European Journal of Cancer 238 (2026) 116677

Contents lists available at ScienceDirect

European Journal of Cancer

journal homepage: www.ejcancer.com

Original research

The development of the European Toolkit for the self-assessment of quality of life across the cancer care continuum (EUonQoL-Kit)

Emma Nicklin [a,*,1], Christopher Bedding [a,1], Sara Alfieri [b], Giovanni Apolone [c], Volker Arndt [d], Nanne Bos [e], Anne Bredart [f,g], Cinzia Brunelli [h], Luana Caselli [h], Gennaro Ciliberto [j], Leslye Rojas-Concha [k], Norbert Couespel [l], Daniela Doege [d], Montse Ferrer [m,n,o], Maria Alice Franzoi [p], Laura Gangeri [b], Olatz Garin [m,n,ac], Emma Gillanders [p], Mogens Groenvold [k,q], Caitriona Higgins [r], Esther C.E. de Jongh [s], Tapani Kalmi [t], Stein Kaasa [u], Claudio Lombardo [v], Elise Martin [p], Helle Pappot [w], Ricardo Pietrobon [x], Gabriella Pravettoni [y], Bianca Scacciati [b], Aude Sirven [z], Maike G. Sweegers [s], Melissa S.Y. Thong [d], Hugo Vachon [aa], Lonneke V. van de Poll-Franse [s,ab], Ines Vaz-Luis [p], Augusto Caraceni [i,2], Galina Velikova [a,2], Alexandra Gilbert [a,2], on behalf of the EUonQOL consortium

[a] Leeds Institute of Medical Research at St James's, University of Leeds, Leeds, United Kingdom
[b] Clinical Psychology Unit, Fondazione IRCCS Istituto Nazionale dei Tumori, Milan, Italy
[c] Scientific Directorate, Fondazione IRCCS Istituto Nazionale Dei Tumori (INT), Milan, Italy
[d] Cancer Survivorship, German Cancer Research Center (DKFZ), Heidelberg, Germany
[e] Netherlands Institute for Health Services Research (Nivel), Utrecht, the Netherlands
[f] Psycho-Oncology Unit, Institut Curie, Paris, France
[g] Psychology Institute, Psychopathology and health process laboratory UR4057, ED 261, Paris City University, France
[h] Palliative care, pain therapy and rehabilitation Unit, Fondazione IRCCS Istituto Nazionale Tumori- Milano, Milan, Italy
[i] Università degli studi di Milano Dipartimento di Scienze Cliniche e di Comunità, Dipartimento di Eccellenza, Milan 2023-2027, Italy
[j] IRCCS National Cancer Center "Regina Elena", on Behalf of DIGICOR, Rome, Italy
[k] Palliative Care Research Unit, Department of Geriatrics and Palliative Medicine GP, Copenhagen University Hospital - Bispebjerg and Frederiksberg, University of Copenhagen, Copenhagen, Denmark
[l] European Cancer Organisation (ECO), Brussels, Belgium
[m] Health Services Research Group, Hospital del Mar Research Institute, Barcelona, Spain
[n] CIBER en Epidemiología y Salud Pública, CIBERESP, Madrid, Spain
[o] Department of Medicine and Life Sciences, Universitat Pompeu Fabra, Barcelona, Spain
[p] Cancer Survivorship Group, Inserm U981, Gustave Roussy, Villejuif, France
[q] Section of Health Services Research, Department of Public Health, University of Copenhagen, Copenhagen, Denmark
[r] Co-researcher, Beaumont RCSI Cancer Centre, Dublin, Ireland
[s] Division of Psychosocial Research and Epidemiology, The Netherlands Cancer Institute, Amsterdam, the Netherlands
[t] Co-researcher, Turku, Finland
[u] European Palliative Care Research Centre (PRC), Department of Oncology, Oslo University Hospital, and Institute of Clinical Medicine, University of Oslo, Oslo, Norway
[v] Organisation of European Cancer Institutes (OECI), Brussels, Belgium
[w] Department of Oncology, Copenhagen University Hospital – Rigshospitalet and Institute of Clinical Medicine, University of Copenhagen, Copenhagen, Denmark
[x] SporeData OÜ, Tallinn, Estonia
[y] Istituto Europeo Di Oncologia IRCCS, Milan, Italy
[z] Unicancer, Paris, France
[aa] European Organisation for Research and Treatment of Cancer, Quality of Life Department, Brussels, Belgium
[ab] Department of Medical and Clinical Psychology, Tilburg University, Tilburg, the Netherlands
[ac] Department of Pharmaceutical Care and Clinical Pharmacy, Faculty of Pharmacy, Universidad de Costa Rica, San Jose, Costa Rica

* Corresponding author.
E-mail address: E.Nicklin@leeds.ac.uk (E. Nicklin).
[1] Joint first authors
[2] Joint last authors

https://doi.org/10.1016/j.ejca.2026.116677

Available online 12 March 2026

ARTICLE INFO

Key words:
Health-related quality of life
Questionnaire
Patient-reported outcomes (PRO)
Cancer Treatment
Palliative Care
Survivorship

ABSTRACT

Purpose: The European Oncology Quality of Life (EUonQoL) project aims to develop a questionnaire toolkit (EUonQoL-Kit) to assess the quality of life (QoL) of cancer patients and survivors across Europe.
Methods: The EUonQoL-Kit development used mixed-methods and a co-design approach. Data was collected in six countries (Denmark, France, Germany, Italy, Netherlands and UK). The target populations were patients in active treatment (A), survivors (B) and patients requiring palliative care (C). A review of existing QoL theoretical models produced an initial EUonQoL conceptual framework. Semi-structured interviews and a Delphi survey evaluated/modified the framework. Existing validated items were used to construct the toolkit, including Computer Adaptive Testing (CAT), where available. A usability study evaluated EUonQoL-Kit.v1. Data triangulation and consensus methodology guided EUonQoL-Kit.v2.
Results: The initial conceptual framework covered four multi-dimensional domains: physical, social and overall health, and psychological wellbeing. The interviews and Delphi survey included 75 and 155 participants, respectively. The domain 'healthcare experience' was identified and included in the framework. EUonQoL-Kit.v1 resulted in three static questionnaires, one for each target population (n items- A=75; B=67; C=79). Following usability testing with 53 participants, EUonQoL-Kit.v2 was produced via a multi-stakeholder consensus development panel, creating a shortened version (n items- A=50; B=50; C=44). Dynamic versions of these questionnaires were developed using the EORTC CAT Core system.
Conclusions: EUonQoL-Kit is a novel toolkit developed to assess QoL across the cancer continuum and inform health policy within Europe. Its psychometric properties are currently being evaluated using data collected on more than 4200 patients across 32 countries.

