



# **EUonQoL**

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

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### **Preface**

This report is written as a product of the project "Quality of Life in Oncology: measuring what matters for cancer patients and survivors in Europe (EUonQoL)". This project is funded by the European Union.

The strict collaboration with the Grant Office IEO provided us valuable feedback, particularly we would like to thank Dr. Elena Dal Zotto and Dr. Ilaria Foti. Their input and suggestions made it possible for us to incorporate their expertise and perspective from the beginning of our tasks. Furthermore, we would like to thank our translation providers for their external services and for their expertise in cultural adaptation and all the clinical centers who collaborated with IEO Team in the preliminary translations.

Also, IEO team would like to thank the EUonQoL Executive Committee for providing us with input on the tasks, roles, and responsibilities, as well as co-researchers involved in this process (Carina Dantas and Laura Pinnavaia).

The authors would like to thank WP3 partners (with particular regard on EORTC group) and WP4 for the collaboration within Task 5.3 of the EUonQoL project.

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### 1. Introduction

The first part of the present report will provide an overview of the EUonQoL project within which this report is situated. Additionally, it will introduce and outline the objectives and contents of the present report. Subsequently, next paragraphs will present and delineate methodologies followed to reach the aim of task 5.3 and the material used to keep track of it. In the final part of the report, conclusions are presented.

This WP is part of an EU funded project entitled "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 (ongoing treatment, palliative care) and survivors. The EUonQoL-Kit has been developed from the patient perspective, administered digitally, and will be available in all 27 European Union (EU) and associated countries languages.

## 1.1. The EUonQoL project

Cancer is the second cause of death and the first cause of suffering for patients and caregivers in Europe, as well as having an enormous financial impact on health services and individuals. There were 2.7 million new cases of cancer and 1.3 million deaths in 2020, which is expected to increase with about 25% by 2035. Additionally, there is an unacceptable variability in terms of access to innovation, quality of care, and outcomes (including QoL), within and between countries in Europe. QoL can be interpreted as satisfaction and happiness measured as the achievement of aspirations and/or the realization of individual expectations. The burden of cancer and cancer treatment on QoL is well-recognized. Nonetheless, implementation of QoL assessment in routine oncology practice is not yet part of standard of care. In the same way, health care systems and cancer control programs do not take into consideration QoL measures when developing clinical, societal, and healthcare policymaking systems.

Emerging needs related to new cancer treatments along with societal developments require a revision of traditional QoL assessment tools, most of which have been developed a few decades ago and are not available in all official and non-official European languages.

Available questionnaires are often "static", presenting the same set of questions/items to all patients, without any difference. Recent innovation in the assessment of HRQoL (Health-Related Quality of Life) in cancer is the development of the Computer-Adaptive Testing (CAT). CAT allows for a more precise assessment of HRQoL, with systems presenting subsequent questions based on answers to the previous ones, ultimately adapting the questions to the health state of the individual patient. In addition, most existing HRQoL tools were developed to be filled out through paper and pencil. These tools will in turn allow for more dynamic instruments, suitable for a personalized patient's experience of data collection. The overall project process wants to ensure that the EUonQoL-Kit and its future development would be a unified, standard European QoL assessment system. For the aforementioned reasons significant focus was directed towards the translation process, in order to ensure a consistently high standard of translated materials and to cover both linguistical and cultural diversity across Europe.

In Table 1 all WPs involved in the project are presented.

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Table 1: Work packages of the EUonQoL EU project

Work Package	WP Title
WP1	Ethics
WP2	Involvement of stakeholders and patients
WP3	Review of existing HRQoL databases, measures and 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

To gain a better understanding of the process utilized in the EUonQoL project, refer to Figure 1, which depicts the flow diagram illustrating the involved Work Packages and their connections.

WP3 – Review of existing HRQoL databases, measures & item libraries

WP6 — Digital tools for data collection

WP7 – EUonQoL-Kit Pilot survey

WP8 – Implementation & Exploitation

WP9 — Dissemination & Communication

Figure 1: Flow diagram of project

# 1.1.1. Population: Active treatment, Survivors, Palliative Care

The aim of the EUonQoL-Kit is to reflect the spectrum of patients diagnosed with cancer. The questionnaires will be administered and validated in three different cancer groups: active treatment, survivors, and palliative care. The definitions outlined within the project might not be exhaustive of the whole cancer patient population, but they are essential to validate the tool and to be able to distinguish three different patient groups with relative precision. As agreed with the EUonQoL Consortium, the target population groups are defined throughout all stages of this study as:

**Group A**. Active Treatment:

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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.

### **Group B**. Survivors:

*i.* At least one year off active treatment (but can be on long-term adjuvant hormonotherapy) 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.

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

- *i.* Patients with projected prognosis <=70 or ECOG <=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.

## 1.1. Aim of the Report

The principal aim of Task 5.3 is to provide high-quality translations and cultural adaptation of the newly developed EUonQoL-Kit to support comparability of survey results across European languages of involved countries. With the present report IEO team wants to highlight its coordination process after the selection of the two most suitable providers for high-quality translation services to reach the goal of the translation and cultural adaptation of the EUonQoL-Kit.

IEO, as Task Leader, together with the other involved clinical centers, worked to address the aim of incorporation and validation in the translated EUonQoL-Kit of cultural elements of the target patients in order to improve their attitudes toward the intervention. In Table 2 all the clinical centers that conducted the preliminary translations of the Toolkit are presented.

Table 2: Eight clinical centers that conducted the preliminary translations of the Toolkit

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COUNTRY	CENTRE NAME	ACRONYM
UK	Leeds Cancer Centre	LEEDS
IT	Fondazione IRCCS Instituto 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	Rigshopitalet, Copenhagen	RH
DK	Bispebjerg Hospital, Copenhagen	BH

Finally, IEO analyzed and summarized the provided translations and sent them to WP6 for the digitalization of the contents and to WP7 for the multi-centred EUonQoL-Kit Pilot survey.

# 2. Methodology

To fulfill the aim of Task 5.3, several methodological steps were followed.

Firstly, IEO supervised the preliminary translation of the EUonQoL-Kit into six languages, including the starting version in English (Danish, Dutch, French, German, Italian); these six translations were internally performed in different clinical centers. The aim of this first step was to allow an initial setting of the Mobile App interfaced with the web-based platform and generate a first draft of the graphical visualization of EUonQoL on the devices. IEO addressed this aim with a strict coordination with WP6 (Leader: DIGICORE) also in order to set-up the conduction of the multi-centered Pilot survey with the final version of the EUonQoL-Kit.

Subsequently, the EUonQoL-Kit developed in English has been translated into the 24 European official languages (Bulgarian, Croatian, Czech, Danish, Dutch, English, Estonian, Finnish, French, German, Greek, Hungarian, Irish, Italian, Latvian, Lithuanian, Maltese, Polish, Portuguese, Romanian, Slovak, Slovenian, Spanish, Swedish) and 7 non-official languages spoken in the associated countries involved in the project (Albanian, Georgian, Moldovan, Norwegian, Serbian, Turkish, Ukrainian).

To perform this activity, IEO was in charge of selecting one or more suitable provider(s) for the best translation service. After the identification of the translation agencies, IEO continuously interacted with the identified contractors to oversee the entire process and monitor that the providers followed the specified steps to reach the aim of the translation and cultural adaptation of the EUonQoL-Kit. Specifically, the translation and cultural adaptation process followed the ISPOR Guidelines, ensuring forward-backward translations and cognitive debriefing. Both translations and debriefing interviews were performed by professional translation agencies as external services providers with experience in PROMs (Patient-

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reported outcome measures) and cultural adaptation methods; these actions were supervised by IEO team, in order to guarantee an adequate high-quality result.

Finally, IEO collected all the provided reports to summarize the entire translation and cultural adaptation process and patients' feedback received during the cognitive debriefing.

In the next paragraphs, a detailed description of each of the listed steps is provided.

### 2.1. Preliminary six translations performed internally

Preliminary translations were carried out by research centers participating in the EUonQoL project, having fluency and good understanding in both the source language (English) and the targeted one (which was one of the following: Danish, Dutch, French, German, Italian).

Additionally, the internal translator was required to show a good expertise and knowledge in not only the two languages (origin/source and target), but also a profound understanding of various aspects associated with QoL in cancer patients and the progression of their disease.

Please See Appendix for more details.

### 2.2. Translation and Cultural Adaptation (TCA) process

The Translation and Cultural Adaptation (TCA) of the EUonQoL-Kit has been completed for all new items, following the ISPOR (International Society for Pharmacoeconomics and Outcomes Research) translation and cultural adaptation guidelines (Wild et al., 2005) and the listed below steps to assess the comprehensibility of the EUonQoL-Kit. The TCA Group formed by ISPOR, developed the Principles of Good Practice (PGP), a report on current methods to be followed during TCA of PROMs.

IEO team placed significant emphasis on overseeing the entire translation process to guarantee a consistent high quality of translated questionnaires.

In order to adhere to TCA guidelines, the subsequent steps were executed:

- **Step 1**: Forward translation/; it is the initial step that occurs after the preparation of items and corresponds to the translation of the English original version (i.e. the source language) into another language (i.e. target language). The translations were performed by two specialized translators who are native speakers of the target language, after the conceptualization of the entire text provided in the EUonQoL-Kit.
- **Step 2**: Reconciliation; in this phase, various translations are compared and merged into a single forward translation; the reconciliation has been performed by a third person to reach the best possible version. After a consensus has been reached between all translators involved.
- **Step 3**: Backward translation; this phase involves the translation from the target language back into the original one, which in this case was English.
- **Step 4**: Harmonization; which is the comparison of back translations of different language versions among themselves and with the original instrument, in order to highlight discrepancies between the original and its derivative translations, as well as to establish a single approach to addressing translation issues, that is essential to inter-translation validity.
- **Step 5**: Cognitive Debriefing (CD); this phase involves testing the instrument on a small group of five cancer patients. The purpose is to evaluate rewordings and to assess the understandability, interpretation, and cultural relevance of each individual translation;

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**Step 6**: Review of CD; at this stage of the process, the outcomes of the CD are compared with the original version of the questionnaire. This process is important to assure cultural relevance of the translation.

**Step 7**: Proofreading; this step entails the final review of the translation to focus on any typographic, grammatical or other errors and to make any necessary corrections.

**Step 8**: Final report; a report is generated at the end of the translation process to document the development of each translation and to ensure the quality of the entire process.

Finally, IEO analyzed and summarized the results and the translations in order to pass them to WP6 for the digitalization of the contents and to give some feedback to WP7 for the multicentered EUonQoL-Kit Pilot survey.

### 2.3. Timelines of TCA process

The TCA process started in mid-January 2024 to March 2024, following a strict coordination between WP4, WP5 and EORTC Group. This collaboration aimed to develop an Excel file which would serve as a shared resource for the selected providers. The primary objective during this phase was to streamline the translation process itself, ensuring efficiency and accuracy in rendering the content of the EUonQoL-Kit into various languages. It is noteworthy that a significant number of core domains items used in the EUonQoL-Kit were already available in most of official and non-official European languages (as the EORTC-QOL Group has an extensive Item library containing validated items and their corresponding translations. By February 2024, this valuable resource had been made accessible to WP5 by EORTC Group, further facilitating the translation process.

This decision was motivated by the aim of accelerating the translation process and mitigate the risk of potential overlap or discrepancies between the EORTC versions and those produced by our chosen providers. During this phase, WP5 team manually retrieved available translations in all EU languages. This activity highlighted the overlapping Turkish translation of both items "Have you felt miserable?" and "Have you felt helpless?" in the item bank ("*Kendinizi çaresiz hissettiğiniz oldu mu?*"), thus leading to the need to reassess the already available translation; this decision was previously discussed and agreed with the EORTC Group.

The secondary phase was characterized by the **conceptualization** of all the terms used in all the items; the conceptualization is defined as the process of understanding and interpreting concepts, ideas, or terms within the context of a specific language or cultur. This involves ensuring that the meaning and intent of the original content (in the source language) are accurately conveyed in the translated version with the target language, considering linguistic nuances, cultural sensitivities, and terminological differences. Conceptualization is crucial for producing translations that are not only linguistically accurate but also contextually appropriate and effective in communicating the intended message to the target audience.

IEO played a pivotal role in facilitating collaboration between translation agencies and WP4, even ensuring a thorough conceptualization process essential for the preparation of translations. Specifically, each item underwent a meticulous definition process, supplemented by explanations through the use of synonyms. This approach aimed to enhance clarity and precision in the translated versions, closely aligning with the standards outlined by ISPOR guidelines for linguistic validation and with the translations used by EORTC Group. Particularly, translators focused their conceptualization on Turkish, Slovak,

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Georgian, and Greek. In the following paragraph, some items will be illustrated that, when translated into the aforementioned target languages, sparked debate during the conceptualization phase, as certain terms needed to be culturally adapted during the Cognitive Debrieging phase.

Of note, one of the translation agencies encountered certain obstacles in recruiting cancer patients in Malta due to the country's limited size. Despite this challenge, the agency diligently addressed the issue in a timely manner. The IEO team closely monitored this situation to ensure meticulous oversight of each stage of the process

### 2.4. Specific Items and terms

### 2.4.1. Items "Did you worry?" nd "Have you felt afraid?" in Slovak

Noteworthy, the item "Did you worry?" from target language to Slovak was changed; indeed, the EORTC translation "Mali ste pocit strachu?" was modified in "Pocit'ovali ste obavy?" in order to accentuate the experience of anxiety more prominently beause its meaning is "Have you felt fear?" and to distinguish this item from the other item: "Have you felt afraid", translated as "Cítili ste strach?". This change was necessary to prevent potential clashes between the two items.

During the Cognitive Debriefing patients were tested with both versions "Mali ste pocit strachu?" and "Pocit'ovali ste obavy?" for the item "Did you worry?", and basically the respondents found the new wording to be slightly clearer as follows: R1: If I felt anxious; I understand both questions, however, the second one is more natural to me, R2: If I felt some fear; I understand both questions and both are equal to me, R3: If I had some worries; I understand both questions, however, the second one sounds more natural for me, R4: If I felt some worries; I understand both questions and both sound equally to me, R5: If I was worried; I understand both questions and I do not know which one is better. They both mean the same to me.

Regarding the item "Have you felt afraid?" respondents reported no difficulties in understanding this item and did not suggest anything for rewording it: R1: If I felt fear, R2: Whether I was afraid of something, R3: If I felt fear, R4: Whether I felt too scared, R5: If I felt hopeless and really afraid.

### 2.4.2. Item "Did you feel depressed?" in Georgian

Also, the item "Did you feel depressed?" translated in Georgian as "გრმნობდით დეპრესიას?", which included the meaning of clinical depression, raised some issues and EORTC group suggested to the translation agency to ask Mapi (who performed their translations in 2013) to look into their files in order to understand why this item was translated in this way. The Cognitive Debriefing process confirmed that the translation provided with "გრმნობდით დეპრესიას?" was suitable as it was understood as follows by the respondents: R1: Were you in a depressed mood?, R2: Have you felt sad, full of sorrow, or hopeless?, R3: Did you feel sad and downhearted?, R4: Did you feel overwhelmed by your problems?, R5: Depressed means when nothing can cheer you up, and you feel pessimistic.

### 2.4.3. Item "Have you lacked appetite?" in Greek

The question "Have you lacked appetite?", defined as lacking the desire or interest to eat, was modified in Greek from "Είχατε ανορεξία," to "Είχατε μειωμένη όρεξη," in order to trial a new version that omits the term anorexia. It's worth noting that anorexia is a distinct condition from reduced appetite. During the Cognitive Debrieging respondents declared the following meanings:

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R1: it means you stop eating because you have body image issues. Usually adolescent girls get it; R2: if I didn't feel like eating; R3: the psychological disorder of stopping to eat completely; R4: the opposite of bulimia. If you're a cancer patient you can't afford not to eat even if it makes you sick; R5: not feeling like eating much. But chiefly the disorder. For these reasons the final translation was "did you have reduced/decreased appetite?", avoiding the term "anorexia" in Greek version.

### 2.4.4. Item "Were you short of breath?" in Greek

Moreover, the item "Were you short of breath?" was tested both in Greek version " $\delta \omega \sigma \pi voia$ " (which is the everyday word for this, using no medical terms but meaning "panting") and " $\Delta \alpha \chi \alpha \nu i \dot{\alpha} \sigma \pi \epsilon$ ;" which means being out of breath. The decision of testing with patients both versions followed the reasoning that "being short of breath" and "to pant" are referred to two different mechanisms in English: although the action of panting may refer to being short of breath, the cause of this mechanism is often different: because "to pant" is what is done after strenuous physical exertion. The agency decided to make the participants choose the best suitable and understandable. The Cognitive Debriefing output were the following: R1: was it difficult for me to breath? R2: it means you can't breathe properly; R3: difficulty breathing.

Regrding the phrase " $Ei\chi \alpha \tau \epsilon \delta i \sigma \pi voi \alpha$ ," it was highlighted that dyspnea may ensue even in a state of calm and repose, without physical exercises or strenuous activities, and was chosen as final version for the Greek translation.

# 2.4.5. Item "Have you been satisfied with your communication with your professional(s)?" in Greek

The source item "Have you been satisfied with your communication with your professional(s)" was challanging for Greek translators because the version provided by EORTC item bank "Εχετε μείνει ικανοποιημένος/η από την επικοινωνία σας με τον (τους) επαγγελματία(ες);" included the term "professionals" which in Greek means any healthcare providers. Indeed, during the Cognitive Debriefing, patients asked the following clarifications: *R1: what professionals?; R2: I don't understand; R3: professional what? Is this a translation of "professionals"? This is so bad! It's not correct in Greek; R4 I don't understand what professionals are you talking about?; R5: this doesn't make sense to me. I don't know whom you are referring to. For these reasons, the translation agency provided the translation using the term "health professionals".* 

The linguistic validation was performed from 10 to 24 April 2024 and the translation agency's team is planning to provide the rationale in the linguistic validation reports by 07May2024.

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### 2.5. Translation agencies' reports

### 2.5.1. Albanian Linguistic Validation Certificate





#### LINGUISTIC VALIDATION CERTIFICATE

EUonQoL v2.0 (EUonQoL v2.0)

This is to certify that ICON Language Services conducted the linguistic validation of the Electronic version of the EUonQoL v2.0 (source file name: English (UK)\_EUonQoL Toolkit V2.0) into Albania - Albanian.

The aim of linguistic validation is to obtain translations that are:

- conceptually equivalent to the original and comparable across languages
- · culturally relevant to the context of the target country
- · easily understood by the people to whom the translated instrument is administered.

This is achieved using a rigorous ISO-17100 certified methodology<sup>1</sup> involving:

- a process which comprises several steps
- the instrument's developer input on conceptual issues
- a skilled team recruited by ICON Language Services in the target country and headed by a consultant with knowledge of
  and experience in the field of Clinical Outcome Assessments. The consultant supervises and coordinates the linguistic
  validation process in his/her country
- a centralized review process coordinated by ICON Language Services, including quality control by linguists and discussions
  about translation decisions with the consultant at each step of the process.
- cross-cultural harmonisation to ensure common understanding of the instrument's concepts by all participants involved in the process and achieve conceptual equivalence across languages.

The aforementioned translation (filename : Albanian (Albania)\_EUonQoL Toolkit V2\_10APR2024, dated 10 April 2024) underwent the following steps:

- Forward Translation step 2 forward translations by qualified translators and reconciliation
- $\bullet \quad \text{Backtranslation step-1 backtranslation by a qualified translator} \\$
- Cognitive Interview step:
  - 5 participants; population: Cancer; group: Adults; age range: 25-70
- Proofreading step

ICON Language Services may not be held liable for any changes made on the translation after completion of project 6353-TR-0001 by ICON Language Services on 10 April 2024.

Sébastien Le Dannois Project Manager ICON Language Services Sebastien Le Dannois
10 Apr 2024 06:09:57 UTC (Z)

REASON: I approve this document

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<sup>1</sup> Reference

<sup>-</sup> Acquadro C., Jambon B., Ellis D. and Marquis P. Language and translation issues. In Spilker B, ed. Quality of Life and Pharmacoeconomics in Clinical Trials. Philadelphia: Lippincott-Raven Publishers, 1996: 575-585. - Linguistic Validation Manual for Health Outcomes Assessments. Acquadro C, Conway K, Giroudet C, Mear I. Second Edition - Mapi Institute, Lyon, France, January 2012 - ISBN: 2-9522021-0-9





### 2.5.2. Bulgarian Linguistic Validation Certificate





#### LINGUISTIC VALIDATION CERTIFICATE

EUonQoL v2.0 (EUonQoL v2.0)

This is to certify that ICON Language Services conducted the linguistic validation of the Electronic version of the EUonQoL v2.0 (source file name: English (UK)\_EUonQoL Toolkit V2.0) into Bulgaria - Bulgarian.

The aim of linguistic validation is to obtain translations that are:

- · conceptually equivalent to the original and comparable across languages
- · culturally relevant to the context of the target country
- · easily understood by the people to whom the translated instrument is administered.

This is achieved using a rigorous ISO-17100 certified methodology involving:

- · a process which comprises several steps
- · the instrument's developer input on conceptual issues
- a skilled team recruited by ICON Language Services in the target country and headed by a consultant with knowledge of and experience in the field of Clinical Outcome Assessments. The consultant supervises and coordinates the linguistic validation process in his/her country
- a centralized review process coordinated by ICON Language Services, including quality control by linguists and discussions about translation decisions with the consultant at each step of the process.
- cross-cultural harmonisation to ensure common understanding of the instrument's concepts by all participants involved in the process and achieve conceptual equivalence across languages.

The aforementioned translation (filename: Bulgarian (Bulgaria)\_EUonQoL Toolkit V2.0\_05APR2024, dated 5 April 2024) underwent the following steps:

- · Forward Translation step 2 forward translations by qualified translators and reconciliation
- Backtranslation step 1 backtranslation by a qualified translator
- · Cognitive Interview step:
  - 5 participants; population: Cancer; group: Adults; age range: 41-70
- Proofreading step

ICON Language Services may not be held liable for any changes made on the translation after completion of project 6353-TR-0001 by ICON Language Services on 5 April 2024.

Cédric Montigny Project Mgr, PCS ICON Language Services Cedric Montigny Cedric Montigry
05 Apr 2024 08:20:10 UTC (Z)

REASON: I approve this document 829779d 1999 4031 a220 88:545578715

EUonQpL v2.0\_Bulgaria/Bulgarian - Version of 05 Apr 2024 - ICON. ID899-TR-0001/Bulgarian (Bulgaria)\_EUonQpL ToolNt v2.0\_054PR2004.CoT

EUonQoL Page 14 of 74

L Reference:

<sup>-</sup> Acquadro C., Jambon B., Ellis D. and Marquis P. Language and translation issues. In Spilker B, ed. Quality of Life and Pharmacoeconomics in Clinical Trials. Philadelphia: Lippincott-Raven Publishers, 1996: 575-585. - Linguistic Validation Manual for Health Outcomes Assessments. Acquadro C, Conway K, Giroudet C, Mear I. Second Edition - Mapi Institute, Lyon, France, January 2012 - ISBN: 2-9522021-0-9





### 2.5.3. Croatian Linguistic Validation Certificate





#### LINGUISTIC VALIDATION CERTIFICATE

EUonQoL v2.0 (EUonQoL v2.0)

This is to certify that ICON Language Services conducted the linguistic validation of the Electronic version of the EUonQoL v2.0 (source file name: English (UK)\_EUonQoL Toolkit V2.0) into Croatia - Croatian.

The aim of linguistic validation is to obtain translations that are:

- conceptually equivalent to the original and comparable across languages
- · culturally relevant to the context of the target country
- · easily understood by the people to whom the translated instrument is administered.

This is achieved using a rigorous ISO-17100 certified methodology involving:

- · a process which comprises several steps
- the instrument's developer input on conceptual issues
- a skilled team recruited by ICON Language Services in the target country and headed by a consultant with knowledge of and experience in the field of Clinical Outcome Assessments. The consultant supervises and coordinates the linguistic validation process in his/her country
- a centralized review process coordinated by ICON Language Services, including quality control by linguists and discussions about translation decisions with the consultant at each step of the process.
- cross-cultural harmonisation to ensure common understanding of the instrument's concepts by all participants involved in the process and achieve conceptual equivalence across languages.

