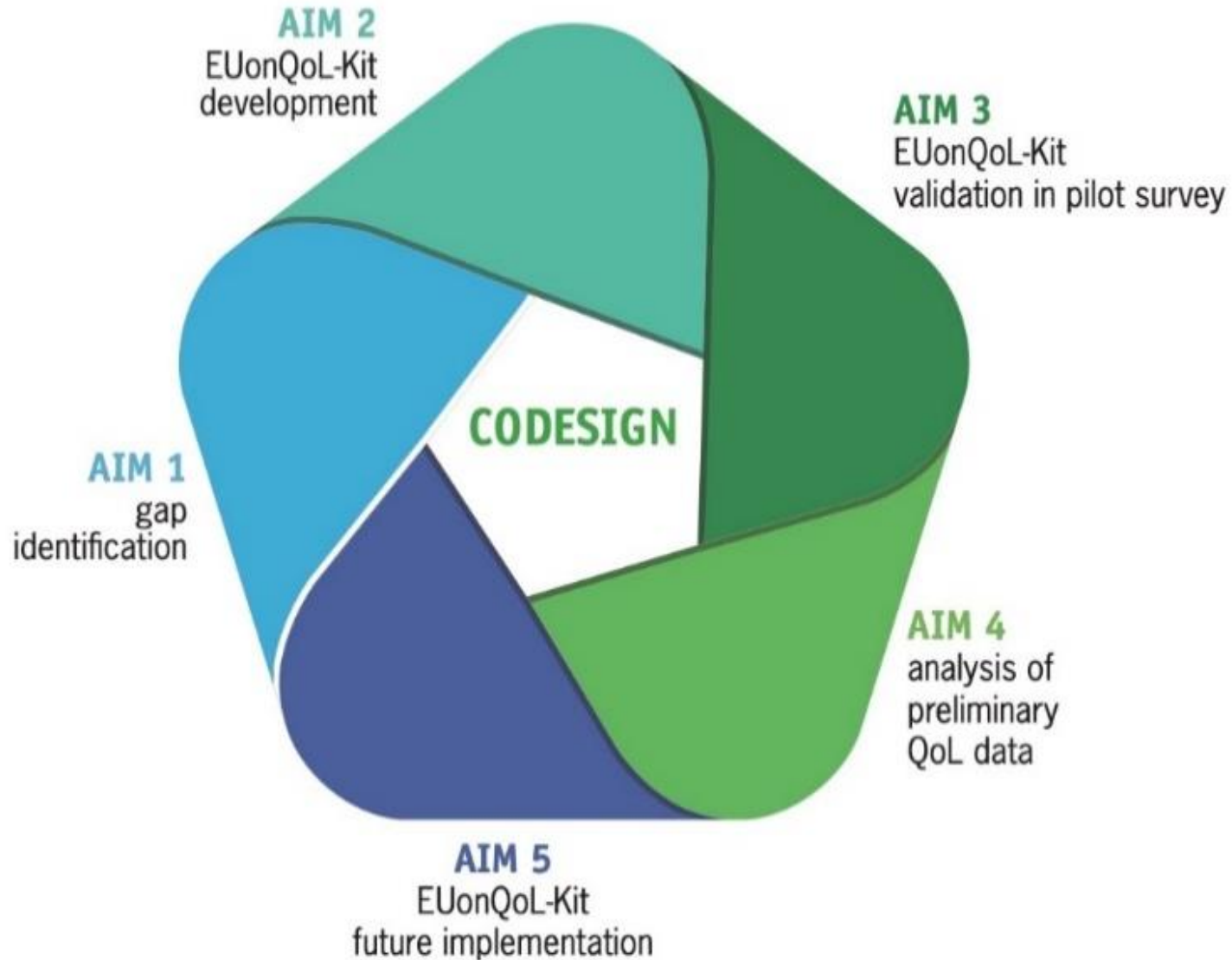
Is aimed at developing, validating and disseminating the European Oncology Quality of Life toolkit (EUonQoL-Kit) among European cancer patients and survivors.

