ALMAC

Partnering to Advance Human Health

Case study

Aligning the digital and physical supply chain with Almac ONE™ delivers agility for global phase III study during COVID-19 pandemic





The onset of the global Coronavirus pandemic in March 2020 left many clinical trial sponsors facing unprecedented challenges.

A complex operation at the best of times, COVID-19 presented additional barriers for sponsors committed to delivering the right drugs to the right patients at the right time and temperature. Clinic closures, travel restrictions and redeployment of site staff significantly heightened the risk of negative patient impact. For other sponsors, entire R&D pipelines were called into question, as the pressure to discover safe and effective treatments and vaccines for the virus intensified.

A key learning from the pandemic has been the importance of clinical supply chain agility. Something that can only be realised when clear and complete visibility over each aspect of the supply chain is available to inform fast and effective decision making.

For one sponsor operating a global phase III open label study to assess the long-term safety of its trial drug designed to treat patients with a progressive respiratory disease, rapidly adapting its distribution strategy would be key to maintaining access to vital medication for its vulnerable patients.

The business challenges

COVID-19 disruptions result in site closures with potential to disrupt the clinical supply chain

To mitigate the risk of vulnerable patients contracting COVID-19, while traveling to or attending site-based appointments, and overcome the barriers of clinic closures in the US, the sponsor needed to implement a Direct to Patient (DtP) distribution strategy mid study.

This would require the introduction of a new emergency COVID process, Almac to Patient (AtP), to create an alternative supply chain solution to leverage medication at Almac depots rather than the clinical sites and distribute this medication safely to patients' homes.

The industry-leading Interactive Response Technology (IRT) system designed and built by Almac Clinical Technologies, known as IXRS®3, had been programmed to underpin distribution from Almac's production facility in Pennsylvania to clinical sites across the US. In order to proceed and safeguard continuous resupply, the IXRS® 3 system needed to be quickly reconfigured to facilitate the AtP strategy in an evolving regulatory environment during the COVID-19 pandemic.





The Almac solution

Alignment between the physical and digital supply chains enables rapid set up of AtP distribution

The situation required a rapid response to achieve the desired outcome quickly as sites were being closed in response to the pandemic. Additionally, nobody was aware of the extent or duration of the pandemic and therefore Almac had to quickly consider a scalable solution.

With a 25-year history of partnering with Almac on hundreds of clinical trials, across multiple drug types and therapeutic areas, the sponsor benefited from Almac's unified clinical trial supply solution, Almac ONE™.

The unique position of Almac ONE™, where the clinical supply chain and IRT are harmonized and managed by Almac, lends itself to this critical situation. With working groups across both disciplines being fully integrated with established communication pathways, Almac were able to immediately plan and assess the initial rapid response, taking into consideration cross functional impacts, risks and dependencies that needed addressed to accommodate the desired change. The cross functional knowledge of processes and systems shared across the supply chain and IRT teams also allowed for immediate insights into the challenges that needed to be overcome.

The Almac ONE™ approach would prove pivotal in helping this sponsor adapt its distribution strategy with both pace and precision. With access to real-time, unified data – and with dual expertise under the same roof negating the need for back and forth between multiple vendors – the Almac ONE™ team were able to quickly establish an emergency procedure to re-code the IRT system by the Almac Clinical Technologies business unit, which was complimented in a Good Practice (GxP) manner by Almac Clinical Services (Distribution) business unit, through rapid process adjustment to accommodate AtP in a compliant manner.

The results

Unified supply chain ensures clinical trial continues as planned

The impact of COVID-19 identified an industry-wide need for flexibility in clinical trial supply chains. Amending an IRT inventory algorithm mid-study ordinarily takes time, can be expensive, and had the sponsor utilized the services of multiple vendors, it would have unwittingly introduced additional layers of complexity and increased risk of misalignment between the physical and digital supply chains. The Almac ONE™ strategy allowed for a rapid, cost effective, emergency response to be developed that allowed for immediate supply chain continuity ensuring patients remained on their treatment course with no delay. Additionally, the well-defined collaboration internally between the two Almac business units allowed for the emergency response to be further developed over time, allowing for dynamic changes later down the line as the COVID-19 pandemic evolves.

By using the Almac ONE™ solution, this sponsor was able to realise a fast turn-around of its IRT system reconfiguration, reducing the risk to incredibly vulnerable patients and enabling the trial to proceed as planned, despite the onset of a global pandemic.

Not only has the rapid implementation of AtP distribution safeguarded fast and continuous resupply to patients, it has also delivered several other benefits. For example, the sponsor has recorded a decrease in drop-out rates due to patients missing clinical visits, it has also improved enrolment rates due to lower travel demands. As a result, Almac is continuing to collaborate with the sponsor to develop and extend use of AtP distribution to optimise processes, improve performance and protect patients through COVID-19 and beyond.

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