



# EORTC QUALITY OF LIFE GROUP TRANSLATION PROCEDURE

Fourth Edition  
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Quality of Life Group

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## ABBREVIATIONS

BT – back translation

EORTC – European Organisation for Research and Treatment of Cancer

FT – forward translation

PROM – patient-reported outcomes measure

QLG – Quality of Life Group

QLQ – quality of life questionnaire

QOL – quality of life

TU – Translation Unit

## INTRODUCTION

The European Organisation for Research and Treatment of Cancer (EORTC) Quality of Life Group (QLG) is a group of international researchers who focus on quality of life research and develop questionnaires to measure the quality of life of cancer patients. With an ever-increasing number of clinical trials performed internationally, in order to measure patients' quality of life across different cultures and countries, it is of paramount importance to ensure consistent translation and cultural equivalence of the measures.

In its questionnaire system, the EORTC QLG has adopted a modular approach, with a core questionnaire (QLQ-C30) that covers problems and symptoms experienced by the general population of cancer patients, and modules that accompany the core questionnaire and are site-, symptom- or treatment-specific. There are also a few stand-alone questionnaires, measuring other aspects such as communication, information or sexual health.

All the EORTC QLG's questionnaires are developed in accordance with the EORTC Guidelines (Johnson 2011), including four phases of development. All phases have to be performed in an international setting and require multiple language versions. The translations used for module development must be developed in accordance with the standard EORTC translation procedure as described in this Translation Manual.

Questionnaires can be used by external users depending on the status of the module. Only fully validated and partially validated (Phase 3 completed) modules are available for use in studies. A full list of validated questionnaires and modules under development is available on the EORTC QLG's website: <http://groups.eortc.be/qol>

All EORTC questionnaires are copyrighted. Information on the licensing and use of the questionnaires is published on the EORTC QLG's website. No unlicensed use of the questionnaires is permitted.

## UPDATE OF THE TRANSLATION PROCEDURE

The current edition is based on the previous editions of the Translation Manual: 1998, 2002, 2009.

This update contains a new step in the translation procedure (proofreading – see [PROOFREADING](#)) and a more detailed explanation of the cultural adaptation process (see [CULTURAL ADAPTATION](#)). The translation procedure has also been described in greater detail and updated according to the latest literature in the field (for example, reconciliation – see [RECONCILIATION](#)).

The procedure is described for the process followed in the case of academic translations. All translations of the EORTC questionnaires, which the EORTC subcontracts to specialised language service providers, follow these steps with additional quality control steps in the form of extra reviews and proofreading stages. The translation process for commercial projects has been summarised in the section titled [COMMERCIAL TRANSLATION PROJECTS](#).

## AIM OF THE TRANSLATION PROCEDURE

A rigorous translation procedure of patient-reported outcome measures (PROMs) enables the collection and pooling of data from various linguistic and cultural regions. All EORTC questionnaires are developed in English as the source language and follow a parallel development that includes a number of countries from various geographical regions to ensure inclusion of a range of linguistic and cultural populations.

All translations of the EORTC questionnaires have to be developed in collaboration with the EORTC and follow the EORTC Translation Procedure. As a result of the translation process, the final version should be correct linguistically and conceptually, comprehensible to people of all levels of education, culturally acceptable and inoffensive, and reflect the source version's wording and structure, as well as the standard layout and formatting of the EORTC questionnaires.

The translation process can be initiated, performed and finalised **ONLY** with prior consent from the EORTC Translation Unit (TU).

## SUMMARY OF THE TRANSLATION PROCESS

The translation process for a new language version starts with a request sent to the TU. The TU makes sure that no such questionnaire already exists or is under development, and prepares a translation package, which contains all necessary templates and pre-translated files.

The next step of the process requires two forward translations of the English version of the questionnaire. The translations must be done by two translators who are native speakers of the target language and can understand the English version. Then a reconciled translation is made on the basis of the two translations – that is, a third person reviews the two translations to achieve the best possible version by choosing one of the two translations or by combining them on the basis of their correctness, wording etc.

