ALMAC

Partnering to Advance Human Health

Fact Sheet

ACCOUNTABILITY & RECONCILIATION TRACKING

Discover the substantial benefits and cost savings of an automated process

What is ART™ Accountability and Reconciliation Tracking?

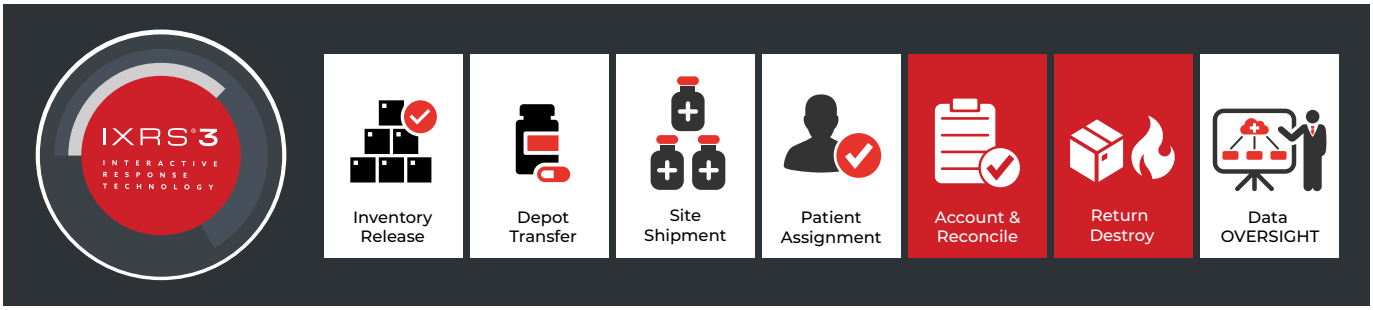
ART™ (Accountability & Reconciliation Tracking) is a component of Almac's IXRS®3 suite providing a digital chain of custody solution for supply accountability and reconciliation that includes the level of data integrity and traceability required by regulatory authorities.

ART™ combats common challenges of reconstructing a complete account of the chain of custody, which is often tedious, error-prone, costly and time consuming. ART addresses these factors and streamlines the process to improve site compliance and incomplete or inaccurate record - keeping across otherwise disparate clinical systems like IRT, EDC and paper forms.

ART™ utilises error-prevention workflows that eliminate data consolidation bottlenecks, and provides total control over and visibility into all supply chain events – transforming your chain of custody into a work of art.

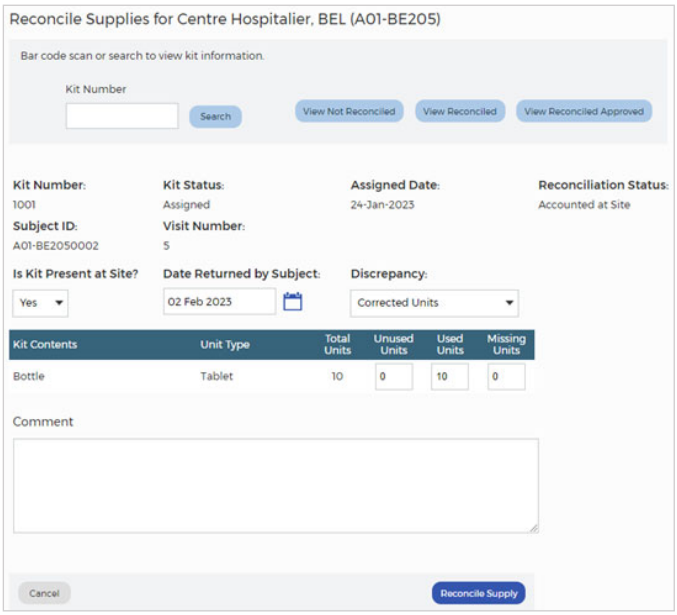
Why do I need Supply Accountability as part of my IXRS®3?

Incorporating ART™ results in an end-to-end system continuing the site's clinical supply management workflow. The data already being collected about the clinical supply product within IXRS®3 can be used to fuel the subsequent accountability steps and provide visibility to the complete chain of custody.



The IXRS®3 tracks drug activity from the point of release through patient dispensing, including details on each individual unit by location, lot and patient. Using this existing IXRS®3 data to inform the accountability, reconciliation, returns and destruction steps streamlines the process, reducing overall efforts. 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.

How ART™ supports the flexibility needed for sponsors' protocols



ART™ is a completely configurable solution to record accountability, reconciliation, returns and destruction of clinical supply that conforms to any protocol – giving you complete control over sites' compliance with GCP and GMP.

ART™ is tailored to the necessary steps and sequence of events for your clinical trial resulting in repeatable processes at sites and depots and compliance enhancement. 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 oversee that the trial is on track, avoiding any end of study push to catch up on tasks and data reconciliation efforts.

ART™ Feature Workflow

Account supplies: IXRS®3 keeps a record of all supplies shipped to a site and prompts accounting of those supplies at the appropriate time (returned by subject, expired, damaged, site close out) Configurations dictate the data collected for the study. Validation checks exist to ensure a high level of accuracy.

Reconcile supplies: This optional step allows a secondary user, like a monitor, to review the accountability data entered. If anomalies are identified, the site will receive a re-accounting request. Upon successful reconciliation, supply moves to the next step for logging a return or destruction.

Return supplies: Sites returning supplies to a destruction facility will record and manage the return shipments within ART™. A running return list will be kept in the system until it is indicated a physical shipment is returned. The site is provided the appropriate return facility and allows capture of tracking information.

Supply destruction: Destruction can be registered at a site or depot level dictated by configured study workflow. Sites will select one or more of the kits that are being destroyed and log the activity date of occurrence. Depots will indicate one or more return shipments to record the destruction activity and log the date of occurrence.

ART™ Benefits

GCP and GMP Compliance:

Ensures all supplies are accounted for throughout the trial lifecycle.
Serves as an extra step in ensuring that the protocol is followed and supplies were administered to patients as intended.

Meets requirements of the latest European Clinical Trial Regulation

Satisfies the requirements for an established procedure for the return and destruction of investigation material.

Increases Site Compliance

By fully integrating this solution within the IXRS® workflow already being used by sites, ART™ minimises the time and effort required by sites for accountability and returns. - No entering data twice, source data already prepopulated.

Produces correct and complete records

Intuitive workflows and validation steps prevent users from omitting steps or committing incorrect data.

Makes monitoring easy

With a consolidated view of clinical and supply information, CRAs can plan their work up front and identify problems that need to be addressed.

Speed study close out

Discrepancies are reduced by systematic data validation which greatly reduces reconciliation tasks.

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