Clinical Outcome Assessment (COA) Translation and Electronic Migration

Communications Among Stakeholders
Challenges and Recommended Approaches

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Developed as part of the *eCOA Translations and Licensing Management* project, a collaboration between Critical Path Institute's PRO Consortium and eCOA Consortium.

SUB-TEAM TITLE

Clinical Outcome Assessment (COA) Translation and Electronic Migration | Communications Among Stakeholders | Challenges and Recommended Approaches

OBJECTIVE

Clinical outcome assessment (COA) translation and electronic migration involves multiple stakeholders with various roles, and in some instances a single stakeholder covering multiple roles. Communication among stakeholders involved in these processes is essential to ensure the quality and robustness of the resulting measures used for collecting COA data. The COA environment is heterogenous, resulting in various challenges in relation to COA translation and electronic migration. The table below provides a list of potential stumbling blocks categorized by topic, the stakeholders involved, a short description of the challenge and recommended approaches to address these challenges where the roles of each stakeholder are highlighted and described.

MEMBERS

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Scope and version changes initiated by the copyright holders/COA developers

STAKEHOLDERS: Copyright holders; COA developers; Licensors; Licensees

CHALLENGE

Licensees (i.e., the institution/organization receiving the license to use the measure) need most up to date information on the COA scope and version history to base their decision on which version of the measure to use, especially when they have used an earlier version in a previous study/trial/ clinical trial.

RECOMMENDED APPROACH

- Copyright holders/COA developers are responsible for preparing and describing changes to the COA between versions and the reasoning driving those changes. Such changes can be in the wording of any of the text (instructions, items, response options) or the format/layout of the measure.
- The copyright holders/COA developers/licensors should provide this document describing version changes together with the latest approved version of the measure available to the licensees unless a previous version is specifically required by the licensee/other stakeholders.
- In case study-specific modifications to a measure deviating from the official version are required (for example changing the recall period), these can only be made by the licensees when in receipt of the documented agreement of the copyright holder/licensor/COA developer.

Translation Methodology Requirements

STAKEHOLDERS: Copyright holders; COA developers; Language Service Providers; Licensors; Licensees

CHALLENGE

Licensees may not be fully aware of COA developers' translation methodology requirements when identifying the need for translations for a particular study. Typically, COA developers require either a country-specific or universal approach, both of which are discussed in the literature (Eremenco et al, 2017; Wild et al, 2005; Wild et al, 2009).

Licensees may find it unclear why country-specific translations would be required for a target country (for example, why would Spanish for Spain not be suitable for Mexico?). On the other hand, licensees may not be familiar with the universal approach, i.e., a single translation for use across all countries where the language is spoken. As a result, the amount of time necessary for the linguistic validation process may not be properly accounted for or the incorrect process may be used.

RECOMMENDED APPROACH

Country-specific translation of COAs is a process managed by the Language Service Provider (LSP), by which wording is adjusted to be specific for a country to account for linguistic and cultural intricacies. Such a version of a measure would incorporate specific vocabulary and terminology characteristic to the use of that language for that specific country.

Although country-specific translations may sometimes require comparatively less time to complete the linguistic validation (LV) process, it is essential that the entire process is performed, even when there are no wording differences between the two versions (which can sometimes be the case).

Universal translation is a process by which experienced linguists from as many different countries which speak the target language as possible are included in the translation methodology focusing on a language's commonalities as opposed to its differences. A rigorous harmonization process is included, and cognitive interviews are conducted in as many countries as possible. Interviews can be prioritized based on the study country inclusion if that information is available. Depending on discussion during the translation phase or data collected during the cognitive interview phase, item-specific adaptations/localizations may be warranted to ensure conceptual equivalence.

The copyright holder/COA developer/licensor is responsible for providing information to the LSP and Sponsor/licensee to clarify the translation methodology requirements, be they country-specific or universal, and the timeline required for project completion that conforms to standards. Should the copyright holder/COA developer/licensor be unable to provide the translation methodology requirements to apply, the LSP should take the responsibility to recommend the best approach to take.