1. Introduction

The burden of cancer on quality of life (QoL) is extensive, and well documented [1,2]. Improving and preserving QoL is a core pillar of the EU Mission on Cancer, which emphasises the need to understand patient experiences across the entire care continuum—from diagnosis and treatment to survivorship, advanced disease, and end-of-life care [3]. Although QoL outcomes are well studied in oncology, their routine collection and integration into cancer surveillance and cross-country comparisons across EU countries remains inconsistent across tumour sites and care settings [4]. Patient-reported outcomes (PROs) offer direct, patient-centred insight into individuals' lived experience, information which is otherwise only indirectly inferred from other clinical measures [5] The limited availability of this data restricts the ability to evaluate the value of PROs for healthcare benchmarking and constrains efforts to assess patient well-being and identify disparities in care [6]. To meet the EU Cancer Mission's policy objectives, it is essential to collect comprehensive, multidimensional QoL data, integrating physical, emotional and social well-being alongside cancer survival, clinician-reported and performance outcomes, to enable the effective design and evaluation of patient-centred health policy interventions [4,7,8].

Numerous validated general cancer and disease site-specific or treatment-specific PROs to measure QoL are available for cancer patients and survivors. Commonly used instruments such as the European Organisation for Research and Treatment of Cancer Core questionnaire (EORTC QLQ-C30) and FACT-G were developed and validated in the early 1990ies for use in clinical trials to evaluate treatment efficacy, toxicity and impact on QoL [9,10] Although primarily created for research purposes, these measures are now frequently used in broader contexts, including routine clinical care and national cancer registries [6]. Several initiatives, such as COnsensus-based Standards for the selection of health Measurement INstruments (COSMIN) and International Consortium for Health Outcomes Measurement (ICHOM) provide methodological frameworks to develop disease-specific outcome sets that include QoL domains, driving international benchmarking and patient-centred health system redesign. A systematic review conducted as part of the European Oncology Quality of Life (EUonQoL) initiative, evaluated the psychometric measurement properties of existing PROs used in the assessment of QoL in European cancer patients and survivors. The EORTC QLQ-C30 (an instrument historically originating from Europe), aligns with COSMIN recommendation criteria and was designed for use across the cancer continuum. However, what is missing from the current PRO literature is evidence supporting the suitability of existing cancer-specific PROs for population-level benchmarking and policy use, ensuring they provide the sensitivity, specificity, flexibility, and policy relevance needed for large-scale health system evaluation [11]. The EUonQoL project, funded by the EU Horizon 2020 programme, aims to address the need for a unified, dynamic system to measure QoL across the cancer continuum for use in health policy benchmarking.

The project recognises that rapid advances in information technology, big data, and artificial intelligence analytics require QoL assessment tools that can be electronically captured (ePROs) and incorporate modern psychometric approaches such as Computerised Adaptive Testing (CAT) [12]. CAT may offer significant advantages when applying PROs in health policy contexts. "Static" PRO instruments, where every patient is asked the same set of questions can lead to floor and ceiling effects [13]. Using item response theory (IRT), CAT selects questions based on an individual's prior responses, ensuring higher measurement precision and minimising patient burden [14]. This ability to improve measurement precision may offer particular advantages for policy benchmarking, where identifying small differences between heterogenous populations matters [15]. In addition, ePROs such as CAT can be integrated into electronic health records, enabling standardised data collection across regions and institutions—essential for long-term implementation.

This paper provides an overview of the initial development of the EUonQoL-Kit including its conceptual framework, item selection process, static and dynamic questionnaire versions, usability testing, and consensus-based refinement. Using existing validated questionnaires as its basis, including the EORTC CAT Core [13], the toolkit aims to capture diverse patient experiences throughout all stages of the cancer journey. By engaging patients, QoL research experts, healthcare professionals, and policymakers from the outset, the project aims to ensure alignment with stakeholder needs and extend QoL measurement beyond clinical utility into health policy and systems planning within Europe.

2. Methods

The development of the EUonQoL-Kit was undertaken using a co-design approach, led by an international, multidisciplinary research team that met weekly to collaboratively guide each stage of the process. Two co-researchers—one with lived experience of cancer and the other

an informal caregiver—were integral to the co-design team, contributing actively to discussions, shaping the toolkit, editing study materials, and co-authoring reports and papers. Further details of co-researcher involvement are reported elsewhere. Broader co-design input was obtained from the EUonQoL consortium, including board members, additional co-researchers, and leaders of other EUonQoL work packages. Ethical approval was secured in accordance with national requirements, and all participants gave informed consent.

A mixed method approach [16–18], aligned with EORTC instrument development guidelines, was used for: (1) identifying target populations; (2) content generation (3) selecting PRO items from existing validated PRO systems and constructing the toolkit (4) pre-testing, and (5) international field-testing. This publication reports on the first four stages (Fig. 1). Field-testing and validation is ongoing [19].

