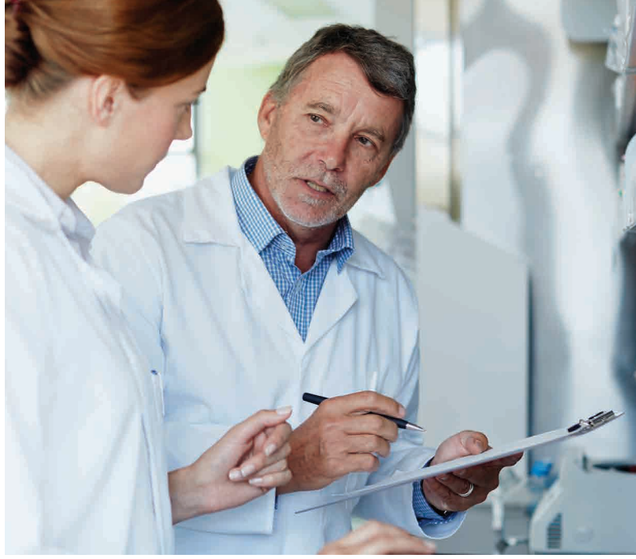
ALMAC

Partnering to Advance Human Health

Case Study

Managing the returns & reconciliation challenges of a Direct to Patient distribution model



Managing the returns & reconciliation challenges of a Direct to Patient distribution model

Effective recruitment and retention is a fundamental building block of successful clinical trials management. It is also a large cost centre, with drug manufacturers investing an estimated $2.28 billion each year in recruiting study participants. Despite this, around two-thirds of clinical sites fall short of their enrollment quotas and the rate of patient drop-outs remains at approximately 30%.

This has given rise to a renewed industry focus on patient centricity. Promoting a positive patient experience is no longer just a moral obligation for sponsors, it's a commercial one too. If recruitment is appropriately incentivised and patient convenience championed, enrollment can be accelerated, drop-outs and delays reduced, and revenues maximised.

One of the ways sponsors can achieve this is by adopting a Direct to Patient distribution model that requires patients to travel to site-based appointments less frequently, if at all; reducing interference with day-to-day life. It opens the door for more patients, who would otherwise struggle to get to appointments, due to location or health limitations. Patients also enjoy greater influence and autonomy over their treatment schedules.

The Direct to Patient model can deliver higher levels of patient centricity, but can also bring new challenges for sponsors to navigate. The additional complexity posed by drug returns and reconciliations is an example, as was the case for one large global pharmaceutical company, operating the model for the first time for its phase II, open label study.

The business challenges

Ineffective returns process places pressure on patients and sites

The aim of the sponsor's study was to assess the safety and efficacy of its investigational product (IP), designed to help pediatric patients living with a rare disorder.

The study involved 50 patients, across multiple regions in Europe and the US. Delivery of the IP was through multiple drug formulations. After patients received 52 weeks of treatment, they were eligible to enter an extension stage of the study.

Keen to support the children enrolled in the study and pose as little inconvenience to them and their families as possible, the sponsor included the Direct to Patient distribution model within its protocol. As such, the sponsor's IP was dispatched from a depot to a clinical site, before being dispensed by a pharmacist to the patient's home.

The sponsor began to experience problems, while attempting to manage the returns and reconciliation of expired, unused or no longer required IP from the patients' homes. This also had an impact at a patient level as individual patients had to be accountable and responsible for the storage of the expired and unused drugs at their homes.

Clinical sites were struggling to keep on top of sporadic drug returns and there was no standardised method of reconciliation across the sites located in many regions, which meant the sponsor struggled to obtain holistic visibility of the scale of the problem. Compliance was also potentially at risk, as it is a regulatory requirement that all unused or expired drug must be accounted for.

Finally, the families were asked to co-ordinate their own drug returns; detracting from the patient centric value the Direct to Patient model was supposed to offer and deliver and risking patient retention.

The sponsor needed to ease the burden on patients, their families and each clinical site, and take back control of its returns and reconciliation process.

