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Evaluating Migration Errors in COA Development and Validation of the IQVIA Migration Error Severity Scale (I-MESS)

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Introduction

- Clinical Outcome Assessment (COA) migration is a complex and challenging process requiring both translation and technical expertise. A standardized migration[1,2] process is used to convert validated paper-based COAs into electronic formats while preserving their original linguistic and conceptual integrity.
- Tight timelines and budget constraints in clinical trials can compromise migration quality, making errors in the end product a known industry-wide pain point. Decisions around electronic COAs (eCOAs) are primarily operational rather than scientific and stakeholders must recognize the importance of inconsistencies even if they may seem minor.
- We evaluated inconsistencies found across studies, assessments and languages using a scientifically developed and validated severity scale.

Figure 1: IQVIA Migration Error Severity Scale overview

1 Low Severity	Primarily used when the error does not impact the patient E.g., related to the copyright
2 Mild Severity	**Has the potential to impact the patient's perception** of the instrument but is unlikely to affect their answer. E.g., typographical error in the question text that does not impact the patient's ability to understand what is being asked.
3 Statistically Addressable Severity	**May affect a specific answer**. E.g., issues with the order of response options that would not affect scoring, errors in the question text that could cause confusion but include context elsewhere in the instrument allowing the patient to answer the question as intended.
4 Sensitivity Analysis Recommended	Likely to **affect the results/data**. E.g., issues with the response option order that affects scoring. Recommended for sensitivity analysis.
5 Sensitivity Analysis Recommended	Likely to result in **unusable data**. E.g., answer option(s) not translated, missing or unselectable. Recommended for sensitivity analysis.

Methods

A comparison of the approved paper version and the electronic version of translated patient reported outcome (PRO) assessments was completed by translation specialists at IQVIA. Inconsistencies identified across eight studies from diverse sponsors, eCOA vendors, indications, and therapeutic areas were analyzed by raters with varied backgrounds within IQVIA, including scientific and operational roles.

The rating process used the IQVIA Migration Error Severity Scale (I-MESS), developed by the Patient Centered Solutions team, which included behavioral scientists and measurement science experts. This scale classifies inconsistencies by severity (from 1 to 5) based on potential impact to patient and data, helping prioritize the urgency of corrective actions (Figure 1). Higher scores indicate greater severity.

Raters were trained on the application of I-MESS and scoring procedures. To confirm interrater agreement, over 20% of the issues were scored by multiple raters, with a target of agreement of at least 80%, as recommended[3].

After training and interrater agreement confirmation, the remaining issues identified in these studies were scored using the scale.

Results

A total of 491 issues were identified across 8 studies (Table 1).

Figure 2 shows severity distribution of the 491 issues by study (Figure 2A) and overall (Figure 2B), with severity levels 2 and 3 being the most frequent.

Approximately 20% (n=107) representing all studies, were randomly selected for double scoring to enable the calculation of interrater agreement. Interrater agreement was achieved by an 89.7% of issues scored identically.

Examples of the issues include categories such as:

- Copyright issues
- Font formatting
- Spacing
- Punctuation
- Grammar
- Gender error (inability to reflect gender variables)
- Incorrect translation
- Modified content
- Missing content
- Untranslated content

Figure 3 illustrates examples of identified issues.

Table 1: Summary of studies included in this research

Study	Therapeutic area	Number of issues	Number of languages impacted	Number of PROs impacted
Study 1	Autoimmune disease	43	11	4
Study 2	Neurodegenerative diseases	115	10	3
Study 3	Inflammatory Bowel Disease	103	22	5
Study 4	Sleep disorders	98	4	11
Study 5	CNS	17	8	1
Study 6	Food, Nutrition, and Metabolism	27	8	1
Study 7	Multiple	80	17	1
Study 8	Respiratory	8	6	1

Figure 2:
A: Distribution of severity levels per study

B: Number of issues by severity level across studies

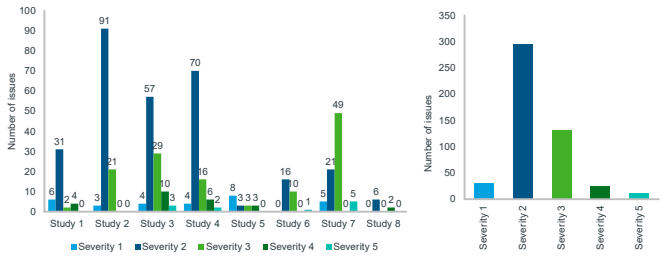
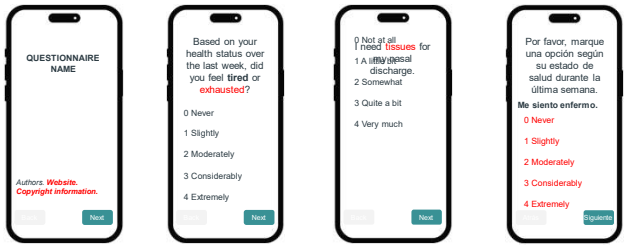


Figure 3: Illustrative examples of the different issues identified.

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.



Copyright issue: The copyright information highlighted in red was incorrect. This was rated as Severity 1.

Font formatting: Adjective in red should have been bolded. This was rated as Severity 2.

Incorrect translation: A trademarked name was used instead of *tissues*, which could cause comprehension issues in the target country. This was rated as Severity 3.

Untranslated content: In the original language, response options were left in English. This was rated as Severity 5.

Conclusions

Migration errors occur across different studies, assessments, languages, language service providers, eCOA vendors and sponsors, underscoring the need for routine identification and assessment of inconsistencies from operational and scientific perspectives. I-MESS enables systematic evaluation of migration errors based on their potential to affect patient experience and data integrity.

The inconsistencies analyzed here demonstrate the widespread nature of these issues and their varying severity levels.

As new technologies such as AI-enabled migration and proofreading tools becomes available, application of the I-MESS could be productively integrated to improve quality outcomes and address errors early through scientific methods.

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