# The EUonQoL – Kit

It will be a **new unified system for the self-assessment of quality of life** in cancer patients undergoing treatment, in cancer survivors and in patient palliative care phase. It will be:

- developed from the patient perspective
- available in several European languages
- Available in static and dynamic versions (computer adaptive testing)
- digitally administrable
- psychometrically sound
- applicable in future periodic surveys for health policy intervention evaluation

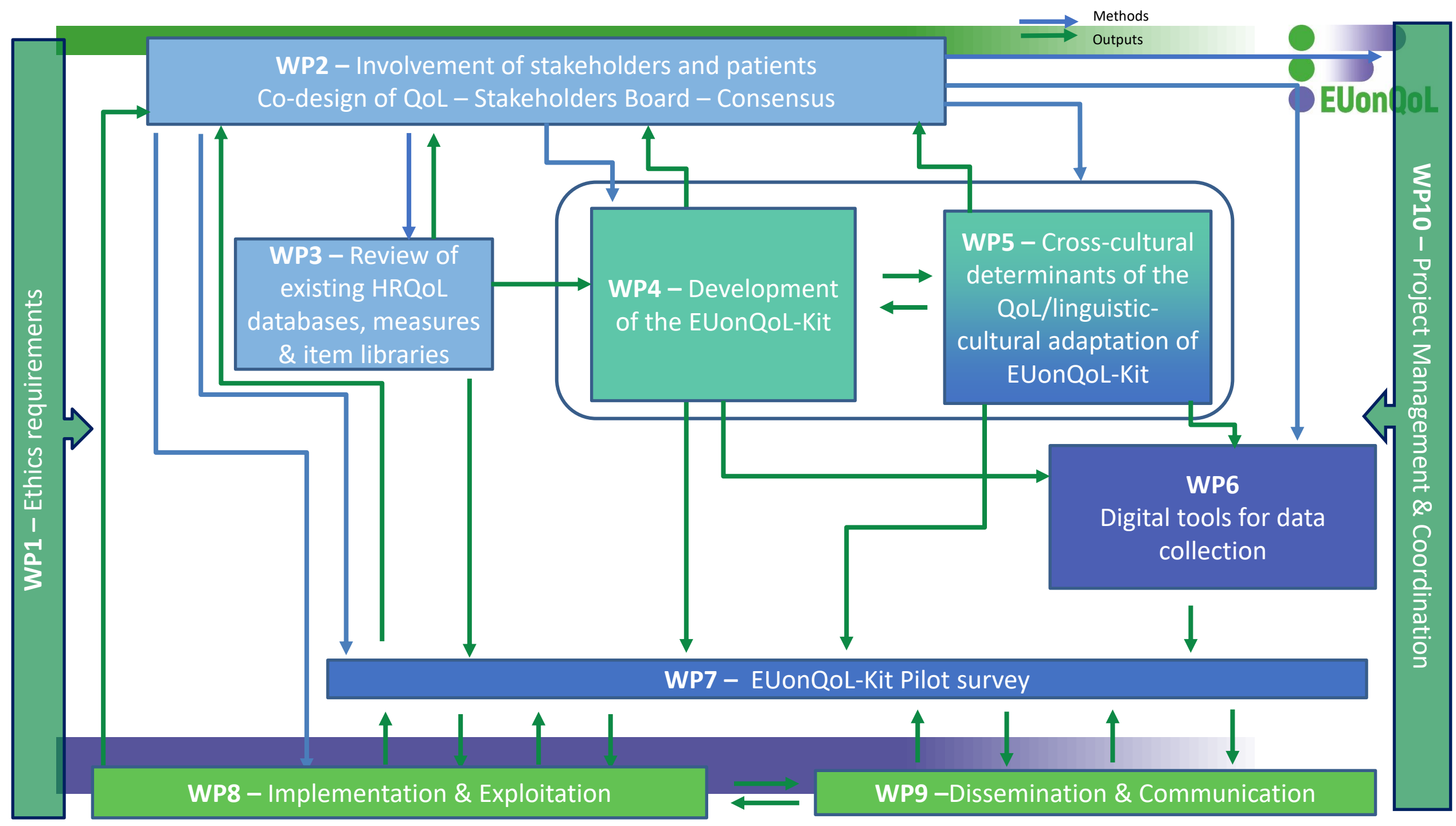
# EUonQoL objectives



# Participatory research

The overall project will be based on participatory co-design research principles through the involvement of a representative panel of stakeholders, including patients and their caregivers.