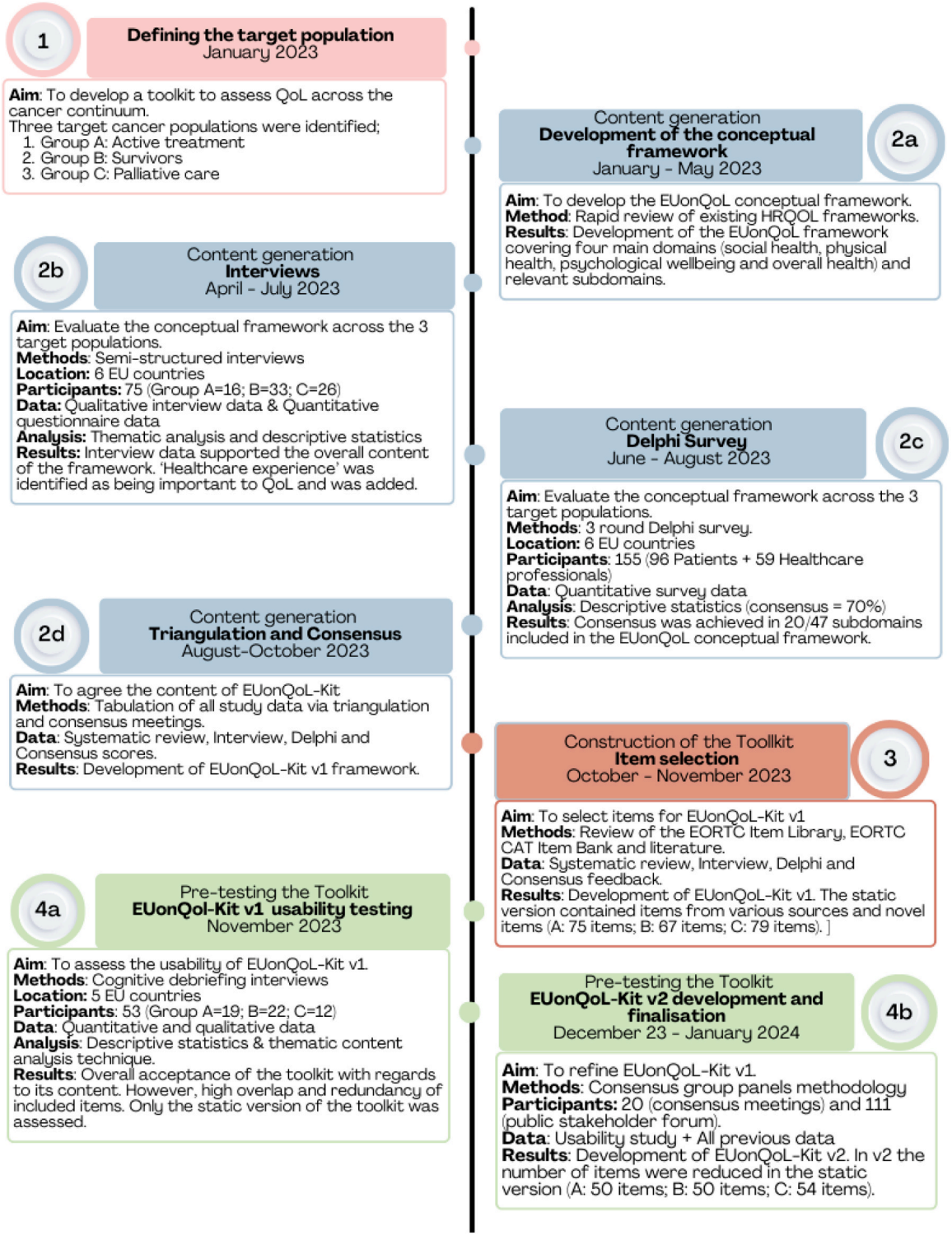

Fig. 1. Steps in EUonQoL-Kit development.

2.1. Definition of target patient population across cancer care continuum (Figure 1.1)

The EUonQoL-Kit was aimed for use in adult cancer patients and survivors. The three target populations were defined as:

A) Patients undergoing active treatment

B) Survivors (disease-free, ≥1 year after completing treatment)

C) Patients requiring palliative care (those referred to palliative services, receiving non-curative treatment, or with an expected survival ≤12 months and ECOG performance status ≥2).

Whilst accepting a level of overlap, these target populations were selected to broadly cover patients and survivors' experiences across the cancer care continuum and agreed by the EUonQOL executive committee.

2.2. Generation of content for the EUonQoL-Kit (Figure 1.2a)

A review of existing QoL frameworks informed the initial content of the EUonQoL conceptual framework [20–22]. The framework consisted of domains and subdomains relevant across the cancer care continuum. Domains were defined as the overall higher-level concept (e.g. physical health), and subdomains were defined as the concepts within a domain (e.g. symptoms). Subdomains included key patient experiences (e.g. pain, breathing problems, symptom worries). Within the toolkit, subdomains were developed into the questionnaire items. The framework was evaluated and refined, via a series of sub-studies, including a systematic review, semi-structured interviews and a Delphi survey.

2.2.1. Interviews (Figure 1.2b)

Semi-structured interviews were planned with ~75 adult cancer patients and survivors from six countries (Denmark, France, Germany, Italy, Netherlands and UK), using purposive sampling to ensure diversity in demographics and clinical backgrounds. Participants were required to understand the local language and have no serious cognitive impairment. The aim was to gather insights from ~25 individuals per target population or until reaching theoretical saturation, meaning we had reached a sufficient depth of understanding, the themes were sufficiently developed to address the objectives, and no new themes were emerging. Theoretical saturation was assessed weekly based on ongoing coding, and discussions around emerging themes.

Semi-structured interviews started with an open discussion on how cancer affected participants' QoL, followed by a review of the initial conceptual framework. Participants provided feedback on the different domains/subdomains using sample questionnaire items to demonstrate how each could be assessed in terms of their content, importance to them, completeness, acceptability (i.e. whether any items were perceived as intrusive) and wording (i.e. clarity across different languages).

Qualitative data were analysed locally using a thematic framework. Study data was aggregated (key messages, themes, and verbatim quotes) by the local researchers at each centre before being sent to the co-ordinators in UK for analysis. Regular team discussions were held to discuss interview progress and emerging themes. Further details are reported elsewhere [16].

2.2.2. Delphi survey (figure 1.2c)

A three round Delphi survey was conducted to obtain consensus on the content of the conceptual framework [23]. A purposive sample of 30 participants per target population (A,B,C) was planned, as well as the addition of 30 health care professionals (HCPs) [24]. HCPs were required to be a doctor, oncology nurse, allied health professional, or researcher involved in cancer care.

Participants rated the initial conceptual framework on a 9-point scale, (1 = limited importance, 9 = critical importance). Patients and survivors self-assigned to one of three target populations (A, B, or C), while HCPs chose based on expertise. Consensus was defined as ≥ 70% of a group rating a subdomain as critically important. Free-text responses in round 1 added new subdomains, which were included in round 2. After each round, participants received feedback before re-rating.

2.2.3. Triangulation and consensus (Figure 1.2d)

To guide EUonQoL-Kit content, data from the interviews, Delphi study, and systematic review, were combined into a master cross-tabulation. Subdomains were coded using a colour system (GREEN: likely include; ORANGE: discuss; RED: likely exclude: Fig. 2). These were reviewed at a consensus meeting using Nominal Group Technique (NGT), where voting consensus participants rated on a scale of 1–10, each subdomain on usefulness, actionability, relevance, and priority. The decision framework was updated based on these scores (see Fig. 2 for worked example).

2.3. Construction of the EUonQoL-Kit – developing subdomains into questionnaire items (Figure 1.3)

The EUonQoL-Kit was developed for both static and dynamic assessment. In dynamic mode, decision rules determine item selection based on previous responses. Item selection was guided by our systematic review. The EORTC Item Library was chosen because it offers a comprehensive, conceptually coherent, and internationally developed pool of cancer-specific QoL items. Priority was given to items from the EORTC CAT Core item banks which support both dynamic and static formats. Items from the previously developed EORTC CAT short forms (3–5 items) were selected based on the expected severity of symptomatology/impairment associated with each target population (e.g. survivors were to receive short forms tailored for a population with mild symptoms). Remaining subdomains were assigned from the EORTC Item Library. When suitable items were not available, published literature was reviewed or novel items were developed following the EORTC Quality of Life Group module development guidelines [25]. The final product of this development process, EUonQoL-Kit version 1 (v1), consisted of three tailored questionnaires—one for each target population—and was approved by the EUonQoL executive committee for usability testing.

2.4. Pre-testing the EUonQoL-Kit

2.4.1. Usability testing (figure 1.4a)

Cognitive debriefing interviews using a think-aloud approach, were conducted to assess the usability and content of EUonQoL-Kit.v1. A purposive sample of ~60 participants from six countries (Denmark, France, Germany, Italy, Netherlands and UK) were asked to complete their relevant questionnaire version. Interviews, guided by prompts and verbal probes, explored item clarity, content, and digital functionality. Data were analysed using descriptive statistics and thematic content analysis, and the findings informed the finalisation of EUonQoL-Kit.v2.

