Case Study

Science First: IQVIA Linguistic Validation Delivers a Complex Cognitive Battery Project on a Tight Timeline

Combining scientific rigor with flexible and agile project management, the IQVIA Linguistic Validation team successfully completed the translation and validation of a series of complex cognitive batteries into Japanese and Spanish (U.S.), delivering the project to a high standard and meeting the submission timelines.

Situation

The project consisted of nine Clinical Outcome Assessments (COAs) for cognitively impaired patients. COAs are used as key endpoints in the study and as such, having a rigorous methodology in place is key to ensure accurate data capture and data quality is crucial. The Linguistic Validation Project Manager (PM) ensures accuracy of scale management through translation.

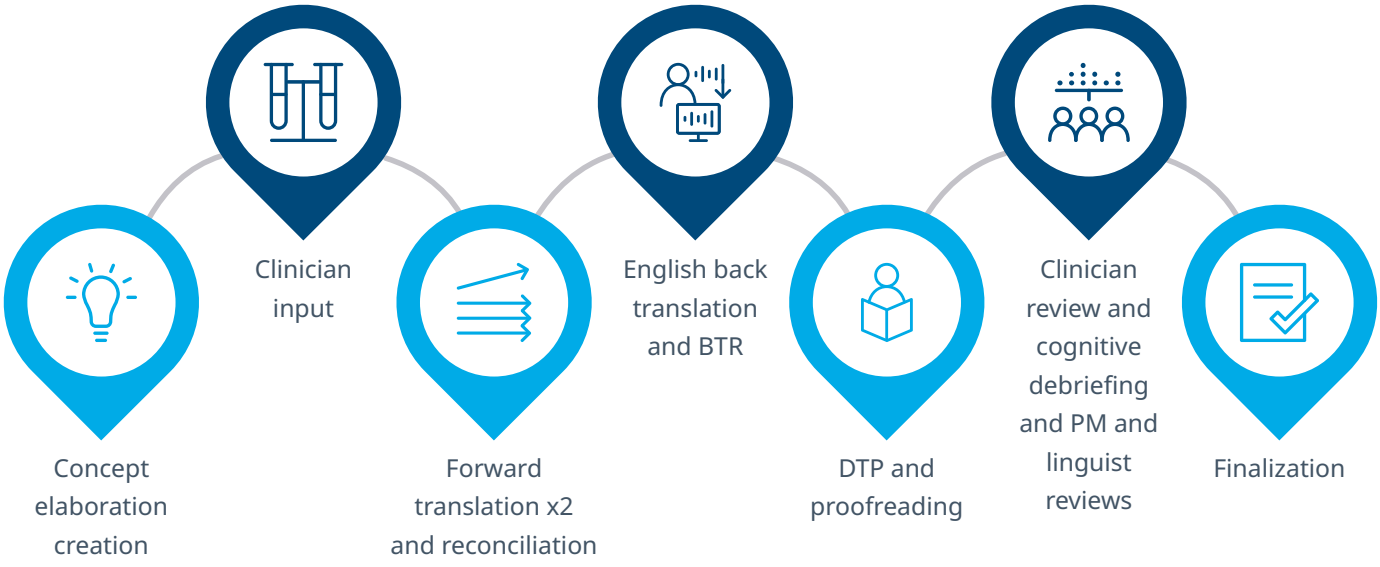
Challenges

- The sponsor was unaware that COAs files would require the linguistic validation process and therefore estimated a timeline of two weeks for the translation to be completed. However, a typical linguistic validation timeline for a scope as large as this would typically be 16-20 weeks.
- The source COAs used in this project caused further challenges as they included cognitive batteries, used to test patients' cognitive function, to be completed by the clinician and observers of the patient. These included recall tests and letter fluency tests that required alternate stimuli to replace the English versions in non-Latin alphabets (for example, the patient is asked to think of as many words as they can starting with the letter 'F', which must be localised to an equivalent Japanese character).
- Complexities can arise during the Linguistic Validation process into Japanese, given the considerable cultural and linguistic differences between the source and target languages.

Outcomes

- IQVIA successfully delivered this project in **12 weeks** and provided drafts for submission in order to **maintain the initial Institutional Review Board (IRB) timelines**. To reduce the timeline without compromising on scientific quality, key tasks such as concept elaboration creation and back translation review were split between two experienced LV PMs, overseen by a Lead PM for consistency. The internal linguists were set up in advance to expect the files to work on as a priority and, as they are internal employees, direct communication and discussion on translation complexities was feasible.

- IQVIA recommended including **additional input from a native clinician working in the target therapeutic area**. This proposed methodology was designed to ultimately remove some of the required discussion throughout the process and therefore save time. In a standard linguistic validation methodology of a Clinical Outcome Assessment (ClinRO) or COA that contains instructions or prompts for a clinician, the clinician review occurs in place of the patient cognitive debriefing. However, for this project our recommendation was to also include this step at project initiation, while still maintaining the standard clinician review and cognitive debriefing step at the end of the project.
- IQVIA created **detailed concept elaborations** to guide the translation process and provided these documents and the source questionnaires to the clinician at the project initiation to collect their feedback on the source documents and linguist reference materials before translation. The integral knowledge of the condition and patient population offered by the clinician was used to lead the translators through the initial linguistic validation translation process of two forward translations, reconciliation, and back translation. The clinician review was then repeated on the Japanese translation, along with cognitive debriefing. An additional language was added later to the project and IQVIA was able to leverage the existing documentation to streamline the process further.



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