

# Validation of the European Oncology Quality of Life Toolkit (EUonQoL-Kit). A European cross-sectional survey.

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## Study protocol

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Luana Caselli  
Fondazione IRCCS Istituto Nazionale Tumori- Milano

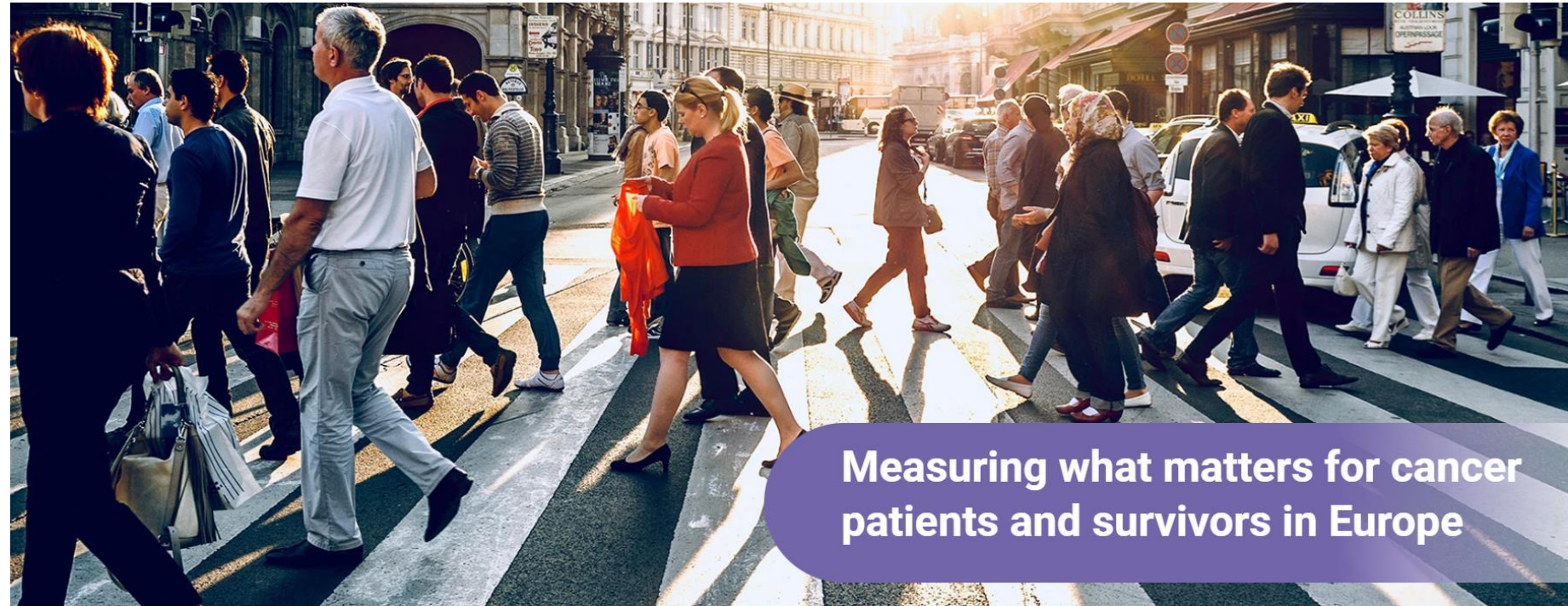
EUonQoL - WP7  
Leader INT - Coleader OEI

