Peer-Review process to improve the Quality of Linguistic Validation Process of COAs Instruments for Clinical Trials

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International Clinical Trials use to apply Linguistic Validation (LV) Standard Process for cultural adaptation of COAs instruments

PROs, ClinPROs, ProxyPROs, PerfROs

To the local translation of sufficient adherence to Concept Definition key items, reports or true awareness of local terminology, language or idiom is critical equivalent adaptation to study population. Culture sensitive.

Linguistic Validation (LV) Standards

Time Pressure, Budget Limitations, Availability of Local Experts etc.

Concept List Availability, Different equivalence criteria (primary vs secondary clinical endpoints)

Measurement Validity, Precision Concerns Across languages

LV Deliverables

Reconciliation Report (also Back Translation Report - BT)

Final Instrument Translated, Formatted and Customized i.e. Scale/Test

Certification of Translation

Measurement Validity

Independent Audit

Second review by an independent local therapeutic area or COA expert

- Based on the audit of reconciliation reports of 10 COAs translated into 18 languages and dialects. The analysis of 200 translations, resulted in 217 findings where, 44% of them were evaluated as a potential impact on measurement of any level, and a 27% rated as a potential significant impact.
- The derived method aims to confirm whether produced linguistic equivalent versions, involves any risk on the measurement precision of the clinical outcome.
- Derived methodology is designed first, to identify and categorize issues and second, to rate them based on the potential impact over clinical outcome measurement.

QUALITY ANALYSIS OF COAs TRANSLATION

1st Step IDENTIFICATION & Categorization (A-E)

Qualitative Analysis

Categorization of findings observed at different steps of the LV process i.e. from BT and from FT review by an English native speaker or local clinicians (bilinguals).
- Inadequate Forming: Error in the formatting of texts or sections.
- Grammar Error: A word’s sentence has a different meaning after an erroneous sentence composition. Inaccurate translations or too literal translations are included also in this category.
- Word/Sentence Modified: The word is changed and it results in a different meaning of the sentence.
- Omission or wrong word addition: Modifications that result in some information lost in the local translation.
- Inadequate Cultural Adaptation: Either full or partial sentence has to be further adapted to the local cultural context.

Evaluation of Impact

Analysis of each finding regarding impact on endpoint measurement by allocating a score to range impact severity from 1 to 5.
- Moderate Impact: The item is almost equivalent as the source English, but changes can be introduced order to improve understanding or to be more specific.
- Major Impact: Impact on measurement because, an important segment of the target population, can potentially make a wrong interpretation of the item.
- Significant or High Impact: Significant because the item is not clear as a half of the population can understand it in one way and the other half in the other.
- Critical or extreme impact: The item has an important mistake (so everyone will answer it wrongly) or it is talking about another factor or about a factor not evaluated in the task.

Scores 3 to 5 are considered to be the most relevant impact levels requiring further resolution before its use.

2nd Step IMPACT EVALUATION

3rd Step FINAL RESOLUTION

Resolution and Final Editing

- Quality summary i.e. % and percentage of issues per category over total segments.
- Potential Impact summary i.e. % and percentage of issues per level of impact.
- Highlight and description of issues with impact scoring ≥ 3 and solutions.
- Look up existing patterns of findings i.e. languages, COA type or length.
- Final decision about impact on measurement and final editing.
- Final edited, new translation version is issued.

The utility of a ”summary impact score” needs to be explored.

APPLICATIONS

- To audit existing translations (from clinical trials or publishers) before going further in drug development projects or international clinical research.
- To audit existing translations in an ongoing basis during clinical trials, when issues are repeatedly reported by site staff.
- To audit new translations conducted from scratch with the aim to confirm measurement precision and to prevent issues on clinical outcomes measurement.

Conflict of Interests Silvia Zaragoza Domingo and Vanitha Krishna were former employees of Cogstate Ltd.

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