

Closed loop technology and integrated expertise mitigates risk



Closed loop technology and integrated expertise mitigates risk, enhances data integrity and champions compliance.

IRT, ERP, forecasting and temperature management systems have the potential to transform clinical trials and their supply chains for the better. Yet, when multiple applications exist in silos, and are operated by multiple vendors, this potential can be lost and the integrity of the data passing between the systems compromised. This in turn can lead to risk – to quality and compliance, to cost and ultimately to patients.

Minimising risk is a fundamental goal in every clinical trial. When a single vendor manages both the digital and physical functions of the supply chain, they can identify and mitigate potential risks that might otherwise go unnoticed.

The checks and balances that come with unified supply chain technology, coupled with a single vendor's oversight and integrated expertise, can not only mitigate the risk of costly errors but promote data integrity and compliance best practice too.

The business challenge:

Data discrepancies create drug supply risk

For one pharmaceutical organisation, preparing for several global phase III studies of an orphan drug, creating a seamless supply chain technology ecosystem – managed by a single vendor with integrated Clinical Supplies and technology-based expertise – was paramount in safeguarding data integrity and reducing risk.

Preparation for all three similar—but not identical—protocols was underway simultaneously, which led to a simple error in the specifications provided. The company's Supplies Manager specified that one particular study would require three kit types.

Meanwhile, the company's IRT Manager requested that the IRT for the same study should be built to accommodate two kit types.

Without the ability to quality check across multiple joined-up systems, and without the visibility that is derived from integrating the physical and digital supply chains, this seemingly minor error had the potential to go unnoticed. If left unchecked, this could pose a significant risk to the studies' drug supply and the patients supported by them.



The Almac solution:

Joined-up technology and a 'one team' approach safeguards quality

As the sponsor was utilising services from Almac ONE, a team of highly experienced IRT and Clinical Supplies professionals – operating from the same location with access to unified supply chain systems – the discrepancy was caught early and the risk removed. This happened as a matter of course when Almac ONE's IRT system, IXRS®3, was being programmed to accommodate the medication number list.

Almac ONE's Program Manager placed an immediate call to the sponsor to learn which set of instructions was correct. Within minutes, it was confirmed that the protocol should involve two kit types (not three). The fix was then relatively simple: Almac ONE modified the medication number list to reflect only two kit types, before updating the IXRS® accordingly.

From the sponsor's perspective, this was a small inconsistency that was caught and corrected quickly. The sponsor was likely unaware of how the error could have led to great expense and delay in the start-up timeline; had the same vendor not been working on both the physical and digital supply chain operations and able to offer robust quality checks across systems and disciplines.

Sponsors using Almac ONE's dual offering of Clinical Supplies expertise and integrated supply chain technology benefit from frequent checkpoints between the two disciplines.

This end-to-end study oversight delivers unrivalled support, with Almac ONE's unified team able to identify potential risks at an early stage in trial planning and take steps to mitigate them.

Furthermore, sponsor organisations, like this one, can take firmer control of quality processes by creating a comprehensive supply chain ecosystem (IRT, ERP, temperature management and forecasting), managed by the same vendor, under the same roof, that connects and shares data in a pre-validated manner, automates quality processes and promotes GDP compliance. For example, seamlessly integrated supply chain technology improves compliance by enforcing business rules relating to uploading temperature monitoring before supplies can be made available to patients in the IRT. This reduces conflict between data in the ERP system and the IRT by creating a dataflow between the two systems.

This approach also facilitates ease of use for clinical sites, as only one system needs to be accessed for processes including temperature control and drug orders. Almac ONE's IRT passes temperature data directly into its temperature management system.

Shipments with excursions are flagged by the temperature management system back into the IRT quarantine.



The client results:

\$50k rework avoided, quality controlled, data integrity and compliance upheld

Such issues arise regularly when a sponsor is running multiple studies at once and/or dealing with multiple vendors. Unifying the digital and physical supply chains makes quality control relating to medication lists, protocol, distribution instructions and drug ordering more robust and less resource intensive. It also delivers process automation of activity such as the release of supplies in the IRT; something that traditionally (using a multi-vendor, disjointed approach) requires manual administration.

Because, in this instance, the incorrect specification was identified early and corrected quickly by Almac ONE, the sponsor was spared the expense and delays involved in reprogramming the systems.

Additionally, the sponsor did not have to face the expense of re-labelling and re-packaging kits that would not have been needed. If the error had gone unnoticed, this would have cost the sponsor approximately \$50k and could have added months to the study timeline.

Ultimately, by championing a unified approach to its supply chain management, this sponsor removed a significant and costly risk and guaranteed data integrity from start-up to completion.

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