

### Methodology Certification Letter

**ICON Language Services**  
**Project No.:**

0189-TR-0311

**Janssen Protocol No.:**

CNT01959HDS2001

#### Source file name(s):

- Dermatology Life Quality Index (DLQI)

**Note:** Existing translations were already available for all the languages listed below and they were provided by the instrument's developer. The patient-specific fields at the top of the source file were missing from the existing translations, therefore they underwent dual forward/dual back translation methodology under this project scope. The entire translations then underwent cognitive debriefing.

**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 Sara Degortes on behalf of Janssen. 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.*	DUAL BACK TRANS.*	COGNITIVE DEBRIEFING**	PROOFREADING & FINAL VERIFICATION
Danish (Denmark)	18JUL2018	☑	☑	☑	☑	☑
Dutch (Netherlands)	17JUL2018	☑	☑	☑	☑	☑
Spanish (United States)	17JUL2018	☑	☑	☑	☑	☑

*\*Only the missing text at the top of the source file underwent these translation steps.*

*\*\*With 5 participants from the general population.*

#### 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. The reconciled forward translation was reviewed and edited by a separate professional linguist before proceeding with the next steps.

### **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**

Prior to proceeding to cognitive debriefing, the existing translation was reviewed by a professional linguist. The translation was then given to 5 participants (as defined above) in the target language group. Each participant was a native speaker of the target language and resident in the target country. Participants 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, such as:

- 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 types of 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.

The cognitive debriefing 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,

**Cristina Vasile**  
**Account Manager, C&SR**  
**ICON Language Services**

Cristina Vasile

**Cristina Vasile** 24 Jul 2018 09:49:038+0000

REASON: I approve this document

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