



LINGUISTIC VALIDATION CERTIFICATE

Patient Reported Outcomes and Adverse Event Reporting Implementation Guide (PRO AE Text (1A))

This is to certify that **ICON Language Services** conducted the linguistic validation of the **paper** version of the **PRO AE Text (1A)** (source file name: **PRO_AE_Text (1A)_AU1.0_eng-USori**) into **Bengali for India**.

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 : PRO_AE_Text (1A)_AU1.0_ben-IN_25AUG2023, dated 25 August 2023) underwent the following steps:

- Proofreading step

The existing version on which the linguistic validation work was based had previously undergone the following steps:

- Forward Translation step
- Backtranslation step
- Cognitive Interview step on 5 respondents who have had influenza
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ICON Language Services may not be held liable for any changes made on the translation after completion of project **0189-TR-0661** by **ICON Language Services** on **25 August 2023**.

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25 Aug 2023 12:09:25 UTC (Z)

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