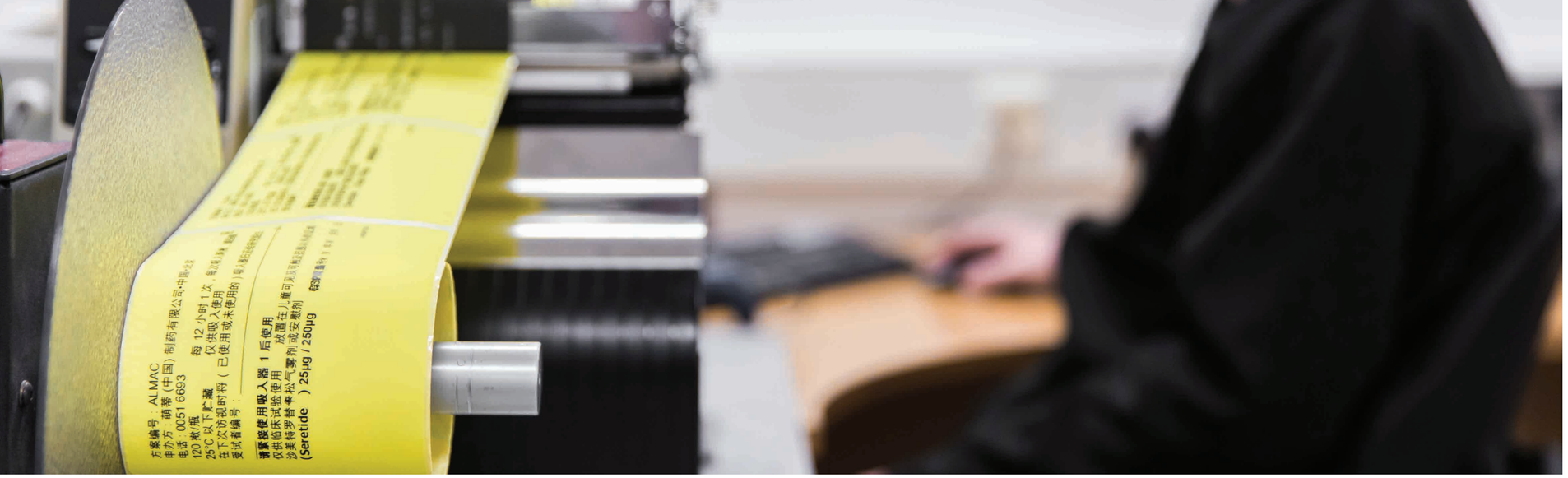
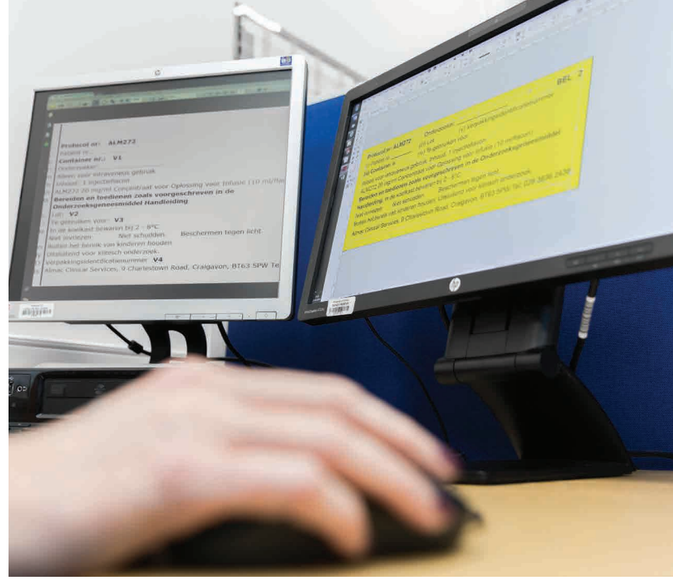
ALMAC

Partnering to Advance Human Health

Case study

Adopting label change best practice to promote clarity and compliance





Adopting label change best practice to promote clarity and compliance

Globalised clinical trials are quickly becoming a pre-requisite for success. This enables sponsors to spread the risks associated with unpredictable patient enrolment by taking advantage of the larger patient pools and population diversity on offer, while simultaneously driving down costs and expediating study timelines.

