

LINGUISTIC VALIDATION CERTIFICATE DERMATOLOGY LIFE QUALITY INDEX (DLQI)

This is to certify that MAPI Institute conducted the linguistic validation of the **Dermatology Life Quality Index (DLQI)** into the language listed on the next page.

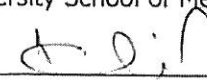


The aim of a linguistic validation is to obtain translations that are:

- conceptually equivalent to the original and comparable across languages;
- culturally relevant to the context of the target country;
- easily understood by the people to whom the translated instrument is administered.

This is achieved using a rigorous methodology¹ involving:

- a process which comprises several steps (see diagram on the last page of this document);
- the collaboration of the instrument's developer and a skilled team recruited by MAPI Institute in the target country which is headed by a consultant with knowledge of and experience in the field of Patient-Reported Outcomes;
- a centralized review process coordinated by MAPI Institute.

The specific methodology used to produce this version of the DLQI is summarized in the table on next page. The linguistic validation process was coordinated and supervised by a consultant in the target country under the guidance of MAPI Institute who performed a quality control and discussed the translation decisions with the consultant at each step of the process.

Dr. Mohammad Khurshid Azam Basra Department of Dermatology Cardiff University School of Medicine Signature: <u></u> Date: <u>05.01.2011</u>	<div style="display: flex; justify-content: space-between;"> <div> MAPI Institute Isabelle Mear Managing Director Signature: <u></u> Date: <u>January 18th, 2011</u> </div> <div style="text-align: right;">  27 rue de la Villette - 69002 LYON Tel. + 33 (0)4 72 13 66 67 Fax + 33 (0)4 72 13 69 50 <small>RCS LYON B 399 281 013 - SA au capital de 80 000 € TVA n° FR 42 399 281 013</small> </div> </div>
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References:

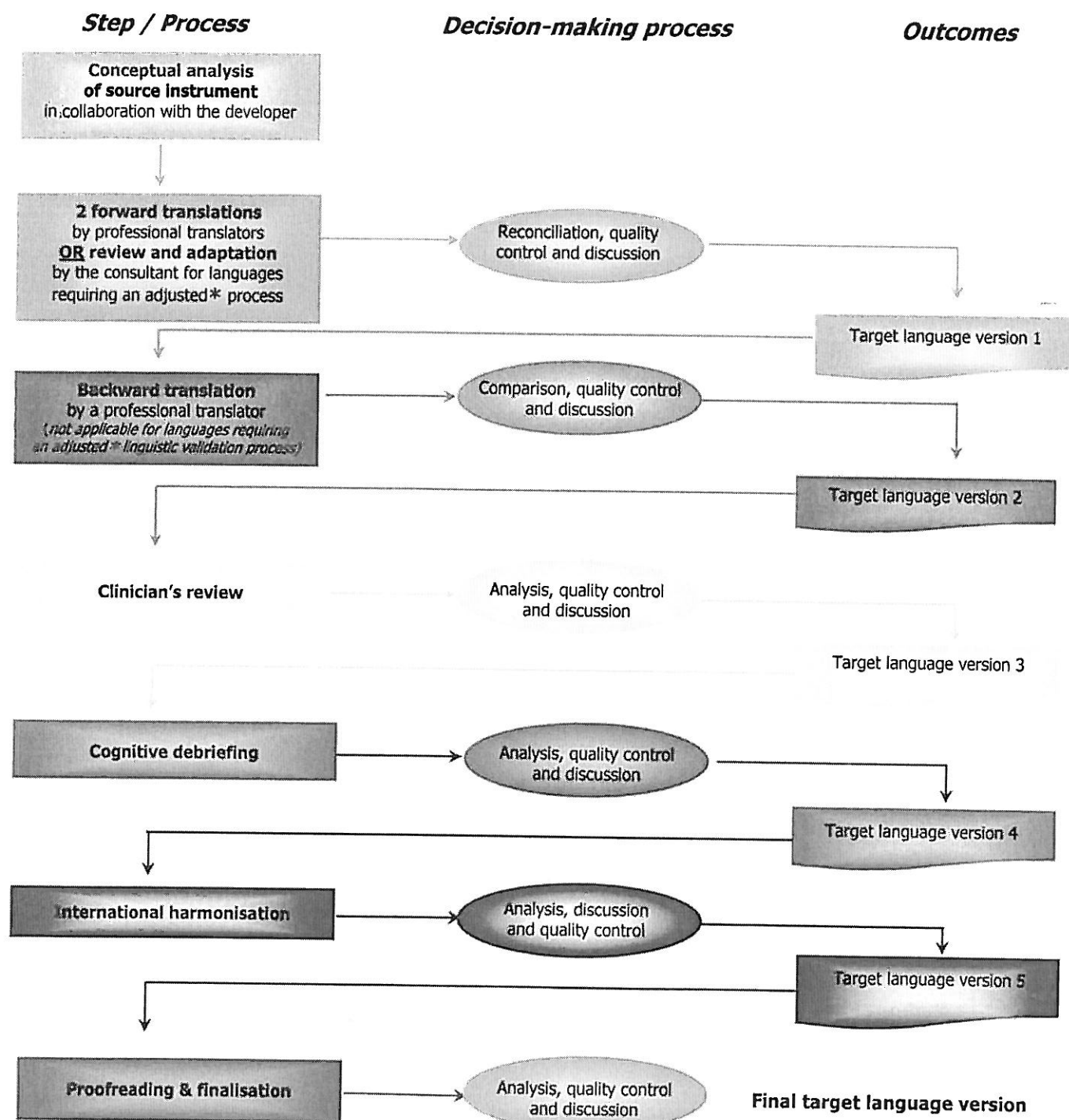
- Acquadro C., Jambon B., Ellis D. and Marquis P. Language and translation issues. In Spilker B, ed. Quality of Life and Pharmacoeconomics in Clinical Trials. Philadelphia: Lippincott-Raven Publishers, 1996: 575-585.
- Acquadro C., Conway K., Giroudet C., Mear I. Linguistic validation Manual for Patient-Reported Outcomes (PRO) Instruments. 2004