2.4.2. Development of EUonQoL-Kit.v2 (Figure 1.4b)

Each item within EUonQoL-Kit.v1 was systematically evaluated for inclusion in v2 by the research team using Consensus Development Panels methodology. A predefined criterion based on the EORTC module development guidelines was used to aid decision making (Table 1).

Provisional decisions were shared at two consortium meetings and a public stakeholder forum, where topics included questionnaire length, subdomains, and item order. Feedback from these sessions was integrated into the iterative decision-making process and discussed further by the research team until consensus was reached.

	A) ACTIVE TREATMENT	B) SURVIVORS	C) IN NEED OF PALLIATIVE CARE
Domain: Physical Health **Subdomain:** Physical symptom – lack of energy **Example item:** Have you lacked energy?			
Systematic review - Quantitative	70% (37)		
Systematic review - Qualitative	Yes	Yes	Yes
Interviews: Priority for inclusion score	67% (12)	69% (32)	85% (26)
Delphi: Consensus score	69% (32)	59% (37)	92% (13)
Consensus meeting: NGT[1] score	7.9	8	8.2
Final decision	**Include**	**Include**	**Include**

Green: Interviews >60%, Delphi >70%, Consensus 8-10; Amber: Interviews 50-59%, Delphi 60-69%, Consensus 6-7.9; Red: Interviews <50%, Delphi <60%, Consensus <6. [1]Nominal Group Technique (NGT).

Fig. 2. Triangulated data and decision-making framework example for the physical symptom – lack of energy.

Table 1
Item retention a priori decision criteria for EUonQoL-Kit.v2.

1. Range > 2 points (need to have 3 different response categories selected for all items)
2. No floor or ceiling effect: responses in categories 3 & 4 or 1 & 2 > **10%***
3. No significant concerns expressed by participants (e.g. item is upsetting, ambiguous)
4. Consistency across languages/cultures
5. Compliance: at least 95% response to the item
6. Missing issues: need to have at least ***10%*** of participants mentioning the issue to include (n = 6)
7. EORTC CAT Core items with the highest precision

*Not formally assessed due to low sample size.

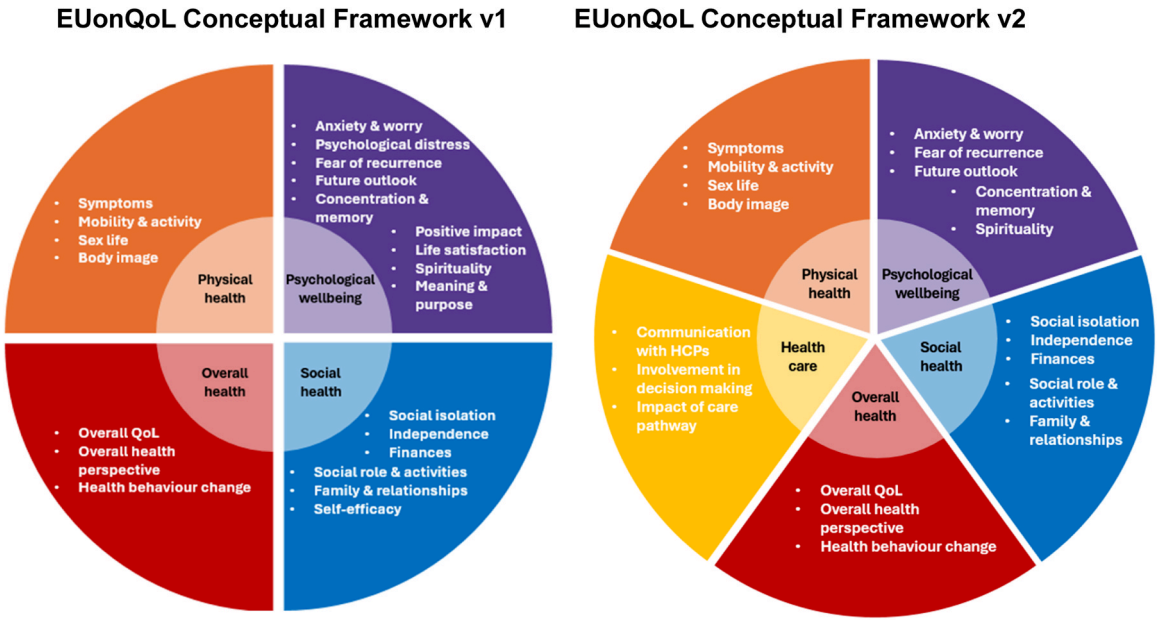

Fig. 3. EUonQoL initial (v1) and adapted (v2) Conceptual Framework.

3. Results

3.1. Generation of content for the EUonQoL-Kit

The initial EUonQoL conceptual framework consisted of four key QoL domains (physical, psychological, social and overall health), each of which included relevant subdomains (e.g. *'family and relationships'*, *'body image'* and *'anxiety and worry'*) (Fig. 3) and was subsequently adapted after the interviews and Delphi survey.

3.1.1. Interviews

Semi-structured interviews (A=16; B=33; C=26) were conducted between April-July 2023 across 6 countries. Patients and survivors with multiple different tumour types, both solid and haematological, were included; 64% of participants were female and 55% aged over 60 years. See Table 2 for sociodemographic characteristics.

Interview findings supported the framework's content, however highlighted *'healthcare experience'* as a key emerging theme influencing QoL. The following quote illustrates how care provision can affect an individual: "*I was followed by the same doctor, a family doctor who knows you, it gave me strength…but in chemotherapy it's never the same doctor, it's difficult seeing different doctors*". As a result, a new domain - *'healthcare experience'* was added to the conceptual framework, including three subdomains, '*communication with healthcare professionals'*, *'involvement in decision-making*' and '*impact of care pathway'* (Fig. 3).

The framework evaluation resulted in the subdomains *'pain'*, *'symptom worries'*, *'impact of treatment side-effects'*, *'anxiety'*, *'depression'*, *'distress'*, *'fear of recurrence'*, *'ability to work'*, *'self-efficacy'* and *'maintaining independence'* being prioritised for inclusion in the EUonQoL-Kit by all three target populations. A further 17 subdomains were ranked as a priority for two target groups and 14 for one target group. Six subdomains were deemed less relevant by all groups: *'Lifting and housework'*, '*sexual interest*', '*body image*', '*weight change*', '*memory and concentration*' and *'spirituality*. See Appendix 1 for complete interview results.

3.1.2. Delphi survey

The Delphi survey round 1 (May 2023) was completed by 155 participants, 62% (96/155) were patients and survivors, 38% were HCPs (59/155) (Table 2). Rounds 2 and 3 (July 2023) had 88 and 93 participants, respectively.