Licensees should ensure they factor in enough time for the entire licensing, linguistic validation, and eCOA migration process into their overall timelines. If needed to meet timelines, the English version of screenshots along with the paper version in the target language(s) may be acceptable before submission for local ethics review.

Awareness around timelines and requirements for the measures

STAKEHOLDERS: Copyright holders; COA developers; eCOA providers; Language Service Providers; Licensors

CHALLENGE

Copyright holders and COA developers may have different requirements for the linguistic validation (LV) process, which may include their team carrying out quality control checks at different time points during the LV work (after forward translation, back-translation, harmonization, clinician review, cognitive debriefing and proofreading). COA developers may or may not have concept definitions to support the translation process of their measure(s).

It may be the case that the copyright holders/authors have additional quality checks for electronic migration of the measure as well.

Licensees/Sponsors may be determining timelines based on an average project duration which may be shorter than the time required for good quality work.

RECOMMENDED APPROACH

Discussion at the beginning of a project on expected timelines and involvement in the project by the different stakeholders is recommended. To set expectations, the sponsor should share as early as possible the planned timelines for key milestones (e.g., Ethics submission, site initiation) where any eCOA set up or translation activities could end up on the critical path; if all stakeholders are involved in developing that timeline, any potential conflicts can be accounted for in advance.

Copyright holder/COA developer: Have process documentation ready to send along with other licensing materials to licensees/sponsors, LSPs, eCOA Providers. Communicate with LSP whether copyright holder and/or author wishes to be involved in the translation process and at what stages, as additional time is required for review rounds that needs to be incorporated into the overall timeline. COAs requiring translations should be accompanied by concept definitions, if available. COA developer, specifically, is responsible for providing feedback/approval on any COA concept definitions developed by the LSP, if these are not already available. At project completion, the COA developer, Licensee, and the LSP should determine who will house, maintain, and receive the concept definitions. It is recommended for the initial author of the concept definitions document (e.g., COA developer or the LSP) to deliver the concept definition document to the licensee/sponsor upon request. There are two potential approaches to recommend for the housing and maintenance of the concept definition document:

- The COA developer should house, maintain (if possible), and circulate the concept definition document for future rounds of work and in instances where multiple LSPs are involved in larger item bank translation initiatives,
- Alternatively, the LSP who originally developed the concept definitions may also house and maintain them for future rounds of work. However, the LSP may need to provide the licensee/sponsor or COA developer with any updates made during a project's lifecycle or over many projects. This would require regular communication from the LSP about changes to the concept definition document.

LSP: If concept definitions do not exist for the COA(s) requiring translation, the LSP is usually charged with developing them, with feedback/approval from the COA developer.

eCOA Provider: COA developer/Copyright holder to communicate their recommendations/requirements to the eCOA Provider.

Discrepancies between eCOA translation and current measure translation

STAKEHOLDERS: Copyright holders; COA developers; Language Service Providers; eCOA providers

CHALLENGE

eCOA Providers at times will overwrite the most recent version of the translation with a prior version retrieved from their own library or from a previous study builds they worked on, unbeknownst to the LSP, and then return that version of the build to the LSP for review. The most recent translation changes are therefore not incorporated.

Alternatively, the eCOA Provider will use the most current version that they are aware of and have in their libraries, but the copyright holder or the COA developer has made a change to the original COA or to a translation without announcing it publicly. In both scenarios, discrepancies exist between the translated eCOA and latest translation of the measure.

RECOMMENDED APPROACH

When working on a build for a new study, eCOA Providers should not re-use builds of the same instruments from previous or existing studies but always use the source files released by the Licensor for the particular study, unless the eCOA Provider has an official library of particular instrument(s) and their translations, and that the right version needed for the study is available in that library which also has an automated validation method to check versioning of the English and any languages stored in the library.

eCOA Providers should be transparent about which translation version is being used when the LSP is reviewing builds or screenshots. Sharing a study build schedule at project kickoff, if possible, is recommended.