# The EUonQoL project

EUonQoL-Kit



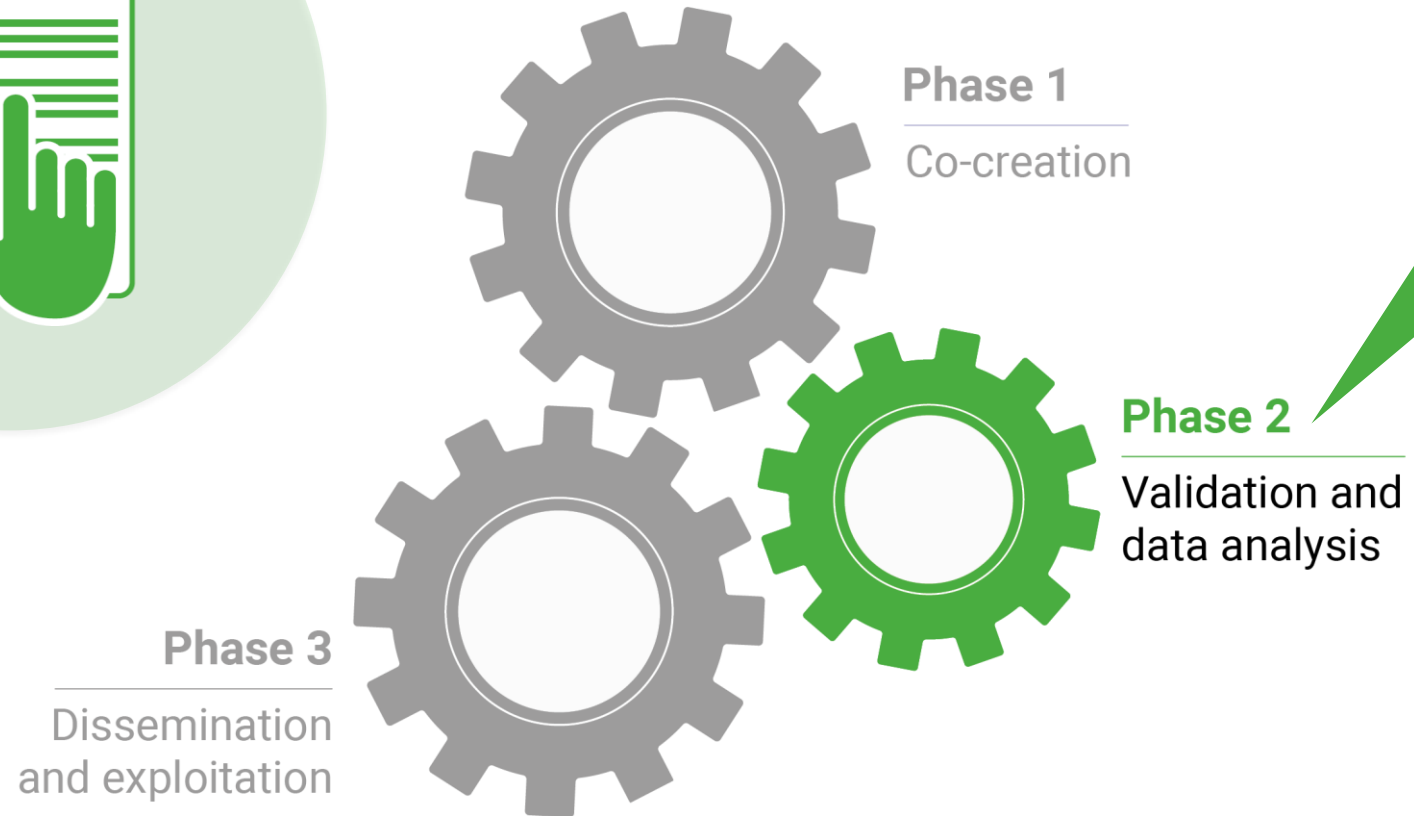
**Goal:** to develop, validate and disseminate the EUonQoL-Kit for the assessment of health-related quality of life (HRQoL) in persons with current or past cancer experience.



Measuring what matters for cancer patients and survivors in Europe

# The EUonQoL project

## Where we are



**EUonQoL  
pilot survey**

Validation  
of EUonQoL-Kit

**Phase 2**

Validation and  
data analysis

# The EUonQoL-Kit

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## Features



- Unified HRQoL assessment tool to be used in European cancer programmes and policies
- Developed from the patients' perspective (co-design approach)
- Available in several European languages of the EU Member States and associated countries
- Electronically administered

# The EUonQoL-Kit

## Features

- Intended to assess HRQoL across the whole cancer care continuum, including people at different stages of their disease trajectory.



