ALMAC

Partnering to Advance Human Health

Case Study

Expertise in Clinical Packaging Delivers Blinding Best Practice for Asia-Pacific Sponsor

Introduction

Operating blinded clinical trials involving reference drugs, vehicle controls and placebos can create additional challenges for sponsors to manage. This has an impact on clinical packaging and labelling strategies, which typically become more complex, risk-intensive and time consuming.

For one Asia-Pacific sponsor, embarking on a phase III study, ensuring each of its three product types were identical in appearance was key to maintaining compliance. It was also vital to keep trial timelines on track. To achieve this ideal, the sponsor would first need to successfully tackle the problem of working with three uniquely designed tubed products.

The business challenge

Differences in primary packaging risks unblinding study

The sponsor's multi-site study aimed to demonstrate the superior clinical effect of the test and reference cream products over that of the placebo, while evaluating the therapeutic equivalence of the two active products and comparing the safety of all three.

Upholding blinding meant ensuring that neither patients nor clinicians would be able to differentiate between products due to the shape, size, colour, texture, weight, smell, rattling or packaging.

However, not only were the label text, graphics, lot numbers and colouring unique to the three product types, the tubes and caps (sourced by the sponsor) were significantly different in size and shape.

To add to the problem, the sponsor had encountered delays while independently sourcing the comparator tube, causing the study's progress to fall behind schedule. In order to get vital timelines back on track, the sponsor needed to find an alternative solution that was both fast and effective.

The Almac solution

New packaging approach overcomes the challenge

Working in partnership with the sponsor and its CRO, Almac proposed blinding to outer carton level in order to maintain the FDA double blind requirements. Due to the sponsor's continued comparator supply issues, there would not be sufficient time to source and conduct stability testing for changing the caps on the tubes.

Almac's packaging design team designed a carton with an insert to hold two tubes. As one of the tubes was shorter in length, an additional insert was created at the bottom of the carton to make up the difference in tube lengths and give the appearance of both tubes being the same size.

To disguise the text, graphics, lot codes and colours of the tubes, Almac's clinical labelling experts created a bespoke diaper label and single panel label to fit both tubes. Utilising label text provided by the sponsor's CRO, Almac also designed a standardised and compliant label for the carton.

The results

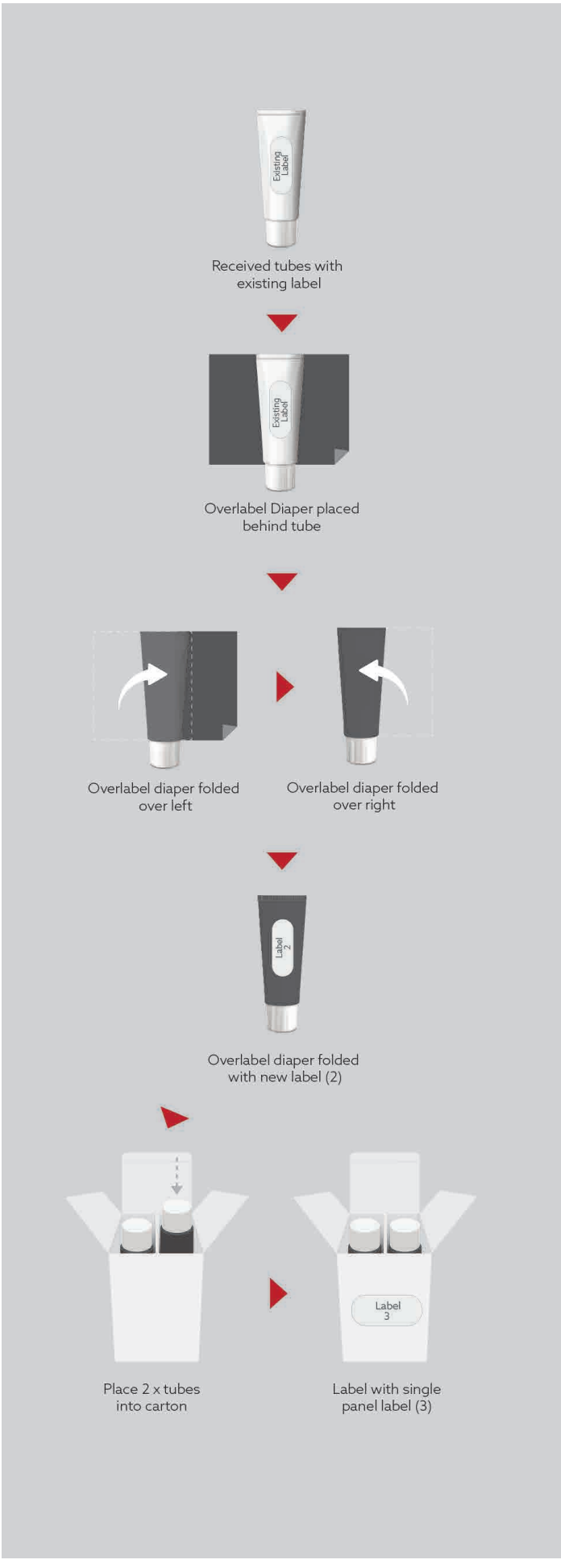
Unified supply chain ensures clinical trial continues as planned

Through a partnership approach, industry-leading expertise and dedicated project management, Almac was able to develop a solution that not only maintained blinding compliance but helped the sponsor recover from the delays caused by its comparator sourcing issues.

Through use of the carton design, Almac enabled the study to start quickly and continue uninterrupted, while ensuring product integrity was protected from production through to patient administration.

Commenting on the project with Almac, a key member of the sponsor's team said:

"The team at Almac understood our concerns, requirements and need to get the trial up and running as quickly and compliantly as possible and worked collaboratively with key stakeholders to help us effectively and efficiently overcome the problem of non-matching stock. Thanks to Almac's experience and expertise we were able to blind the tubes in line with regulation and deliver them on time."



almacgroup.com

Get in touch

Global HQ
+44 28 3836 2436

US HQ
+1 215 660 8500

Asia HQ
+65 6309 0720

EU HQ
+353 42 932 0718

Durham, NC, USA
+1 (919) 479 8850

Japan
+81 3 4233 9178

clinicalservices@almacgroup.com