The benefits of extending clinical trials outside of traditional study locations in favour of emerging regions are obvious. Yet the complexity of assuring compliant and timely supply to patients across hundreds of clinical sites, spread over multiple countries, can result in additional burden for sponsors to shoulder. The penalty of failing to appropriately manage this additional complexity not only limits sponsors' ability to capitalise on the potential benefits of global trials, but also increases the risk of negatively impacting patients and compromising compliance.

A by-product of operating global trials is the constant evolution of study protocols, as sponsors grapple with accommodating new countries with specific demands. The knock-on effect such changes and updates have on clinical labelling functions can be significant.

As one sponsor recently discovered, without effective processes in place or capable suppliers to hand, failing to manage label change appropriately against challenging timelines can quickly become an unwelcome reality.

The business problem: addition of multiple new countries risks labelling chaos

The sponsor was in the early stages of its phase III, randomised, double blind, active controlled study. Designed to compare the efficacy and safety of its novel antimicrobial IMP with the current treatment for Clostridium Difficile Infection (CDI), the study's goal was to achieve comparable cure rates to the standard of care, while reducing rates of recurrent disease – a central unmet medical need.

With phase II results providing a proof of concept, the sponsor was keen to further demonstrate the study drug's attributes in relation to this goal and accelerate its time to market in a bid to reduce morbidity and mortality rates for patients with the condition. This meant expanding the trial to more countries than were included in the original study protocol. This mid-study amendment required the drug to be compliantly and cost-effectively labelled for distribution to 32 countries, in 35 separate languages.

With new countries being added to the trial over the course of 18 months, the constant changes and updates risked injecting confusion and chaos into the clinical labelling process.

It was necessary for the sponsor's label text translations to be managed in batches, meaning each was at different stages of completion at any one time. The sponsor needed to uphold clinical labelling compliance, yet the disjointed process of effecting label change was creating unnecessary risk. For instance, the sponsor needed to provide feedback in relation to label text translations to its partner, Almac Clinical Services, to be reviewed against the corresponding file and correctly implemented. However, because both sponsor and CRO were requesting multiple, and sometimes conflicting, updates to label text, keeping track of the flow of information and ensuring that implemented changes remained attributable to the reviewer source, was incredibly challenging.

Without appropriate timely intervention, control could quickly be lost, and compliance compromised.

The Almac solution: comprehensive process to better manage change

To take back control of the situation, remove the compliance risk and support the sponsor to successfully accommodate new countries into its trial, Almac drew upon its project management and clinical supply expertise to establish a workable solution.

Taking a partnership approach, Almac worked closely with its specialist regulatory and translation partner to facilitate the compliant and cost-effective on-boarding of new countries to the sponsor's study.

Not only was Almac's specialist supplier able to provide industry-leading regulatory guidance on all changes, such as when the sponsor's CRO requested that product destined for Brazil should incorporate 'not for sale' to maintain compliance.

Alongside access to unrivalled knowledge and expertise in global labelling regulation, Almac was also able to provide the sponsor with a comprehensive overview of all label change requests within a short timeframe.

This was achieved by breaking the mass of information orbiting the clinical labelling function into clearly defined summaries of several key stages in the project to provide clear versioning of label text, along with a record of the requester source. This was essential in order to successfully document changes and ensure all feedback had been considered in the finalised label text that would be used to create the country-specific label for the study drug.

The results: best practice approach delivers clarity and compliance

The 'tracker', developed specifically to meet this sponsor's needs, provided a clear and consistent method of managing changes and open queries. It empowered all appropriate study stakeholders to obtain instant visibility over the status, and the associated audit trail, of changes made to label source text files. Effective management of the complex and changing requirements was greatly facilitated by the central approach to label text development, where a single team coordinated the country requirements and translations.

As a result, the sponsor was able to extend its trial into new countries without risking labelling non-compliance, and the associated disruption, delay and escalating costs; empowering the sponsor to continue on its mission to improve the health outcomes for millions of patients affected by CDI worldwide.

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