

LINGUISTIC VALIDATION CERTIFICATE
PAPER VERSION OF THE CHILDREN'S DERMATOLOGY LIFE QUALITY INDEX CARTOON
QUESTIONNAIRE (CDLQI CARTOON)

This is to certify that Mapi conducted the linguistic validation of the paper version of the **Children's Dermatology Life Quality Index Cartoon (CDLQI Cartoon) questionnaire** into the languages listed 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 **CDLQI Cartoon** 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.

Isabelle Mear *PO/Marketing*
Managing Director *Operations Manager*

Mapi - Linguistic Validation

Signature: _____

Date: *5/05/2014*

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

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 (2 translations by qualified translators → reconciliation) | Backward Translation Step (1 translation by a qualified translator) | Update (1) | Adaptation Step (Review and adaptation of the mother language version to context of the target country) | Clinician's Review Step (Sponsor-appointed clinician) |
|-----------------------------|---|--|--|-------------------------------------|--|--|
| COUNTRIES | LANGUAGES | | | | | |
| Australia | English (based on original UK English version) | N/A | N/A | N/A | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> |
| Austria | German (based on German version for Germany) | N/A | N/A | N/A | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> |
| Czech Republic | Czech | <input type="checkbox"/> | <input type="checkbox"/> | <input checked="" type="checkbox"/> | N/A | <input type="checkbox"/> |
| United Kingdom | English | Original instrument | | | | |
| United States | English | <input type="checkbox"/> | <input type="checkbox"/> | <input checked="" type="checkbox"/> | N/A | <input type="checkbox"/> |
| United States | Spanish | <input type="checkbox"/> | <input type="checkbox"/> | <input checked="" type="checkbox"/> | N/A | <input type="checkbox"/> |

N/A: Not applicable

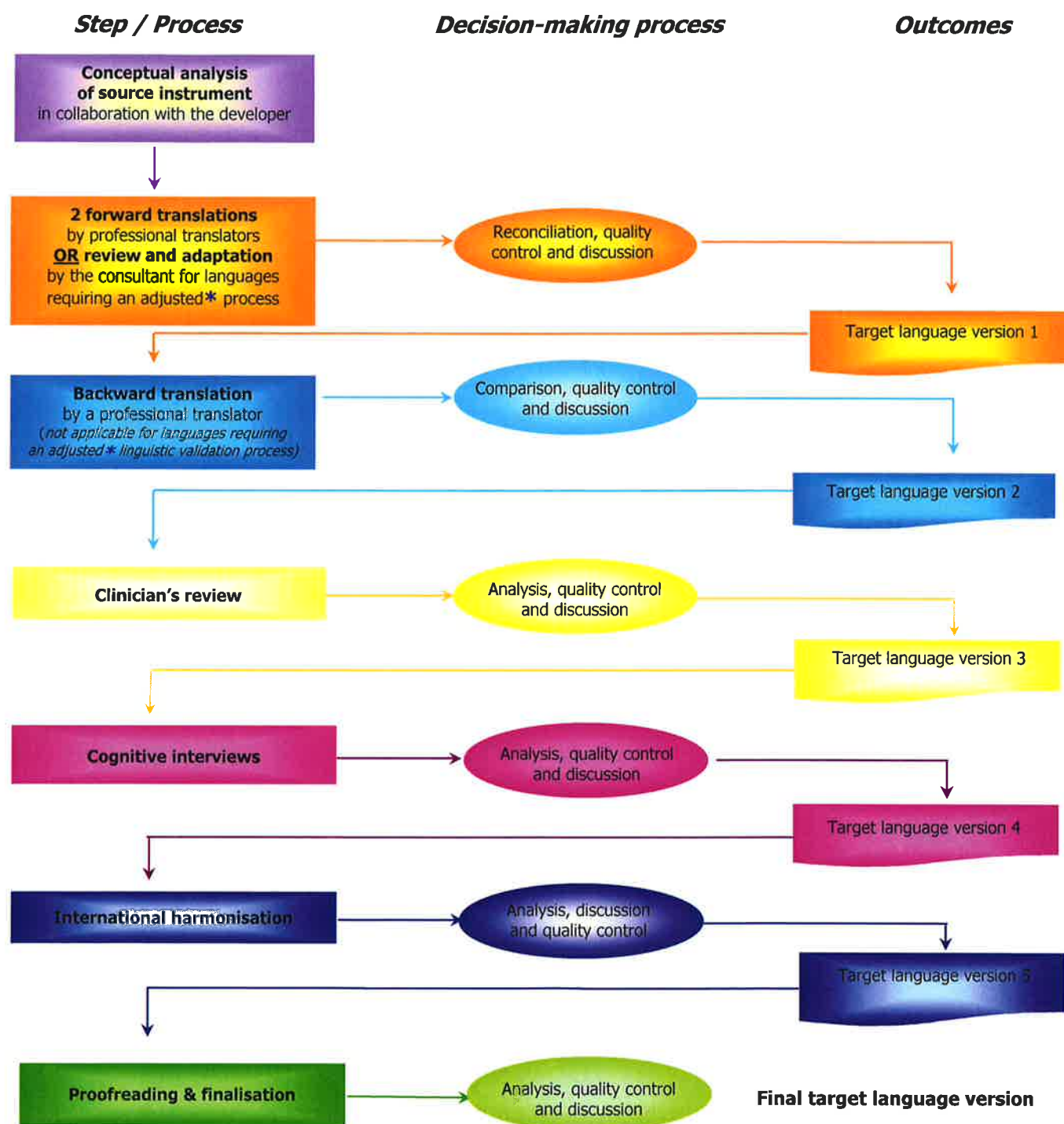
☒: Step performed

☐: Step not performed

Important remarks for US Spanish: in order to encompass the multi-ethnic dimension of US Spanish, the *forward* translations were produced by one Mexican and one South American translator respectively and reconciled during a meeting held by the consultant with the forward translators and three other translators of Caribbean, Mexican and Central American origins. The individuals interviewed during cognitive debriefing were of the same origins i.e. 2 Mexicans, 1 Caribbean, 1 Central American and 1 South American.

(1) Existing versions provided by the author formatted to be in line with the CDLQI Cartoon template.

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.