Migration Inconsistencies in Electronic Quality of Life (QOL) Instruments in Clinical Trials

Lindsay Hughes[1], Margalida Frau[2], Elinor Rees[3]
[1]IQVIA New York, US; [2]IQVIA Madrid, Spain; [3]IQVIA Reading, UK

Background

- Ensuring scientific integrity in clinical research requires that trials are designed and conducted so participants receive information and assessments in their native language. This is especially important for achieving representation in clinical trials, but also for maintaining the integrity of the data collected – since language and cultural context can influence how participants interpret and respond to assessments

Introduction

- A standardized migration[1,2] process is used to convert validated paper-based Clinical Outcome Assessments (COAs) into electronic formats while preserving their original linguistic and conceptual integrity (i.e., maintaining the same wording in the electronic formats and making slight adjustments where necessary to account for electronic administration). This involves collaboration with eCOA providers, language experts, and native speakers. The result is a set of electronic files used to generate screenshots for review and validation. Depending on the instrument's complexity, this process may take several weeks
- Despite these rigorous procedures, there is an industry-wide challenge in the eCOA migration process. Inconsistencies across languages and countries are common and can compromise data quality, reduce credibility, and discourage participant engagement
- This research focuses on migration-related challenges in less common languages compared to those frequently used in Quality of Life (QOL) instruments in clinical trials

Methods

Trials were selected based on two criteria: the availability of COAs measuring QOL and the presence of both common and less common languages

Common languages	Less common languages
Those frequently used in clinical research settings (Spanish, German, Japanese, French)	Those spoken in countries where eCOA use is limited or where the languages are considered unofficial, minority or primarily associated with immigrant populations (Haitian Creole, Vietnamese, Cebuano, Armenian, Farsi)

Qualified linguists under the oversight of IQVIA's Translation Services (ITS) team compared paper- and migrated version of COAs to identify migration-related challenges and translation issues across multi-sponsor studies covering various indications and therapeutic areas. PCS Scientific team then reviewed these findings and categorized the issues to highlight patterns and support further investigation

Results

- The total number of issues was similar across common and less common languages (Table 1). However, the mean number of issues per trial was higher in less common languages than in common ones (42 vs 8, respectively; Figure 1)
- The inconsistencies identified were distributed across the following categories (Examples can be observed in Figure 2):
  - Copyright issues
  - Emphasis (e.g., bolded text)
  - Punctuation
  - Translation mismatch
  - Electronic wording
  - Grammatical error
  - Screen format
  - Untranslated content

	Number of issues
Common languages	**222**
Spanish	35
German	102
Japanese	9
French	76
Less common languages	**209**
Haitian Creole	62
Vietnamese	42
Cebuano	1
Armenian	22
Farsi	82