The aforementioned translation (filename: Croatian (Croatia)\_EUonQoL Toolkit V2.0\_04APR2024, dated 4 April 2024) underwent the following steps:

- Forward Translation step 2 forward translations by qualified translators and reconciliation
- Backtranslation step 1 backtranslation by a qualified translator
- Cognitive Interview step:
  - 5 participants; population: Cancer; group: Adults; age range: 41-70
- Proofreading step

ICON Language Services

ICON Language Services may not be held liable for any changes made on the translation after completion of project 6353-TR-0001 by ICON Language Services on 4 April 2024.

Cédric Montigny
Cédric Montigny
Cédric Montigny
Cédric Montigny
Codric Montigny
O4 Apr 2024 08:09:08 UTC (Z)
Project Mgr, PCS
REASON: I approve this document

BLIonQpL v2.0\_Croatia/Croatian - Version of 04 Apr 2024 - ICON. ID6953-TR-0001 / Croatian (Croatia)\_BUonQpL Toolkit v2.0\_044PR2024.CoT

DocUUID : d9447057-01th-4405-009b-01tb55773a7b0

EUonQoL Page 15 of 74

<sup>1&</sup>lt;sub>Reference</sub>

Acquadro C., Jambon B., Ellis D. and Marquis P. Language and translation issues. In Spilker B, ed. Quality of Life and Pharmacoeconomics in Clinical Trials. Philadelphia: Lippincott-Raven Publishers, 1996: 575-585. - Linguistic Validation Manual for Health Outcomes Assessments. Acquadro C, Conway K, Giroudet C, Mear I. Second Edition - Mapi Institute, Lyon, France, January 2012 -ISBN: 2-9522021-0-9





### 2.5.4. Czech Linguistic Validation Certificate





#### LINGUISTIC VALIDATION CERTIFICATE

EUonQoL v2.0 (EUonQoL v2.0)

This is to certify that ICON Language Services conducted the linguistic validation of the Electronic version of the EUonQoL v2.0 (source file name: English (UK)\_EUonQoL Toolkit V2.0) into Czech Republic - Czech.

The aim of linguistic validation is to obtain translations that are:

- conceptually equivalent to the original and comparable across languages
- · culturally relevant to the context of the target country
- · easily understood by the people to whom the translated instrument is administered.

This is achieved using a rigorous ISO-17100 certified methodology<sup>1</sup> involving:

- · a process which comprises several steps
- the instrument's developer input on conceptual issues
- a skilled team recruited by ICON Language Services in the target country and headed by a consultant with knowledge of and experience in the field of Clinical Outcome Assessments. The consultant supervises and coordinates the linguistic validation process in his/her country
- a centralized review process coordinated by ICON Language Services, including quality control by linguists and discussions about translation decisions with the consultant at each step of the process.
- cross-cultural harmonisation to ensure common understanding of the instrument's concepts by all participants involved in the process and achieve conceptual equivalence across languages.

The aforementioned translation (filename: Czech (Czech Republic)\_EUonQoL Toolkit V2.0\_05APR2024, dated 5 April 2024) underwent the following steps:

- Forward Translation step 2 forward translations by qualified translators and reconciliation
- Backtranslation step 1 backtranslation by a qualified translator
- · Cognitive Interview step:
  - 5 participants; population: Cancer
- Proofreading step

ICON Language Services may not be held liable for any changes made on the translation after completion of project 6353-TR-0001 by ICON Language Services on 5 April 2024.

Alexia Dos Santos Campanha Project Manager

**ICON Language Services** 

Alexia Dos Santos Campanha
Alexia Dos Santos Campanha
OS Apr 2024 08:36:18 UTC (Z)

REASON: I approve this document 8x30xxc7 6756 4032 bc19 9c9c74319639

BJonQoL v2.0 - Czech Republic/Czech - Version of 05 Apr 2024 - ICON. ID6363-TR-0001 / Czech (Czech Republic)\_EUonQoL Toolkt V2.0\_06APR2034\_CoT

DocUUID: 146b126c-5602-4646-6c15-7201ad3fed7e

EUonQoL Page 16 of 74

<sup>\*</sup>References

<sup>-</sup> Acquadro C., Jambon B., Ellis D. and Marquis P. Language and translation issues. In Spilker B, ed. Quality of Life and Pharmacoeconomics in Clinical Trials. Philadelphia: Lippincott-Raven Publishers, 1996: 575-585. - Linguistic Validation Manual for Health Outcomes Assessments. Acquadro C, Conway K, Giroudet C, Mear I. Second Edition - Mapi Institute, Lyon, France, January 2012 - ISBN: 2-9522021-0-9





### 2.5.5. Danish Linguistic Validation Certificate





#### LINGUISTIC VALIDATION CERTIFICATE

EUonQoL v2.0 (EUonQoL v2.0)

This is to certify that ICON Language Services conducted the linguistic validation of the Electronic version of the EUonQoL v2.0 (source file name: English (UK)\_EUonQoL Toolkit V2.0) into Denmark - Danish.

The aim of linguistic validation is to obtain translations that are:

- conceptually equivalent to the original and comparable across languages
- · culturally relevant to the context of the target country
- · easily understood by the people to whom the translated instrument is administered.

This is achieved using a rigorous ISO-17100 certified methodology involving:

- · a process which comprises several steps
- the instrument's developer input on conceptual issues
- a skilled team recruited by ICON Language Services in the target country and headed by a consultant with knowledge of and experience in the field of Clinical Outcome Assessments. The consultant supervises and coordinates the linguistic validation process in his/her country
- a centralized review process coordinated by ICON Language Services, including quality control by linguists and discussions about translation decisions with the consultant at each step of the process.
- cross-cultural harmonisation to ensure common understanding of the instrument's concepts by all participants involved in the process and achieve conceptual equivalence across languages.

The aforementioned translation (filename: Danish (Denmark)\_EUonQoL Toolkit V2.0\_08APR2024, dated 8 April 2024) underwent the following steps:

- Forward Translation step 2 forward translations by qualified translators and reconciliation
- Backtranslation step 1 backtranslation by a qualified translator
- Cognitive Interview step:
  - 5 participants; population: Cancer; group: Adults; age range: 41-80
- Proofreading step

ICON Language Services may not be held liable for any changes made on the translation after completion of project 6353-TR-0001 by ICON Language Services on 8 April 2024.

Caroline Price

Caroline Price O8 Apr 2024 14:11:25 UTC (Z)

Associate project manager ICON Language Services

REASON: I approve this document

EUonQoL v2.0\_Denmark/Danish - Version of 08 Apr 2024 - ICON. ID6863-TR-0001/Danish (Danmark\_EUonQoL Todikt V20\_08APR20A.CoT

DocUUID: 72x0e4d-4001-49e6-ee7e-e540072ade73

EUonQoL Page 17 of 74

<sup>1</sup> References

Acquadro C., Jambon B., Ellis D. and Marquis P. Language and translation issues. In Spilker B, ed. Quality of Life and Pharmacoeconomics in Clinical Trials. Philadelphia: Lippincott-Raven Publishers, 1996: 575-585. - Linguistic Validation Manual for Health Outcomes Assessments. Acquadro C, Conway K, Giroudet C, Mear I. Second Edition - Mapi Institute, Lyon, France, January 2012 -ISBN: 2-9522021-0-9





### 2.5.6. Dutch Linguistic Validation Certificate





#### LINGUISTIC VALIDATION CERTIFICATE

EUonQoL v2.0 (EUonQoL v2.0)

This is to certify that ICON Language Services conducted the linguistic validation of the Electronic version of the EUonQoL v2.0 (source file name: English (UK)\_EUonQoL Toolkit V2.0) into Netherlands - Dutch.

The aim of linguistic validation is to obtain translations that are:

- conceptually equivalent to the original and comparable across languages
- · culturally relevant to the context of the target country
- · easily understood by the people to whom the translated instrument is administered.

This is achieved using a rigorous ISO-17100 certified methodology involving:

- · a process which comprises several steps
- the instrument's developer input on conceptual issues
- a skilled team recruited by ICON Language Services in the target country and headed by a consultant with knowledge of and experience in the field of Clinical Outcome Assessments. The consultant supervises and coordinates the linguistic validation process in his/her country
- a centralized review process coordinated by ICON Language Services, including quality control by linguists and discussions about translation decisions with the consultant at each step of the process.
- cross-cultural harmonisation to ensure common understanding of the instrument's concepts by all participants involved in the process and achieve conceptual equivalence across languages.

The aforementioned translation (filename: Dutch (Netherlands)\_EUonQoL Toolkit V2.0\_09APR2024, dated 9 April 2024) underwent the following steps:

- Forward Translation step 2 forward translations by qualified translators and reconciliation
- Backtranslation step 1 backtranslation by a qualified translator
- Cognitive Interview step:
  - 5 participants; population: Cancer; group: Adults
- Proofreading step

ICON Language Services may not be held liable for any changes made on the translation after completion of project 6353-TR-0001 by ICON Language Services on 9 April 2024.

Agnes Kiss Project Manager ICON Language Services agnes Liss OP Apr 2024 21:29:17 UTC (Z)

REASON: I approve this document 2051593a 3429 4c2a b6ac ed9c252188c5

BJonQoL v2.0\_Netherlands/Dutch - Version of 09 Apr 2024 - ICON. ID6953-TR-0001 / Dutch (Natherlands)\_BJonQoL Toolkt v2.0\_09APR2024.CoT

DocUUID : a6bc59df-3e4a-40ac-6055-3c4aa577339a2

EUonQoL Page 18 of 74

<sup>\*</sup>References

Acquadro C., Jambon B., Ellis D. and Marquis P. Language and translation issues. In Spilker B, ed. Quality of Life and Pharmacoeconomics in Clinical Trials. Philadelphia: Lippincott-Raven Publishers, 1996: 575-585. - Linguistic Validation Manual for Health Outcomes Assessments. Acquadro C, Conway K, Giroudet C, Mear I. Second Edition - Mapi Institute, Lyon, France, January 2012 -ISBN: 2-9522021-0-9





### 2.5.7. Estonian Linguistic Validation Certificate





#### LINGUISTIC VALIDATION CERTIFICATE

EUonQoL v2.0 (EUonQoL v2.0)

This is to certify that ICON Language Services conducted the linguistic validation of the Electronic version of the EUonQoL v2.0 (source file name: English (UK)\_EUonQoL Toolkit V2.0) into Estonia - Estonian.

The aim of linguistic validation is to obtain translations that are:

- · conceptually equivalent to the original and comparable across languages
- culturally relevant to the context of the target country
- · easily understood by the people to whom the translated instrument is administered.

This is achieved using a rigorous ISO-17100 certified methodology involving:

- · a process which comprises several steps
- · the instrument's developer input on conceptual issues
- a skilled team recruited by ICON Language Services in the target country and headed by a consultant with knowledge of and experience in the field of Clinical Outcome Assessments. The consultant supervises and coordinates the linguistic validation process in his/her country
- a centralized review process coordinated by ICON Language Services, including quality control by linguists and discussions about translation decisions with the consultant at each step of the process.
- · cross-cultural harmonisation to ensure common understanding of the instrument's concepts by all participants involved in the process and achieve conceptual equivalence across languages.

The aforementioned translation (filename : Estonian (Estonia)\_EUonQoL Toolkit V2.0\_09APR2024, dated 9 April 2024) underwent the following steps:

- · Forward Translation step 2 forward translations by qualified translators and reconciliation
- Backtranslation step 1 backtranslation by a qualified translator
- · Cognitive Interview step:
  - · 5 participants; population: Cancer; group: Adults
- Proofreading step

ICON Language Services may not be held liable for any changes made on the translation after completion of project 6353-TR-0001 by ICON Language Services on 9 April 2024.

Project Manager ICON Language Services

agnes Liss Agnes Kiss 09 Apr 2024 21:29:16 UTC(Z)

REASON: I approve this document

BJbnQbL v2.0\_Estonia/Estonian - Version of 09 Apr 2024 - IOON. ID6353-TR-0001 / Estonian (Estonia)\_EUonQoL ToolNt V2:0\_00APR2094.CoT

DocUUID : 6bb4dx3F7556-4e42-829-e36

**EUonQoL** Page 19 of 74

<sup>-</sup> Acquadro C., Jambon B., Ellis D. and Marquis P. Language and translation issues. In Spilker B, ed. Quality of Life and Pharmacoeconomics in Clinical Trials. Philadelphia: Lippincott-Raven Publishers, 1996: 575-585. - Linguistic Validation Manual for Health Outcomes Assessments. Acquadro C, Conway K, Giroudet C, Mear I. Second Edition - Mapi Institute, Lyon, France, January 2012 -ISBN: 2-9522021-0-9





### 2.5.8. Finnish Linguistic Validation Certificate





#### LINGUISTIC VALIDATION CERTIFICATE

EUonQoL v2.0 (EUonQoL v2.0)

This is to certify that ICON Language Services conducted the linguistic validation of the Electronic version of the EUonQoL v2.0 (source file name: English (UK)\_EUonQoL Toolkit V2.0) into Finland - Finnish.

The aim of linguistic validation is to obtain translations that are:

- conceptually equivalent to the original and comparable across languages
- · culturally relevant to the context of the target country
- · easily understood by the people to whom the translated instrument is administered.

This is achieved using a rigorous ISO-17100 certified methodology involving:

- · a process which comprises several steps
- the instrument's developer input on conceptual issues
- a skilled team recruited by ICON Language Services in the target country and headed by a consultant with knowledge of and experience in the field of Clinical Outcome Assessments. The consultant supervises and coordinates the linguistic validation process in his/her country
- a centralized review process coordinated by ICON Language Services, including quality control by linguists and discussions about translation decisions with the consultant at each step of the process.
- cross-cultural harmonisation to ensure common understanding of the instrument's concepts by all participants involved in the process and achieve conceptual equivalence across languages.

The aforementioned translation (filename: Finnish (Finland)\_EUonQoL Toolkit V2.0\_10APR2024, dated 10 April 2024) underwent the following steps:

- Forward Translation step 2 forward translations by qualified translators and reconciliation
- Backtranslation step 1 backtranslation by a qualified translator
- Cognitive Interview step:
  - 5 participants; population: Cancer; group: Adults
- Proofreading step

ICON Language Services may not be held liable for any changes made on the translation after completion of project 6353-TR-0001 by ICON Language Services on 10 April 2024. Becki Elismore

Becki Ellsmore Associate Project Manager ICON Language Services Becki Ellsmore 10 Apr 2024 14:16:23 UTC (Z)

REASON: I approve this document d79d211b 27.st 48ab 963c ac7acad28t7a

EUonQpL v2.0\_Finland/Finnish - Version of 10 Apr 2024 - ICON.

D6663-TR-0001/Finland/Finland\_EUonQpL Toolkit v2.0\_10AFR2024\_CoT

DeciUID : 3248c772-00s-4-4025-0005-414s6695s-d55

EUonQoL Page 20 of 74

<sup>\*</sup>References

Acquadro C., Jambon B., Ellis D. and Marquis P. Language and translation issues. In Spilker B, ed. Quality of Life and Pharmacoeconomics in Clinical Trials. Philadelphia: Lippincott-Raven Publishers, 1996: 575-585. - Linguistic Validation Manual for Health Outcomes Assessments. Acquadro C, Conway K, Giroudet C, Mear I. Second Edition - Mapi Institute, Lyon, France, January 2012 -ISBN: 2-9522021-0-9





### 2.5.9. French Linguistic Validation Certificate





#### LINGUISTIC VALIDATION CERTIFICATE

EUonQoL v2.0 (EUonQoL v2.0)

This is to certify that ICON Language Services conducted the linguistic validation of the Electronic version of the EUonQoL v2.0 (source file name: English (UK)\_EUonQoL Toolkit V2.0) into France - French.

The aim of linguistic validation is to obtain translations that are:

- conceptually equivalent to the original and comparable across languages
- · culturally relevant to the context of the target country
- · easily understood by the people to whom the translated instrument is administered.

This is achieved using a rigorous ISO-17100 certified methodology involving:

- · a process which comprises several steps
- the instrument's developer input on conceptual issues
- a skilled team recruited by ICON Language Services in the target country and headed by a consultant with knowledge of and experience in the field of Clinical Outcome Assessments. The consultant supervises and coordinates the linguistic validation process in his/her country
- a centralized review process coordinated by ICON Language Services, including quality control by linguists and discussions about translation decisions with the consultant at each step of the process.
- cross-cultural harmonisation to ensure common understanding of the instrument's concepts by all participants involved in the process and achieve conceptual equivalence across languages.

The aforementioned translation (filename: French (France)\_EUonQoL Toolkit V2.0\_02APR2024, dated 2 April 2024) underwent the following steps:

- Forward Translation step 2 forward translations by qualified translators and reconciliation
- Backtranslation step 1 backtranslation by a qualified translator
- Cognitive Interview step:
  - 5 participants; population: Cancer; group: Adults; age range: 31-70
- Proofreading step

ICON Language Services may not be held liable for any changes made on the translation after completion of project 6353-TR-0001 by ICON Language Services on 2 April 2024.

Clemence Gallud Project Coordinator ICON Language Services

Clemence Gallud Clemence Gallud O2 Apr 2024 08:58:34 UTC (Z)

REASON: I approve this document

BJbnQoL v2.0\_France/French - Version of 02 Apr 2024 - IOON. ID6353TR-0001 / French (France)\_EUonQoL TooMI v2.0\_02APR2024.CoT

DucUUID : 25566006-5000-4096-5451-2c15e-6024c5

EUonQoL Page 21 of 74

<sup>1</sup> Reference:

Acquadro C., Jambon B., Ellis D. and Marquis P. Language and translation issues. In Spilker B, ed. Quality of Life and Pharmacoeconomics in Clinical Trials. Philadelphia: Lippincott-Raven Publishers, 1996: 575-585. - Linguistic Validation Manual for Health Outcomes Assessments. Acquadro C, Conway K, Giroudet C, Mear I. Second Edition - Mapi Institute, Lyon, France, January 2012 -ISBN: 2-9522021-0-9





### 2.5.10. Georgian Linguistic Validation Certificate





#### LINGUISTIC VALIDATION CERTIFICATE

EUonQoL v2.0 (EUonQoL v2.0)

This is to certify that ICON Language Services conducted the linguistic validation of the Electronic version of the EUonQoL v2.0 (source file name: English (UK)\_EUonQoL Toolkit V2.0) into Georgia - Georgian.

The aim of linguistic validation is to obtain translations that are:

- conceptually equivalent to the original and comparable across languages
- · culturally relevant to the context of the target country
- · easily understood by the people to whom the translated instrument is administered.

This is achieved using a rigorous ISO-17100 certified methodology<sup>1</sup> involving:

- · a process which comprises several steps
- the instrument's developer input on conceptual issues
- a skilled team recruited by ICON Language Services in the target country and headed by a consultant with knowledge of and experience in the field of Clinical Outcome Assessments. The consultant supervises and coordinates the linguistic validation process in his/her country
- a centralized review process coordinated by ICON Language Services, including quality control by linguists and discussions about translation decisions with the consultant at each step of the process.
- cross-cultural harmonisation to ensure common understanding of the instrument's concepts by all participants involved in the process and achieve conceptual equivalence across languages.

The aforementioned translation (filename: Georgia)\_EUonQoL Toolkit V2.0\_03APR2024, dated 3 April 2024) underwent the following steps:

- Forward Translation step 2 forward translations by qualified translators and reconciliation
- Backtranslation step 1 backtranslation by a qualified translator
- Cognitive Interview step:
  - 5 participants; population: Cancer; group: Adults; age range: 18-80+
- · Proofreading step

ICON Language Services may not be held liable for any changes made on the translation after completion of project 6353-TR-0001 by ICON Language Services on 3 April 2024.

Veronica Gonzalez De La Rosa Project Manager ICON Language Services Veronica Gonzalez de la Rosa Veronica Gonzalez de la ROSI 04 Apr 2024 15:13:14 UTC (Z)

REASON: I approve this document

BLIonQoL v2.0\_Georgia/Georgian - Version of 03 Apr 2024 - IDON. ID6955-TR-0001/Georgian/Georgia)\_EUonQoL TooMt v2.0\_09APR2024.CoT

DocUUID : 159a148o-5b114895-949e-ab60993a7043d

EUonQoL Page 22 of 74

<sup>&</sup>lt;sup>⊥</sup> References

Acquadro C., Jambon B., Ellis D. and Marquis P. Language and translation issues. In Spilker B, ed. Quality of Life and Pharmacoeconomics in Clinical Trials. Philadelphia: Lippincott-Raven Publishers, 1996: 575-585. - Linguistic Validation Manual for Health Outcomes Assessments. Acquadro C, Conway K, Giroudet C, Mear I. Second Edition - Mapi Institute, Lyon, France, January 2012 -ISBN: 2-9522021-0-9





### 2.5.11. German Linguistic Validation Certificate





#### LINGUISTIC VALIDATION CERTIFICATE

EUonQoL v2.0 (EUonQoL v2.0)

This is to certify that ICON Language Services conducted the linguistic validation of the Electronic version of the EUonQoL v2.0 (source file name: English (UK)\_EUonQoL Toolkit V2.0) into Germany - German.

The aim of linguistic validation is to obtain translations that are:

- conceptually equivalent to the original and comparable across languages
- · culturally relevant to the context of the target country
- · easily understood by the people to whom the translated instrument is administered.

This is achieved using a rigorous ISO-17100 certified methodology involving:

- · a process which comprises several steps
- the instrument's developer input on conceptual issues
- a skilled team recruited by ICON Language Services in the target country and headed by a consultant with knowledge of and experience in the field of Clinical Outcome Assessments. The consultant supervises and coordinates the linguistic validation process in his/her country
- a centralized review process coordinated by ICON Language Services, including quality control by linguists and discussions about translation decisions with the consultant at each step of the process.
- cross-cultural harmonisation to ensure common understanding of the instrument's concepts by all participants involved in the process and achieve conceptual equivalence across languages.

The aforementioned translation (filename: German (Germany)\_EUonQoL Toolkit V2\_10APR2024, dated 10 April 2024) underwent the following steps:

- Forward Translation step 2 forward translations by qualified translators and reconciliation Backtranslation step
- -1 backtranslation by a qualified translator
- Cognitive Interview step:
  - 5 participants; population: 2 participants with breast cancer, 1 with ovarian cancer and 2 with lung cancer;
     group: Adults; age range: 18-80+
- Proofreading step

ICON Language Services may not be held liable for any changes made on the translation after completion of project 6353-TR-0001 by ICON Language Services on 10 April 2024.

Laurine Labbe Associate PM ICON Language Services

Laurine Labbe 10 Apr 2024 09:09:32 UTC (Z)

REASON: I approve this document 8512aa70 69ac 1at2 aaa9 cb8fb111629c

EUbnQpL v2.0\_Germany/German - Version of 10 Apr 2024 - IOON. ID885-TR-0001/German/Germany/\_EUonQpL.Tooktiv2\_104PR2094.CoT

DocUUID : a7f8bc94-811c-4527-918a-5cc7160dc22

EUonQoL Page 23 of 74

<sup>1</sup> Reference:

<sup>-</sup> Acquadro C., Jambon B., Ellis D. and Marquis P. Language and translation issues. In Spilker B, ed. Quality of Life and Pharmacoeconomics in Clinical Trials. Philadelphia: Lippincott-Raven Publishers, 1996: 575-585. - Linguistic Validation Manual for Health Outcomes Assessments. Acquadro C, Conway K, Giroudet C, Mear I. Second Edition - Mapi Institute, Lyon, France, January 2012 - ISBN: 2-9522021-0-9





### 2.5.12. Greek Linguistic Validation Certificate





#### LINGUISTIC VALIDATION CERTIFICATE

EUonQoL v2.0 (EUonQoL v2.0)

This is to certify that ICON Language Services conducted the linguistic validation of the Electronic version of the EUonQoL v2.0 (source file name: English (UK)\_EUonQoL Toolkit V2.0) into Greece - Greek.

The aim of linguistic validation is to obtain translations that are:

- conceptually equivalent to the original and comparable across languages
- · culturally relevant to the context of the target country
- · easily understood by the people to whom the translated instrument is administered.

