

LINGUISTIC VALIDATION CERTIFICATE

Patient-Oriented Eczema Measure (POEM)

This is to certify that Mapi Language Services conducted the linguistic validation of the paper version of the POEM (source file name: POEM-Adult-SA_AU1.0_eng-GBori.docx) into Italian for Italy.

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 : POEM-Adult-SA_AU1.0_ita-IT.doc, dated 11 April 2019) underwent the following steps:

- Forward Translation step 2 forward translations by qualified translators and reconciliation
- Backtranslation step 1 backtranslation by a qualified translator
- Proofreading step

Mapi Language Services may not be held liable for any changes made on the translation after completion of project 4476-TR-0002 by Mapi Language Services on 11 April 2019.

Approved By:

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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