



Partnering to Advance Human Health

Case Study

Unified IRT and clinical supply aligns processes to meet timeline



Unified IRT and Clinical Supply aligns processes to meet aggressive drug delivery timeline for investor-backed study.

Privately funded clinical trials bring with them added complexities, with securing ongoing investment often dependant on the research organisation's ability to meet a series of ambitious key performance indicators, within short, inflexible timeframes.

Against this demand, the need to reduce errors that lead to delays, and wasted time that could be put to better use elsewhere in the study, are apparent ones. As is the need to establish an optimal balance of inventory to minimise supply costs, while maximising efficient and effective patient resupply throughout a study's lifecycle.

For one pharmaceutical company, responding to investor demands to drastically shorten drug delivery timeframes by 25%, meant unifying IRT and Clinical Supplies processes with speed and precision to secure vital funding, optimise operations and save time.

The business challenge:

When a shortened timeline threatens study success

Operating in oncology research, the sponsor was planning a phase III trial that would involve over 500 patients, close to 100 sites, across the US, Canada, Asia Pacific and Europe. The team was small, yet innovative and enterprising in its approach to getting a much-needed drug to market.

The sponsor lacked the in-depth expertise and workforce-based resource required to manage its Clinical Supply operations and IRT (Interactive Response Technology) systems in-house. Wasting its valuable (and limited) internal resource co-ordinating multiple vendors to resolve issues and errors that arise due to misaligned communication, bridging fragmented workflows and manually cross referencing digital and physical supply chains was not considered a feasible option.

When the pressure was on to meet the investor's aggressive new deadline, the sponsor needed to take both urgent and effective action to ensure IPO criteria was met.

The sponsor needed to effectively manage the key components of its trial. From screening and randomisation all the way through to inventory, patient tracking and clinical outcome assessments. An IRT system would provide a centralised hub to manage these processes, and the data generated by them, but who would manage the IRT system? And how would that IRT system and its operators interact with Clinical Supply functions to help optimise the physical supply chain?

The sponsor had just one chance to get the answers right and time was of the essence.



The Almac solution:

Unifying IRT and Clinical Supplies functions

For most studies, there is a responsibility gap between the place IRT functions end and Clinical Supply functions begin. Bridging this gap requires unifying these functions to achieve greater speed, accuracy, visibility and control. Bridging this gap requires Almac ONE: highly experienced IRT and Clinical Supplies professionals working as one team, under one roof, combined with tailored technology, to harmonise processes, harness study data to solve problems and identify opportunities for continuous service improvement.

Having the right people, in the right place, at the right time, the Almac ONE team was able to take the sponsor's problem and develop and deliver a workable solution within two hours.

This rapid response would not have been possible with a multiple vendor approach. Instead the sponsor would have needed between three and four working days to bring two organisations together, set expectations, await individual proposals, merge plans and co-ordinate processes, people and systems.



The client results:

Deadline met & ongoing time savings generated

The sponsor did not have to coordinate or manage any part of the process of developing a new and significantly shortened timeline. Responsibility was with Almac ONE at every step of the journey, allowing the sponsor to rest assured that its study was in safe hands, its deadlines would be met and its patients best supported with minimal time investment from the sponsor.

In fact, the single point of contact and unified approach to digital and physical supply chain management reduced the sponsor's time spent managing multiple vendors by up to three hours per week. Because Almac ONE is based in the same physical location, the unified team can react quickly and accurately to evolving study demands, while working with data to pro-actively fine tune operations. Again, this is helping to establish streamlined, efficient, integrated processes that free up the sponsor's time.

In addition, the complexity of working with multiple vendors has also been removed, leading to an estimated 80% fewer errors when releasing inventory and raising shipping orders.

Because errors take considerable time to rectify, further time savings have been made possible as a by-product.

Ultimately, thanks to Almac ONE and its team of IRT and Clinical Supplies experts, the sponsor was able to respond with speed and accuracy to its investor's demands, meet its study milestones, successfully launch onto the stock market and benefit from ongoing efficiencies.

The trial is now up and running and, with the ongoing support and expertise of Almac ONE, is working with patients around the world.

When asked to sum up their experience of Almac ONE, the sponsor said: "Almac was responsive, expedient and flexible."

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