LINGUISTIC VALIDATION OF CLINICAL OUTCOME ASSESSMENT (COA) MEASURES

CLIENT PROFILE: *A global Contract Research Organization (CRO) dedicated to ensuring rigorous clinical research.*

OBJECTIVES

Provide **linguistically accurate**, **conceptually equivalent**, and **culturally tailored translations** of two critical tools:

1. **Patient-Reported Outcomes (PRO) measure:** To gauge patient-assessed pain intensity.
2. **Clinician-Reported Outcome (ClinRO) measure:** For clinicians to evaluate the pain's influence on daily patient life and overall well-being.

BENEFITS

1. Robust Reliability

With linguistic validation, the PRO and ClinRO measures are primed to offer enhanced reliability and genuine insights in clinical trials.

2. Cultural & Clinical Relevance

The PRO and ClinRO measures ensure cultural sensitivity and clinical relevance, to obtain authentic and bias-free responses from patients and clinicians.

3. Ready for Clinical Trial

Linguistic validation is crucial for the COA measures' acceptability and use in clinical trials, ensuring consistent and reliable feedback across diverse linguistic landscapes.

AT A GLANCE

CHALLENGES

- Upholding clinical and emotional nuances during translations.
- Striking a balance between cultural relevance and the original tool's essence.
- Efficiently weaving together diverse feedback for clarity and authenticity.

BENEFITS

- Enhanced tool reliability in clinical trials due to meticulous linguistic validation.
- Amplified role of patient and clinician feedback in assessing treatment impacts.
- Clinically, culturally, and globally vetted tools for universal application.

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ana@anasofiacorreia.com

APPROACH

1. Familiarization with Materials: Performed an in-depth analysis of the COA measures to appreciate their nuances and objectives.

2. Linguist, Clinician, and Patient Recruitment:

- Experienced forward and back translators familiar with COA measures.
- An expert clinician in the therapeutic area to review the ClinRO.
- Five patients from the target population through patient associations and social media.

3. Forward Translation: Outsourced two forward translations of the original PRO and ClinRO into the target language, ensuring the retention of its clinical nuances and subjective sentiment.

4. Reconciliation: Collaborated closely with both forward translators to reconcile the two versions, ensuring a harmonized and precise version.

5. Back Translation: Outsourced the back translation of the reconciled version into English to pinpoint potential inconsistencies or misinterpretations.

6. Review: Conducted an in-depth review of the back translation against the original and the reconciled version to ensure the fidelity of the content and adherence to the original's intent.

7. Cognitive Debriefing (PRO): Interviewed five patients from the target demographic, extracting feedback on clarity, relevance, and emotional resonance of the translated PRO measure.

8. Clinician Review (ClinRO): Collaborated with the clinician to review the ClinRO, ensuring its linguistic precision and clinical appropriateness.

9. Incorporation of Feedback: Adjusted the PRO based on feedback from the cognitive debriefing and modified the ClinRO based on the clinician's insights.

10. Final Review and Approval: Ensured that both the PRO and ClinRO aligned closely with the original content.

11. Documentation & Reporting: Produced a comprehensive report detailing the methodologies, challenges, feedback, and decisions made.

THANK YOU FOR READING!

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