This is achieved using a rigorous ISO-17100 certified methodology involving:

- · a process which comprises several steps
- the instrument's developer input on conceptual issues
- a skilled team recruited by ICON Language Services in the target country and headed by a consultant with knowledge of and experience in the field of Clinical Outcome Assessments. The consultant supervises and coordinates the linguistic validation process in his/her country
- a centralized review process coordinated by ICON Language Services, including quality control by linguists and discussions about translation decisions with the consultant at each step of the process.
- cross-cultural harmonisation to ensure common understanding of the instrument's concepts by all participants involved in the process and achieve conceptual equivalence across languages.

The aforementioned translation (filename: Greek (Greece)\_EUonQoL Toolkit V2.0\_09APR2024, dated 9 April 2024) underwent the following steps:

- Forward Translation step 2 forward translations by qualified translators and reconciliation
- Backtranslation step 1 backtranslation by a qualified translator
- Cognitive Interview step:
  - 5 participants; population: Cancer; group: Adults; age range: 18-80+
- Proofreading step

ICON Language Services may not be held liable for any changes made on the translation after completion of project 6353-TR-0001 by ICON Language Services on 9 April 2024.

Laurine Labbe Associate PM ICON Language Services Laurine Labbe Laurine Labbe 09 Apr 2024 14:37:40 UTC (Z)

REASON: I approve this document

1 References

- Acquadro C., Jambon B., Ellis D. and Marquis P. Language and translation issues. In Spilker B, ed. Quality of Life and Pharmacoeconomics in Clinical Trials. Philadelphia: Lippincott-Raven Publishers, 1996: 575-585. - Linguistic Validation Manual for Health Outcomes Assessments. Acquadro C, Conway K, Giroudet C, Mear I. Second Edition - Mapi Institute, Lyon, France, January 2012 - ISBN: 2-9522021-0-9

BJonQpL v2.0\_Greece/Greek - Version of 09 Apr 2024 - ICON. D6953-TR-0001/Greek(Greece)\_BJonQpl. Toolkt v2.0\_09APR2024.CoT

DocUUID : d4950c3f-ca17-4060-b133-65b00814832f

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### 2.5.13. Hungarian Linguistic Validation Certificate





#### LINGUISTIC VALIDATION CERTIFICATE

EUonQoL v2.0 (EUonQoL v2.0)

This is to certify that ICON Language Services conducted the linguistic validation of the Electronic version of the EUonQoL v2.0 (source file name: English (UK)\_EUonQoL Toolkit V2.0) into Hungary - Hungarian.

The aim of linguistic validation is to obtain translations that are:

- conceptually equivalent to the original and comparable across languages
- · culturally relevant to the context of the target country
- · easily understood by the people to whom the translated instrument is administered.

This is achieved using a rigorous ISO-17100 certified methodology involving:

- · a process which comprises several steps
- the instrument's developer input on conceptual issues
- a skilled team recruited by ICON Language Services in the target country and headed by a consultant with knowledge of and experience in the field of Clinical Outcome Assessments. The consultant supervises and coordinates the linguistic validation process in his/her country
- a centralized review process coordinated by ICON Language Services, including quality control by linguists and discussions about translation decisions with the consultant at each step of the process.
- cross-cultural harmonisation to ensure common understanding of the instrument's concepts by all participants involved in the process and achieve conceptual equivalence across languages.

The aforementioned translation (filename: Hungarian (Hungary)\_EUonQoL Toolkit V2.0\_09APR2024, dated 9 April 2024) underwent the following steps:

- Forward Translation step 2 forward translations by qualified translators and reconciliation
- Backtranslation step 1 backtranslation by a qualified translator
- Cognitive Interview step:
  - 5 participants; population: Cancer; group: Adults
- Proofreading step

ICON Language Services may not be held liable for any changes made on the translation after completion of project 6353-TR-0001 by ICON Language Services on 9 April 2024.

Becki Ellsmore Associate Project Manager ICON Language Services Becki Ellsmore O9 Apr 2024 16:04:34 UTC (Z)

REASON: I approve this document d79d211b 27df 18ab 963c ac7acad28f7a

BUonQoL v2.0\_Hungary/Hungarian - Version of 09 Apr 2024 - ICON. ID6863-TR-0001/Hungarian(Hungary)\_BUonQoL Toolkt V2.0\_09APR2024\_CoT

DocUUID : 1e75e80e-8e5d-665-saas-7a6d8b52bs11

EUonQoL Page 25 of 74

<sup>1</sup> References

Acquadro C., Jambon B., Ellis D. and Marquis P. Language and translation issues. In Spilker B, ed. Quality of Life and Pharmacoeconomics in Clinical Trials. Philadelphia: Lippincott-Raven Publishers, 1996: 575-585. - Linguistic Validation Manual for Health Outcomes Assessments. Acquadro C, Conway K, Giroudet C, Mear I. Second Edition - Mapi Institute, Lyon, France, January 2012 -ISBN: 2-9522021-0-9





### 2.5.14. Italian Linguistic Validation Certificate





#### LINGUISTIC VALIDATION CERTIFICATE

EUonQoL v2.0 (EUonQoL v2.0)

This is to certify that ICON Language Services conducted the linguistic validation of the Electronic version of the EUonQoL v2.0 (source file name: English (UK)\_EUonQoL Toolkit V2.0) into Italy - Italian.

The aim of linguistic validation is to obtain translations that are:

- conceptually equivalent to the original and comparable across languages
- culturally relevant to the context of the target country
- · easily understood by the people to whom the translated instrument is administered.

This is achieved using a rigorous ISO-17100 certified methodology involving:

- · a process which comprises several steps
- the instrument's developer input on conceptual issues
- a skilled team recruited by ICON Language Services in the target country and headed by a consultant with knowledge of and experience in the field of Clinical Outcome Assessments. The consultant supervises and coordinates the linguistic validation process in his/her country
- a centralized review process coordinated by ICON Language Services, including quality control by linguists and discussions about translation decisions with the consultant at each step of the process.
- cross-cultural harmonisation to ensure common understanding of the instrument's concepts by all participants involved in the process and achieve conceptual equivalence across languages.

The aforementioned translation (filename: Italian (Italy)\_EUonQoL Toolkit V2\_04APR2024, dated 4 April 2024) underwent the following steps:

- Forward Translation step 2 forward translations by qualified translators and reconciliation
- Backtranslation step 1 backtranslation by a qualified translator
- Cognitive Interview step:
  - 5 participants; population: Cancer; group: Adults; age range: 25-70
- Proofreading step

ICON Language Services may not be held liable for any changes made on the translation after completion of project 6353-TR-0001 by ICON Language Services on 4 April 2024.

Jade Mermet-Grossi Project Manager ICON Language Services Jade Mermet-Grossi
04 Apr 2024 13:08:49 UTC (Z)

REASON: I approve this document

cOcOaba6 bf55 4b99 abf0 985a26676582

BLIonQoL v2.0\_ltally/ltalian - Version of 04 Apr 2024 - IOON. ID6953-TR-0001 / Italian (Italy)\_BLIonQoL Toolkt v2\_044PR2004.CoT

DocUUID: 7d08d151-75ec-4e90-8c85-4179859e649

EUonQoL Page 26 of 74

<sup>1</sup> Reference:

<sup>-</sup> Acquadro C., Jambon B., Ellis D. and Marquis P. Language and translation issues. In Spilker B, ed. Quality of Life and Pharmacoeconomics in Clinical Trials. Philadelphia: Lippincott-Raven Publishers, 1996: 575-585. - Linguistic Validation Manual for Health Outcomes Assessments. Acquadro C, Conway K, Giroudet C, Mear I. Second Edition - Mapi Institute, Lyon, France, January 2012 - ISBN: 2-9522021-0-9





### 2.5.15. Latvian Linguistic Validation Certificate





#### LINGUISTIC VALIDATION CERTIFICATE

EUonQoL v2.0 (EUonQoL v2.0)

This is to certify that ICON Language Services conducted the linguistic validation of the Electronic version of the EUonQoL v2.0 (source file name: English (UK)\_EUonQoL Toolkit V2.0) into Latvia - Latvian.

The aim of linguistic validation is to obtain translations that are:

- conceptually equivalent to the original and comparable across languages
- · culturally relevant to the context of the target country
- easily understood by the people to whom the translated instrument is administered.

This is achieved using a rigorous ISO-17100 certified methodology<sup>1</sup> involving:

- a process which comprises several steps
- the instrument's developer input on conceptual issues
- a skilled team recruited by ICON Language Services in the target country and headed by a consultant with knowledge of
  and experience in the field of Clinical Outcome Assessments. The consultant supervises and coordinates the linguistic
  validation process in his/her country
- a centralized review process coordinated by ICON Language Services, including quality control by linguists and discussions
  about translation decisions with the consultant at each step of the process.
- cross-cultural harmonisation to ensure common understanding of the instrument's concepts by all participants involved in the process and achieve conceptual equivalence across languages.

The aforementioned translation (filename: Latvian (Latvia)\_EUonQoL Toolkit V2.0\_10APR2024, dated 10 April 2024) underwent the following steps:

- Forward Translation step 2 forward translations by qualified translators and reconciliation
- Backtranslation step 1 backtranslation by a qualified translator
- Cognitive Interview step:
  - 5 participants; population: Cancer; group: Adults
- Proofreading step

ICON Language Services may not be held liable for any changes made on the translation after completion of project 6353-TR-0001 by ICON Language Services on 10 April 2024.

Emilie Crespo De Place Project Manager, PCS ICON Language Services Emilie Crespo de Place 10 Apr 2024 09:34:48 UTC (Z)

REASON: I approve this document acb39de3-66a9-4573-8a2c-f1a5e5828df2

BJonQoL v2.0\_Latvia/Latvian - Version of 10 Apr 2024 - ICON. ID6353-TR-0001/Latvian (Latvia)\_BJonQoL Toolkit v2.0\_10APR2024.CoT

DocUUID : de5e679d-b04e-4fd6-ae89-0be261e6d83b

EUonQoL Page 27 of 74

<sup>1</sup> References

<sup>-</sup> Acquadro C., Jambon B., Ellis D. and Marquis P. Language and translation issues. In Spilker B, ed. Quality of Life and Pharmacoeconomics in Clinical Trials. Philadelphia: Lippincott-Raven Publishers, 1996: 575-585. - Linguistic Validation Manual for Health Outcomes Assessments. Acquadro C, Conway K, Giroudet C, Mear I. Second Edition - Mapi Institute, Lyon, France, January 2012 - ISBN: 2-9522021-0-9





### 2.5.16. Lithuanian Linguistic Validation Certificate





#### LINGUISTIC VALIDATION CERTIFICATE

EUonQoL v2.0 (EUonQoL v2.0)

This is to certify that ICON Language Services conducted the linguistic validation of the Electronic version of the EUonQoL v2.0 (source file name: English (UK)\_EUonQoL Toolkit V2.0) into Lithuania - Lithuanian.

The aim of linguistic validation is to obtain translations that are:

- conceptually equivalent to the original and comparable across languages
- · culturally relevant to the context of the target country
- · easily understood by the people to whom the translated instrument is administered.

This is achieved using a rigorous ISO-17100 certified methodology involving:

- · a process which comprises several steps
- the instrument's developer input on conceptual issues
- a skilled team recruited by ICON Language Services in the target country and headed by a consultant with knowledge of and experience in the field of Clinical Outcome Assessments. The consultant supervises and coordinates the linguistic validation process in his/her country
- a centralized review process coordinated by ICON Language Services, including quality control by linguists and discussions about translation decisions with the consultant at each step of the process.
- cross-cultural harmonisation to ensure common understanding of the instrument's concepts by all participants involved in the process and achieve conceptual equivalence across languages.

The aforementioned translation (filename: Lithuanian (Lithuania)\_EUonQoL Toolkit V2.0\_09APR2024, dated 9 April 2024) underwent the following steps:

- Forward Translation step 2 forward translations by qualified translators and reconciliation
- Backtranslation step 1 backtranslation by a qualified translator
- Cognitive Interview step:
  - 5 participants; population: Cancer; group: Adults
- Proofreading step

ICON Language Services may not be held liable for any changes made on the translation after completion of project 6353-TR-0001 by ICON Language Services on 9 April 2024.

Emilie Crespo De Place Project Manager, PCS ICON Language Services Emilie Crespo de Place
On Apr 2024 15:22:10 UTC (Z)

REASON: I approve this document asb39de3 6649 4573 842s 1145e5828482

BJonQoL v2.0\_Lithuania/Lithuanian - Version of 09 Apr 2024 - IOON. ID6963-TR-0001/Lithuanian (Lithuania)\_EUonQoL Toolkt v2.0\_094PR2024.CoT

DocUUID : 3934250-7459-4029-0409-19340050916

EUonQoL Page 28 of 74

<sup>1</sup> References

Acquadro C., Jambon B., Ellis D. and Marquis P. Language and translation issues. In Spilker B, ed. Quality of Life and Pharmacoeconomics in Clinical Trials. Philadelphia: Lippincott-Raven Publishers, 1996: 575-585. - Linguistic Validation Manual for Health Outcomes Assessments. Acquadro C, Conway K, Giroudet C, Mear I. Second Edition - Mapi Institute, Lyon, France, January 2012 -ISBN: 2-9522021-0-9





### 2.5.17. Maltese Linguistic Validation Certificate





#### LINGUISTIC VALIDATION CERTIFICATE

EUonQoL v2.0 (EUonQoL v2.0)

This is to certify that ICON Language Services conducted the linguistic validation of the Electronic version of the EUonQoL v2.0 (source file name: English (UK)\_EUonQoL Toolkit V2.0) into Malta - Maltese.

The aim of linguistic validation is to obtain translations that are:

- conceptually equivalent to the original and comparable across languages
- · culturally relevant to the context of the target country
- · easily understood by the people to whom the translated instrument is administered.

This is achieved using a rigorous ISO-17100 certified methodology involving:

- · a process which comprises several steps
- the instrument's developer input on conceptual issues
- a skilled team recruited by ICON Language Services in the target country and headed by a consultant with knowledge of and experience in the field of Clinical Outcome Assessments. The consultant supervises and coordinates the linguistic validation process in his/her country
- a centralized review process coordinated by ICON Language Services, including quality control by linguists and discussions about translation decisions with the consultant at each step of the process.
- cross-cultural harmonisation to ensure common understanding of the instrument's concepts by all participants involved in the process and achieve conceptual equivalence across languages.

The aforementioned translation (filename: Maltese (Malta)\_EUonQoL Toolkit V2.0\_10APR2024, dated 10 April 2024) underwent the following steps:

- Forward Translation step 2 forward translations by qualified translators and reconciliation
- Backtranslation step 1 backtranslation by a qualified translator
- Cognitive Interview step:
  - 5 participants; population: Cancer; group: Adults
- Proofreading step

ICON Language Services may not be held liable for any changes made on the translation after completion of project 6353-TR-0001 by ICON Language Services on 10 April 2024.

Adrien Bonnier Project Manager ICON Language Services Adrien Bonnier Adrien Bonnier
10 Apr 202408:58:21 UTC (Z)

REASON: I approve this document 78bibood 7c20 4995 ab86 3cda3b24326d

BJonQoL v2.0\_Malta/Maltese - Version of 10 Apr 2024 - ICON. ID6953-TR-0001 / Maltese (Malta)\_BJonQoL Tocikit v2.0\_10APR2024.CoT

DocUUID: 077ca38e-a893-4997-98e8-453d9414a9e4

EUonQoL Page 29 of 74

<sup>1</sup> References

Acquadro C., Jambon B., Ellis D. and Marquis P. Language and translation issues. In Spilker B, ed. Quality of Life and Pharmacoeconomics in Clinical Trials. Philadelphia: Lippincott-Raven Publishers, 1996: 575-585. - Linguistic Validation Manual for Health Outcomes Assessments. Acquadro C, Conway K, Giroudet C, Mear I. Second Edition - Mapi Institute, Lyon, France, January 2012 -ISBN: 2-9522021-0-9





### 2.5.18. Moldovan Linguistic Validation Certificate





#### LINGUISTIC VALIDATION CERTIFICATE

EUonQoL v2.0 (EUonQoL v2.0)

This is to certify that ICON Language Services conducted the linguistic validation of the Electronic version of the EUonQoL v2.0 (source file name: English (UK)\_EUonQoL Toolkit V2.0) into Moldova - Romanian.

The aim of linguistic validation is to obtain translations that are:

- conceptually equivalent to the original and comparable across languages
- · culturally relevant to the context of the target country
- · easily understood by the people to whom the translated instrument is administered.

This is achieved using a rigorous ISO-17100 certified methodology involving:

- · a process which comprises several steps
- the instrument's developer input on conceptual issues
- a skilled team recruited by ICON Language Services in the target country and headed by a consultant with knowledge of and experience in the field of Clinical Outcome Assessments. The consultant supervises and coordinates the linguistic validation process in his/her country
- a centralized review process coordinated by ICON Language Services, including quality control by linguists and discussions about translation decisions with the consultant at each step of the process.
- cross-cultural harmonisation to ensure common understanding of the instrument's concepts by all participants involved in the process and achieve conceptual equivalence across languages.

The aforementioned translation (filename: Romanian (Moldova)\_EUonQoL Toolkit V2.0\_05APR2024, dated 5 April 2024) underwent the following steps:

- Adaptation step based on the Romanian version for Romania in order to render the translation appropriate for the context of Moldova
- · Cognitive Interview step:
  - 5 participants; population: Cancer; group: Adults; age range: 18-80+
- Proofreading step

The mother version on which the linguistic validation work was based had previously undergone the following steps:

- Forward Translation
- Back Translation

ICON Language Services may not be held liable for any changes made on the translation after completion of project 6353-TR-0001 by ICON Language Services on 5 April 2024.

Veronica Gonzalez De La Rosa Project Manager ICON Language Services Veronica Gonzalez de la Rosa Veronica Gonzalez de la Roll (05 Apr 2024 07:55:38 UTC (Z)

REASON: I approve this document d9db16af 2af6 4382 9acd 6157219b6289

BJonQoL v2.0\_Moldova/Romanian - Version of 05 Apr 2024 - IOON. ID6953-TR-0001 / Romanian (Moldow)\_BJonQoL Toolkit v2.0\_05APR2024.CoT

DocUUID : 62e18556-866d-670-e2e8-elbecc22e76d

EUonQoL Page 30 of 74

References

Acquadro C., Jambon B., Ellis D. and Marquis P. Language and translation issues. In Spilker B, ed. Quality of Life and Pharmacoeconomics in Clinical Trials. Philadelphia: Lippincott-Raven Publishers, 1996: 575-585. - Linguistic Validation Manual for Health Outcomes Assessments. Acquadro C, Conway K, Giroudet C, Mear I. Second Edition - Mapi Institute, Lyon, France, January 2012 -ISBN: 2-9522021-0-9





### 2.5.19. Norwegian Linguistic Validation Certificate





#### LINGUISTIC VALIDATION CERTIFICATE

EUonQoL v2.0 (EUonQoL v2.0)

This is to certify that ICON Language Services conducted the linguistic validation of the Electronic version of the EUonQoL v2.0 (source file name: English (UK)\_EUonQoL Toolkit V2.0) into Norway - Norwegian.

The aim of linguistic validation is to obtain translations that are:

- conceptually equivalent to the original and comparable across languages
- · culturally relevant to the context of the target country
- · easily understood by the people to whom the translated instrument is administered.

This is achieved using a rigorous ISO-17100 certified methodology involving:

- · a process which comprises several steps
- the instrument's developer input on conceptual issues
- a skilled team recruited by ICON Language Services in the target country and headed by a consultant with knowledge of and experience in the field of Clinical Outcome Assessments. The consultant supervises and coordinates the linguistic validation process in his/her country
- a centralized review process coordinated by ICON Language Services, including quality control by linguists and discussions about translation decisions with the consultant at each step of the process.
- cross-cultural harmonisation to ensure common understanding of the instrument's concepts by all participants involved in the process and achieve conceptual equivalence across languages.

The aforementioned translation (filename: Norwegian (Norway)\_EUonQoL Toolkit V2.0\_04APR2024, dated 4 April 2024) underwent the following steps:

- Forward Translation step 2 forward translations by qualified translators and reconciliation
- Backtranslation step 1 backtranslation by a qualified translator
- Cognitive Interview step:
  - 5 participants; population: Cancer; group: Adults
- Proofreading step

ICON Language Services may not be held liable for any changes made on the translation after completion of project 6353-TR-0001 by ICON Language Services on 4 April 2024.

Adrien Bonnier Project Manager ICON Language Services Adrien Bonnier Adrien Bonnier
04 Apr 2024 10:51:08 UTC (Z)

REASON: I approve this document 78b/b06d 7c20 4995 ab86 3cda3b24326d

BJonQoL v2.0\_Norway/Norwegian - Version of 04 Apr 2024 - IOON. ID6363-TR-0001 / Norwegian (Norway)\_BJonQoL Toolkit v2.0\_044FR2024.CoT

DocUUID : 47/8797F-03F-9900-origa-5099Ho4s7852

EUonQoL Page 31 of 74

<sup>\*</sup>References

Acquadro C., Jambon B., Ellis D. and Marquis P. Language and translation issues. In Spilker B, ed. Quality of Life and Pharmacoeconomics in Clinical Trials. Philadelphia: Lippincott-Raven Publishers, 1996: 575-585. - Linguistic Validation Manual for Health Outcomes Assessments. Acquadro C, Conway K, Giroudet C, Mear I. Second Edition - Mapi Institute, Lyon, France, January 2012 -ISBN: 2-9522021-0-9





### 2.5.20. Polish Linguistic Validation Certificate





#### LINGUISTIC VALIDATION CERTIFICATE

EUonQoL v2.0 (EUonQoL v2.0)

This is to certify that ICON Language Services conducted the linguistic validation of the Electronic version of the EUonQoL v2.0 (source file name: English (UK)\_EUonQoL Toolkit V2.0) into Poland - Polish.

The aim of linguistic validation is to obtain translations that are:

- conceptually equivalent to the original and comparable across languages
- · culturally relevant to the context of the target country
- · easily understood by the people to whom the translated instrument is administered.

This is achieved using a rigorous ISO-17100 certified methodology involving:

- · a process which comprises several steps
- the instrument's developer input on conceptual issues
- a skilled team recruited by ICON Language Services in the target country and headed by a consultant with knowledge of and experience in the field of Clinical Outcome Assessments. The consultant supervises and coordinates the linguistic validation process in his/her country
- a centralized review process coordinated by ICON Language Services, including quality control by linguists and discussions about translation decisions with the consultant at each step of the process.
- cross-cultural harmonisation to ensure common understanding of the instrument's concepts by all participants involved in the process and achieve conceptual equivalence across languages.

The aforementioned translation (filename: Polish (Poland)\_EUonQoL Toolkit V2.0\_08APR2024, dated 8 April 2024) underwent the following steps:

- Forward Translation step 2 forward translations by qualified translators and reconciliation
- Backtranslation step 1 backtranslation by a qualified translator
- Cognitive Interview step:
  - 5 participants; population: Cancer; group: Adults; age range: 31-80
- Proofreading step

ICON Language Services may not be held liable for any changes made on the translation after completion of project 6353-TR-0001 by ICON Language Services on 8 April 2024.

Caroline Price

Associate project manager ICON Language Services Caroline Price O8 Apr 2024 14:12:16 UTC (Z)

REASON: I approve this document 28b32c82 c148 4c3a 990d cb17269ca43f

BUonQoL v2.0\_Poland/Polish - Version of 08 Apr 2024 - ICON. ID6963-TR-0001 / Polish (Poland)\_BUonQoL Toolkt v2.0\_08APR2024.CoT

DocUUID : b5188009-7705-49-0-6bs3-71s907676000

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<sup>1</sup> References

Acquadro C., Jambon B., Ellis D. and Marquis P. Language and translation issues. In Spilker B, ed. Quality of Life and Pharmacoeconomics in Clinical Trials. Philadelphia: Lippincott-Raven Publishers, 1996: 575-585. - Linguistic Validation Manual for Health Outcomes Assessments. Acquadro C, Conway K, Giroudet C, Mear I. Second Edition - Mapi Institute, Lyon, France, January 2012 -ISBN: 2-9522021-0-9





### 2.5.21. Portuguese Linguistic Validation Certificate





#### LINGUISTIC VALIDATION CERTIFICATE

EUonQoL v2.0 (EUonQoL v2.0)

This is to certify that ICON Language Services conducted the linguistic validation of the Electronic version of the EUonQoL v2.0 (source file name: English (UK)\_EUonQoL Toolkit V2.0) into Portugal - Portuguese.

