

LINGUISTIC VALIDATION CERTIFICATE

Family Reported Outcome Measure (FROM-16)

This is to certify that **Mapi Language Services** conducted the linguistic validation of the **paper** version of the **FROM-16** (source file name: **FROM-16_AU1.0_eng-USori.docx**) into **French for France**.

The aim of 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;
- the instrument's developer input on conceptual issues;
- a skilled team recruited by **Mapi Language Services** in the target country and headed by a consultant with knowledge of and experience in the field of Clinical Outcome Assessments. The consultant supervises and coordinates the linguistic validation process in his/her country;
- a centralized review process coordinated by **Mapi Language Services**, including quality control by linguists and discussions about translation decisions with the consultant at each step of the process.
- cross-cultural harmonisation to ensure common understanding of the instrument's concepts by all participants involved in the process and achieve conceptual equivalence across languages.

The aforementioned translation (filename : FROM-16_AU1.0_fre-FR, dated 17 April 2020) underwent the following steps:

- Forward Translation step – 2 forward translations by qualified translators and reconciliation
- Backtranslation step – 1 backtranslation by a qualified translator
- Cognitive Interview step on 5 patients from the general population
- Proofreading step

Mapi Language Services may not be held liable for any changes made on the translation after completion of project **5194-TR-0001** by **Mapi Language Services** on **17 April 2020**.

Approved By:

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Becki Ellsmore 17 Apr 2020 13:16:030+0000

REASON: I approve this document

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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