



Partnering to Advance Human Health

Case Study

Consolidating IRT and clinical supply management to save time and cost





One vendor, one vision: Consolidating IRT and Clinical Supply Management to save time and cut costs.

It is relatively easy to quantify the hard costs of managing a clinical trial, but much more difficult to measure the soft costs involved. One factor that is guilty of contributing to spiralling soft costs is time. For example, the time spent coordinating between multiple vendors to ensure alignment, create integrations, bridge communication, merge plans and timelines and resolve issues that arise due to the complex and disjointed nature of the arrangement.

What, then, is the value of turning to a single vendor for both the physical and digital sides of the supply chain? How can unifying IRT and Clinical Supply Management deliver positive and tangible change that ticks all the right boxes in relation to time savings, cost reduction and patient experience?

One sponsor – a top pharma company – was familiar with the management challenges of using multiple vendors and keen to embrace an innovative new approach to streamline its clinical trial operations and champion industry best practice.



The business challenge:

Navigating the complexity of multiple vendors

The sponsor had traditionally turned to different vendors to provide IRT and Clinical Supply Management services. And, because each function was managed by a different department within the sponsor company, the job of coordinating specifications and deliverables across internal and external teams required significant time, effort and expertise.

The two internal managers responsible for a trial's IRT and for the Clinical Supply at the sponsor company needed to oversee communication with, and coordination between, multiple vendors in order to:

- Share and agree upon requirements
- Ensure compatibility between the IRT and the system that supports drug distribution
- Review documents to ensure alignment, both during the initial system development and upon making any amendments

- Resolve the inevitable conflicts that arise
- Address protocol changes and analyse impact holistically

Even without issues, this process required considerable management time from the sponsor. However, when issues arose, an unsustainable level of time and resource was needed to remedy the problem. Time and resource the sponsor could put to profitable use elsewhere in its business. Worse still, these regular issues posed a risk to the integrity of the trial and the safety of its patients. In one instance, an initially unnoticed snag in the integration between one vendor's IRT system and another vendor's supply chain system caused a critical delay in the drug replenishment process. As a result, patients were lost to the study.

Multiple vendors were multiplying risk, along with the time and cost associated with mitigating them. Something had to change.

The Almac solution:

Unified IRT and Clinical Supply Services

The sponsor recognised an opportunity to significantly reduce the amount of time it spent, and financial resource it dedicated to, managing IRT and Clinical Supply by unifying the functions: aligning both its digital and physical supply chains. This pharma industry leader needed a vendor with the expertise and the proven technology to achieve this objective. The sponsor needed Almac ONE.

Almac ONE harmonises the processes and technologies that support the digital and physical supply chain, through an integrated team with a shared strategy and vision for delivering both services on time and on budget.

Service Delivery Leads work with sponsor organisations, as part of the Almac ONE offering, to train and upskill staff, monitor service levels and identify opportunities for improvement using data captured from the systems and resolve any issues that should arise. As such, the Almac ONE team would be able to establish and maintain efficient and effective project delivery for this sponsor through:

- **Constant, routine communication across business units.** This aligns requirements, proactively identifies inconsistencies, weighs the impact of decisions and quickly resolves issues. When questions or issues arise, they're dealt with in a matter of hours.

- **Fully integrated technologies.** Almac ONE's core IRT system (IXRS®3) handles automatic, real-time data exchanges on inventory releases and drug orders with COSMOS, Almac ONE's ordering and supply management system. The integration is pre-built, its quality is tested and proven and it comes as a standard feature.
- **Full supply shipment traceability.** Drug orders are automatically transferred from IXRS® to COSMOS and shipment dispatches from COSMOS are uploaded back into IXRS®.
- **Real-time supply forecasting.** A virtuous cycle of information on actual product demand allows this sponsor to optimise its approach as its trials progress.

In addition, Almac ONE's Service Delivery Lead can take over the management of several core areas, which under a multi-vendor arrangement would have fallen within the sponsor's remit. For example, the identification of IXRS® user roles for depot, temperature, clinical supplies and project staff from the clinical study and the collection and submission of clinical study staff details to create user accounts.

The client results:

Time saved, costs reduced, risks mitigated

After adopting a single vendor approach to IRT and Clinical Supplies Management with Almac ONE, the sponsor realised several quantifiable benefits. Looking at the time commitments of individuals within the sponsor's team prior to working with Almac ONE, it was estimated that (over the course of a two-year study) up to 3 hours per week were wasted managing multiple vendors and coordinating activity. This wasted time equated to the following (approximate) costs of sponsor staff time, per study:

- \$6,000 in meetings to coordinate efforts and resolve conflicts
- \$3,200 in reviewing documents
- \$4,000 for ensuring that protocol changes are properly addressed across vendors
- \$20,000 (based on 1-2 hours per week) for troubleshooting supply release and ordering issues

All totalled, the sponsor's management expenditure related to working with two vendors instead of one averaged \$33,200 per trial, a figure that is likely representative of most sponsors. By centrally coordinating all patient recruitment, clinical supply and IRT strategies through Almac ONE, this sponsor saved up to three hours per week (per trial) of its precious internal resource, which could be refocused on more important tasks, such as patient recruitment and treatment.

Ultimately, by working with Almac ONE, this sponsor's estimated study costs were reduced by 15%; helping to achieve its objectives of streamlined operations and best practice IRT and Clinical Supplies Management.



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