Table 1. Number of issues per language and group of languages

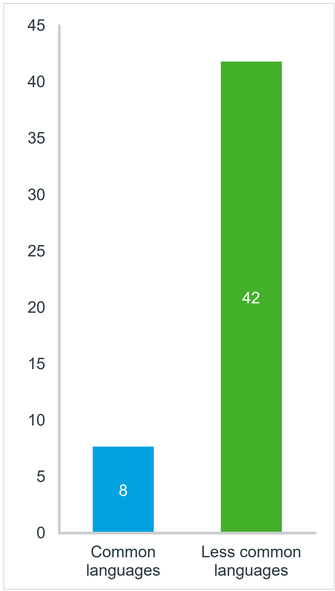
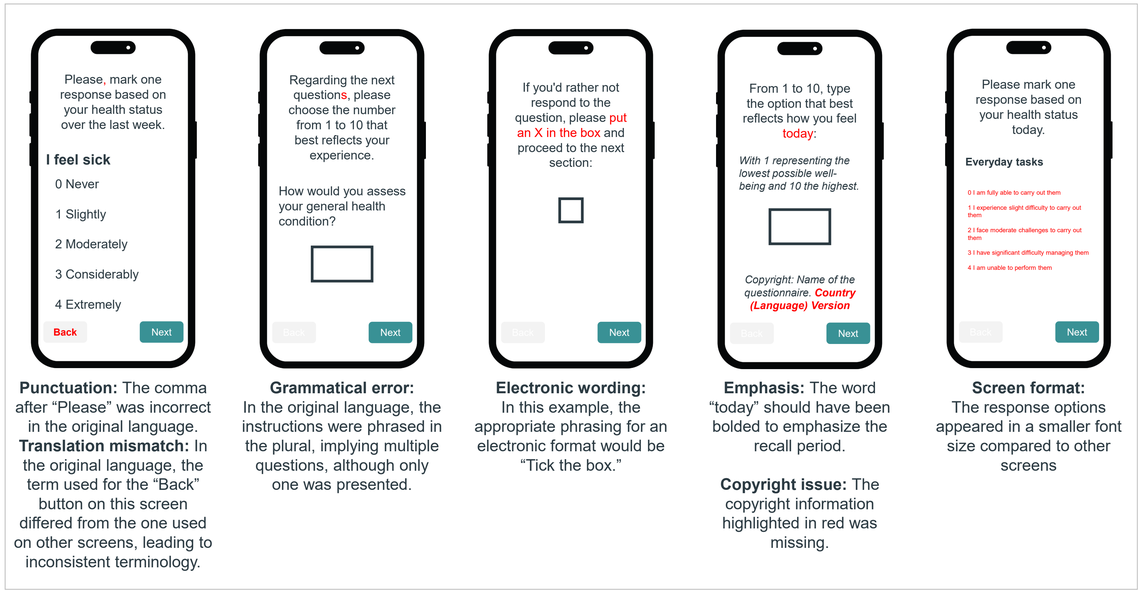


Figure 1. Mean of issues per trial in common and less common languages



Punctuation: The comma after "Please" was incorrect in the original language. **Translation mismatch:** In the original language, the term used for the "Back" button on this screen differed from the one used on other screens, leading to inconsistent terminology.

Grammatical error: In the original language, the instructions were phrased in the plural, implying multiple questions, although only one was presented.

Electronic wording: In this example, the appropriate phrasing for an electronic format would be "Tick the box."

Emphasis: The word "today" should have been bolded to emphasize the recall period.

Copyright issue: The copyright information highlighted in red was missing.

Screen format: The response options appeared in a smaller font size compared to other screens

Figure 2. Illustrative examples of the different types of issues identified
This figure shows illustrative examples due to copyright restrictions. Original content was translated and adapted for dissemination and does not exactly reflect the original wording

Conclusions

- Language and cultural diversity are essential for inclusive clinical trials and reliable outcomes. Minor inconsistencies – especially in language – can affect patient experience and introduce bias, risking data integrity
- To prevent this, it is essential to ensure that the full migration process is also carried out by trained native-speaking linguists who have been provided with clear instructions. Automation is strongly encouraged to reduce manual intervention and ensure adherence to legacy text. In regions with limited eCOA experience, enhanced automation and extra review cycles are necessary to meet industry standards

References

[1]Shalhoub, H., Turner, M., Bradley-Gilbride, A., Eremenco, S., Muehlan, H., Parks-Vernizzi, E., Arnold, B., Kuliś, D., Anfray, C., Chaplin, J. E., & Repo, J. P. (2025). Principles of good practice for translation of electronic clinical outcome assessments. Journal of Patient-Reported Outcomes, 9(26).
[2]Mowlem, F. D., Elash, C. A., Dumais, K. M., Haenel, E., O'Donohoe, P., Olt, J., Kalpadakis-Smith, A. V., James, B., Balestrieri, G., Becker, K., Newara, M. C., & Kern, S. (2024). Best Practices for the Electronic Implementation and Migration of Patient-Reported Outcome Measures. Value in Health, 27(1), 79–94.

ISOQOL 32nd Annual Conference 22-25 October 2025 Milwaukee, Wisconsin, USA