

ICON Language Services Project No.:

0189-TX-0057

Janssen Protocol No.:

CNT01959PSO3001_2_3

Source file name(s): Dermatology Life Quality Index (DLQI)

[DLQI_UK-English source from website.docx]

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 Barbara Sabatino at Janssen R&D (US). Translations are intended to be complete and accurate translations of a corresponding source file.

ICON Language Services is an EN 15038-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 EN 15038 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. | DEVELOPER REVIEW | PROOFREADING |
|-------------------------|----------------------|-------------------------------------|-------------------------------------|-------------------------------------|-------------------------------------|-------------------------------------|
| Chinese Malaysia | 12AUG2014 | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> |
| Malay Malaysia | 17SEP2014 | <input checked="" type="checkbox"/> | <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.

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.

Developer Review

The back translation or in-country review report was passed to the developer. The developer reviewed the translation to ensure that it was linguistically and culturally appropriate for use in the target country, and that it was acceptable for use with patients. Any suggestions or issues were passed to the lead translator who, in conjunction with the project manager, worked to resolve any problems and further refine the

translation.

Proofreading

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

Sincerely,

Adelina Lear
Associate Translation Coordinator
ICON Language Services