

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:

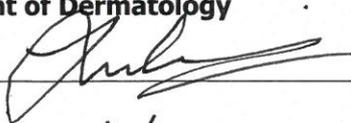
- conceptually equivalent to the original and comparable across languages;
- culturally relevant to the context of the target country;
- easily understood by the people to whom the translated instrument is administered.

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.

<p>On behalf of Professor Andrew Y. Finlay, Dr Faraz Mahmood Ali MBBCh MRCP <i>Clinical Research Fellow in Dermatology</i></p> <p>Cardiff University School of Medicine Department of Dermatology</p> <p>Signature: </p> <p>Date: <u>13/11/2015</u></p>	<p>Ana Bayles Managing Director Mapi – Language Services</p> <p></p> <p>Date: 13 November 2015</p> <p align="right"> Mapi SAS SAS au capital de 434 700 euros 27 rue de la Villette 69003 LYON Tél. 04 72 13 66 67 - Fax 04 72 13 69 50 RCS Lyon 378 472 872 - TVA n° FR 66 378 472 872 </p>
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¹ **References:**

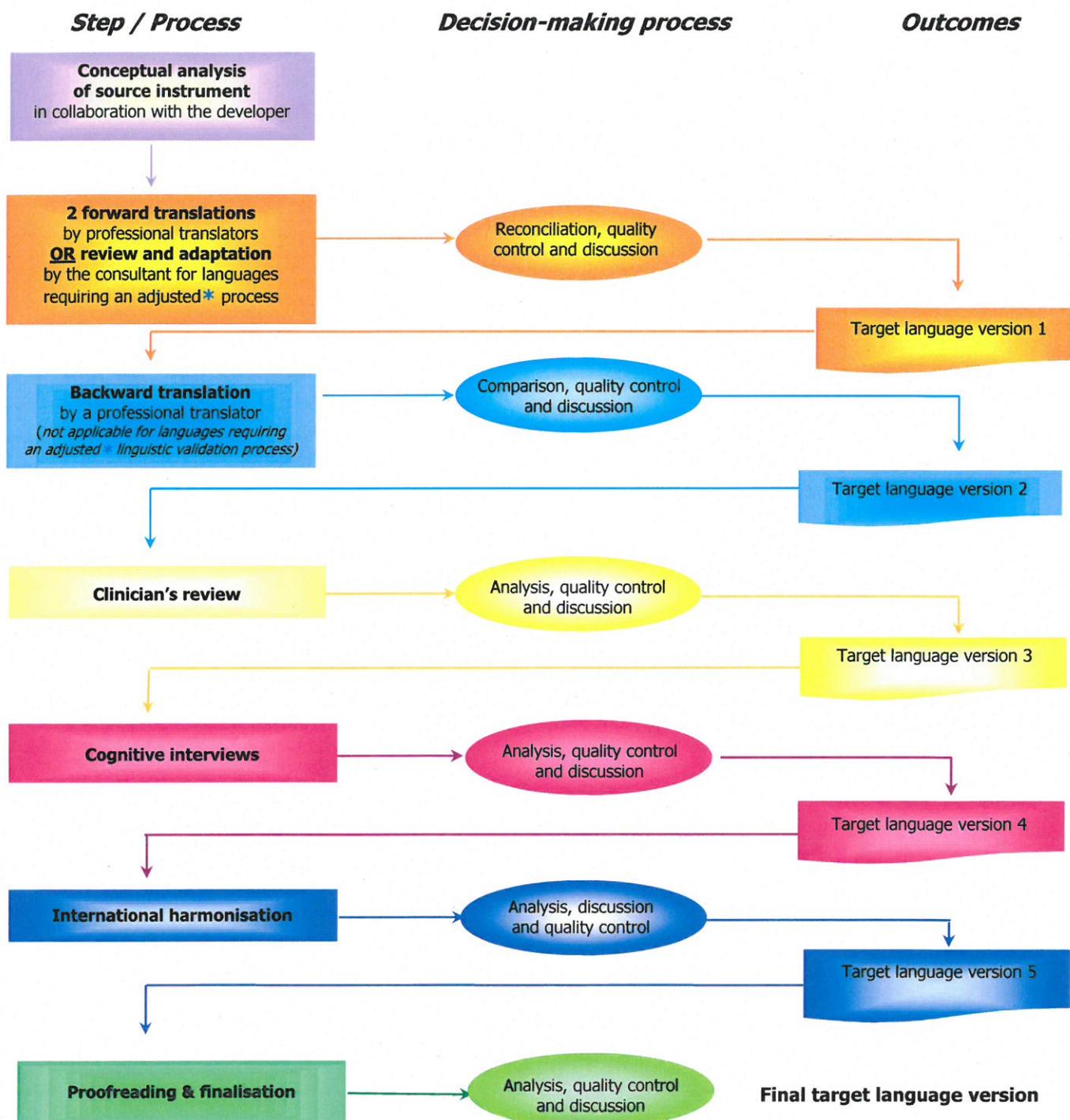
- Acquadro C., Jambon B., Ellis D. and Marquis P. Language and translation issues. In Spilker B, ed. Quality of Life and Pharmacoeconomics in Clinical Trials. Philadelphia: Lippincott-Raven Publishers, 1996: 575-585.
- Linguistic Validation Manual for Health Outcomes Assessments. Acquadro C, Conway K, Giroudet C, Mear I. Second Edition - MAPI Institute, Lyon, France, January 2012 - ISBN: 2-9522021-0-9

LINGUISTIC VALIDATION STEPS		Forward Translation Step	Backward Translation Step	Adaptation Step	Clinician's Review Step	Cognitive Interviews Step
		(2 translations by qualified translators → reconciliation)	(1 translation by a qualified translator)	(Review and adaptation of the mother language version to context of the target country)	(Sponsor-appointed clinician)	(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	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Austria	German (based on the German version for Germany)	N/A	N/A	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
France	French	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	N/A	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Germany	German	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	N/A	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Italy	Italian	<input type="checkbox"/>	<input checked="" type="checkbox"/> (1)	N/A	<input checked="" type="checkbox"/>	<input type="checkbox"/>
The Netherlands	Dutch	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/> (2)	N/A	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Romania	Romanian	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/> (2)	N/A	<input type="checkbox"/>	<input checked="" type="checkbox"/>
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.

