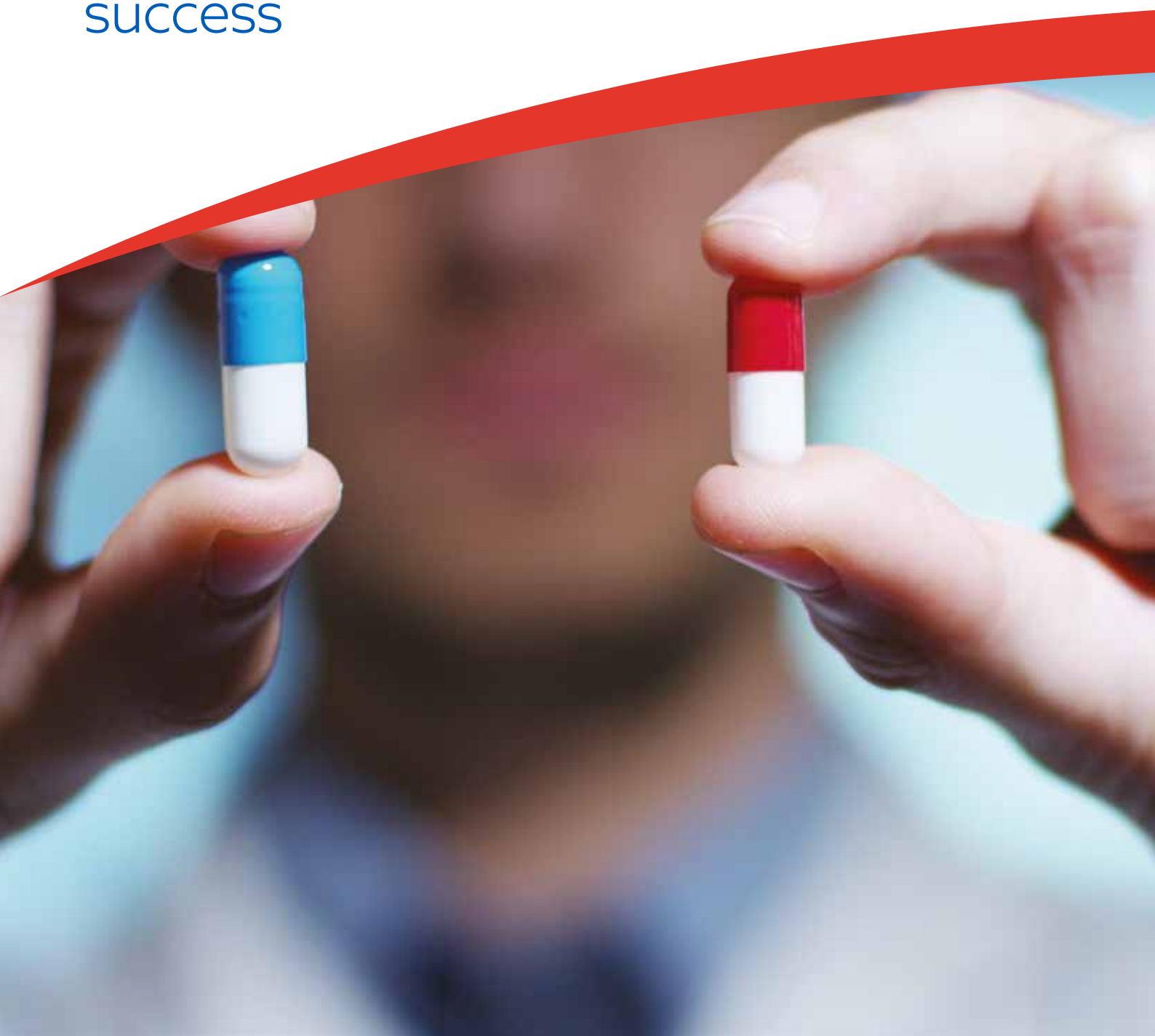
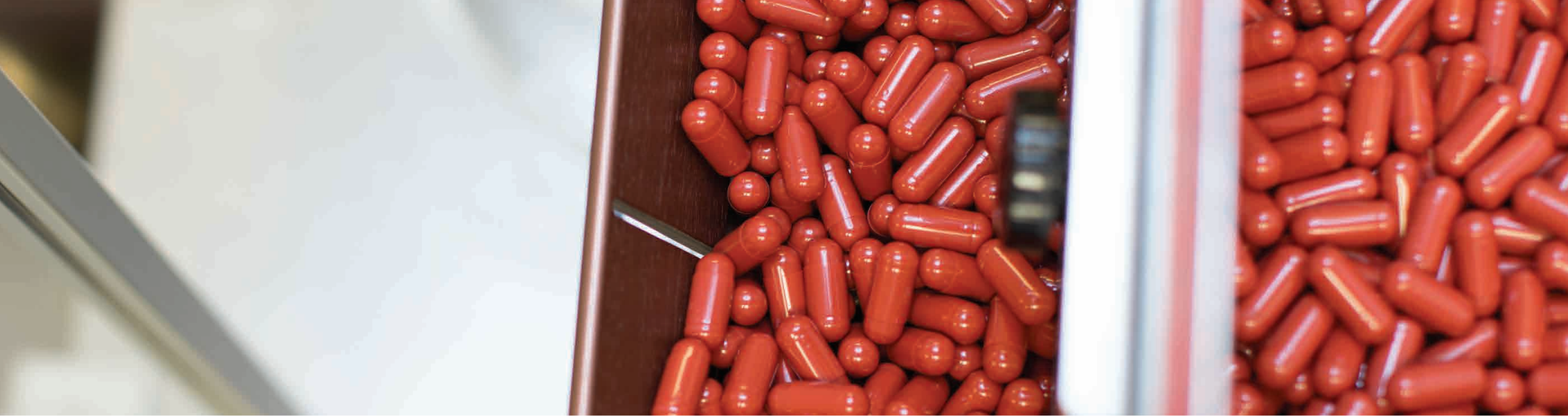
ALMAC