WP Title	Lead and co-lead Participants
<b>WP1</b> Ethics requirements	INT
<b>WP2</b> Involvement of stakeholders and patients	NIVEL/ECO
<b>WP3</b> Review of existing HRQoL databases, measures & item libraries	EORTC/IMIM
<b>WP4</b> Development of the EUonQoL-Kit	UNIVLEEDS/UMIL
<b>WP5</b> Cross-cultural determinants of the QoL and linguistic and cultural adaptation of EUonQoL-Kit	IEO/SPOREDATA
<b>WP6</b> Digital tools for data collection	DIGICORE/RH
<b>WP7</b> EUonQoL-Kit Pilot Survey	INT/OECI
<b>WP8</b> Implementation/Exploitation	OUS/UNICANCER
<b>WP9</b> Dissemination/Communication	OECI/ECO
<b>WP10</b> Project Management/Coordination	INT



# EUonQoL consortium



## Coordinator

Fondazione IRCCS Istituto Nazionale dei Tumori (INT), Milan, Italy

## 13 Countries 26 Partner/Affiliated/Associated Partner

Austria	Medical University of Innsbruck (MUI)
Belgium	Digital Institute For Cancer Outcomes Research (DIGICORE)
	European Organisation for Research and Treatment of Cancer AISBL (EORTC)
	European Association of Palliative Care (EAPC)
	European Cancer Organisation (ECO)
	Organisation of European Cancer Institutes (OECI)
Bulgaria	Association of Cancer Patients and Friends (APOZ)
Denmark	Region Hovedstaden (RH)
Estonia	Sporedata OÜ (SPOREDATA)
France	Institut Curie (CURIE)
	Institut Gustave Roussy (GR)
	Unicancer (UNICANCER)
Germany	Deutsches Krebsforschungszentrum Heidelberg (DFKZ)
Italy	Alleanza Contro il Cancro (ACC)
	Federazione Italiana delle Associazioni di Volontariato in Oncologia (FAVO)
	Istituto Europeo di Oncologia (IEO)
	Istituto Nazionale Tumori Fondazione Pascale (INT-NA)
	Istituti Fisioterapici Ospitalieri (IFO)
	Universita Degli Studi di Milano (UMIL)
Norway	Oslo Universitetssykehus Hf (OUS)
Romania	Asociatiilor Bolnavilor de Cancer (FABC)
Spain	Fundacio Institut Mar d'Investigacions Mediques (IMIM)
The Netherlands	Stichting Het Nederlands Kanker Instituut-Anton (NKI)
	Stichting Nederlands Instituut Voor Onderzoek Van De Gezondheidszorg (NIVEL)
United Kingdom	University of Leeds (UNIVLEEDS)
	Leeds Teaching Hospital Trust's (LTHT)

# Project Data

- Starting date: 1 January 2023
- End date: 31 December 2026
- Duration: 48 months (M24 tool validation)
- Total cost including UK: € 10.999.810,76
- EU financial contribution: € 10.607.311,00
- Number of beneficiaries: 24
- Number of affiliated entities: 3

## *Pilot survey participants*

- Number of beneficiaries involved in the pilot survey: 10
- Number of other cancer centres: 35

