

Case study



Seamless mid-study IRT implementation:

Preserving data integrity with
retrospective manual entry

Summary

When a late-stage protocol amendment expanded an oncology study and introduced randomisation, the Sponsor (who had been conducting the study without any IRT) needed to implement IRT mid-study, without disrupting sites or compromising data integrity. Almac Clinical Technologies was brought in to lead the controlled transition to IXRS®. Almac's IRT reconstructed the complete patient and inventory history through carefully governed manual data entry.

The result: a compliant, audit-ready system aligned with actual site activity and EDC records, delivered on schedule with zero site disruption.

Client situation

The study began as low-enrolment with no randomisation, so IRT was not included. A mid-study protocol change increased enrolment and added a formal randomisation process. This created operational complexity and heightened risk of data inconsistencies across systems. To protect study integrity and ensure a consistent source of truth, the Sponsor elected to implement IRT mid-execution and asked Almac to lead the transition, data migration, and IXRS® readiness.

Strategic decision: Manual, retrospective entry to de-risk the transition

Although IXRS® supports validated automation, Almac recommended, and the Sponsor approved, manual data entry for all retrospective subject transactions. This quality-first approach ensured:

Tight control of sequencing: Preserved correct Screening IDs, Randomisation IDs, and Cohort assignments.

Real-time verification: Matched every entry to actual site events, preventing IXRS®/EDC discrepancies.

Lower systemic risk: Enabled precise, step-by-step handling of sensitive study data and integrations.

This decision reflected Almac's commitment to proactive risk mitigation and regulatory compliance.

Execution overview

Almac onboarded five clinical sites and their associated depots, configured the supply chain, and activated IXRS® to begin subject-level reconstruction. Key activities included:

- Manual authorisation of IP release at each depot
- 15 depot-to-site shipments processed and recorded
- Complete entry and verification of 43 screened subjects, 28 randomised subjects, and ~60 follow-up visits

Throughout, the team maintained strict, chronological alignment between site activity and IXRS® entries, supported by hands-on validation and close cross-functional communication.

Key Challenges We Solved



1. Data completeness & accuracy

All subject, visit, and inventory data - demographics, randomisation records, dispensation history, lot/expiry details were rigorously verified prior to entry.



2. Visit date fidelity

System-generated dates were deliberately adjusted to match actual visit dates for each retrospective entry.



3. IXRS® ↔ Electronic Data Capture (EDC) consistency

Screening and randomisation data flowed to EDC in a defined sequence to prevent misalignment. File generation and integration followed a locked, stepwise process.



4. Global, time-critical delivery

Teams in Singapore, the UK, the US, and China collaborated across time zones, extending hours and weekends, to complete data entry between IRT go-live and restoration of site access.



5. High-touch coordination

Subject entry, inventory reconciliation, QC reviews, visit corrections, and EDC integration were orchestrated across specialised Almac teams with a single program cadence.

Solution Approach

Aligned teams. Clear gates. Strong governance. Success depended on coordinated execution across Almac Inventory Management, Customer Solutions, Data Transfer, and Project / Design Management.

1 Detailed action planning

Roles, responsibilities, and timelines were clearly defined with measurable checkpoints.

2 Proactive data collection & QC

End-to-end quality checks covered vial counts, lot numbers, expiry dates, shipment IDs, demographics, visit dates, and cohort assignments. Discrepancies were escalated immediately, with rapid Sponsor input to keep momentum.

3 Controlled transition window ("blackout")

Once data was approved, Almac executed:

- Controlled manual entry into IXRS®
- Secure EDC data transfers
- Parallel QC by Almac and the Sponsor

4 Risk assessment & dry-runs

Simulations validated workflows and ensured visit date corrections flowed cleanly into EDC.

5 Inventory readiness

To reduce downtime, inventory setup began early: 1,890 vials released to depots and 490 vials prepared for depot-to-site shipments.

6 Optimised entry sequence

Screening and randomisation were prioritised to enable timely EDC integration. All 43 screenings, 28 randomisations, and ~60 visits were entered in strict order.

7 Phased site access

Almac completed all pre-transition entries before granting sites access to IXRS®, ensuring a clean transition.

8 Follow-the-sun collaboration

Extended coverage minimised the cutover window and reduced site burden.

9 Transparent Sponsor communication

Daily status updates, swift issue resolution, and clear escalation paths sustained alignment and trust.

10 Regulatory compliance

Ensured full audit trail and documentation of all steps taken, satisfying regulatory requirements and enabling complete reconstruction of actions if required by authorities.

Results

Delivered on schedule with zero site disruption. The study proceeded seamlessly under the new randomisation-enabled workflow, with IXRS® reflecting a complete and accurate history.

Operational accuracy & data integrity

Two complete retrospective data sets were entered and fully validated, capturing:



Additional outcomes:

- All 15 depot-to-site shipments re-entered with full lineage tracking
- 207 kits underwent comprehensive QC (lot numbers, expiry, and dispensation alignment)

This meticulous process - spanning more than 200 controlled transactions - produced an audit-ready IRT record, mitigated regulatory risk, and eliminated downstream reconciliation issues.

Proven partnership value

Daily check-ins, rapid escalations, and transparent communication kept all parties in lockstep. The Sponsor shared their appreciation:

"A BIG THANK YOU for the IRT manual data entry project. We truly appreciate the team's dedication and responsiveness throughout this process."

Why sponsors choose Almac for IRT

-  **Integrity by design:** We prioritise data accuracy and sequencing control—especially in high-risk, mid-study transitions.
-  **Hands-on expertise:** Deep IRT/EDC integration experience and disciplined QC safeguard study credibility.
-  **Global, responsive delivery:** Follow-the-sun teams compress timelines while maintaining quality.
-  **Predictable execution:** Clear governance, structured workflows, and tested cutover methods reduce operational risk.
-  **End-to-end support:** From inventory preparation to EDC alignment, Almac aligns people, process, and platform to protect your study.

Looking ahead

Beyond the immediate success, this engagement established a reliable execution model for retrospective data reconstruction and high-accuracy clinical data migrations. Most importantly, it reinforced Almac's reputation for mobilising quickly, collaborating effectively, and upholding exceptional data integrity, so Sponsors can move forward with confidence.

At-a-Glance



Study type: Oncology, mid-study shift to randomisation



Scope: 5 sites + associated depots; IXRS® activation and full history reconstruction



Transactions: 43 screenings, 28 randomisations, ~60 follow-ups; 15 shipments; 207 kits QC'd



Inventory: 1,890 vials released; 490 vials staged for site shipments



Outcome: On-time transition, zero site disruption, audit-ready IRT aligned to EDC

About Almac IXRS®3

IXRS®3 is Almac's industry-leading Interactive Response Technology (IRT) solution designed to streamline participant randomisation and clinical trial supply management across every study phase. Highly configurable and fully customisable, IXRS®3 supports simple to complex adaptive designs with the reliability, scalability, and flexibility sponsors need to execute successful clinical trials worldwide.

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

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