Consensus was achieved in 20 out of 47 subdomains - 15 in round 2 and 5 in round 3 (Appendix 2). Eleven subdomains were categorised as low priority for inclusion with low scores across each target group (*'sexual pleasure'*, *'sexual problems'*, *'body image'*, *'changes in weight'*, *'sensory neuropathy'*, *'meaning and purpose'*, *'spirituality'*, *'positive affect'*, *'leisure travel'*, *'fertility'* and *'insurance'*).

Following the results of the interviews and Delphi surveys, the domains and subdomains included within the conceptual framework were updated, see Fig. 3.

Consensus meeting and triangulation

The conceptual framework and triangulated results were presented at the consensus meeting on 11/10/2023–13 voting consortium stakeholders (8 stakeholder board members and 5 co-researchers) and participating researchers from relevant EUonQOL work packages. There was overall agreement for the inclusion of many subdomains within the 'social health', 'overall health' and 'healthcare experience' domains. Consensus scores within the 'physical health' domain were more varied, for example, '*body image*' and specific symptom related issues ('*appetite loss*', '*breathing problems*' and '*tingling and numbness*') received particularly low scores. While '*Pain*', '*lack of energy*' and *'impact of treatment side effects'* had the highest levels of consensus. The 'psychological well-being' domain showed lower consensus, with '*spirituality*,' *'positive impact*,' and '*meaning and purpose'* receiving particularly low scores.

Following the consensus meeting, triangulated results, organised by subdomain were consolidated in a table (Table 3). For included domains

Table 2
Sociodemographic details from the interview, Delphi and usability studies.

	Interviews		Delphi				Usability	
	Patients and survivors		Patients and survivors		HCPs		Patients and survivors	
Demographics	N	%	N	%	N	%	N	%
Sample size	75	100	96	62	59	38	53	100
Gender								
Female	48	64	55	57	45	76	32	60
Male	27	36	41	43	14	24	21	40
Age								
18–39	9	12	13	14	18	31	4	8
40–59	25	33	36	38	28	47	8	15
> 60	41	55	47	49	13	22	41	77
Target Population								
A – Active Treatment	16	21	30	31	25	42	19	36
B – Survivors	33	44	52	54	22	37	22	42
C – Palliative care	26	35	14	15	12	20	12	23
Country								
UK	9	12	11	11	7	12	12	23
Italy	16	21	17	18	8	14	13	25
France	30	40	10	10	14	24	11	21
Netherlands	10	13	22	23	5	8	6	11
Germany	7	9	23	24	13	22	11	21
Denmark	3	4	13	14	12	20	0	0
Employment								
Employed	17	23	38	40	-	-	17	32
Unemployed	9	12	5	5	-	-	0	0
Retired	20	27	34	35	-	-	29	55
Disabled	8	11	2	2	-	-	3	6
Homemaker	0	0	4	4	-	-	0	0
Student	0	0	2	2	-	-	0	0
Other:	4	5	10	10	-	-	3	6
Missing	17	23	1	1	-	-	1	2
Marital status								
Divorced	-	-	8	8	-	-	3	6
Married/living together	-	-	62	65	-	-	32	60
Partner living apart	-	-	7	7	-	-	3	6
Single	-	-	16	17	-	-	1	2
Widowed	-	-	2	2	-	-	13	25
Missing	-	-	1	1	-	-	1	2
Education								
None/ primary school only	0	0	6	6	-	-	14	26
High school	34	45	18	19	-	-	14	26
College or University	34	45	71	74	-	-	18	34
Missing	7	9	1	1	-	-	7	13
Clinical Characteristics								
Disease location								
Breast cancer	25	33	26	27	-	-	11	21
Colorectal cancer	13	17	9	9	-	-	11	21
Prostate cancer	2	3	8	8	-	-	5	9
Lymphoma	3	4	4	4	-	-	3	6
Bladder cancer	2	3	3	3	-	-	0	0
Gynaecological cancer	6	8	6	6	-	-	2	4
Head and neck cancer	3	4	12	13	-	-	1	2
Lung cancer	5	7	8	8	-	-	9	17
Melanoma	2	3	2	2	-	-	1	2
Glioma	1	1	0	0	-	-	0	0
Testicular cancer	0	0	3	3	-	-	0	0
Other:	9	12	14	15	-	-	10	19
Missing	4	5	1	1	-	-	0	0
Demographics - HCP								
Profession								
Medical specialist	-	-	-	-	19	32	-	-
Mental health specialist	-	-	-	-	8	14	-	-
Nurse	-	-	-	-	7	12	-	-
Nursing specialist	-	-	-	-	5	8	-	-
Physical activity specialist	-	-	-	-	1	2	-	-
Primary care physician	-	-	-	-	1	2	-	-
Researcher	-	-	-	-	11	19	-	-
Other	-	-	-	-	7	12	-	-

Footnote: HCP= Health care professionals; (-) data was not collected.

Table 3
Consolidated results from the interviews, Delphi survey and consensus meeting.

	Interview			Delphi			Consensus			
	A	B	C	A	B	C	A	B	C	Included in V1
Sub(domains)										
PHYSICAL HEALTH										**Included**
Physical symptoms										
Pain/pain interference										A, B, C
Lack of energy										A, B, C
Sleeping problems										A, B, C
Loss of appetite										
Changes in eating habits										A, C
Nausea										A, C
Constipation										C
Diarrhoea										
Breathing problems										C
Tingling and numbness										
Symptom worries										A, B, C
Impact of treatment side-effects										A, B, C
Mobility and activity										**Included**
Mobility										A, B, C
Sex life										**Included**
Sexual problems (physical)										A, B
Body Image										**Included**
Body Image										B
PSYCHOLOGICAL WELLBEING										
Anxiety and worry										**Included**
Anxiety										A, B, C
Depression/Sadness										A, B, C
Psychological distress										**Excluded**
Distress /Stressed										
Fear of recurrence										**Included**
Fear of recurrence										A, B
Future outlook										**Included**
Future health outlook										A, B, C
Future Life plans										A, B, C
Memory and concentration										**Included**
Memory and concentration										A, B, C
Positive impact										**Excluded**
Positive impact										
Life satisfaction										**Excluded**
Positive life outlook										
Spirituality										**Included**
Spirituality										A, B, C
Meaning and purpose										**Excluded**
Meaning and purpose										
SOCIAL HEALTH										
Social roles & activities										**Included**
Ability to Work										A, B, C
Family and Relationships										**Included**
Impact on children/family										A, B, C
Partner relationship										A, B, C
Social isolation and connectivity										**Included**
Social isolation and connectivity										A, B, C
Self-efficacy										**Excluded**
Self-efficacy										
Maintain independence										**Included**
Maintain independence										A, B, C
Financial aspects										**Included**
Financial difficulties										A, B, C
OVERALL HEALTH										**Included**
Overall QOL										A, B, C
Overall health perspective										A, B, C
Health behaviour change										A, B
HEALTHCARE										**Included**
Communication with HCPs										A, B, C
Involvement in decision-making										A, B, C
Impact of care pathway										A, B, C

and subdomains, prioritisation was given to consensus views. For items rated lower than 8 by consensus participants and rated 'to discuss' or 'for exclusion' we referred back to our decision framework prior to the consensus meeting to see if results were concordant or not. Final decisions were balanced between the comprehensiveness of the toolkit and potential burden to determine the final inclusion of subdomains in EUonQoL-Kit.v1.