The aim of linguistic validation is to obtain translations that are:

- conceptually equivalent to the original and comparable across languages
- · culturally relevant to the context of the target country
- · easily understood by the people to whom the translated instrument is administered.

This is achieved using a rigorous ISO-17100 certified methodology involving:

- · a process which comprises several steps
- the instrument's developer input on conceptual issues
- a skilled team recruited by ICON Language Services in the target country and headed by a consultant with knowledge of and experience in the field of Clinical Outcome Assessments. The consultant supervises and coordinates the linguistic validation process in his/her country
- a centralized review process coordinated by ICON Language Services, including quality control by linguists and discussions about translation decisions with the consultant at each step of the process.
- cross-cultural harmonisation to ensure common understanding of the instrument's concepts by all participants involved in the process and achieve conceptual equivalence across languages.

The aforementioned translation (filename: Portuguese (Portugal)\_EUonQoL Toolkit V2.0\_25MAR2024, dated 25 March 2024) underwent the following steps:

- Forward Translation step 2 forward translations by qualified translators and reconciliation
- Backtranslation step 1 backtranslation by a qualified translator
- Cognitive Interview step:
  - 5 participants; population: Cancer
- Proofreading step

ICON Language Services may not be held liable for any changes made on the translation after completion of project 6353-TR-0001 by ICON Language Services on 25 March 2024.

Alexia Dos Santos Campanha Project Manager ICON Language Services Alexia Dos Santos Campanha
Alexia Dos Santos Campanha
25 Mar 2024 14:17:53UTC (Z)

REASON: I approve this document 8a30ace7 6756 4032 bc19 9c9c74319639

BJonQoL v2.0 - Portugal/Portuguese - Version of 25 Mar 2024 - ICON. ID6363TR-0001/Portuguese (Portugal)\_BJonQoLTociktiv2.0\_25MAR2034\_CoT

DecUUID : a1675290-e2x8-499Fe1b2-3250abab1607

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References

<sup>-</sup> Acquadro C., Jambon B., Ellis D. and Marquis P. Language and translation issues. In Spilker B, ed. Quality of Life and Pharmacoeconomics in Clinical Trials. Philadelphia: Lippincott-Raven Publishers, 1996: 575-585. - Linguistic Validation Manual for Health Outcomes Assessments. Acquadro C, Conway K, Giroudet C, Mear I. Second Edition - Mapi Institute, Lyon, France, January 2012 - ISBN: 2-9522021-0-9





### 2.5.22. Romanian Linguistic Validation Certificate





#### LINGUISTIC VALIDATION CERTIFICATE

EUonQoL v2.0 (EUonQoL v2.0)

This is to certify that ICON Language Services conducted the linguistic validation of the Electronic version of the EUonQoL v2.0 (source file name: English (UK)\_EUonQoL Toolkit V2.0) into Romania - Romanian.

The aim of linguistic validation is to obtain translations that are:

- conceptually equivalent to the original and comparable across languages
- · culturally relevant to the context of the target country
- · easily understood by the people to whom the translated instrument is administered.

This is achieved using a rigorous ISO-17100 certified methodology involving:

- · a process which comprises several steps
- · the instrument's developer input on conceptual issues
- a skilled team recruited by ICON Language Services in the target country and headed by a consultant with knowledge of and experience in the field of Clinical Outcome Assessments. The consultant supervises and coordinates the linguistic validation process in his/her country
- a centralized review process coordinated by ICON Language Services, including quality control by linguists and discussions about translation decisions with the consultant at each step of the process.
- cross-cultural harmonisation to ensure common understanding of the instrument's concepts by all participants involved in the process and achieve conceptual equivalence across languages.

The aforementioned translation (filename: Romanian (Romania)\_EUonQoL Toolkit V2\_04APR2024, dated 4 April 2024) underwent the following steps:

- Forward Translation step 2 forward translations by qualified translators and reconciliation
- Backtranslation step 1 backtranslation by a qualified translator
- Cognitive Interview step:
  - 5 participants; population: Cancer; group: Adults; age range: 25-80
- · Proofreading step

ICON Language Services may not be held liable for any changes made on the translation after completion of project 6353-TR-0001 by ICON Language Services on 4 April 2024.

Jade Mermet-Grossi Project Manager ICON Language Services

Jack Mestret-Grossi Jack Mermet-Grossi 04 Apr 2024 13:08:50 UTC (Z)

REASON: Lapprove this document

<sup>1</sup> References

\_\_\_\_\_

BUonQoL v2.0\_Romania/Romanian - Version of 04 Apr 2024 - ICON. ID6993-TR-0001/Romania (Romania)\_BUorQoL TooMI v2\_044FR2094.CoT

DodUUID: 57dd5d51-1692-409e-8506-830d89ad8773

EUonQoL Page 34 of 74

<sup>-</sup> Acquadro C., Jambon B., Ellis D. and Marquis P. Language and translation issues. In Spilker B, ed. Quality of Life and Pharmacoeconomics in Clinical Trials. Philadelphia: Lippincott-Raven Publishers, 1996: 575-585. - Linguistic Validation Manual for Health Outcomes Assessments. Acquadro C, Conway K, Giroudet C, Mear I. Second Edition - Mapi Institute, Lyon, France, January 2012 - ISBN: 2-9522021-0-9





### 2.5.23. Serbian Linguistic Validation Certificate





#### LINGUISTIC VALIDATION CERTIFICATE

EUonQoL v2.0 (EUonQoL v2.0)

This is to certify that ICON Language Services conducted the linguistic validation of the Electronic version of the EUonQoL v2.0 (source file name: English (UK)\_EUonQoL Toolkit V2.0) into Serbia - Serbian - Latin.

The aim of linguistic validation is to obtain translations that are:

- conceptually equivalent to the original and comparable across languages
- · culturally relevant to the context of the target country
- · easily understood by the people to whom the translated instrument is administered.

This is achieved using a rigorous ISO-17100 certified methodology involving:

- · a process which comprises several steps
- the instrument's developer input on conceptual issues
- a skilled team recruited by ICON Language Services in the target country and headed by a consultant with knowledge of and experience in the field of Clinical Outcome Assessments. The consultant supervises and coordinates the linguistic validation process in his/her country
- a centralized review process coordinated by ICON Language Services, including quality control by linguists and discussions about translation decisions with the consultant at each step of the process.
- cross-cultural harmonisation to ensure common understanding of the instrument's concepts by all participants involved in the process and achieve conceptual equivalence across languages.

The aforementioned translation (filename: Serbian (Serbia)\_EUonQoL Toolkit V2.0\_09APR2024, dated 9 April 2024) underwent the following steps:

- Forward Translation step 2 forward translations by qualified translators and reconciliation
- Backtranslation step 1 backtranslation by a qualified translator
- Cognitive Interview step:
  - 5 participants; population: Cancer; group: Adults; age range: 41-80
- · Proofreading step

ICON Language Services may not be held liable for any changes made on the translation after completion of project 6353-TR-0001 by ICON Language Services on 9 April 2024.

Caroline Price

Caroline Price 09 Apr 2024 14:49:30 UTC (Z)

Associate project manager ICON Language Services

REASON: I approve this document

EUonQpL v2.0\_Serbia/Serbian - Latin - Version of 09 Apr 2024 - ICON. ID6993-TR-0001/Serbian (Serbia)\_EUxnQpl. TooRitv20\_09APR209A.CoT

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DocUUID : 73ce17b0-as71-4dt

**EUonQoL** 

<sup>&</sup>lt;sup>1</sup> References

Acquadro C., Jambon B., Ellis D. and Marquis P. Language and translation issues. In Spilker B, ed. Quality of Life and Pharmacoeconomics in Clinical Trials. Philadelphia: Lippincott-Raven Publishers, 1996: 575-585. - Linguistic Validation Manual for Health Outcomes Assessments. Acquadro C, Conway K, Giroudet C, Mear I. Second Edition - Mapi Institute, Lyon, France, January 2012 -ISBN: 2-9522021-0-9





### 2.5.24. Slovak Linguistic Validation Certificate





#### LINGUISTIC VALIDATION CERTIFICATE

EUonQoL v2.0 (EUonQoL v2.0)

This is to certify that ICON Language Services conducted the linguistic validation of the Electronic version of the EUonQoL v2.0 (source file name: English (UK)\_EUonQoL Toolkit V2.0) into Slovakia - Slovak.

The aim of linguistic validation is to obtain translations that are:

- · conceptually equivalent to the original and comparable across languages
- · culturally relevant to the context of the target country
- · easily understood by the people to whom the translated instrument is administered.

This is achieved using a rigorous ISO-17100 certified methodology involving:

- · a process which comprises several steps
- the instrument's developer input on conceptual issues
- a skilled team recruited by ICON Language Services in the target country and headed by a consultant with knowledge of and experience in the field of Clinical Outcome Assessments. The consultant supervises and coordinates the linguistic validation process in his/her country
- a centralized review process coordinated by ICON Language Services, including quality control by linguists and discussions about translation decisions with the consultant at each step of the process.
- cross-cultural harmonisation to ensure common understanding of the instrument's concepts by all participants involved in the process and achieve conceptual equivalence across languages.

The aforementioned translation (filename: Slovak (Slovakia)\_EUonQoL Toolkit V2.0\_09APR2024, dated 9 April 2024) underwent the following steps:

- Forward Translation step 2 forward translations by qualified translators and reconciliation
- Backtranslation step 1 backtranslation by a qualified translator
- Cognitive Interview step:
  - 5 participants; population: Cancer; group: Adults; age range: 25-60
- · Proofreading step

ICON Language Services may not be held liable for any changes made on the translation after completion of project 6353-TR-0001 by ICON Language Services on 9 April 2024.

Rocio Lorenzo Lopez Project Manager ICON Language Services ROUG LOYENZO LOYEZ 09 Apr 2024 10:49:48 UTC (Z)

REASON: I approve this document

BLIonQpL v2.0\_Slovekia/Slovek - Version of 09 Apr 2024 - ICON. ID6955-TR-0001/Slovek(Slovekia)\_EUonQpL. TooMI v2.0\_0MPR2004.CoT

DocUUID : 10e413e2-c9d3-436F6c05-2ded2e58cecd

EUonQoL Page 36 of 74

<sup>1</sup> References

Acquadro C., Jambon B., Ellis D. and Marquis P. Language and translation issues. In Spilker B, ed. Quality of Life and Pharmacoeconomics in Clinical Trials. Philadelphia: Lippincott-Raven Publishers, 1996: 575-585. - Linguistic Validation Manual for Health Outcomes Assessments. Acquadro C, Conway K, Giroudet C, Mear I. Second Edition - Mapi Institute, Lyon, France, January 2012 -ISBN: 2-9522021-0-9





#### 2.5.25. Slovenian Linguistic Validation Certificate





#### LINGUISTIC VALIDATION CERTIFICATE

EUonQoL v2.0 (EUonQoL v2.0)

This is to certify that ICON Language Services conducted the linguistic validation of the Electronic version of the EUonQoL v2.0 (source file name: English (UK)\_EUonQoL Toolkit V2.0) into Slovenia - Slovenian.

The aim of linguistic validation is to obtain translations that are:

- conceptually equivalent to the original and comparable across languages
- · culturally relevant to the context of the target country
- · easily understood by the people to whom the translated instrument is administered.

This is achieved using a rigorous ISO-17100 certified methodology<sup>1</sup> involving:

- · a process which comprises several steps
- the instrument's developer input on conceptual issues
- a skilled team recruited by ICON Language Services in the target country and headed by a consultant with knowledge of and experience in the field of Clinical Outcome Assessments. The consultant supervises and coordinates the linguistic validation process in his/her country
- a centralized review process coordinated by ICON Language Services, including quality control by linguists and discussions about translation decisions with the consultant at each step of the process.
- cross-cultural harmonisation to ensure common understanding of the instrument's concepts by all participants involved in the process and achieve conceptual equivalence across languages.

The aforementioned translation (filename: Slovenian (Slovenia)\_EUonQoL Toolkit V2.0\_08APR2024, dated 8 April 2024) underwent the following steps:

- Forward Translation step 2 forward translations by qualified translators and reconciliation
- Backtranslation step 1 backtranslation by a qualified translator
- Cognitive Interview step:
  - 5 participants; population: Cancer; group: Adults; age range: 31-70
- · Proofreading step

ICON Language Services may not be held liable for any changes made on the translation after completion of project 6353-TR-0001 by ICON Language Services on 8 April 2024.

Rocio Lorenzo Lopez Project Manager ICON Language Services ROUG LOYENZO LOYEZ 08 Apr 2024 08:05:02 UTC (Z)

REASON: I approve this document a36c0a82 6bc9 45c6 9553 8d90bad92a17

EUonCpL v2.0\_Slovenia/Slovenian - Version of 08 Apr 2024 - ICON. ID695-TR-0001/Slovenian(Slovenia)\_EUonCpL Toolkt v2.0\_084PR2034.CoT

DocUUID : of528466-c785-4325-a743-d6496ex3da75

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<sup>\*</sup> References

Acquadro C., Jambon B., Ellis D. and Marquis P. Language and translation issues. In Spilker B, ed. Quality of Life and Pharmacoeconomics in Clinical Trials. Philadelphia: Lippincott-Raven Publishers, 1996: 575-585. - Linguistic Validation Manual for Health Outcomes Assessments. Acquadro C, Conway K, Giroudet C, Mear I. Second Edition - Mapi Institute, Lyon, France, January 2012 -ISBN: 2-9522021-0-9





#### 2.5.26. Spanish Linguistic Validation Certificate





#### LINGUISTIC VALIDATION CERTIFICATE

EUonQoL v2.0 (EUonQoL v2.0)

This is to certify that ICON Language Services conducted the linguistic validation of the Electronic version of the EUonQoL v2.0 (source file name: English (UK)\_EUonQoL Toolkit V2.0) into Spain - Spanish (European).

The aim of linguistic validation is to obtain translations that are:

- conceptually equivalent to the original and comparable across languages
- · culturally relevant to the context of the target country
- · easily understood by the people to whom the translated instrument is administered.

This is achieved using a rigorous ISO-17100 certified methodology involving:

- · a process which comprises several steps
- the instrument's developer input on conceptual issues
- a skilled team recruited by ICON Language Services in the target country and headed by a consultant with knowledge of and experience in the field of Clinical Outcome Assessments. The consultant supervises and coordinates the linguistic validation process in his/her country
- a centralized review process coordinated by ICON Language Services, including quality control by linguists and discussions about translation decisions with the consultant at each step of the process.
- cross-cultural harmonisation to ensure common understanding of the instrument's concepts by all participants involved in the process and achieve conceptual equivalence across languages.

The aforementioned translation (filename: Spanish (Spain)\_EUonQoL Toolkit V2.0\_03APR2024, dated 3 April 2024) underwent the following steps:

- Forward Translation step 2 forward translations by qualified translators and reconciliation
- Backtranslation step 1 backtranslation by a qualified translator
- Cognitive Interview step:
  - 5 participants; population: Cancer; group: Adults; age range: 18-80+
- · Proofreading step

ICON Language Services may not be held liable for any changes made on the translation after completion of project 6353-TR-0001 by ICON Language Services on 3 April 2024.

Veronica Gonzalez de la Rosa

Veronica Gonzalez De La Rosa Project Manager ICON Language Services Veronica Gonzalez de la Rosa Veronica Gonzalez de la Rosa 04 Apr 2024 15:13:13 UTC (Z)

REASON: I approve this document

EUonQoL v2.0\_Spain/Spanish (European) - Version of 03 Apr 2024 - IOON. IDESS-TR-0001/Sparish (Spain)\_EUonQoL TodNKV20\_084PR2084CoT

DodUUID : 1c74cocb-31s9-4475a9b9-14909a6191

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<sup>&</sup>lt;sup>⊥</sup> References

Acquadro C., Jambon B., Ellis D. and Marquis P. Language and translation issues. In Spilker B, ed. Quality of Life and Pharmacoeconomics in Clinical Trials. Philadelphia: Lippincott-Raven Publishers, 1996: 575-585. - Linguistic Validation Manual for Health Outcomes Assessments. Acquadro C, Conway K, Giroudet C, Mear I. Second Edition - Mapi Institute, Lyon, France, January 2012 -ISBN: 2-9522021-0-9





#### 2.5.27. Swedish Linguistic Validation Certificate





#### LINGUISTIC VALIDATION CERTIFICATE

EUonQoL v2.0 (EUonQoL v2.0)

This is to certify that ICON Language Services conducted the linguistic validation of the Electronic version of the EUonQoL v2.0 (source file name: English (UK)\_EUonQoL Toolkit V2.0) into Sweden - Swedish.

The aim of linguistic validation is to obtain translations that are:

- conceptually equivalent to the original and comparable across languages
- · culturally relevant to the context of the target country
- · easily understood by the people to whom the translated instrument is administered.

This is achieved using a rigorous ISO-17100 certified methodology involving:

- · a process which comprises several steps
- the instrument's developer input on conceptual issues
- a skilled team recruited by ICON Language Services in the target country and headed by a consultant with knowledge of and experience in the field of Clinical Outcome Assessments. The consultant supervises and coordinates the linguistic validation process in his/her country
- a centralized review process coordinated by ICON Language Services, including quality control by linguists and discussions about translation decisions with the consultant at each step of the process.
- cross-cultural harmonisation to ensure common understanding of the instrument's concepts by all participants involved in the process and achieve conceptual equivalence across languages.

The aforementioned translation (filename: Swedish (Sweden)\_EUonQoL Toolkit V2.0\_05APR2024, dated 5 April 2024) underwent the following steps:

- Forward Translation step 2 forward translations by qualified translators and reconciliation
- Backtranslation step 1 backtranslation by a qualified translator
- Cognitive Interview step:
  - 5 participants; population: Cancer; group: Adults; age range: 18-80+
- Proofreading step

ICON Language Services may not be held liable for any changes made on the translation after completion of project 6353-TR-0001 by ICON Language Services on 5 April 2024.

Veronica Gonzalez De La Rosa Project Manager ICON Language Services Veronica Gonzalez de la Rosa Veronica Gonzalez de la Rosa Veronica Gonzalez de la Rosa OS Apr 2024 07:55:36 UTC (Z)

REASON: I approve this document

BJonQpL v2.0\_Sweden/Swedish - Version of 05 Apr 2024 - ICON. ID6953-TR-0001/Swedish (Swedish)\_BJonQpL Toolkt V2.0\_054PR2024.CoT

DocUUID : 9+0540x3-6bx6-4x75-x052-6x3x55x9x3xb

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<sup>\*</sup> References

Acquadro C., Jambon B., Ellis D. and Marquis P. Language and translation issues. In Spilker B, ed. Quality of Life and Pharmacoeconomics in Clinical Trials. Philadelphia: Lippincott-Raven Publishers, 1996: 575-585. - Linguistic Validation Manual for Health Outcomes Assessments. Acquadro C, Conway K, Giroudet C, Mear I. Second Edition - Mapi Institute, Lyon, France, January 2012 -ISBN: 2-9522021-0-9





#### 2.5.28. Turkish Linguistic Validation Certificate





#### LINGUISTIC VALIDATION CERTIFICATE

EUonQoL v2.0 (EUonQoL v2.0)

This is to certify that ICON Language Services conducted the linguistic validation of the Electronic version of the EUonQoL v2.0 (source file name: English (UK)\_EUonQoL Toolkit V2.0) into Turkey - Turkish.

The aim of linguistic validation is to obtain translations that are:

- conceptually equivalent to the original and comparable across languages
- · culturally relevant to the context of the target country
- · easily understood by the people to whom the translated instrument is administered.

This is achieved using a rigorous ISO-17100 certified methodology involving:

- · a process which comprises several steps
- the instrument's developer input on conceptual issues
- a skilled team recruited by ICON Language Services in the target country and headed by a consultant with knowledge of and experience in the field of Clinical Outcome Assessments. The consultant supervises and coordinates the linguistic validation process in his/her country
- a centralized review process coordinated by ICON Language Services, including quality control by linguists and discussions about translation decisions with the consultant at each step of the process.
- cross-cultural harmonisation to ensure common understanding of the instrument's concepts by all participants involved in the process and achieve conceptual equivalence across languages.

The aforementioned translation (filename: Turkish (Turkey)\_EUonQoL Toolkit V2\_09APR2024, dated 9 April 2024) underwent the following steps:

- Forward Translation step 2 forward translations by qualified translators and reconciliation
- Backtranslation step 1 backtranslation by a qualified translator
- Cognitive Interview step:
  - 5 participants; population: Cancer; group: Adults; age range: 18-80+
- Proofreading step

ICON Language Services may not be held liable for any changes made on the translation after completion of project 6353-TR-0001 by ICON Language Services on 9 April 2024.

Sébastien Le Dannois Project Manager ICON Language Services Sebastien Le Dannois Op Apr 2024 09:47:13 UTC (Z)

REASON: I approve this document c7d1c7bb fc89 4a4a 8589 1c4cd12dc169

BJonQoL v2.0\_Turkey/Turkish - Version of 09 Apr 2024 - ICON. ID6953-TR-0001/Turkish (Turkey)\_EllonQoLToolkt v2\_00APR2024.CoT

DocUUID : 93ac1a8b-ac43-4491-9886-a512aa3a7819

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<sup>1</sup> References

Acquadro C., Jambon B., Ellis D. and Marquis P. Language and translation issues. In Spilker B, ed. Quality of Life and Pharmacoeconomics in Clinical Trials. Philadelphia: Lippincott-Raven Publishers, 1996: 575-585. - Linguistic Validation Manual for Health Outcomes Assessments. Acquadro C, Conway K, Giroudet C, Mear I. Second Edition - Mapi Institute, Lyon, France, January 2012 -ISBN: 2-9522021-0-9





#### 2.5.29. Ukrainian Linguistic Validation Certificate





#### LINGUISTIC VALIDATION CERTIFICATE

EUonQoL v2.0 (EUonQoL v2.0)

This is to certify that ICON Language Services conducted the linguistic validation of the Electronic version of the EUonQoL v2.0 (source file name: English (UK)\_EUonQoL Toolkit V2.0) into Ukraine - Ukrainian.

The aim of linguistic validation is to obtain translations that are:

- conceptually equivalent to the original and comparable across languages
- · culturally relevant to the context of the target country
- · easily understood by the people to whom the translated instrument is administered.

This is achieved using a rigorous ISO-17100 certified methodology<sup>1</sup> involving:

- · a process which comprises several steps
- the instrument's developer input on conceptual issues
- a skilled team recruited by ICON Language Services in the target country and headed by a consultant with knowledge of and experience in the field of Clinical Outcome Assessments. The consultant supervises and coordinates the linguistic validation process in his/her country
- a centralized review process coordinated by ICON Language Services, including quality control by linguists and discussions about translation decisions with the consultant at each step of the process.
- cross-cultural harmonisation to ensure common understanding of the instrument's concepts by all participants involved in the process and achieve conceptual equivalence across languages.

The aforementioned translation (filename: Ukrainain (Ukraine)\_EUonQoL Toolkit V2.0\_09APR2024, dated 9 April 2024) underwent the following steps:

- Forward Translation step 2 forward translations by qualified translators and reconciliation
- Backtranslation step 1 backtranslation by a qualified translator
- Cognitive Interview step:
  - 5 participants; population: Cancer; group: Adults; age range: 41-70
- Proofreading step

ICON Language Services may not be held liable for any changes made on the translation after completion of project 6353-TR-0001 by ICON Language Services on 9 April 2024.

