

# Managing supplies of a controlled substance

Supply With Care™





## Success hinges on an accurate forecast, efficient distribution and streamlined reconciliation

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, pediatric 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 patient could choose between two different tablet sizes (to accommodate difficulty in swallowing)
- Slow recruitment resulted in expiring materials
- One of the three 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 and tablet choices 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

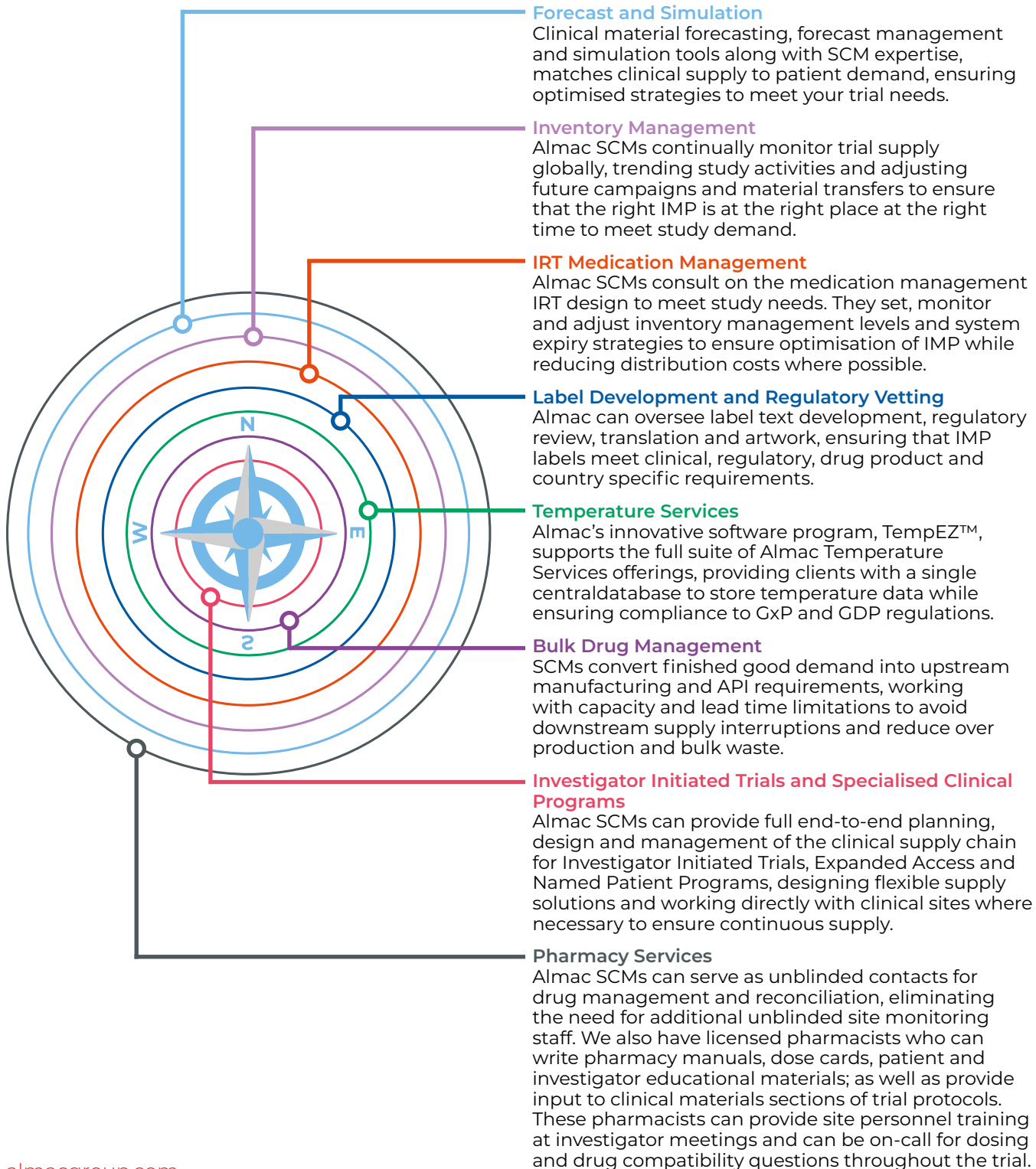
Almac's SCM team managed the supply process flawlessly. The appropriate products were always on hand in every site, in every country, to meet patient demand. The SCM took into account:

- Site storage limitations
- Variability in the dosing and tablet sizes
- 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.



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