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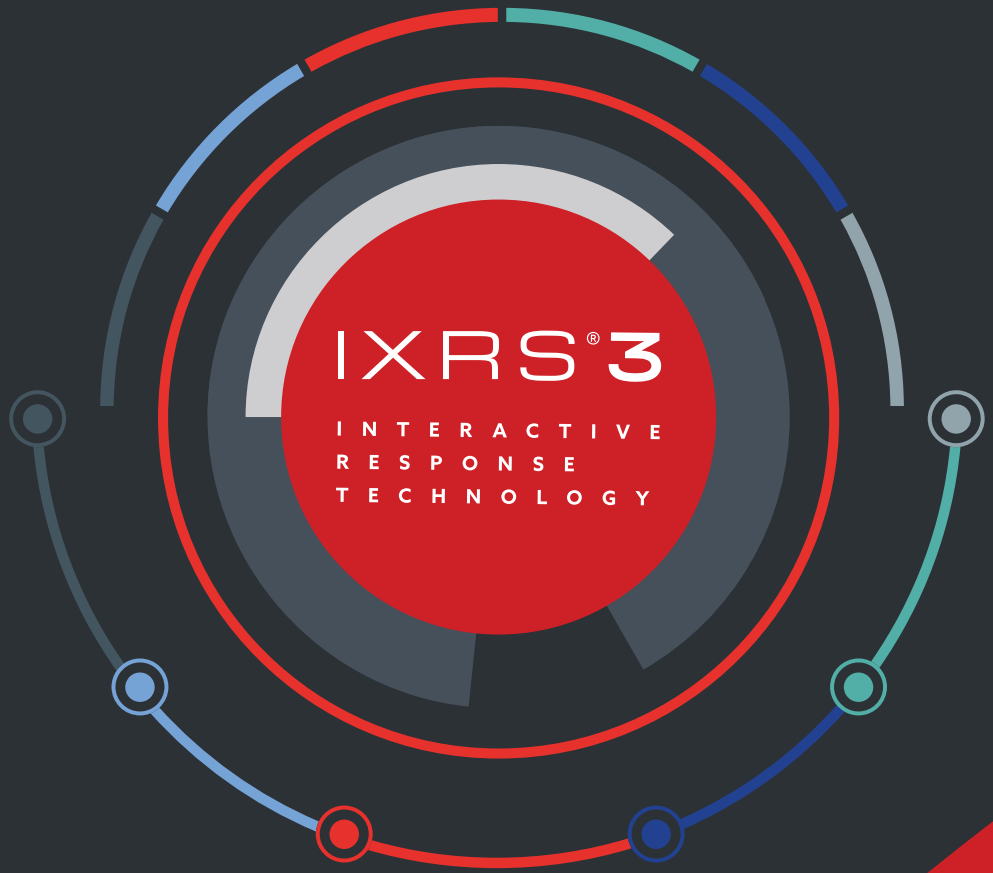
Fact Sheet

On-demand IRT boosters & services available for IXRS®3



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Beyond the IRT

Almac's suite of tools and services helps sponsors align and digitise a previously disjointed and often paper-based network of critical clinical trial functions into one central platform.

How will you manage supply accountability?

When it comes to accountability, reconciliation, returns and destruction, paper records are time consuming and error prone. Usage of multiple systems results in duplicate data entry and reconciliation challenges.

Centralize and digitize your chain of custody through IRT

How will you conduct and document IRT user training?

Training is required for all personnel involved in a clinical study. Regulatory guidelines recommend that training is documented and available for auditing and inspection purposes.

Certify users via on-demand, web-based training modules prior to system use

How will you ensure the required IRT data oversight?

Regulatory requirements mandate that IRT audit data logs be periodically reviewed, and Sponsors must promptly address any data that raises quality, security, or integrity concerns.

Let the IRT provide the necessary insights and trends

Do you require verifiable evidence for your randomization and kit assignment data?

Our Biostatistics Data Monitoring Service provides Plan Documentation and Evidence-Based Reports that follow the regulatory recommendations.

Get Biostatistics Data Monitoring from IRT-specialised Biostatisticians

How will sites save their IRT data at the end of the study?

Regulations state that any system where investigators enter data should be provided with end-of-study data at the conclusion of a clinical trial.

Enable sites to download their end-of-study IRT data with a one click solution

How do you ensure temperature data is returned for every shipment?

With Almac's TempEZ solution clinical sites upload every temperature monitor received as part of their acknowledgement in the IXRS. Alarmed monitors will cause auto-quarantine, protecting patients whilst material is under adjudication

Streamline the return of temperature data whilst protecting patients

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On-Demand Boosters & Services Available for IXRS®3

