

## *DATATRAK ONE*<sup>®</sup> Strategic Partnership Efforts Recognized by PMDA

### OVERVIEW

As trials continue to become more global in nature there is a need to emphasize good practice around translation needs. At *DATATRAK* we have driven an optimized translation process, as recognized by a leading regulatory agency, by working closely with long-term partners who understand local requirements in detail. The commended solution takes a holistic approach to support local sites not only translating the eCRF but also the instructions for the completion of the eCRFs, boosting site compliance and effective completion of the eCRFs, and providing local helpdesk support.

A leading global CRO ran a series of three trials on behalf of a U.S. based Top 20 pharmaceutical sponsor. *DATATRAK* was selected as the EDC provider for one of the trials and also provided in-country help desk support, leveraging an established long-term partnership. The other two trials utilized a different EDC provider. This comparison of approaches showed that by anticipating the needs of each clinical site location overall trial costs can be reduced and timelines accelerated.

### Challenge

Providing translation services and in-country help desk support is not unique in the current global clinical trial industry. However, having the experience to proactively anticipate study needs and knowing when to provide those services and implementing them quickly and efficiently requires local expertise and implementation by a true partner.

### Translation

The series of three trials all included sites in Japan. To ensure the most productive, efficient and compliant trial process, a thorough understanding of the study protocol and study conduct guidelines is imperative. When site staff is non-English speaking, translation of support study documents is needed but often overlooked. While translation services abound, the time to provide these support services are often overlooked as they are viewed as services that only add to the timeline and expense.

### In-Country Support

In a similar circumstance, ensuring each trial location has access to a local Help Desk during the trial reduces complexity and improves productivity. Training a local Help Desk provider again adds cost and time to an already lengthy and costly process.

### Solution

*DATATRAK* has a depth of experience with global sites and in this case, Japan. Anticipating the needs of conducting efficient trials in all areas of the world, *DATATRAK* developed a strategic partnership in Japan that is empowered with full expertise in the *DATATRAK ONE*<sup>®</sup> platform and in-depth experience with the PMDA. In cooperation with the client, *DATATRAK* and our strategic partner anticipated the needs of the sites and successfully collaborated to provide the client with detailed eCRF completion guidelines in Kanji.

*DATATRAK* and the client recognized that help desk support during the trial was crucial to ensure minimal disruption in the trial process and timeline. In cooperation with the same strategic partner, local Help Desk support was available to all trial professionals and patients, erasing the issue of time zone differences.

### Results

Upon completion of the three trials' design, the CRO & sponsor submitted the results to the PMDA. The PMDA reviewed the trials and found only one trial, the *DATATRAK* trial, had translated the eCRF guidelines. The other two trials did not complete the translation of these essential documents.

The PMDA recognized and commended the *DATATRAK* trial for the proactive approach and required the sponsor to complete the translation of the eCRF Completion Guidelines for each of the sister trials. The *DATATRAK ONE*<sup>®</sup> partnership and trial was recognized in the PMDA audit as the preferred methodology and required no additional revisions.

By leveraging our long-term strategic partnership in Japan to anticipate the needs of both our client and the PMDA, the *DATATRAK* trial cleared regulatory approval and, in comparison to the sister studies reviewed by the PMDA during the audit, delivered both cost and time savings to our client.

Contact *DATATRAK* to see how we can help you optimize every phase of every trial around the globe, *from Concept to Cure*<sup>®</sup>.