Clemence Gallud Project Coordinator ICON Language Services

Clemence Gallud Clemence Gallud
09 Apr 2024 12:25:55 UTC (Z)

REASON: I approve this document

c5240128 96f0 4319 bc5c 89c92cb8c284

BUonQoL v2.0\_Ukraine/Ukrainian - Version of 09 Apr 2024 - IOON. ID6953-TR-0001/Ukrainian (Ukrainia)\_BUonQoL Toolkit v2.0\_09APR2024.CoT

DocUUID : 654s713e-e95e-4770-804b-be19464so469

EUonQoL Page 41 of 74

<sup>1</sup> Reference:

Acquadro C., Jambon B., Ellis D. and Marquis P. Language and translation issues. In Spilker B, ed. Quality of Life and Pharmacoeconomics in Clinical Trials. Philadelphia: Lippincott-Raven Publishers, 1996: 575-585. - Linguistic Validation Manual for Health Outcomes Assessments. Acquadro C, Conway K, Giroudet C, Mear I. Second Edition - Mapi Institute, Lyon, France, January 2012 -ISBN: 2-9522021-0-9





#### 3. Conclusions

Based on the aspects outlined in the provided document, the following conclusions can be drawn. Successful Completion of Translation and Cultural Adaptation (TCA) Process; the TCA of the EUonQoL-Kit has been accomplished for all the items incuded in the kit, adhering to ISPOR guidelines and the Principles of Good Practice (PGP) developed by the TCA Group. The IEO team played a significant role in ensuring the high quality and consistency of the translated questionnaires. Indeed, the translation process followed a meticulous eight-step procedure, including forward translation, reconciliation, backward translation, harmonization, cognitive debriefing, review, proofreading, and the generation of an overall final report.

Noteworthy the use of extensive **item library** containing validated translations from the EORTC-QOL Group facilitated the translation process and minimized duplication efforts, specifically during the **conceptualization** phase. Certain items underwent modification during the TCA process to enhance clarity and cultural relevance. Feedback from **cognitive debriefing** sessions informed adjustments to ensure understandability and appropriateness across different target languages and cultural contexts. The entire translation process involved continuous review and refinement, with feedback from Cognitive Debriefing sessions; this iterative approach aimed to enhance the accuracy in the translations' process. During this phase, challenges such as overlapping translations and conceptual nuances culturally determined, were addressed through collaborative decision-making processes involving translation agencies, the IEO team, and the EORTC Group. Resolution strategies included reassessment of translations, conceptualization refinement, and adaptation for clarity and cultural appropriateness.

In conclusion, the TCA process for the EUonQoL-Kit showed a systematic and collaborative approach to ensure the linguistic validity, cultural relevance, and overall quality of translated questionnaires, facilitating the successful implementation of multicentered surveys and promoting cross-cultural comparability in outcomes research.

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# 4. Appendix/Table

# **4.1. Preliminary translations**

#### 4.1.1. English-Dutch

Items - English	Dutch
We are interested in some things about	Wij zijn geïnteresseerd in bepaalde dingen
you and your health. Please answer all of	over u en uw gezondheid. Wilt u alle vragen
the questions yourself by SELECTING the	beantwoorden door het getal te selecteren
number that best applies to you. There are	dat het meest op u van toepassing is? Er
no "right" or "wrong" answers.	zijn geen "juiste" of "onjuiste" antwoorden
Do you have any trouble doing strenuous	Heeft u moeite met het doen van inspannende
activities, like carrying a heavy shopping bag	activiteiten zoals het dragen van een zware
or a suitcase?	boodschappentas of een koffer?
	Heeft u moeite met het maken van een lange
Do you have any trouble taking a long walk?	wandeling?
Do you need help caring for your feet (e.g. cutting your toenails)?	Heeft u hulp nodig bij de verzorging van uw voeten (bv. uw teennagels knippen)?
Do you have any trouble carrying a heavy bag upstairs?	Heeft u moeite om een zware tas de trap op te dragen?
Do you have any trouble taking a long walk	Heeft u moeite om een lange wandeling te
carrying a heavy pack on your back (e.g. a filled rucksack)?	maken met een zware tas op uw rug (bv. een volle rugzak)?
Do you have any trouble taking a short walk outside of the house?	Heeft u moeite met het maken van een korte wandeling buitenshuis?
Do you need help undressing?	Heeft u hulp nodig bij het uitkleden?
Do you have any trouble walking for 30 min.?	Heeft u moeite om 30 minuten te wandelen?
During the past week:	Gedurende de afgelopen week:
Have you been limited in doing light housework (e.g. dusting or making the bed)?	Was u beperkt in het uitvoeren van lichte huishoudelijke taken (bv. stof afnemen of het bed opmaken)?
Have you been limited in doing physically	Was u beperkt in het uitoefenen van lichamelijk
demanding recreational activities (e.g.,	zware recreatieve activiteiten (bv. zwemmen of
swimming or cycling)?	fietsen)?
Were you limited in doing either your work or	Was u beperkt bij het doen van uw werk of
other daily activities?	andere dagelijkse bezigheden?
Have you been limited in doing heavy	Was u beperkt in het uitvoeren van zware
housework (e.g., washing floors or	huishoudelijke taken (bv. de vloer schrobben of
vacuuming)?	stofzuigen)?

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Were you limited in pursuing your hobbies or	Was u beperkt bij het uitoefenen van uw hobby's of bij andere bezigheden die u in uw
other leisure time activities?	vrije tijd doet?
Did pain interfere with your daily activities?	Heeft pijn u gehinderd bij uw dagelijkse bezigheden?
Have you had pain?	Heeft u pijn gehad?
Has pain interfered with your social activities?	Heeft pijn uw sociale activiteiten in de weg gestaan?
Has pain made it difficult for you to do the jobs that you usually do around the house?	Heeft pijn het u moeilijk gemaakt om uw gebruikelijke taken in en rond het huis uit te voeren?
Have you had severe pain?	Heeft u hevige pijn gehad?
Were you tired?	Bent u moe geweest?
Have you felt weak?	Heeft u zich slap gevoeld?
Have you felt exhausted?	Heeft u zich uitgeput gevoeld?
Have you become easily tired?	Werd u gemakkelijk moe?
Have you lacked energy?	Had u een gebrek aan energie?
Have you required frequent or long periods of rest?	Heeft u regelmatige of langere periodes van rust nodig gehad?
Have you had a feeling of overwhelming and prolonged lack of energy?	Heeft u het gevoel gehad dat u een overweldigend en langdurig gebrek aan energie had?
Have you had trouble sleeping?	Heeft u moeite met slapen gehad?
Have you had trouble getting a good night's sleep?	Heeft u moeite gehad om een goede nachtrust te hebben?
Have you had trouble staying asleep?	Heeft u moeite gehad om door te slapen?
Have you woken up for long periods during the night?	Bent u 's nachts langere periodes wakker gebleven?
Have you forced yourself to eat?	Heeft u zichzelf gedwongen om te eten?
Have you lacked appetite?	Heeft u gebrek aan eetlust gehad?
Have you lacked interest in eating?	Heeft u een gebrek aan belangstelling om te eten gehad?
Have you felt nauseated?	Heeft u zich misselijk gevoeld?
Have you vomited?	Heeft u overgegeven?
Has nausea or vomiting been a problem for you?	Is misselijkheid of overgeven een probleem voor u geweest?
Has nausea or vomiting interfered with your physical activities like taking a walk?	Heeft misselijkheid of overgeven uw lichamelijke activiteiten belemmerd, zoals een wandeling maken?
Have you been constipated?	Had u last van obstipatie (was u verstopt)?

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1	
Have you had stools that were too hard to	Heeft u ontlasting gehad die te hard was om
pass?	uw behoefte te doen?
Have your stools been so hard that they were	Heeft u ontlasting gehad die zo hard was dat
painful to pass?	naar de WC gaan pijnlijk was?
Were you short of breath?	Bent u kortademig geweest?
Did you have severe shortness of breath?	Bent u erg buiten adem geweest?
Were you short of breath when walking more than 100 m (100 yds)?	Was u buiten adem wanneer u meer dan 100 meter liep?
Were you short of breath when walking less than 100 m (100 yds)?	Was u buiten adem wanneer u minder dan 100 meter liep?
Did you feel tense?	Heeft u zich gespannen gevoeld?
Have you felt vulnerable?	Heeft u zich kwetsbaar gevoeld?
Have you felt that nothing could cheer you	Heeft u het gevoel gehad dat niets u kon
up?	opvrolijken?
Have you felt miserable?	Heeft u zich ellendig gevoeld?
Did you feel depressed?	Heeft u zich neerslachtig gevoeld?
Did you worry?	Maakte u zich zorgen?
Have you felt sad?	Heeft u zich verdrietig gevoeld?
Have you been watching yourself closely for	Heeft u zich nauwkeurig gecontroleerd op het
any new symptoms?	voorkomen van nieuwe symptomen?
To what extent have you been troubled with	In hoeverre heeft u last gehad van bijwerkingen
side-effects from your treatment?	van uw behandeling?
Have you worried about recurrence of your	Heeft u zich zorgen gemaakt over het
disease?	eventueel terugkeren van de ziekte?
Have you been afraid of tumor progression?	Bent u bang geweest voor progressie van uw tumor?
Have you worried about your health in the	Heeft u zich zorgen gemaakt over uw
future?	gezondheid in de toekomst?
How much has your disease been a burden	In welke mate is uw ziekte een belasting voor u
to you?	geweest?
Because of your experience with cancer,	
have you had to limit your life plans or	Heeft u uw levensplannen of levensdoelen
goals?	moeten inperken?
I have felt at peace with myself	Voelde ik me innerlijk rustig
Have very bod difficulty managed animal thin and	Heeft u moeite gehad met het zich herinneren
Have you had difficulty remembering things?	van dingen?
Have you had difficulty in concentrating on	Heeft u moeite gehad met het concentreren op dingen, zoals een krant lezen of televisie
things, like reading a newspaper or watching television?	kijken?
Have you been forgetful?	Bent u vergeetachtig geweest?
Have you had difficulty remembering what	Heeft u moeite gehad om u te herinneren wat
someone just told you?	iemand u net vertelde?

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Have you had difficulty maintaining	
concentration even when doing something	Heeft u moeite gehad om geconcentreerd te
important?	blijven zelfs terwijl u iets belangrijks deed?
As a result of your physical condition or	Heeft u als gevolg van uw lichamelijke toestand
medical treatment, have you preferred to	of medische behandeling de voorkeur gehad
spend time alone?	om tijd alleen door te brengen?
As a result of your physical condition or	Bent u als gevolg van uw lichamelijke toestand
medical treatment have you been less able to	of medische behandeling minder in staat
see your family or friends?	geweest om uw familie of vrienden te zien?
As a result of your physical condition or	Heeft u als gevolg van uw lichamelijke toestand
medical treatment, have you spent less time	of medische behandeling minder tijd met uw
with your family or friends?	familie of vrienden doorgebracht?
As a result of your physical condition or	Heeft u zich als gevolg van uw lichamelijke
medical treatment, have you felt isolated from	toestand of medische behandeling afgezonderd
your family or friends?	gevoeld van uw familie en vrienden?
As a result of your physical condition or	Heeft u als gevolg van uw lichamelijke toestand
medical treatment, have you found it hard to	of medische behandeling het moeilijk gevonden
make contact with people?	om contact te maken met mensen?
make contact with people:	Heeft uw lichamelijke toestand of medische
Has your physical condition or medical	behandeling uw familieleven in de weg
treatment interfered with your family life?	gestaan?
Has your physical condition or medical	Heeft uw lichamelijke toestand of medische
treatment interfered with your social	behandeling u belemmerd bij uw sociale
activities?	bezigheden?
Has your physical condition or medical	Heeft uw lichamelijke toestand of medische
treatment interfered with your relationships	behandeling uw relaties met familie of vrienden
with your family or friends?	belemmerd?
Have you been dissatisfied with your physical	Bent u ontevreden geweest over hoe uw
appearance?	lichaam eruitziet?
Has the disease or treatment affected your	Heeft de ziekte of behandeling invloed gehad
sex life (for the worse)?	op uw seksleven?
Have you worried about your ability to have	Heeft u zich zorgen gemaakt over uw
children?	mogelijkheid om kinderen te krijgen?
Have you worried that you are a burden to	Heeft u zich zorgen gemaakt dat u anderen tot
other people	last zult zijn?
	,
Have you worried about becoming dependent on others?	Heeft u zich zorgen gemaakt afhankelijk te worden van anderen door uw ziekte?
on others?	
Has your physical condition or modical	Heeft uw lichamelijke toestand of medische
Has your physical condition or medical	behandeling financiële moeilijkheden met zich
treatment caused you financial difficulties?	meegebracht?
Has your physical condition or modical	Heeft uw lichamelijke toestand of medische
Has your physical condition or medical	behandeling financiële moeilijkheden veroorzaakt, waardoor u uw levensstijl moest
treatment caused you financial difficulties	rveroorzaaki waarooorii ilw levenssiii moest - L
leading to changes in your lifestyle?	aanpassen?

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As a regult of your physical condition or	Hooft u ala gavala van usu liahamaliika taastand
As a result of your physical condition or	Heeft u als gevolg van uw lichamelijke toestand
medical treatment, have you had less money	of medische behandeling minder geld gehad
to spend on yourself (e.g., for buying yourself	om iets voor uzelf te kopen (bijv. om iets voor
something that you would like to have but	uzelf te kopen dat u graag wilt hebben maar
don't necessarily need)?	niet echt nodig heeft)?
As a result of your physical condition or	Heeft u als gevolg van uw lichamelijke toestand
medical treatment, have you had difficulties	of medische behandeling moeite gehad om uw
paying any of your regular expenses (e.g.	vaste lasten te betalen (bijv. huur, verzekering,
rent, insurance, phone)?	telefoonrekening)?
Since the diagnosis and treatment of your	Sinds de diagnose en behandeling van uw
cancer: Have you had problems with	kanker: Heeft u problemen gehad met het
obtaining insurance, loans, and/or	verkrijgen van verzekeringen, leningen en/of
a mortgage?	een hypotheek?
	Sinds de diagnose en behandeling van uw
Since the diagnosis and treatment of your	kanker: Heeft u ondersteuning gekregen van
cancer: Have you received support from your	uw werkgever, b.v. het regelen van flexibel
employer e.g. arranging flexible working?	werken?
	Sinds de diagnose en behandeling van uw
Since the diagnosis and treatment of your	kanker: Heeft u uw levensstijl op een positieve
cancer: Have you made positive lifestyle	manier veranderd (bv. meer
changes (e.g., more exercise, healthy food,	lichaamsbeweging, gezond eten, minder
cutting down smoking)?	roken)?
For the following questions please circle	Wilt u voor de volgende vragen het getal
the number between 1 and 7 that	tussen 1 en 7 omcirkelen dat het meest op u
best applies to you.	van toepassing is?
How would you rate your overall quality of life	Hoe zou u uw algehele "kwaliteit van het leven"
during the past week?	gedurende de afgelopen week beoordelen?
How would you rate your overall health	Hoe zou u uw algehele gezondheid gedurende
during the past week?	de afgelopen week beoordelen
Have you had any other significant symptoms	Heeft u andere belangrijke symptomen of
or problems that have not been mentioned in	problemen gehad die niet in bovenstaande
the questions above?	
•	vragen zijn genoemd?
Yes. Please write down the most	
Yes. Please write down the most important ones (up to three), and rate to	Ja. Noteer de belangrijkste (maximaal drie)
Yes. Please write down the most important ones (up to three), and rate to what extent you have experienced these	Ja. Noteer de belangrijkste (maximaal drie) en geef aan in welke mate u deze
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	Ja. Noteer de belangrijkste (maximaal drie) en geef aan in welke mate u deze symptomen of problemen gedurende de
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:	Ja. Noteer de belangrijkste (maximaal drie) en geef aan in welke mate u deze symptomen of problemen gedurende de afgelopen week heeft ervaren:
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	Ja. Noteer de belangrijkste (maximaal drie) en geef aan in welke mate u deze symptomen of problemen gedurende de afgelopen week heeft ervaren:  In welke mate heeft u gedurende de
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: <u>During the past week, to what extent have you experienced:</u>	Ja. Noteer de belangrijkste (maximaal drie) en geef aan in welke mate u deze symptomen of problemen gedurende de afgelopen week heeft ervaren:  In welke mate heeft u gedurende de afgelopen week het volgende ervaren:
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:	Ja. Noteer de belangrijkste (maximaal drie) en geef aan in welke mate u deze symptomen of problemen gedurende de afgelopen week heeft ervaren:  In welke mate heeft u gedurende de afgelopen week het volgende ervaren:  Symptoom/probleem A:
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: <u>During the past week, to what extent have you experienced:</u>	Ja. Noteer de belangrijkste (maximaal drie) en geef aan in welke mate u deze symptomen of problemen gedurende de afgelopen week heeft ervaren:  In welke mate heeft u gedurende de afgelopen week het volgende ervaren:

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We are interested in your MOST RECENT	Wij zijn geïnteresseerd in uw MEEST
experience of the care you have received	RECENTE ervaring met de zorg die u heeft
and the communication you have had with	ontvangen en de communicatie die u heeft
the professional(s) who treat you.	gehad met uw zorgverlener(s).
Have you been satisfied with your	Bent u tevreden over de communicatie met uw
communication with your professional(s)?	zorgverlener(s)?
Have your professional(s) spent enough time	Nam(en) uw zorgverlener(s) voldoende tijd om
talking with you?	met u te praten?
Have your professional(s) used language that	Gebruikte(n) uw zorgverlener(s) begrijpelijke
you understand (avoided medical jargon,	taal (medische termen vermeden, duidelijke
used clear terms)?	bewoordingen gebruikt)?
Have your professional(s) taken into account	Hield(en) uw zorgverlener(s) er rekening mee
how you prefer to receive information?	hoe u de informatie wilde ontvangen?
Have you felt that you and your	Had u het gevoel dat u en uw zorgverlener(s)
professional(s) had a shared understanding	dezelfde opvatting hadden over uw aandoening
of your disease and treatment?	en behandeling?
My decisions about care and treatment have	Mijn beslissingen over zorg en behandeling zijn
been respected by my professional(s)	gerespecteerd door mijn zorgverlener(s)
	lk heb de mogelijkheid gekregen om mijn
I have been given the opportunity to discuss	behandelplan te bespreken met mijn
my treatment plan with my professional(s)	zorgverlener(s)
Have you felt satisfied with the care you have	Was u tevreden met de zorg die u heeft
received?	gekregen?
Have you felt satisfied with the information	Was u tevreden met de informatie die u heeft
you have received (e.g. about the disease	gekregen (bijvoorbeeld over de ziekte of over
and its treatment)?	de behandeling)?
During the past 4 weeks:	Gedurende de afgelopen 4 weken:
My medical appointments have interfered	Mijn medische afspraken hebben mij gehinderd
with my work / household activities	in mijn werk/huishoudelijke activiteiten
My medical appointments have caused	Mijn medische afspraken hebben problemen
problems for my family / carer	veroorzaakt voor mijn familie/verzorger
How would you rate the services and care	Hoe beoordeelt u de diensten en organisatie
organisation of the most recent care you	van de meest recente zorg die u hebt
have received, in terms of:	ontvangen, in termen van:
	Het aanbieden van follow-up door de
The provision of follow-up by the different	verschillende zorgverleners (artsen,
caregivers (doctors, nurses, physiotherapists,	verpleegkundigen, fysiotherapeuten,
psychologists, etc.) after treatment?	psychologen, enz.) na de behandeling?

#### 4.1.2. English-French

Items - English	French
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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.	Nous nous intéressons à vous et à votre santé. Répondez vous-même à toutes les questions en sélectionnant le numéro qui correspond le mieux à votre situation. Il n'y a pas de réponse juste ou fausse. Ces informations sont strictement confidentielles.
	<del>-</del>
Do you have any trouble doing strenuous activities, like carrying a heavy shopping bag or a suitcase?	Avez-vous des difficultés à faire certains efforts physiques pénibles comme porter un sac à provisions chargé ou une valise?
Do you have any trouble taking a long walk?	Avez-vous des difficultés à faire une longue promenade ?
Do you need help caring for your feet (e.g. cutting your toenails)?	Avez-vous besoin d'aide pour prendre soin de vos pieds (p. ex. pour vous couper les ongles des orteils) ?
Do you have any trouble carrying a heavy bag upstairs?	Avez-vous des difficultés à monter un sac lourd à l'étage ?
Do you have any trouble taking a long walk carrying a heavy pack on your back (e.g. a filled rucksack)?	Avez-vous des difficultés à faire une longue marche en portant une charge lourde sur le dos (p. ex. un sac à dos plein) ?
Do you have any trouble taking a short walk outside of the house?	Avez-vous des difficultés à faire un petit tour dehors ?
Do you need help undressing?	Avez-vous besoin d'aide pour vous déshabiller?
Do you have any trouble walking for 30 min.?	Avez-vous des difficultés à marcher pendant 30 minutes ?
During the past week:	Au cours de la semaine passée :
Have you been limited in doing light housework (e.g. dusting or making the bed)?	Avez-vous été gêné(e) dans la réalisation de petits travaux ménagers (p. ex. faire la poussière ou le lit) ?
Have you been limited in doing physically demanding recreational activities (e.g., swimming or cycling)?	Avez-vous été gêné(e) dans la réalisation d'activités de loisirs physiquement exigeantes (p. ex. nager ou faire du vélo) ?
Were you limited in doing either your work or other daily activities?	Avez-vous été gêné(e) pour faire votre travail ou vos activités de tous les jours ?
Have you been limited in doing heavy housework (e.g., washing floors or vacuuming)?	Avez-vous été gêné(e) dans la réalisation de gros travaux ménagers (p. ex. laver le sol ou passer l'aspirateur) ?
Were you limited in pursuing your hobbies or other leisure time activities?	Avez-vous été gêné(e) dans vos activités de loisirs ?
Did pain interfere with your daily activities?	Des douleurs ont-elles perturbé vos activités quotidiennes ?
Have you had pain?	Avez-vous ressenti de la douleur ?
Has pain interfered with your social activities?	Vos douleurs ont-elles perturbé vos activités sociales ?

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	Avez-vous eu des difficultés à effectuer les
Has pain made it difficult for you to do the	tâches que vous avez l'habitude de faire chez
jobs that you usually do around the house?	vous à cause de vos douleurs ?
Have you had severe pain?	Avez-vous ressenti des douleurs intenses ?
Were you tired?	Avez-vous été fatigué(e) ?
Have you felt weak?	Vous êtes-vous senti(e) faible ?
Have you felt exhausted?	Vous êtes-vous senti(e) épuisé(e) ?
Have you become easily tired?	Vous êtes-vous senti(e) facilement fatigué(e) ?
Have you lacked energy?	Avez-vous manqué d'énergie ?
Have you required frequent or long periods	Avez-vous ressenti des besoins de repos
of rest?	fréquents ou longs ?
Have you had a feeling of overwhelming	Vous êtes-vous senti(e) accablé(e) par un
and prolonged lack of energy?	manque d'énergie prolongé ?
Have you had trouble sleeping?	Avez-vous eu des difficultés à dormir ?
Have you had trouble getting a good night's sleep?	Avez-vous eu des difficultés à passer une bonne nuit de sommeil ?
Have you had trouble staying asleep?	Avez-vous eu du mal à rester endormi(e)?
Have you woken up for long periods during	Êtes-vous resté éveillé(e) durant de longues
the night?	périodes pendant la nuit ?
Have you forced yourself to eat?	Vous êtes-vous forcé(e) à manger ?
Have you lacked appetite?	Avez-vous manqué d'appétit ?
	Avez-vous ressenti un manque d'intérêt pour la
Have you lacked interest in eating?	nourriture ?
Have you felt nauseated?	Avez-vous eu des nausées (mal au cœur) ?
Have you vomited?	Avez-vous vomi?
Has nausea or vomiting been a problem for you?	Les nausées ou les vomissements ont-ils été un problème pour vous ?
Has nausea or vomiting interfered with	Les nausées ou les vomissements ont-ils perturbé vos activités physiques, comme faire
your physical activities like taking a walk?	une promenade ?
Have you been constipated?	Avez-vous été constipé(e) ?
Have you had stools that were too hard to	Avez-vous eu des selles qui étaient trop dures
pass?	pour être éliminées ?
Have your stools been so hard that they	Vos selles ont-elles été dures au point d'être
were painful to pass?	douloureuses à éliminer ?
Were you short of breath?	Avez-vous été essoufflé(e) ?
Did you have severe shortness of breath?	Avez-vous eu un essoufflement sévère ?
Were you short of breath when walking	Avez-vous eu le souffle court en marchant plus
more than 100 m (100 yds)?	de 100m ?
Were you short of breath when walking	Avez-vous eu le souffle court en marchant moins
less than 100 m (100 yds)?	de 100m ?