The next step is to translate the reconciled version back into English, again done by two translators who should be native speakers of English or at least have a very good command of English. The results of all these steps (forward translation, reconciliation and backward translation with comments) should be put into a back translation report which will allow the TU to review the process. The report should also include comments as to which forward translation is used in the reconciled version.

Once the report has been reviewed and all issues have been resolved, the preliminary translation is proofread by an external proofreader (a translator from a translation agency chosen by the TU) and all their suggestions/corrections are analysed and discussed. Once the discussion has reached a consensus, the translation can undergo linguistic validation, the so-called pilot-testing. It includes a group of 10–15 patients, who comment on the comprehensibility of the translation. All their comments are pooled and summarised in a pilot-testing report, which should be sent for review to the TU. Once all comments have been analysed and discussed, the TU prepares the final version of the translation and closes the project.

This manual is directed at academic researchers wishing to develop a new language version of an EORTC questionnaire. It ensures that the translations fulfil EORTC quality standards.

In addition, translations commissioned by the EORTC from professional translation services providers on a project-based level must adhere to the described standards, although additional elements of their own SOPs can also be used with the prior consent of the EORTC.

## ROLES AND RESPONSIBILITIES

### Roles

#### TU – Translation Unit

Any member of the EORTC Translation Unit coordinating the translation project. The TU is responsible for informing the requesters about the translation process, preparing the files, reviewing the reports, finalising the project and general communication with the collaborators.

#### TC – Translation Coordinator

Most of the time the person that requested a new language version and has decided to translate it into their native language. The TC is responsible for organising the translation process, collecting the forward translations, reconciling them (or having them reconciled by a third person), collecting the back translations, preparing reports, answering queries, performing the pilot-testing and updating the TU on the progress of the project.

#### FT translators – Forward translators

Native speakers of the target language who perform the translation from English into the required language.

#### BT translators – Back translators

English native speakers or native speakers of the target language with fluency in English who perform the translation of the reconciled version back into English.

#### Proofreader

A professional translator collaborating with a translation agency who performs proofreading of the reconciled translation.

### Responsibilities matrix

	Forward translation	Reconciliation	Back translation	Report	Review	Proof-reading	Review	Pilot-testing	Report	Review	Final steps
Forward translators	X										
TC		X		X			X	X	X		
Back translators			X								
TU					X					X	X
Proofreader						X					

## 1. PREPARATION STAGE

The TU has to be contacted in order to grant permission for the development of each and every new language version. No translation can be done without the consent and involvement of the TU without breaching the copyright of the QOL questionnaires. Moreover, it is the only way to ensure that there is not already an existing or ongoing translation, and to avoid duplicates, which are not allowed.

Once contacted, the TU checks whether or not the translation already exists, is ongoing or was ever started. They communicate the status to the requester and, if there is no such translation, explain how it can be developed. If the requester confirms their willingness to perform the translation process, the TU prepares the necessary files: the English original, a file with any pre-translations, and in the case of previously started and then cancelled projects, any files with those steps of the procedure that have already been performed.

The TC prepares the files with pre-translations by:

- 1) consulting the EORTC Item Library;
- 2) pre-processing the files using the translation memory software.

The files contain translations of identical or similar versions of the instructions, time frames, response scales and items, developed in the past for other modules translated into the language in question. The existing translation of instructions, time frames and response scales should be used without changes, unless there is a major reason for modifications. In such a case, all suggested changes should be explained in the back translation report together with a new version of the translation and a back translation into English. All changes have to be approved by the TU.

The items provided as pre-translations should always be reviewed. In order to remain consistent with other modules, the identical items should be used without changes, unless there are major mistakes, such as mistranslations, typos, grammatical errors, etc. All such problems should be described in the back translation report together with suggestions on how they can be corrected, as well as back translations of the new versions.

The pre-translations of items that are similar should be used as a model to be followed in the correct translation. For example, if the original item reads “Have you had pain in your jaw?” and the pre-translation reads “Have you had pain in your back?”, the new, correct translation should use the provided wording for “Have you had pain in your...” and only change the noun from “back” to “jaw”. This way the items within one language are consistent throughout the modules.

The forward translators should receive the English original and the pre-translations.