Ongoing communication between the LSP and eCOA Provider is essential to provide notification of any previously unscheduled study build updates, as well. It is recommended to hold 'check-point meetings' to confirm that all requirements have been considered and implemented throughout the project, as well as verifying that the most up-to-date translation has been migrated. If the Copyright Holder or the COA developer is involved, they could also review final electronic versions. A close collaboration between the eCOA developer/copyright holder and the LSP is recommended when working on edits to COA translations; any changes to previously approved translations should be documented and tracked to ensure the control of the version history.

Any changes made by any of the stakeholders involved need to be cross-communicated and the last step in finalization of the eCOA should be cross-checking that the translation used is indeed the relevant licensed version in the target language that matches the original version in the source language built in the device.

Review of eCOA build and source screenshots prior to translation

STAKEHOLDERS: Copyright holders; COA developers; Language Service Providers; eCOA providers; Sponsors/licensees

CHALLENGE

During finalization of the English source build and screenshots, it is noted that the source formatting is not displaying correctly and/or as intended due to eCOA Provider platform limitations.

RECOMMENDED APPROACH

Consult with the eCOA Provider to confirm if the technology limitation can be fixed within the necessary timeframe to have materials ready for the study. If the limitation cannot be fixed as needed, the eCOA Provider should present alternative options for the sponsor/licensee to choose from. License agreement may further require that the COA developer or Copyright holder is involved in the decision-making process.

Distinction between eCOA User Acceptance Testing and Usability Testing

STAKEHOLDERS: Copyright holders; COA developers; Language Service Providers; eCOA providers; Sponsors/licensees

CHALLENGE

Sponsors/licensees often confuse User Acceptance Testing (UAT) and Usability Testing (UT) and when each is needed.

RECOMMENDED APPROACH

Education from eCOA Providers and LSPs that UAT aims to ensure that the product meets the sponsors/licensees' requirements while UT examines whether respondents from the target population are able to use the software and the device appropriately (Coons et al, 2009). UAT is a standard and necessary step in eCOA system development. While there are legacy guidelines that note UT is required, it is important to understand those guidelines may not represent current industry thinking which accounts for digital modalities now being mainstream in clinical trials. Most eCOA apps and platforms have established usability evidence so the same need for UT does not exist. If the license agreement does not specify the requirement to perform a UT, sponsors/licensees need to discuss with eCOA Providers and LSPs to determine if there is a value-add in this service for their study, which is likely only for some specific populations or new apps/platforms with substantial differences from existing ones.

Cognitive debriefing interviews

STAKEHOLDERS: Copyright holders; COA developers; Language Service Providers

CHALLENGE

Two main problems seem to recur. The first is difficulty finding respondents that suit the population for which the COA is designed. The second is difficulty extracting enough information about the respondents' understanding of the items and concepts, due to the lack of information documented during the interviews.

RECOMMENDED APPROACH

Communication of expectations between Copyright holder, COA developer and LSP is recommended. It is recommended that the stakeholder requesting the cognitive debriefing in the context of linguistic validation provides the LSP with a detailed description of characteristics required for the respondents, as well as suggestions for alternative approaches (e.g., alternative population selection criteria, alternative recruitment options) if recruitment proves difficult. Any Personal Health Information (PHI) or Personal Identifiable Information (PII) collected (following European Global Data Protection Regulation [GDPR]) by the LSP should be done in a manner that conforms to protecting the respondent's confidentiality and be maintained/archived/destroyed in accordance with the sponsor's or other stakeholder's study requirements as related to the treatment of human subject data. Some copyright holders choose to provide the LSP with an interview template detailing the way the measures are expected to be administered, recommendations on how the interviews are to be run, and what information regarding respondent comprehension is critical for collection to linguistically validate the measure.

References

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