



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

**Deliverable number: D4.3**

**Deliverable title: Final set of questionnaires of the EUonQoL-Kit**

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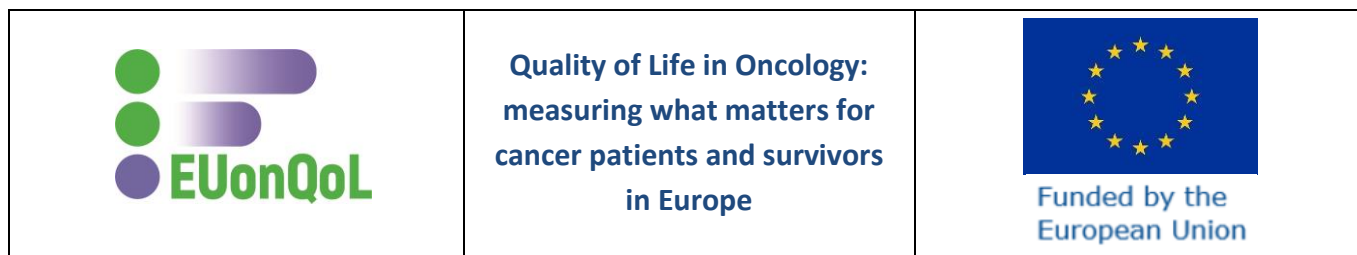
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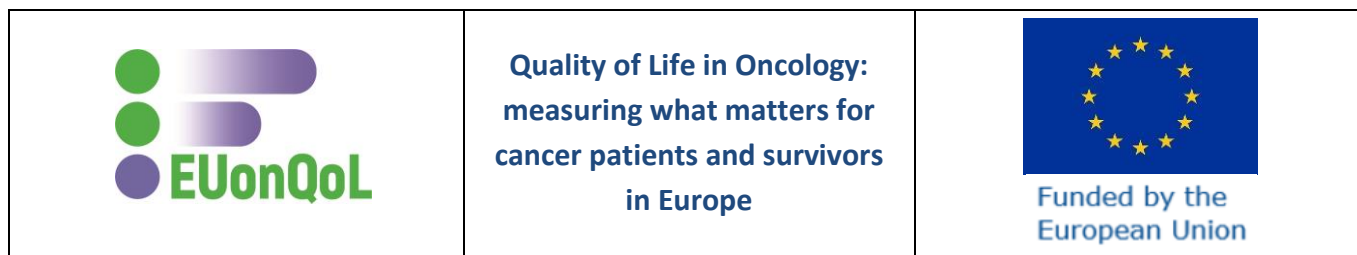


## Abbreviations and Definitions

AE	Adverse events
QOL	Quality of Life
PRO	Patient reported outcomes
EORTC	European Organisation for Research and Treatment of Cancer
QLG	Quality of Life Group
WHO	World Health Organisation
ICF	International Classification of Functioning, Disability and Health
CAT	Computer Adaptive Testing
HRQOL	Health related quality of life
EU	European Union
EUonQoL-Kit	European Oncology Quality of Life toolkit
WP	Workpackage

## General Information

This report provides detail on the results from workpackage 4 (WP4). This workpackage is part of an EU funded project “EUonQoL-Quality of Life in Oncology: measuring what matters for cancer patients and survivors in Europe” grant agreement n° 101096362). The overall project aims to develop, pilot and validate the European Oncology Quality of Life toolkit (EUonQoL-Kit), a patient co-researcher driven, unified system for the assessment of quality of life (QoL) based on the evaluations and preferences of cancer patients and survivors. The EUonQoL-Kit will be developed from the patient perspective, administered digitally, available in all 27 European Union (EU) and associated countries languages, applicable for use in future, periodic surveys to contribute to the EU’s mission on cancer and inform health policy. Workpackage 4’s aims are to develop the toolkit using mixed methods and then present the results of initial usability testing. This report describes the results of the usability study to support modifications to the toolkit prior to pilot testing in WP7. Table below summarizes the different workpackages.

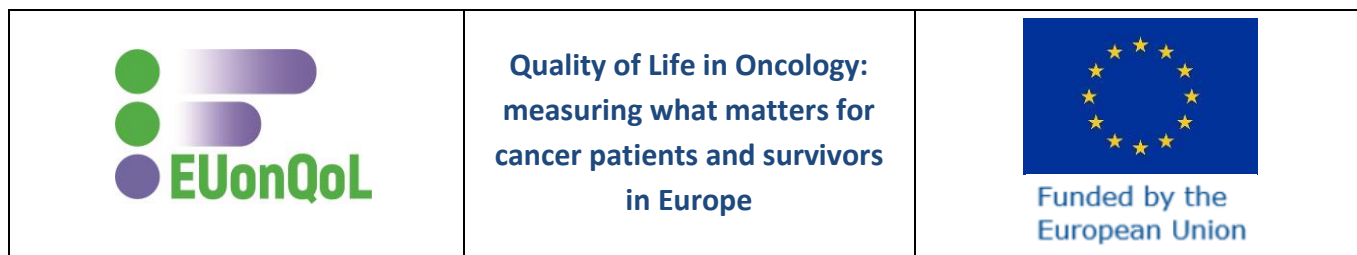


**Table 1. Overview of the different workpackages.**

Workpackage (WP)	Workpackage Title
WP1	Ethics
WP2	Involvement of stakeholders and patients
WP3	Review of existing HRQoL databases, measures & item libraries
WP4	Development of the EUonQoL-Kit
WP5	Cross-cultural determinants of the QoL and linguistic and cultural adaptation of EUonQoL-Kit
WP6	Digital tools for data collection
WP7	EUonQoL-Kit Pilot Survey
WP8	Implementation
WP9	Dissemination
WP10	Project Management/Coordination

## 1. Study Summary

This report describes the process in which the EUonQoL-Kit version 2 (v2) was systematically co-produced following the previous work outlined in deliverables D4.1 and D4.2. Initial WP4 development work used mixed methods methodology to explore patient views and preferences through combining: 1) patient interviews, 2) Delphi survey for multiple stakeholders across seven centres in six countries (Table 2). The triangulated results led to selection of specific items to include within the draft toolkit. The quantitative and qualitative results were presented at a stakeholder consensus meeting organized by WP2 which included representation from co-researchers, workpackage researchers, and stakeholder board. Following this, version 1 of EUonQoL-Kit version 1 (v1) was developed and tested in a usability study, using both online and paper methods, testing also the digital IT infrastructure used to administer the questionnaire and supporting information. An open online public stakeholder forum was held in addition to two consortium meetings which were triangulated with the results from the usability study, and previous development work to finalise version 2 of EUonQoL-Kit (v2) for pilot testing in the following phases of the EUonQoL project.



**Table 2. Participating Centres**

COUNTRY	CENTRE NAME	ACRONYM
UK	Leeds Cancer Centre	LEEDS
IT	Fondazione IRCCS Istituto Nazionale Tumori-Milano	INT
FR	Institut Gustave Roussy,	GR
FR	Institut Curie	CURIE
NL	Netherlands Cancer Institute	NKI
DE	German Cancer Research Center	DKFZ
DK	Rigshospitalet, Copenhagen	RH
DK	Bispebjerg Hospital, Copenhagen	BH

## Compliance

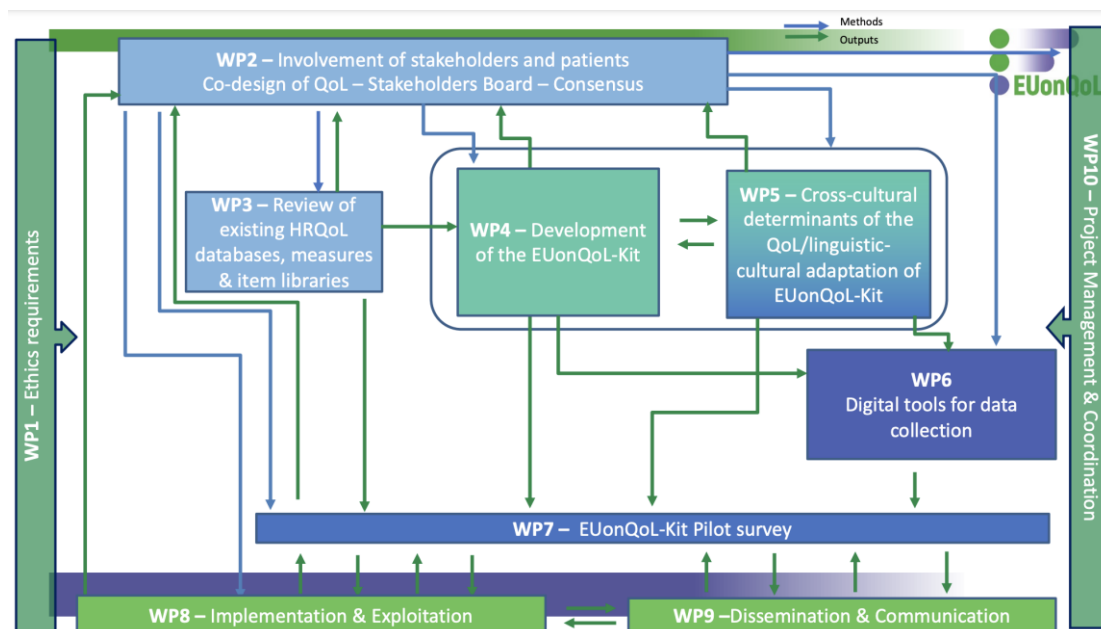
All aspects of the study were undertaken in accordance with the MRC Good Research Practice guidelines, Good Clinical Practice (GCP) guidelines, the Data Protection Act (2018), and the EU Clinical Trials Directive (although this study does not come under the scope of the directive).

## Funder

The study is funded by an EU Horizons 2020 grant (EUonQoL - 101096362 - DLV-101096362).

## Flow diagram of Overall Project

This flow diagram outlines the overall EUonQoL project (Figure 1).



**Figure 1. Flow of project.**

## Report Summary

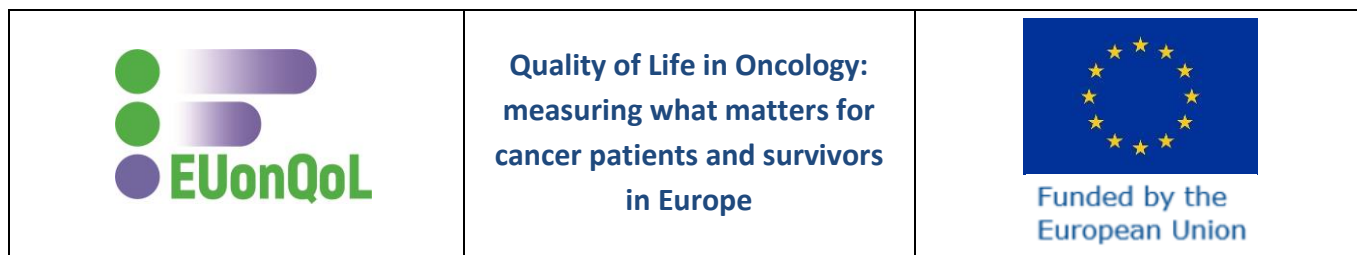
### Aim

The overall aim of this project is to develop a questionnaire toolkit called the EUonQoL-Kit intended to assess quality of life (QOL) across the whole cancer continuum of patients within Europe. The toolkit will assess QOL in three target groups of patients:

- (A) cancer patients receiving active treatment (curative and non-curative)
- (B) cancer survivors for patients aged 18 years and older
- (C) cancer patients receiving palliative care

This stage of the project aimed to develop the final EUonQoL-Kit (v2) approved for pilot testing in WP7. This process was iterative and involved working closely with researchers involved in WP4 and other WPs, co-researchers (WP2) as well as external stakeholders to make decisions and finalise the EUonQoL-Kit v2. Data from the usability study provided feedback on the coverage of QOL items included in EUonQoL-Kit v1 and were used to guide the decision-making process in this current phase of the project.

### Method



The development process was a collaborative and iterative approach which involved multiple stakeholders and the triangulation of multiple data sources to produce EUonQoL-Kit v2. Quantitative and qualitative data from the Usability study were presented during several consensus development panels (Waggoner et al. 2016) to facilitate the decision-making process and bring together the multi-disciplinary network of EUonQoL. This included EUonQoL working groups, as well as broader stakeholders such as leading experts within the field, co-researchers and board members. The methods utilised ensured transparency and provided opportunity for all stakeholders to have input into the development of EUonQoL-Kit v2. Decisions were documented throughout by the workpackage leads.

## Results

Over a 6-week period, WP4 held regular meetings to develop and finalise EUonQoL-Kit v2. In addition to this, two EUonQoL Consortium meetings and a public stakeholder forum were held whereby decision and recommendations were made. EUonQoL-Kit v2 was significantly shorter in length than version 1, whilst however included additional sub-domains to provide greater actionability of the toolkit. EUonQoL-Kit v1 contained 75, 67 and 79 items for the respective target groups (Active Treatment, Survivors & Palliative care). EUonQoL-Kit v2 consisted of 50, 50 and 44 items for the respective groups. Additional sub-domains and items now included in version 2 were related to diarrhoea, sex life/intimacy and continuity and coordination of care. Further to this, an open question was included at the end of the toolkit to capture the QoL related issues most important to the individual. With regards to the structure of the toolkit, updates to the timescales and response scales were made following the Usability results. Final decisions were made resulting in the development of both a static and dynamic version of EUonQoL-Kit v2.

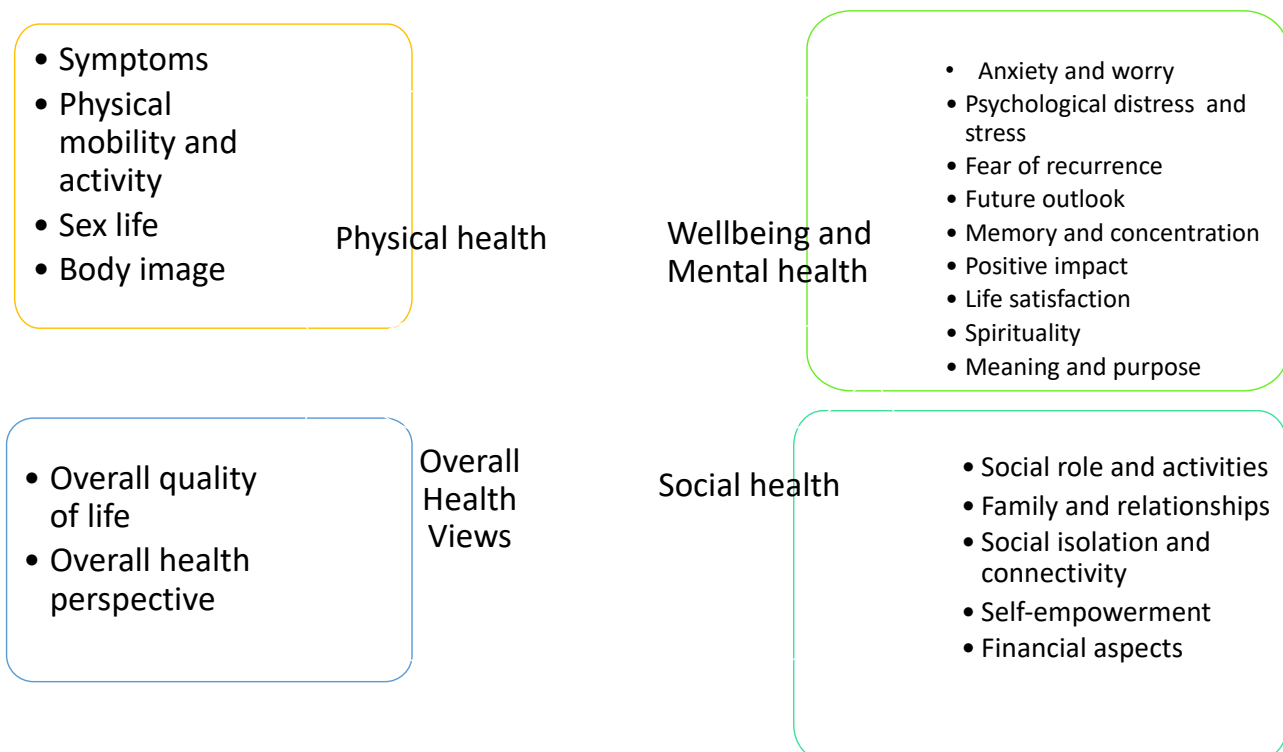
## Discussion

EUonQoL-Kit v2 was a significant upgrade on version 1, not only is it shorter and less burdensome for people to complete it now includes additional sub-domains and items to capture important issues and increasing the actionability of the toolkit.



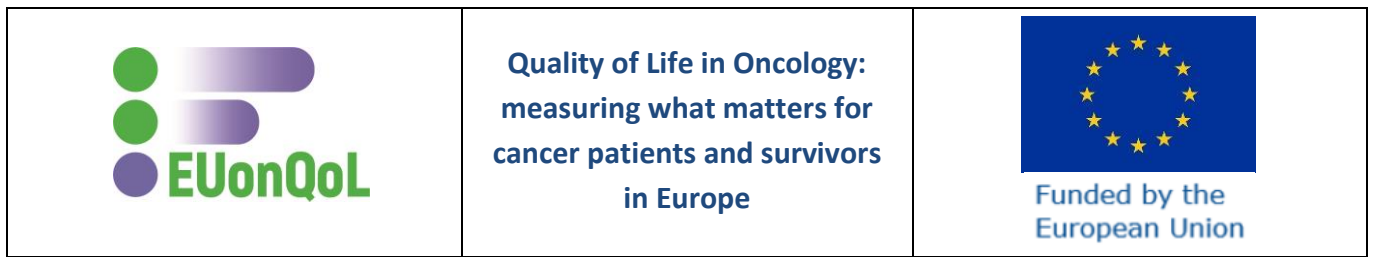
## 2. Introduction

This report follows on from report D4.1 - Patients priorities and preferences and D4.2 - Report on usability tests with patients. In report D4.1, we described the rationale for this project and the initial phases of the development of the EUonQoL-Kit v1. Using existing QoL frameworks from the literature, a conceptual model was developed and used to structure the content of the toolkit at a domain level. The summarised domains and subdomains of the conceptual model are presented in Figure 2. These domains and subdomains were assessed via interviews and a Delphi survey of patients and healthcare professionals, which explored patient views and preferences towards the toolkit content. This was an iterative process carried out in parallel across six countries (UK, The Netherlands, France, Denmark, Germany and Italy).