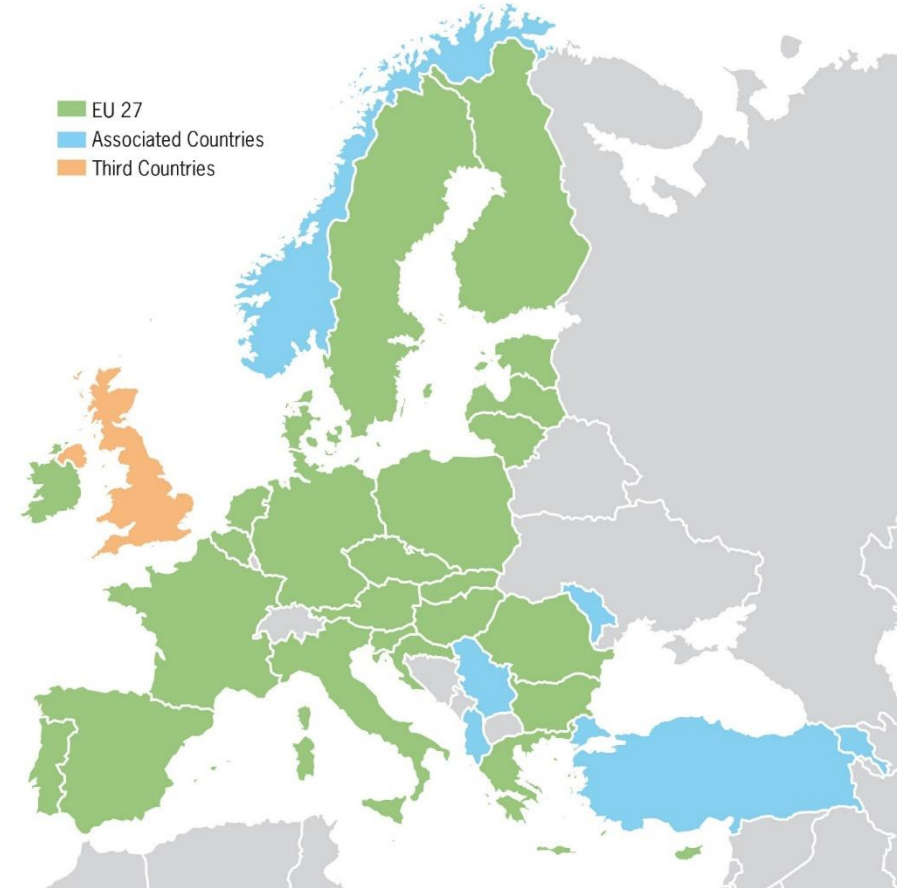
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# EUonQoL-Kit

## pan European pilot survey.

An overall sample of 4,000 among cancer patients in treatment, cancer survivors and patients in palliative care phase, will be enrolled in a cooperative network of European cancer centres



# Study objectives

**Primary** To assess **validity** and **reliability** of the EUonQoL-Kit among cancer patients and survivors in Europe (psychometric validation)

# Study objectives

## Secondary

1. Assess the acceptability of the EUonQoL-Kit and reasons for refusal, including patient burden in filling in the questionnaire
2. Validate the Computer Adaptive Testing (CAT) version of the EUonQoL-Kit
3. Provide estimates of QoL across different European countries
4. Analyse socio-demographic and clinical factors potentially associated to QoL in European cancer patients and survivors
5. Analyse QoL inequalities across clusters of populations, countries, and healthcare systems

# Study design



Observational multicentre cross-sectional study, focused on the validation of the newly developed EUonQoL-Kit.



# Study population

Patients in one of the following conditions:

A. In treatment

B. Survivors

C. In need of PC

Detailed definitions  
are provided

# Eligibility criteria

## Inclusion

- Age 18 years or more
- Present or past histologically confirmed diagnosis of solid tumor or haematological malignancy
- Being in one of the 3 conditions:
  - A) In treatment; B) Survivors; C) In need of PC
- Written informed consent to the study

