ALMAC

Partnering to Advance Human Health

Fact Sheet

IXRS®3

Archival Site Data

Investigator Access

Provide investigators easy access to download their site's end of study data.

The Archival Site Data IXRS® feature allows investigators on demand, web-based, access to download their site's IRT data at study closeout, prior to the IRT system being taken offline.

Almac's Archival Site Data solution provides investigators and any other designated personnel with the unblinded subject and kit audit trail data, thus allowing them to have full traceability and visibility for all data at their site. This ensures full regulatory compliance for investigators to have a copy of all site data, for archival purposes.

Do I need Archival Site Data Investigator Access?

Regulatory processes and guidelines stress the investigator is responsible and should maintain control of data entered into the IRT

The archival site data feature within the IXRS® provides the site with cumulative IRT data which accurately provides full traceability and history of their site's subject and clinical supply data.

This embedded IRT solution provides a mechanism for investigators to obtain access to the unblinded cumulative IRT data for trial archival, for which they are responsible for. This solution eliminates the need to be reliant upon other manual processes, like filtering and downloading multiple data report exports or relying on external systems which may have incomplete data.

This solution was designed based on feedback from our users, providing a one button download of the necessary site data, which maintains control around the timely release of access to the unblinded data. This was also developed to meet regulatory guidelines stating that *"any system where investigators enter data should be providing this data at the conclusion of a Clinical Trial".*

Now, you can enable investigators and other personnel to download unblinded trial data exports for a limited time during study closeout and receive prompt reminders to do so.

Solution overview

Providing sites with the necessary IRT data at the end of the study becomes easy with a one click solution

1. At the appropriate time, the IXRS® setting is turned on, allowing investigator access to download the unblinded dataset for end of study archival. Other user types can be granted access as well.
2. Sites receive email alert notification that the data is available for download.
3. Sites log on to IXRS® and are able to download the unblinded data export containing all of their site's data for archival.
4. Sites will receive weekly reminder alerts until the download has been completed.
5. Study managers can view progress of site download compliance activity.

Benefits of enabling Archival Site Data in your IXRS®3

Compliance and audit-readiness
Your trial data is maintained per regulatory guidelines.

One-click enablement
Once the time is right, effortlessly launch access for each site.

Safety and control
See which sites have completed the data export.

Peace of mind
Prepare for smooth study closeout from the start.

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