The objective of this study was to identify terminologies found in PROs that cause difficulty in translation and comprehension. Identifying such terminology, and studying how to improve translation and patient feedback about it, is critical to increasing the validity of PROs and their treatment insights.

The four PRO instruments analyzed and the number of languages each was translated into are presented in Table 1. The languages were translated by a third party language service provider (LSP) with expertise in the target language and cultural context. The translation process consisted of four main steps: (1) translation by a professional translator, (2) back translation by another professional translator, (3) harmonization of the forward and back translation, and (4) review by a project manager and a survey research analyst. The harmonized translation is then provided to a third party to translate into the target language.

The distribution of patient feedback about disease activity (N=48) is shown in Table 2. The most common feedback category was thoughts about possible definitions (N=11), followed by instructions for responding (N=44), suggestions for improvement (N=23), and instructions for responding (N=44).

The high comprehension error rate for disease activity was as significant as the fact that significant percentages of the languages and countries tested here showed comprehension problems related to the term. The high error rate for disease activity implies that the term needs to be redefined or rephrased to improve comprehension.

Conclusions: Due to the ambiguity and unfamiliarity of the disease activity concept, difficulties in translation and comprehension continue to impede the use of PROs in clinical trials. Careful study of the language and cultural context of the target population is needed to improve the validity and utility of PROs.