ALMAC

Partnering to Advance Human Health

CASE STUDY

SUPPLYING COSTLY INVESTIGATIONAL PRODUCT: PRE-RANDOMISATION APPROACH REDUCES DRUG WASTAGE

Certainly, every sponsor wants to minimise wastage in clinical trial supplies, but the motivation to do so is extraordinary when the product under study is unusually expensive. A top-tier, international pharmaceutical company engaged Almac to ensure that it did not incur undue drug supply costs for a global study involving a very expensive investigational product. With some ingenuity and customisations to the IXRS® platform for managing patients, supplies, and trial data, Almac helped the client re-envision its study design and supply strategy.

THE BUSINESS CHALLENGE: A HIGH RISK OF WASTAGE

The sponsor's Phase III trial was scheduled to run for several years in a large number of sites around the world with a relatively small number of patients at each site. The study involved investigational product that had a limited shelf life, and supplies for the trial would run into tens of millions of dollars. The costs had the potential to escalate unless supplies were managed very carefully; the sponsor thus asked for Almac's help in minimizing drug wastage by avoiding oversupply of product to sites.

Almac's challenge was to recommend a statistically sound approach to randomisation that would use Integrated Response Technology (IRT) to control when products were shipped, thereby minimizing drug wastage.

The traditional approach—assigning patients to a treatment group through centralised randomisation—means that the treatment group for each patient cannot be predicted. To compensate for this, sites must be supplied with sufficient stock to cover all combinations of treatment. This commonly results in sites receiving more investigational product than they will need. An alternative approach involves assigning blocks of randomisation numbers to sites; this allows the treatment assignment to be accurately predicted. It was quickly determined that in this instance, due to the high site-to-patient ratio, there was an increased probability that at the end of the study incomplete randomisation blocks would remain, creating an imbalance among treatment groups.

ALMAC'S APPROACH ALLOWED THE SITE'S AUTOMATED SHIPMENT TO BE TAILORED TO REFLECT ONLY THE KIT TYPES ASSOCIATED WITH THE PATIENT'S TREATMENT GROUP

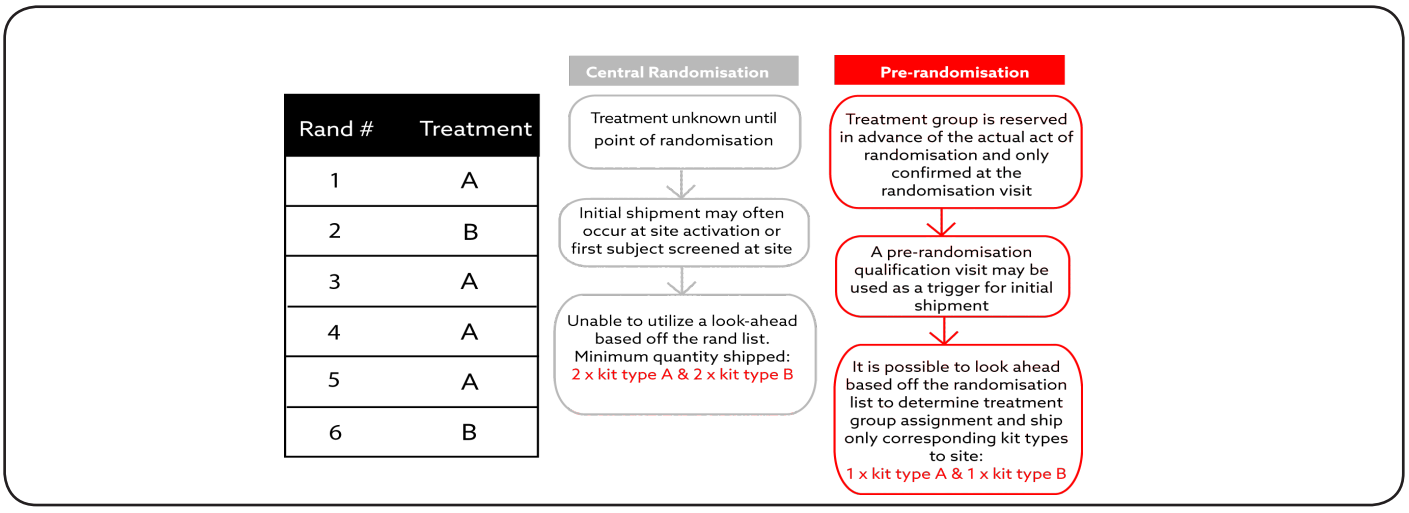
THE ALMAC SOLUTION: TECHNOLOGY TO SUPPORT A CREATIVE SUPPLY STRATEGY

Drawing on its supply chain management and biostatistical expertise, the Almac project team assessed a variety of alternative solutions to aid the client's decision-making process.

The client opted for a pre-randomisation methodology whereby a patient's treatment group is reserved in advance of the actual act of randomisation and only confirmed at the randomisation visit. This approach allows the site's automated shipment to be tailored to reflect only the kit types associated with the patient's treatment group. Although this may lead to an increase in the overall number of shipments, this cost is greatly outweighed by the savings from reducing drug wastage.

Almac's drug ordering system within IXRS was modified to support the strategy to ensure efficient product distribution (see Figure 1).

FIGURE 1: Shipping Triggers in Traditional vs. Pre-randomisation Methodology



THE CLIENT RESULTS: GREATER FLEXIBILITY AND IMPROVED EFFICIENCIES

The overriding objective—to ensure that the right kits are arriving just in time for pre-randomised patients and for subsequent treatment visits—is being met, thanks to the alerts and automated ordering process provided by IXRS.

This is resulting in:

- Reduced product inventory. Expensive products are not stockpiled at sites where they could be expiring. Only the medication that is needed for the patient's treatment group is shipped.
- Simpler drug reconciliation and accountability. Because inventory is not left on shelves to expire, drug reconciliation is greatly reduced, and coordination with the CRO is streamlined.
- Minimal drug wastage. Product supplies are less likely to expire, leading to reduced wastage, fewer returns and lower supply costs.

Almac's comprehensive and innovative solution is assisting this sponsor in keeping its outlay for expensive investigational product to a minimum throughout the study supply chain.

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