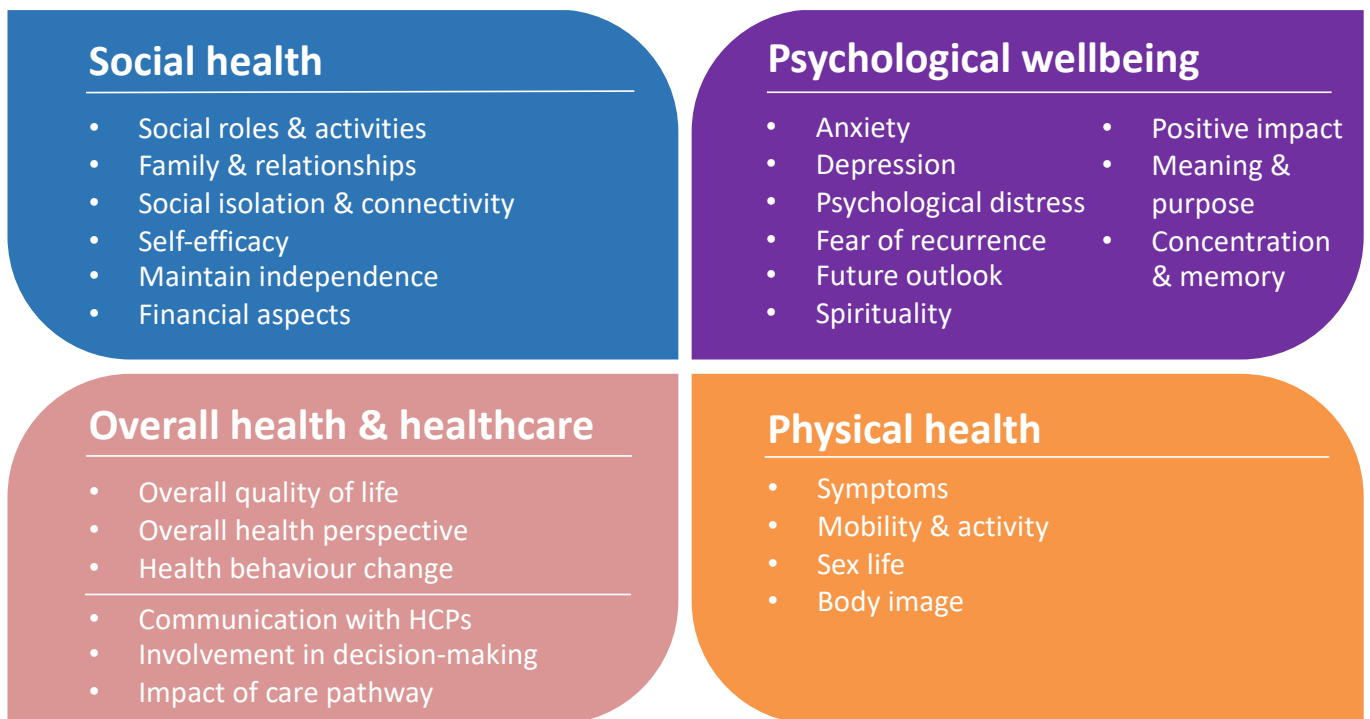


**Figure 2. Initial conceptual framework.**

Following the Interviews and the Delphi survey, the domains and subdomains included within the conceptual framework were updated and shown in Figure 3. In addition to the original 4 domains: social health, physical health, psychological health and wellbeing and overall health, the additional domain of 'Healthcare' was included after it was identified as important to include following the initial round of the

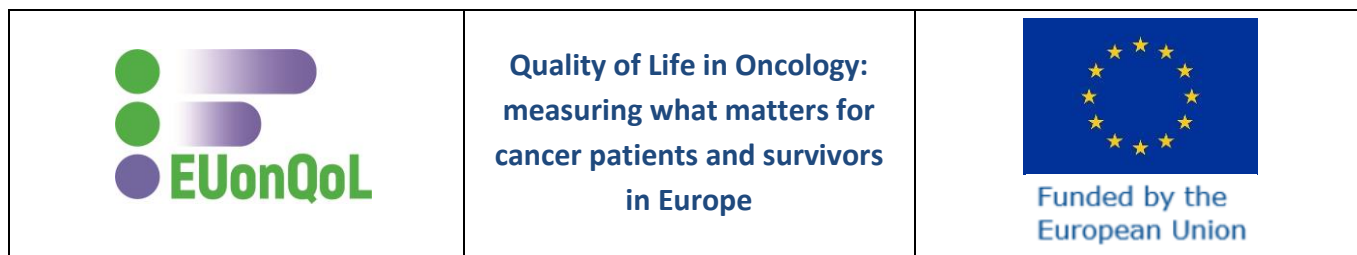


Delphi and initial interviews. The results of the complete interviews and Delphi survey (rounds 1-3) were then combined with the results from two systematic reviews (WP3; report 3.1) using a process of triangulation. The combined results were presented at a stakeholder consensus meeting on 11<sup>th</sup> October 2023 for consensus voting using a nominal technique to decide on the subdomains for inclusion. Following on from this meeting, using a further process of triangulation, all results were combined, prioritising patient and stakeholder views, supported by co-researchers, to decide on the subdomains for inclusion. The final initial draft toolkit (version 1; v1) mapped the list of domains and subdomains onto 60 CAT items, 24 items from the EORTC item library and 1 novel item and was approved by the ExCo and co-researchers. We opted to include more items rather than fewer items at the usability stage in order to establish the ‘best’ items to cover a particular subdomain in areas where CAT was not an option or where we had decided not to use CAT within the usability study.



**Figure 3. Updated Conceptual Framework after Interviews and Delphi.**

In report D4.2, we described the results of initial usability testing with patients, using mixed qualitative and quantitative methodology, to establish patients’ views regarding the EUonQoL-Kit v1. Participants from each of the target groups (Active Treatment, Survivors and Palliative Care) completed the respective EUonQoL



questionnaires as part of a cognitive interview which provided feedback on the usability and acceptability of the toolkit. Due to timing restrictions, only the static version of the EUonQoL-Kit were tested, however were tested both digitally via a tablet application and via pen and paper method. The results of the usability testing were presented and discussed across multiple platforms including our regular WP4 weekly meetings as well as at two internal consortium meetings (5<sup>th</sup> & 13<sup>th</sup> December 2023) and at a public Stakeholder Forum event (12<sup>th</sup> December 2024). Regular discussions with the key stakeholders resulted in an iterative approach to finalising version 2 of the EUonQoL-Kit. The processes of which are to be discussed further in this report.

The objective of this report is to describe the development and content of the EUonQoL-Kit v2, developed following the completion of the Usability study of the EUonQoL-kit V1, reported in D4.2.

### 3. Methodology

#### Definition of the target population

The target population groups defined throughout all stages of the EUonQoL project are reported in D4.1 and here below:

##### A. Active Treatment:

- I. Curative treatment - undergoing or recently completed curative treatment for early-stage cancers.

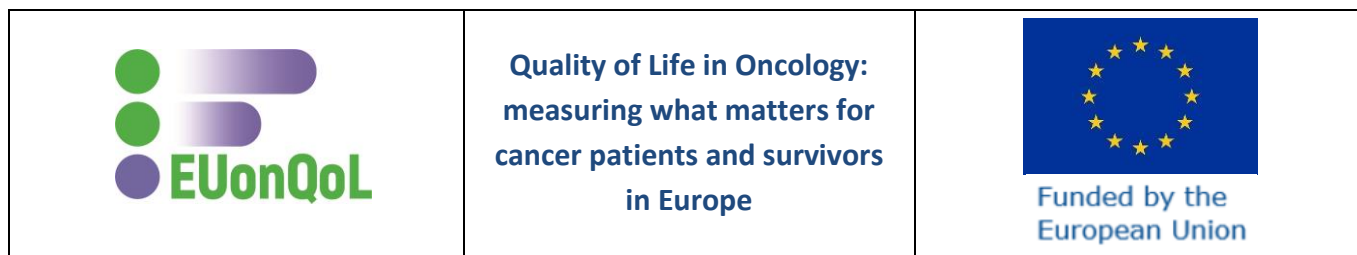
Examples:

- Early stage 1-2 breast cancer during or up to 3 months following radiotherapy, surgery or systemic treatments.

- II. Non-curative treatment for advanced/metastatic cancers, including disease controlling/life prolonging tumour-directed treatment (e.g. patients with metastatic disease receiving chemotherapy, immunotherapy or targeted agents)

Examples:

- Metastatic breast cancer on 1st line palliative chemotherapy.
- Lung cancer on immunotherapy.



**B. Survivors:** At least one year off active treatment (but can be on long-term adjuvant hormone therapy) and being disease-free without evidence of active cancer. We will aim to recruit survivors >5 years.

Examples:

- ER/PR+ breast cancer treated with surgery, adjuvant radiotherapy and on 10 years of hormonal treatment.

**C. Palliative care:** Patients with advanced cancers who meet at least one of the following criteria:

- I. Patients with projected prognosis <12 months with a Performance Status (PS)/Karnofsky (KPS)  $\leq 70$  or ECOG  $\leq 2$ .
- II. Patients referred to a specialist palliative care team for symptom control.
- III. Patients may be receiving non-curative treatment purely for symptom control (including palliative radiotherapy and/or systemic treatment).

Examples:

- Patients with castrate-resistant prostate cancer, progressed through systemic treatment options referred for radiotherapy for bone pain.
- Metastatic breast cancer patient on 5th line systemic treatment.

## Materials

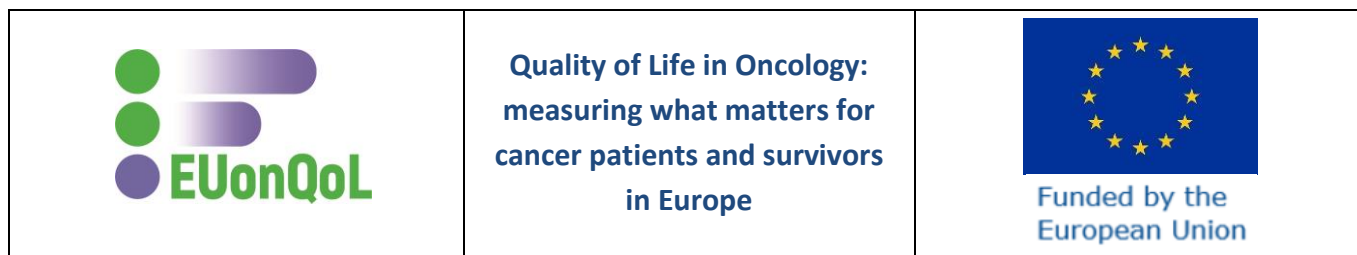
EUonQoL-Kit v1 provided the foundation from which v2 was developed. The development and content of the EUonQoL-Kit v1 are outlined and described in previous reports (D4.1 & D4.2), however in summary, the number of items included within the version v1 varied by target group:

Active Treatment (Group A) – 75 items

Survivors (Group B) – 67 items

Palliative Care (Group C) – 79 items

Version 1 of the EUonQoL-Kit were developed in accordance the conceptual framework described in Figure 3 and included items from across the Physical, Psychological, Social and Overall health domains. In addition to this, the toolkit captured patient experiences relating to their Healthcare. Version 1 was designed following an inclusive inclusion strategy whereby a greater number of items were included to EUonQoL



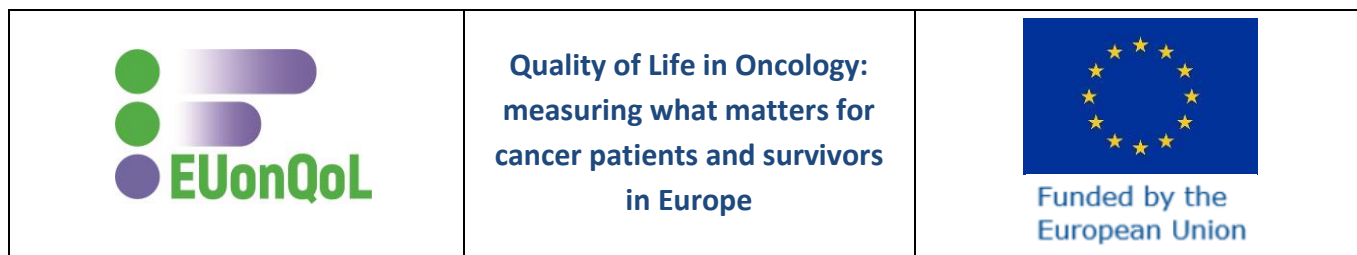
collect additional data in the Usability study and thus facilitate the decision-making process for selecting item to be included in v2.

Most items included in EUonQoL-Kit v1 were selected from the EORTC Item Library and EORTC CAT item bank. These are internationally validated items from existing questionnaires. In addition to this, five new items were also added. Of these, four were modified items from the Chronic Cancer Experience Questionnaire CCEQ (Harley et al. 2019) and one novel item developed by WP4 in collaboration with co-researchers.

For the majority of items, the response scale consisted of 4-likert scale response categories: 1: not at all, 2: a little, 3: quite a bit and 4: very much. For all items there was an option to not complete ('prefer not to answer') and for some items, a 'not applicable' option was also included. The Overall QOL and Overall health response categories range from 1: Very poor to 7: Excellent. One item within the Healthcare domain employed a 5-likert scale response 1: Poor, 2: Fair, 3: Good, 4: Very good and 5: Excellent. With regards to the timescales provided, most items had a one-week recall period, however a four-week recall was included for some. The remaining items included the timescale within the item stem, for example, 'Since the diagnosis and treatment of your cancer'. Please see Appendix 8.1 for the items included in EUonQoL-Kit v1. Feedback on timescales and response options was collected in the Usability study.

## Procedure

The development process was an iterative approach and employed the triangulation of various data to produce version 2 of the toolkit. It was a collaborative process involving a multitude of different stakeholders and collaborations. A variation of Consensus development panels method was used to make decisions and reach agreement on what was included in EUonQoL-Kit v2. This method of reaching agreement is commonly utilised within healthcare research, particularly research aimed at developing strategic plans and policies, as it facilitates a multidisciplinary approach to decision-making (Waggoner et al. 2016). It is an efficient, cost-effective method of synthesising data in order to make valid decisions on a given topic (Waggoner et al. 2016). Whilst this method is often completed face-to-face, this project conducted the consensus meetings online as this method facilitated the inclusions of experts and key stakeholders from across the EU. To ensure the highest level of expert engagement, several different meeting designs were used. This included regular weekly WP4 meetings, two wider consortium meetings and a public stakeholder forum. Guidance provided by Waggoner et al., suggests the panels should be made up experts in the field and consist of between 8-12 members. The weekly WP4 meetings consisted



of 8-25 participants, the consortium meetings held 20+ and whilst the Stakeholder forum had approximately 100 delegates, the breakout sessions consisted of around 15-20 people.

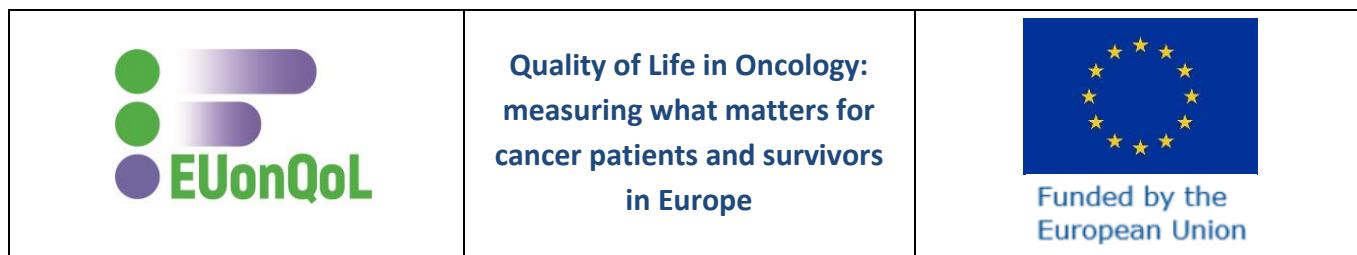
A pragmatic, systematic and transparent approach to the development of EUonQoL-Kit v2 was adopted. Each domain, sub-domain and individual item was systematically reviewed for inclusion by WP4 and its collaborators. The available data were summarised and presented to the stakeholders during the meetings where provisional decisions were made and documented. These decisions were then presented again at the subsequent meetings and discussed until an agreement was reached between the key stakeholders (WP4, co-researchers, CAT Team and collaborators from other workpackages e.g. WP3, 5, 7). Data from the stakeholder forum and consortium meetings were introduced into this iterative process and discussed in line with the available evidence. For example, the overall number of items selected for inclusion was guided by the criteria set during the consortium meeting. Table 3 highlights the decision criteria outlined prior to the study.

**Table 3. Item retention decision criteria.**

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 patients (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 <b>10%</b> of patients mentioning this to include (n=6)
7. CAT items with the highest precision

\*Not formally assessed due to low sample size.

Further guidance from Waggoner et al. 2016 suggested the method of analysis must be reasonable for the study objective, as well as providing rigor to the data. In this study, rigor was provided through the use of empirical evidence collected from the EUonQoL workpackages, predefined inclusion criteria, diligent note taking and executive summaries from the meetings. The study utilised data from the Usability study (presented in D4.2) and earlier development work (presented in D4.1) where relevant, throughout the decision-making process. The data was used to justify the inclusion or exclusion of items and consisted of both quantitative and qualitative data. Key data from the qualitative results included information and feedback on the overlapping and/or repetitive items as well as those that were potentially upsetting, those with language related issues and any formatting issues. Key criteria from Quantitative data included the



range of responses (including Not applicable and prefer not to answer), the response rate (95% or higher) and means. These provided the evidence and rational from which all decisions were made. For transparency, these decisions are documented and presented in the Appendix 8.2.

## Consortium meetings

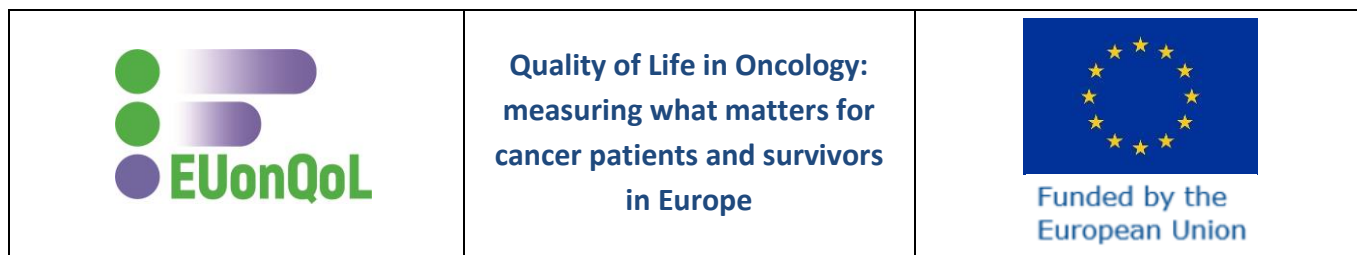
Two consortium meetings were held via Microsoft Teams to decide on the structure and overall content of the EUonQoL-Kit v2. The meetings were 2.5hrs long and included a consortium of members involved across the wider EUonQoL project, not just those involved in WP4. The first meeting was held on 5<sup>th</sup> December 2023, the second on 13<sup>th</sup> December 2023. The second meeting was used to finalise any outstanding decisions from the first meeting as well as discuss the topics and feedback that was generated from the public stakeholder forum that was held on 12<sup>th</sup> December 2023.

The group contained leading experts from across the EU. The aims of the meetings were to agree upon a proposed total number of items, as well as deciding the number of CAT subdomains that were to be included and which items would be the CAT starting items. At this stage it was important to consider the overall balance of the EUonQoL-Kit, for example, number of physical, social etc items, and its structure e.g. presentation and ordering of the domains and their corresponding items, in line with the aims of the project. They were also used to agree upon the inclusion of new subdomains and items not previously included in version 1.

## Stakeholder forum

A public and open stakeholder forum was held on 12<sup>th</sup> December 2023. The stakeholder forum was a 2-hour virtual session where interested stakeholders from outside of the EUonQoL project could join and provide comments and feedback on the EUonQoL-Kits v1. The event was publicised by WP2 via social media and the website, in total, there were over 110 delegates in attendance including EUonQoL workpackage member, co-researchers, stakeholder board members as well as those joining from outside of the EUonQoL project. The aim of the stakeholder forum was to engage with a much wider audience and to generate feedback from external stakeholders and incorporate this data into the development of EUonQoL-Kits v2. Further details of the forum will be published by WP2.

The forum consisted of two sessions, the first outlined the aims and progress of the project and provided necessary the background and context to generate useful discussion in the second session. In the second session, four breakout rooms were held whereby each domain included in the toolkit was presented and



discussed. Within these sessions the preliminary results from the Usability study were also discussed. Stakeholders and members of WP4 discussed the content of the toolkits. Suggestions and feedback were noted and subsequently used in the decision-making process for EUonQoL-Kit v2.

