Garbage In, Garbage Out: Can AI Reduce the Impact of Human Error in eCOA Localized Text Migration?

YPrime

CO125

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OBJECTIVE

eCOA localization is often cited as a major concern for study teams considering the use of eCOA to capture data within their clinical trials[1,2]. With eCOA adoption rising (as demonstrated by an increase in the number of publications reporting clinical eCOA application from 2-4 per year in the early 2000s to 42 in 2023[3]), addressing this concern is of increasing importance. This research assesses the potential for reducing eCOA localization timelines by leveraging Artificial Intelligence (AI) for eCOA migration, with the aim of eliminating human error and the resulting duration of eCOA screenshot proofreading.

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BACKGROUND

eCOA localization requires that existing COA translations (e.g., those licensed from copyright holders or taken from the public domain) be migrated from paper formats (Word or Excel) into eCOA systems. The quality of this often-overlooked step drives the duration of the part of the process seen as taking too long (eCOA proofreading), as errors introduced necessitate additional rounds of screen report generation and linguist review. Yet, industry discussions often focus on the efficacy of this proofreading process, rather than the primary cause of the errors found: the migration of translated COAs.

In eCOA localization, "migration" means replacing English strings in an eCOA platform with their target language equivalent, and this can be challenging for several reasons. First, existing paper content must be mapped to its electronic counterpart (usually within an exported technical file). However, as COA design varies greatly, paper files and technical files can follow very different structures, often making this difficult.

Secondly, as response options often qualify the symptoms specified in a question (e.g., "very severe"), moving from consolidated paper formats (such as tables) to single-item eCOA formats often requires linguistic adjustments to ensure grammatical accuracy. Implementing both changes correctly is challenging as it is often unclear which strings of text in a technical file will be displayed together on the device. Further, as the syntax of many languages differs to English, the placement of HTML tags also must often change. As a result, accurately migrating COAs across languages is highly susceptible to human error.

To date, migration has mostly been handled by Language Service Providers (LSPs), some of which use linguists not necessarily familiar with technical file types, while others use internal technical experts who may not speak the target language and therefore may introduce linguistic errors. However, whichever method is utilized, to be commercially viable their solutions for this task must work across a range of eCOA provider file types. Given how much these vary, it is challenging for third parties to build tools that handle all files equally well and keep pace as changes are made. eCOA providers, on the other hand, only need to develop tools that work with their own bespoke file types. Therefore, if the required language knowledge can be embedded in an eCOA provider's own tools, rather than outsourced to an LSP, it stands to reason that this process could be innovated more effectively.

Since AI is purported to possess both technical and linguistic skill sets, YPrime wanted to explore whether an eCOA provider could leverage AI to manage target-language migrations themselves, combining AI knowledge of the target language with in-depth training on the nuances of the relevant technical files to improve system import quality, enhance screen report accuracy, and ultimately reduce eCOA proofreading timelines.

FIGURE 1: Example comparing paper presentation and corresponding technical file structure.

Paper COA

In the last 7 days, how **severe** was your…	**Very** severe	**Somewhat** severe	**Not very** severe	**No** symptom
nausea?	☐	☐	☐	☐
pain?	☐	☐	☐	☐
sleep disturbance?	☐	☐	☐	☐

Technical File

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<p>In the last 7 days, how <strong><u>severe</u></strong> was your&hellip;</p>
<p><span style=" font-style: italic;" >nausea?</span></p>
<p><span style=" font-style: italic;" >pain?</span></p>
<p><span style=" font-style: italic;" >sleep disturbance?</span></p>
<p><strong>Very</strong> severe</p>
<p><strong>Somewhat</strong> severe</p>
<p><strong>Not very</strong> severe</p>
<p><strong>No</strong> symptom</p>
<p><strong>Very</strong> severe</p>
<p><strong>Somewhat</strong> severe</p>
<p><strong>Not very</strong> severe</p>
<p><strong>No</strong> symptom</p>
<p><strong>Very</strong> severe</p>
<p><strong>Somewhat</strong> severe</p>
<p><strong>Not very</strong> severe</p>
<p><strong>No</strong> symptom</p>
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METHODS

Using a convenience sample of studies (n=15), YPrime reviewed Round 1 eCOA screen report proofreading comments to identify errors introduced during human-led migration. Then, YPrime repeated the migration process, replacing the human with a proprietary AI-powered tool. The human and AI outputs were then compared to see if the human-introduced errors persisted and if AI introduced additional errors.

