ALMAC

Partnering to Advance Human Health

Case Study

Maintaining uninterrupted drug supply in the midst of product relabelling

Expiry date updates

Expiry date updates are a common aspect of clinical supply chain management, as product stability profiles are often developing, concurrent to the conduct of clinical trials. Expiry date extensions often result in relabelling activities at depots and sites throughout the distribution network. These activities must be carefully planned and closely monitored to ensure that there is no disruption to patient activities due to insufficiently labelled supplies. For this sponsor, the multifaceted relabelling process was successfully overseen by Almac's Supply Chain Manager (SCM).

The business challenge:

Optimising the drug supply while relabelling depot inventory

A sponsor conducting a multi-centre, Phase II trial contracted Almac mid-way through the study to coordinate and oversee the expiry update labelling of investigative drug at numerous depots around the world. The following considerations were necessary:

- No additional supplies were to be released, so existing supplies were needed to meet ongoing demand to the end of the trial
- Multiple drug lots were expiring at different times in different places
- Multiple country label groupings had been developed throughout the study, resulting in a variety of label configurations, including single panel and booklets
- Supply demand was unclear due to outdated forecasts
- All sponsor team members needed to remain blinded

Consequently, the goal at this critical point in the study was to update the labels, whilst making sure that drug quantities were distributed optimally to study sites and patients. This exercise had many moving pieces and required full visibility and experience to execute seamlessly. It was also a process that could take considerable time to coordinate.

The Almac solution:

Simultaneous inventory and expiry management

The Almac SCM, having dealt with similar situations many times before, developed a logical and methodical plan, and saw it through to execution.

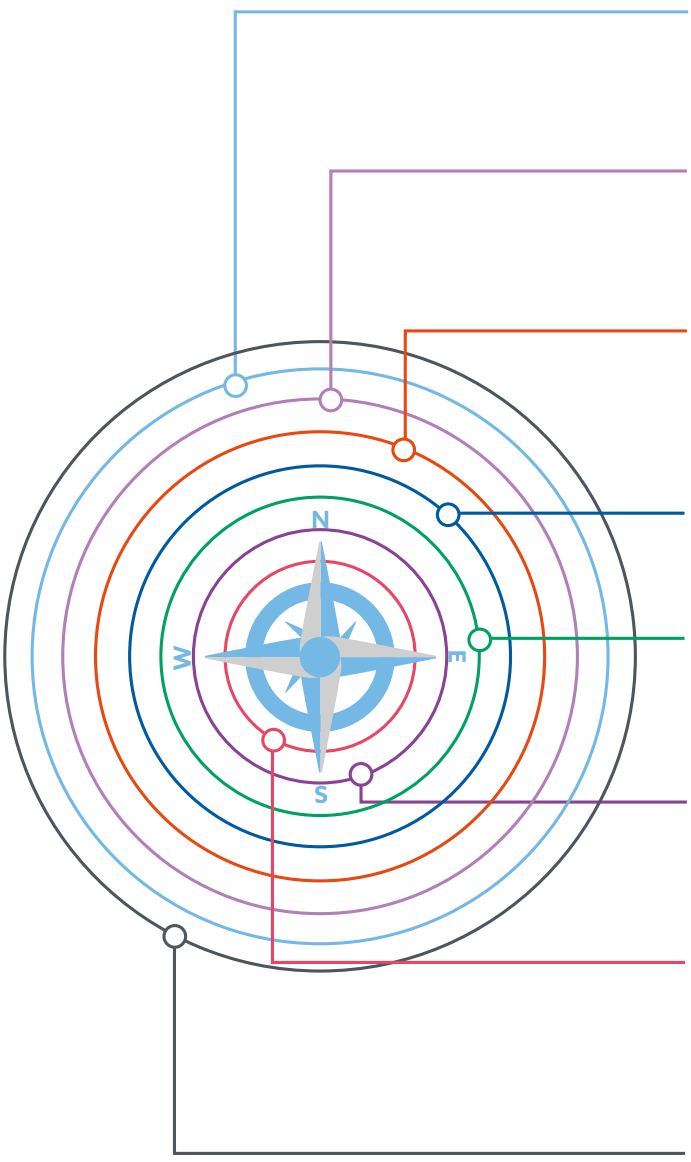
1. The first step was to update the supply forecast in order to understand the inventory demand at each depot. The SCM reviewed study and country patient enrollment data to establish current and future product demand.
2. Next, the SCM reviewed the Interactive Response Technology (IRT) settings and strategies, assessing key system-driven expiry events and milestones.
3. The third step was to establish a detailed project plan for updating all labels with the new expiry dates, accounting for label printing and shipping lead times. This would be done in priority order according to the most imminent expirations.
4. The SCM then orchestrated the multi-phased re-labelling operation, quarantining partial supply quantities in the IRT for relabelling while keeping other materials available for ongoing site shipments.
5. Material was relabelled at global depots according to controlled GMP processes, quality released and returned to active status within the IRT. Virtual depots were created within the IRT, to isolate single panel supplies to appropriate countries, reserving the globally labelled booklet materials for all other countries. Throughout this process, careful attention was taken to maintain the blinded status of clinical team personnel.

All of the above activities required close and frequent coordination with the IRT vendor, depot teams and distribution partners to sustain drug supply to study patients, whilst ensuring that no patient received a kit with a label indicating that the product had expired.

The client results:

Sufficient supplies preserve study timeline and patient safety

Almac's SCM conducted the process with foresight and precision. Drug supply remained uninterrupted and wastage was minimised, optimising the available materials. There were no delays due to drug shortages and patients neither missed their treatments nor received a kit with an outdated label. The company was left with little heavy lifting. The work done on this study has led to a long term partnership with the sponsor, who continually leverage the Almac SCM consultancy service.



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.

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