Target population A) patients in active treatment (including patients treated with curative and non-curative intent); B) post-treatment survivors (individuals disease-free 1 or more years after active treatment); and C) patients in need of palliative care (referred to specialist palliative services or receiving non-curative treatment or an expected survival less than 12-months with an ECOG $\leq$2). The traffic light colour scheme highlights the decisions made: GREEN highlights a subdomain for inclusion, AMBER: requires more discussion, and RED is for subdomains for possible exclusion.

3.2. Construction of the EUonQoL-Kit – developing subdomains into questionnaire items

A total of 98 items were selected to assess the included subdomains: 67 items from the EORTC CAT item banks (all part of the EORTC Item Library), 26 additional items from elsewhere within the EORTC Item Library, four wording-modified items from the Chronic Cancer Experiences Questionnaire [26] and one newly developed item on employer support.

EUonQoL-Kit.v1 consisted of three static questionnaires (dynamic versions were not developed in v1), each including only the most relevant and important items for each specific target population. The number of items in each questionnaire were as follows, 75 (A), 67 (B) and 79 (C). The content of each EOonQOL-Kit.v1 questionnaire is shown in Appendix 3.

3.3. Pre-testing the EUonQoL-Kit

3.3.1. Usability study

The sample included 53 participants (A=19; B=22; C=12) from five countries (Table 2); 60% were female and 77% over 60 years. Recruitment took place between November-December 2023. Toolkits were completed both on paper (49%) and digitally (51%).

Overall, patients and survivors found the questionnaires easy to complete with no significant gaps in content. Quantitative data indicated high response rates, and no overtly upsetting items. The 'not applicable' response option was found to be important for items relating to '*sex life*', '*fertility*' and '*finance*'. Suggested areas for improvement included modifications to the response scales within the 'healthcare domain', as well as increasing the response timeframes from 1 week to 1 month for '*body image*', '*sex life*', '*finance*' and '*future outlook*'.

Qualitative data revealed overlap and redundancy of items within EUonQoL-Kit.v1. Redundancy was particularly important for those in the palliative care group who found answering similar items to be frustrating. Participants also preferred items containing more specific content, for example '*trouble walking for 30 min*' over '*trouble taking a short walk*'.

3.3.2. The development of EUonQoL-Kit.v2

Version 2 (v2) modifications were established and approved at two consortium meetings (05/12/2023 and 13/12/2023) and one online open public stakeholder forum (12/12/2023).

The online public forum, with 111 attendees, offered insight from a broader perspective as it was open to anyone with an interest in the project/subject area. In particular, forum delegates argued the symptom '*diarrhoea*' should be covered by the EUonQoL-Kit as a common and upsetting problem for pelvic cancers and a sequalae of a range of treatments (radiotherapy, surgery, immunotherapy). 'Diarrhoea' was therefore included in EUonQOL-Kit.v2.

Weekly research team meetings were key in making the final inclusion/exclusion decisions for EUonQoL-Kit.v2. Important decisions were made across several weeks, such as timescale modifications, and the development of three new items: 1. Continuity of care: "*Do you feel doctors, nurses and other professionals involved in your care work together as a team?*"; 2. Overall QoL ranking: "*Having completed the questionnaire, what do you feel most impacts your Quality of Life?*"; *and* 3. Symptom worries: "*To what extent have you been troubled with physical symptoms from your disease or treatment?*". A fourth item modified from the Danish Palliative care questionnaire was added to capture intimacy within the sex life subdomain.

The dynamic versions of EUonQoL-Kit.v2 used CAT to assess the same subdomains (listed in Table 3), with a maximum of 82 items for the active treatment and survivor populations and 78 for the palliative care population. A stopping rule embedded into the algorithm prevented the dynamic versions asking more than 6–7 items per subdomain.

Following the multi-stakeholder consensus process, the most relevant and important items for each target population were selected resulting in 50-item questionnaires for active treatment patients and survivors, and 44-items for the palliative care version. The three EUonQoL-Kit.v2 static questionnaires are reported here. Based on co-researcher and multi-stakeholder consensus feedback to enhance completeness, the final toolkit update included a novel free-text option for ranking the most important factors impacting the patient's QoL and the EORTC's 'write in three symptoms or problems' (WISP) item to capture missing issues [27] resulting in two free-text based items within EUonQoL-Kit.v2.

4. Discussion

The EUonQoL-Kit is a newly developed toolkit, based on existing validated PROs, designed to assess QoL across the cancer care continuum at a population-level. It aims to contribute to more consistent and patient-centred QoL measurement across European contexts, with a goal to inform EU cancer policy. Developed through a multi-country, stakeholder-informed process involving 277 participants from six European countries, the toolkit comprises six tailored questionnaires—static and dynamic versions for three target populations (active treatment, survivorship, and palliative care)—covering five domains: physical, psychological, social, overall health, and healthcare experience. While both formats share a common conceptual framework to enable comparability, item sets differ to suit the delivery mode.

From the conceptualisation of the EUonQoL framework to the selection of individual items, the decision-making process was grounded by the literature and empirical data generated throughout the project. Initial decisions were made at the domain/subdomain level to establish a comprehensive framework. Semi-structured interviews identified the theme of '*healthcare experience*', which was subsequently added to the conceptual framework. Its inclusion was further supported by data from the Delphi survey, systematic reviews, usability study and consensus panel. The inclusion of both PROs and patient-reported experiences (PREs) enhances the comprehensiveness of the toolkit and reduces the need for multiple instruments to assess related concepts. This approach aligns with existing programmes and research that use PRE data to inform improvements in healthcare systems. [33, 48]

As the EUonQoL-Kit incorporates the EORTC CAT Core, it is useful to consider how it relates to other CAT-based PRO systems, such as PROMIS. PROMIS, is a well-recognised, generic system developed in the United States for use across multiple disease conditions, offers available translations. However, it was not designed to address the cultural diversity of European populations or the heterogeneity of European healthcare systems and cancer care, which are essential for population-level benchmarking In addition, PROMIS is not currently available in all European languages, many translations require substantial licensing fees, and its non–oncology-specific item banks may limit sensitivity to cancer-related and survivorship concerns.

In contrast, the EUonQoL-Kit is oncology-specific and was developed with direct input from European stakeholders to reflect the lived experiences of cancer patients and survivors. While PROMIS item banks are extensive, they may lack sensitivity to cancer-specific domains prioritised within the EUonQoL framework.

