



LINGUISTIC VALIDATION CERTIFICATE

Family Reported Outcome Measure (FROM-16)

This is to certify that **ICON Language Services** conducted the linguistic validation of the Paper version of the FROM-16 (source file name: FROM-16_AU1.1_eng-GBori) into United States - English.

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 ISO-17100 certified methodology¹ involving:

- a process which comprises several steps
- the instrument's developer input on conceptual issues
- a skilled team recruited by **ICON 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 **ICON 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_AU1.1_eng-US_30AUG2024, dated 30 August 2024) underwent the following steps:

- Adaptation step based on the English version for United Kingdom in order to render the translation appropriate for the context of United States
- Cognitive Interview step:
 - 5 participants; population: General population; group: Adults; age range: 18+
- Proofreading step

The linguistic validation work was based on the Original source for United Kingdom.

ICON Language Services may not be held liable for any changes made on the translation after completion of project **0027-TR-0007** by **ICON Language Services** on **30 August 2024**.

Agnes Kiss
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ICON Language Services

DocuSigned 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