## 2. FORWARD TRANSLATIONS

The forward translation step requires two separate, independently done translations from English into the target language. The translations should be done by native speakers of the native language with a very good command of English. They do not have to be professional translators.

The forward translators should receive the English original questionnaire and the file with any pre-translations. They should review the pre-translated items and use them as much as possible. In the translation process they should make sure that the translations are correct when it comes to grammar, syntax, orthography and punctuation, that the language is of current use and comprehensible, and that the wording and structure of the translation follows the English original.

## 3. RECONCILIATION

The two forward translations are reconciled into one by either the TC or a third translator. The aim of the reconciliation is to choose or build from the two forward translations an optimal translation of each item.

The reconciliation process has been described in: Koller M. *et al. The process of reconciliation: evaluation of guidelines for translating quality-of-life questionnaires*. Expert Rev Pharmacoecon Outcomes Res 2012 Apr;12(2): 189-197.

As described in the above-mentioned paper, the options for reconciliation are as follows:

- 1 to use forward translation A without changes
- 2 to use forward translation B without changes
- 3 to slightly change translation A
- 4 to slightly change translation B
- 5 to make a new translation out of the two by adapting translation A to translation B
- 6 to make a new translation out of the two by adapting translation B to translation A
- 7 to make a new translation out of the two with some modifications/additions, adapting translation A to B
- 8 to make a new translation out of the two with some modifications/additions, adapting translation B to A
- 9 to prepare a completely new translation C (only if there are major reasons why neither of the two forward translations can be used).

The criteria for choosing any of these options are:

- 1 Source and comprehensibility:

- 1.1 Reflects best the conceptual definitions and meaning of the source text – what is the concept of the source item? Which translation reflects it in the closest way?
- 1.2 Reflects best the stress of the source text (what the source text's main point is) – what is the main point of the source item? Which translation reflects it in the closest way?
- 1.3 Is understandable for a lay person without medical knowledge – are there any medical terms which might be difficult for a lay person?
- 1.4 Is understandable to a population of varied education levels – are there any words or structures that might be difficult for people with a low education level?
- 1.5 Is as close as possible to the source text – which translation is generally closer to the source item, following the same structure, not adding any information that is not present in the source, etc.?
- 1.6 Reads more naturally in the target language – which translation sounds more natural in the target language, less like a translation and more like it has been written originally in this language?
- 2 Cultural:
  - 2.1 Is culturally appropriate in the scope of sensitive topics
  - 2.2 Is culturally appropriate in the scope of cultural differences of life
- 3 Grammatical:
  - 3.1 The syntax is correct
  - 3.2 The verb forms and tenses are correct
  - 3.3 Gender and number are adapted and correct
  - 3.4 Other elements are correct (especially articles, prepositions, etc.)
- 4 Terminology:
  - 4.1 Includes all the keywords
  - 4.2 Is semantically precise
  - 4.3 Vocabulary/terminology is consistent throughout the translation

## 4. BACK TRANSLATIONS

The reconciled translation is translated back into English by two translators working independently of one another. Optimally they should be native speakers of English, but if there are difficulties finding such people, the back translations can be done by people who are not native speakers but have a good command of English. They do not have to be professional translators.

The two translators should receive only the reconciled translation and should work independently and without knowing the original questionnaire in English. In their translations they should follow the structure and wording as closely as possible in order to reflect the translation in an accurate way that allows the TU to review the back translations.

## 5. BACK TRANSLATION REPORT

The back translation report should include all five translations: two forward translations from English into the required language, the reconciled translation, the two back translations into English and any comments regarding the translations.

All changes to the pre-translated items should be marked and explained. The new suggested version should be included and back translated into English.

The completed report is then sent to the TU for review. The TU will review the report, checking whether it is complete, and analysing the reconciliation process and the relationship between the English original and the two back translations. If there are any questions, the TU will add them into the report and send it back to the TC.

The TC provides answers to the questions and sends them back to the TU. The process is repeated until all questions have been answered and a consensus on the wording has been reached.

On the basis of the consensus wording, the TU prepares a preliminary translation.

