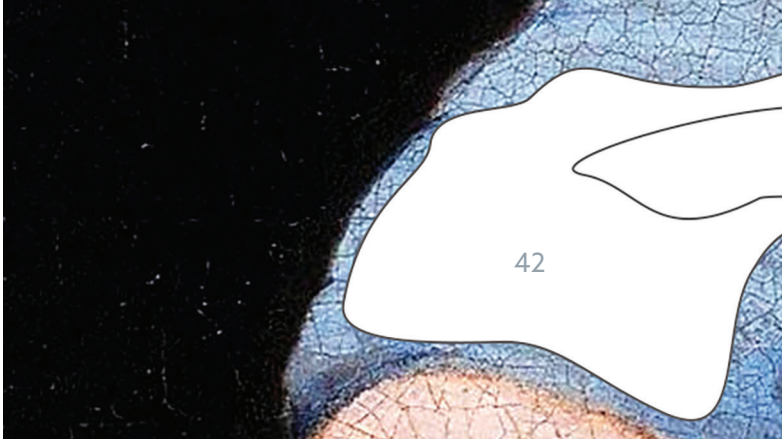
ALMAC

Partnering to Advance Human Health

ART™ - Accountability & Reconciliation Tracking
Fact sheet for Clinical Operations

ART™ by Almac.

"Tracking by the numbers."



When a work process is viewed as a "necessary evil," it's time to innovate. Time to automate. Time to streamline. For the industry's accountability and reconciliation procedures, that time has come.

Almac Clinical Technologies' Accountability & Reconciliation Tracking (ART™) functionality within IXRS® 3, Almac's Interactive Response Technology (IRT), does away with the paper records, transcription errors, and multiple systems that lead to missing data and errors. With ART™, you reduce risk to patients, speed trial close-out, and prevent the kinds of issues that lead to warning letters from regulators.

A flexible, configurable system to support Good Clinical Practices

ART™ is a completely configurable solution for accountability and reconciliation that conforms to any protocol - giving you complete control over sites' compliance with Good Clinical Practice (GCP). Real-time error prevention and traceability of clinical supplies means that at study closeout, reconciliation is a mere formality. Say goodbye to lengthy delays in sorting through discrepancies, correcting errors, and chasing missing information.

Intuitive workflows within IXRS® 3 give users access to comprehensive features designed to improve compliance, minimize errors, ease frustrations, and save time and money. ART™ gives you:

Flexibility to support any workflow and Standard Operating Procedures (SOPs)

ART™ is fully configurable, to account for the great variations among protocols and supply designs. From kit or unit level accountability, one or two-step reconciliation, site level destruction capabilities, or depot returns, this tool can be configured quickly to accommodate a variety of workflows and variations for accountability, reconciliation, returns and destruction, without adding to the trial's startup time.

Accountability and returns management can be configured and changed throughout the course of a study to account for changing or unforeseen needs.

System is designed to support compliance throughout the accountability process

IXRS® 3 being an IRT system, is the source for supply assignment to patient. As such is the natural system to assess protocol compliance and catch dispensing errors.

IXRS® 3 is highly configurable. Mandatory fields can be determined, so that site users are unable to successfully complete transactions until they've complied with all data entries required for accountability, preventing the loss of critical information. Business logic can prevent capturing of invalid information, helping to ensure accurate entries. Complete information is captured correctly, the first time, significantly reducing accountability discrepancies that stem from paper-based processes and transcription errors. The built-in 'smart-logic' greatly reduces the overall volume of site queries from CRAs and depots.

Streamline the reconciliation process

IXRS® 3 enables the adoption of a risk-based approach to monitoring, providing a drastic reduction in billable hours of costly resources. Site monitors can receive alerts when accountability discrepancies appear (for example, if investigational product return counts are not in accordance with drug assignments). Monitors can then immediately access site records and comprehensive reports to remotely assess discrepancies, perform root cause analysis, prioritize and plan site visits, and prepare timely remediation plans, if necessary.

Traceability throughout the supply chain

At every point in a kit's journey through a trial, the kits history and its details can be accessed. This is especially important in ensuring compliance with assigned supplies and proper documentation and tracking of all conditions and custody points for each kit. Root-cause analysis efforts are streamlined via real-time access of kit history information and status reports of the entire chain of custody of supplies are available real-time at the, kit, site, depot and study levels, to facilitate continuous monitoring and auditing.