To achieve this, the sponsor turned to Almac Clinical Services to solve the issue and maximise the potential of its Direct to Patient distribution model.

The Almac solution

Partnering to build a fit for purpose protocol

Almac's Clinical Services team quickly set about reviewing the shortfalls of the existing returns and reconciliations process. Almac worked with the sponsor and a specialist courier provider to develop a new, fit-for-purpose protocol which would promote both patient centricity and enhanced operational efficiency.

Almac's new protocol for drug returns and reconciliations was developed with patients firmly in mind. It involved a courier driver, highly trained in handling clinical supplies, collecting the returning IP and signing it out of the patient's home, before storing it compliantly within their vehicle. This created an audit trail for enhanced visibility over the drug returns process, while maintaining regulatory compliance.

The next stage of the process required the driver to deliver the new IP to the patient. Completing the process in this order and in separate transactions was a vital component of the revised protocol and would remove the risk of mix-ups and mistakes.

Once these stages were complete, the courier would take the returned IP to the site for standardised reconciliation. The process then specified that the returned IP be sent to an Almac facility for reconciliation and destruction.

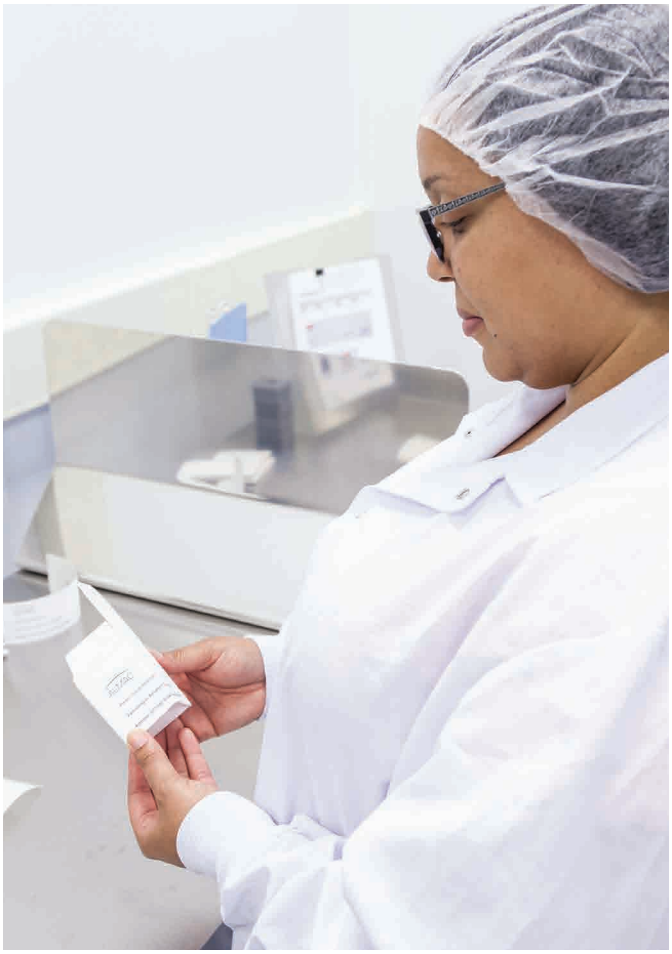
The results

Patient centricity restored, pressure on sites reduced

Committed to supporting the sponsor with its mission of causing as little inconvenience to its patients and their families as possible, Almac's mid-trial intervention was delivered quickly and effectively, ensuring the seamless continuation of the study and maximising patient centricity.

Providing Direct to Patient deliveries and returns services has removed the responsibility initially placed on site personnel to arrange collection of expired or unused IP from patients' homes. This has helped to free vital resources that can now be refocused elsewhere. It has also alleviated pressure on the sponsor, who struggled to achieve bigger picture visibility of the study's drug returns.

Perhaps, most importantly, parents and guardians of patients enrolled in the study no longer deal with the administration and inconvenience of co-ordinating drug returns. Instead they can focus on what matters most: spending quality time with their children and supporting them through the treatment process.



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