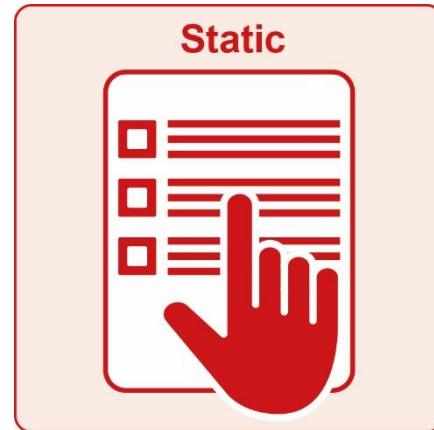
**3 operational target groups**

<b>A Active treatment</b>	Undergoing or being eligible to curative or life-prolonging tumor-directed treatment
<b>B Survivors</b>	Being at least one year off treatment and being disease-free without evidence of active cancer
<b>C Palliative care</b>	Having metastatic or locally advanced disease and receiving tumor-directed treatment with palliative intent (only for symptom control) or being not eligible to any tumor-directed treatment

# The EUonQoL-Kit

## Features

- Administered in both **static** and **dynamic** modes.



### Classical testing

Fixed set of pre-selected questions presented to every respondent

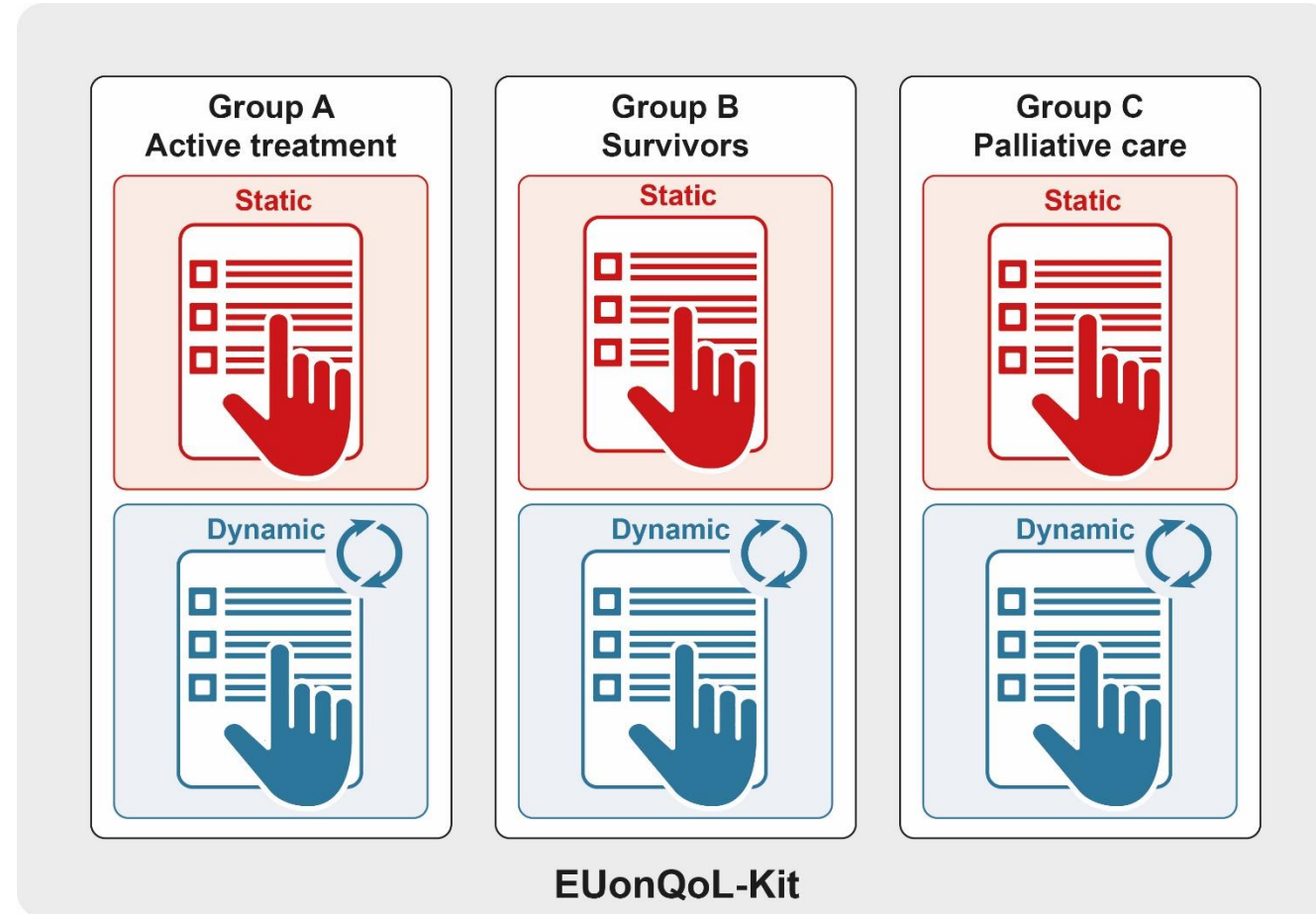


### Computer Adaptive Testing (CAT)

Questions automatically selected based on the respondent's answers during questionnaire completion

# The EUonQoL-Kit

## Structure



# The EUonQoL pilot study

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## Objectives

### Primary

- Assess **validity** and **reliability** of the EUonQoL-Kit (psychometric validation)

### Secondary

- Assess EUonQoL-Kit acceptability and patient burden
- Cross-validate the static and dynamic administration modes
- Explore individual factors potentially affecting HRQoL
- Explore HRQoL inequalities across European countries



