



LINGUISTIC VALIDATION CERTIFICATE

Patient Global Impression of Severity – Fatigue (PGIS_Fatigue)

This is to certify that **ICON Language Services** conducted the linguistic validation of the Paper version of the PGIS_Fatigue (source file name: PGIS_Fatigue_002_en_US_v1.0_29May2025) into India - 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 : PGIS_Fatigue_002_en_IN_v1.0_10Oct2025, dated 10 October 2025) underwent the following steps:

- Update - by a native speaker to bring existing version in line with an upgraded original version
- Cognitive Interview step:
 - 3 participants; population: IPSS-R Very Low, Low Risk, or Intermediate Risk Myelodysplastic Syndrome; group: Adults; age range: 18+
 - 2 participants; population: Leukemia ; group: Adults; age range: 18+
- Proofreading step

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

- Adaptation
- Proofreading

ICON Language Services may not be held liable for any changes made on the translation after completion of project **0021-TR-0109** by **ICON Language Services** on **10 October 2025**.

Petra Hergibo
Senior Project Manager
ICON Language Services

Signed by:

Petra Hergibo



Signer Name: Petra Hergibo
Signing Reason: I approve this document
Signing Time: 14-Oct-2025 | 07:42:43 BST

35101FA2F9404CF4B3B081BAEE9C6D1A

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