ALMAC

Partnering to Advance Human Health

Case Study

Getting it Right the First time: Maximizing efficiencies with end-to-end, technology-driven biologics supply chain management

Making the transition from operating clinical trials involving conventional drug products to biologics can be difficult. And while some principles of effective clinical trial management involving chemically synthesized therapeutics are transferable, many are not.

Operating biologics-based clinical trials presents several unique challenges and requires experience, understanding and the ability to develop new ideas. If approached incorrectly or with inexperience, delays – which can cause sponsors to compete for patients, miss key study milestones, and extend the drug's time to market – become an inevitability. Not only can this waste time and result in a significant loss of investment, vulnerable patients can be left without access to much-needed medication, when and where they need it.

The biologics clinical supply chain is rife with challenges, from preventing temperature excursions in line with strict stability data to sourcing packaging and labelling materials and adhesives able to withstand ultra-low temperatures. To add to the pressure, the cost involved in developing these pioneering drugs leaves little margin for error.

For one sponsor, embarking upon its first clinical trial of biologics, successfully navigating the unchartered territory of the clinical supply chain was essential. The sponsor couldn't afford a trial and error approach. To maximise operational efficiencies and deliver value to all trial stakeholders, especially patients, the sponsor had to get its supply strategy right first time.

The Business Challenge

Complex requirements, limited experience

Expanding its drug portfolio into the field of biologics, the sponsor was entering a multi-country, phase III study of an oncology medication to determine safety and efficacy criteria for several therapeutic applications.

Being new to biologics, the sponsor lacked the historical data needed to effectively predict drug assignments. The high cost of the sponsor's products, coupled with limited quantities, demanded an optimised clinical supply chain. Yet, without the ability to accurately forecast demand, manage inventory or adapt to variable recruitment, typical with trials of biologics, the sponsor would increase the risk of both wasted product and negative patient impact.

To add to this, the sponsor's drug had a very complex weight-based dosing protocol. The sponsor also required multiple kit types of varying strength and was dealing with a very expensive comparator drug product. These factors combined meant the sponsor's clinical supply chain had the potential to make or break the overall success of the study.

The Almac Solution

Effective end-to-end supply chain management

Already providing packaging, labelling and distribution services, the sponsor turned to Almac to assist with the development and implementation of a clinical supply chain strategy. The objective was clear: identify the key areas that impacted the sponsor's supply chain, determine where protocol specific optimisations could be made and implement change to minimise risk.

Taking ownership of forecasting drug supply requirements, Almac's supply chain management (SCM) experts began by creating baselines to assess various scenarios for procurement and production planning and distribution. Working closely with the sponsor's medical team, Almac ensured projections aligned with the reality of initiating a clinical study on such a scale, involving 24 countries and 9 depots.

Almac was also responsible for manufacturing and distribution strategy. This was informed by the accurate and agile drug forecast, close inventory management oversight at both depot and clinical sites, expiry date tracking and management and returns and accountability management.

To help facilitate an optimised clinical supply chain strategy and benefit from access and analysis of trial data, Almac's SCM team worked in partnership with the sponsor to define, develop and implement an Interactive Response Technology (IRT) system. Centralizing and digitalizing all supply chain data, Almac's IXRS system was used to control drug assignments by

considering multiple factors including, patient weight, site drug availability and depot drug availability. As a result, the IXRS was built to further streamline supply processes by assigning kits to patients, and ordering and consuming supplies, in the most efficient and cost-effective way. This helped to minimise waste and allow more flexibility in recruitment in each country.

One feature of this highly customised IXRS was a priority drug assignment table within the system. This allowed the sponsor to specify the exact combinations of kits needed to be assigned to patients at each specific weight and dose range and allow flexibility in dosing should a subject's weight increase or decrease between treatment cycles.

Extracting data from the IXRS, identifying trends and tweaking supply strategies to optimise the supply plan in real time was key to success; helping Almac SCM experts to make educated decisions when drug planning on behalf of the sponsor. This facilitated far greater alignment with the clinical operations group, as the country and patient enrolment scenarios changed throughout the study.