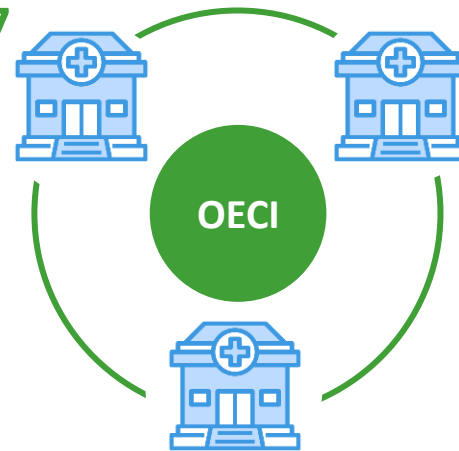
# The EUonQoL pilot study

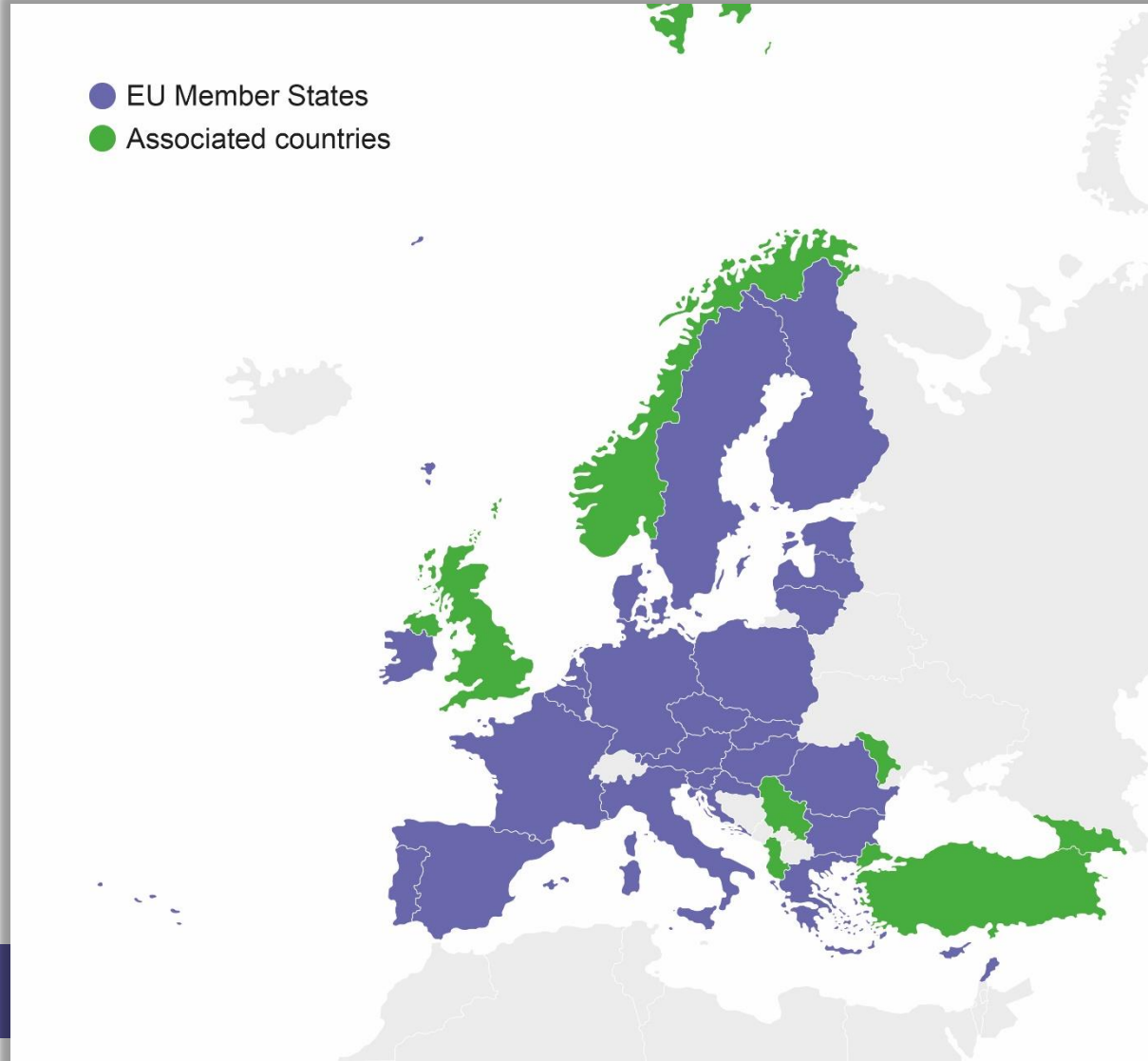
## Design

- Multicentre observational cross-sectional study

45 clinical centres from 25 EU Member States and 7 associated countries

Coordinated by OEIC



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- EU Member States
  - Associated countries

# The EUonQoL pilot study

## Design

- Multicentre observational cross-sectional study

Participants will not receive any kind of intervention (pharmacological or non-pharmacological)

