SIGNANT HEALTH
THE EVIDENCE GENERATION COMPANY™

The Signal

eCOA Best Practices: Ensuring Timely Delivery of Translations

With more than half of all registered studies occurring in locations outside of the U.S. and the continued upward trajectory of this trend, sponsors increasingly must account for clinical instrument translations in their project planning. For protocols that rely on clinical outcome assessment data to support efficacy and other endpoints, study teams should endeavor to maintain standardization and measurement equivalence by applying a thorough translation process to the study's instruments. This can be a time-consuming factor in study setup, especially when instruments need to be implemented on electronic devices for administration through an eCOA system. Often, even the most experienced research teams underestimate the timeline for this process, which in turn impacts the overall study schedule and delays dependent milestones. Each project has its own unique timeline but setting realistic expectations, involving all stakeholders, and beginning the process as early as possible will help keep translations off the critical path and the study on track.

From an operational standpoint, sponsors and the eCOA project team begin by acquiring instruments in a base language (usually US-English), followed by designing and building out the eCOA system. That process entails approximately six to eight weeks but could require extra time for instrument owner/author approvals and user acceptance testing. At Signant, our scale management team may get involved in this stage if the instruments are not available in an electronic, validated format. On behalf of sponsors, they will leverage an extensive network of existing relationships with copyright holders to acquire and license source documents as well as any commercially available translations.

From here, the process of developing additional translations can begin following the project kickoff meeting. The recommended timeline to account for in the project schedule varies greatly from study to study and depends on the same factors – scale acquisition, quantity of instruments and languages, and the commercial availability of existing translations and validated electronic versions.

In many cases, existing translations of paper versions require just minor modifications to instructional language to be represented in each language version. However, when new full instrument translations are required, Signant's language management team, as part of the larger eCOA project team, will oversee a comprehensive linguistic validation process, following ISPOR recommendations to translate, back translate, reconcile, harmonize, and validate translations. While intensive, this process satisfies regulatory requirements and ensures native speakers fully comprehend study-related information in the same

way as its source documentation intends. It's also critical for endpoint reliability. Once completed, however, the newly translated instrument can be retained electronically for rapid implementation in other studies requiring the same instrument and language.

To ensure these processes are complete and meet deadlines, we recommend sponsors collaborate with all stakeholders as early as possible and that the project teams work together to establish realistic timelines. Signant provides sponsors and CROs with a dedicated project team consisting of experienced project managers as well as an eCOA science team replete with the clinical and technical specialists the study will need to develop and implement fully translated and validated electronic clinical instruments in preparation for multinational clinical research.