## Weekly WP4 meetings

Throughout the development process of the EUonQoL-Kit, WP4 and its collaborators have held hourly weekly meetings which have been critical for achieving the objectives of WP4. The meetings began July 2023 and continue up until the present time. During the development of EUonQoL-Kit v2, these meetings were instrumental in making decisions and agreeing on the final toolkit. Over a six-week period between December/January, additional meetings were also held with smaller groups outside of these meetings to discuss each domain. Each sub-domain and its subsequent items were reviewed in turn and a decision was made for each. Where no consensus or agreement on which items to include were made, further meetings were held, and discussions continued until all were confirmed. The results of which were discussed at the wider weekly meetings.

## 4. Results

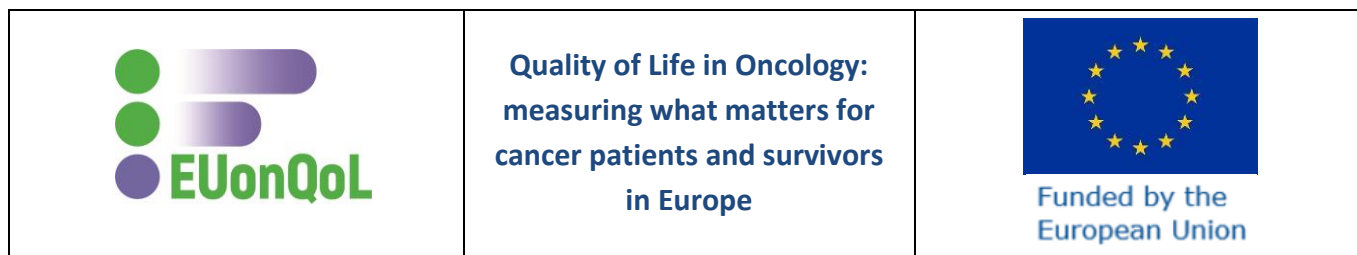
The development of EUonQoL-Kit version 2 (v2) was an iterative process drawing on various sources of data and information. The decisions that led to the development of version 2 are presented below and grouped in accordance with the three main methods. The results are reported chronologically, with the key final decisions presented. As this was an iterative process, decisions did not happen in isolation. Wider, and more global decisions were made at the consortium and stakeholder level, whilst the final decisions were made at WP4 weekly meetings.

### Consortium meetings

Two consortium meetings were held either side of the public stakeholder forum (05/12/23 & 13/12/23). The results from the consortium meetings are presented below. The decisions were made at a global level and related to the structure and overall content of the EUonQoL-Kit. This included the decisions on both the Static and Dynamic versions and resulted in the development of a framework from which EUonQoL-Kits v2 were structured.

The overall structure of version 2 was discussed, and an agreement was reached to maintain the format as tested in EUonQoL-Kit version 1 (v1). The presentation of EUonQoL v2 adopted the same overall



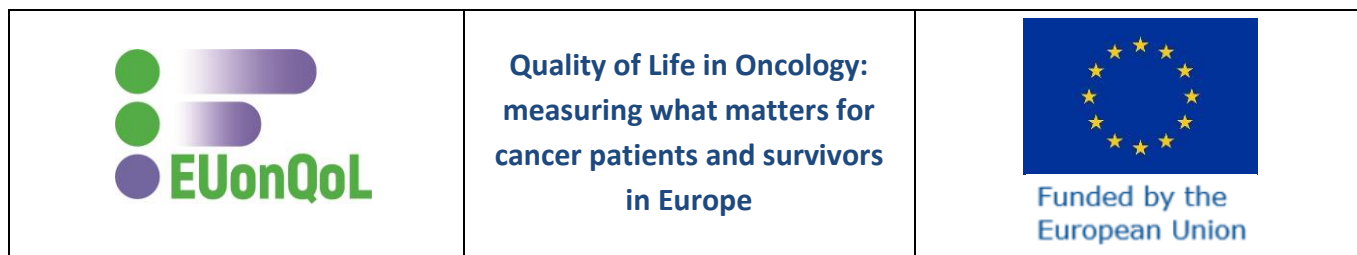


structure to that of EUonQoL-Kit v1 whereby physical issues and symptoms were presented first, followed by a mix of social and psychological issues and the overall health domain completed the patient reported outcomes section. The final section of the EUonQoL-Kit included the Healthcare domain, which consisted of items relating to patient reported experience of care. To distinguish these sections, the Write in three symptoms or problems (WISP) item was used to bookend the PRO section before participants then moved onto the patient reported experience items. Co-researchers provided further support on the proposed structure, stating that *“when completing QoL related questionnaires, people expect to see physical symptoms first as this is what is familiar to them. Therefore, it is acceptable to maintain a similar structure for the Toolkit v2”*.

Other factors that influenced the structure of the EUonQoL-Kit included the timescales associated with the items as well as the content of the items, for instance whether or not an item was perceived to be of a sensitive nature. It was agreed that maintaining the continuity of the EUonQoL-Kit and creating an easy-to-follow questionnaire was important, therefore it was agreed that items with a similar timescale would be grouped together. In addition to this, items relating to sex life, intimacy and body image were positioned in the centre of the questionnaire as this is common practice when designing questionnaires (Bowling 2005).

The Usability results identified the need to reduce and refine the number of items included in version 2. Specifically, feedback from participants highlighted the inclusion of many overlapping and/or repetitive items. Taking into account version 1 was designed to be over inclusive of items to facilitate the decision-making process on the final item choice and wording, the consortium took the necessary action to reduce the total number of items included in version 2.

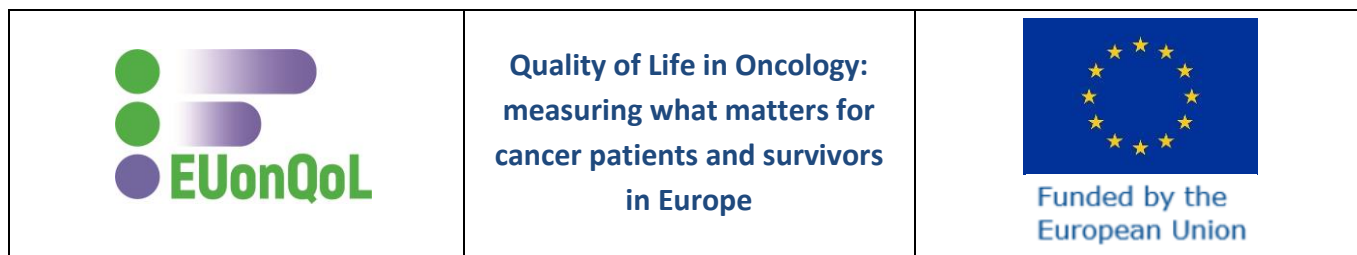
The consortium decided that reducing the number of dynamic CAT dimensions included in the toolkit would help lower the total number of items and avoid repetitive items. Following a review of the Usability data, five sub-domains previously selected as dynamic CAT dimensions in EUonQoL-Kit v1 were downgraded to static, non-CAT sub-domains. The five sub-domains included Appetite, Nausea/Vomiting, Constipation, Dyspnoea and Cognitive Function. It is important to note that whilst these sub-domains were removed as CAT dimensions, the issues remained as static items in EUonQoL-Kit v2. Evidence from the Usability study identified these five issues as having high levels of overlap between the included items. For example, in version 1 up to four items were included for Dyspnoea and participants reported this as being excessive and unnecessary as the issue could be captured by significantly fewer items. This was a common theme across these five sub-domains.



Further evidence from the Usability and stakeholder feedback supporting the reduction of items was also taken into consideration when making these decisions. The feedback was focused on reducing the burden placed on those completing the EUonQoL-Kit. This was of particular concern for patients in the palliative care group whose frailer condition may limit their ability to complete long questionnaires. When reviewing EUonQoL-Kit v1 and the results from the Usability study, Appetite, Constipation and Dyspnoea accounted for a large number of items which were predominantly being asked to the palliative care group. Therefore, the decision was taken to convert these to non-CAT sub-domains not only to reduce the total number of items, but it also to significantly reduce the number of items presented to this target group, whilst not compromising the overall measurement properties of the Toolkit. Table 4 presents the list of sub-domains included as dynamic CAT dimensions in EUonQoL-Kit v1 and those no longer included as CAT dimensions in version 2.

**Table 4. List of dynamic CAT subdomains included in EUonQoL-Kit v2.**

Included CAT Dimensions EUonQoL-Kit v1	Included CAT Dimensions EUonQoL-Kit v2
Physical Functioning	Physical Functioning
Role Functioning	Role Functioning
Pain	Pain
Fatigue	Fatigue
Sleep	Sleep
(Lack of) appetite	Emotional Functioning
Nausea/Vomiting	Social Function
Constipation	Financial Difficulties
Dyspnoea	
Emotional Functioning	
Cognitive Functioning	
Social Function	
Financial Difficulties	



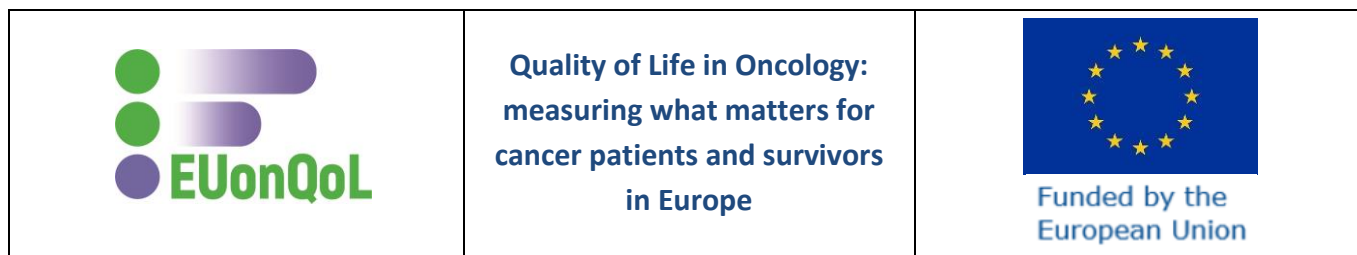
Having established the eight sub-domains that were to be included as dynamic CAT dimensions, a strategy for the selection of items in both the static and dynamic EUonQoL-Kit was agreed. Table 5 presents the initial framework proposed at the consortium meeting to guide the item selection process for the CAT dimensions. For both versions of the EUonQoL-Kit, the number of items to be included in each dimension were proposed by the specialist CAT Team from the EORTC Quality of Life Group (EORTC QLG). The recommendations were based on factors such as the precision and number of items necessary for the development of scales. These recommendations were used in combination with the item retention rules presented in Table 3. It was agreed that for the static version, the total number of items would be approximately 52 for Groups A and B and 40 for Group C. The dynamic version would consist of 50 CAT based items plus the additional static or non-CAT items resulting in a final total of between 80-85 items.

**Table 5. Provisional framework for selecting items for version 2.**

Domain	Static version			Dynamic version		
	Group A	Group B	Group C	Group A	Group B	Group C
Mobility & Activity / physical functioning (PF)	3	3	2	7	7	7
Social role & Activities / Role functioning (RF)	2	2	1	6	6	6
Pain (PA)	2	1	1	6	6	6
Energy / fatigue (FA)	2	1	1	6	6	6
Insomnia / sleeping problems (SL)	1	1	1	6	6	6
Anxiety and worry / emotional functioning (EF)	3	4	2	7	7	7
Family and Relationships /social functioning (SF)	2	3	1	6	6	6
Financial aspects/difficulties (FI)	2	3	1	6	6	6
<b>Total From CAT Scales</b>	<b>17</b>	<b>18</b>	<b>10</b>	<b>50</b>	<b>50</b>	<b>50</b>
Physical symptoms - single items (5+1)	6	6	6	6	6	6
Other non-CAT items	14	15	9	14	15	9
PREMs	12	10	12	12	10	12
OVERALL+WISP	3	3	3	3	3	3
<b>Final Total</b>	<b>52</b>	<b>52</b>	<b>40</b>	<b>85</b>	<b>84</b>	<b>80</b>

## Stakeholder Forum

The public stakeholder forum was held on 12<sup>th</sup> December 2023. The results of which were processed by WP2 and formatted into an executive summary from which the stakeholder feedback was extrapolated



and included in the decision-making process for the development of EUonQoL-Kit v2. An overview of the feedback is provided below.

### **Physical domain:**

There was an agreement between stakeholders that EUonQoL-Kit v1 was missing the common symptom of diarrhoea and thus proposed its inclusion in version 2. As a result, diarrhoea was subsequently included in EUonQoL-Kit v2, see section (Diarrhoea) below for details. Diarrhoea was originally included in the initial phase of the development, and was only removed to reduce patient burden as it was not ranked as high as other issues in the interviews and Delphi studies. Oral health was raised by one participant as being a sub-domain that was potentially missing from the toolkit. This was discussed amongst the stakeholders; however, the final result was that it would not be included in version 2 due to being a specific side effect of a particular treatment and thus did not meet the brief in which the EUonQoL-Kit is to be used.

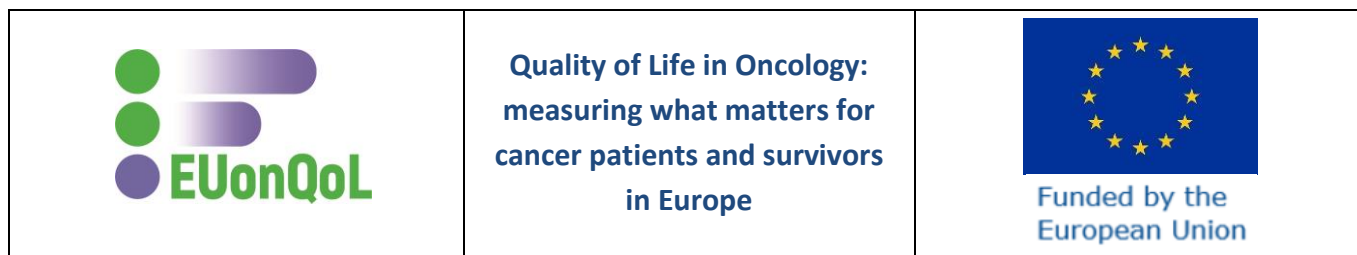
The omission of a question addressing the sex life of those in the palliative group was raised and discussed by the stakeholders. It was agreed that whilst this sub-domain is important for all groups, a different item should be asked to group C that is more sensitive to their condition. Stakeholders identified a question relating to intimacy as a potential option for Group C. Further to this the discussion identified that, in error, an item previously considered for inclusion in version 1 was in fact not included. The item related to the impact on partner relationships. This was discussed in greater detail within the WP4 weekly meetings, the outcome of which was that it was reintroduced in version 2 and further details are presented in section (Sex life sub-domain) below.

### **Social health:**

The discussions within the social health domain highlighted the importance of assessing financial toxicity within a cancer population as it can have a wide-ranging impact on QoL. Other comments related to the sex life sub-domain, which whilst was not conceptually assigned to the social domain, was a key point of discussion for the members of the forum. When reviewing the comments with those held in the physical domain session, there was clear overlap and agreement that the palliative care group should be asked an item relating to sex life or intimacy.

### **Psychological domain:**

Key sub-domains were identified as being important for inclusion in the EUonQoL-Kit and included items relating to fatigue, worry and anxiety. There was the suggestion of adding an overall open question to



allow for the additional reporting of problems and to mitigate the known limitations of closed questions; this is covered by the WISP question.

### **Overall health and Healthcare:**

Stakeholders were in favour of a free text or free comment item at the end of the EUonQoL-Kit to allow for the further expression of details by the participants. The inclusion of the Overall Health and Healthcare domain was supported, specifically around the communication and HCP interactions sub-domains. Subsequent discussion led to the proposal of including a new sub-domain addressing the 'coordination and continuity of care'. This proposal was taken forward and discussed in WP4 weekly meetings whereby a new item was developed and included in EUonQoL-Kit v2. Further details can be seen below in section (New sub-domains).

### **General feedback:**

More general feedback from the stakeholders supported the inclusion of open questions, such as the WISP and a free comment item at the end of the toolkit. They highlighted the importance in having clear definitions of the three target groups, as each group will have different experiences that should be accounted for within the EUonQoL-Kit. These discussions support the rationale to have three toolkits to address these specific needs. In addition to this, the importance of ensuring the EUonQoL-Kit is user friendly, and the importance of clear instructions or guidance and clear structure/layout were pointed out. This led to the introductory text being expanded and the addition of a closing statement at the end of the Toolkit, discussed further in section (Updated instructions for participants).

## **WP4 weekly meetings**

The triangulation of evidence was routinely presented and discussed at weekly meetings which resulted in the finalisation of EUonQoL-Kit v2. The qualitative and quantitative data provided in the Usability study was utilised in the decision-making process. Decisions were made at the sub-domain and item level and are presented in Appendix 8.2. The main results are presented below.



### **Selection of CAT starting items**

As discussed in section (Selection of CAT starting items), eight sub-domains were included as CAT dimensions. In the dynamic version of the EUonQoL-Kit, for each dimension, a prespecified number of items will be presented to participants. The content of the items is determined by the CAT algorithm which selects the most appropriate item for the participant from the Item Bank. Therefore, the CAT version only

required the selection of a 'start item' which is asked to all participants of group A, B, or C using the dynamic version. The starting items to be included in the dynamic versions are highlighted in Yellow (Table 6). In the static version of the EUonQoL-Kit, it was necessary to select specific items that best captured these sub-domains. For EUonQoL-Kit v1 the items selected were based on existing data separating responses in mild, moderate and severe criteria. The final decisions for inclusion in EUonQoL-kit v2 were based of the Usability results and the expert knowledge of the CAT Team. The items selected for inclusion in each of the static version EUonQoL-Kit are denoted in Green in Table 6. Subsequently, items included in version 2 are denoted by the symbol 'v2'.

**Table 6. CAT dimensions and their corresponding starting item for the dynamic version of the EUonQoL-Kit.**

Item Library Code	Items - English	ACTIVE (Group A)	SURVIVORS (Group B)	PALLIATIVE (Group C)
CAT - Physical Function				
Q4	Do you have any trouble doing strenuous activities, like carrying a heavy shopping bag or a suitcase?	v2	v2	
Q5	Do you have any trouble taking a long walk?		v2	
Q641	Do you have any trouble carrying a heavy bag upstairs?	v2	v2	
Q631	Do you have any trouble walking for 30 min.?	v2		v2
Q9	Do you need help with eating, dressing, washing yourself or using the toilet?			v2
CAT - Role Functioning				
Q7	Were you limited in doing either your work or other daily activities?	v2	v2	v2
Q10	Were you limited in pursuing your hobbies or other leisure time activities?	v2	v2	v2
CAT - Pain				
Q12	Have you had pain?	v2	v2	v2
Q22	Did pain interfere with your daily activities?	v2	v2	v2
CAT - Fatigue				
Q21	Were you tired?	v2	v2	v2
Q743	Have you required frequent or long periods of rest?	v2	v2	v2
CAT - Sleep				
Q14	Have you had trouble sleeping?	v2	v2	v2
CAT - Emotional Functioning				
Q665	Have you felt miserable?	v2	v2	v2
Q27	Did you feel depressed?	v2	v2	v2

	<p align="center"><b>Quality of Life in Oncology: measuring what matters for cancer patients and survivors in Europe</b></p>	 <p align="center">Funded by the European Union</p>
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Q25	Did you worry?	v2	v2	v2
CAT - Social Function				
Q30	Has your physical condition or medical treatment interfered with your social activities?	v2	v2	v2
Q721	Has your physical condition or medical treatment interfered with your relationships with your family or friends?	v2	v2	v2
Q719	As a result of your physical condition or medical treatment, have you felt isolated from your family or friends?	v2	v2	v2
CAT - Financial Difficulties				
Q31	Has your physical condition or medical treatment caused you financial difficulties?	v2	v2	v2
Q850	As a result of your physical condition or medical treatment, have you had difficulties paying any of your regular expenses (e.g. rent, insurance, phone)?	v2	v2	

v2; indicated which items were included in EUonQoL-Kit version 2 across the respective target groups. Green further highlights its inclusion in version 2. Yellow indicates the starting items selected in the dynamic versions of the toolkit.

