

Methodology Certification Letter

ICON Language Services Project No.: 2732-TR-0007

Source file name(s):

- CDI-HRQOL\_AU1.0\_eng-USori.doc

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 Sonia BOTHEREL at MAPI. Translations are intended to be complete and accurate translations of a corresponding source file.

ICON Language Services' translation process is ISO 17100-certified. ICON Language Services is a translation provider with over 18 years of experience specializing in the translation and linguistic validation of documentation related to global clinical research. 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.

TARGET LANGUAGE/COUNTRY	DATE OF FINALIZATION	CONCEPT ELABORATION	DUAL FORWARD TRANS.	BACK TRANSLATION	PROOFREADING & FINAL VERIFICATION
Italian (Italy)	13JAN21	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Polish (Poland)	14JAN21	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Spanish (European) (Spain)	13JAN21	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>

**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.

**Back Translation**

The forward translation was back translated into its original language. This step was performed by a separate qualified linguist blinded to the original source file (the source file from which the translated file was rendered). The back translation was reviewed against the original source text from which the translation was rendered. Any issues noted were reconciled in the forward translation and/or back translation until the final wording was determined.

The back translation review report was then passed to the instrument developer for him or her to review. Any suggestions or issues were passed to lead translator who, in conjunction with the project manager, worked to resolve any problems and further refine the translation.

**Proofreading & final verification**

The translation was proofread for accuracy and layout by a separate professional linguist before finalization. A member of the project management team verified the translated file(s) conformed to the agreed project process before release to the client.

Sincerely,

Fatima Scipione  
 Client Services Associate I- PCS  
 ICON Language Services

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Fatima Scipione

03 Feb 2021 14:25:028+0000

REASON: I approve this document

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