## 6. PROOFREADING

The preliminary translation is sent to a professional proofreader (a translator working for one of the translation agencies with whom the TU collaborates) for a review. The proofreader compares the preliminary translation with the English source questionnaire, and prepares a report with all the changes and suggestions together with explanations of why they are needed.

The TU sends the report to the TC for approval. No changes are made to the translation at this step without the approval of the TC. All questions of the TC are sent to the TU and discussed with the proofreader in order to reach a consensus.

When the wording has been agreed, the TU prepares the interim translation ready for pilot-testing.

## 7. PILOT-TESTING

The translated questionnaire should be pilot-tested on a group of patients in order to check its comprehensibility in the target language. The group should comprise 10–15 patients who belong to the population that is the target of the questionnaire. If a questionnaire includes sections intended for specific populations (for example only for women or only for patients after surgery), each such section should be pilot-tested on at least 5 patients who fulfil the criteria.

All patients should be native speakers of the target language and constitute a representative group in terms of the socio-demographic characteristics (gender, age and education).

The pilot-testing step consists of two parts:

1. Patients receive the translated questionnaire and fill it in.
2. A researcher discusses the translation with the patients individually or in a focus group setting.

### 7.1 PILOT-TESTING INTERVIEW

During the debriefing the interviewing researcher should go through each part of the questionnaire asking the patients whether the translation was:

1. Difficult to answer
2. Confusing
3. Difficult to understand
4. Upsetting/offensive

A probe for general comprehension is the question: How would you ask this question in your own words?

If there are any comments, the patients should be invited to reword the question in a way that would be easier to understand, less confusing, upsetting or offensive.

All comments should be recorded on the patient response sheets. The patient response sheet template is included in Appendix 3.

## 7.2 PILOT-TESTING REPORT

On the basis of the results of the pilot-testing, the TC should compile a summary in the translation report. All items that elicited comments should be filled in with information on what the problem was, with the patients' comments translated into English, and analysis of the comments. If changes to the wording are suggested, they should be explained and the new version should be back translated into English.

An electronic copy of the questionnaires filled in by patients and the patient response sheets should be added as an appendix to the report.

The pilot-testing report is then sent to the TU for review. The comments and suggestions are analysed and any questions will be sent back to the TC.

## 7.3 RE-TESTING

If any items elicited comments because of problems with comprehensibility and the TC or interviewer suggested a change in the wording that was approved, the item has to be re-tested on a few patients, including the patients that reported the comprehension problems and some that did not report any problems. The re-test serves to ensure that the problem has been solved and that the new version is understandable for everybody.

In the re-test the interviewer should only check the problematic items with the patients and not the whole questionnaire. The comments should be communicated to the TU as a written report.

When all issues have been solved and all changes approved, the TU prepares the final translation based on the wording agreed in the pilot-testing phase.

## 8. FINAL TRANSLATION

The final translation is sent to the TC for final approval. Once approved, the TU closes the project, making the translation available for use, archiving the files from the translation process, and adding it to the EORTC Item Library and/or translation memory.

## CULTURAL ADAPTATION

The cultural adaptation procedure applies to languages which are spoken in more than one country or as variants. Requests are analysed by the TU on a case-by-case basis. As a general rule, no cultural adaptations of the English version are possible and the English questionnaire is to be used in one form in all English-speaking countries and populations.

For a number of languages used in the module development process, the strategy of involving forward translators from two main variants of the language is applied; for example, a translator from France and the French-speaking part of Belgium for European French, a translator from Germany and Austria for German, and a translator from the Netherlands and the Dutch-speaking part of Belgium for Dutch.

To avoid the proliferation of inconsistent translations, cultural adaptations are always made from one basic version, as in the case of Spanish, where all adaptations are based on the Spanish for Spain translation.

In case the need for a cultural adaptation is not clear, the requester might be asked by the TU to provide evidence that the local variant of the language differs substantially from the existing translation. Examples of evidence are:

1. Results of pilot-testing on at least 5 patients that show lack of comprehension of the current translation.
2. Results of a survey among at least 10 health-care providers, indicating that the current translation does not correctly describe symptoms or problems.
3. A reference to a language academy, a dictionary or other source, describing and explaining any problems with the current translation.

