



**Patient-Reported Outcomes Version of the Common Terminology Criteria for Adverse Events Pediatric Module
(Ped-PRO-CTCAE™ and Ped-PRO-CTCAE™[Caregiver])
Item Library (version 1)
Certified Translation**

This is to certify that the Pediatric Module of the Patient-Reported Outcomes Version of the Common Terminology Criteria for Adverse Events (Ped-PRO-CTCAE and Ped-PRO-CTCAE [Caregiver]) Item Libraries (version 1) were translated from English to Italian using a universal translation methodology, including representation from Italian speakers residing in Italy.

This translation followed the translation methodology recommended by the 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 Pediatric Module of the Patient-Reported Outcomes Version of the Common Terminology Criteria for Adverse Events (Ped-PRO-CTCAE and Ped-PRO-CTCAE [Caregiver]) Item Libraries (version 1) were linguistically validated by testing with children and parents to confirm the suitability of the translations for speakers of Italian residing in Italy. All translation work was performed by members of the Italian translation team to the best of their abilities as native speakers of Italian (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 general 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 Pediatric Module of the Patient-Reported Outcomes Version of the Common Terminology Criteria for Adverse Events (Ped-PRO-CTCAE and Ped-PRO-CTCAE [Caregiver]) Item Libraries (version 1).

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Date: *Feb 23 / 2021*

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