

Expert forecasting delivers study closure on time and on budget with Almac's SupplyWise

Supply With Care™





In the world of modern clinical trials management, which often involves thousands of patients, across multiple sites throughout the world, keeping pace with demand, while actively avoiding product waste, is a difficult balance to master.

It is a balance that is made even more challenging for sponsors developing biologics or personalised medicines. The high cost of R&D, combined with notoriously low product yields, short expiration and difficult-to-maintain drug stability can remove the luxury of stockpiling for pooled distribution. These factors can also make creating excess overage 'just in case' demand spikes a commercially unviable option.

To get the balance right, sponsors need to effectively forecast patient demand and plan production and distribution activity accordingly.

For one sponsor, preparing for a global phase 2 study to assess the safety, tolerability and efficacy of a biologic IMP, striking the right balance was key.

This biotech was met with a need to navigate their stretched internal resources and ever evolving enrolment assumptions while solidifying its approach to demand forecasting, in order to reduce product waste, safeguard patient access and meet vital trial timelines. Here's how they did it.

The business challenges

Managing stretched in-house capabilities with considerations to minimize excess overage, cost and delay

During the start-up phase of the study, which would involve 320 patients and 62 sites throughout the US, EU and APAC regions, the sponsor identified several potential challenges with its approach to demand forecasting.

The sponsor had previously performed forecasting functions in-house. However, with limited resources, this had resulted in 100% overage being added to the clinical projections. While this went some way to mitigate the risk of missed patient visits, by promoting a readily available supply of study drug, it produced significant waste and leftover product. Not only did this increase production costs but incurred additional returns, reconciliation and destruction administration and expense.

With a single individual responsible for overseeing supply, enrolment assumptions constantly evolving, and limited technology available; obtaining holistic visibility over requirements was not readily available to aid in proactive decision making, which in turn was leading to time and resource constraints.

Keen to avoid this challenge escalating and creating delays that could compromise trial timelines, the sponsor recognised the need for a more robust method of achieving visibility over supply and demand. Without this, it would continue to be unmanageable for the sponsor to accurately forecast drug need and assure timely, cost-effective supply to patients.

The Almac solution

Supply chain management expertise and technology optimise forecasting ability

Recognising the resource limitations, the sponsor had decided to strategically partner with Almac Clinical Services. Already reliant on Almac expertise to manage clinical labelling, production and distribution - and determined to rise to the unique supply challenges of the upcoming trial - the sponsor decided to outsource this critical element of supply chain management to Almac.

Despite being in the planning phase of the study, speed was of the essence. Almac proactively set about collating the information needed to create an agile and effective clinical supply forecast. Delivering the forecast within just one day, Almac experts were able to design multiple demand profiles and supply scenarios that would help the sponsor to make informed decisions relating to how best to approach the trial and maximise supply.

To achieve this fast turn around and accurate demand modelling, Almac utilised its end-to-end clinical trial supply forecasting technology, SupplyWise.

As enrolment activity progressed at each of the sponsor's 62 global sites, Almac was able to run reports to create new scenario outputs that would facilitate agile and aligned production and distribution planning.

And because SupplyWise has been designed to organise complex information and automate the production of easy to understand insights, Almac's Supply Chain Manager was able to spend more time providing their expertise in collaborating with the sponsor's study team on how to further optimise the trial's clinical supply chain.

