

LINGUISTIC VALIDATION CERTIFICATE
PAPER VERSION OF THE FAMILY DERMATOLOGY LIFE QUALITY INDEX QUESTIONNAIRE
(FDLQI)

This is to certify that Mapi conducted the linguistic validation of the paper version of the **Family Dermatology Life Quality Index (FDLQI)** into the languages on the following 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 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.

The specific methodology used to produce these versions of the **FDLQI** is summarized in the table on the following page. For each language, the linguistic validation process was coordinated and supervised by a consultant in the target country under the guidance of Mapi who performed a quality control and discussed the translation decisions with the consultant at each step of the process.

Throughout the process, Mapi's project team focused on cross-cultural harmonisation in order to ensure common understanding of the instrument's concepts by all participants and achieve conceptual equivalence across languages.

On behalf of Professor Andrew Y. Finlay,
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13/11/2015

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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.
- Linguistic Validation Manual for Health Outcomes Assessments. Acquadro C, Conway K, Giroudet C, Mear I. Second Edition - MAPI Institute, Lyon, France, January 2012 - ISBN: 2-9522021-0-9

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 (Sponsor-appointed clinician)	Cognitive Interviews Step (on 5 individuals from the general population 5)
COUNTRIES	LANGUAGES					
Australia	English (based on the English for the United Kingdom original)	N/A	N/A	☑	☑	☐
Austria	German (based on the German version for Germany)	N/A	N/A	☑	☑	☐
France	French	☑	☑	N/A	☑	☐
Germany	German	☑	☑	N/A	☑	☐
Italy	Italian	☐	☑ (1)	N/A	☑	☐
The Netherlands	Dutch	☑	☑ (2)	N/A	☐	☑
Romania	Romanian	☑	☑ (2)	N/A	☐	☑
United Kingdom	English		Original	Instrument		

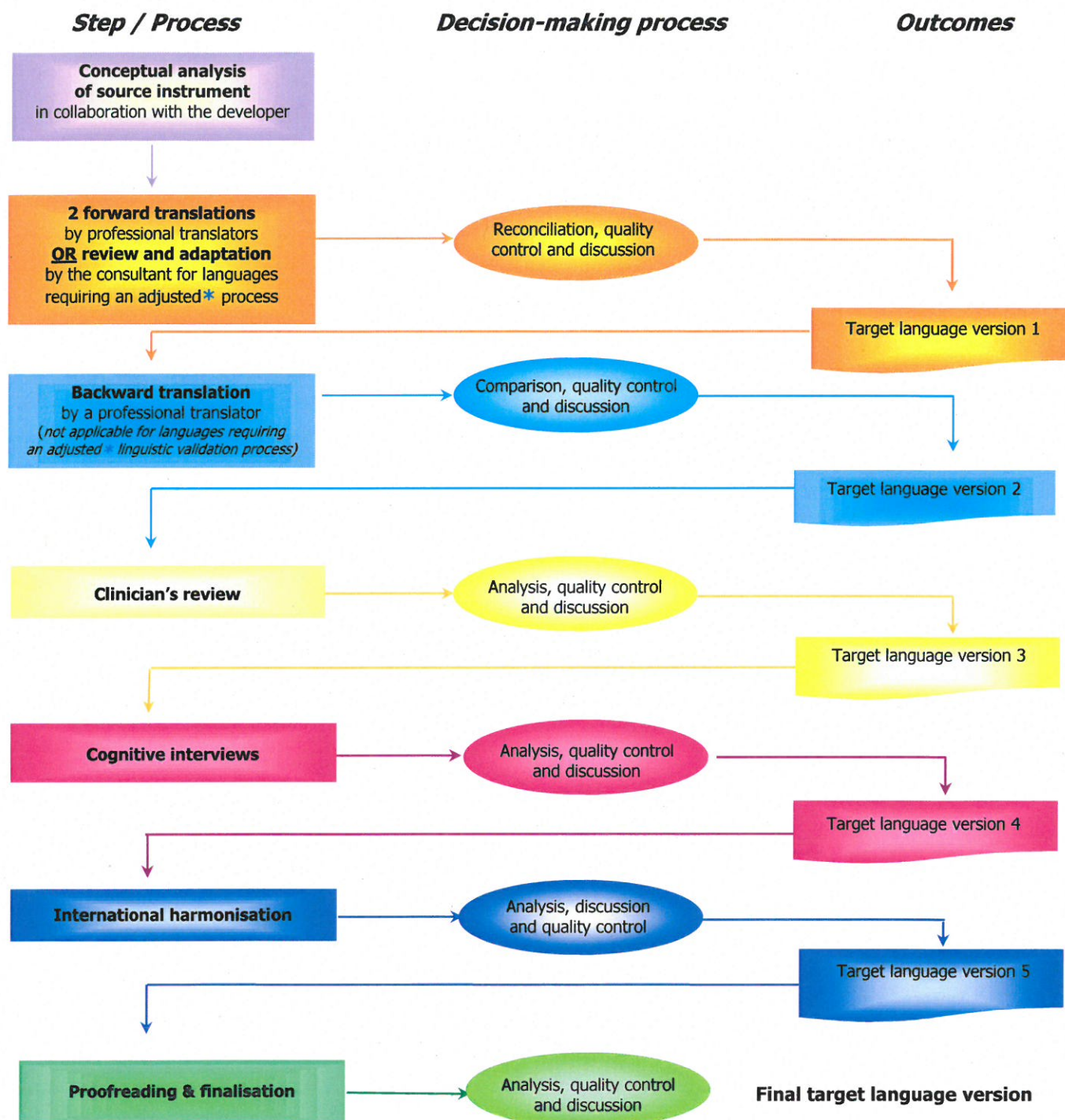
N/A: Not applicable

☑: Step performed

☐: Step not performed

- (1) Quality check through a backward translation of an existing version provided by the Developer, to ensure conceptual equivalence with the original instrument.
- (2) The Backward translation step was composed of 2 translations performed by 2 qualified translators and included a review by the Developer.

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.

