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From Translation to Patient Screen

Three Critical Points Where COA Localization Can Affect Data Quality

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01 | Introduction

Clinical Outcome Assessment (COA) localization is often described as a translation activity. In reality, translation is only one part of a much longer journey.

A COA may begin as an approved source instrument, move through linguistic validation, be implemented on an electronic platform, reviewed in screenshots, and eventually appear on a patient's device. At every stage, decisions are made that can influence how the assessment is understood and completed.

This matters because COAs are not simply patient-facing content. They are measurement instruments, and their data is used in clinical trials to provide meaningful endpoints. A translation can be linguistically accurate, but interpreted differently by patients if not culturally adapted. An approved translation can be implemented incorrectly on screen. A quality protection review process can become inefficient if it repeatedly

catches problems that originated much earlier. These three areas are closely connected.

This eBook looks at the COA localization journey through three questions:

- Can two accurate translations produce different patient data?
- Can a correct translation become incorrect during eCOA implementation?
- Why does screenshot review so often become the place where those problems are finally discovered?

Ultimately, localization quality cannot be assessed at a single point in the process. It must be protected from the first linguistic decision through to the screen the patient ultimately sees.

02 | Why Two Perfectly Accurate Translations Can Produce Different Patient Data

In COA translation, accuracy is essential. However, accuracy alone doesn't mean two translations will perform in exactly the same way.

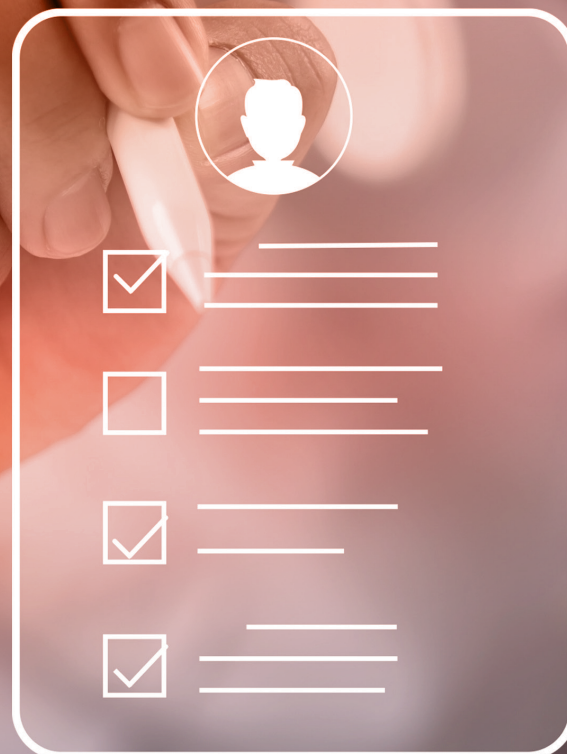
Two linguists can translate the same item, produce versions that are grammatically correct and faithful to the source, and still make choices that influence how a patient understands and answers the question. This is one reason linguistic validation differs from conventional translation. The objective is to preserve the concept being measured and the way respondents are expected to interpret it.

Consider a hypothetical statement:

“During the past 7 days,
how often did you feel
exhausted?”

Depending on the target language, “exhausted” may have several plausible translations. Each carries slightly different associations with physical tiredness, lack of energy, or a broader feeling of exhaustion. None is necessarily wrong, but if respondents understand those terms differently, they may answer differently — even when their underlying health status is the same.

The same challenge appears with concepts such as pain, discomfort, difficulty, tiredness, frequency, and severity. It can also affect recall periods and response options.



A hand holding a white pen is shown pointing at a digital form overlay. The form features a circular icon of a person's head and shoulders at the top. Below this, there are four rows, each starting with a checkbox. The first, third, and fourth checkboxes are marked with a checkmark, while the second is empty. To the right of each checkbox are three horizontal lines for text input. The background of the entire page is a blurred image of a person in a white lab coat, likely a healthcare professional, holding a pen.