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Did you feel tense?	Vous êtes-vous senti(e) tendu(e) ?
Have you felt vulnerable?	Vous êtes-vous senti(e) vulnérable ?
Have you felt that nothing could cheer you	Avez-vous eu le sentiment que rien ne pouvait
up?	vous remonter le moral ?
	Vous êtes-vous senti(e) profondément
Have you felt miserable?	malheureux(-se) ?
Did you feel depressed?	Vous êtes-vous senti(e) déprimé(e) ?
Did you worry?	Vous êtes-vous fait du souci ?
Have you felt sad?	Vous êtes-vous senti(e) triste ?
Have you been watching yourself closely	Vous êtes-vous observé(e) de près pour détecter
for any new symptoms?	d'éventuels nouveaux symptômes ?
To what extent have you been troubled	Dans quelle mesure avez-vous été gêné(e) par
with side-effects from your treatment?	les effets secondaires de votre traitement ?
Have you worried about recurrence of your	Vous êtes-vous inquiété(e) d'une récidive
disease?	éventuelle de la maladie ?
Have you been afraid of tumor	
progression?	Avez-vous eu peur d'une progression tumorale?
Have you worried about your health in the	Vous êtes-vous inquiété(e) de votre santé pour
future?	l'avenir ?
How much has your disease been a	
burden to you?	À quel point votre maladie vous a-t-elle pesé?
Because of your experience with cancer,	
have you had to limit your life plans or	Avez-vous été obligé(e) de limiter vos projets ou
goals?	vos objectifs de vie ?
I have felt at peace with myself	Je me suis senti(e) en paix avec moi-même.
Have you had difficulty remembering	Avez-vous eu des difficultés à vous souvenir de
things?	certaines choses ?
Have you had difficulty in concentrating on	Avez-vous eu des difficultés à vous concentrer
things, like reading a newspaper or	sur certaines choses, par exemple, pour lire le
watching television?	journal ou regarder la télévision ?
Have you been forgetful?	Vous est-il arrivé d'avoir des trous de mémoire ?
	Avez-vous éprouvé des difficultés à vous
Have you had difficulty remembering what	souvenir de ce qu'une personne venait de vous
someone just told you?	dire ?
Have you had difficulty maintaining	Avez-vous éprouvé des difficultés à rester
concentration even when doing something	concentré(e) même lorsque vous faisiez quelque
important?	chose d'important ?
As a result of your physical condition or	A cause de votre état physique ou de votre
medical treatment, have you preferred to	traitement médical, avez-vous préféré passer du
spend time alone?	temps seul(e) ?
As a result of your physical condition or	En raison de votre état physique ou de votre
medical treatment have you been less able	traitement médical, avez-vous été moins en
to see your family or friends?	mesure de voir votre famille ou vos amis ?

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As a result of your physical condition or	À cause de votre état physique ou de votre
medical treatment, have you spent less	traitement médical, avez-vous passé moins de
time with your family or friends?	temps avec votre famille ou vos amis?
As a result of your physical condition or	À cause de votre état physique ou de votre
medical treatment, have you felt isolated	traitement médical, vous êtes-vous senti(e)
from your family or friends?	isolé(e) de votre famille ou de vos amis ?
As a result of your physical condition or	À cause de votre état physique ou de votre
medical treatment, have you found it hard	traitement médical, avez-vous eu des difficultés à
to make contact with people?	entrer en contact avec les gens ?
Has your physical condition or medical	Votre état physique ou votre traitement médical
treatment interfered with your family life?	vous ont-ils gêné(e) dans votre vie familiale ?
	Votre état physique ou votre traitement médical
Has your physical condition or medical	vous ont-ils gêné(e) dans vos activités sociales
treatment interfered with your social	(par exemple, sortir avec des amis, aller au
activities?	cinéma)?
Has your physical condition or medical	Votre état physique ou votre traitement médical
treatment interfered with your relationships	vous ont-ils gêné(e) dans vos relations avec votre
with your family or friends?	famille ou vos amis ?
Have you been dissatisfied with your	Avez-vous été mécontent(e) de votre apparence
physical appearance?	physique?
Has the disease or treatment affected your	La maladie ou son traitement ont-ils eu un impact
sex life (for the worse)?	défavorable sur votre vie sexuelle ?
Have you worried about your ability to	Vous êtes-vous inquiété(e) de pouvoir avoir des
have children?	enfants ?
Have you worried that you are a burden to	Vous êtes-vous inquiété(e) d'être un fardeau pour
other people	les autres ?
Have you worried about becoming	Avez-vous été inquiet(ète) de devenir dépendant
dependent on others?	des autres du fait de votre maladie ?
Has your physical condition or medical	Votre état physique ou votre traitement médical
treatment caused you financial difficulties?	vous ont-ils causé des problèmes financiers ?
	Votre état physique ou votre traitement médical
Has your physical condition or medical	ont-ils entraîné des problèmes financiers ayant
treatment caused you financial difficulties	conduit à des changements de votre style de vie
leading to changes in your lifestyle?	?
As a result of your physical condition or	À cause de votre état physique ou de votre
medical treatment, have you had less	traitement médical, avez-vous eu moins d'argent
money to spend on yourself (e.g., for	à vous consacrer (p. ex. pour vous acheter
buying yourself something that you would	quelque chose que vous aimeriez avoir mais dont
like to have but don't necessarily need)?	vous n'avez pas nécessairement besoin) ?
As a result of your physical condition or	À cause de votre état physique ou de votre
medical treatment, have you had	traitement médical, avez-vous eu des difficultés à
difficulties paying any of your regular	payer vos dépenses courantes (p. ex. le loyer,
expenses (e.g. rent, insurance, phone)?	l'assurance, le téléphone) ?

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Since the diagnosis and treatment of your	Danuis la diagnostia et la traitement de vetre
Since the diagnosis and treatment of your	Depuis le diagnostic et le traitement de votre
cancer: Have you had problems with	cancer: Avez-vous eu des difficultés avec (pour
obtaining insurance, loans, and/or	obtenir) une assurance, un prêt ou un emprunt immobilier ?
a mortgage?	
Since the diagnosis and treatment of your	Depuis le diagnostic et le traitement de votre
cancer: Have you received support from	cancer: Avez-vous reçu du soutien de votre
your employer e.g. arranging flexible	employeur par exemple pour organiser votre
working?	travail de manière flexible?
	Depuis le diagnostic et le traitement de votre
Since the diagnosis and treatment of your	cancer: Avez-vous apporté des changements
cancer: Have you made positive lifestyle	positifs dans votre style de vie (p. ex. plus
changes (e.g., more exercise, healthy	d'exercice, alimentation plus saine, fumer moins)
food, cutting down smoking)?	?
For the following questions please	Pour les questions suivantes, veuillez
circle the number between 1 and 7 that	répondre en entourant le chiffre entre 1 et 7
best applies to you.	qui s'applique le mieux à votre situation :
How would you rate your overall quality of	Comment évalueriez-vous votre état de santé au
life during the past week?	cours de la semaine passée ?
How would you rate your overall health	Comment évalueriez-vous l'ensemble de votre
during the past week?	qualité de vie au cours de la semaine passée ?
Have you had any other significant	Avez-vous eu d'autres symptômes ou problèmes
symptoms or problems that have not been	significatifs qui n'auraient pas été mentionnés
mentioned in the questions above?	dans les questions ci-dessus ?
Yes. Please write down the most	
important ones (up to three), and rate to	Oui. Veuillez noter les plus importants (trois
what extent you have experienced these	maximum) et évaluer dans quelle mesure
symptoms or problems during the past	vous avez été affecté(e) par ces symptômes
week:	ou problèmes au cours de la semaine passée.
During the past week, to what extent	Au cours de la semaine passée, dans quelle
have you experienced:	mesure avez-vous été affecté(e) par :
Symptom/problem A:	Symptôme/problème A :
Symptom/problem B:	Symptôme/problème B :
Symptom/problem C:	Symptôme/problème C :
We are interested in your MOST	
RECENT experience of the care you	Nous nous intéressons à votre experience la
have received and the communication	plus récente des soins que vous avez reçu et
you have had with the professional(s)	à la communication avec le(s)
who treat you.	professionnel(s) qui vous soignent.
Have you been satisfied with your	Avez-vous été satisfait(e) de votre communication
communication with your professional(s)?	avec vos professionnels de santé ?
Have your professional(s) spent enough	Votre (vos) professionnel(s) a-t-il (ont-ils) passé
time talking with you?	suffisamment de temps à échanger avec vous ?

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Have your professional(s) used language that you understand (avoided medical	Votre (vos) professionnel(s) a-t-il (ont-ils) utilisé un langage que vous comprenez (éviter le jargon
jargon, used clear terms)? Have your professional(s) taken into account how you prefer to receive information?	médical, utiliser des termes clairs)?  Votre (vos) professionnel(s) a-t-il (ont-ils) pris en compte la façon dont vous préférez recevoir des informations?
Have you felt that you and your professional(s) had a shared understanding of your disease and treatment?	Avez-vous eu l'impression d'avoir le même point de vue que vos professionnels de santé sur votre maladie et votre traitement ?
My decisions about care and treatment have been respected by my professional(s)	Mes décisions en matière de soins et de traitement ont été respectées par mon (mes) professionnel(s)
I have been given the opportunity to discuss my treatment plan with my professional(s)	J'ai eu la possibilité de discuter de mon plan de traitement avec mon (mes) professionnel(s)
Have you felt satisfied with the care you have received?	Avez-vous été satisfait(e) des soins reçus ?
Have you felt satisfied with the information you have received (e.g. about the disease and its treatment)?	Avez-vous été satisfait(e) de la quantité d'informations reçues (p. ex. sur votre maladie et son traitement) ?
During the past 4 weeks:	Au cours des 4 dernières semaines
My medical appointments have interfered with my work / household activities	Mes rendez-vous médicaux ont causé des problèmes à mon travail/mes activités domestiques
My medical appointments have caused problems for my family / carer	Mes rendez-vous médicaux ont causé des problèmes à ma famille ou à mon proche.
How would you rate the services and care organisation of the most recent care you have received, in terms of:	Dans l'unité ambulatoire de cet hôpital, comment évalueriez-vous l'organisation des services et des soins concernant :
The provision of follow-up by the different caregivers (doctors, nurses, physiotherapists, psychologists, etc.) after treatment?	Le suivi assuré par les différents soignants (ex : médecins, infirmier(-ère)s, kinésithérapeutes, psychologues, etc.) après le traitement ?

#### 4.1.3. English-German

Items - English	German
We are interested in some things about	Wir sind an einigen Angaben interessiert, die
you and your health. Please answer all	Sie und Ihre Gesundheit betreffen. Bitte
of the questions yourself by	beantworten Sie die folgenden Fragen selbst,
SELECTING the number that best	indem Sie die Zahl wählen, die am besten auf

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applies to you. There are no "right" or "wrong" answers.	Sie zutrifft. Es gibt keine "richtigen" oder "falschen" Antworten. Ihre Angaben werden streng vertraulich behandelt.
Do you have any trouble doing strenuous activities, like carrying a heavy shopping bag or a suitcase?	Bereitet es Ihnen Schwierigkeiten sich körperlich anzustrengen (z. B. eine schwere Einkaufstasche oder einen Koffer zu tragen)?
Do you have any trouble taking a long walk?	Bereitet es Ihnen Schwierigkeiten, einen längeren Spaziergang zu machen?
Do you need help caring for your feet (e.g. cutting your toenails)?	Benötigen Sie Hilfe bei der Fußpflege (z. B. beim Schneiden der Zehennägel)?
Do you have any trouble carrying a heavy bag upstairs?	Bereitet es Ihnen Schwierigkeiten, eine schwere Tasche die Treppe hoch zu tragen?
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 short	Bereitet es Ihnen Schwierigkeiten, mit einer schweren Last (z. B. einem vollen Rucksack) auf dem Rücken eine lange Strecke zu gehen? Bereitet es Ihnen Schwierigkeiten, eine kurze
walk outside of the house?	Strecke außer Haus zu gehen?
Do you need help undressing?  Do you have any trouble walking for 30 min.?	Benötigen Sie Hilfe beim Ausziehen? Bereitet es Ihnen Schwierigkeiten, 30 Minuten zu gehen?
During the past week:	Während der letzten Woche:
Have you been limited in doing light housework (e.g. dusting or making the bed)?	Waren Sie bei leichten Hausarbeiten eingeschränkt (z. B. Staubwischen oder Betten machen)?
Have you been limited in doing physically demanding recreational activities (e.g., swimming or cycling)?	Waren Sie bei Freizeit- oder Sportaktivitäten eingeschränkt (z. B. Schwimmen oder Radfahren)?
Were you limited in doing either your work or other daily activities?	Waren Sie bei Ihrer Arbeit oder bei anderen tagtäglichen Beschäftigungen eingeschränkt?
Have you been limited in doing heavy housework (e.g., washing floors or vacuuming)?	Waren Sie bei schweren Hausarbeiten eingeschränkt (z. B. Böden wischen oder Staubsaugen)?
Were you limited in pursuing your hobbies or other leisure time activities?	Waren Sie bei Ihren Hobbys oder anderen Freizeitbeschäftigungen eingeschränkt?
Did pain interfere with your daily activities?	Fühlten Sie sich durch Schmerzen in Ihrem alltäglichen Leben beeinträchtigt?
Have you had pain?	Hatten Sie Schmerzen?
Has pain interfered with your social activities?	Haben Schmerzen Ihr Sozialleben beeinträchtigt?
Has pain made it difficult for you to do the jobs that you usually do around the house?	Ist es Ihnen aufgrund von Schmerzen schwergefallen, Ihre normalen Aufgaben rund ums Haus zu erledigen?
Have you had severe pain?	Hatten Sie starke Schmerzen?
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Were you tired?	Waren Sie müde?
Have you felt weak?	Fühlten Sie sich schwach?
Have you felt exhausted?	Fühlten Sie sich erschöpft?
Have you become easily tired?	Wurden Sie leicht müde?
Have you lacked energy?	Fehlte es Ihnen an Energie?
Have you required frequent or long	Mussten Sie sich oft bzw. über längere Zeit
periods of rest?	ausruhen?
Have you had a feeling of overwhelming	Hatten Sie das Gefühl einer sehr starken und
and prolonged lack of energy?	anhaltenden Energielosigkeit?
Have you had trouble sleeping?	Hatten Sie Schlafstörungen?
Have you had trouble getting a good	Hatten Sie Schwierigkeiten, nachts gut zu
night's sleep?	schlafen?
Have you had trouble staying asleep?	Hatten Sie Schwierigkeiten durchzuschlafen?
Have you woken up for long periods	Sind Sie nachts aufgewacht und haben längere
during the night?	Zeit wachgelegen?
Have you forced yourself to eat?	Haben Sie sich zum Essen gezwungen?
Have you lacked appetite?	Hatten Sie Appetitmangel?
Have you lacked interest in eating?	Hat es Ihnen an Interesse am Essen gefehlt?
Have you felt nauseated?	War Ihnen übel?
Have you vomited?	Haben Sie erbrochen?
Loc nouses or veniting been a problem	
Has nausea or vomiting been a problem	Westille Heiter Edward and Balley (1. 0. 0.
for you?	War Übelkeit oder Erbrechen ein Problem für Sie?
for you?	Hat Übelkeit oder Erbrechen Sie bei Ihren
for you?  Has nausea or vomiting interfered with	Hat Übelkeit oder Erbrechen Sie bei Ihren körperlichen Aktivitäten beeinträchtigt, z. B. beim
for you?  Has nausea or vomiting interfered with your physical activities like taking a walk?	Hat Übelkeit oder Erbrechen Sie bei Ihren körperlichen Aktivitäten beeinträchtigt, z. B. beim Spazierengehen?
for you?  Has nausea or vomiting interfered with your physical activities like taking a walk?  Have you been constipated?	Hat Übelkeit oder Erbrechen Sie bei Ihren körperlichen Aktivitäten beeinträchtigt, z. B. beim Spazierengehen? Hatten Sie Verstopfung?
for you?  Has nausea or vomiting interfered with your physical activities like taking a walk?  Have you been constipated?  Have you had stools that were too hard to	Hat Übelkeit oder Erbrechen Sie bei Ihren körperlichen Aktivitäten beeinträchtigt, z. B. beim Spazierengehen? Hatten Sie Verstopfung? War Ihr Stuhl so hart, dass Sie ihn nicht
for you?  Has nausea or vomiting interfered with your physical activities like taking a walk?  Have you been constipated?	Hat Übelkeit oder Erbrechen Sie bei Ihren körperlichen Aktivitäten beeinträchtigt, z. B. beim Spazierengehen? Hatten Sie Verstopfung?
for you?  Has nausea or vomiting interfered with your physical activities like taking a walk?  Have you been constipated?  Have you had stools that were too hard to pass?	Hat Übelkeit oder Erbrechen Sie bei Ihren körperlichen Aktivitäten beeinträchtigt, z. B. beim Spazierengehen? Hatten Sie Verstopfung? War Ihr Stuhl so hart, dass Sie ihn nicht ausscheiden konnten?
for you?  Has nausea or vomiting interfered with your physical activities like taking a walk?  Have you been constipated?  Have you had stools that were too hard to pass?  Have your stools been so hard that they	Hat Übelkeit oder Erbrechen Sie bei Ihren körperlichen Aktivitäten beeinträchtigt, z. B. beim Spazierengehen? Hatten Sie Verstopfung? War Ihr Stuhl so hart, dass Sie ihn nicht ausscheiden konnten? War Ihr Stuhl so hart, dass Sie Schmerzen bei der
for you?  Has nausea or vomiting interfered with your physical activities like taking a walk?  Have you been constipated?  Have you had stools that were too hard to pass?  Have your stools been so hard that they were painful to pass?	Hat Übelkeit oder Erbrechen Sie bei Ihren körperlichen Aktivitäten beeinträchtigt, z. B. beim Spazierengehen? Hatten Sie Verstopfung? War Ihr Stuhl so hart, dass Sie ihn nicht ausscheiden konnten? War Ihr Stuhl so hart, dass Sie Schmerzen bei der Ausscheidung hatten?
for you?  Has nausea or vomiting interfered with your physical activities like taking a walk?  Have you been constipated?  Have you had stools that were too hard to pass?  Have your stools been so hard that they were painful to pass?  Were you short of breath?	Hat Übelkeit oder Erbrechen Sie bei Ihren körperlichen Aktivitäten beeinträchtigt, z. B. beim Spazierengehen? Hatten Sie Verstopfung? War Ihr Stuhl so hart, dass Sie ihn nicht ausscheiden konnten? War Ihr Stuhl so hart, dass Sie Schmerzen bei der Ausscheidung hatten? Waren Sie kurzatmig?
for you?  Has nausea or vomiting interfered with your physical activities like taking a walk?  Have you been constipated?  Have you had stools that were too hard to pass?  Have your stools been so hard that they were painful to pass?  Were you short of breath?  Did you have severe shortness of breath?  Were you short of breath when walking more than 100 m (100 yds)?	Hat Übelkeit oder Erbrechen Sie bei Ihren körperlichen Aktivitäten beeinträchtigt, z. B. beim Spazierengehen? Hatten Sie Verstopfung? War Ihr Stuhl so hart, dass Sie ihn nicht ausscheiden konnten? War Ihr Stuhl so hart, dass Sie Schmerzen bei der Ausscheidung hatten? Waren Sie kurzatmig? Waren Sie sehr kurzatmig? Waren Sie kurzatmig, wenn Sie mehr als 100 m zu Fuß gingen?
for you?  Has nausea or vomiting interfered with your physical activities like taking a walk? Have you been constipated? Have you had stools that were too hard to pass? Have your stools been so hard that they were painful to pass? Were you short of breath? Did you have severe shortness of breath? Were you short of breath when walking more than 100 m (100 yds)? Were you short of breath when walking	Hat Übelkeit oder Erbrechen Sie bei Ihren körperlichen Aktivitäten beeinträchtigt, z. B. beim Spazierengehen? Hatten Sie Verstopfung? War Ihr Stuhl so hart, dass Sie ihn nicht ausscheiden konnten? War Ihr Stuhl so hart, dass Sie Schmerzen bei der Ausscheidung hatten? Waren Sie kurzatmig? Waren Sie sehr kurzatmig? Waren Sie kurzatmig, wenn Sie mehr als 100 m zu Fuß gingen? Waren Sie kurzatmig, wenn Sie weniger als 100 m
for you?  Has nausea or vomiting interfered with your physical activities like taking a walk?  Have you been constipated?  Have you had stools that were too hard to pass?  Have your stools been so hard that they were painful to pass?  Were you short of breath?  Did you have severe shortness of breath?  Were you short of breath when walking more than 100 m (100 yds)?  Were you short of breath when walking less than 100 m (100 yds)?	Hat Übelkeit oder Erbrechen Sie bei Ihren körperlichen Aktivitäten beeinträchtigt, z. B. beim Spazierengehen? Hatten Sie Verstopfung? War Ihr Stuhl so hart, dass Sie ihn nicht ausscheiden konnten? War Ihr Stuhl so hart, dass Sie Schmerzen bei der Ausscheidung hatten? Waren Sie kurzatmig? Waren Sie sehr kurzatmig? Waren Sie sehr kurzatmig, wenn Sie mehr als 100 m zu Fuß gingen? Waren Sie kurzatmig, wenn Sie weniger als 100 m zu Fuß gingen?
for you?  Has nausea or vomiting interfered with your physical activities like taking a walk?  Have you been constipated?  Have you had stools that were too hard to pass?  Have your stools been so hard that they were painful to pass?  Were you short of breath?  Did you have severe shortness of breath?  Were you short of breath when walking more than 100 m (100 yds)?  Were you short of breath when walking less than 100 m (100 yds)?  Did you feel tense?	Hat Übelkeit oder Erbrechen Sie bei Ihren körperlichen Aktivitäten beeinträchtigt, z. B. beim Spazierengehen? Hatten Sie Verstopfung? War Ihr Stuhl so hart, dass Sie ihn nicht ausscheiden konnten? War Ihr Stuhl so hart, dass Sie Schmerzen bei der Ausscheidung hatten? Waren Sie kurzatmig? Waren Sie sehr kurzatmig? Waren Sie kurzatmig, wenn Sie mehr als 100 m zu Fuß gingen? Waren Sie kurzatmig, wenn Sie weniger als 100 m zu Fuß gingen? Fühlten Sie sich angespannt?
for you?  Has nausea or vomiting interfered with your physical activities like taking a walk?  Have you been constipated?  Have you had stools that were too hard to pass?  Have your stools been so hard that they were painful to pass?  Were you short of breath?  Did you have severe shortness of breath?  Were you short of breath when walking more than 100 m (100 yds)?  Were you short of breath when walking less than 100 m (100 yds)?  Did you feel tense?  Have you felt vulnerable?	Hat Übelkeit oder Erbrechen Sie bei Ihren körperlichen Aktivitäten beeinträchtigt, z. B. beim Spazierengehen? Hatten Sie Verstopfung? War Ihr Stuhl so hart, dass Sie ihn nicht ausscheiden konnten? War Ihr Stuhl so hart, dass Sie Schmerzen bei der Ausscheidung hatten? Waren Sie kurzatmig? Waren Sie sehr kurzatmig? Waren Sie sehr kurzatmig, wenn Sie mehr als 100 m zu Fuß gingen? Waren Sie kurzatmig, wenn Sie weniger als 100 m zu Fuß gingen? Fühlten Sie sich angespannt? Haben Sie sich verletzlich gefühlt?
Has nausea or vomiting interfered with your physical activities like taking a walk? Have you been constipated? Have you had stools that were too hard to pass? Have your stools been so hard that they were painful to pass? Were you short of breath? Did you have severe shortness of breath? Were you short of breath when walking more than 100 m (100 yds)? Were you short of breath when walking less than 100 m (100 yds)? Did you feel tense? Have you felt vulnerable? Have you felt that nothing could cheer you	Hat Übelkeit oder Erbrechen Sie bei Ihren körperlichen Aktivitäten beeinträchtigt, z. B. beim Spazierengehen? Hatten Sie Verstopfung? War Ihr Stuhl so hart, dass Sie ihn nicht ausscheiden konnten? War Ihr Stuhl so hart, dass Sie Schmerzen bei der Ausscheidung hatten? Waren Sie kurzatmig? Waren Sie sehr kurzatmig? Waren Sie kurzatmig, wenn Sie mehr als 100 m zu Fuß gingen? Waren Sie kurzatmig, wenn Sie weniger als 100 m zu Fuß gingen? Fühlten Sie sich angespannt? Haben Sie sich verletzlich gefühlt? Hatten Sie das Gefühl, dass nichts Sie aufheitern
for you?  Has nausea or vomiting interfered with your physical activities like taking a walk?  Have you been constipated?  Have you had stools that were too hard to pass?  Have your stools been so hard that they were painful to pass?  Were you short of breath?  Did you have severe shortness of breath?  Were you short of breath when walking more than 100 m (100 yds)?  Were you short of breath when walking less than 100 m (100 yds)?  Did you feel tense?  Have you felt vulnerable?	Hat Übelkeit oder Erbrechen Sie bei Ihren körperlichen Aktivitäten beeinträchtigt, z. B. beim Spazierengehen? Hatten Sie Verstopfung? War Ihr Stuhl so hart, dass Sie ihn nicht ausscheiden konnten? War Ihr Stuhl so hart, dass Sie Schmerzen bei der Ausscheidung hatten? Waren Sie kurzatmig? Waren Sie sehr kurzatmig? Waren Sie sehr kurzatmig, wenn Sie mehr als 100 m zu Fuß gingen? Waren Sie kurzatmig, wenn Sie weniger als 100 m zu Fuß gingen? Fühlten Sie sich angespannt? Haben Sie sich verletzlich gefühlt?