RESULTS

From the data collected from the convenience sample and remigration activities, YPrime identified that:

1. Human-led migration resulted in 43 screen reports containing errors. When AI repeated the process, this reduced by 60% (n=26).
2. Human-led migration resulted in a total of 76 errors across all the screen reports reviewed. When AI repeated the process, this reduced by 74% (n=56).
3. The AI tool introduced 0 new errors requiring correction.

DISCUSSION

In eCOA localization, screen report proofreading directly follows the migration process and consists of an average of 1-3 review rounds per language, with each featuring a screen report generation stage and a linguist proofreading stage. Ideally, linguists would identify all migration errors in the first round of review and, following error correction, the screen reports would then be approved. However, this is rarely the case. Consequently, eCOA projects generally plan for up to three (3) rounds of review. Therefore, in addition to ensuring the efficacy of screen report proofreading, it is evidently worthwhile exploring ways of addressing the cause of these issues as a way of reducing eCOA localization timelines.

This study identified that, across the sample of work chosen, replacing humans with AI for migration would have reduced the number of screen reports requiring re-generation and re-proofreading by 60%. At the language level, 50% (n=9) of the 18 languages analyzed would have instead been approved after the first round of review. Compared to the industry average of three rounds, this constitutes a 67% reduction. For sponsors, this translates into earlier delivery of certified screen reports, a key requirement for regulatory submissions. Additionally, as eCOA providers generally require approved screen reports to release a localized study build, earlier approval means an earlier start to in-country data collection.

Timeline reductions of this magnitude are not just a competitive advantage for sponsors and their partners; facilitating earlier submissions and data collection have material financial impact, too. There are obvious advantages to bringing medicinal products to market faster and avoiding administrative costs associated with delayed site activation. Therefore, industry innovations ensuring the earlier approval of screen reports prove advantageous both to sponsors and to patients, enabling quicker access to treatment interventions.

A reduction of 74% in the total number of errors clearly demonstrates that AI has the potential to positively impact the migration process. Fewer errors not only mean fewer rounds of review but also reduced cognitive burden for human proofreaders. An unfortunately common issue in eCOA localization is the persistence of errors even after linguist approval. This phenomenon is often the result of heavy workloads, rushed timelines, and overall eCOA complexity. As stakeholders are usually ill-equipped to identify persisting errors (due to the need to speak the target language), enabling linguists to perform higher quality reviews by providing higher quality materials reduces the risk of data-impacting errors being present post approval.

In this sample, AI-powered migration did not return any new issues that were not also introduced by humans. While too small a sample size to make any definitive claims, this supports an initial finding that AI is not inherently more dangerous or error prone than its human counterpart for this particular task, but it does improve quality and increase speed.

Despite the promising results, it is important to acknowledge both the study's limitations and the continued role of humans in eCOA localization. The convenience sample size of 15, while representative, is only a fraction of the studies developed each year. Therefore, AI's performance in this area should be closely monitored as it is embedded into eCOA localization processes. Additionally, given the abundance of languages in the world, results from a study which only included eleven (11) unique languages[4] cannot be taken to be representative of global performance. While the results are promising, and while this approach reduces the manual work a human reviewer needs to do, we do not recommend removing the human from the loop. Instead, we should use the technology to remove mundane, automatable steps from their workload so that they can focus on quality.

CONCLUSION

In this study, AI demonstrated the ability to affect meaningful improvements in eCOA localization timelines by reducing the errors introduced in the migration process, which leads to quicker screen report approvals. However, YPrime recognizes the need for additional research in this area, both with a larger sample size and with additional languages to test the global impact of the solution. Regarding eCOA migration specifically, YPrime believes that this research shows that AI provides a meaningful opportunity for innovation for clinical study teams looking to launch studies quicker with a higher guarantee of quality.

SOURCES / FOOTNOTES

[1] Selecting an eCOA Vendor to Best Fit Localization Needs (TransPerfect Life Sciences, 2024) *(https://lifesciences.transperfect.com/blog/selecting-ecoa-vendor-best-fit-localization-needs)*

[2] 3 Common eCOA Implementation Challenges and How to Solve Them (Applied Clinical Trials, 2025) *(https://www.appliedclinicaltrialsonline.com/view/common-ecoa-implementation-challenges-how-to-solve)*

[3] Sustainability and Time Trends in Electronic Patient-Reported Outcome Assessment in Routine Cancer Care: Systematic Scoping Review and Follow-Up Survey (JMIR, 2024) *(https://www.jmir.org/2025/1/e69398/)*

[4] Arabic, Chinese (Simplified), Czech, Dutch, English, French, German, Hebrew, Italian, Japanese, Spanish