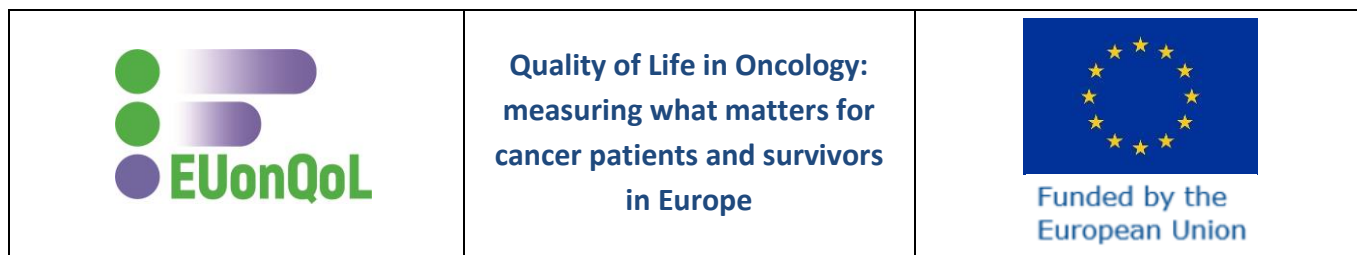
### Significant updates from EUonQoL-Kit v1

#### Diarrhoea

Diarrhoea was originally excluded from EUonQoL v1 based on the available data from the interviews, Delphi and results of the consensus meeting. However, following evidence from the Usability study and public stakeholder forum, WP4 and its collaborators revisited this symptom and considered its inclusion in EUonQoL-Kit v2. It was determined that the added value this symptom may add warranted it being reintroduced into version 2. The symptom was included and positioned after constipation with the other single symptom items and included for all three target groups.

#### Symptom worries

Three items were included for the Symptom worries sub-domain. Two items were from EUonQoL-Kit v1, and the third was a novel item created by WP4 and its collaborators. The new item was developed to assess the physical impact or burden the disease and/or treatment has on the individual at a more global level. It was hypothesised that the inclusion of such an item may reduce the need to ask numerous physical symptom items. Data from the new item is to be further explored using the data from the Pilot study. This data will facilitate future decisions on what items are included in the final toolkit. Q46 '*How much has your disease been a burden to you?*' was retained despite the Usability data highlighting German and French translation of the term 'Burden' can potentially be understood either as psychological or as physical. The



rational for its inclusion was due to the fact stakeholders thought it important that the toolkit assessed the impact of the disease at a global level, in addition to assessing the impact of treatment.

New: *'To what extent have you been troubled with physical symptoms from your disease or treatment?'*

Q46: *'How much has your disease been a burden to you?'*

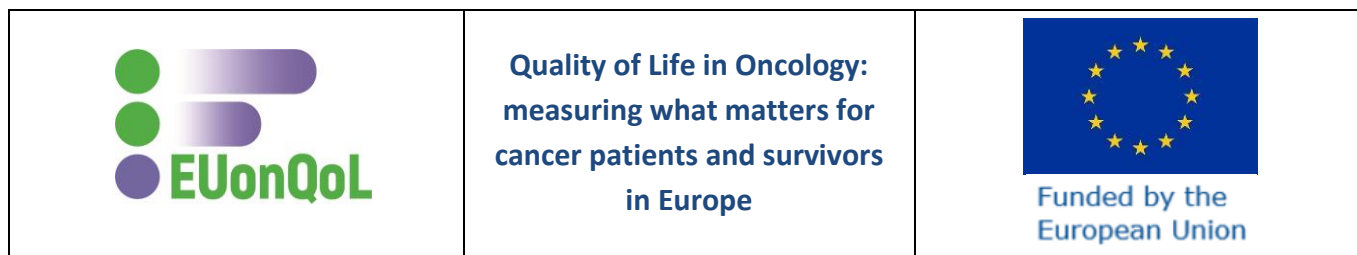
### ***Cognitive function - Concentration & Memory***

Originally a CAT dimension, the sub-domain of 'Concentration & Memory' was downgraded to a static sub-domain following the results of the Usability testing and wider discussions with the Consortium. The selection of items for assessing this sub-domain were discussed at the weekly WP4 meetings whereby it was confirmed EUonQoL-Kit v2 would contain a single item on concentration. The item selected focused on the ability to concentrate on important things as this item was reported to carry more significance to both participants and stakeholders. The exclusion of memory-based items was due the fact the Usability results indicated these items were difficult for participants to answer as they were related more to age than their cancer.

### ***Social functioning***

For the static EUonQoL-Kit, three CAT items were selected for all three target groups. The two additional non-CAT items assessed partner relationship and fertility, the latter being asked to Group A and B only with a 'not applicable' response option. The item on impact on partner relationship was originally shortlisted for inclusion in version 1, however when the sub-domains were combined to form social functioning the item was not included. The original rationale was to use this item to assess the potential breakdown of relationships and capture the loss of intimacy within Group C in lieu of a direct question about sex life. Following discussion and feedback from the stakeholder forum it was made clear that this item should be added to version 2 as it has potential to be actionable for health policy, in particular health economics. The item *'Since the diagnosis and treatment of your cancer: Is your relationship with your partner stronger?'* was therefore added to EUonQoL-Kit v2. In addition to this, a second non-CAT item was included to assess issues surrounding fertility. This is a key issue, particularly for the younger population and was therefore included *'Have you worried about your ability to have children?'* The social isolation question was highlighted as key in the stakeholder/consensus meetings and was included in the static version.





### ***Sex life sub-domain***

Within the sex life sub-domain, a single item was included in EUonQoL-Kit v1 for target groups A and B only. The omission of a direct or indirect question for the Palliative group was discussed at length across the weekly meetings and the issue was also raised by various stakeholders. In recognition of this, the item about partner relations (Q1004) was reintroduced and further to this, a new item modelled on the Danish Palliative care questionnaire was drafted and included for Group C in version 2 to meet the needs of this target group. The new item was, *'Have you been missing intimacy (e.g. closeness, fondness, sex)?'*

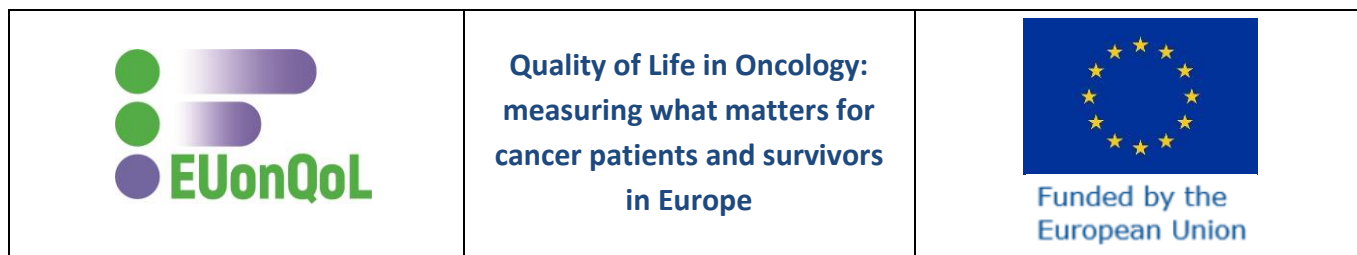
### ***Impact of care pathway - PREMs***

A resulting change saw the inclusion and adaptation of the items included within the 'impact of care pathway' sub-domain. Three items were selected in total, one from the EORTC Item Library, and two from the Chronic Cancer Experience Questionnaire (CCEQ) (Harley et al. 2019). The CCEQ items included in version 1 were presented as statements, as per the original questionnaire. However, to ensure the continuity of the EUonQoL-Kits, WP4 and its collaborators felt it necessary to update and transform these statements into questions to ensure the toolkit was unified. Therefore, the two CCEQ items were drafted and discussed, the resulting wording can be seen in EUonQoL-Kit v2 (Appendix 8.3).

### ***New sub-domains***

A major addition to EUonQoL-Kit v2 was the addition of a new sub-domain not previously included. This domain arose from within the Stakeholder forum and consensus meeting in Utrecht October 2023. It included an item assessing the 'Continuity and coordination of care'. The item itself was new, modelled on Q870 from the EORTC PAT-SAT questionnaire. Workpackage 4 and Co-researchers created this new item to assess the perceptions towards the continuity and coordination of their care. It was thought that this item may provide useful information at a policy level. The final item wording included in version 2 was *'Do you feel doctors, nurses and other professionals involved in your care work together as a team?'*

Another new addition for version 2 was the inclusion of a final question asking participants to rank which domains and/or sub-domains are most important to their QoL. This additional was a result of the consensus meeting held in Utrecht in October 2023 as this is where the idea first originated. WP4 then took this idea and explored the opportunities to include it in the toolkit. Over the course of several meetings, including the consortium meetings an agreement was reached on how such an item could be integrated. The final wording can be seen in EUonQoL-Kit v2, *'Having completed the questionnaire, what do you feel most impacts your Quality of Life?'*



The rationale for the inclusion of such an item was to provide a free text response option (limited in the number of characters) for participants to express their thoughts on which of the QoL domains are of most importance. It is thought that this item may provide important information into the significance and importance of particular dimensions that may be of interest to the policy makers. It is important to note that this item differs from the WISP item as it is asking participants to rank at a domain/subdomain, whereas the WISP provides participants the opportunity to record any symptoms or problems not already covered by the EUonQoL-Kit.

### ***Change of timeframes***

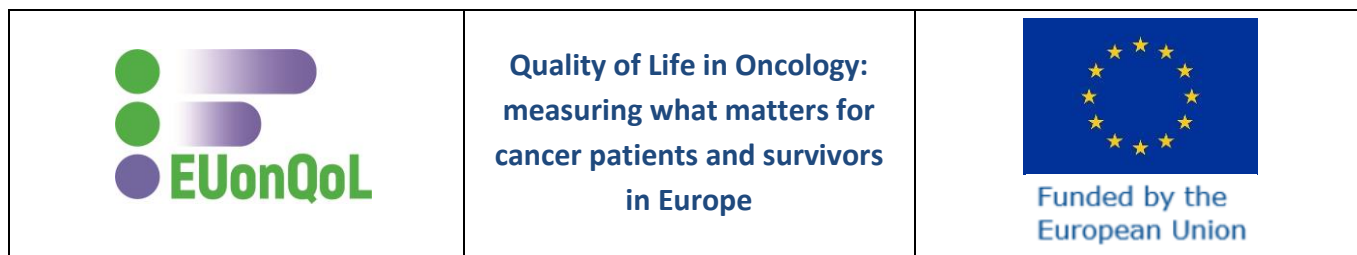
Feedback from the Usability study highlighted several items that were presented with a timescale that was perceived as being too short. These items included sex life, body image and fertility questions. In response to this feedback, these items were removed from the 'past week' timescale and instead presented as 'During the past 4 weeks'.

### ***Updated instructions for participants***

Following the Usability study, modifications to the instructional information included within the EUonQoL-Kit were made. Results indicated that participants wanted more information in the opening statement to make completing the Toolkit easier for them. Specifically, a greater degree of context was added to the start to better inform the participants. The instructions preceding the PREM items were also modified to again provide participants with additional context to aid their completion. In this instance, the term healthcare professional was defined with examples. A closing statement was added detailing instructions for the participant to contact their medical team should they require assistance with any of the symptoms or problems reported in the EUonQoL-Kit was included to ensure that participants are fully aware their answers will not be seen by the medical team.

### ***Changes to response scales***

Important changes were also made to the response scales for the items included within the Healthcare domain. In EUonQoL-Kit v1, the standard EORTC 4-point Likert scale was used throughout the healthcare domain, except for one item on impact of care pathway which had a 5-point scale. The decision to include a 5-point Likert scale across this domain in EUonQoL-Kit v2 was based on a literature search and the experience of leading experts in the field of PREM development. Following discussion and debate, two different 5-point scales were included for the PREM items. The first was applied to items related to 'satisfaction'. This was a 5-point positively phrased response scale from the EORTC satisfaction questionnaire (Poor, Fair, Good, Very Good & Excellent). The scale has been used internationally and the



positive direction of the scale enables more discriminative answers due to the known ceiling effects associated with satisfaction questions (Bredart et al. 2005).

The second scale was applied to the remaining items that address reports of care events in terms of a 5-point frequency scale (Never, Sometimes, Usually, Almost Always & Always). The decision to include a frequency scale was based on the input from expert collaborators who have experience in the development and validation of patient experience measures. Feedback and data from a recent pilot study of over 200 people, found that frequency-based scales were perceived better by patients.

## Final results – EUonQoL-Kit v2

### Static Questionnaires

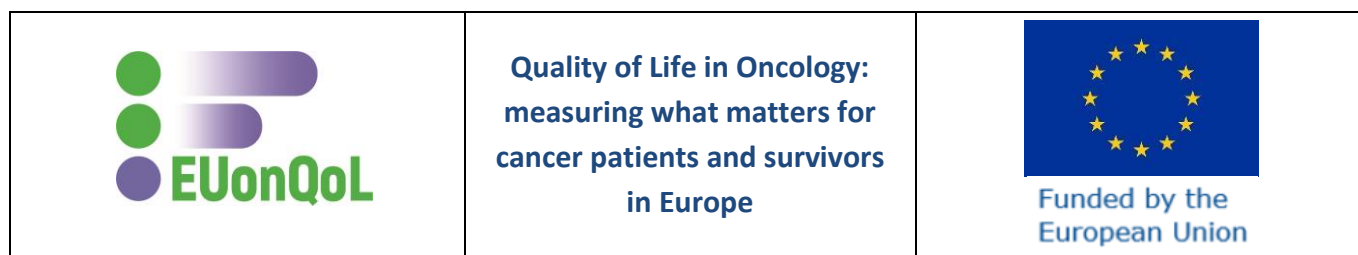
The final version of EUonQoL v2 was submitted on 15<sup>th</sup> January 2024. Version 2 will undergo a formal translation process coordinated by WP5 before being tested in the Pilot study (WP7).

The balance between the number of items included for each of the included domains was an important consideration. It was therefore decided that weighting of EUonQoL-Kit v2 would be in line with version 1, with the aim of reducing the proportion of physical items where possible. Overall, EUonQoL-Kit v2 was well balanced between the assessment of physical and non-physical domains (Table 7).

**Table 7. Proportion of items included for each domain within the three different versions of the EUonQoL-Kit.**

Domain	Number of items v1 (%)	Number of items v2 (%)
Physical	43 (44)	23 (41)
Social	22 (22)	12 (21)
Psychological	17 (17)	9 (16)
Overall health	4 (4)	4 (7)
Healthcare	12 (12)	8 (14)
Total	98 (100)	56 (100)

The final characteristic of the static EUonQoL-Kit v2 are outlined in Table 8 **Errore. L'origine riferimento non è stata trovata.** and Table 9. The EUonQoL-Kit for both Active Treatment (Group A) and Survivors (Group B) each contains a total of 50 items. The EUonQoL-Kit v2 for Palliative care (Group C) contains 44 EUonQoL



items. All three toolkits were considerably shorter than their respective version 1 counterpart (Group A – 75 items, Group B – 67 & Group C - 79) due to removal of overlapping items. Whilst version 2 is shorter, the content of the EUonQoL-Kit has been expanded with the inclusion of new subdomains and items not previously included in version 1. Importantly, the number of items included in Group C was significantly reduced as a key concern related to its burden on patients in this group. Please see Appendix 8.3 for the final static EUonQoL-Kits v2.

**Table 8. Final characteristics of the three static EUonQoL-Kit as per domain.**

Domain	Number of items		
	EUonQoL-Kit A_v2 (%)	EUonQoL-Kit B_v2 (%)	EUonQoL-Kit C_v2 (%)
Physical	18	19	17
Social	12	12	9
Psychological	8	8	7
Overall health	4	4	3
Healthcare	7	6	7
Other	1	1	1
Total	50	50	44

Each questionnaire covers several Quality-of-Life (QoL) dimensions, as well as Patient Reported Experience Measures (PREMs), two items on overall health and QoL perception, one open-ended question to report about symptoms and problems not covered by the questionnaire (“Write in three symptoms and problems” - WISP item), and a general open-ended question regarding what mostly impacts the responders’ QoL. Table 9 shows the item composition of the 3 static questionnaires.

**Table 9. Item composition of EUonQoL-Kit – static questionnaires.**

Dimensions	Number of items		
	Group A	Group B	Group C
	Active Treatment	Survivors	Palliative Care
Mobility & Activity / Physical Functioning (PF)	3	3	2
Social Role & Activities / Role Functioning (RF)	2	2	2
Pain (PA)	2	2	2
Energy / Fatigue (FA)	2	2	2
Sleeping problems (SL)	1	1	1
Anxiety & Worry / Emotional Functioning (EF)	3	3	3



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Family & Relationships / Social Functioning (SF)	3	3	3
Financial aspects /difficulties (FI)	2	2	1
Total items included in CAT	18	18	16
Other physical symptoms - single items*	6	6	6
Other mixed items**	15	16	11
PREMs (Patient Reported Experience Measures)	7	6	7
Overall health and QoL + WISP (Write In 3 Symptoms/Problems)	3	3	3
General QoL Open-ended question	1	1	1
Total number non-CAT	32	32	28
<b>Total number of items</b>	<b>50</b>	<b>50</b>	<b>44</b>

\* Other single-item physical symptoms cover appetite, nausea, constipation, diarrhoea, breathing problems and symptom side effects;

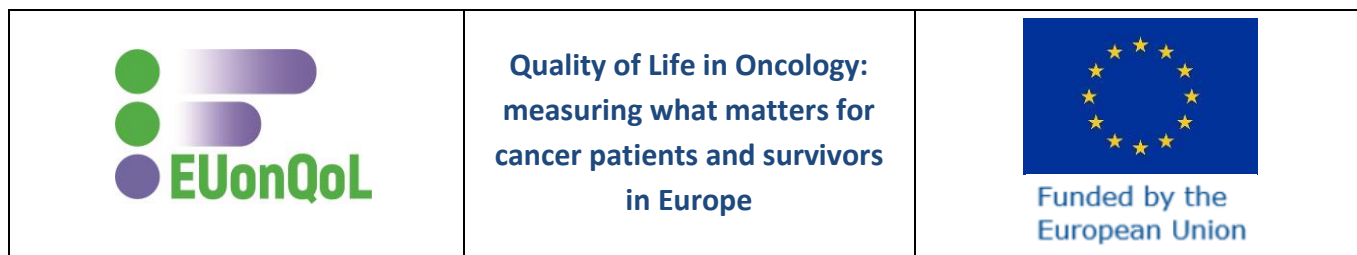
\*\* Other mixed items cover fear of recurrence, future outlook, spirituality, concentration, body image, sex life/intimacy, maintenance of independence, health behavioural change, and symptom worries.

## Dynamic Questionnaires

The final version of each questionnaire is composed of a dynamic CAT part (blue section in Table 10), and a static part (red section in Table 10), replicated from the static questionnaires described above. For further details of the dynamic EUonQoL-Kit, please see Appendix 8.4. Overall, the dynamic toolkits for those on Active treatment, Survivors and Palliative care consisted of 82, 82 and 78 items respectively.