IXRS®3 boosters & services	Why we developed this solution	How it works	Why an IXRS® integrated solution is better
IXRS®3 ART ACCOUNTABILITY & RECONCILIATION TRACKING	It is a **regulatory requirement** that a **complete chain of custody** and accountability records be maintained for all investigational products. Challenges with site compliance and timely data entry across disparate systems (IRT, EDC, CTMS, Paper forms) makes the process tedious, error-prone and time-consuming.	ART™ provides users with an application, as part of the IXRS®3, to **manage the accountability, reconciliation, returns, and destruction supply management** steps. ART™ can be tailored to the necessary sequential steps for the study and provides users with a repeatable, user-friendly, process at sites and depots. It ensures all protocol-required data points are captured and helps to identify errors through system validations. Reporting and alert mechanisms are included to help ensure that these activities are on track, avoiding any end-of-study push to catch up on tasks and drug reconciliation efforts.	The **data already being collected** about the clinical supply product within IXRS®3 is used to fuel the subsequent accountability steps and provide visibility to the complete chain of custody. Accountability steps are prompted at the appropriate time for each kit within the study, enhancing compliance and accuracy of the data and **removing the burden of duplicate and manual data entry.** Incorporating ART™ results in an **end-to-end system** continuing the site's clinical supply management workflow.
IXRS®3 VERSIGHT™ TRIAL DATA INTEGRITY MONITORING SYSTEM	ICH, MHRA, and FDA **guidelines require documented evidence** of study data integrity surveillance from sponsors. While raw site, kit, and subject data is always recorded in the IRT, it's challenging to **identify potential anomalies** without exporting and manually analysing the data. We developed OVERSIGHT for IXRS®3 to ease this analysis burden.	OVERSIGHT™ is a suite of analytic reports which **automatically organises the IRT data and transaction history for ease of data integrity reviews.** It provides several layers in which to view transactions and data processing. Summary views aid in identifying irregularities such as sites or users making high-risk data edits and or unexpected system transactions. When you can see the outliers - you can investigate and take timely action.	OVERSIGHT™ automatically organizes and provides summary data on-demand **directly in the IXRS®3 platform**, minimising the amount of time that it takes to perform study data integrity reviews.
IXRS®3 UNIVERSITY IRT TRAINING & CERTIFICATION	Training is required for all individuals involved in conducting clinical trials, which includes the use of computerised systems such as IRT*. **Regulatory guidelines indicate that "training should be documented, and the records retained and available for monitoring, auditing, and inspections."** **EMA/INS/GCP/112288/2023 Good Clinical Practice Inspectors Working Group (GCP IWG)*	IXRS® University is Almac's IXRS®3 training system that delivers user training via interactive online modules. The training curriculum is configured per study based on user role and included IXRS® features. Users will be **required to complete training prior to the use of the IXRS® for the study.** Each user is **certified** upon training completion and provided a certificate via download. Study-level reports are available for sponsors to track training completion and as proof of compliance.	IXRS® University is **seamlessly integrated into the system with Single Sign On, validated (21 CFR part 11 compliant), and available at study go-live.**

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IXRS®3 BIOSTATISTICS Data Monitoring Service	Recent regulatory guidance recommends sponsors focus monitoring on areas critical to the reliability of trial results such as Randomisation, to **clearly document the Monitoring Plan** for each area, and to provide **Monitoring Activity Reports with Verifiable Evidence.** Thus, we developed a robust **Biostatistics Data Monitoring Service** that follows this guidance.	All Data Monitoring activities are erformed by Almac's Biostats Group. This includes development of a **Documented Plan** (detailing who, what, when, how) and producing **Monitoring Activity Reports with Verifiable Evidence** via SAS programming. Randomisation / Kit Assignment Monitoring is performed independently on accumulated data extracted from the IXRS®.	**Almac's Biostats Group is uniquely positioned** to perform such reviews: they are unblinded, have access to the data, and have the highest level of specialised IRT Randomisation expertise. Our **Biostatistics Data Monitoring materials** provide a well-documented plan and reports with verifiable evidence, of which can readily be included in the TMF / used to support regulatory submissions.
IXRS®3 Archival Site Data Investigator Access	Per regulatory guidelines, the Sponsors' responsibility is that: "Any system where investigators enter data should be providing this data at the conclusion of a Clinical Trial". However, **when your study is closed and archived, the investigators are no longer able to access cumulative IRT data**. Should a site be audited, it would not have sufficient cumulative IRT data to accurately recreate the full traceability and history of subject and kit data.	This tool allows **investigators and other designated personnel to download unblinded trial data for their site via data export at study closeout.** Sites will be prompted via email notification when the study has been enabled to allow end of study downloads. Sites will also receive follow up reminders if they have not performed this task. Study reports will be available to provide visibility of each site completing this step to allow monitoring and ensure site compliance.	**Providing investigators with cumulative IRT data at the end of a study is challenging.** Using the IRT directly is the best true way to ensure all the investigator owned IRT data is provided. Otherwise, you may be relying on external systems containing partial data or taking on the manual task of parsing and distributing data yourself. This IXRS®3 tool automates the process of providing the necessary comprehensive data directly to sites at the right time.
TempEZ™ Temperature Management	GDP regulations require Sponsors to maintain label storage claims during transportation. Without temperature data from all the monitors shipped, it is impossible to be sure that this has been the case. TempEZ™ was developed to give Sponsors a cloud-based solution to centralise and streamline the management of temperature data.	When a clinical site receives a shipment, they use the IXRS®3 platform to acknowledge it. Integrated with TempEZ™, the IRT system prompts the site to upload temperature data from the monitor received with the shipment. If TempEZ™ indicates an alarmed monitor status, the IXRS®3 system automatically quarantines associated supplies, ensuring drug cannot be assigned to a patient whilst under adjudication.	The site already has to acknowledge the shipment in the IXRS®3 system, so asking the site to upload the temperature data as part of this streamlines the return of this information and reduces the burden on the site. The auto-quarantine functionality ensures that there is no element of human risk at play; sites could easily select an incorrect monitor status when performing a manual process. Ultimately, Sponsors can **be sure there is no risk to patient safety as the drug remains in quarantine** until the temperature excursion has been adjudicated and IXRS®3 status updated.

IXRS®3 IRT Platform

Available in multiple modalities, our market-leading solution for patient randomisation and trial supply management is the most configurable and customisable Interactive Response Technology available.

From Phase I through to IV, simple designs to complex adaptive trials, IXRS®3 will easily accommodate any permutation of study objectives, and with it comes a team of professional biostatisticians, language and integration experts who are at the ready 24/7.

IXRS® Boosters are innovative on-demand features we developed in response to regulatory guidelines changes and Sponsors' needs. Adding them to your IRT platform boosts its ability to centrally support critical processes required to run a successful clinical study.

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