Only asked to fill in one or more questionnaires at a single point in time (except for the re-test, 1 hour apart)



# The EUonQoL pilot study

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## Eligibility criteria

### Inclusion

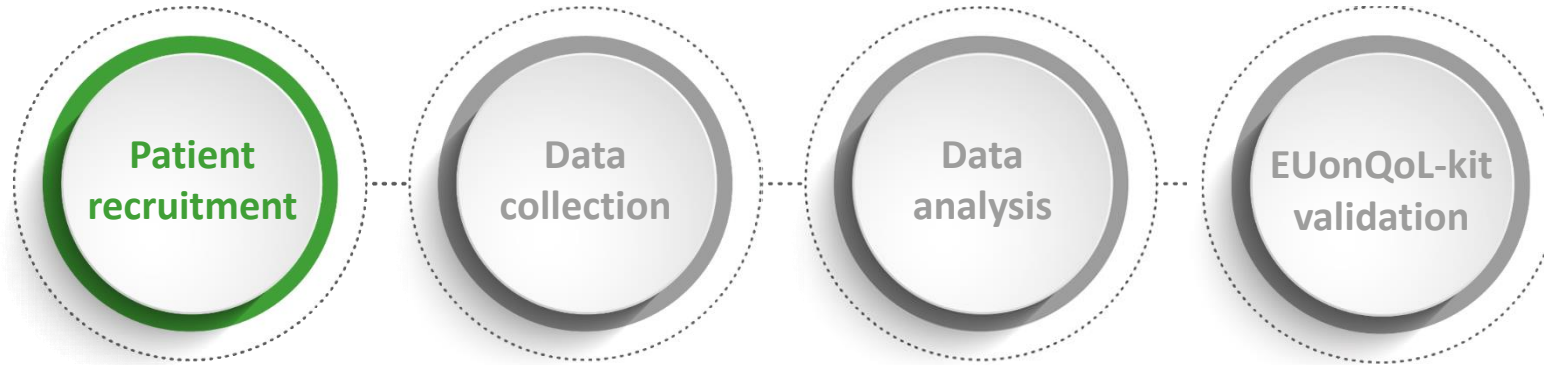
- Age 18 years or more
- Present or past histologically confirmed diagnosis of solid tumor or haematological malignancy
- Being in one of the 3 conditions: A) Active treatment; B) Survivors; C) Palliative care
- Native tongue or fluent in the language of the questionnaire
- Written consent to the study