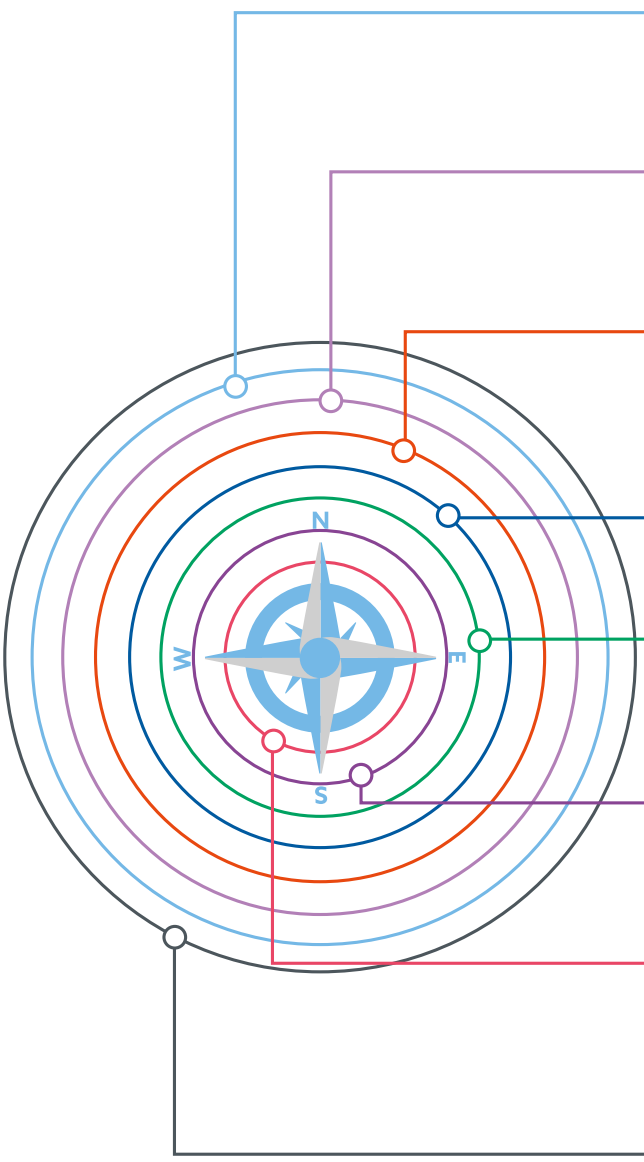
The results

Expertise + technology = flawless medication management

The intricate nature of this sponsor's clinical supply chain necessitated a robust, well-developed clinical supply strategy. By teaming up with Almac's SCM experts, each well-versed in the sponsor's therapeutic area of focus, with highly customisable IRT software, the sponsor was able to better plan and react to changes in its clinical trial. Specifically, oversight by Almac's supply chain management team allowed a reduction in agreed drug overage from 20% down to 12% globally, with some regions even experiencing a reduction as low as 6%, and led to a $5 million underspend on the study budget for comparator procurement.

Almac's SCM team empowered the sponsor to prevent the loss of expensive and limited drug product to non-recruiting sites and embrace agility to effectively accommodate constantly changing country-specific, recruitment plans. In addition, the sponsor was also able to achieve greater accuracy relating to the clinical operations' team assumptions regarding subject dosing and better react to changing drug availability and multiple expiry events through the study's lifecycle.

Despite being faced with complex and unfamiliar challenges, by partnering with Almac, this sponsor successfully harnessed technology-driven, biologics supply chain management best practice. With a 'right first time' vision, combined with the tools and expertise to deliver continuous process optimisation, flawless and cost-effective medication management was realized and positive patient experience upheld.



Forecast and Simulation
Clinical material forecasting, forecast management and simulation tools along with SCM expertise, matches clinical supply to patient demand, ensuring optimised strategies to meet your trial needs.

Inventory Management
Almac SCMs continually monitor trial supply globally, trending study activities and adjusting future campaigns and material transfers to ensure that the right IMP is at the right place at the right time to meet study demand.

IRT Medication Management
Almac SCMs consult on the medication management IRT design to meet study needs. They set, monitor and adjust inventory management levels and system expiry strategies to ensure optimisation of IMP while reducing distribution costs where possible.

Label Development and Regulatory Vetting
Almac can oversee label text development, regulatory review, translation and artwork, ensuring that IMP labels meet clinical, regulatory, drug product and country specific requirements.

Temperature Services
Almac's innovative software program, TempEZ™, supports the full suite of Almac Temperature Services offerings, providing clients with a single central database to store temperature data while ensuring compliance to GxP and GDP regulations.

Bulk Drug Management
SCMs convert finished good demand into upstream manufacturing and API requirements, working with capacity and lead time limitations to avoid downstream supply interruptions and reduce over production and bulk waste.

Investigator Initiated Trials and Specialised Clinical Programs
Almac SCMs can provide full end-to-end planning, design and management of the clinical supply chain for Investigator Initiated Trials, Expanded Access and Named Patient Programs, designing flexible supply solutions and working directly with clinical sites where necessary to ensure continuous supply.

Pharmacy Services
Almac SCMs can serve as unblinded contacts for drug management and reconciliation, eliminating the need for additional unblinded site monitoring staff. We also have licensed pharmacists who can write pharmacy manuals, dose cards, patient and investigator educational materials; as well as provide input to clinical materials sections of trial protocols. These pharmacists can provide site personnel training at investigator meetings and can be on-call for dosing and drug compatibility questions throughout the trial.

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