ALMAC

Partnering to Advance Human Health

Case study

Overcoming IRT challenges for small and emerging biotech

The benefits of IXRS®3



Small and emerging biotech companies face unique challenges when setting up an Interactive Response Technology (IRT) system. These challenges stem from lean organisational structures, limited in-house expertise, and strict budgetary constraints. This case study explores how Almac's IXRS®3 IRT system supported a sponsor preparing for a Phase III confirmatory trial, helping to overcome technical, operational, and strategic hurdles. Highlighting how the right clinical technology partner can bridge resource and knowledge gaps, ensuring the IRT system supports the trial efficiently and effectively.

Challenges faced by the sponsor

1 Limited internal resources

With a lean team, the sponsor's internal staff were responsible for a wide range of responsibilities. Technical operations, including IRT implementation, had previously been managed by dedicated departments in larger companies. At the time of trial preparation, the sponsor lacked in-house experience with IRT systems.

2 Need for a comprehensive, integrated partner

Due to the sponsor's limited internal capacity, there was a need for an external partner to support not only IRT implementation but also the broader clinical supply chain including packaging, labelling, distribution, and returns management. A single vendor approach was preferred to reduce complexity and rise.

3 Maintaining blinding across the sponsor's team

All staff involved in the study at the sponsor organisation were required to remain blinded, including senior leadership. This presented a logistical challenge in trial management, especially around forecasting and supply planning.

Almac's approach

Strategic partnership & consultation

Almac worked closely with the sponsor from early planning stages to define system requirements. Recognising the sponsor's limited internal experience, Almac provided consultative guidance, sharing industry best practices and implementation strategies. This helped the sponsor understand the rationale behind the system's structure and complexity.

"At the beginning, I didn't fully understand why the requirements were so detailed. But as we progressed, it became clear that thorough planning was essential to avoid costly mid-study changes."

Blinded supply management

To support the sponsor's need for full blinding, Almac provided an external Drug Supply Manager who worked collaboratively with the sponsor's production team. This ensured alignment in supply plans while maintaining the blind across the sponsor organisation.

Streamlined communication

A single point of contact was assigned to the sponsor, supported by a documented escalation path. This consistent project management approach provided continuity and helped foster a close, effective working relationship.

"Despite being a large organisation, Almac operated with the responsiveness and cohesion of a smaller team. We always felt like our needs were prioritised."

Transparent costing & change management

Almac's proposal and invoicing processes provided the sponsor with clear visibility into costs. Options presented during design phases included associated budget impacts, enabling the sponsor to make informed, timely decisions in line with their financial constraints.

Results and outcomes

- The IRT system was successfully implemented to support a global Phase III study.
- The sponsor achieved full compliance with blinding requirements without compromising operational efficiency.
- The integrated IRT and clinical supply services reduced handoffs and supported a streamlined trial start-up.
- Transparent costing helped the sponsor manage their budget confidently.

Lessons learned from the sponsor

The sponsor emphasised the value of a trusted, experienced partner in building a first IRT system and offered four key takeaways:

Define requirements clearly:

Understanding what is needed upfront simplifies the process.

Seek expert input:

Use your vendor's experience to inform decisions, especially if internal expertise is limited.

Balance instinct with data:

Use both to guide decisionmaking when working in unfamiliar areas.

Select partners thoughtfully:

Consider not just technical capabilities but also values, responsiveness, and collaborative culture.

About Almac IXRS®3

IXRS®3 is Almac's industry-leading IRT platform, designed to provide flexibility, scalability, and integration across all phases of clinical trials. Its adaptability makes it a strong fit for small to mid-sized biotech companies looking for robust technology and dependable support.

For more information on how Almac can support your IRT needs, visit almacgroup.com or contact us at info@almacgroup.com.

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