ALMAC

Partnering to Advance Human Health

Case Study

Manual intervention overrides IRT to ensure continuity of care

Pharmaceutical companies sponsoring global clinical trials rely on Interactive Response Technology (IRT) systems to manage drug orders in a way that minimises wastage of expensive products while preventing stock outs that could jeopardise patient safety and trial results. These automated systems facilitate medication management on a scale that would not otherwise be possible. But, when IRT settings are out of sync with study designs, the system can quickly deplete drug supply. Thorough understanding and close oversight of system settings is therefore very important. For one sponsor, the quick actions of the Almac Clinical Services team saved the day—and study participation for 150 patients.

The business challenge: inaccurate resupply order of drug in short supply

The sponsor of a long-term, global, Phase III study in gastroenterology needed to closely manage production timelines and resupply orders to its European depots, as bulk supply of the expensive Investigational Product (IP) was very limited. Near the conclusion of a nine-year study, the delayed release of additional IP left the company struggling to ensure that EU sites received sufficient drug supply.

The IRT had not been programmed to include a global end date for trial participants in line with the study design. Instead, the system was built to predict patient demand until a specified visit number, without regard for the study end date.

When the IP was eventually released, the IRT triggered orders to resupply the sites, over-allocating the entire supply of kits to just one third of the sites. Many sites would have been unable to use their supply before the end of the study. In fact, some of the sites had no patient demand, so the entirety of those shipments would have been wasted. At the same time, orders failed for the remaining two-thirds of the sites. This would have led to stock outs affecting 150 patients. Had the system been programmed correctly, the released batch would have been sufficient to supply patient demand across the EU sites for the next two months—bridging to the next release of material.

The Almac solution: a dedicated team to oversee IP allocation

An Almac Supply Chain Manager (SCM) was brought in mid-trial to act as Global Clinical Study Manager. The SCM, who was monitoring IRT activity, was on the alert when IP was released to the system. The release—and automated resupply orders by the IRT—took place after business hours on a Friday evening, but that did not stop the SCM from taking quick action.

That night, the global team reviewed the system-generated orders, noted the failed orders, and immediately instructed the Almac depot in the UK to disregard all IRT shipment requests for that study. They then had the resupply function disabled in the IRT and erased the existing orders. Next, the team manually reviewed the inventory at all sites and calculated how to distribute the remaining inventory appropriately. The team then issued new orders to the Almac depot, prioritising the shipment requests. Because the shipments would be arriving over a holiday period, they worked with the Contract Research Organisation (CRO) to ensure that sites would be open to receive the shipments. They also provided the CRO with a tracker that listed each order number, courier information, and expected delivery dates.

The Almac SCM continued to monitor and evaluate all IRT orders produced over the next three months—until the IRT programming was adjusted and many EU countries had completed the study.

The client results: sufficient IP supplies through the course of the study

Almac's quick, manual intervention avoided:

- **Stock outs at sites that would have affected continuity of care for 150 patients.** There was no treatment alternative available, so any stock out would have had a serious impact on patient care.

- **£122,000 in additional costs.**
  The automated system had instructed the depot to send kits to sites that could not have used them before the end of the study. Additional kits would need to be packaged and distributed to the sites with patients.

The sponsor company was so pleased with the dedication and intervention of the Almac team that it extended the contract for its dedicated Global Clinical Study Manager. The sponsor also expanded its partnership with Almac such that Almac is now the company's preferred provider for global supply chain management services.

To find out more about how Almac can support your clinical trial contact us now.

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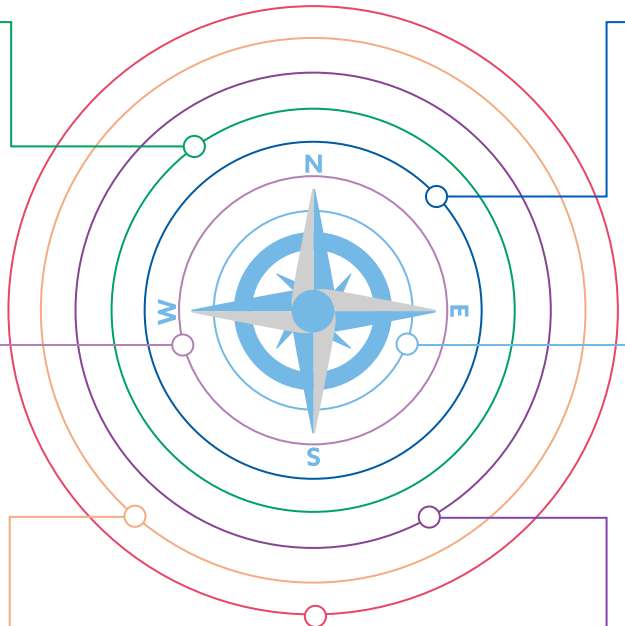
Almac Supply Chain Management Solutions -

Navigating the complexities of the Clinical Supply Chain



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.

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.

Inventory management
Supply Chain Managers 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.

Temperature management solutions
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.

IRT Medication management
Supply Chain Managers 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.

Other services
Almac Supply Chain Managers can provide end to end management of investigator sponsored trials, provide pharmacy services and draft pharmacy manuals. They can also act as unblinded contacts for the site management of clinical supplies.

Bulk drug management
Supply Chain Managers 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.

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