**Table 10. Item composition of the final EUonQoL-Kit – dynamic (CAT) questionnaires.**

Dimensions	Number of items		
	Group A	Group B	Group C
	Active Treatment	Survivors	Palliative Care
Mobility & Activity / Physical Functioning (PF)	7	7	7
Social Role & Activities / Role Functioning (RF)	6	6	6
Pain (PA)	6	6	6
Energy / Fatigue (FA)	6	6	6
Sleeping problems (SL)	6	6	6
Anxiety & Worry / Emotional Functioning (EF)	7	7	7
Family & Relationships / Social Functioning (SF)	6	6	6
Financial aspects /difficulties (FI)	6	6	6
<b>Total number of dynamic items</b>	<b>50</b>	<b>50</b>	<b>50</b>
Other physical symptoms - single items*	6	6	6
Other mixed items**	15	16	11
PREMs (Patient Reported Experience Measures)	7	6	7



Overall health and QoL + WISP (Write In 3 Symptoms/Problems)	3	3	3
General QoL Open-ended question	1	1	1
<b>Total number of Static items</b>	<b>32</b>	<b>32</b>	<b>28</b>
<b>Total number of dynamic + static items</b>	<b>82</b>	<b>82</b>	<b>78</b>

\* Other single-item physical symptoms cover appetite, nausea, constipation, diarrhoea, breathing problems and symptom side effects;

\*\* Other mixed items cover fear of recurrence, future outlook, spirituality, concentration, body image, sex life/intimacy, maintenance of independence, health behavioural change, and symptom worries + non-CAT financial aspects and non-CAT Family and relationships.

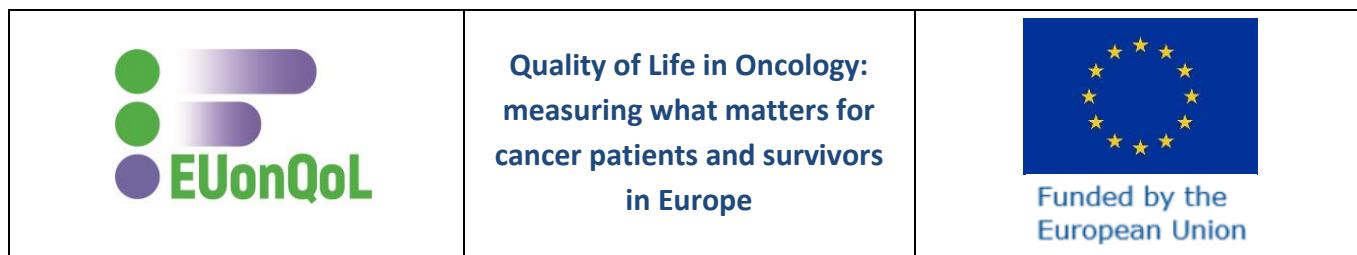
## 5. Discussion

The purpose of this deliverable was to document and describe the process in which EUonQoL-Kit v2 was developed. The resulting work led to the development of both a static and dynamic version of the toolkit approved for pilot testing in WP7.

A key result of this work was the reduction of the total number of items included within the toolkit, without compromising the content coverage or measurement precision. To achieve this, the decision-making process drew on the empirical evidence collected by WP4 throughout the development work (Interview study, Delphi study and Usability study), WP3 systematic reviews, as well as input from key stakeholders and experts within the field. The data were triangulated and formally discussed resulting in the development of EUonQoL-Kit v2. The reduction of the total number of items included in the toolkit was a major achievement as it was important as to not overburden those completing the questionnaire, particularly those within the palliative care group. Version 2 was significantly shorter, yet WP4 and its collaborators were able to expand the content coverage to capture additional sub-domains and issues not previously captured by version 1. Overall, version 2 of the toolkit was shown to be well balanced in assessing a range of domains including physical, psychological, social and overall QoL. Version 2 was also developed to capture issues relating to patient reported experience as this was considered to be an emerging and important domain throughout the development process.

The two consortium meetings were important in reaching agreement for the overall structure and framework of the EUonQoL-Kit. They facilitated important discussion around the length and conceptual framework from which the toolkit was developed. These meetings were of particular significance in agreeing upon the inclusion and exclusion of the CAT dimensions. These decisions were made in collaboration with the expert CAT Team from the EORTC Quality of Life Group and resulted in the inclusion of eight sub-domains as CAT dimensions. In the static version, a limited number of items were selected from the CAT item bank, whereas in the dynamic version, these sub-domains were assessed using the full dynamic CAT system. The decision rules and technical guidelines are provided in Appendix 8.4.

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The open forum offered further insight into the toolkit’s development from a broader perspective as it was open to the public and anyone with an interest in the project or subject area were free to attend. This was important as it allowed WP4 to take stock of its achievement and re-evaluate previous decisions. For example, from the forum, it was clear from the delegates that diarrhoea should be covered by the EUonQoL-Kit and was subsequently included in version 2.

The WP4 regular meetings were key in the decision-making process and is where the decisions on individual items were finalised. Discussions were held until an agreement was reached for each of the included sub-domains. Several important decisions were made across many weeks resulting in the final version 2 of the toolkit, such as the inclusion and development of new items, modifying of timescales and response scales plus many others discussed above.



A strength of the research was the methodology utilised. The iterative process combined with the use of multiple meeting modalities and broad inclusion of stakeholders to obtain agreement provided both rigor and transparency to the development and decision-making process.

A limitation of the study were the time pressures associated with delivering version 2 of the toolkit. This put huge demand and pressure on all collaborators involved and required a high level of engagement across many different stakeholders. Fortunately, a strong collaboration partnership was forged, and the team were able to deliver high quality research, resulting in a robust final product. It was a true testament to those involved and a great achievement for all.

WP4, and its collaborators, successfully delivered both the static and dynamic versions of the EUonQoL-Kit v2 in January 2024. The EUonQoL-Kit are to be fully translated by a professional translation company before being piloted in the next phase of the study. It is important that members of WP4 remain involved and integrated in the future development of the toolkits as the wealth of knowledge and understanding developed from the initial conception to the development of version 2 will be highly valuable.

## 6. Conclusions

The development of EUonQoL-Kit v2 provided a significant upgrade on version 1, not only is it shorter and less burdensome for people to complete, but it also now includes additional sub-domains and items that capture important issues and thus increase the actionability of the EUonQoL-Kit.

	<p style="text-align: center;"><b>Quality of Life in Oncology: measuring what matters for cancer patients and survivors in Europe</b></p>	 <p style="text-align: center;">Funded by the European Union</p>
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## 8. Appendix



## 8.1 EUonQoL-Kit v1. Active Treatment, Survivors and Palliative care.

**We are interested in some things about you and your health. Please answer all of the questions yourself by SELECTING the number that best applies to you. There are no "right" or "wrong" answers.**

Q4 Item Code	Not at all	A little	Quite a bit	Very much	Prefer not to answer	Target Group		
						A	B	C
Q4 Do you have any trouble doing strenuous activities, like carrying a heavy shopping bag or a suitcase?	1	2	3	4		Y	Y	Y
Q5 Do you have any trouble taking a long walk?	1	2	3	4			Y	
Q628 Do you need help caring for your feet (e.g. cutting your toenails)?	1	2	3	4			Y	
Q641 Do you have any trouble carrying a heavy bag upstairs?	1	2	3	4		Y	Y	Y
Q644 Do you have any trouble taking a long walk carrying a heavy pack on your back (e.g. a filled rucksack)?	1	2	3	4			Y	
Q6 Do you have any trouble taking a short walk outside of the house?	1	2	3	4		Y		Y
Q647 Do you need help undressing?	1	2	3	4		Y		Y
Q631 Do you have any trouble walking for 30 min.?	1	2	3	4		Y		Y
<b><u>During the past week:</u></b>						Y	Y	Y
Q673 Have you been limited in doing light housework (e.g. dusting or making the bed)?	1	2	3	4		Y		Y
Q674 Have you been limited in doing physically demanding recreational activities (e.g., swimming or cycling)?	1	2	3	4			Y	
Q7 Were you limited in doing either your work or other daily activities?	1	2	3	4		Y	Y	Y
Q679 Have you been limited in doing heavy housework (e.g., washing floors or vacuuming)?	1	2	3	4		Y		Y



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Q10	Were you limited in pursuing your hobbies or other leisure time activities?	1	2	3	4	Y	Y	Y
Q22	Did pain interfere with your daily activities?	1	2	3	4	Y	Y	Y
Q12	Have you had pain?	1	2	3	4	Y	Y	Y
Q758	Has pain interfered with your social activities?	1	2	3	4	Y	Y	Y
Q750	Has pain made it difficult for you to do the jobs that you usually do around the house?	1	2	3	4		Y	
Q759	Have you had severe pain?	1	2	3	4	Y		Y
Q21	Were you tired?	1	2	3	4	Y	Y	Y
Q15	Have you felt weak?	1	2	3	4	Y	Y	Y
Q502	Have you felt exhausted?	1	2	3	4	Y	Y	Y
Q737	Have you become easily tired?	1	2	3	4		Y	
Q159	Have you lacked energy?	1	2	3	4		Y	
Q743	Have you required frequent or long periods of rest?	1	2	3	4	Y		Y
Q740	Have you had a feeling of overwhelming and prolonged lack of energy?	1	2	3	4	Y		Y
Q14	Have you had trouble sleeping?	1	2	3	4	Y	Y	Y
Q789	Have you had trouble getting a good night's sleep?	1	2	3	4	Y	Y	Y
Q788	Have you had trouble staying asleep?	1	2	3	4		Y	
Q790	Have you woken up for long periods during the night?	1	2	3	4	Y		Y
Q303	Have you forced yourself to eat?	1	2	3	4			Y
Q16	Have you lacked appetite?	1	2	3	4			Y
Q783	Have you lacked interest in eating?	1	2	3	4			Y
Q17	Have you felt nauseated?	1	2	3	4	Y		Y



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Q18	Have you vomited?	1	2	3	4	Y	Y
Q767	Has nausea or vomiting been a problem for you?	1	2	3	4	Y	Y
Q768	Has nausea or vomiting interfered with your physical activities like taking a walk?	1	2	3	4	Y	Y
Q19	Have you been constipated?	1	2	3	4		Y
Q825	Have you had stools that were too hard to pass?	1	2	3	4		Y
Q826	Have your stools been so hard that they were painful to pass?	1	2	3	4		Y
Q11	Were you short of breath?	1	2	3	4	Y	Y
Q804	Did you have severe shortness of breath?	1	2	3	4		Y
Q807	Were you short of breath when walking more than 100 m (100 yds)?	1	2	3	4		Y
Q817	Were you short of breath when walking less than 100 m (100 yds)?	1	2	3	4		Y
Q24	Did you feel tense?	1	2	3	4	Y	Y
Q655	Have you felt vulnerable?	1	2	3	4	Y	Y
Q660	Have you felt that nothing could cheer you up?	1	2	3	4	Y	Y
Q665	Have you felt miserable?	1	2	3	4	Y	Y
Q27	Did you feel depressed?	1	2	3	4	Y	Y
Q25	Did you worry?	1	2	3	4		Y
Q669	Have you felt sad?	1	2	3	4		Y
Q556	Have you been watching yourself closely for any new symptoms?	1	2	3	4	Y	Y
Q168	To what extent have you been troubled with side-effects from your treatment?	1	2	3	4	Y	Y
Q364	Have you worried about recurrence of your disease?	1	2	3	4		Y
Q587	Have you been afraid of tumor progression?	1	2	3	4	Y	



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Q41	Have you worried about your health in the future?	1	2	3	4	Y	Y	Y
Q46	How much has your disease been a burden to you?	1	2	3	4	Y	Y	Y
Q988	Because of your experience with cancer, have you had to limit your life plans or goals?	1	2	3	4	Y	Y	Y
Q596	I have felt at peace with myself	1	2	3	4	Y	Y	Y
Q28	Have you had difficulty remembering things?	1	2	3	4	Y	Y	Y
Q23	Have you had difficulty in concentrating on things, like reading a newspaper or watching television?	1	2	3	4	Y	Y	Y
Q692	Have you been forgetful?	1	2	3	4		Y	
Q695	Have you had difficulty remembering what someone just told you?	1	2	3	4	Y		Y
Q703	Have you had difficulty maintaining concentration even when doing something important?	1	2	3	4	Y	Y	Y
Q714	As a result of your physical condition or medical treatment, have you preferred to spend time alone?	1	2	3	4		Y	
Q715	As a result of your physical condition or medical treatment have you been less able to see your family or friends?	1	2	3	4	Y		Y
Q718	As a result of your physical condition or medical treatment, have you spent less time with your family or friends?	1	2	3	4	Y	Y	Y
Q719	As a result of your physical condition or medical treatment, have you felt isolated from your family or friends?	1	2	3	4	Y	Y	Y
Q720	As a result of your physical condition or medical treatment, have you found it hard to make contact with people?	1	2	3	4	Y	Y	Y
Q29	Has your physical condition or medical treatment interfered with your family life?	1	2	3	4	Y	Y	Y
Q30	Has your physical condition or medical treatment interfered with your social activities?	1	2	3	4	Y	Y	Y



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Q721	Has your physical condition or medical treatment interfered with your relationships with your family or friends?		1	2	3	4		Y	Y	
Q981	Have you been dissatisfied with your physical appearance?		1	2	3	4			Y	
Q467	Has the disease or treatment affected your sex life (for the worse)?	N / A	1	2	3	4		Y	Y	
Q155	Have you worried about your ability to have children?	N / A	1	2	3	4		Y	Y	
Q294	Have you worried that you are a burden to other people		1	2	3	4		Y	Y	Y
Q209	Have you worried about becoming dependent on others?		1	2	3	4		Y	Y	Y
Q31	Has your physical condition or medical treatment caused you financial difficulties?		1	2	3	4		Y	Y	Y
Q848	Has your physical condition or medical treatment caused you financial difficulties leading to changes in your lifestyle?		1	2	3	4		Y	Y	Y
Q849	As a result of your physical condition or medical treatment, have you had less money to spend on yourself (e.g., for buying yourself something that you would like to have but don't necessarily need)?		1	2	3	4		Y	Y	Y
Q850	As a result of your physical condition or medical treatment, have you had difficulties paying any of your regular expenses (e.g. rent, insurance, phone)?		1	2	3	4		Y		Y
Q1011	Since the diagnosis and treatment of your cancer: Have you had problems with obtaining insurance, loans, and/or a mortgage?	N / A	1	2	3	4		Y	Y	
New	Since the diagnosis and treatment of your cancer: Have you received support from your employer e.g. arranging flexible working?	N / A	1	2	3	4		Y	Y	Y
Q1012	Since the diagnosis and treatment of your cancer: Have you made positive lifestyle changes (e.g., more exercise, healthy food, cutting down smoking)?		1	2	3	4		Y	Y	



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**For the following questions please circle the number between 1 and 7 that best applies to you.**

		Very poor				Excellent			
Q33	How would you rate your overall quality of life during the past week?	1	2	3	4	5	6	7	Y Y Y
Q32	How would you rate your overall health during the past week?	1	2	3	4	5	6	7	Y Y Y
WISP	Have you had any other significant symptoms or problems that have not been mentioned in the questions above?		No	Yes					Y Y Y
<p><b>Yes. Please write down the most important ones (up to three), and rate to what extent you have experienced these symptoms or problems during the past week:</b>  <b><u>During the past week, to what extent have you experienced:</u></b></p>									
	Symptom/problem A:		1	2	3	4			Y Y Y
	Symptom/problem B:		1	2	3	4			Y Y Y
	Symptom/problem C:		1	2	3	4			Y Y Y
<p><b><u>We are interested in your MOST RECENT experience of the care you have received and the communication you have had with the professional(s) who treat you.</u></b></p>									
Q429	Have you been satisfied with your communication with your professional(s)?		1	2	3	4			Y Y Y
Q401	Have your professional(s) spent enough time talking with you?		1	2	3	4			Y Y Y
Q409	Have your professional(s) used language that you understand (avoided medical jargon, used clear terms)?		1	2	3	4			Y Y Y
Q421	Have your professional(s) taken into account how you prefer to receive information?		1	2	3	4			Y Y Y
Q398	Have you felt that you and your professional(s) had a shared understanding of your disease and treatment?		1	2	3	4			Y Y Y
CCEQ - mod	My decisions about care and treatment have been respected by my professional(s)		1	2	3	4			Y Y

CCEQ - mod	I have been given the opportunity to discuss my treatment plan with my professional(s)	1	2	3	4		Y	Y
Q386	Have you felt satisfied with the care you have received?	1	2	3	4		Y	Y
Q387	Have you felt satisfied with the information you have received (e.g. about the disease and its treatment)?	1	2	3	4		Y	Y
CCEQ - mod	<b><u>During the past 4 weeks:</u></b> My medical appointments have interfered with my work / household activities	1	2	3	4		Y	Y
CCEQ - mod	My medical appointments have caused problems for my family / carer	1	2	3	4		Y	Y
	<b><u>How would you rate the services and care organisation of the most recent care you have received, in terms of:</u></b>							
Q884	The provision of follow-up by the different caregivers (doctors, nurses, physiotherapists, psychologists, etc.) after treatment?	1	2	3	4	Very good 5	Y	Y

## 8.2 The development of EUonQoL-Kit v2. Decision framework

**Item code:** The code assigned to each item by the EORTC Item Library. **Sub-Domain (Domain):** The Sub-domain for which the items relate, the overall domain is provided in brackets.

**Toolkit v1 (A,B,C):** Highlights if the sub-domain was included as a CAT dimension, those coded in Green were the items included in Toolkit v1 for the respective target groups.

**Usability Results – Summary:** Qualitative + Quantitative summaries from the Usability study. **Decision:** Evidence of the decisions resulting in the selection of items in Toolkit v2.

**Toolkit v2 (A,B,C):** Highlights whether the sub-domain was included as a CAT dimension, those coded in Dark Green were the items included in Toolkit v2 for the respective target groups. Those coded Yellow highlight the starting items for the dynamic CAT Toolkit, these were also included in Toolkit v2. **Comments:** Item level comments relating to the inclusion or exclusion of items.

Item Code	Sub-Domain (Domain)	Toolkit v1			Usability Results - Summary	Decision	Toolkit v2			Comments
		A	B	C			A	B	C	
	<b>Physical Function - Mobility &amp; Activity (Physical)</b>	<b>V1_CAT</b>					<b>V2_CAT</b>			
Q4	Do you have any trouble doing strenuous activities, like carrying a heavy shopping bag or a suitcase?				Items too general - no reference to whether its referring to cancer related experience. Age related.  Overlapping - Carrying bags and Walking. To be reduced/combined. Group B has issues with redundancy.	Provisional items were proposed by the CAT team based on the performance of the items. WP4 Team then reviewed the suggested items for their content and a joint decision on which items were to be included was made. It was important to reduce the number of overlapping items whilst still maintaining the precision of the measurement properties of the item/scale.				Include for Group A & B. CAT Team = Good performance. Included in C30 and item wording provides additional context that participants preferred.
Q5	Do you have any trouble taking a long walk?									Include for Group B. CAT = Good performance of item.
Q628	Do you need help caring for your feet (e.g. cutting your toenails)?				Language - Ambiguous e.g. what is 'long' – with patients preferring more specific descriptors e.g. 30mins.					Exclude. Usability results were not favourable to this item.
Q641	Do you have any trouble carrying a heavy bag upstairs?									Include. CAT Team recommended due to strong performance.
Q644	Do you have any trouble taking a long walk carrying a heavy pack on your back (e.g. a filled rucksack)?				<u>Quantitative</u> High response rates. Wide range of responses given for this subdomain. Mean scores suggested Q647 had floor effects. Q628 had a higher	It was decided that Group A and B would include 3 items and Group C include 2. Participants in the Usability preferred items that had more context rather than the vague ones e.g. Q631 vs Q6. The addition of Q9 to Group C only was made due to the fact the				Exclude. Overlap with Q641. Q641 had the better measurement properties.
Q6	Do you have any trouble taking a short walk outside of the house?									Exclude. Overlap with Q631. Usability results = preference for items with more context.



