

ICON Language Services
Project No.:

0189-TR-0191

Janssen Protocol No.:

CNTO1959PSA3001_2

Source file name:

- Dermatology Life Quality Index (DLQI)

Source language: English

This letter is to certify the translation and linguistic validation methodology used for the document(s) listed above. The source file was provided to ICON Language Services by Kristin Rozanski at Janssen. 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 18 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.

TARGET LANGUAGE/COUNTRY	DATE OF FINALIZATION	CONCEPT ELABORATION	ADAPT	PROOFREADING & FINAL VERIFICATION
Dutch (Belgium)	22SEP2016	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
English (Malaysia)	04OCT2016	<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.

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.

The in-country review report was then passed to the instrument developer for him or her to review. 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 & 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
ICON Language Services

Cristina Vasile

Cristina Vasile 04 Nov 2016 14:03:036+0000

I approve this document.

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