## Exclusion

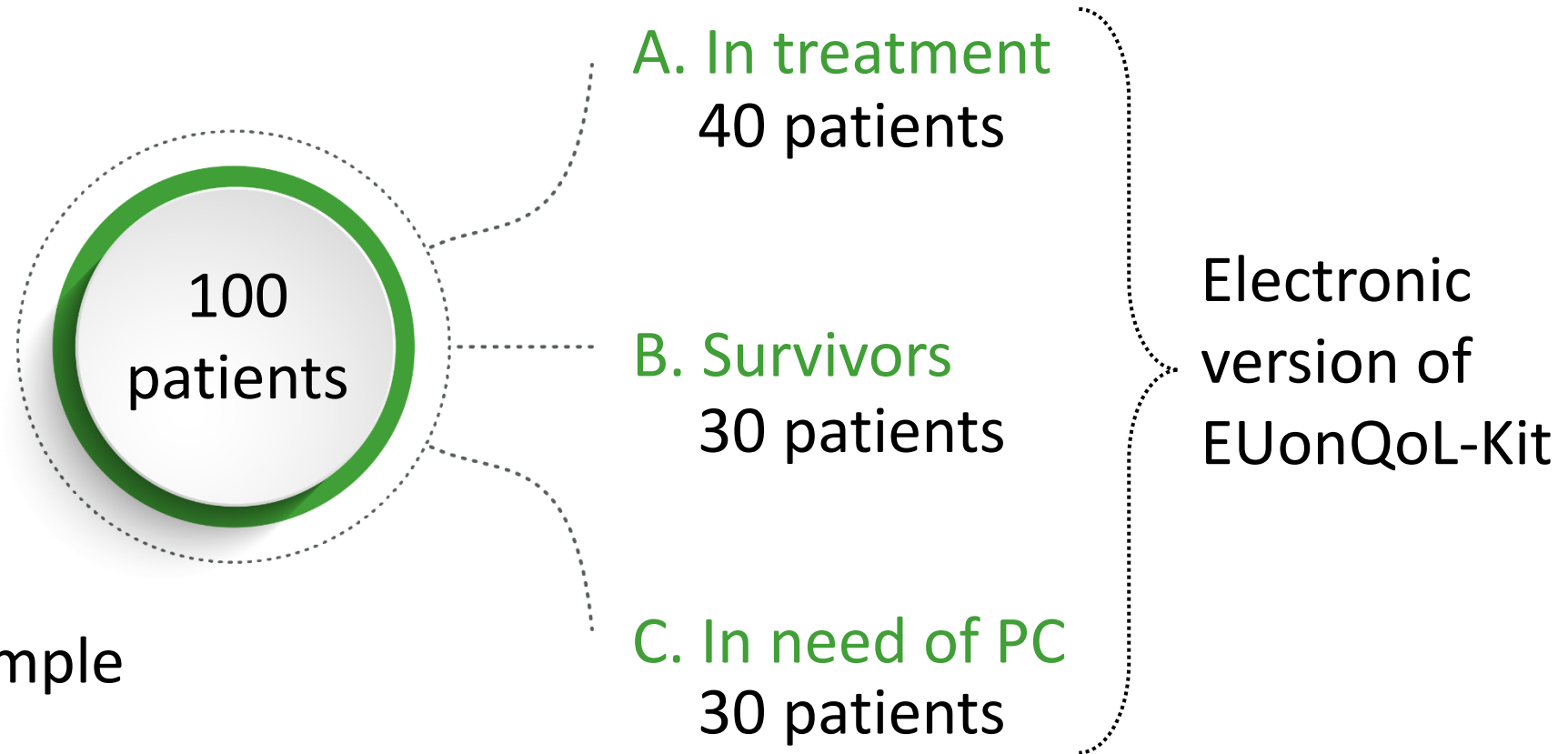
- Cognitive impairment preventing the completion of the questionnaire

# Study procedures

## Patient recruitment

Each centre will recruit 100 patients with pre-defined sub-groups

(at least 40 centres for expected minimum sample size of 4.000 patients)



# Where are we now

- Kick-off meeting on January 2023
- First investigator meeting end February 2023
- Preparatory tasks ongoing (agreements, ethical approvals...)
- Ad hoc preparatory meetings with centres will start from Autumn 2023.



Measuring what matters for cancer patients and survivors in Europe

[www.euonqol.eu](http://www.euonqol.eu)

## Our ambition



The project is aimed to contribute to the EU initiatives against cancer, by developing the European Oncology Quality of Life Toolkit (EUonQoL-kit), a patient-centred unified tool for the assessment of quality of life among cancer patients and survivors.

[Read more >](#)

## The EUonQoL- kit



The EUonQoL-Kit is a set of questionnaires, specifically designed for the self-assessment of quality of life at different disease phases, characterized by innovative features.

[Read more >](#)

## The partners



The EUonQoL project is based on a European network of research institutions, cancer centres, as well as scientific, professional, and patient representative organisations with the most relevant expertise in the field of quality-of-life research.

[Read more >](#)

- Availability EUonQoL-Kit will be a system to identify patient needs and assess the impact of health care policies.
- Implementation and results dissemination through a wide stakeholder network will likely promote the routine use of PROMs in clinical practice.
- Routine collection of PROMs data will add patient perspectives within multi-omics personalized oncology (... PROMICS), ultimately constitutes an important new opportunity in the progress toward patient-centred care.