Important differences between target populations were considered throughout development, particularly regarding questionnaire content and length. For example, the questionnaire for palliative care patients was intentionally shorter to minimise burden yet retained key content areas. Patients in this group emphasised the importance of intimacy and emotional closeness over physical sexual activity, leading to a revised item wording that better reflected their priorities. This unified and iterative approach contrasts with traditional methods that often develop tools first for those receiving active treatment before then adapting them for survivors and those in need of palliative care. [14, 49, 50]

In terms of methodological rigor, the EUonQoL-Kit aligns with international standards, such as those outlined by the COSMIN initiative. The development process was transparent and iterative, involving literature review, expert consultation, patient engagement, and multiphase testing. Content validity was prioritised through qualitative interviews, Delphi surveys, and consensus panels, consistent with COSMIN recommendations. Nonetheless, further psychometric evaluation—including reliability, responsiveness, and cross-cultural validity—is ongoing and essential to establish the toolkit's robustness and substantiate its utility in informing health policy.

Although efforts were made to ensure diversity in clinical characteristics, the development sample was limited in geographic and socioeconomic representation, with most participants from Western European countries. However, the EORTC QLQ-C30 and EORTC Item Library on which the EUonQOL-Kit was based, has significant data on efficacy in multiple cultural settings and the EORTC QLQ-C30 is available in 143 different languages (accessed 5/12/25). In addition, the pilot study—conducted with over 4200 participants from 25 EU and seven affiliated countries—including Eastern Europe and a broad range of healthcare contexts was undertaken. Analyses are currently ongoing, but preliminary findings available on the EUonQoL website indicate promising psychometric properties of the kit [28].

Due to time constraints, the initial usability evaluation was limited to static formats; however, comprehensive assessment of both static and dynamic versions is currently underway in the pilot study.[25] The pilot study also aims to improve diversity, and follows ISPOR guidelines for translation and cultural adaptation, which should reduce barriers to future implementation.[33, 51]

5. Conclusion

The EUonQoL-Kit offers a promising advance in the assessment of QoL in oncology for health policy contexts. Developed through a multicountry, stakeholder-informed process, it aims to standardise QoL measurement across the cancer continuum in Europe. Its inclusion of both static and CAT-enabled formats, and its integration of patient-reported outcome and experience measures, reflects a growing recognition of the need for more nuanced, patient-centred tools.

CRediT authorship contribution statement

Augusto Caraceni: Writing – review & editing, Methodology, Funding acquisition, Conceptualization. **Ines Vaz-Luis:** Writing – review & editing, Investigation, Formal analysis, Data curation. **Christopher Bedding:** Writing – review & editing, Writing – original draft, Visualization, Resources, Project administration, Investigation, Formal analysis, Data curation. **Alexandra Gilbert:** Writing – review & editing, Validation, Supervision, Resources, Project administration, Methodology, Investigation, Funding acquisition, Formal analysis, Conceptualization. **Galina Velikova:** Writing – review & editing, Validation, Supervision, Methodology, Funding acquisition, Formal analysis, Conceptualization. **de Jongh Esther C.E:** Writing – review & editing, Investigation, Formal analysis, Data curation. **Caitriona Higgins:** Writing – review & editing, Visualization, Validation, Resources, Formal analysis. **Lonneke V van de Poll-Franse:** Writing – review & editing, Investigation, Formal analysis, Data curation. **Emma Nicklin:** Writing – review & editing, Writing – original draft, Validation. **Hugo Vachon:** Writing – review & editing, Methodology, Funding acquisition, Conceptualization. **Tapani Kalmi:** Writing – review & editing, Visualization, Validation, Resources, Formal analysis. **Nanne Bos:** Writing – review & editing, Methodology, Funding acquisition, Conceptualization. **Volker Arndt:** Writing – review & editing, Investigation, Formal analysis, Data curation. **Cinzia Brunelli:** Writing – review & editing, Supervision, Resources, Project administration, Methodology, Funding acquisition, Conceptualization. **Anne Bredart:** Writing – review & editing, Investigation, Formal analysis, Data curation. **Giovanni Apolone:** Writing – review & editing, Supervision, Resources, Project administration, Methodology, Funding acquisition, Formal analysis, Conceptualization. **Sara Alfieri:** Writing – review & editing, Investigation, Formal analysis, Data curation. **Elise Martin:** Writing – review & editing, Investigation, Formal analysis, Data curation. **Claudio Lombardo:** Writing – review & editing, Methodology, Funding acquisition, Conceptualization. **Ricardo Pietrobon:** Writing – review & editing, Methodology, Funding acquisition, Conceptualization. **Helle Pappot:** Writing – review & editing, Investigation, Funding acquisition, Formal analysis, Data curation. **Gennaro Ciliberto:** Writing – review & editing, Methodology, Funding acquisition, Conceptualization. **Luana Caselli:** Writing – review & editing, Investigation, Formal analysis, Data curation. **Stein Kaasa:** Writing – review & editing, Methodology, Funding acquisition, Conceptualization. **Norbert Couespel:** Writing – review & editing, Methodology, Funding acquisition, Conceptualization. **Leslye Rojas-Concha:** Writing – review & editing, Investigation, Formal analysis, Data curation. **Melissa S.Y. Thong:** Writing – review & editing, Investigation, Formal analysis, Data curation. **Bianca Scacciati:** Writing – review & editing, Investigation, Formal analysis, Data curation. **Gabriella Pravettoni:** Writing – review & editing, Methodology, Funding acquisition, Conceptualization. **Maike G Sweegers:** Writing – review & editing, Investigation, Formal analysis, Data curation. **Aude Sirven:** Writing – review & editing, Methodology, Funding acquisition, Conceptualization. **Olatz Garin:** Writing – review & editing, Investigation, Data curation. **Laura Gangeri:** Writing – review & editing, Investigation, Formal analysis, Data curation. **Mogens Groenvold:** Writing – review & editing, Methodology, Funding acquisition, Formal analysis, Conceptualization. **Emma Gillanders:** Writing – review & editing, Investigation, Formal analysis, Data curation. **Daniela Doege:** Writing – review & editing, Investigation, Formal analysis, Data curation. **Maria Alice Franzo:** Writing – review & editing, Investigation, Formal analysis, Data curation. **Montse Ferrer:** Writing – review & editing, Methodology, Funding acquisition, Conceptualization.

Funding

This project has received funding from the European Union's Horizon Europe Research and Innovation Programme under Grant Agreement No 101096362. Views and opinions expressed are however those of the author(s) only and do not necessarily reflect those of the European Union or European Health and Digital Executive Agency (HADEA). Neither the European Union nor the granting authority can be held responsible for them.

Declaration of Competing Interest

The authors declare the following financial interests/personal relationships which may be considered as potential competing interests:

Maria Alice Franzoi reports a relationship with Resilience Care (INstitution) that includes: funding grants. Maria Alice Franzoi reports a relationship with Novartis (Institution) that includes: speaking and

lecture fees. Maria Alice Franzoi reports a relationship with Gilead Sciences (Institution) that includes: funding grants.

