Managing supplies of a controlled substance
Nearly each and every clinical study brings with it particular supply challenges and circumstances. Patients and doctors rely on time critical management of investigational supply to ensure patient safety and compliance and it is the responsibility of sponsoring companies to ensure there is no interruption to supply lines. Controlled substances carry a unique set of considerations that add logistical complexity and heightened accountability requirements to the already weighty task of patient demand forecasting. Almac’s Supply Chain Management group helps clients navigate these challenges, ensuring drug is always on hand when and where it is needed. This is one such case.

The business challenge: meeting demand for a controlled substance with complex dosing

One sponsor company turned to Almac Clinical Services for help with inventory management and forecasting for a global trial involving a controlled substance. The following circumstances were considered when developing the supply strategy:

- Sites had limited storage space for a controlled substance (that must be locked)
- Import regulations for a controlled substance vary from country to country
- Medication dose was based upon patient weight
- At each visit, the study medication assigned could change
- Slow recruitment resulted in expiring materials
- One of the study medications was in short supply
- Controlled drug products require 100% accountability

These combined factors left the sponsor with two difficult to answer questions: How to ensure there was always sufficient supplies of each combination of medication at each site for patient needs? How could it most efficiently manage returns and reconciliation?
The Almac solution: hands-on management of all supply chain details

Almac’s Supply Chain Management (SCM) team assumed responsibility for many aspects of the supply chain, to include:

- **Interactive Response Technology (IRT) medication management**: The SCM assisted with the development of the user specification requirements, performing user acceptance testing (UAT) along with the client’s study team, reviewing system performance and serving as the liaison with the IRT developer - Almac Clinical Technologies.

- **Inventory management**: The Almac team provided the initial forecast (based on several assumptions about product demand), set supply strategies (taking sites’ storage limitations into account) and continually monitored patient dosing to ensure that the supply forecast reflected actual demand.

- **Contract Research Organisation (CRO) communication**: The Almac SCM developed a close working relationship with the CRO, resulting in efficient and effective communication pathways to identify and mitigate risks at an early stage.

- **Distribution oversight**: Due to the import requirements for controlled drug, the SCM managed supplies at a country level via the local depots. The SCM provided the required information for the local depots to secure import licenses for each shipment then requested the export license to have the material shipped from the UK to the appropriate depot.

- **Medication return and reconciliation**: A customised returns module in Almac’s IRT, designed to the Supply Chain Manager’s specifications, allowed Clinical Research Associates (CRA) to raise return shipments from sites with a list of each included kit. The depot could then simply acknowledge the shipment and confirm receipt of each included kit. Reconciliation in the IRT would then be carried out to the appropriate level.

The client results: smooth distribution and returns...with no stockouts

Almac’s SCM team managed the supply process flawlessly. The appropriate products were always on hand in every site, in every country, to meet patient demand. The SCM took into account:

- Site storage limitations
- Variability in the dosing
- Provision and maintenance of an accurate demand forecasting
- Maintaining efficient supply strategies
- IRT design requirements
- Shipment timelines
- Controlled drug import/export requirements

The team gained efficiency during IRT development because SCMs were able to work closely with colleagues in Almac Clinical Technologies to define the system requirements. A customised returns module was designed to enhance full traceability of the medication to a tablet and controlled substance content level.

The return process was greatly streamlined, and reconciliation was continually performed as the trial progressed expediting study close. The reconciliation and returns process was clearly defined for the CRAs and communication pathways for query resolution were established.

The Almac SCM team continued to plan the supply strategy and maintained oversight, avoiding any issues. By delegating to Almac, the sponsor study team was able to devote resources to other critical study activities. This study served as a spring board to a long-term partnership.
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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