Partnering to Advance Human Health

Case study

Leveraging global relationships in response to comparator drug discontinuation delivers study success





Leveraging global relationships in response to comparator drug discontinuation delivers study success.

While globalisation and the rapid development of innovative new drugs are contributing to improved human health, it is also introducing additional challenges for sponsors to overcome.

Comparator sourcing is no exception. Take for example the field of oncology, which already makes up 25 per cent of the global late stage pipeline and where innovation in cancer drug development is predicted to continue to surge over the next five years[i]. With most investigational products studied against the existing standard of care, the demand for comparator products in this therapeutic area – as well as others - is forecast to rise dramatically[ii] . Indeed, patterns are already beginning to emerge that indicate that timely availability of comparator products (or a lack there of) are posing a significant threat to clinical trials.

With 1 in 3 trial operators experiencing out-of-stock problems when attempting to source comparator products, this is fast becoming an industry-wide problem, with wider implications that simply cannot be ignored. According to the Food and Drug Association (FDA) this problem has tripled since 2005[iii].

A shortfall in comparator drug availability can have a domino effect on the entire clinical supply chain; jeopardising vital study timelines and negatively impacting both patients and commercial performance.

One sponsor operating a phase III study of an innovative Investigational Product (IP), designed for the treatment of prostate cancer, was in the midst of its global, open label clinical trial when it received news about its comparator drug that had the potential to compromise its entire operation.

The challenges

Comparator discontinuation threatens patient access to medication

The biotechnology company's randomised, multicenter study involved approximately 400 patients, spread over 125 clinical study sites worldwide. The randomised patients were scheduled to receive either the IP or physician's choice of comparator therapy, which had been pre-designated prior to randomised.

The trial was on-plan, with packaging and labelling functions – as well as blinding of the IP and the comparator product – progressing without issue. The comparator product had been pre-designated during the planning phase of the study and the function, along with other key aspects of the supply chain, and had been outsourced to Almac Clinical Services to fulfil.

However, mid-way through the study, the marketing authorisation holder discontinued the drug format being used. Switching from the pre-approved drug to an alternative commercially available comparator would require an updated Clinical Trial Authorisation (CTA) from both the Medicines and Healthcare products Regulatory Agency (MHRA) and FDA. This would take both time and resource to administrate. To prevent delay, which could easily cause missed patient visits, the sponsor had to find a different way forward. A way forward that would promote supply chain harmony and ensure patients continued to receive the right drugs, at the right time, in the right place and under the correct conditions.

The Almac solution

Long-standing relationships secure trial continuity

Having decided to outsource comparator sourcing to Almac Clinical Services, the sponsor had access to Almac's vast experience of successfully sourcing comparator products across all clinical markets and assuring comparator supply for thousands of clinical trials globally.

With experience comes strong commercial relationships that, when coupled with Almac's global footprint and standing in the industry, this equals immeasurable bargaining power. Almac understood the critical importance of seamless comparator supply to this sponsor's overall trial success and was determined to prevent the need to obtain an updated CTA, which would lead to delays and cause a knock-on effect to other areas of the trial operation. Almac harnessed its long-standing relationship with the manufacturer to successfully secure a commitment that the commercial drug would continue to be manufactured in the required format throughout the duration of the study.

The results

Trial continues without delay or disruption

Through Almac's long-standing relationship with the drug manufacturer, they were able to ensure continued drug supply and prevent the need to obtain an updated CTA.

This in turn removed the risk of delay and the knock-on effect this would have caused to the rest of the clinical supply chain, in the form of waste due to product expiration and cost brought about through the subsequent need to rework materials – such as updating and amending labels, cartons and processes.

Almac's swift action also removed the risk of negative patient impact stemming from a lack of availability of comparator product in the interim before a new CTA could be obtained. Instead of instigating a costly and time-consuming mid-study change, the sponsor was able to uphold patient experience and enjoy operational continuity, free from disruption or delay, throughout the duration of its study.

References

[i] A. M. Huss Analyzing Trends in Global Comparator Sourcing and Distribution in 2015 – A Preview-Journal of Clinical Research. April 2015

[ii] http://www.quintiles.com/~/media/library/white%20papers/expected-growth-of-industry-sponsored-clinic

[iii] The Future of Clinical Trial Supply – Trends and Challenges 2015 Report (http://www.pharma-iq.com/logistics/white-papers/the-future-of-clinical-trial-supply-trends-and-cha/)

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
+81 367 218720

clinicalservices@almacgroup.com