Q647	Do you need help undressing?				proportion of participants respond as 'N/A'.	other Groups having higher performance status and the floor effects associated with this.				Exclude. Considered for Group C. Too specific, co-researcher suggested Q9.	
Q631	Do you have any trouble walking for 30 min.?										Include. Usability = Good item as it includes greater context than 'short' or 'long' walk.
Q9	Do you need help with eating, dressing, washing yourself or using the toilet?										Include this item as it has high performance and will diversify the scale in terms of content. Supported by Co-researcher.
Q8	Do you need to stay in bed or a chair during the day?										This item was considered but CAT Team highlight its lower performance and overlap with Fatigue and when used in a small scale it was advised a different item be selected.
<b>Role Functioning - Social role &amp; Activities (Social)</b>		<b>V1_CAT</b>						<b>V2_CAT</b>			
Q673	Have you been limited in doing light housework (e.g. dusting or making the bed)?				General - Housework N/A to some.  Recall period - Make 'in the past week clearer. Participants often didn't respond to this recall period. Or consider extending.  Language - Difficulty understanding Q674 'recreational' & 'physically demanding' (Dutch). German translation issues Q679.  <u>Quantitative</u> Response rates above 95%. Wide range of responses given.	The two Role Functioning items were selected for their performance properties (Q7 & Q10). These two items are scaled in the EORTC C30 and have been shown to perform well.				Exclude. Usability results = not relevant to everyone.	
Q674	Have you been limited in doing physically demanding recreational activities (e.g., swimming or cycling)?										Exclude. Usability results = complex item, difficult to understand.
Q7	Were you limited in doing either your work or other daily activities?										Include. EORTC QLQ-C30 scale.
Q679	Have you been limited in doing heavy housework (e.g., washing floors or vacuuming)?										Exclude. Usability results = not relevant to everyone.
Q10	Were you limited in pursuing your hobbies or other leisure time activities?										Include. EORTC QLQ-C30 scale.
<b>Pain (Physical)</b>		<b>V1_CAT</b>								<b>V2_CAT</b>	
Q22	Did pain interfere with your daily activities?				General – “hard to answer because of co-morbidities”.	The two Pain items were selected for their performance				Include. Ask after Q12 - reorder.	

Q12	Have you had pain?				Overlapping - Pain questions repetitive. Conditional to if experienced Pain.	properties. These two items are scaled in the EORTC QLQ-C30. Usability results also supported the inclusions of Pain related questions and that Q12 should be asked first.				Include. Ask before Q22 - reorder.
Q758	Has pain interfered with your social activities?									Exclude. Covered by Q22.
Q750	Has pain made it difficult for you to do the jobs that you usually do around the house?				Formatting - Q12 should come first. Recall period - Make clear 'in the past week'.					Exclude. Covered by Q22.
Q759	Have you had severe pain?				Language - 'Severe' item not understood (x1)  <u>Quantitative</u> Nothing of note - overall good performance of items.					Exclude. Usability results = Intensity question not always understood.
<b>Fatigue - Lack of energy (Physical)</b>		<b>V1_CAT</b>						<b>V2_CAT</b>		
Q21	Were you tired?				General - Age related? Need more info at start of questionnaire e.g. is it specific to cancer.	For Fatigue it was decided that 2 items for each Target Group should be included. Q21 is included in the EORTC QLQ-C30. Q743 was more discriminative between the target groups as many of the fatigue items scored highest in the survivor group.				Include. Important general item to ask.
Q15	Have you felt weak?				Overlapping - repetitive items. Recall period - Make clear 'in past week'.					Exclude. Usability results = participants sometimes perceived this as psychological weakness.
Q502	Have you felt exhausted?				Language - 'Weak' & 'Exhausted' sometimes perceived as psychological. Some items too vague.					Exclude.
Q737	Have you become easily tired?				<u>Quantitative</u> Overall good performance of items. Q740 had slightly lower response rate (96%).					Exclude.
Q159	Have you lacked energy?									Exclude.
Q743	Have you required frequent or long periods of rest?									Include. This item captures the more severe end of the spectrum. More discriminative, particularly with Group B.
Q740	Have you had a feeling of overwhelming and prolonged lack of energy?									Exclude.
<b>Sleep issues (Physical)</b>		<b>V1_CAT</b>						<b>V2_CAT</b>		

Q14	Have you had trouble sleeping?				General - Q14 key item.  Overlapping - repetitive, not necessary to ask all.	Downgrading Sleep from a CAT scale to a single item was considered. It was decided to keep as CAT due to its high relevance across the target groups. In the static Toolkits, item Q14 was selected as this was the best item to capture the issue using a single item. it is also included in the EORTC QLQ-C30.				Include. EORTC QLQ-C30 item. Most encompassing and simple wording
Q789	Have you had trouble getting a good night's sleep?				Language - Q788 + Q790 problematic in understanding the item.  <u>Quantitative</u> Overall good performance of items.					Exclude. Usability = repetitive/same as Q14.
Q788	Have you had trouble staying asleep?									Exclude. Usability = difficulty understanding item.
Q790	Have you woken up for long periods during the night?									Exclude.
<b>Appetite (Physical)</b>		<b>V1_CAT</b>					<b>V2_Non-CAT</b>			
Q303	Have you forced yourself to eat?				No comments	The issue was assessed as a CAT Shortform in the Usability study. As a result of the study, this issue was downgraded from a full CAT issue to a single item.				Exclude.
Q16	Have you lacked appetite?				<u>Quantitative</u> Overall good performance of items.					Include. Best item + in the EORTC QLQ-C30.
Q783	Have you lacked interest in eating?									Exclude.
<b>Nausea + Vomiting (Physical)</b>		<b>V1_CAT</b>			<b>V2_Non-CAT</b>					
Q17	Have you felt nauseated?				General - Conditional, not necessary to ask all items.  Overlapping - All items repetitive. Mixed feedback on which items to include out of Q17, Q18 & Q35.	The issue was assessed as a CAT Shortform in the Usability study. As a result of the study, this issue was downgraded from a full CAT issue to a single item as many participants found these items to be repetitive and overlapping. They felt it was not necessary to ask all of the included items in Toolkit v1. Q17 was included as it is a well validated item used in the EORTC QLQ-C30 and nausea is more common than vomiting. To reduce the number of overall items included in the Toolkit, only				Include. Strong item, well tested (EORTC QLQ-C30 item) and more common than vomiting.
Q18	Have you vomited?									Exclude. Usability = Lower scores from participants.
Q767	Has nausea or vomiting been a problem for you?				<u>Quantitative</u> Relatively low Mean scores, lowest was Q768 (1.2), highest was Q17 (1.54) for this sub-domain. Good Range and Response Rate for all items.					Exclude.
Q768	Has nausea or vomiting interfered with your physical activities like taking a walk?									Exclude.

				1 item was selected for this sub-domain.			
<b>Constipation (Physical)</b>		<b>V1_CAT</b>			<b>V2_Non-CAT</b>		
Q19	Have you been constipated?			<p>Missing diarrhoea</p> <p><u>Quantitative</u> Relatively low Mean scores, lowest was Q826 (1.15), highest was Q19 (1.36) for this sub-domain. Good Range and Response Rate for all items.</p>	<p>The issue was assessed as a CAT Shortform in the Usability study. As a result of the study, it was downgraded from a full CAT issue to a single item. No specific qualitative feedback from the usability but was identified as a sub-domain that could be reduced in size in order to limit the burden of questions in the overall Toolkit. Therefore, it was downgraded from CAT to a single item. This sub-domain did cause several participants to question where the Diarrhoea question was, which led to the inclusion of diarrhoea as a single item in Toolkit V2.</p>		Include. Well validated item (EORTC QLQ-C30 item.)
Q825	Have you had stools that were too hard to pass?						Exclude. Not necessary to ask all items
Q826	Have your stools been so hard that they were painful to pass?						Exclude. Not necessary to ask all items
<b>Diarrhoea (Physical)</b>		<b>N/A</b>			<b>V2_Non-CAT</b>		
Q20	Have you had diarrhoea?			<p>Missing diarrhoea</p> <p><u>Quantitative</u> N/A</p>	<p>This was not included in Toolkit v1 based on the results of the Consensus meeting (D4.1). Following the Usability study, it was added back to Toolkit v2 along with the other single item physical symptom questions.</p>		Include. Well validated item (EORTC QLQ-C30 item.)
<b>Shortness of breath (Physical)</b>		<b>V1_CAT</b>			<b>V2_Non-CAT</b>		
Q11	Were you short of breath?			<p>Overlapping - Not necessary to ask all.</p> <p><u>Quantitative</u></p>	<p>The issue was assessed as a CAT Shortform in the Usability study. As a result of the study, it was downgraded from a full CAT</p>		Include. Group C. Well validated item (EORTC QLQ-C30 item.) Most appropriate content for Group C.

Q804	Did you have severe shortness of breath?				<p>Relatively low Mean scores, lowest was Q804 (1.02), highest was Q11 (1.43) for this sub-domain. Good Response Rate for all items. Range was lower (1-3) for Q804, Q807, Q817 but only had 12 participants respond.</p> <p>issue to a static sub-domain. Collaborator feedback suggested it was necessary to ask Q11 only. However, Q11 was included for Group C only due to high mean scores for Group B. Q807 was deemed a better item to differentiate scores between the groups. The decision was also about the appropriateness of the content, it was felt some patients in Group C may not be able to answer Q807 due to their performance status. Hence Q11 was selected for this group.</p>				Exclude. Not necessary to ask all items
Q807	Were you short of breath when walking more than 100 m (100 yds)?								Include. Group A + B. Not appropriate for Group C as they may not be able to walk 100m.
Q817	Were you short of breath when walking less than 100 m (100 yds)?								Exclude. Not necessary to ask all items
<b>Emotional Function (Psychological)</b>		<b>V1_CAT</b>				<b>V2_CAT</b>			
Q24	Did you feel tense?				<p>General - Comments around items not being specific to cancer.</p> <p>Overlapping - Q655, 665, 27,25 669. Repetitive and overlapping items.</p> <p>Language - Interpretation of items were sometimes seen as physical Q24, Q655. Translation German Q665, Dutch Q669.</p> <p><u>Quantitative</u> Overall good performance of items. Q660 had low Mean score (1.19) in comparison to the other items e.g. Q25 (2.49).</p> <p>The CAT Team suggested the three best items from a performance perspective and was agreed by the WP4 Team. It was also agreed that these items would be asked across all three Target Groups. 'Miserable' wording raised initial concerns due to translations, however on further examination, no issues were found when this item was developed. These items cover both anxiety and depression.</p>				Exclude. Overlapping
Q655	Have you felt vulnerable?								Exclude. Overlapping and language issues.
Q660	Have you felt that nothing could cheer you up?								Exclude. Low Mean scores.
Q665	Have you felt miserable?								Include. CAT Team = Strong item performance
Q27	Did you feel depressed?								Include. CAT Team = Strong item performance
Q25	Did you worry?								Include. CAT Team = Strong item performance
Q669	Have you felt sad?								Exclude.
<b>Symptom worries (Physical)</b>		<b>V1_Non-CAT</b>				<b>V2_Non-CAT</b>			

Q556	Have you been watching yourself closely for any new symptoms?				<p><u>Qualitative</u> General - Very important to ask. Add N/A for Q556. Linked to Anxiety/worry. Language - German - Q46 wording 'Burden' physical or psychological?</p> <p><u>Quantitative</u> Overall Strong performance of items. New item not included in Usability study.</p> <p>WP4 collaborators discussed the inclusion/exclusion of Q46 over several meetings, largely due to the potential translation issues of the term 'Burden' and the importance of having a global question to assess physical burden of disease. This is due to the idea that a global question addressing physical symptoms and/or side effects may replace the individual symptoms in future version of the Toolkit.</p> <p>It was decided that Q46 should be retained in Toolkit V2, but also that a new item, following the style of Q168 should be included to capture the issue as described above. WP4 and co-researchers drafted the new item seen here. It was noted that this new item should be positioned away from the others to reduce the feeling of repetitiveness.</p>				Include. Overlap with Fear of recurrence sub-domain.
Q46	How much has your disease been a burden to you?								Include. This item was linked to the 'disease' so was important to include as well as the items about symptoms.
NEW	To what extent have you been troubled with physical symptoms from your disease or treatment?								Include. New item created to cover physical symptoms, with the idea of exploring if a general item such as this can be used instead of including multiple individual symptoms.
<b>Symptom side effects (Physical)</b>		<b>V1_Non-CAT</b>			<b>V2_Non-CAT</b>				

Q168	To what extent have you been troubled with side-effects from your treatment?			<p>General - Not relevant to Group B</p> <p>Recall period - Hard to answer 'in the past week.</p> <p>Response scale – Difficulty answering for one participant (GER), too few options.</p> <p><u>Quantitative</u> Good overall performance of the item. 5 counts of 'N/A' response.</p>	<p>This item is important from an FDA perspective. Whilst some participants from the usability study felt it not relevant/ difficult to answer for Group B, however WP4 felt this item could identify or highlight the impact of the long-term effects caused by the disease and/or treatments. It was therefore included for all three groups.</p>			Include. Important item from a regulatory perspective.
<b>Fear of recurrence (Psychological)</b>		<b>V1_Non-CAT</b>					<b>V2_Non-CAT</b>	
Q364	Have you worried about recurrence of your disease?			<p>General - important to ask these items.</p> <p>Recall period - Participants suggested the recall period of 'past week' might be too short.</p> <p>Language – 'Progression' might be difficult to comprehend for those with lower literacy levels.</p> <p>Translation issue in German Q364.</p> <p><u>Quantitative</u> Means above 2. Full Range for both items (1-4). 100% response rate.</p>	To include as per Toolkit V1. Q364 included for Group B and Q587 for Group A. not appropriate to as Group C.			Include. Group B only. Monitor German translations.
Q587	Have you been afraid of tumor progression?							Include. Group A only. Monitor German translations.
<b>Future outlook (Psychological)</b>		<b>V1_Non-CAT</b>					<b>V2_Non-CAT</b>	

Q41	Have you worried about your health in the future?			<p>General - Participants suggested the answers may be related more to Age.</p> <p>Overlapping - Select one item to ask as there is overlap.</p> <p>Recall period - difficult to answer as within 'past week'</p> <p>Response scale - could be widened for these types of items.</p> <p><u>Quantitative</u> Means above 2. Full Range for both items (1-4). 100% response rate.</p>	<p>WP4 decided to include both items from this sub-domain in Toolkit v2. It was noted that although they both assess Future outlook, they are different conceptually and thus both were included. The 'past week' timescale for Q988 was dropped and now no longer has a specified timescale. This was to address the comments made in the usability study.</p>			Include.
Q988	Because of your experience with cancer, have you had to limit your life plans or goals?			<p><u>Quantitative</u> Means above 2. Full Range for both items (1-4). 100% response rate.</p>				Include. Removed 'past week' timescale.
<b>Spirituality (Psychological)</b>		<b>V1_Non-CAT</b>				<b>V2_Non-CAT</b>		
Q596	I have felt at peace with myself			<p>General - somewhat mixed feedback with participants reporting the question was unclear, difficult to answer and one found it to be upsetting which could related to the translation in German. Positive wording was confusing for some.</p> <p><u>Quantitative</u> Mean above 2. Full Range (1-4). 96% response rate. 1 'prefer not to answer' and 1 'N/A'.</p>	<p>This item was discussed at length by the WP4 Team as to whether it was to be included in version 2 of the Toolkit. Having considered the feedback from the usability within these discussions, the final decision that this item should be included as it addresses a potentially important sub-domain. It was also considered that the item wording be rephrased into a question, however, it was decided to keep the item as it was as it has previously been rigorously tested and developed by the EORTC.</p>			Include. Consider issues in translation/language (GER).
<b>Cognitive function - Concentration &amp; Memory (Psychological)</b>		<b>V1_CAT</b>				<b>V2_Non-CAT</b>		



Q28	Have you had difficulty remembering things?				<p>General - very relevant sub-domain for some. Many raised issues around memory issues being related to age rather than cancer. This was a strong theme.</p> <p>Overlapping - many found this sub-domain to include repetitive and redundant items.</p> <p><u>Quantitative</u> Overall good performance of items.</p>	<p>The sub-domain was assessed as a CAT Shortform in the Usability study. As a result of the study, this issue was downgraded from a full CAT issue to a single item. Interviews suggest cancer patients found memory to be more related to age and were difficult to answer. Concentration was very relevant and therefore Q703 was selected. Q703 was proposed by the CAT Team as this was the start item for the CAT system and was therefore selected over the C30 item Q23. However, the CAT was dropped for this sub-domain, but the selected item remains.</p>				Exclude. Usability Results = Linked to Age, difficult to answer.	
Q23	Have you had difficulty in concentrating on things, like reading a newspaper or watching television?										Exclude. Context of concentration relating to important things was important to participants Q703 explicitly references this.
Q692	Have you been forgetful?										Exclude. Usability Results = Linked to Age, difficult to answer.
Q695	Have you had difficulty remembering what someone just told you?										Exclude. Usability Results = Linked to Age, difficult to answer.
Q703	Have you had difficulty maintaining concentration even when doing something important?										Include. Usability results, participants felt this item had more significance than Q23 e.g., it did not matter if they could not focus on the TV but did matter if they could concentrate on important things like hospital appointments. The item was recommended by the CAT team in the original selection phase as it was the CAT starting item. However, this sub-domain is no longer a CAT domain.
<b>Social Functioning - Family and Relationships (Social)</b>		<b>V1_CAT +1 single items</b>					<b>V2_CAT +2 single items</b>				
Q714	As a result of your physical condition or medical treatment, have you preferred to spend time alone?				General - Q29 was perceived as good. Q714 could be difficult for those living alone. Q719 was 'Prefer not to answer' by 2 due	Initial suggestions were to include two items; however, it was later decided that Q719 should also be included to				Exclude.	

Q715	As a result of your physical condition or medical treatment have you been less able to see your family or friends?				to recall period difficulties. Q155 - N/A for most due to Age.	ensure we capture isolation in the static version as this was a key issue for participants. Q155 and Q1004 are a non-CAT item however were added as a single item to this sub-domain. Q1004 was an important item missed from the usability testing and was initially included to assess the impact on relationships with a potential health economics perspective e.g., the breakdown of relationships. It was thought that the positive wording of the item should not impact participants and may act as a moment of reflection and thus preventing participants from speedily completing the Toolkit without much added thinking.				Exclude.	
Q718	As a result of your physical condition or medical treatment, have you spent less time with your family or friends?				Overlapping - Lots of items for this topic, could ask fewer. Repetitive.						Exclude.
Q719	As a result of your physical condition or medical treatment, have you felt isolated from your family or friends?				Recall period - difficulties answering, 'in past week'.						Include. Isolation was a key issue for participants.
Q720	As a result of your physical condition or medical treatment, have you found it hard to make contact with people?				Language - Issues having both 'Family' & 'Friends' in the same item. Made it difficult to answer for some. Take 'As a result of...' out the item and add above.						Exclude.
Q29	Has your physical condition or medical treatment interfered with your family life?				<u>Quantitative</u> This domain saw a small number of instances (2) were 'prefer not to answer' and 'N/A' response options were selected.						Exclude.
Q30	Has your physical condition or medical treatment interfered with your social activities?				Linked to Language and timeframe issues. The exception to this was Q155, which saw 24 counts of 'N/A'. This was linked to Age.						Include. CAT Team = Strong item
Q721	Has your physical condition or medical treatment interfered with your relationships with your family or friends?										Include. CAT Team = Strong item
Q155	Have you worried about your ability to have children?										Include. Non-CAT item but an important construct to assess.
Q1004	Since the diagnosis and treatment of your cancer: Is your relationship with your partner stronger?										Include. Non-CAT but an important concept to assess. Possible importance from a health economics perspective.
<b>Maintain independence (Social)</b>		<b>V1_Non-CAT</b>						<b>V2_Non-CAT</b>			
Q294	Have you worried that you are a burden to other people				General - Important issue. Could be made more specific. One	Both items were included in Toolkit V1 with the purpose of				Exclude. Translation issues with 'burden'.	

