



Patient-Reported Outcomes Version of the Common Terminology Criteria for Adverse Events (PRO-CTCAE) Item Library (version 1)

Certified Translation

This is to certify that the Patient-Reported Outcomes Version of the Common Terminology Criteria for Adverse Events (PRO-CTCAE) Item Library (version 1) was translated from English to Croatian using a universal translation methodology, including representation from Croatian speakers from Croatia and Bosnia and Herzegovina, by qualified translators employed by RWS Lifesciences under the direction of the US National Cancer Institute.

This translation followed the translation methodology recommended by International Society of Pharmacoeconomic and Outcomes Research (ISPOR) a methodology established to ensure that resulting translations of patient-reported outcome measures reflect conceptual equivalence with the source document rendered in language that is culturally acceptable and relevant to the target population. This rigorous methodology requires two forward translations into the target language by native speakers, a reconciled version of the two forward translations done by a third independent translator who is a native speaker of the target language, a back translation of the reconciled version by a native English speaker fluent in the target language, and an independent review by a native speaker trained as a physician or nurse in oncology.

After the translation phase was completed, the PRO-CTCAE Item Library (version 1) was linguistically validated by testing with patients to confirm the suitability of the translations with speakers of Croatian in Croatia and in Bosnia and Herzegovina. All translation work was performed by members of the Croatian translation team to the best of their abilities as native speakers of Croatian (or English in the case of the back-translator), and as translators and researchers experienced in the field of health-related quality of life and patient-reported outcomes survey research under the direction of the undersigned.

This translation is, to the best of my knowledge, a valid and accurate translation of the corresponding original English language version of the PRO-CTCAE Item Library (version 1).

Name: Sandra A. Mitchell, PhD, CRNP Title: Research Scientist and Program Director;
Outcomes Research Branch;
US National Cancer Institute

Sandra A. Mitchell
Signature:

Date: *May 1/2023*

Matthew S. Marinucci
MATTHEW S. MARINUCCI
NOTARY PUBLIC STATE OF MARYLAND
My Commission Expires September 2, 2025