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CASE STUDY

UNITED WITH TECHNOLOGY & TRIUMPHS

Automation slashes turnaround time for critical trial labeling

Alternative translation and label approval system (ATLAS[SM]) does the heavy lifting

A major global pharmaceutical Sponsor was seeking a new approach to enhance the efficiency of its clinical trial supply chain process. One major target in its sights was the labeling and translation management process.

This group had traditionally managed all development of label text, translations and approvals internally, using their in-country affiliates to support all translations. In addition, the team had a proprietary in-house system with a phrase library. This internal system was capable of printing single label panels for clinical trials. All booklet labels were developed through the in-house team but the materials were manufactured through external vendors. The Sponsor was seeking a way to reduce the four to six months it took on average for labeling and translation management. This approach would automate and optimize multi-lingual label development.

With a commitment to partner with Thermo Fisher Scientific on future label production, the Sponsor gained access to our proprietary Alternative Translation and Label Approval System[SM]. ATLAS supports the requirements for translation and regulatory services, delivers a paperless approval process, and expedites text generation and proof approval.

As its name suggests, ATLAS is designed to tackle one of the biggest challenges facing clinical trial supply chain managers – meeting timelines. With the growing expansion of clinical programs to a greater number of countries and clinical sites, the timeline challenges have continued to multiply for Sponsors working in multiple regions.

ATLAS provides online ordering of translations and label proofs, and the ability to approve online with an electronic signature. The system includes reminder triggers to facilitate this process.

It also ensures globally consistent terminology and phrases, leading to a major reduction in translation error rates.

The capabilities of ATLAS are supported by a leading industry provider that specializes in translations and regulatory label compliance for pharmaceuticals. This support gave the Sponsor assurance that the system and processes could continue to grow with their needs and the needs of a dynamic industry.

The first step in the project was to update and upgrade the Sponsor's phrase library. This involved a full review of the current phrase library, and combining it with combining it with Patheon™ Fisher Clinical Services℠ label services template phrase library.. A team reviewed the output, removed redundancies and ensured inclusion of any specialized text that had been developed over the past three years.

The output was a standardized, validated phrase library that complied with regulatory guidelines and eliminated the redundancy in the original library. In addition, the team now had access to the translation provider's resources, removing the burden that had been placed on the country affiliates.

With this responsibility off their list, the affiliates could redirect their efforts to higher value projects that made the most of their local expertise.

With the migration to the ATLAS system, the Sponsor immediately reduced turnaround times for label approvals from four to six months down to 57 days. Additional improvements cut that time to less than 30 days. The kicker is that this 30-day period includes label manufacturing in addition to the content!

The new turnaround time is miles away from the industry standard 120 days to approve label text for a multi-national clinical trial. Reflecting on the new system, one of the Sponsor consultants said, "Thank you for a very simple, straightforward system that's easy to access, understand and use. Whoever conceived gets a gold star as the concise format is appreciated!"

+1 919 226 3200 • thermofisher.com/patheon • pharmaservices@thermofisher.com

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