LINGUISTIC VALIDATION STEPS		Forward Translation Step (2 translations by qualified translators → reconciliation)	Backward Translation Step (1 translation by a qualified translator)	Adaptation Step (Review and adaptation of the mother language version to context of the target country)	Clinician's Review Step	Cognitive Debriefing Step (on 5 patients with hives, unless otherwise specified)	International Harmonisation Step
COUNTRIES	LANGUAGES						
Denmark	Danish	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	N/A	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
France	French	<input type="checkbox"/>	<input type="checkbox"/>	N/A	<input type="checkbox"/>	<input checked="" type="checkbox"/> (1)	<input checked="" type="checkbox"/>
Germany	German	<input type="checkbox"/>	<input type="checkbox"/>	N/A	<input type="checkbox"/>	<input checked="" type="checkbox"/> (1)	<input checked="" type="checkbox"/>
Italy	Italian	<input type="checkbox"/>	<input type="checkbox"/>	N/A	<input type="checkbox"/>	<input checked="" type="checkbox"/> (1)	<input checked="" type="checkbox"/>
Korea	Korean	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	N/A	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/> (on 5 patients with psoriatic arthritis)	<input type="checkbox"/>
Latvia	Latvian	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	N/A	<input type="checkbox"/>	<input checked="" type="checkbox"/> (on 5 patients with atopic dermatitis)	<input type="checkbox"/>
Spain	Spanish	<input type="checkbox"/>	<input type="checkbox"/>	N/A	<input type="checkbox"/>	<input checked="" type="checkbox"/> (1)	<input checked="" type="checkbox"/>
Taiwan	Mandarin Chinese	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	N/A	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/> (on 5 patients with psoriatic arthritis)	<input type="checkbox"/>
United Kingdom	English	Original instrument					

N/A: Not applicable ☒: Step performed ☐: Step not performed

(1) work based on existing versions provided by the author, Dr Finlay, to Mapi Institute.

The linguistic validation process



* For some languages that are close to one another (e.g. British and American English; French for France and Belgium), the complete standard linguistic validation process outlined above with *forward* and *backward* translation steps may not be appropriate. For such cases, an **adjusted** linguistic validation process has been established. The *forward* and *backward* translation steps are replaced by a review and adaptation step, where the work is based on a version considered as the "mother language" version. The subsequent steps are identical to those used in the standard linguistic validation process.