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CROSS-CULTURAL EQUIVALENCE IN TRANSLATION ENABLING CROSS-CULTURAL DATA COMPARISON

14 LANGUAGES | 4 CONTINENTS | 3 PRO INSTRUMENTS

Linguistic Validation of Hemophilia-Specific Patient-Reported Outcome Measures in 14 Languages

BioMarin engaged Lionbridge Life Sciences to provide the linguistic validation services for its Phase 3 study program conducted to evaluate the efficacy and safety of the study drug in adult patients with severe hemophilia A.

Hemophilia is a rare condition caused by a missing or defective protein needed for blood clotting. It affects almost exclusively males. The condition is mainly passed down from parents to children, although about a third of cases are caused by a spontaneous mutation. The two main types of the condition are hemophilia A and hemophilia B; each type ranges in severity from mild, to moderate, to severe.

The clinical manifestations of severe hemophilia A are frequent spontaneous bleeding episodes, predominantly in joints and soft tissue, with a substantially increased risk of death from bleeding when the brain is involved.

There is currently no cure for hemophilia, though treatment has advanced dramatically over the past decades, especially with the advent of gene therapy. As management of the condition has improved, recognition around the importance of patient-reported outcome (PRO) measures in evaluating the effects of treatment from the patient perspective has also increased.

About the Customer

BioMarin Pharmaceutical Inc. is a global biotechnology company that develops and commercializes innovative therapies for people with serious and life-threatening rare disorders. With solid development experience and worldwide infrastructure, it has a long-standing commitment to the patients and communities it serves.

The Challenge

Lionbridge was tasked with the translation of the 3 PRO instruments used to measure the impact of hemophilia on the patient's functional abilities, work productivity and quality of life. The translations were needed for 14 languages spreading across four continents: North America, Europe, Asia and Africa. Due to the variety of conceptual, linguistic and cultural nuances across the target countries, it was critical to ensure that a robust and comprehensive translation process was carried out to enable pooling and comparison of PRO data obtained from the global sites participating in this study program.

Quick identification and recruitment of respondents with hemophilia for cognitive debriefing interviews in the target countries were essential to the timely completion of the translation process in order to meet the varying IRB/IEC submission deadlines. Cognitive debriefing interviews are conducted to collect patient input on the translations to gauge their conceptual and cultural relevance and how well target population groups understood the translated content.

As some countries were going to be brought into the program later than others, effective synchronization and coordination of multiple schedules and resource teams were paramount to the overall success of the project.

The Solution

To develop linguistically validated translations, Lionbridge used an industry-recognized methodology for translation and cross-cultural adaptation of PROs. First, the concepts in the original questionnaires were defined to provide clarity during translation and to promote translation harmonization across all language versions. The original questionnaires then went through the dual forward translation, reconciliation, back-translation, comparative review and resolution steps. In some instances, an adjusted adaptation process was applied where the same language was used in different countries.

Following that, Lionbridge's in-country experts tested the translations with a small group of patients with hemophilia A via semi-structured cognitive debriefing interviews. The results of these interviews were analyzed and summarized by the debriefers in cognitive debriefing reports. The reports were reviewed and discussed between Lionbridge's project team, debriefers and translators, and the translations were fine-tuned, formatted, checked for quality and then finalized. The results achieved were translations of high conceptual, linguistic and cultural equivalence and quality.

Each step of process was documented in linguistic validation reports, which were provided to BioMarin together with the final deliverables and certificates of translation. For regulatory authorities, linguistic validation reports serve as important documentary evidence of content validity and comparability between the original and new translated PRO instruments.

To ensure alignment of multiple translation schedules with the IRB/IEC submission dates, Lionbridge's project team employed a risk-based project planning strategy. For example, in the case of translations into German for Belgium, cognitive debriefing was replaced with review by an expert clinician. Due to a small target population group, the time needed for the identification and recruitment of respondents for cognitive debriefing would have otherwise jeopardized the submission deadline. In the case of translations into German for Austria, cognitive debriefing was arranged to be conducted via telephone (instead of in-person) interviews as the respondents were geographically dispersed relative to the location where the interviews were to take place.

By proactively identifying risks and advising BioMarin on alternative solutions based on the industry standards and best practices, Lionbridge ensured that the project schedules remained on track without sacrificing the quality of the linguistic validation process.

CONCLUSION

Linguistic validation projects are complex in their nature and have to be meticulously planned and executed to achieve success.

Effective project management, teamwork, close collaboration and transparent communication between Lionbridge and its linguists and subject-matter experts, and between Lionbridge and BioMarin, resulted in the successful realization of the project's intended outcomes.

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