### Exclusion

- Cognitive impairment preventing questionnaire completion

# The EUonQoL pilot study

## Procedures



Study population  
(4,000 patients)








		Lung	Breast	Colorectal	Haematol.	Prostate	Other	
100 patients (per CC)	40	Active treatment	6	6	6	6	6	10
	30	Survivors	5	5	4	4	4	8
	30	Palliative care	5	5	4	4	4	8

# The EUonQoL pilot study

## Procedures

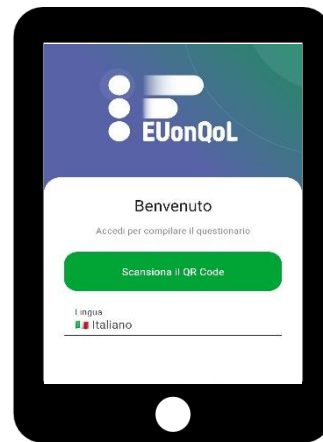
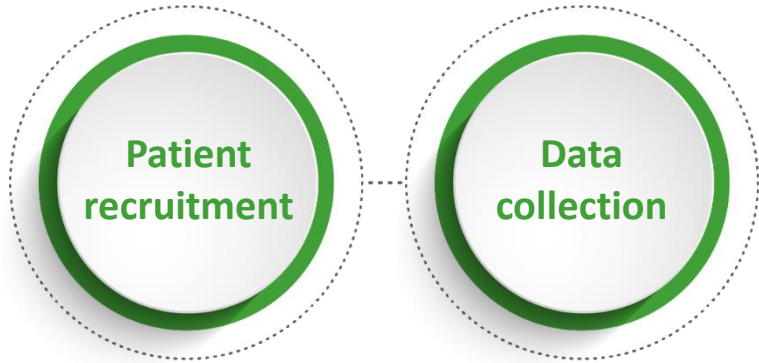


100 patients (per CC)

	<p>EUonQoL-Kit static</p> 	<p>EUonQoL-Kit static    FACT-G EQ-5D-5L</p>  	<p>EUonQoL-Kit static    EUonQoL-Kit dynamic</p>  	<p>EUonQoL-Kit static    EUonQoL-Kit static</p>  
	70%	10%	10%	10%
	EUonQoL-Kit sample	Concurrent validity sample	Dynamic (CAT) sample	Test re-test sample

# The EUonQoL pilot study

## Procedures



### Where

- In pre-identified outpatient clinics and inpatient wards of each clinical centre

### When

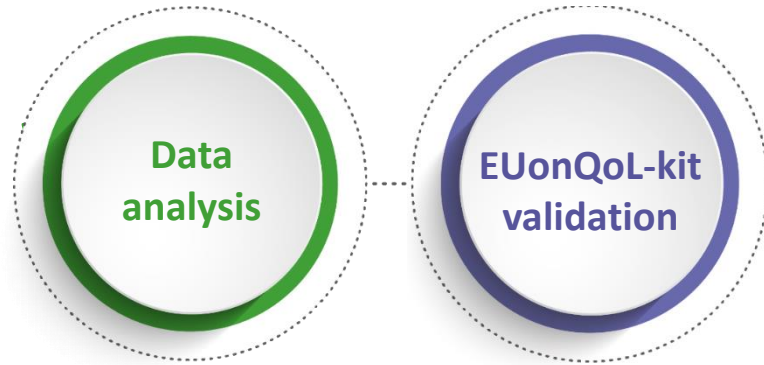
- 2<sup>nd</sup> half of 2024 (during specific days previously agreed with each clinical centre)

### How

- Patient registration and data collection will be centralized through a dedicated web-platform
- Questionnaires will be administered through tablet devices via a mobile APP

# The EUonQoL pilot study

## Output



- Based on the validation study results, the toolkit will be further refined and finalised.
- Different implementation strategies will be put in place to guide and disseminate the use of the tool:
  1. To support the core principles of EU Mission on Cancer (improving and preserving QoL)
  2. To complement existing health outcome measures of other EU-funded projects
  3. To inform evidence-based policies addressing cancer inequalities across Europe

# Thanks for your attention!



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