

Translation Methodology Certification Letter

ICON Language Services Project No.: 0189-TR-0509

Source/Questionnaire Name(s): Family-Reported-Outcome-Measure-FROM-16-English-version

Source Language: English

This letter is to certify the translation and linguistic validation methodology used for the document(s) listed above. The source file(s) was provided to ICON Language Services by Janssen R&D. Translations are intended to be complete and accurate translations of a corresponding source file.

ICON Language Services is an ISO 17100-certified translation provider with over 15-years of experience specializing in the translation of documentation related to global clinical research. ICON Language Services specializes in the translation and linguistic validation of patient reported outcomes (PRO) measures. All linguists (translators and proofreaders) used on this project meet the minimum requirements of the ISO 17100 standard.

The table below indicates the methodology used for the translation task. The process was overseen by a project manager at ICON Language Services. When linguistic validation is performed, the translation task is also overseen by a qualified and experienced individual in the target country ("lead translator").

TARGET LANGUAGE/COUNTRY	DATE OF FINALIZATION	CONCEPT ELABORATION	DUAL FORWARD TRANS.	DUAL BACK TRANS.	COGNITIVE DEBRIEFING [‡]
Italian (Italy)	11OCT2021	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>

[‡] With 5 healthy subjects

Concept Elaboration

The ICON LS project manager assessed the English source text and developed translation guidelines which elaborated on any text that posed an observable risk for variance in interpretation by linguists throughout the world. The result of this stage was a report which was sent along with the source English text to all translators involved.

Dual Forward Translation (including reconciliation)

The source text was translated into the target language by two independent translators. Each forward translator was a native speaker of the target language or qualified to translate into that language. The first forward translation was done by the lead translator. The second forward translation was done by an independent translator. The two forward translations were then reconciled into a third translation by the lead translator. Any issues that arose from this stage were discussed with the project manager.

Dual Back Translation (including review)

The reconciled translation was back translated into English by two independent translators. Each back translator was a native English speaker or qualified to translate into English, fluent in the target language, and had no prior knowledge of the source document.

The back translations were reviewed against the source document by the project manager. Any issues arising from this review were passed to the lead translator for comment. Where appropriate, the lead translator provided alternative wordings (along with their own back translation) in order to get closer to achieving conceptual equivalence with the original English.

Cognitive Debriefing

The translation was given to 5 subjects (as defined above) in the target language group. Each subject was a native speaker of the target language and resident in the target country.

Respondents were asked to read through and follow any instructions given, and then complete the document as instructed.

Following completion, the lead translator (or interviewer) asked a series of questions aimed at gauging their comprehension of the wording of the translation, including:

- Do you understand this?
- What does this mean to you? Can you explain it in your own words?
- Can you suggest any alternative wordings?

The answers to these questions, along with any other relevant comments and suggestions were summarized in a report which was then sent to the project manager. The project manager then reviewed this report. Any issues arising were sent to the lead translator for further review or revision. Any changes to the wording resulting from the interviews were fully documented and explained.

Proofreading

The translation was proofread for accuracy and layout by two separate professional linguists before finalization.

Sincerely,

A handwritten signature in black ink that reads "Charlotte Traynor".

Charlotte Traynor

11 Oct 2021 17:42:026+0000

REASON: I approve this document

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Charlotte Mulheir-Traynor
Project Manager
ICON Language Services