When Synonyms Are Not Equivalent

Translation discussions often reach a point where two alternatives are both considered linguistically acceptable. From a measurement perspective, however, synonyms are not always interchangeable. Take an illustrative response scale moving from “a little difficult,” to “moderately difficult,” to “very difficult.” The translator should consider the relationship between each of the individual responses. If the target-language equivalent of “moderately” feels much closer to “very” than it does in the source, the progression of the scale may change.

This is why context is so important. Linguists need to understand what an item measures, how it relates to surrounding items, and what distinctions the developer intends respondents to make.

Concept Elaboration Helps Remove Assumptions

A useful concept elaboration explains not only what an item means, but sometimes what it does not mean. For example, if “difficulty walking” is intended to describe the effort required to walk rather than the pain experienced while walking, that distinction can change the most appropriate translation.

Without that information, translators may make different, but perfectly reasonable, assumptions.

Why Respondent Input Still Matters

Linguistic review can determine whether a translation is accurate, natural, and conceptually defensible. It cannot always predict how the intended population will interpret it. That’s where cognitive debriefing adds value. It can explore what the respondent thought the question meant, what they considered when answering, and whether any terms or response options created ambiguity.



Ultimately, the goal is consistent measurement intent. Even once that intent has been successfully preserved in translation, another challenge begins. It’s vital to ensure the intent survives the transition from the approved validated translation to the electronic environment.

References

Wild D, Grove A, Martin M, et al. *Principles of Good Practice for the Translation and Cultural Adaptation Process for Patient-Reported Outcomes (PRO) Measures: Report of the ISPOR Task Force for Translation and Cultural Adaptation.* *Value in Health.* 2005;8(2):94–104.

FDA. *Patient-Focused Drug Development: Selecting, Developing, or Modifying Fit-for-Purpose Clinical Outcome Assessments. Final Guidance, October 2025.*



03 | 7 Ways a Correct COA Translation Can Go Wrong During eCOA Implementation

If a COA translation has completed linguistic validation and the translation is correct, then these stages have occurred:

- Terminology has been agreed
- Required reviews are completed
- It's gone through cognitive debriefing
- Final Certificate of Translation has been produced

Importantly, the version the patient most frequently interacts with these days is an electronic version of that translation. eCOA migration sits between the approved file and the patient-facing screen. The migration process introduces another opportunity for discrepancies to arise between the approved translation and the version ultimately presented to the respondent. These are the seven ways it could create discrepancies.

1. Text Gets Truncated

Languages expand differently. Content that fits comfortably within an English interface may be considerably longer in another language. If the interface does not accommodate this, translated text can be cut off, overlap other elements, or require unexpected scrolling.

2. Line Breaks Change How the Item Reads

Line breaks may appear cosmetic, but they can alter comprehension. A poorly placed line break can separate a qualifier from the phrase it modifies. Or it could change how an instruction is visually interpreted. The words are still correct, but their presentation is not.

3. Response Options Are Displayed Incorrectly

Response scales can be affected when options appear in the wrong order, labels become disconnected from buttons, or the visual relationship between responses changes. A correct translation cannot compensate for an incorrectly implemented response structure. It also can't remedy serious issues like copyright infringement.





4. Meaningful Formatting Disappears

Bolding, capitalization, spacing, or indentation may distinguish instructions, emphasize recall periods, or guide the respondent through an assessment. If these distinctions disappear during migration, all of the correct words may still be present, but the experience has changed.

5. The Platform Does Not Behave Naturally in the Language

Right-to-left languages are an obvious example. Appropriate implementation involves more than right-aligning translated text. Navigation, response scales, numbers, and mixed-direction content all need to behave naturally. Other languages introduce challenges around character sets, fonts, and text expansion.

6. A Late Change Creates Multiple Versions of the Truth

If a linguistic change is approved after migration has started, it can create discrepancies. The approved file could be updated, but perhaps the electronic build hasn't been updated. Maybe screenshots are generated without the change, or not every stakeholder is working from the same version. The risk is that the correct translation exists in one location, while an outdated version is used elsewhere.

7. Correct Content is Implemented in the Wrong Place

The translation may be correct, but mapped to the wrong item, instruction, or response option. This can be particularly difficult to detect when large volumes of multilingual content are being implemented. The patient sees the screen, but does not interact with the approved translation file, linguistic validation report, or translation certificate. Most likely, they interact with the app or desktop version. This means quality cannot stop at linguistic approval. It must continue through migration, testing, and deployment.