Q209	Have you worried about becoming dependent on others?			<p>participant preferred Q294 over Q209.</p> <p>Language - Q294 (Dutch) translation clashes with recall period.</p> <p><u>Quantitative</u> Means - Q294 (1.85), Q209 (2.06). Full response Range (1-4) for both items. Q294 99% response rate, Q209 100%. Q209 1 'prefer not to answer' and 1 'N/A'.</p>	<p>collecting more data to make the decision on which to include. The results of the usability and consensus of WP4 Team was that Q209 was the better item. It had fewer translation issues.</p>			<p>Include. Usability results slightly favour this item which has a better phrasing.</p>
<b>Body Image (Physical)</b>		<b>V1_Non-CAT</b>				<b>V2_Non-CAT</b>		
Q981	Have you been dissatisfied with your physical appearance?			<p>Language – One reported issue interpreting 'physical appearance' (GER). Requires participants to be self-critical.</p> <p><u>Quantitative</u> Mean above 2. Full Range (1-4). 100% response rate.</p>	<p>This item was included, and the timescale increased from 'past week' to '4 weeks' based on feedback from the usability study.</p>			<p>Include.</p>
<b>Sex Life (Physical)</b>		<b>V1_Non-CAT</b>				<b>V2_Non-CAT</b>		
Q467	Has the disease or treatment affected your sex life (for the worse)?			<p>General - No issues asking this question. N/A important, most cases was Age related. Recall period - past week is too short. Could be 4 weeks or since diagnosis or no recall period.</p> <p><u>Quantitative</u> Q467. Mean almost 3 (2.98). Full Range (1-4). 98% response rate. 10 'N/A'. Linked to Age. New item not included in Usability.</p>	<p>Very important sub-domain to be included. This has been highlighted throughout the project. At this stage the decision was taken to improve this sub-domain by including an item for Group C, as in Toolkit V1 there was no item for this group. Adding a question about intimacy was raised during the stakeholder forum and was therefore included for Group C in</p>			<p>Include. Group A+B. Widen timescale to 4 weeks. Feedback was not appropriate for Group C.</p>
NEW	Have you been missing intimacy (e.g. closeness, fondness, sex)?							<p>Include. New item for Group C.</p>

					Toolkit V2. Time scale was increased to 'past 4 weeks'.				
<b>Financial (Social)</b>		<b>V1_CAT +2 single items</b>					<b>V2_CAT +2 single items</b>		
Q31	Has your physical condition or medical treatment caused you financial difficulties?				General - important domain, Q31 good as its General but also people liked the more specific items too.	Whist this is a CAT sub-domain, it is important to note the addition of 2 extra items - Q1011 and a NEW item about employer support. Q850 was included to diversify the content of the items in this domain. Not all finance questions were included for Group C as there was a concern of over burdening these patients with a long questionnaire. Therefore, for some sub-domains only the most relevant items were asked to this group. The Non-CAT items will address the wider issues over a larger time period. The non-CAT items were deemed important for health policy.			Include. CAT Team = Strong item
Q848	Has your physical condition or medical treatment caused you financial difficulties leading to changes in your lifestyle?				Overlapping - Q848 & Q850 overlap with Q77.				Exclude.
Q849	As a result of your physical condition or medical treatment, have you had less money to spend on yourself (e.g., for buying yourself something that you would like to have but don't necessarily need)?				Recall period - More specific items harder to answer in past week (Q1011, 850 & NEW. Mixed recall periods in the same domain.				Exclude.
Q850	As a result of your physical condition or medical treatment, have you had difficulties paying any of your regular expenses (e.g. rent, insurance, phone)?				Language - Item stems are too long, they make the questions harder to answer.  NEW item – potential issues with if this is physical or emotional support, mixed recall period as asked with past week section. Participants also felt it was a good question to ask. Q848 'Prefer not to answer' because it was viewed as a vulnerable line of questioning.				Include. These issues were raised in consensus meeting and linked to health economics. As well as being mentioned in interviews.
Q1011	Since the diagnosis and treatment of your cancer: Have you had problems with obtaining insurance, loans, and/or a mortgage?								Include. Original qualitative interviews. Highlighted as very important for health policy
New	Since the diagnosis and treatment of your cancer: Have you received support from your employer e.g. arranging flexible working?				<u>Quantitative</u> Overall Means were low for items in this sub-domain. Q850 had the lowest Mean (1.04). N/A response option was				Include. All groups to collect additional data on the new item.

			important for Q1011 and the New item about employer support. The new item also saw a 94% response rate.			
<b>Health behaviour change (Overall Health)</b>		<b>V1_Non-CAT</b>			<b>V2_Non-CAT</b>	
Q1012	Since the diagnosis and treatment of your cancer: Have you made positive lifestyle changes (e.g., more exercise, healthy food, cutting down smoking)?		<p>General - Mixed feedback. Some say good to ask this question, others felt N/A because they already had positive lifestyle before diagnosis.</p> <p>Recall period - doesn't fit with the 'past week', should be longer. Result of an IT formatting issue.</p> <p><u>Quantitative</u> Mean above 2. Full Range (1-4). 100% response rate. 1 'N/A' response.</p>	Usability results indicated this subdomain as being important. Incorrect IT formatting led to an error in the timescale presented, this will be resolved for Toolkit V2 and should not cause the same confusion for participants.		Include. Not appropriate for Group C as they are at end of life.
<b>OVERALL QOL (Overall Health)</b>		<b>V1_Non-CAT</b>			<b>V2_Non-CAT</b>	
Q33	How would you rate your overall quality of life during the past week?		<p>Overlapping - Similar to Q32. Recall period - one suggestion of changing to 'past 4 weeks'.</p> <p>Response scale - some issues with changing scales and lack of labelling was strange. Others had no issue with this.</p> <p><u>Quantitative</u> Mean 4.13. Response Range 1-6 (1-7). 94% response rate. 1 'Prefer not to answer' response.</p>	Important item to be included in a QOL Toolkit.		Include.

Overall health perspective (Overall Health)		V1_Non-CAT			V2_Non-CAT		
Q32	How would you rate your overall health during the past week?				General - will capture variance across illness phases.  <u>Quantitative</u> Mean 3.98. Response Range 1-6 (1-7). 94% response rate.	Important items to be included in a QOL Toolkit.	Include.
WISP (?)		V1_Non-CAT			V2_Non-CAT		
WISP	Have you had any other significant symptoms or problems that have not been mentioned in the questions above?				The Write in Symptoms or Problems was not adequately assessed as the digital app was unable to accommodate this style of question.  Overall feedback was that this type of question was important to include to allow participants to write in any missing issues they have.  <u>Quantitative</u> N/A -	WISP was also highly regarded by participants within the usability and offered the opportunity to discuss any missing symptoms or problems. It was identified that diarrhoea was potentially missing from the Toolkit. It was included for all three groups for Toolkit V2.	Include. Positive feedback in interviews for this type of item.
Impact of care pathway (Healthcare)		V1_Non-CAT			V2_Non-CAT		
Q386	Have you felt satisfied with the care you have received?				Language - Q884 problematic due to wording 'after treatment' N/A for group A and C. Too long and translation issues (Dutch).  Recall period - Consider 'past 4 weeks'.	Collaborators were happy with the two 5-point scale proposed. This was based on Annes literature search and feedback from collaborators doing work in this area whereby in a study of over 200 people of PREMs during their piloting they found frequency scales were better for patients. EORTC satisfaction Q's used the EORTC positive 5-point scale.	Include as a global question. 5-point Likert scale - positive. Extended scale combined with positive framing to provide better measurement of 'satisfaction' issues as they often score highly by patients.
Q387	Have you felt satisfied with the information you have received (e.g. about the disease and its treatment)?				Response scale - Several participants not satisfied with scale as the responses did not fit with the scale e.g., should		Exclude. Asking about 'experience' was deemed more of a priority than satisfaction.

CCEQ - mod	Have your medical appointments interfered with your work / household activities?			include 'very satisfied'.  <u>Quantitative</u> Satisfaction items (Q386 & 387) high Means above 3. Full Range (1-4). Q386 had 99% response rate, 1 'N/A', and 1 'prefer not to answer'. CCEQ items. Means below 1.5. Full Range (1-4) and 100% response rate.	CCEQ items were modified from statements into questions.				Include. 4 N/A. Reworded into a question rather than a statement.
CCEQ - mod	Have your medical appointments caused problems for your family / carer?			Q884. Mean of 3.98. Full Range (1-5), 99% response rate. 1 'N/A', and 1 'prefer not to answer'.					Include. 2 N/A. Reworded into a question rather than a statement.
Q884	The provision of follow-up by the different caregivers (doctors, nurses, physiotherapists, psychologists, etc.) after treatment?								Exclude. Poor usability results = after treatment confused participants in Group A and C
	<b>Involvement in decision making (Healthcare)</b>	<b>V1_Non-CAT</b>						<b>V2_Non-CAT</b>	
Q398	Have you felt that you and your professional(s) had a shared understanding of your disease and treatment?			Language - CCEQ 91 French translation issue. Q398 Prefer not to answer due to unclear wording.	It was felt that the modified CCEQ item "Have you been given the opportunity to discuss your treatment plan with your professional(s)?" was the most appropriate for this sub-domain. The other two items were somewhat challenging for participants to understand and there for the item above was selected for Groups A and C. It was not included in Group B as survivors were no long receiving treatment for cancer.				Exclude. The wording of the item was not clear. For some participants it was not clear what was meant by 'shared understanding'.
CCEQ - mod	My decisions about care and treatment have been respected by my professional(s)			Response scale - Several participants not satisfied with scale as the responses did not fit with the scale e.g., should include 'very satisfied'.					Exclude. 2 'N/A' responses. Difficult for patients to answer as they were not always aware or involved in making decisions about their own care.
CCEQ - mod	Have you been given the opportunity to discuss your treatment plan with your professional(s) ?			<u>Quantitative</u> Means above 3. Full Range (1-4). Q398 had a 100% response rate, CCEQ items =99%. Q398 had 1 'N/A' response and 1 'prefer not to answer'. CCEQ had 1 'N/A', and 2 'prefer not to answer'.					N/A - Group B. Reworded into a question rather than a statement.
	<b>Communication with HCPs (Healthcare)</b>	<b>V1_Non-CAT</b>						<b>V2_Non-CAT</b>	

Q429	Have you been satisfied with your communication with your professional(s)?			Overlapping - Repetitive Q401 covered by Q429.	All items in the Healthcare domain will employ a 5-point Likert scale. The scale will differ for those items asking about 'satisfaction' which will use a positive scale to avoid ceiling effects. Q429 and Q409 were considered to be the best items to take forward into Toolkit 2 due to overlap and poor performance of the other items.				Include. 5-point Likert scale - positive
Q401	Have your professional(s) spent enough time talking with you?			Recall period - Issues with 'Most Recent' What does this refer too?					Exclude. Covered by Q429.
Q409	Have your professional(s) used language that you understand (avoided medical jargon, used clear terms)?			Language - Issues with 'professionals' who are they. Q421 extremely problematic with regards to comprehension and the word Professionals (German).					Include. Item is clear and provides the added the context participants liked.
Q421	Have your professional(s) taken into account how you prefer to receive information?			Response scale - could be extended to include more options. Several participants not satisfied with scale as the responses did not fit with the scale e.g., should include 'very satisfied'.  <u>Quantitative</u> Means above 3. Full Range (1-4). 100% response rate. 1 'N/A' response. Q409 1 'N/A', Q421 1 'prefer not to answer' 1 'N/A'.					Exclude. Poor usability results = difficult to understand. This related to participants not understanding the 'modality' concept of how people can receive information. E.g., written verbal etc.
<b>Continuity and coordination of care (Healthcare)</b>		<b>N/A</b>					<b>V2_Non-CAT</b>		



NEW	Do you feel doctors, nurses and other professionals involved in your care work together as a team?				N/A - not included in usability.	<p>This was a new sub-domain that was added to Toolkit V2 as a result of the stakeholder forum and consensus meeting. It was a somewhat difficult sub-domain to conceptualise however WP4 and Co-researchers created this new item to assess the perceptions towards their continuity and coordination of care. It was thought that this item may provide useful information at a policy level.</p> <p>Several variations to the wording were developed some of which used the 'have you' format, however 'do you feel' was preferred as it was thought to capture the participants views rather than the reality. For example, this wording will capture the participants perspective rather than the reality e.g., they may not know if their HCPs work together as a team. This item was modified from the EORTC item from the PAT-SAT Q870.</p>				Include. EORTC item - Modified PAT-SAT Q870. New item for all Groups. Concept originated in the Stakeholder meeting.	
	<b>Overall QOL Ranking (?)</b>	<b>N/A</b>					<b>V2_Non-</b>	<b>CAT</b>			

NEW	Having completed the questionnaire, what do you feel most impacts your Quality of Life?			N/A - not included in usability.	This New item was added following discussions and the consensus and consortium meetings and was added post usability study to capture what participants feel are the most import factors impacting their quality of life. It will have a free text response option that will be limited in the number of characters. It will be positioned at the end of the Toolkit.				Include. New item for all Groups
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### 8.3 Static EUonQoL-Kit v2- Paper

Target Group A – Active Treatment

#### EUonQoL-Kit v2: Group A

**Thank you for taking the time to complete this questionnaire which asks you questions about your health and quality of life as a person with cancer experience. Your answers will be used to better understand cancer patients' needs across Europe.**

**Please complete the questions by choosing the answer that best applies to you. There are no "right" or "wrong" answers. The information that you provide will remain strictly confidential. Your answers will not be shared with your medical team.**

	N/A	Not at all	A little	Quite a bit	Very much
1 Do you have any trouble doing strenuous activities, like carrying a heavy shopping bag or a suitcase?		1	2	3	4
2 Do you have any trouble carrying a heavy bag upstairs?		1	2	3	4
3 Do you have any trouble walking for 30 min.?		1	2	3	4
<b><u>During the past week:</u></b>					
4 Were you limited in doing either your work or other daily activities?		1	2	3	4
5 Were you limited in pursuing your hobbies or other leisure time activities?		1	2	3	4
6 Have you had pain?		1	2	3	4
7 Did pain interfere with your daily activities?		1	2	3	4
8 Were you tired?		1	2	3	4
9 Have you required frequent or long periods of rest?		1	2	3	4
10 To what extent have you been troubled with physical symptoms from your disease or treatment?		1	2	3	4
11 Have you had trouble sleeping?		1	2	3	4
12 Have you lacked appetite?		1	2	3	4
13 Have you felt nauseated?		1	2	3	4
14 Have you been constipated?		1	2	3	4
15 Have you had diarrhoea?		1	2	3	4
16 Were you short of breath when walking more than 100 m (100 yds)?		1	2	3	4
17 Have you felt miserable?		1	2	3	4
18 Did you feel depressed?		1	2	3	4
19 Did you worry?		1	2	3	4
20 Have you been watching yourself closely for any new symptoms?		1	2	3	4
21 To what extent have you been troubled with side-effects from your treatment		1	2	3	4
22 Have you been afraid of tumor progression?		1	2	3	4
	N/A	Not at all	A little	Quite a bit	Very much

23	Have you worried about your health in the future?		1	2	3	4
24	How much has your disease been a burden to you?		1	2	3	4
25	I have felt at peace with myself		1	2	3	4
26	Have you had difficulty maintaining concentration even when doing something important?		1	2	3	4
27	Has your physical condition or medical treatment interfered with your social activities?		1	2	3	4
28	Has your physical condition or medical treatment interfered with your relationships with your family or friends?		1	2	3	4
29	As a result of your physical condition or medical treatment, have you felt isolated from your family or friends?		1	2	3	4
30	Have you worried about becoming dependent on others?		1	2	3	4
	<b>(No timeframe)</b>					
31	Since the diagnosis and treatment of your cancer: Is your relationship with your partner stronger?	N/A	1	2	3	4
32	Because of your experience with cancer, have you had to limit your life plans or goals?		1	2	3	4
	<b><u>During the past 4 weeks:</u></b>					
33	Has the disease or treatment affected your sex life (for the worse)?	N/A	1	2	3	4
34	Have you worried about your ability to have children?	N/A	1	2	3	4
	<b><u>During the past week:</u></b>					
35	Has your physical condition or medical treatment caused you financial difficulties?		1	2	3	4
36	As a result of your physical condition or medical treatment, have you had difficulties paying any of your regular expenses (e.g. rent, insurance, phone)?		1	2	3	4
	<b>(No timeframe)</b>					
37	Since the diagnosis and treatment of your cancer: Have you had problems with obtaining insurance, loans, and/or a mortgage?	N/A	1	2	3	4
38	Since the diagnosis and treatment of your cancer: Have you received support from your employer e.g. arranging flexible working?	N/A	1	2	3	4
39	Since the diagnosis and treatment of your cancer: Have you made positive lifestyle changes (e.g., more exercise, healthy food, cutting down smoking)?		1	2	3	4

**For the following questions please SELECT the number between 1 and 7 that best applies to you.**

						Very poor						Excellent
40	How would you rate your overall quality of life during the past week?	1	2	3	4	5	6	7				
41	How would you rate your overall health during the past week?	1	2	3	4	5	6	7				
42	Have you had any other significant symptoms or problems that have not been mentioned in the questions above?	No	Yes									

**Yes. Please write down the most important ones (up to three), and rate to what extent you have experienced these symptoms or problems during the past week:**

**During the past week, to what extent have you experienced:**

Symptom/problem A:	_____	1	2	3	4
Symptom/problem B:	_____	1	2	3	4
Symptom/problem C:	_____	1	2	3	4

**We are interested in your MOST RECENT experiences of the care you have received by the healthcare professional(s) who have treated you (doctors, nurses, and others).**

		Never	Someti mes	Usually	Almost Always	Always	
43	Have your medical appointments interfered with your work / household activities?	N/A	1	2	3	4	5
44	Have your medical appointments caused problems for your family / carer?	N/A	1	2	3	4	5
45	Have you been given the opportunity to discuss your treatment plan with your professional(s)?	N/A	1	2	3	4	5
46	Have your professional(s) used language that you understand (e.g. avoided medical jargon, used clear terms)?	N/A	1	2	3	4	5
47	Do you feel doctors, nurses and other professionals involved in your care work together as a team?	N/A	1	2	3	4	5
			Poor	Fair	Good	Very Good	Excellent
48	Have you been satisfied with your communication with your professional(s)?	N/A	1	2	3	4	5
49	Have you felt satisfied with the care you have received?	N/A	1	2	3	4	5
50	Having completed the questionnaire, what do you feel most impacts your Quality of Life?	_____					
		_____					

**Please note that your answers will not appear in your medical record. If you experience symptoms or side-effects or are in need of help, please report them to your doctor or nurse specialist.**

Target Group B – Survivors

## EUonQoL-Kit v2: Group B

**Thank you for taking the time to complete this questionnaire which asks you questions about your health and quality of life as a person with cancer experience. Your answers will be used to better understand cancer patients' needs across Europe.**

**Please complete the questions by choosing the answer that best applies to you. There are no "right" or "wrong" answers. The information that you provide will remain strictly confidential. Your answers will not be shared with your medical team.**

	N/A	Not at all	A little	Quite a bit	Very much
1 Do you have any trouble doing strenuous activities, like carrying a heavy shopping bag or a suitcase?		1	2	3	4
2 Do you have any trouble taking a long walk?		1	2	3	4
3 Do you have any trouble carrying a heavy bag upstairs?		1	2	3	4
<b><u>During the past week:</u></b>					
4 Were you limited in doing either your work or other daily activities?		1	2	3	4
5 Were you limited in pursuing your hobbies or other leisure time activities?		1	2	3	4
6 Have you had pain?		1	2	3	4
7 Did pain interfere with your daily activities?		1	2	3	4
8 Were you tired?		1	2	3	4
9 Have you required frequent or long periods of rest?		1	2	3	4
10 To what extent have you been troubled with physical symptoms from your disease or treatment?		1	2	3	4
11 Have you had trouble sleeping?		1	2	3	4
12 Have you lacked appetite?		1	2	3	4
13 Have you felt nauseated?		1	2	3	4
14 Have you been constipated?		1	2	3	4
15 Have you had diarrhoea?		1	2	3	4
16 Were you short of breath when walking more than 100 m (100 yds)?		1	2	3	4
17 Have you felt miserable?		1	2	3	4
18 Did you feel depressed?		1	2	3	4
19 Did you worry?		1	2	3	4
20 Have you been watching yourself closely for any new symptoms?		1	2	3	4
21 To what extent have you been troubled with side-effects from your treatment		1	2	3	4
	N/A	Not at all	A little	Quite a bit	Very much
22 Have you worried about recurrence of your disease?		1	2	3	4

