

Almac maps road to success for sponsor by unifying physical and digital supply chains





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Operating successful supply chains in today's clinical trial landscape requires an abundance of infrastructure and expertise that span multiple disciplines.

The complexity involved warrants an army of supply chain and clinical technology specialists. Yet for many sponsors, including organisations with limited internal resource, possessing these vital specialist skill sets 'in-house' isn't a commercially viable option.

The traditional alternative has been to outsource the physical supply chain management to multiple vendors and the digital aspect to others. This approach is not without pitfalls – most notably, excessive communication, the potential for confusion, lack of accountability and delay that can manifest as a result of multiple parties operating in silos.

Keen to avoid these risks and champion a harmonised approach to clinical supply, while maintaining a lean internal headcount, one sponsor specialising in the treatment of rare diseases opted for a better approach.

The business challenges

Limited resource and experience increases risk

Planning its inaugural clinical trial, the sponsor was preparing to run a randomised, double blind, placebo controlled, dose-ranging phase II study of its investigational therapy. The study had the potential to transform the lives of patients living with established cardiovascular disease.

Despite limited resource and expertise of its own, the sponsor needed to effectively plan and execute its clinical supply chain strategy from study start-up to close out, across all core areas. This included Interactive Response Technology (IRT) design, packaging and label design, QP review, distribution and import licencing activity, in addition to Supply Chain Management (SCM) and Trial Master File (TMF) documentation.

As the sponsor's first study, the pressure was on to deliver patient-centric programs, on time and within budget.

The Almac solution

Fast-tracking study completion with a 'ONE stop shop' of clinical supply chain and IRT expertise

In order to deliver on this objective and reduce unnecessary delay, the sponsor needed a single-vendor to manage its physical and digital supply chain requirements. After reviewing several vendors with the experience and global capabilities needed, the sponsor enlisted Almac and its unified clinical trial supply solution, Almac ONE™, to provide IRT and packaging and distribution services.

The Almac ONE partnership kicked off with an initial scoping meeting, where the sponsor's unique requirements and challenges were discussed, along with the role of the Almac ONE Program Manager, who would be responsible for oversight of all Almac activity through the duration of the study. This was formalised with a relationship management plan to detail communication and escalation pathways and ensure efficient and current information sharing; something that would be used to standardise the sponsor's subsequent studies. A program Dashboard and GAID (Gap, Action, Issue, Decision) tracker document were also created to enable the clear and concise tracking of study activities.

In combination with the continuous knowledge, oversight and leadership of the Almac ONE Program Manager, this approach ensured seamless links between the multiple experts and systems responsible for developing a robust and effective method of delivering the right amount of product, to the right place, at the right time and under the correct handling conditions. This approach proved crucial in keeping timelines as efficient as possible, both for the initial start-up and during the management of scope changes, which would enhance cost control, accelerate study completion and ultimately safeguard patients, all of which were key goals for the sponsor.

The results

Unified supply chain reduces timelines and facilitates successful study outcome

By streamlining communication and standardising Almac's deliverables, the management of the studies became a far less complex undertaking for the sponsor, from initiation to close out. Instead of siloed trouble shooting and enduring delays going back and forth between vendors, Almac's harmonized, responsive, end-to-end approach effectively bridged the gap between the physical and digital components for the sponsor to deliver enhanced visibility and accuracy.

By leveraging Almac ONE and the Program Manager role, the sponsor was able to focus its limited resources on other core activities, including patient recruitment, while effortlessly scaling up the activity for the clinical program. Part of the physical supply strategy included the use of a pooled supply packaging approach. This reduced costs in procurement and supply of unpackaged material and increased flexibility to support studies based on recruitment needs so that the addition of new countries could be easily accommodated. Although pooling supplies would have been possible with a multi-vendor approach, communication around what product to release for what study within the IRT – to ensure alignment with the physical release of drugs - would have been far more complex and demanded much greater oversight and resource from the sponsor.

A further benefit of embracing Almac ONE and the sponsor's commitment to develop a standardised approach to both IRT and packaging/labelling activities to the clinical program was more efficient timelines and reduced scope changes.

Ultimately, the timely completion of the sponsor's first study resulted in the IMP being successfully sold to a leading pharmaceutical company. This cemented the sponsor's commercial position and bolstered its ability to continue developing innovative new therapeutics: an outcome that would have been more complex, costly and time-intensive to realise without the support of Almac ONE.

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