References

Mowlem FD, Elash CA, Dumais KM, et al. *Best Practices for the Electronic Implementation and Migration of Patient-Reported Outcome Measures.* *Value in Health.* 2024;27(1):79–94. doi:10.1016/j.jval.2023.10.007.

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Romero H, DeBonis D, O'Donohoe P, et al. *Recommendations for the Electronic Migration and Implementation of Clinician-Reported Outcome Assessments in Clinical Trials.* *Value in Health.* 2022;25(7):1090–1098.



This is precisely why screenshot review is such an important part of eCOA localization. It provides one of the final opportunities to confirm that the patient-facing version still reflects what was originally approved. The challenge is what happens when that final verification step starts finding 'too many' problems.

04 | Why eCOA Screenshot Review Becomes a Bottleneck

Screenshot review is an important quality control step in multilingual eCOA implementation. Once translated COA content has been implemented on an electronic platform, screenshots are generated and reviewed to confirm that the approved linguistic content has been transferred and is displaying correctly.

While the principle is straightforward, the process can become resource-intensive in large global studies. Multiple review rounds may be required, queries can move between several stakeholders, and corrections often require new screenshots to be generated and reviewed. Late changes to the source instrument or approved translations may require further checks despite previously having undergone review.

The impact becomes particularly visible when multiple instruments and languages are involved.



What begins as a final QC activity can quickly develop into a significant operational bottleneck, particularly when screenshot review identifies issues that originated earlier in the localization or implementation process.

Screenshot Review Can Expose Upstream Issues

By the time a screenshot reaches a linguistic reviewer, these activities have already taken place:

- Selection of source instrument
- Translation and linguistic validation completed
- Transfer of approved content to eCOA provider
- Configuration of electronic build

Some findings can only be identified once translated content is viewed in its final context. These findings may include:

- Truncated or missing text
- Inappropriate line breaks
- Incorrect formatting or layout
- Problems with response-option presentation
- Language-specific display issues

Other findings may become visible during screenshot review, but have their root cause earlier in the process. A discrepancy between a screenshot and the approved translation, for example, may result from an outdated file, an incorrect content transfer, poor version control, or a linguistic change that wasn't consistently communicated across stakeholders.

Understanding this distinction is important. Correcting the screenshot resolves the immediate issue, but it doesn't necessarily address the process that created it.



Not Every Screenshot Problem Originates in the Screenshot

When the same type of defect recurs across languages, instruments, or studies, reviewing and correcting each occurrence individually can lead to significant rework. Root-cause analysis can help identify whether recurring findings point to broader weaknesses in areas such as:

- Version and change control
- Content transfer between language and eCOA providers
- Implementation specifications
- Communication of approved linguistic changes
- Platform constraints that were identified too late

This changes the focus from increasing the speed of screenshot review to reducing the number of preventable findings that reach this stage in the first place.

Scale Amplifies Small Inefficiencies

The effect of additional review cycles increases considerably in global studies. With multiple instruments, languages, and screens, even one additional round can create a substantial volume of repeat review.

Late changes have a similar multiplying effect. An early-in-the-process source update may affect a single asset. Once content has been translated, migrated, and reviewed across multiple languages, the same update can trigger changes to translations, electronic builds, screenshots, and associated approvals.

Effective change control is therefore closely linked to screenshot review efficiency. The later a change occurs, the more downstream assets and stakeholders risk being affected.

Measuring Quality Beyond the Number of Reviews

Additional checks may be necessary in regulated workflows, but the number of review rounds alone is not necessarily an indication of a stronger quality process. It can also indicate that defects are repeatedly being introduced earlier in the workflow.