If the TU decides that the need for a cultural adaptation is substantiated, the requester will receive an e-mail with information on the process, all templates and the existing translation.

### 1. REVIEW OF THE EXISTING TRANSLATION

The first step of the cultural adaptation process is the review of the existing translation; for example, of the Spanish for Spain translation in the case of an adaptation for Mexico. The TC prepares a report including all items that in their opinion require changes. In the report they should include the existing version, the new version, a back translation of the new version and explanation on what was changed and what were the reasons for the change.

The report is then sent to the TU for review. If there are any questions, the report is sent back to the TC and the process is reiterated until consensus has been reached.

## 2. FURTHER PROCESS

The further process of cultural adaptation is identical to steps 6–8 of the standard translation procedure.

## COMMERCIAL TRANSLATION PROJECTS

Commercial translation projects are done upon request from commercial users of the EORTC instruments. Such users should first set up a user agreement for the use of the questionnaires with an appendix for the development of a new language version.

All translation projects are sub-contracted out and coordinated by the TU, and performed by one of the selected language services providers. Translations of the EORTC instruments done by other companies or not contracted through the TU cannot be used due to breach of copyright of the QOL questionnaires.

The translation process includes all the steps of the standard translation procedure plus additional reviews/proofreading. The language service providers are bound by agreements and obliged to follow the EORTC Translation Procedure along with any additional in-house standard operating procedures as long as they do not interfere with the EORTC standards.