# The working group



**Thank you for your attention**



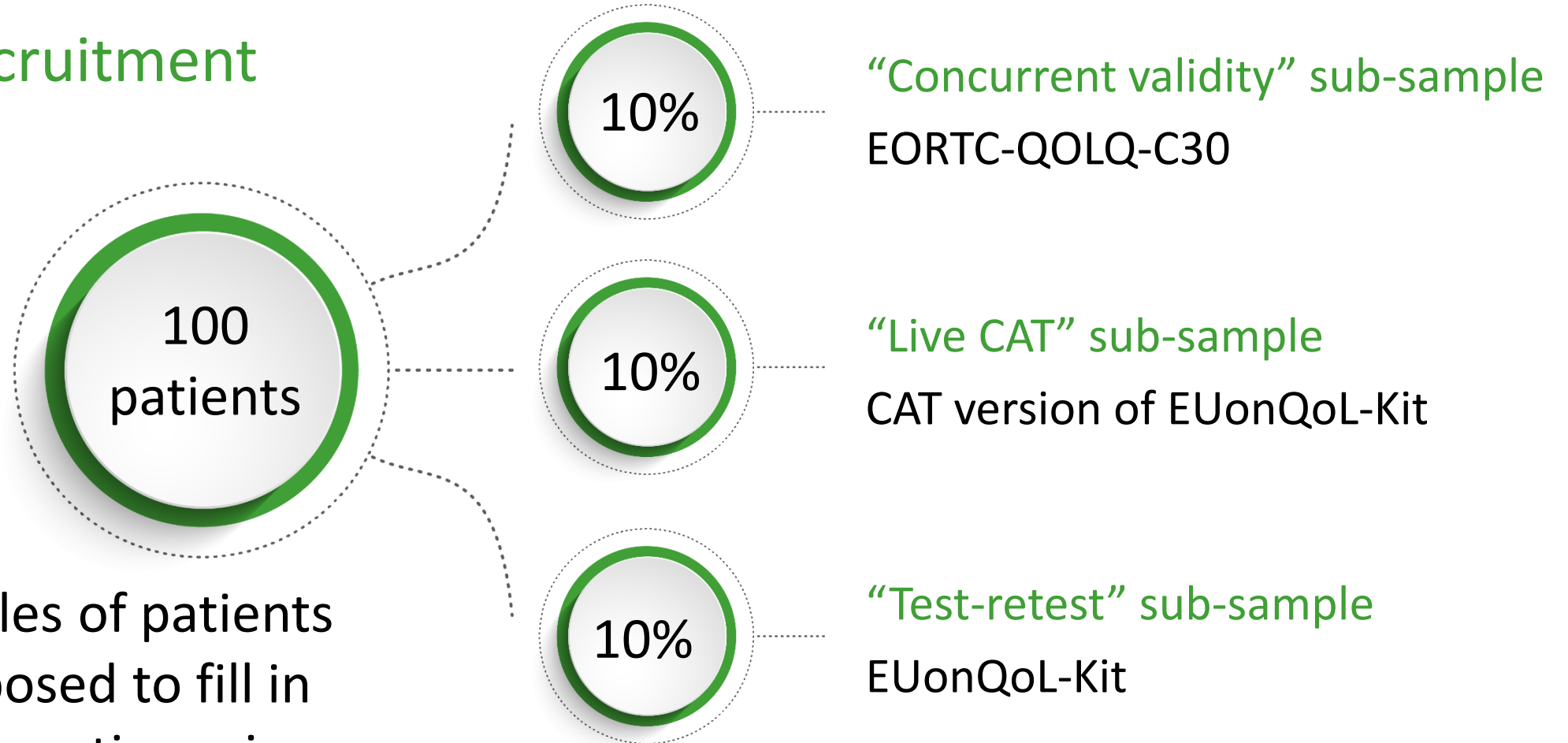
This project received funding from the European Union  
Horizon Europe Research and Innovation Programme  
Grant Agreement N. 101096362





# Study procedures

## Patient recruitment



3 sub-samples of patients will be proposed to fill in *additional* questionnaires