23	Have you worried about your health in the future?		1	2	3	4
24	How much has your disease been a burden to you?		1	2	3	4
25	I have felt at peace with myself		1	2	3	4
26	Have you had difficulty maintaining concentration even when doing something important?		1	2	3	4
27	Has your physical condition or medical treatment interfered with your social activities?		1	2	3	4
28	Has your physical condition or medical treatment interfered with your relationships with your family or friends?		1	2	3	4
29	As a result of your physical condition or medical treatment, have you felt isolated from your family or friends?		1	2	3	4
30	Have you worried about becoming dependent on others?		1	2	3	4
	<b>(No timeframe)</b>					
31	Since the diagnosis and treatment of your cancer: Is your relationship with your partner stronger?	N/A	1	2	3	4
32	Because of your experience with cancer, have you had to limit your life plans or goals?		1	2	3	4
	<b><u>During the past 4 weeks:</u></b>					
33	Have you been dissatisfied with your physical appearance?		1	2	3	4
34	Has the disease or treatment affected your sex life (for the worse)?	N/A	1	2	3	4
35	Have you worried about your ability to have children?	N/A	1	2	3	4
	<b><u>During the past week:</u></b>					
36	Has your physical condition or medical treatment caused you financial difficulties?		1	2	3	4
37	As a result of your physical condition or medical treatment, have you had difficulties paying any of your regular expenses (e.g. rent, insurance, phone)?		1	2	3	4
	<b>(No timeframe)</b>					
38	Since the diagnosis and treatment of your cancer: Have you had problems with obtaining insurance, loans, and/or a mortgage?	N/A	1	2	3	4
39	Since the diagnosis and treatment of your cancer: Have you received support from your employer e.g. arranging flexible working?	N/A	1	2	3	4
40	Since the diagnosis and treatment of your cancer: Have you made positive lifestyle changes (e.g., more exercise, healthy food, cutting down smoking)?		1	2	3	4

**For the following questions please SELECT the number between 1 and 7 that best applies to you.**

		Very poor					Excellent
41	How would you rate your overall quality of life during the past week?	1	2	3	4	5	6 7
42	How would you rate your overall health during the past week?	1	2	3	4	5	6 7
43	Have you had any other significant symptoms or problems that have not been mentioned in the questions above?	No	Yes				



**Yes. Please write down the most important ones (up to three), and rate to what extent you have experienced these symptoms or problems during the past week:**

**During the past week, to what extent have you experienced:**

Symptom/problem A:	_____	1	2	3	4
Symptom/problem B:	_____	1	2	3	4
Symptom/problem C:	_____	1	2	3	4

**We are interested in your MOST RECENT experiences of the care you have received by the healthcare professional(s) who have treated you (doctors, nurses, and others).**

		Never	Someti mes	Usually	Almost Always	Always	
44	Have your medical appointments interfered with your work / household activities?	N/A	1	2	3	4	5
45	Have your medical appointments caused problems for your family / carer ?	N/A	1	2	3	4	5
46	Have your professional(s) used language that you understand (e.g. avoided medical jargon, used clear terms)?	N/A	1	2	3	4	5
47	Do you feel doctors, nurses and other professionals involved in your care work together as a team?	N/A	1	2	3	4	5
			Poor	Fair	Good	Very Good	Excellent
48	Have you been satisfied with your communication with your professional(s)?	N/A	1	2	3	4	5
49	Have you felt satisfied with the care you have received?	N/A	1	2	3	4	5
50	Having completed the questionnaire, what do you feel most impacts your Quality of Life?	_____					
		_____					

**Please note that your answers will not appear in your medical record. If you experience symptoms or side-effects or are in need of help, please report them to your doctor or nurse specialist.**

Target Group C – Palliative Care

## EUonQoL-Kit v2: Group C

**Thank you for taking the time to complete this questionnaire which asks you questions about your health and quality of life as a person with cancer experience. Your answers will be used to better understand cancer patients' needs across Europe.**

**Please complete the questions by choosing the answer that best applies to you. There are no "right" or "wrong" answers. The information that you provide will remain strictly confidential. Your answers will not be shared with your medical team.**

	N/A	Not at all	A little	Quite a bit	Very much
1 Do you have any trouble walking for 30 min.?		1	2	3	4
2 Do you need help with eating, dressing, washing yourself or using the toilet?		1	2	3	4
<b><u>During the past week:</u></b>					
3 Were you limited in doing either your work or other daily activities?		1	2	3	4
4 Were you limited in pursuing your hobbies or other leisure time activities?		1	2	3	4
5 Have you had pain?		1	2	3	4
6 Did pain interfere with your daily activities?		1	2	3	4
7 Were you tired?		1	2	3	4
8 Have you required frequent or long periods of rest?		1	2	3	4
9 To what extent have you been troubled with physical symptoms from your disease or treatment?		1	2	3	4
10 Have you had trouble sleeping?		1	2	3	4
11 Have you lacked appetite?		1	2	3	4
12 Have you felt nauseated?		1	2	3	4
13 Have you been constipated?		1	2	3	4
14 Have you had diarrhoea?		1	2	3	4
15 Were you short of breath?		1	2	3	4
16 Have you felt miserable?		1	2	3	4
17 Did you feel depressed?		1	2	3	4
18 Did you worry?		1	2	3	4
19 Have you been watching yourself closely for any new symptoms?		1	2	3	4
20 To what extent have you been troubled with side-effects from your treatment?		1	2	3	4
21 Have you worried about your health in the future?		1	2	3	4
22 How much has your disease been a burden to you?		1	2	3	4

		N/A	Not at all	A little	Quite a bit	Very much
24	I have felt at peace with myself		1	2	3	4
25	Have you had difficulty maintaining concentration even when doing something important?		1	2	3	4
26	Has your physical condition or medical treatment interfered with your social activities?		1	2	3	4
27	Has your physical condition or medical treatment interfered with your relationships with your family or friends?		1	2	3	4
28	As a result of your physical condition or medical treatment, have you felt isolated from your family or friends?		1	2	3	4
	<b>(No timeframe)</b>					
29	Since the diagnosis and treatment of your cancer: Is your relationship with your partner stronger?	N/A	1	2	3	4
30	Because of your experience with cancer, have you had to limit your life plans or goals?		1	2	3	4
	<b><u>During the past 4 weeks:</u></b>					
31	Have you been missing intimacy (e.g. closeness, fondness, sex)?	N/A	1	2	3	4
	<b><u>During the past week:</u></b>					
32	Has your physical condition or medical treatment caused you financial difficulties?		1	2	3	4
	<b>(No timeframe)</b>					
33	Since the diagnosis and treatment of your cancer: Have you received support from your employer e.g. arranging flexible working?	N/A	1	2	3	4

**For the following questions please SELECT the number between 1 and 7 that best applies to you.**

		Very poor					Excellent
34	How would you rate your overall quality of life during the past week?	1	2	3	4	5	6 7
35	How would you rate your overall health during the past week?	1	2	3	4	5	6 7
36	Have you had any other significant symptoms or problems that have not been mentioned in the questions above?	No	Yes				

**Yes. Please write down the most important ones (up to three), and rate to what extent you have experienced these symptoms or problems during the past week:**

**During the past week, to what extent have you experienced:**

		Not at all	A little	Quite a bit	Very much
Symptom/problem A:	_____	1	2	3	4
Symptom/problem B:	_____	1	2	3	4
Symptom/problem C:	_____	1	2	3	4

**We are interested in your MOST RECENT experiences of the care you have received by the healthcare professional(s) who have treated you (doctors, nurses, and others).**

		Never	Sometimes	Usually	Almost Always	Always	
37	Have your medical appointments interfered with your work / household activities?	N/A	1	2	3	4	5
38	Have your medical appointments caused problems for your family / carer ?	N/A	1	2	3	4	5
39	Have you been given the opportunity to discuss your treatment plan with your professional(s) ?	N/A	1	2	3	4	5
40	Have your professional(s) used language that you understand (e.g. avoided medical jargon, used clear terms)?	N/A	1	2	3	4	5
41	Do you feel doctors, nurses and other professionals involved in your care work together as a team?	N/A	1	2	3	4	5
			Poor	Fair	Good	Very Good	Excellent
42	Have you been satisfied with your communication with your professional(s)?	N/A	1	2	3	4	5
43	Have you felt satisfied with the care you have received?	N/A	1	2	3	4	5
44	Having completed the questionnaire, what do you feel most impacts your Quality of Life?	_____					
		_____					

**Please note that your answers will not appear in your medical record. If you experience symptoms or side-effects or are in need of help, please report them to your doctor or nurse specialist.**

## 8.4 Dynamic EUonQoL-Kit v2

Table 11 shows the item administration rules of the dynamic part within each questionnaire for the 3 groups of participants included in the “Live CAT” sub-sample:

- **Starting item:** each group is assigned a specific starting item for each of the 8 dimensions in the dynamic module.
- **Stopping rule:** each group is assigned a fixed number of items to answer for each QoL dimension. Based on the response provided to the starting item, the CAT-engine automatically selects the next most relevant item from a CAT item bank (Table 12). This step (response and item selection) is repeated until the expected number of items is reached (stopping rule) for a given QoL dimension. This process is performed for every QoL dimension.

Please, note that: 1) The stopping rule implies that the items, although fixed in number, vary in content, as their selection is based on the responses to previous items; 2) The total number of items in the CAT bank is 145 (Table 12) but patients will only be asked for 50, according to the above administration rules.

**Table 11. CAT item administration rules.**

Dimensions	Number of items		
	EUonQoL-D-AT	EUonQoL-D-SU	EUonQoL-D-PC
	Group A	Group B	Group C
	Active Treatment	Survivors	Palliative Care
<b>Mobility &amp; Activity / Physical Functioning (PF)</b>			
Starting item	Do you have any trouble walking for 30 min.?	Do you have any trouble carrying a heavy bag upstairs?	Do you have any trouble walking for 30 min.?
Stopping rule (# of items)	7	7	7
<b>Social Role &amp; Activities / Role Functioning (RF)</b>			
Starting item	Were you limited in doing either your work or other daily activities?		
Stopping rule (# of items)	6	6	6
<b>Pain (PA)</b>			
Starting item	Have you had pain?		
Stopping rule (# of items)	6	6	6
<b>Energy / Fatigue (FA)</b>			
Starting item	Were you tired?		
Stopping rule (# of items)	6	6	6
<b>Sleeping problems (SL)</b>			
Starting item	Have you had trouble sleeping?		
Stopping rule (# of items)	6	6	6
<b>Anxiety &amp; Worry / Emotional Functioning (EF)</b>			
Starting item	Have you felt miserable?		
Stopping rule (# of items)	7	7	7
<b>Family &amp; Relationships / Social Functioning (SF)</b>			
Starting item	Has your physical condition or medical treatment interfered with your social activities?		
Stopping rule (# of items)	6	6	6
<b>Financial aspects /difficulties (FI)</b>			
Starting item	Has your physical condition or medical treatment caused you financial difficulties?		
Stopping rule (# of items)	6	6	6
<b>Total number of items</b>	<b>50</b>	<b>50</b>	<b>50</b>

**Table 12. Full list of CAT items.**

EUnQoL-D item list	
Item description	Response options  (same as in the corresponding items in the static version)
<b>Mobility &amp; Activity / Physical Functioning (PF)</b>	
Do you have any trouble lifting a full cup or glass to your mouth?	
Do you have any trouble walking 100 m/100 yds?	
Do you need help caring for your feet (e.g. cutting your toenails)?	
Do you have any trouble walking up a flight of stairs?	
Do you need help with eating, dressing, washing yourself or using the toilet?	
Do you need help with grooming (e.g. cleaning nails, brushing teeth, combing your hair)?	
Do you have any trouble walking for 30 min?	
Do you have any trouble lifting a box weighing about 10 kg/20 lbs?	
Do you have any trouble hiking 3 km/2 mi on uneven surfaces?	
Do you need help dressing?	
Do you have any trouble walking outdoors on flat ground?	
Do you have any trouble walking a few steps?	
Do you need to stay in bed or a chair during the day?	
Do you need help putting on a shirt?	
Do you have any trouble doing strenuous activities, like carrying a heavy shopping bag or a suitcase?	
Do you have any trouble reaching and getting down an object weighing about 2 kg/4 lbs (such as a bag of flour) from just above your head?	
Do you have any trouble bending over to pick up a light object from the floor?	
Do you have any trouble running fast?	
Do you have any trouble taking a short walk outside of the house?	
Do you have any trouble carrying a heavy bag upstairs?	
Do you need help washing your face and hands?	
Do you have any trouble running 100 m/100 yds?	
Do you have any trouble taking a long walk carrying a heavy pack on your back (e.g. a filled rucksack)?	
Do you have any trouble taking a <u>long</u> walk?	
Do you have any trouble carrying something weighing about 5 kg/10 lbs?	
Do you need help to walk about outside (e.g. a walking stick or someone to support you)?	
Do you need help undressing?	

Do you have any trouble carrying something in both hands (e.g. shopping bags) while climbing a flight of stairs?	
Do you need help eating?	
Do you have any trouble lifting a full teapot/coffee pot?	
Do you have any trouble running a short distance, such as to catch the bus?	
<b>Anxiety &amp; Worry / Emotional Functioning (EF)</b>	
Did you feel tense?	
Have you felt helpless?	
Have you felt panic?	
Have you lost interest in things, such as recreational or social activities (independently of your actual ability to do them)?	
Have you felt vulnerable?	
Have you felt frustrated?	
Have you felt worthless?	
Have you felt discouraged?	
Have you had emotional outbursts?	
Have you felt that nothing could cheer you up?	
Have you felt afraid?	
Have you felt that pleasure has gone from your life?	
Have you had difficulty relaxing?	
Have you lost interest in your appearance?	
Have you felt miserable?	
Did you feel depressed?	
Did you feel irritable?	
Have you felt useless?	
Did you worry?	
Have you felt desperate?	
Have you been afraid of losing control?	
Have you felt sad?	
Have you felt like giving up?	
Have you felt that you have nothing to look forward to?	
<b>Social Role &amp; Activities / Role Functioning (RF)</b>	
Have you been limited in completing your household tasks?	
Have you been limited in doing light housework (e.g. dusting or making the bed)?	
Have you been limited in doing physically demanding recreational activities (e.g., swimming or cycling)?	
Have you needed assistance in doing your work or daily activities?	

Have you been limited in doing light recreational activities (e.g., watching TV, playing cards, or reading)?	
Have you been limited in doing minor household repairs and maintenance (e.g., changing a light bulb or hanging up a picture)?	
Have you been limited in taking care of personal or household financial affairs (e.g. paying bills)?	
Were you limited in doing either your work or other daily activities?	
Have you been limited in doing heavy housework (e.g., washing floors or vacuuming)?	
Were you limited in pursuing your hobbies or other leisure time activities?	
<b>Family &amp; Relationships / Social Functioning (SF)</b>	
Has your physical condition or medical treatment stopped you from looking forward to seeing your family or friends?	
As a result of your physical condition or medical treatment, have you felt you did not know what to say to your family or friends?	
As a result of your physical condition or medical treatment, have you preferred to spend time alone?	
As a result of your physical condition or medical treatment have you been less able to see your family or friends?	
As a result of your physical condition or medical treatment, have you felt you were no longer interested in social activities with other people?	
As a result of your physical condition or medical treatment, have you felt you no longer had a lot in common with your family or friends?	
As a result of your physical condition or medical treatment, have you spent less time with your family or friends?	
As a result of your physical condition or medical treatment, have you felt isolated from your family or friends?	
As a result of your physical condition or medical treatment, have you found it hard to make contact with people?	
Has your physical condition or medical treatment interfered with your <u>family</u> life?	
Has your physical condition or medical treatment interfered with your <u>social</u> activities?	
Has your physical condition or medical treatment interfered with your relationships with your family or friends?	
Has your physical condition or medical treatment caused you to argue with your family or friends?	
<b>Energy / Fatigue (FA)</b>	
Have you been so tired it was difficult keeping your eyes open during daytime?	
Have your muscles felt very tired after physical activity like taking a long walk?	
Have you woken up with a feeling of exhaustion?	
Have you started things without difficulty but got weak as you went on?	
Have you lacked the energy to do things?	



Have you felt slowed down?	
Have you been too tired to do your usual activities?	
Have you felt drained?	
Have you been so exhausted it felt almost impossible to move your body?	
Have you had trouble starting things because you were tired?	
Have you been too tired to do even simple things?	
Have you found shopping and doing errands exhausting?	
Have you felt physically exhausted?	
Have you found leisure and recreational activities exhausting?	
Have you felt weak in your arms or legs?	
Have you felt exhausted?	
Were you tired?	
Have you had to sleep for long periods during daytime?	
Have you lacked energy?	
Have you become easily tired?	
Have you had trouble sitting up because you were tired?	
Have you felt weak?	
Have you felt worn out?	
Have you had a feeling of overwhelming and prolonged lack of energy?	
Have you had trouble finishing things because you were tired?	
Have you become tired from walking up stairs?	
Did you need to rest?	
Have you required frequent or long periods of rest?	
Have you been too tired to eat?	
Have you become tired from carrying out your duties and responsibilities?	
Have you had an extreme need for rest?	
Have you become exhausted from dressing?	
Have you felt tired for a long time after physical activity like taking a long walk?	
Have you become exhausted from taking a shower?	
<b>Pain (PA)</b>	
Have you had any trouble falling asleep because of pain?	
Has pain made it difficult for you to do the jobs that you usually do around the house?	
Have you had extreme pain?	
Has pain made it difficult for you to stand for more than a few minutes?	
Have you had pain you could not ignore?	
Have you had to stay in bed during the day because of pain?	

Has pain limited your ability to concentrate on work or other daily activities?	
Have you had any trouble sleeping because of pain?	
Has pain interfered with your leisure activities (e.g. sports and hobbies)?	
Has pain interfered with your social activities?	
Have you had severe pain?	
Have you woken up earlier than you wanted to because of pain?	
Has pain made it difficult for you to sit for more than 1 hour?	
Did pain interfere with your daily activities?	
Have you had any trouble taking a walk because of pain?	
Have you had pain?	
<b>Sleeping problems (SL)</b>	
Has your sleep been restless?	
Have you woken up during the night?	
Have you woken up too early?	
Have you had trouble staying asleep?	
Have you had trouble sleeping?	
Have you had trouble getting a good night's sleep?	
Have you woken up for long periods during the night?	
Have you felt tired (not rested) when you woke up?	
<b>Financial aspects /difficulties (FI)</b>	
Has your physical condition or medical treatment caused you financial difficulties?	
As a result of your physical condition or medical treatment, have you had extra expenses you had difficulties paying?	
As a result of your physical condition or medical treatment, have you had any extra expenses (e.g., for medication, transport, aids)?	
As a result of your physical condition or medical treatment, have you lacked money to buy basic things like food or clothes?	
As a result of your physical condition or medical treatment, have you found yourself in debt?	
Has your physical condition or medical treatment caused you financial difficulties leading to changes in your lifestyle?	
As a result of your physical condition or medical treatment, have you had less money to spend on yourself (e.g., for buying yourself something that you would like to have but don't necessarily need)?	
As a result of your physical condition or medical treatment, have you had difficulties paying any of your regular expenses (e.g. rent, insurance, phone)?	
As a result of your physical condition or medical treatment, have you had to borrow money or sell personal belongings?	

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