Useful measures of process performance could include:

- First-time-right implementation rates
- Average number of screenshot review rounds
- Number and type of findings per review cycle
- Recurring defect categories and their root causes

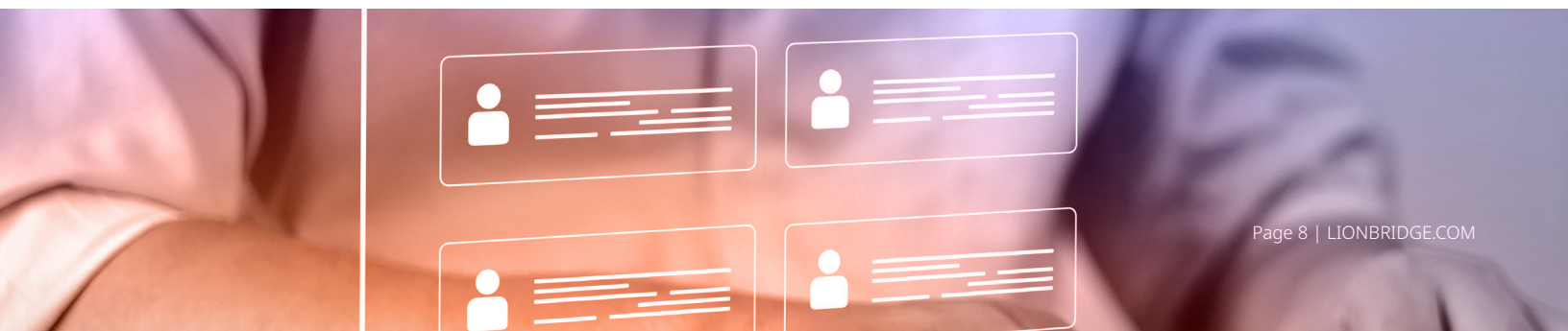
Technology can also support some of the more repetitive comparison activities. Automated checks, for example, can help identify missing content, version discrepancies, and differences between approved linguistic content and the implemented version. Expert review remains important when determining whether a detected difference has implications for linguistic meaning, usability, or the integrity of the assessment.

The objective should therefore be to strengthen quality controls throughout the workflow, to reduce preventable issues during screenshot review. Used in this way, screenshot review can fulfill its intended role as a final verification of the patient-facing implementation, rather than becoming a repeated correction cycle for upstream issues.

References

Mowlem FD, Elash CA, Dumais KM, et al. *Best Practices for the Electronic Implementation and Migration of Patient-Reported Outcome Measures.* *Value in Health.* 2024;27(1):79–94. doi:10.1016/j.jval.2023.10.007.

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05 | Conclusion

Protecting Quality Throughout the COA Localization Journey

COA localization involves a series of connected activities, each of which can influence the integrity of the final patient-facing assessment. Linguistic validation must preserve the intended concept and interpretation. eCOA migration must transfer the approved content accurately into the electronic environment. Lastly, screenshot review must verify that the final implementation reflects what was intended.

The three stages discussed in this eBook also demonstrate how decisions and issues can slip downstream. An unclear source concept can create uncertainty during translation. Weak version or change control can introduce discrepancies during migration. Implementation issues can then generate additional findings and review cycles during screenshot QC. The later these problems are identified, the more languages, assets, and stakeholders they are likely to affect.

An effective end-to-end localization approach should focus on several connected priorities:

- **Conceptual Clarity:** Providing linguists with sufficient context to preserve the intended meaning of the source instrument
- **Controlled Migration:** Maintaining clear version control and accurate content transfer from approved translation through electronic implementation.
- **Early Identification of Constraints:** Considering language-specific and platform-specific requirements before they become implementation issues.
- **Efficient Quality Control:** Using screenshot review to verify the final implementation while investigating the root causes of recurring findings.
- **Appropriate Use of Technology:** Automating repetitive comparison activities where possible while retaining expert judgment for decisions that may affect meaning, usability, or measurement integrity.



Viewing translation, migration, and screenshot review as interconnected parts of the same process provides a stronger basis for both quality and operational efficiency. Improvements made upstream can reduce downstream corrections, while better visibility across the workflow can help teams identify potential risks before they become larger issues.

Ultimately, the quality of COA localization is demonstrated in the assessment presented to the respondent. Protecting that final experience requires consistency throughout the process, from interpreting the source concept to implementing and verifying the final patient-facing content.



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