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Did you feel depressed?	Fühlten Sie sich niedergeschlagen?
Did you worry?	Haben Sie sich Sorgen gemacht?
Have you felt sad?	Haben Sie sich traurig gefühlt?
Have you been watching yourself closely	Haben Sie sich selbst genau beobachtet in Bezug
for any new symptoms?	auf irgendwelche neuen Symptome?
	In welchem Ausmaß fühlten Sie sich durch
To what extent have you been troubled	Nebenwirkungen Ihrer Behandlung
with side-effects from your treatment?	belästigtbeeinträchtigt?
Have you worried about recurrence of	Haben Sie sich Sorgen darüber gemacht, dass
your disease?	Ihre Krankheit erneut auftreten könnte?
Have you been afraid of tumor	
progression?	Hatten Sie Angst, dass Ihr Tumor fortschreitet?
Have you worried about your health in the	Haben Sie sich Sorgen um Ihre zukünftige
future?	Gesundheit gemacht?
How much has your disease been a	Wie sehr fühlten Sie sich durch Ihre Erkrankung
burden to you?	belastet?
Because of your experience with cancer, have you had to limit your life plans or	Aufgrund Ihrer Erfahrung mit Krebs: Mussten Sie
goals?	Ihre Lebenspläne oder Ziele einschränken?
I have felt at peace with myself	Ich fühlte mich mit mir selbst im Einklang
Have you had difficulty remembering	Hatten Sie Schwierigkeiten, sich an Dinge zu
things?	erinnern?
Have you had difficulty in concentrating	Hatten Sie Schwierigkeiten, sich auf etwas zu
on things, like reading a newspaper or	konzentrieren, z. B. auf das Zeitunglesen oder das
watching television?	Fernsehen?
Have you been forgetful?	Sind Sie vergesslich gewesen?
Have you had difficulty remembering what	Hatten Sie Schwierigkeiten sich zu erinnern, was
someone just told you?	jemand gerade zu Ihnen gesagt hat?
Have you had difficulty maintaining	
concentration even when doing something	Hatten Sie Schwierigkeiten konzentriert zu
important?	bleiben, selbst wenn Sie etwas Wichtiges taten?
As a result of your physical condition or	Haben Sie es aufgrund Ihres körperlichen
medical treatment, have you preferred to	Zustands oder Ihrer medizinischen Behandlung
spend time alone?	bevorzugt, Ihre Zeit alleine zu verbringen?
	War es Ihnen aufgrund Ihres körperlichen
As a result of your physical condition or	Zustands oder Ihrer medizinischen Behandlung
medical treatment have you been less	seltener möglich, Ihre Familie oder Freunde zu
able to see your family or friends?	sehen?
As a result of your physical condition or	Haben Sie aufgrund Ihres körperlichen Zustands
medical treatment, have you spent less	oder Ihrer medizinischen Behandlung weniger Zeit
time with your family or friends?	mit Ihrer Familie oder Freunden verbracht?

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As a result of your physical condition or	Haben Sie sich aufgrund Ihres körperlichen
medical treatment, have you felt isolated from your family or friends?	Zustands oder Ihrer medizinischen Behandlung von Ihrer Familie oder Freunden isoliert gefühlt?
As a result of your physical condition or	Fanden Sie es aufgrund Ihres körperlichen
medical treatment, have you found it hard	Zustands oder Ihrer medizinischen Behandlung
to make contact with people?	schwierig, mit Menschen in Kontakt zu kommen?
	Hat Ihr körperlicher Zustand oder Ihre
Has your physical condition or medical	medizinische Behandlung Ihr Familienleben
treatment interfered with your family life?	beeinträchtigt?
	Hat Ihr körperlicher Zustand oder Ihre
Has your physical condition or medical	medizinische Behandlung Ihr Zusammensein oder
treatment interfered with your social	Ihre gemeinsamen Unternehmungen mit anderen
activities?	Menschen beeinträchtigt?
Has your physical condition or medical	Hat Ihr körperlicher Zustand oder Ihre
treatment interfered with your	medizinische Behandlung die Beziehung zu Ihrer
relationships with your family or friends?	Familie oder Freunden gestört?
Have you been dissatisfied with your	Waren Sie unzufrieden mit Ihrer äußeren
physical appearance?	Erscheinung?
Has the disease or treatment affected	Hat die Krankheit oder Behandlung Ihr
your sex life (for the worse)?	Sexualleben beeinflusst? (zum Schlechten)
Have you worried about your ability to	Haben Sie sich Sorgen darüber gemacht, ob Sie
have children?	noch Kinder bekommen bzw. zeugen können?
Have you worried that you are a burden to	Haben Sie sich Sorgen darüber gemacht, anderen
other people	zur Last zu fallen?
Have you worried about becoming	Haben Sie sich Sorgen darüber gemacht, dass Sie
dependent on others?	von anderen abhängig werden könnten?
Has your physical condition or medical	Hat Ihr körperlicher Zustand oder Ihre
treatment caused you financial	medizinische Behandlung für Sie finanzielle
difficulties?	Schwierigkeiten mit sich gebracht?
	Sind Sie aufgrund Ihres körperlichen Zustands
Has your physical condition or medical	oder Ihrer medizinischen Behandlung in finanzielle
treatment caused you financial difficulties	Schwierigkeiten geraten, durch die sich Ihr
leading to changes in your lifestyle?	Lebensstil geändert hat?
As a result of your physical condition or	Haben Sie aufgrund Ihres körperlichen Zustands
medical treatment, have you had less	oder Ihrer medizinischen Behandlung weniger
money to spend on yourself (e.g., for	Geld gehabt, das Sie für sich selbst ausgeben
buying yourself something that you would	konnten (z. B. um sich Dinge zu kaufen, die Sie
like to have but don't necessarily need)?	gerne hätten, aber nicht unbedingt brauchen)?
	Haben Sie aufgrund Ihres körperlichen Zustands
As a result of your physical condition or	oder Ihrer medizinischen Behandlung
medical treatment, have you had	Schwierigkeiten gehabt, Ihre regelmäßigen
difficulties paying any of your regular	Ausgaben zu bezahlen (z. B. Miete,
expenses (e.g. rent, insurance, phone)?	Versicherungen, Telefon)?

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Since the diagnosis and treatment of your	Seit der Diagnose und der Behandlung Ihrer
cancer: Have you had problems with	Krebserkrankung: Hatten Sie Probleme mit einer
obtaining insurance, loans, and/or	Versicherung, Krediten und/oder einer Hypothek
a mortgage?	(diese abzuschließen)?
Since the diagnosis and treatment of your	Seit der Diagnose und der Behandlung Ihrer
cancer: Have you received support from	Krebserkrankung: Haben Sie von Ihrem
your employer e.g. arranging flexible	Arbeitgeber Unterstützung erhalten, z. B. bei der
working?	Vereinbarung flexibler Arbeitszeiten?
Since the diagnosis and treatment of your	Seit der Diagnose und der Behandlung Ihrer
cancer: Have you made positive lifestyle	Krebserkrankung: Haben Sie Ihren Lebensstil
changes (e.g., more exercise, healthy	positiv geändert (z. B. mehr Bewegung, gesundes
food, cutting down smoking)?	Essen, das Rauchen eingeschränkt)?
For the following questions please	Bitte kreisen Sie bei den folgenden Fragen die
circle the number between 1 and 7 that	Zahl zwischen 1 und 7 ein, die am besten auf
best applies to you.	Sie zutrifft:
How would you rate your overall quality of	Wie würden Sie insgesamt Ihre Lebensqualität
life during the past week?	während der letzten Woche einschätzen?
	Wie würden Sie insgesamt Ihren
How would you rate your overall health	Gesundheitszustand während der letzten Woche
during the past week?	einschätzen?
Have you had any other significant	Sind bei Ihnen andere erhebliche Symptome oder
symptoms or problems that have not been	Probleme aufgetreten, die in den Fragen oben
mentioned in the questions above?	nicht erwähnt wurden?
Yes. Please write down the most	la Nationau Cia bitta dia miabtimatau (bia
important ones (up to three), and rate	Ja. Notieren Sie bitte die wichtigsten (bis zu
to what extent you have experienced	drei) und bewerten Sie, inwieweit diese
these symptoms or problems during the past week:	Symptome oder Probleme in der letzten Woche bei Ihnen aufgetreten sind:
During the past week, to what extent	Inwieweit ist bei Ihnen in der letzten Woche
have you experienced:	Folgendes aufgetreten:
Symptom/problem A:	Symptom/problem A:
Symptom/problem B:	Symptom/problem B:
Symptom/problem C:	Symptom/problem C:
We are interested in your MOST	Wir interessieren uns für Ihre ZULETZT
RECENT experience of the care you	GEMACHTEN Erfahrungen bezüglich der
have received and the communication	Versorgung, die Sie erhalten haben, und
you have had with the professional(s)	bezüglich der Kommunikation mit Ihren
who treat you.	Behandler/innen.
Have you been satisfied with your	Waren Sie mit der Kommunikation mit Ihren
communication with your professional(s)?	Behandler/innen zufrieden?
Have your professional(s) spent enough	Haben Ihre Behandler/innen sich genug Zeit für
time talking with you?	das Gespräch mit Ihnen genommen?

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Have your professional(s) used language that you understand (avoided medical	Haben Ihre Behandler/innen im Gespräch verständlich ausgedrückt (medizinische Begriffe
jargon, used clear terms)?	vermieden, verständliche Ausdrücke verwendet)?
Have your professional(s) taken into	,
account how you prefer to receive	Haben Ihre Behandler/innen berücksichtigt, wie
information?	Sie Informationen erhalten wollten?
Have you felt that you and your	
professional(s) had a shared	Hatten Sie das Gefühl, dass Sie und Ihre
understanding of your disease and	Behandler/innen ein gemeinsames Verständnis
treatment?	von Ihrer Krankheit und Behandlung hatten?
My decisions about care and treatment	Meine Entscheidungen über meine Versorgung
have been respected by my	und Behandlung wurde von meinen
professional(s)	Behandler/innen respektiert
I have been given the opportunity to	Ich habe die Gelegenheit bekommen, meinen
discuss my treatment plan with my	Behandlungsplan mit meinen Behandler/innen zu
professional(s)	besprechen
Have you felt satisfied with the care you	Waren Sie mit der erhaltenen Pflege/Betreuung
have received?	zufrieden?
Have you felt satisfied with the information	
you have received (e.g. about the disease	Waren Sie mit den erhaltenen Informationen
and its treatment)?	zufrieden (z.B. zur Erkankung und ihrer Therapie)?
<b>During the past 4 weeks:</b>	Während der letzten vier Wochen:
My medical appointments have interfered	Meine Behandlungstermine haben meine Arbeit/
with my work / household activities	häuslichen Aktivitäten beeinträchtigt
My medical appointments have caused	Meine Behandlungstermine haben Probleme für
problems for my family / carer	meine Familie/ Pflegende verursacht
	Wie würden Sie die Dienstleistungen und die
	Organisation der Betreuung in der Arztpraxis,
How would you rate the services and	<u>Ambulanz</u>
care organisation of the most recent	oder dem Krankenhaus, wo sie zuletzt
care you have received, in terms of:	behandelt wurden, bezogen auf folgende:
The provision of follow-up by the different	Das Angebot von Nachkontrollen durch die
caregivers (doctors, nurses,	verschiedenen Berufsgruppen (Ärzte, Pflegekräfte,
physiotherapists, psychologists, etc.) after	Physiotherapeuten, Psychologen usw.), die in Ihre
treatment?	Behandlung eingebunden sind?

#### 4.1.4. English-Italian

Items - English	Italian
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	Siamo interessati a conoscere alcuni aspetti
We are interested in some things about	della sua esperienza di cura e del suo stato
We are interested in some things about	di salute. La preghiamo di rispondere
you and your health. Please answer all of the questions yourself by SELECTING	personalmente a tutte le domande SCEGLIENDO il numero che meglio descrive
the number that best applies to you.  There are no "right" or "wrong" answers.	la sua condizione. Non ci sono risposte "giuste" o "sbagliate".
Do you have any trouble doing strenuous	Ha difficoltà nello svolgere attività faticose,
activities, like carrying a heavy shopping bag	come portare una borsa della spesa pesante o
or a suitcase?	una valigia?
	i
Do you have any trouble taking a long walk?	Ha difficoltà nel fare una lunga passeggiata?
Do you need help caring for your feet (e.g.	Ha bisogno di aiuto nel curarsi i piedi (ad
cutting your toenails)?	esempio tagliarsi le unghie)?
Do you have any trouble carrying a heavy	Ha difficoltà nel portare una borsa pesante al
bag upstairs?	piano superiore?
Do you have any trouble taking a long walk	Ha difficoltà nel fare una passeggiata lunga con
carrying a heavy pack on your back (e.g. a	un carico pesante sulla schiena (ad esempio
filled rucksack)?	uno zaino pieno)?
Do you have any trouble taking a short walk	Ha difficoltà nel fare una breve passeggiata fuori
outside of the house?	casa?
Do you need help undressing?	Ha bisogno di aiuto per svestirsi?
Do you have any trouble walking for 30	
min.?	Ha difficoltà nel camminare per 30 minuti?
During the past week:	<u>Durante l'ultima settimana:</u>
	È stato/a limitato/a nello svolgere lavori
Have you been limited in doing light	domestici leggeri (ad esempio spolverare o
housework (e.g. dusting or making the bed)?	rifare il letto)?
Have you been limited in doing physically	È stato/a limitato/a nello svolgere attività fisiche
demanding recreational activities (e.g.,	ricreative (ad esempio nuotare o andare in
swimming or cycling)?	bicicletta)?
Were you limited in doing either your work or	
other daily activities?	attività quotidiane?
Have you been limited in doing heavy	E stato/a limitato/a nello svolgere lavori
housework (e.g., washing floors or	domestici pesanti (ad esempio lavare i
vacuuming)?	pavimenti o passare l'aspirapolvere)?
	Ha avuto limitazioni nel praticare i Suoi
Were you limited in pursuing your hobbies or	passatempi-hobby o altre attività di divertimento
other leisure time activities?	o svago?
	Il dolore ha interferito con le Sue attività
Did pain interfere with your daily activities?	quotidiane?
Have you had pain?	Ha avuto dolore?
Has pain interfered with your social	
activities?	Il dolore ha interferito con le Sue attività sociali?

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Has pain made it difficult for you to do the	Il dolore ha reso difficile svolgere i lavori che
jobs that you usually do around the house?	solitamente compie in casa?
Have you had severe pain?	Ha avuto un dolore forte?
Were you tired?	Ha sentito stanchezza?
Have you felt weak?	Ha sentito debolezza?
Have you felt exhausted?	Si è sentito esausto?
Have you become easily tired?	Si è stancato/a facilmente?
Have you lacked energy?	Ha avvertito mancanza di energia?
Have you required frequent or long periods of rest?	Ha avuto necessità di periodi frequenti o prolungati di riposo?
Have you had a feeling of overwhelming and prolonged lack of energy?	Ha avvertito un'opprimente e prolungata di mancanza di energie?
Have you had trouble sleeping?	Ha avuto difficoltà a dormire?
Have you had trouble getting a good night's sleep?	Ha avuto problemi a trascorrere una notte di sonno normale?
Have you had trouble staying asleep?	Ha avuto problemi a rimanere addormentato/a?
Have you woken up for long periods during the night?	Ha avuto risvegli notturni prolungati?
Have you forced yourself to eat?	Ha mangiato in modo forzato?
Have you lacked appetite?	Le è mancato l'appetito?
Have you lacked interest in eating?	Ha perso interesse per il cibo?
Have you felt nauseated?	Ha avuto un senso di nausea?
Have you vomited?	Ha vomitato?
Has nausea or vomiting been a problem for you?	La nausea o il vomito è stato per Lei un problema?
Has nausea or vomiting interfered with your physical activities like taking a walk?	La nausea o il vomito ha interferito con le Sue attività fisiche come fare una passeggiata?
Have you been constipated?	Ha avuto problemi di stitichezza?
Have you had stools that were too hard to	
pass?	Ha avuto feci troppo dure per essere espulse?
Have your stools been so hard that they were painful to pass?	Le sue feci sono state così dure da causare dolore all'espulsione?
Were you short of breath?	Le è mancato il fiato?
Did you have severe shortness of breath?	Le è capitato di provare un forte accorciamento del respiro?
Were you short of breath when walking more than 100 m (100 yds)?	Si è sentito/a affannato/a dopo aver camminato per oltre 100 m?
Were you short of breath when walking less than 100 m (100 yds)?	Si è sentito/a affannato/a dopo aver camminato per meno di 100 m?
Did you feel tense?	Si è sentito(a) teso(a)?
Have you felt vulnerable?	Si è sentito/a vulnerabile?
	1

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Have you felt that nothing could cheer you up?	Ha avuto l'impressione che niente potesse rallegrarLa?
Have you felt miserable?	Si è sentito/a infelice?
Did you feel depressed?	Ha avvertito uno stato di depressione?
Did you worry?	Ha avuto preoccupazioni?
Have you felt sad?	Si è sentito/a triste?
Have you been watching yourself closely for	Ha prestato maggiore attenzione a eventuali
any new symptoms?	nuovi sintomi?
To what extent have you been troubled with	Quanto è stato/a disturbato/a dagli effetti
side-effects from your treatment?	collaterali della terapia?
Have you worried about recurrence of your	
disease?	Ha temuto il ripresentarsi della malattia?
Have you been afraid of tumor progression?	Ha temuto la progressione del tumore?
Have you worried about your health in the future?	Ha avuto preoccupazioni per la Sua salute futura?
How much has your disease been a burden	
to you?	Quanto Le è pesata la malattia?
Because of your experience with cancer,	
have you had to limit your life plans or	Ha dovuto limitare i Suoi obiettivi di vita o
goals?	progetti?
I have felt at peace with myself	Mi sento in pace con me stesso
Have you had difficulty remembering	
things?	Ha avuto difficoltà a ricordare le cose?
Have you had difficulty in concentrating on	
things, like reading a newspaper or watching	
television?	leggere un giornale o guardare la televisione?
Have you been forgetful?	Le è capitato di dimenticare facilmente le cose?
Have you had difficulty remembering what	Ha avuto difficoltà a ricordare cosa Le era stato
someone just told you?	appena detto?
Have you had difficulty maintaining	Ha avuto difficoltà a mantenere la
concentration even when doing something	concentrazione, anche mentre faceva qualcosa
important?	di importante?
As a result of your physical condition or	A causa delle Sue condizioni fisiche o della
medical treatment, have you preferred to spend time alone?	terapia, ha preferito trascorrere tempo da solo/a?
As a result of your physical condition or	A causa delle Sue condizioni fisiche o della
medical treatment have you been less able	terapia, è stato/a meno in grado di vedere i Suoi
•	riciapia, e siaio/a meno in grado di vedere i Suoi
to see your family or friends?	familiari o gli amici?
to see your family or friends?  As a result of your physical condition or	familiari o gli amici?  A causa delle Sue condizioni fisiche o della
As a result of your physical condition or medical treatment, have you spent less time	familiari o gli amici?  A causa delle Sue condizioni fisiche o della terapia, ha trascorso meno tempo insieme ai

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As a result of your physical condition or medical treatment, have you felt isolated	A causa delle Sue condizioni fisiche o della terapia, si è sentito/a isolato/a dai Suoi familiari
from your family or friends?	o dagli amici?
As a result of your physical condition or medical treatment, have you found it hard to make contact with people?	A causa delle Sue condizioni fisiche o della terapia, Le è stato difficile stabilire un contatto con le persone?
The state of the s	Le Sue condizioni fisiche o il Suo trattamento
Has your physical condition or medical treatment interfered with your family life?	medico hanno interferito con la Sua vita familiare?
Has your physical condition or medical	Le Sue condizioni fisiche o il Suo trattamento
treatment interfered with your social	medico hanno interferito con le Sue attività
activities?	sociali?
Has your physical condition or medical	Le Sue condizioni fisiche o la terapia hanno
treatment interfered with your relationships	interferito nei rapporti con la Sua famiglia o gli
with your family or friends?	amici?
Have you been dissatisfied with your physical appearance?	Ha provato insoddisfazione per il Suo aspetto fisico?
Has the disease or treatment affected your	La malattia o il trattamento hanno influenzato (in
sex life (for the worse)?	negativo) la Sua vita sessuale?
Have you worried about your ability to have	
children?	Ha temuto di non essere in grado di avere figli?
Have you worried that you are a burden to	Si è preoccupato/a di diventare un peso per gli
other people	altri?
Have you worried about becoming	
dependent on others?	Ha temuto di diventare dipendente dagli altri?
Has your physical condition or medical	Le Sue condizioni fisiche o il Suo trattamento
treatment caused you financial difficulties?	medico Le hanno causato difficoltà finanziarie?
Has your physical condition or medical	Le Sue condizioni fisiche o la terapia hanno
treatment caused you financial difficulties	comportato per Lei difficoltà finanziarie che
leading to changes in your lifestyle?	L'hanno portata a modificare il Suo stile di vita?
As a result of your physical condition or	A causa delle Sue condizioni fisiche o della
medical treatment, have you had less	terapia, ha avuto meno denaro da spendere per
money to spend on yourself (e.g., for buying	sé (ad esempio per comperare qualcosa che
yourself something that you would like to	avrebbe desiderato avere ma di cui non aveva
have but don't necessarily need)?	una stretta necessità)?
As a result of your physical condition or	A causa delle Sue condizioni fisiche o della
medical treatment, have you had difficulties	terapia, ha avuto difficoltà a pagare alcune
paying any of your regular expenses (e.g.	spese fisse (ad esempio affitto, assicurazione,
rent, insurance, phone)?	telefono)?
Since the diagnosis and treatment of your	
cancer: Have you had problems with	Dalla diagnosi e dal trattamento del Suo cancro:
obtaining insurance, loans, and/or	Ha avuto problemi con assicurazioni, prestiti e/o
a mortgage?	mutui (e per ottenerli)?

