CLINICAL RESEARCH NEWS
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How to Make Translations Work for Everyone

Contributed Commentary by Adina Tapalaga

April 19, 2021 | When conducting a clinical trial on a global scale, sponsors assume a certain amount of risk in addition to significant management challenges, many of which can be attributed to communication. The ongoing research enabled by clinical trials is critical to the development of medicines that have the potential to change patients' lives, and a patient's ability to understand everything a medical trial involves is paramount to the trial's success. This is especially true in countries where a patient's only access to medical care may be through the clinical trial experience. For this reason, comprehensive translation strategies are important to consider prior to moving forward with a clinical trial.

For background, the 20 largest pharmaceutical companies based in the U.S. conduct an estimated 50% of their clinical trials in other countries, which can lead to different types of challenges depending on the location. Additionally, each country has different languages and cultural customs that can lead to confusion if not properly addressed at the outset of a trial.

The risk of mistranslation is too significant to ignore. Improper translations can cause a patient to misunderstand or not properly follow the trial guidelines, decrease the likelihood of appropriate follow-up, decrease the likelihood of seeking treatment for side effects and cause disparities in prescription. Moreover, mistranslations can cause a significant hit to a sponsor's credibility and put it at a serious risk of not being able to move forward with a clinical trial. This is detrimental not just to the company, but also the number of patients looking to seek medical treatment to improve their quality of life.

So, what should teams look to do when developing translations for a clinical trial? It's important to know that clinical trial translations differ significantly from other types of translations. The terminology used is very specific to the individual trial and is filled with industry-specific language and technical terminology. Sponsors need to ensure that all patients understand the material at the most basic level, which can be challenging at the outset.

Sponsors can achieve this by working in partnership with service providers to ensure material is appropriately captured at the local level. Additionally, teams should understand the geographic reach of the trial and the languages required to ensure its success and prioritize the most far-reaching translations based on realistic timelines. Once this is determined, the translation process should follow the ISPOR guidelines. Linguistic validation can ensure that the translation reflects the source version accurately and that it will be understood by patients of varying educational and economic backgrounds.

Sponsors and other stakeholders should plan to discuss necessary strategies and contingencies at the outset. The considerations described can help sponsors and researchers manage uncertainty and engage with patients effectively as they navigate the landscape. As an industry, the opportunity to proactively address patient safety and access to studies is critical and will ensure broader participation in current and future clinical research.

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