The results

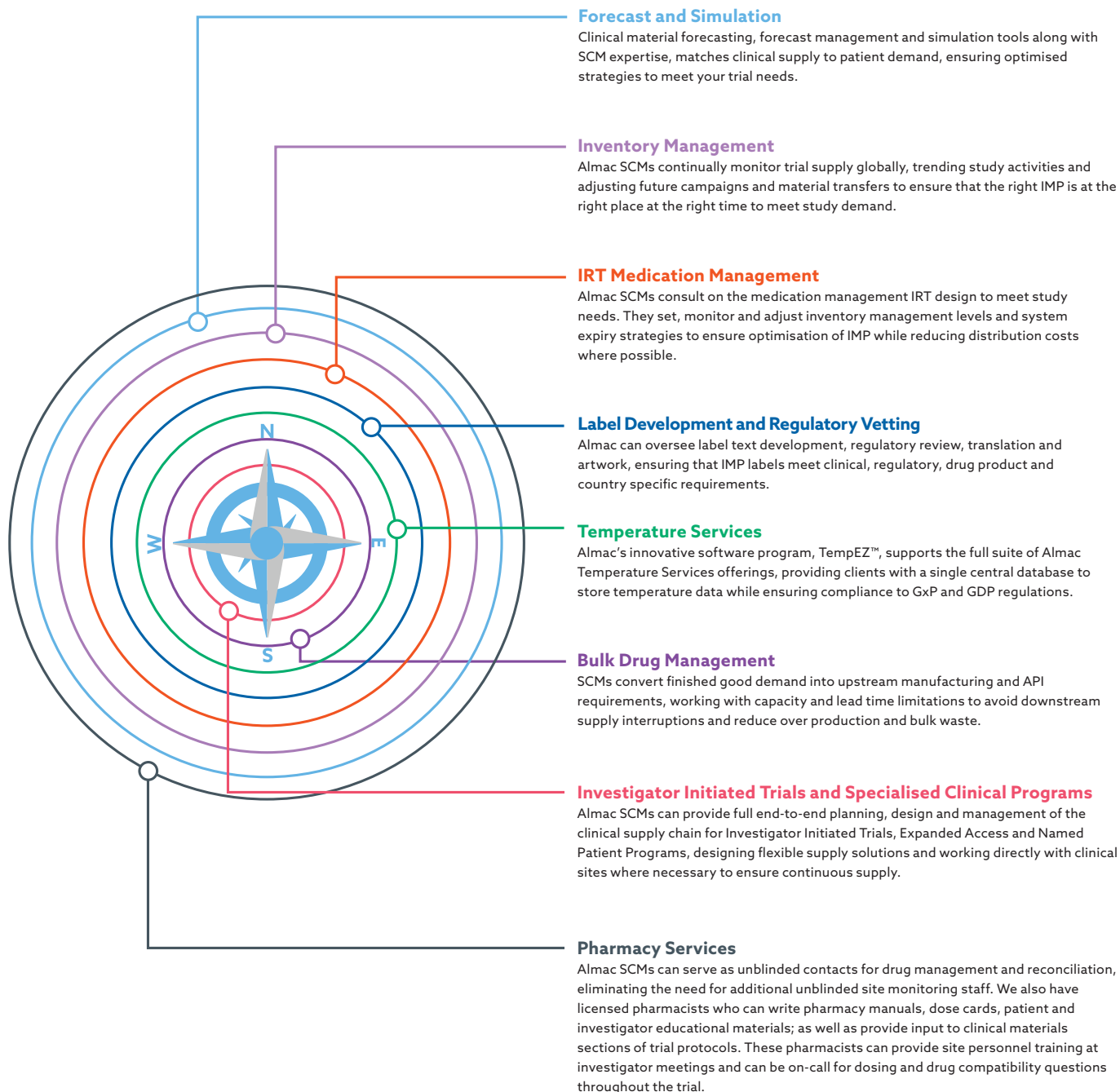
Holistic visibility of global demand reduces product waste and delivers study closure on time and on budget

While strategically partnering with Almac's team of supply chain management experts, and leveraging the forecasting capabilities within SupplyWise; the sponsor was able to utilize the timely and accurate data available from the technology to select the most appropriate supply approach and country profile for the study. This empowered the sponsor to meet vital study timelines and reduce costs, not just during the start-up phase but throughout the duration of the 12-month trial.

SupplyWise made the very best use of the sponsor's available material, by creating new supply chain visibility that improved the sponsor's ability to align production planning and distribution activity precisely with patient demand. This resulted in lower levels of product lost to expiration, minimised waste (in the form of overage) and an overall reduction in overheads.

This newfound supply chain visibility also led to streamlined quality control and allowed the sponsor to effectively tackle risks, while facilitating greater responsiveness and flexibility to adapt to events that unfolded during the study.

By harnessing a technology-enabled approach to demand forecasting during the planning stage of its clinical trial, this sponsor achieved bigger picture visibility over its clinical supply chain and was able to successfully optimise operations, reduce risk and deliver study closure on time and on budget. What's more, through optimising its clinical supply chain with Almac's leading forecasting services and technology, the sponsor became one step closer to bringing a much-needed drug to market.



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

Souderton PA USA
+1 (215) 660-8520

Japan
+81 3 4233 9178

clinicalservices@almacgroup.com

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