A remote-based approach to ensuring dosing compliance and drug accountability
Oncology trials involving weight-based dosing and delivery via infusion put the onus on site pharmacists to prepare, administer, and document the proper dosing. Clearly, much can go wrong that can compromise both patient safety and the integrity of study data. Almac’s Clinical Services’ centralised monitoring by a licensed pharmacist is an efficient way to ensure that sites follow the protocol and complete the necessary documentation.

It is an innovative, remote-based approach to drug accountability.

The Business challenge:

Ensuring Dosing Precision

For one global pharmaceutical company’s pivotal Phase III oncology trial, onsite pharmacists were required to mix the patient doses for delivery via infusion using unblinded drug supplies provided in multiple strengths.

The prescribed dosing was based on the patient’s weight, and treatments were administered over a four month period. The study duration was two years.

The sponsor sought a way to monitor pharmacists’ dosing to ensure that:

- The proper vials, as assigned by the IRT (Almac’s IXRS™), were actually used
- Individual patient doses were prepared in the correct volume and concentration
- The dose was administered within the prescribed treatment window
- Administration to patients was properly documented

The trial was being conducted in more than 100 sites across 17 countries. Clinical Research Associates (CRAs) would be visiting sites throughout the study duration.

Due to the study design, only unblinded CRAs could review pharmacy records, which would require two separate CRAs monitoring site compliance and study data.
The Almac solution:

Compliance monitoring by licensed pharmacists

Almac Clinical Services was responsible for ensuring accountability of the investigational and comparator drugs throughout the trial in a way that was quality based, streamlined and cost efficient. This involved proactively collecting, reviewing, and reconciling temperature logs, drug assignments, and patient dosing records. The Almac approach decreased site monitoring costs, by providing a centralised remote solution.

From the initial shipment of product until the last patient was dosed, Almac’s Clinical staff reviewed temperature logs to verify that no temperature excursions had occurred. They also collected and reviewed sites’ drug accountability logs, checking them for completeness and to ensure that each vial assignment in the Interactive Response Technology (IRT) was carried out with the correct vial number, vial type, patient ID, and date.

And, perhaps most importantly, Almac Pharmacy staff monitored site pharmacists’ compliance with the dosing requirements. Specifically, they reviewed the patient dosing worksheets for accuracy and completeness, monitoring how sites had calculated the volume and concentration of the infusion. They watched for developing trends that suggested the need for intervention by unblinded CRAs, followed up with sites on any issues, and kept the sponsor’s Contract Research Organisation (CRO) informed of the status of compliance. They documented progress, captured issues, and tracked issue resolution.

Overall, Almac staff maintained awareness among site personnel and CRAs of the importance of providing all necessary dosing documentation. Automated e-mail reminders were sent monthly. In addition, the team took advantage of the existing channels of communication with sites, such as a study newsletter and routine meetings, to promote compliance.

The client results:

100% of all documentation complete, without delaying study close

Over the course of the study, Almac’s Clinical Services team reviewed 15,000 drug assignments and thousands of patient dose worksheets, drug accountability logs, and temperature logs.

These logs accounted for over 300,000 data points. The streamlined process performed routinely as the study progressed, allowed the sponsor to close the study promptly, without the holdup that drug accountability usually presents when it is performed as a last step.

The central team was able to identify any potential issues quickly and intervene, as necessary. Almac staff were able to spot patterns in noncompliance, sometimes suggesting that one aspect of the protocol was posing a problem or that one site or another was consistently having difficulties. Had monitoring been performed exclusively by CRA site visits, issues could not have been identified as promptly, since CRAs were only able to visit sites periodically.

Nor could CRAs, each with a view of data from only a few sites, have been able to spot trends and patterns across multiple sites.

When it came to patient dosing, site pharmacists appreciated the fact that a licensed pharmacist was reviewing their work; they understood that the review was not a critique of their work, but a safety check and, queries on dosing were between professionals, which only increased site cooperation.

This process provided the CRO with up-to-date, clean data over the course of the study and ultimately improved the quality of the study data needed for regulatory submission. By the end of the study, Almac had received and reconciled 100 percent of all temperature, drug accountability, and dosing documents.
Forecast and simulation
Clinical material forecasting, forecast management and simulation tools along with SCM expertise, matches clinical supply to patient demand, ensuring optimised strategies to meet your trial needs.

Inventory management
Supply Chain Managers continually monitor trial supply globally, trending study activities and adjusting future campaigns and material transfers to ensure that the right IMP is at the right place at the right time to meet study demand.

IRT Medication management
Supply Chain Managers consult on the medication management IRT design to meet study needs. They set, monitor and adjust inventory management levels and system expiry strategies to ensure optimisation of IMP while reducing distribution costs where possible.

Label development and regulatory vetting
Almac can oversee label text development, regulatory review, translation and artwork, ensuring that IMP labels meet clinical, regulatory, drug product and country specific requirements.

Temperature management solutions
Almac’s innovative software program, TempEZ™, supports the full suite of Almac Temperature Services offerings, providing clients with a single central database to store temperature data while ensuring compliance to GxP and GDP regulations.

Bulk drug management
Supply Chain Managers convert finished good demand into upstream manufacturing and API requirements, working with capacity and lead time limitations to avoid downstream supply interruptions and reduce over production and bulk waste.

Other services
Almac Supply Chain Managers can provide end to end management of investigator sponsored trials, provide pharmacy services and draft pharmacy manuals. They can also act as unblinded contacts for the site management of clinical supplies.