

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	ADAPT OF EXISTING VERSION	COGNITIVE DEBRIEFING [‡]
Swedish (Finland)	13OCT2021	<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.

Adaptation of Existing Version

Where a language version existed but was developed for use in another country (e.g. French for France), in order to make it appropriate for use in a second country in the same language (e.g. French for Belgium), an in-country review was performed in place of the forward and backward translation steps.

The existing language version was reviewed by the lead translator, who suggested any changes which were necessary to make the translation more culturally and linguistically appropriate in the new target country. These changes were then reviewed by the project manager, and discussed by the project manager and lead translator where appropriate.

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,

Yang ZHAI
Associate Project Manager
ICON Language Services

Yang Zhai
13 Oct 2021 14:33:027+0000

REASON: I approve this document

732d579e-7747-46e0-a2eb-bebd570a5c37