Peer-Review process to improve the Quality of Linguistic Validation Process of COAs Instruments for Clinical Trials
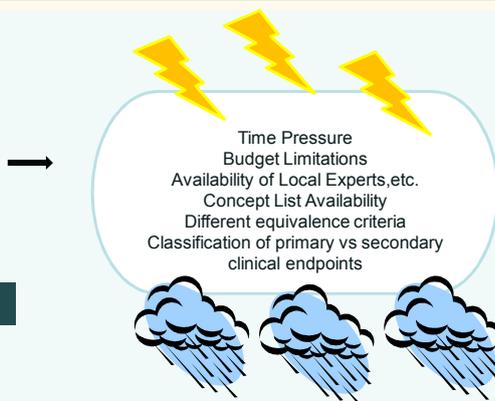
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International Clinical Trials use to apply *Linguistic Validation (LV) Standard Process* for cultural adaptation of COAs instruments

PROs, ClinPROs, ProxyPROs, PerfROs

Time Pressure
Budget Limitations
Availability of Local Experts,etc.
Concept List Availability
Different equivalence criteria
Classification of primary vs secondary
clinical endpoints

COAs Final Translations "Linguistically y& Culturally Equivalent"

Measurement Validity Precision Concerns Across Languages

Too literal translations Insufficient adherence to Concept Definition Missing sentence segments or items Inaccuracy of local terminology Inadequacy of stimuli in PerfRO Insufficient adaptation to study population Confusing instructions

LV Deliverables

Reconciliation Report
(also Back Translation Report -BT)

The review work varies depending on the process contracted to vendors. A final Clinician's review step use to be included.

+

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

+

Certification of Translation

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)

2nd Step
IMPACT EVALUATION (1-5)

3rd Step
FINAL RESOLUTION

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).
A. Inadequate Formatting: Error in the formatting of texts or sections.
B. Grammar Error: A word / sentence has a different meaning after an inadequate sentence composition. Inaccurate translations or too literal translations are included also in this category.
C. Word/Sentence Modified: One word is changed and it results in a different meaning of the sentence.
D. Omission or wrong word addition: Modifications that that results in some information lost in the local translation.
E. 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.
1. None or low impact: Impact is not expected on measurement but in order to concur with other items, tests or evaluations it needs to be changed.
2. Minor or Mild Impact: The item is almost equivalent as the source English, but changes can be introduced order to improve understanding or to be more specific.
3. Moderate Impact: Impact on measurement because, an important segment of the target population, can potentially make a wrong interpretation of the item.
4. Significant or high impact: Significant because the item is not clear so a half of the population can understand it in one way and the other half in the other.
5. 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 test.

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

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.
- If edited, a new translation version is issued.
- Update the Certification of Translation in order to mention this final quality analysis.

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.