Ines Vaz-Luis reports a relationship with Amgen that includes: speaking and lecture fees. Ines Vaz-Luis reports a relationship with AstraZeneca that includes: speaking and lecture fees. Ines Vaz-Luis reports a relationship with Pfizer that includes: speaking and lecture fees. Ines Vaz-Luis reports a relationship with Novartis that includes: speaking and lecture fees. Ines Vaz-Luis reports a relationship with Sandoz Inc that includes: speaking and lecture fees. Ines Vaz-Luis reports a relationship with Resilience Care (Institutional) that includes: funding grants. Ines Vaz-Luis reports a relationship with Travelling Novartis that includes: funding grants.

If there are other authors, they declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Acknowledgements

We would like to thank the large team of clinicians, patients, survivors, carers and researchers who helped with the development of the EUonQoL-Kit.

Appendix A. Supporting information

Supplementary data associated with this article can be found in the online version at doi:10.1016/j.ejca.2026.116677.

References

[1] Wu H-S, Harden JK. Symptom burden and quality of life in survivorship: a review of the literature. Cancer Nurs 2015;38(1):E29–54.
[2] Deshields TL, et al. The persistence of symptom burden: symptom experience and quality of life of cancer patients across one year. Support Care Cancer 2014;22(4):1089–96.
[3] European Commission. *EU Mission: Cancer. Scope of the Mission.* 2025 [cited 2025 July]; Available from: https://research-and-innovation.ec.europa.eu/funding/funding-opportunities/funding-programmes-and-open-calls/horizon-europe/eu-missions-horizon-europe/eu-mission-cancer_en.
[4] Minvielle E, et al. The use of patient-reported outcome and experience measures for health policy purposes: a scoping review in oncology. Health Policy 2023;129:104702.
[5] U.S. Food and Drug Administration. *Core Patient-Reported Outcomes in Cancer Clinical Trials: Guidance for Industry.* 2024 [cited Feb 2026 27]; Available from: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/core-patient-reported-outcomes-cancer-clinical-trials.
[6] Bonsel JM, et al. The use of patient-reported outcome measures to improve patient-related outcomes–a systematic review. Health Qual Life Outcomes 2024;22(1):101.
[7] Calvert M, et al. Putting patient-reported outcomes on the 'Big Data Road Map. J R Soc Med 2015;108(8):299–303.
[8] Jeyaraman N, et al. Voices that matter: the impact of patient-reported outcome measures on clinical decision-making. World J Methodol 2025;15(2):98066.
[9] Aaronson NK, et al. The European Organization for Research and Treatment of Cancer QLQ-C30: a quality-of-life instrument for use in international clinical trials in oncology. JNCI Journal National Cancer Institute 1993;85(5):365–76.
[10] Cella DF, et al. The Functional Assessment of Cancer Therapy scale: development and validation of the general measure. J Clin Oncol 1993;11(3):570–9.
[11] Luckett T, et al. Choosing between the EORTC QLQ-C30 and FACT-G for measuring health-related quality of life in cancer clinical research: issues, evidence and recommendations. Ann Oncol 2011;22(10):2179–90.
[12] Petersen MA, et al. The EORTC CAT Core—The computer adaptive version of the EORTC QLQ-C30 questionnaire. Eur J Cancer 2018;100:8–16.
[13] Petersen MA, et al. International validation of the EORTC CAT Core: a new adaptive instrument for measuring core quality of life domains in cancer. Qual Life Res 2020;29(5):1405–17.
[14] Petersen MA, et al. The EORTC computer-adaptive tests measuring physical functioning and fatigue exhibited high levels of measurement precision and efficiency. J Clin Epidemiol 2013;66(3):330–9.
[15] Reeve BB, et al. Psychometric evaluation and calibration of health-related quality of life item banks: plans for the Patient-Reported Outcomes Measurement Information System (PROMIS). Med care 2007;45(5):S22–31.
[16] Gilbert, A., et al., *The EUonQoL project: Report on patient priorities and preferences.* ⟨https://euonqol.eu/docs/results/D4_1_Report_on_patient_priorities_and_preferences.pdf⟩. 2023. **2024**(01 May).
[17] Gilbert, A., et al. *The EUonQoL project: Report on usability tests with patients*. https://euonqol.eu/docs/results/D4_2_Report_on_usability_tests_with_patients.pdf. 2023 [cited 2024 01 May].
[18] Gilbert, A., et al. *The EUonQoL project: Final set of questionnaires of the EUonQoL-Kit. https://euonqol.eu/docs/results/D4_3_Final_set_of_questionnaires_of_the_EUonQoL-Kit.pdf*. 2024 [cited 2024 01 May]; Available from: https://euonqol.eu/results.
[19] Apolone G, et al. Validation of the European Oncology toolkit for the self-assessment of Quality of Life (EUonQoL-Kit) in cancer patients and survivors: study protocol of a pan European survey. BMC Public Health 2024;24(1):3517.
[20] World Health Organization, *International Classification of Functioning, Disability, and Health: Children & Youth Version: ICF-CY*. 2007: World Health Organization.
[21] Wilson IB, Cleary PD. Linking clinical variables with health-related quality of life: a conceptual model of patient outcomes. Jama 1995;273(1):59–65.
[22] Ferrans CE, et al. Conceptual model of health-related quality of life. J Nurs Scholarsh 2005;37(4):336–42.
[23] Sweegers MG, et al. Development of a unified system for assessing health related quality of life across the cancer care continuum: the EUonQoL Delphi study to identify priorities for quality of life domains. J PatientRep Outcomes 2025;9(1):70.
[24] Campbell S, et al. Purposive sampling: complex or simple? Research case examples. J Res Nurs 2020;25(8):652–61.
[25] Bjordal K, B.A., Gilbert A., Martinelli F., Pe M., Sztankay M., et al. EORTC Quality of Life Group Module Development Guidelines [Internet]. 2021; 5th ed.:[Available from: ⟨https://qol.eortc.org/manuals/⟩.
[26] Harley C, et al. Evaluating the experiences and support needs of people living with chronic cancer: development and initial validation of the Chronic Cancer Experiences Questionnaire (CCEQ). BMJ Support Palliat care 2019;9(1). e15-e15.
[27] Rojas-Concha L, et al. Acceptability and usefulness of the EORTC 'Write In three Symptoms/Problems'(WISP): a brief open-ended instrument for symptom assessment in cancer patients. Health Qual Life Outcomes 2024;22(1):28.
[28] Luana Caselli, C.B., Montse Ferrer Forés, Olatz Garin, Àngels Pont Acuña, Morten Aagaard Petersen, Mogens Grønvold, Leslye Alejandra Rojas Concha. *Quality of Life in Oncology: measuring what matters for cancer patients and survivors in Europe. Report on psychometric data analysis* 2023 [cited 2025 Aug]; Deliverable 7.4]. Available from: https://euonqol.eu/results.