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	Della diamanai a del trattamanta del Cua consus.
Since the diagnosis and treatment of your	Dalla diagnosi e dal trattamento del Suo cancro:
cancer: Have you received support from	Ha ricevuto supporto dal suo datore di lavoro,
your employer e.g. arranging flexible	per esempio la possibilità di svolgere il suo
working?	lavoro in modo flessibile?
	Dalla diagnosi e dal trattamento del Suo cancro:
Since the diagnosis and treatment of your	Successivamente alla diagnosi e ai trattamenti:
cancer: Have you made positive lifestyle	ha migliorato alcuni aspetti del suo stile di vita
changes (e.g., more exercise, healthy food,	(es. maggiore esercizio fisico, alimentazione
cutting down smoking)?	sana, riduzione del fumo)?
For the following questions please circle	Per le seguenti domande, la preghiamo di
the number between 1 and 7 that	indicare un numero da 1 a 7 che meglio
best applies to you.	descrive la sua esperienza.
How would you rate your overall quality of	Come valuterebbe in generale la Sua qualità di
life during the past week?	vita durante gli ultimi sette giorni?
How would you rate your overall health	Come valuterebbe in generale la Sua salute
during the past week?	durante gli ultimi sette giorni?
Have you had any other significant	
symptoms or problems that have not been	Ha avuto altri sintomi o problemi significativi che
mentioned in the questions above?	non sono stati citati nelle domande precedenti?
Yes. Please write down the most	
important ones (up to three), and rate to	Sì. La preghiamo di indicare i più significativi
what extent you have experienced these	(fino a un massimo di tre), e a valutare in che
symptoms or problems during the past	misura ha manifestato tali sintomi o
week:	problemi durante gli ultimi sette giorni:
<b>During the past week, to what extent</b>	Durante gli ultimi sette giorni, in quale
have you experienced:	misura si sono manifestati:
Symptom/problem A:	Sintomo/problema A
Symptom/problem B:	Sintomo/problema B
Symptom/problem C:	Sintomo/problema C
	Siamo interessati a conoscere alcuni aspetti
We are interested in your MOST RECENT	della sua più recente esperienza di cura e di
experience of the care you have received	relazione/comunicazione con gli operatori
and the communication you have had	sanitari (medici, infermieri, fisioterapisti,
with the professional(s) who treat you.	psicologi, ecc.) che l'hanno assistita.
Have you been satisfied with your	È rimasto/a soddisfatto/a della comunicazione
communication with your professional(s)?	tra Lei e gli operatori sanitari?
	Gli operatori sanitari le hanno dedicato
Have your professional(s) spent enough	abbastanza tempo per comunicare e
time talking with you?	confrontarsi con Lei?
	COMMONITOR CONTROL
6 ,	Gli operatori sanitari hanno utilizzato un
Have your professional(s) used language that you understand (avoided medical	

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Have your professional(s) taken into account	Gli operatori sanitari hanno considerato la modalità con la quale preferisce ricevere le
how you prefer to receive information?	informazioni?
Have you felt that you and your	Ha avuto la sensazione che tra Lei e gli
professional(s) had a shared understanding	operatori sanitari vi fosse un'intesa comune in
of your disease and treatment?	merito alla Sua malattia e alla terapia?
	Le mie decisioni in merito all'assistenza e al
My decisions about care and treatment have	trattamento sono state rispettate dagli operatori
been respected by my professional(s)	sanitari che mi curano.
	Mi è stata data l'opportunità di discutere il mio
I have been given the opportunity to discuss	piano di cura con gli operatori sanitari che mi
my treatment plan with my professional(s)	assistono.
Have you felt satisfied with the care you	È rimasto/a soddisfatto/a delle cure che ha
have received?	ricevuto?
Have you felt satisfied with the information	È rimasto/a soddisfatto/a delle informazioni che
you have received (e.g. about the disease and its treatment)?	
	ha ricevuto (per es. sulla malattia e la terapia)?
During the past 4 weeks:	Durante le ultime quattro settimane:
My modical appaintments have interfered	Gli appuntamenti per le cure e le visite mediche
My medical appointments have interfered	hanno interferito con il mio lavoro/attività domestiche.
with my work / household activities	
My medical appointments have caused	Gli appuntamenti per le cure e le visite mediche hanno causato problemi alla mia famiglia e/o
problems for my family / carer	alle persone che mi assistono.
How would you rate the services and	alle persone the mi assistono.
care organisation of the most recent care	
you have received, in terms of:	
The provision of follow-up by the different	
caregivers (doctors, nurses,	Le visite di controllo fornite dai diversi operatori
physiotherapists, psychologists, etc.) after	sanitari (medici, infermieri, fisioterapisti,
treatment?	psicologi, ecc.) dopo il trattamento?

#### 4.1.5. Eglish-Danish

Items - English	Danish
We are interested in some things about	
you and your health. Please answer all	Vi er interesserede i at vide noget om dig og
of the questions yourself by	dit helbred. Vær venlig at besvare alle
SELECTING the number that best	spørgsmålene selv ved at sætte en ring
applies to you. There are no "right" or	omkring det svar (tal), som passer bedst på
"wrong" answers.	dig. Der er ingen rigtige eller forkerte svar.

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Do you have any trouble doing strenuous activities, like carrying a heavy shopping	Har du nogen vanskeligheder ved at udføre anstrengende aktiviteter, som f.eks. at bære en
bag or a suitcase?  Do you have any trouble taking a long walk?	tung indkøbstaske eller en kuffert? Har du nogen vanskeligheder ved at gå en lang tur?
Do you need help caring for your feet (e.g. cutting your toenails)?	Har du brug for hjælp til at pleje dine fødder (f.eks. klippe tånegle)?
Do you have any trouble carrying a heavy bag upstairs?	Har du nogen vanskeligheder ved at bære en tung pose op ad trappe?
Do you have any trouble taking a long walk carrying a heavy pack on your back (e.g. a filled rucksack)?	Har du nogen vanskeligheder ved at gå en lang tur, mens du bærer en tung taske på ryggen (f.eks. en fyldt rygsæk)?
Do you have any trouble taking a short walk outside of the house?	Har du nogen vanskeligheder ved at gå en kort tur udendørs?
Do you need help undressing? Do you have any trouble walking for 30	Har du brug for hjælp til at tage tøjet af?
min.?	Har du nogen vanskeligheder ved at gå i 30 min.?
During the past week:	<u>I den forløbne uge:</u>
Have you been limited in doing light housework (e.g. dusting or making the bed)?	Har du været begrænset i udførelsen af let husligt arbejde (f.eks. støve af eller rede seng)?
Have you been limited in doing physically	arbojae (neke. elbve ar eller rede eerig).
demanding recreational activities (e.g., swimming or cycling)?	Har du været begrænset i udførelsen af fysiske fritidsaktiviteter (f.eks. svømning eller cykling)?
Were you limited in doing either your work or other daily activities?	Var du begrænset i udførelsen af enten dit arbejde eller andre daglige aktiviteter?
Have you been limited in doing heavy housework (e.g., washing floors or vacuuming)?	Har du været begrænset i udførelsen af tungt husligt arbejde (f.eks. vaske gulve eller støvsuge)?
Were you limited in pursuing your hobbies or other leisure time activities?	Var du begrænset i at dyrke dine hobbyer eller andre fritidsaktiviteter?
Did pain interfere with your daily activities?	Vanskeliggjorde smerter dine daglige gøremål?
Have you had pain?	Har du haft smerter?
Has pain interfered with your social activities?	Har smerter vanskeliggjort dine sociale aktiviteter?
Has pain made it difficult for you to do the jobs that you usually do around the house?	Har smerter gjort det svært for dig at udføre de opgaver, du plejer at gøre i huset?
Have you had severe pain?	Har du haft svære smerter?
Were you tired?	Har du været træt?
Have you felt weak?	Har du følt dig svag?
Have you felt exhausted?	Har du følt dig udmattet?

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Har du følt at du manglede energi? Have you required frequent or long periods of rest? Have you had a feeling of overwhelming and prolonged lack of energy? Have you had trouble sleeping? Have you had trouble sleeping? Have you had trouble staying a good night's sleep? Have you had trouble staying asleep? Have you had trouble staying asleep? Have you had trouble staying asleep? Have you woken up for long periods during the night? Have you woken up for long periods during the night? Have you lacked appetite? Have you lacked appetite? Have you lacked interest in eating? Have you left nauseated? Har du haft besvær med at få en god nats søvn? Har du været vågen i lange perioder i løbet af natten? Have you lacked appetite? Har du manglet appetit? Have you lacked interest in eating? Har du manglet interesse for at spise? Har du haft kvalme? Har du haft kvalme? Har du haft kvalme? Har du sastet op? Har kvalme eller opkastning været et problem for dig? Has nausea or vomiting interfered with your physical activities like taking a walk? Have you bad stools that were too hard to pass? Have you short of breath? Have you short of breath? Har du haft inføring, som var for hård til, at du kunne komme af med den? Har du haft forstoppelse? Har du haft forstoppelse? Har du haft forstoppelse? Har du haft inføring været så hård, at det gjorde ondt at komme af med den? Har du haft forstoppelse? Har du haft forstoppelse? Har du haft forstoppelse? Har du haft inføring været så hård, at det gjorde ondt at komme af med den? Har du haft forstoppelse? Have you short of breath when walking less than 100 m (100 yds)? Have you felt that nothing could cheer you up? Have you felt that nothing could cheer you up? Have you felt that nothing could cheer you up? Var du bekymret? Var du bekymret? Var du bekymret?	Have you become easily tired?	Er du let blevet træt?
Har du trængt til hyppige eller lange hvileperioder?	Have you lacked energy?	Har du følt at du manglede energi?
Have you had a feeling of overwhelming and prolonged lack of energy? Have you had trouble sleeping? Have you had trouble getting a good night's sleep? Have you had trouble staying asleep? Have you had trouble staying asleep? Have you woken up for long periods during the night? Have you lacked appetite? Have you lacked appetite? Have you lacked interest in eating? Have you lacked interest in eating? Have you vomited? Have you vomited? Have you wormited? Har du haft besvær med at blive ved med at sove? Har du været vågen i lange perioder i løbet af natten? Har du været vågen i lange perioder i løbet af natten? Har du manglet appetit? Har du manglet appetit? Har du manglet appetit? Har du manglet interesse for at spise? Har du haft kvalme? Har du haft kvalme? Har du haft kvalme? Har du haft walme? Har walme eller opkastning været et problem for dig? Has nausea or vomiting interfered with your physical activities like taking a walk? Have you been constipated? Have you shod stools that were too hard to pass? Have you shod stools that were too hard to pass? Har du haft forstoppelse? Har du haft sifving, som var for hård til, at du kunne komme af med den? Har du haft åndenød?	Have you required frequent or long	
and prolonged lack of energy? Have you had trouble sleeping? Have you had trouble getting a good night's sleep? Have you had trouble staying asleep? Have you woken up for long periods during the night? Have you woken up for long periods during the night? Have you lacked appetite? Have you lacked appetite? Have you lacked interest in eating? Have you lacked interest in eating? Have you lacked interest in eating? Har du manglet appetit? Har du manglet appetit? Har du haft besvær med at blive ved med at sove? Har du været vågen i lange perioder i løbet af natten? Have you lacked appetite? Har du manglet interesse for at spise? Har du haft kvalme? Har du haft kvalme? Har du kastet op? Har kvalme eller opkastning været et problem for dig? Har kvalme eller opkastning været et problem for dig? Have you been constipated? Har du haft forstoppelse? Har du haft afføring, som var for hård til, at du kunne komme af med den? Har du haft afføring været så hård, at det gjorde ondt at komme af med den? Were you short of breath? Were you short of breath when walking more than 100 m (100 yds)? Were you short of breath when walking less than 100 m (100 yds)? Have you felt tulnerable? Have you felt tulnerable? Har du følt dig sårbar? Har du følt dig elendigt til mode? Did you feel depressed? Følte du dig deprimeret? Did you feel depressed? Did you feel depressed? Følte du dig deprimeret? Did you feel depressed? Følte du dig deprimeret? Var du bekymret?	periods of rest?	Har du trængt til hyppige eller lange hvileperioder?
Have you had trouble sleeping? Have you had trouble getting a good night's sleep? Have you had trouble staying asleep? Have you had trouble staying asleep? Have you woken up for long periods during the night? Have you forced yourself to eat? Have you lacked appetite? Have you lacked appetite? Have you lacked appetite? Have you lacked interest in eating? Have you lacked interest in eating? Have you vomited? Har du manglet interesse for at spise? Har du haft kvalme? Har du manglet interesse for at spise? Har du haft kvalme? Har wou vomiting been a problem for dig? Has nausea or vomiting interfered with your physical activities like taking a walk? Have you been constipated? Have you had stools that were too hard to pass? Have you short of breath when walking less than 100 m (100 yds)? Were you short of breath when walking less than 100 m (100 yds)? Were you short of breath when walking less than 100 m (100 yds)? Have you felt tulnerable? Have you felt that nothing could cheer you up? Har du falf wall at flip and		Har du haft en følelse af en overvældende og
Have you had trouble getting a good night's sleep?  Have you had trouble staying asleep?  Har du haft besvær med at få en god nats søvn?  Have you woken up for long periods during the night?  Have you worced yourself to eat?  Have you lacked appetite?  Have you lacked appetite?  Have you lacked interest in eating?  Have you lacked interest in eating?  Have you felt nauseated?  Har du manglet interesse for at spise?  Har du haft kvalme?  Har du manglet interesse for at spise?  Har du haft kvalme?  Har du haft spise?  Har du haft kvalme?  Har du haft kvalme?  Har du haft forstoppelse?  Har valme eller opkastning været et problem for dig?  Har valme eller opkastning været et problem for dig?  Har valme eller opkastning været et problem for dig?  Har valme eller opkastning været et problem for dig?  Har valme eller opkastning været et problem for dig?  Har du haft forstoppelse?  Har du haft afføring, som var for hård til, at du kunne komme af med den?  Har du haft afføring været så hård, at det gjorde ondt at komme af med den?  Har du haft åndenød?  Did you have severe shortness of breath?  Har du haft åndenød?  Have you short of breath when walking more than 100 m (100 yds)?  Have du åndenød, når du gik mere end 100 m?  Have du åndenød, når du gik mindre end 100 m?  Have du åndenød, når du gik mindre end 100 m?  Have du åndenød, når du gik mindre end 100 m?  Have du åndenød, når du gik mindre end 100 m?  Have du åndenød, når du gik mindre end 100 m?  Have du åndenød, når du gik mindre end 100 m?  Have du åndenød, når du gik mindre end 100 m?  Have du åndenød, når du gik mindre end 100 m?  Have du åndenød har du gik mindre end 100 m?  Have du åndenød har du gik mindre end 100 m?  Have du åndenød har du gik mindre end 100 m?  Have du åndenød har du gik de gelendigt til mode?  Have you felt miserable?  Har du følt dig elendigt til mode?	and prolonged lack of energy?	langvarig mangel på energi?
Har du haft besvær med at få en god nats søvn? Have you had trouble staying asleep? Har du haft besvær med at blive ved med at sove? Have you woken up for long periods during the night? Have you forced yourself to eat? Har du været vågen i lange perioder i løbet af natten? Have you lacked appetite? Har du manglet appetit? Have you lacked interest in eating? Har du manglet interesse for at spise? Har du haft kvalme? Har du haft sate top? Har kvalme eller opkastning været et problem for dig? Har kvalme eller opkastning vanskeliggjort fysiske aktiviteter som at gå en tur? Har du haft forstoppelse? Har du haft afføring, som var for hård til, at du kunne komme af med den? Har din afføring været så hård, at det gjorde ondt at komme af med den? Were you short of breath when walking more than 100 m (100 yds)? Were you short of breath when walking less than 100 m (100 yds)? Have du åndenød, når du gik mere end 100 m? Did you feel tense? Har du følt dig sårbar? Have you felt tulnerable? Har du følt dig sårbar?	Have you had trouble sleeping?	Har du haft besvær med at sove?
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Did you worry? Var du bekymret?		
	•	
HI AVE YOU IER SAU! HOAF OU IVII OU IVII OU IVIST	Have you felt sad?	Har du følt dig trist?

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Have you been watching yourself closely	Har du holdt tæt øje med eventuelle nye
for any new symptoms?	symptomer?
To what extent have you been troubled	I hvilken grad har du været generet af bivirkninger
with side-effects from your treatment?	ved din behandling?
Have you worried about recurrence of	Har du været bekymret for at din sygdom skal
your disease?	vende tilbage?
Have you been afraid of tumor	Tondo madger
progression?	Har du været bange for tumor udvikling?
Have you worried about your health in the	That du vacrot bange for tamor duvitaing.
future?	Har du været bekymret for dit helbred i fremtiden?
How much has your disease been a	That du været bertyffinet for dit fielibred i fremtidelit.
burden to you?	Hvor meget har din sygdom belastet dig?
Because of your experience with cancer,	
have you had to limit your life plans or	Har du været nødt til at begrænse dine planer eller
goals?	mål for livet?
I have felt at peace with myself	Har du følt indre ro?
Have you had difficulty remembering	Llow du bott over the distribution
things?	Har du haft svært ved at huske?
Have you had difficulty in concentrating on	Handy bott averet yed at least a strong discount in a
things, like reading a newspaper or	Har du haft svært ved at koncentrere dig om ting
watching television?	som f.eks. at læse avis eller se fjernsyn?
Have you been forgetful?	Har du været glemsom?
Have you had difficulty remembering what	Har du haft svært ved at huske, hvad nogen lige
someone just told you?	fortalte dig?
Have you had difficulty maintaining	
concentration even when doing something	Har du haft svært ved at fastholde
important?	koncentrationen, selv når du lavede noget vigtigt?
As a result of your physical condition or	
medical treatment, have you preferred to	Har du som følge af din fysiske tilstand eller
spend time alone?	medicinsk behandling foretrukket at være alene?
As a result of your physical condition or	Har du som følge af din fysiske tilstand eller
medical treatment have you been less	medicinsk behandling haft sværere ved at se
able to see your family or friends?	familie og venner?
As a result of your physical condition or	Har du som følge af din fysiske tilstand eller
medical treatment, have you spent less	medicinsk behandling brugt mindre tid sammen
time with your family or friends?	med familie eller venner?
As a result of your physical condition or	Har du som følge af din fysiske tilstand eller
medical treatment, have you felt isolated	medicinsk behandling følt dig isoleret fra familie
from your family or friends?	eller venner?
As a result of your physical condition or	Har du som følge af din fysiske tilstand eller
medical treatment, have you found it hard	medicinsk behandling fundet det vanskeligt at tage
to make contact with people?	kontakt til andre mennesker?

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Has your physical condition or medical	Har din fysiske tilstand eller medicinske
treatment interfered with your family life?	behandling vanskeliggjort dit familieliv?
Has your physical condition or medical	Har din fysiske tilstand eller medicinske
treatment interfered with your social	
activities?	behandling vanskeliggjort din omgang med andre mennesker?
	memesker:
Has your physical condition or medical	Har din fusicka tiletand allar madicinak hahandling
treatment interfered with your	Har din fysiske tilstand eller medicinsk behandling
relationships with your family or friends?	vanskeliggjort dit forhold til familie eller venner?
Have you been dissatisfied with your	Llow du verret utilfre de med dit fueielse udee ende?
physical appearance?	Har du været utilfreds med dit fysiske udseende?
Has the disease or treatment affected	Har din sygdom eller behandling påvirket dit sexliv
your sex life (for the worse)?	(gjort det dårligere)?
Have you worried about your ability to	
have children?	Har du været bekymret for din evne til at få børn?
Have you worried that you are a burden to	Har du været bekymret for at blive en byrde for
other people	andre?
Have you worried about becoming	Har du været bekymret for at blive afhængig af
dependent on others?	andre?
	Har din fysiske tilstand eller medicinske
Has your physical condition or medical	behandling medført økonomiske vanskeligheder
treatment caused you financial difficulties?	for dig?
Has your physical condition or medical	Har din fysiske tilstand eller medicinske
treatment caused you financial difficulties	behandling givet dig økonomiske problemer, der
leading to changes in your lifestyle?	har medført ændringer i din livsstil?
As a result of your physical condition or	Har du, som følge af din fysiske tilstand eller
medical treatment, have you had less	medicinske behandling, haft færre penge at bruge
money to spend on yourself (e.g., for	på dig selv (f.eks. til at købe noget til dig selv, som
buying yourself something that you would	du gerne vil have, men ikke nødvendigvis har brug
like to have but don't necessarily need)?	for)?
As a result of your physical condition or	Har du, som følge af din fysiske tilstand eller
medical treatment, have you had	medicinske behandling, haft problemer med at
difficulties paying any of your regular	betale dine faste udgifter (f.eks. husleje, forsikring,
expenses (e.g. rent, insurance, phone)?	telefon)?
Since the diagnosis and treatment of your	
cancer: Have you had problems with	Siden diagnosticeringen og behandlingen af din
obtaining insurance, loans, and/or	kræft: Har du haft problemer med at få forsikring,
a mortgage?	lån og/eller et realkreditlån?
Since the diagnosis and treatment of your	Siden diagnosticeringen og behandlingen af din
cancer: Have you received support from	kræft: Har du været tilfreds med den støtte du har
your employer e.g. arranging flexible	modtaget fra din arbejdsgiver fx med at arrangere
working?	fleksible arbejdstider?
Since the diagnosis and treatment of your	Siden diagnosticeringen og behandlingen af din
cancer: Have you made positive lifestyle	kræft: Har du lavet positive ændringer af din livsstil

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changes (e.g., more exercise, healthy	(f.eks. mere motion, sund mad, skåret ned på
food, cutting down smoking)?	rygning)?
For the following questions please	
circle the number between 1 and 7 that	For de følgende spørgsmål bedes du vælge et
best applies to you.	tal mellem 1 og 7
How would you rate your overall quality of	Hvordan vil du vurdere din samlede livskvalitet i
life during the past week?	den forløbne uge?
How would you rate your overall health	Hvordan vil du vurdere dit samlede helbred i den
during the past week?	forløbne uge?
Have you had any other significant	Har du haft andre væsentlige symptomer eller
symptoms or problems that have not been	problemer, som ikke er nævnt i spørgsmålene
mentioned in the questions above?	ovenfor?
Yes. Please write down the most	
important ones (up to three), and rate	
to what extent you have experienced	Hvis Ja, skriv de vigtigste (højst 3) og angiv i
these symptoms or problems during	hvilken grad du har haft symptomet eller
the past week:	problemet i den sidste uge:
During the past week, to what extent	Gennem den sidste uge, i hvilken grad har du
have you experienced:	haft:
Symptom/problem A:	Symptom 1
Symptom/problem B:	Symptom 2
Symptom/problem C:	Symptom 3
We are interested in your MOST	
RECENT experience of the care you	Vi er interesseret i dine AKTUELLE oplevelser
have received and the communication	med den pleje du har fået og den
you have had with the professional(s)	kommunikation du har haft med de
who treat you.	sundhedsprofessionelle der behandler dig.
Have you been satisfied with your	Har du været tilfreds med kommunikationen
communication with your professional(s)?	mellem dig og de sundhedsprofessionelle?
	Har du følt at du og de sundhedsprofessionelle, du
Have your professional(s) spent enough	var i kontakt med, havde en fælles forståelse af
time talking with you?	din sygdom og din behandling?
11.	Hvordan vil du vurdere opfølgning på den
Have your professional(s) used language	pleje/behandling du senest har fået af forskellige
that you understand (avoided medical	sundhedsprofessionelle (læger, sygeplejersker,
jargon, used clear terms)?	fysioterapeuter, psykologer osv.)?
Have your professional(s) taken into	
account how you prefer to receive	Har du været tilfreds med den pleje du har fået
information?	gennem den sidste uge?
Have you felt that you and your	
professional(s) had a shared	Har du været tilfreds med den information du har
understanding of your disease and	fået gennem den sidste uge (fx om sygdommen
treatment?	og dens behandling)?

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My decisions about care and treatment	
have been respected by my	Mine beslutninger om pleje og behandling er
professional(s)	blevet respekteret af mine professionelle
I have been given the opportunity to	
discuss my treatment plan with my	Jeg har fået mulighed for at diskutere min
professional(s)	behandlingsplan med mine fagpersoner
Have you felt satisfied with the care you	Har du været tilfreds med den behandling, du har
have received?	fået?
Have you felt satisfied with the information	
you have received (e.g. about the disease	Har du været tilfreds med de oplysninger, du har
and its treatment)?	fået (fx om sygdommen og behandlingen)?
<b>During the past 4 weeks:</b>	
My medical appointments have interfered	Mine lægeaftaler har forstyrret mit
with my work / household activities	arbejde/husholdningsaktiviteter
My medical appointments have caused	Mine lægeaftaler har forårsaget problemer for min
problems for my family / carer	familie/plejer
How would you rate the services and	Hvordan vil du vurdere ydelserne og
care organisation of the most recent	plejeorganiseringen af den seneste pleje, du
care you have received, in terms of:	har modtaget i forhold til:
	Har du haft nogen yderligere vigtige symptomer
	eller problemer, som ikke er blevet nævnt i
The provision of follow-up by the different	spørgsmålene ovenfor? (Have you had any
caregivers (doctors, nurses,	additional, important symptoms or problems that
physiotherapists, psychologists, etc.) after	have not been mentioned in the questions
treatment?	above?)

#### 5. References

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