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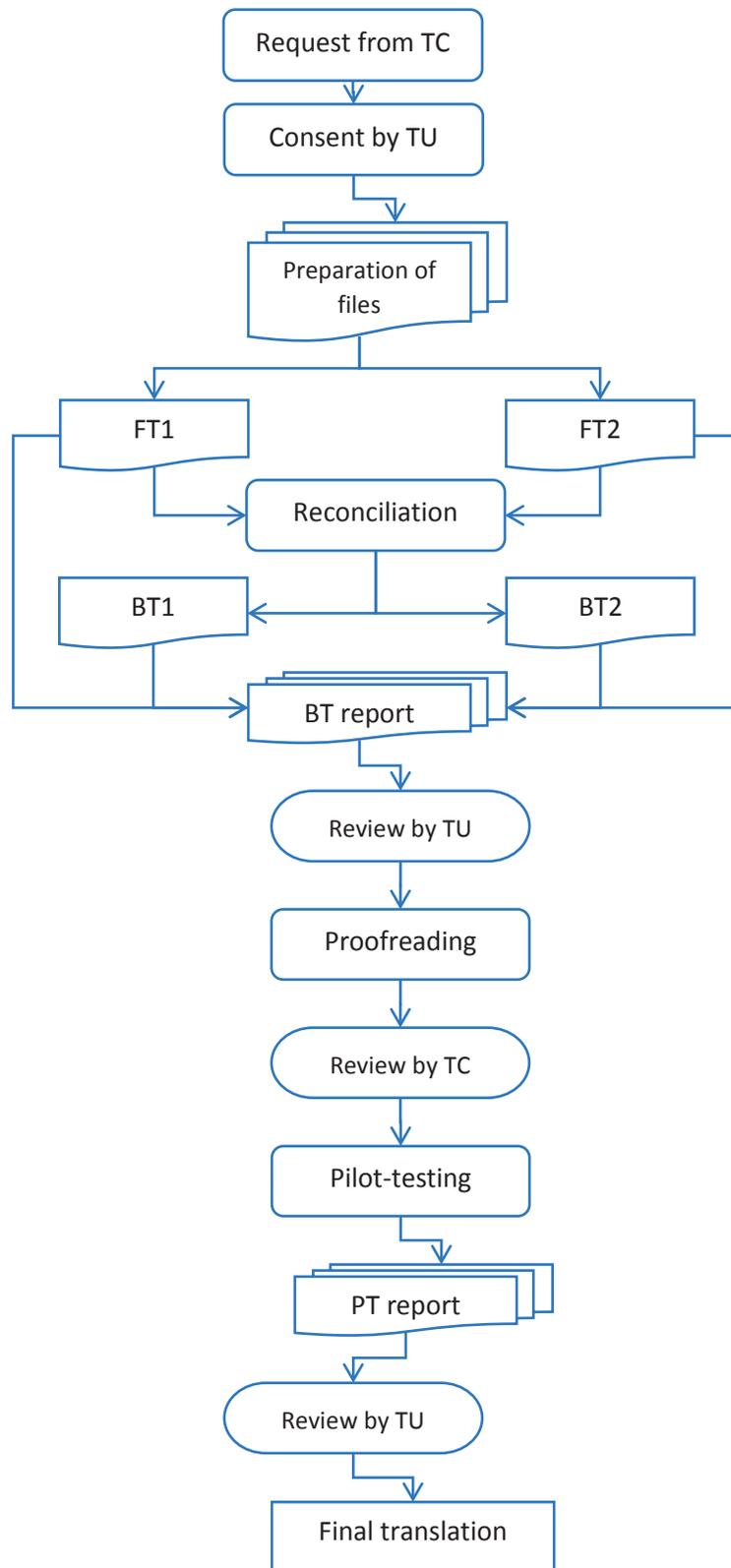
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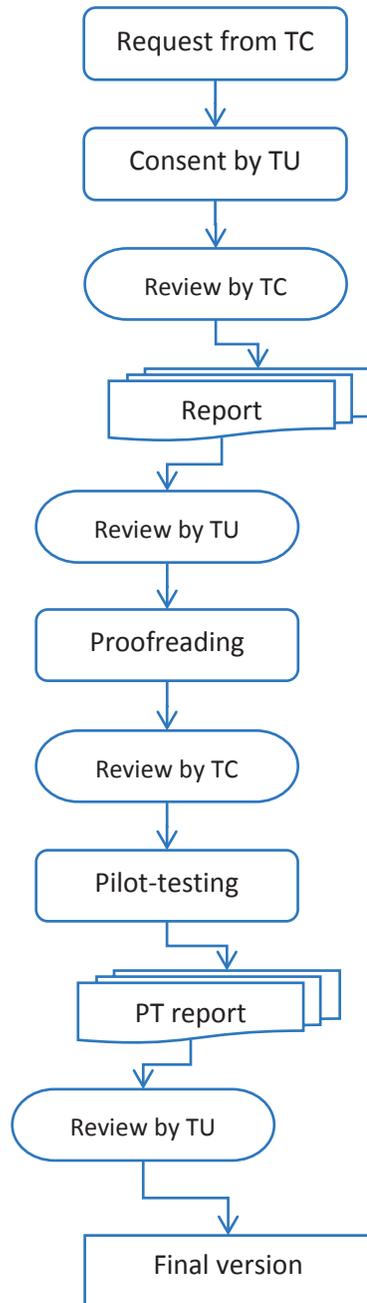
## APPENDICES

APPENDIX 1  
Translation flowchart



## APPENDIX 2

### Cultural adaptation flowchart



APPENDIX 3

Pilot-testing templates – item sheet

**Pilot-Testing:                      Sample of a patient response sheet  
(to be completed by the interviewer)**

**Question number** \_\_\_\_\_

**Comments**

a.    Difficult?                      Yes

---

---

b.    Confusing?                      Yes

---

---

c.    Difficult words?                      Yes

---

---

d.    Upsetting?                      Yes

---

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e.    How would you paraphrase this question? How would you ask it?

---

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APPENDIX 4

Pilot-testing templates – summary per item

**Pilot-Testing: Summary of patient responses by item**

(Total number of patients interviewed = N)

Question number \_\_\_\_\_

	Number of patients who answered “Yes”	Comments
a. Difficult?	<input type="checkbox"/>	<hr/> <hr/> <hr/>
b. Confusing?	<input type="checkbox"/>	<hr/> <hr/> <hr/>
c. Difficult words?	<input type="checkbox"/>	<hr/> <hr/> <hr/>
d. Upsetting?	<input type="checkbox"/>	<hr/> <hr/> <hr/>
e. Alternative wording suggested by patients		<hr/> <hr/> <hr/> <hr/>





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