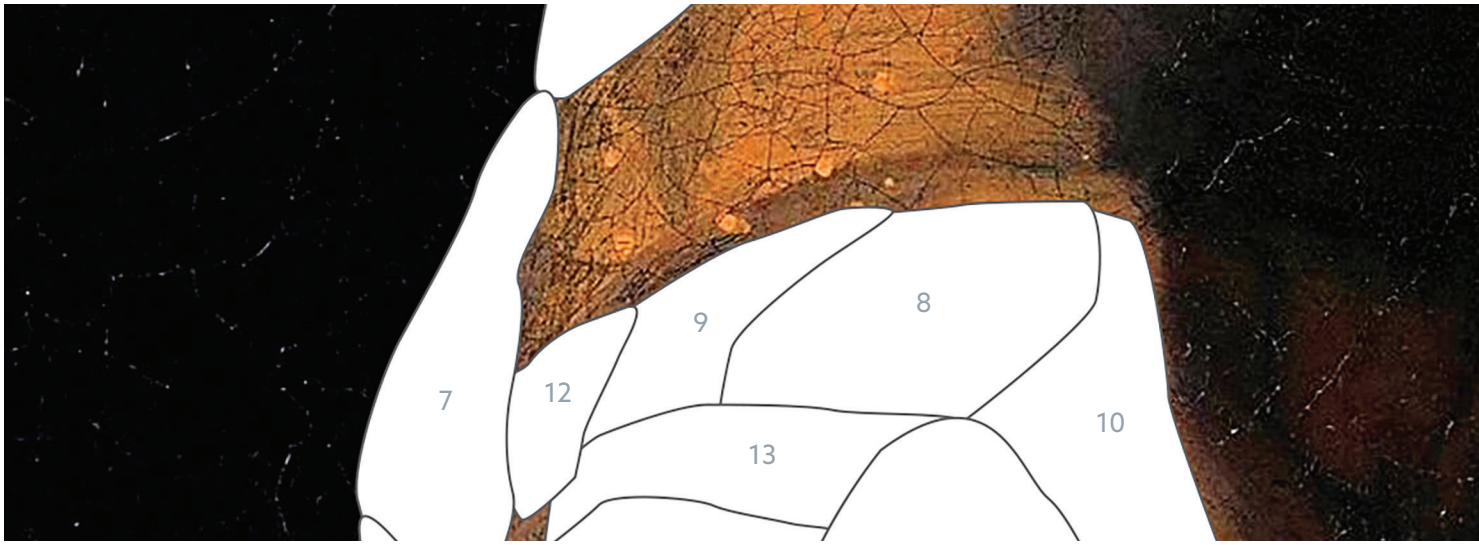
Adding the ART™ functionality to your IXRS® 3:

- **Protects patient safety.** Real-time validation checks throughout all medication-related events and visibility to the condition of drugs throughout the supply chain reduce the opportunity for patients to be given the wrong or unsafe medication. Should there be a safety issue, you can quickly perform a root-cause analysis through a comprehensive "Kit History and Custody Report."
- **Reinforces compliance.** Because the software captures both the drug assignment (within the core IXRS® 3 functionality) and details on the investigational product that is administered to the patient and subsequently returned, it serves as an extra step to ensure that what was dispensed to, and consumed by, the patient followed the protocol. Non-compliance is reduced and highlighted.
- **Minimizes risk.** Capturing accountability and reconciliation information in the IRT, eliminates transcription errors, and the challenges and inaccuracies that stem from paper processes. Compliance is improved and risks to the trial are greatly reduced.
- **Improves completeness and accuracy of accountability data.** The system guides site users through the process of documenting returned investigational product (used, unused, missing, and damaged). Users are "forced" to complete all of the required fields, and logic checks prevent data entry errors.
- **Speeds study close-out.** When used as the primary method for accountability data capture and reconciliation, IXRS® 3 prohibits users from entering erroneous data which prevents discrepancies from occurring and greatly reduces time spent on drug reconciliation during the closeout phase.
- **Streamlines operations/reduces costs.** The tedious and time-consuming steps in reconciling discrepancies that appear in paper records, or records kept in multiple systems are all but eliminated. Site monitors can use their time more productively, focusing their attention on potential problem sites/procedures. The time spent at sites, therefore, can be reduced dramatically.

A power tool for Clinical Operations!

Users—whether at sites, depots, Contract Research Organizations (CROs), or sponsors—will be able to use the toolkit for their accountability and reconciliation processes using a series of intuitive workflows and real time reports. The configurations and navigation is uncluttered and straightforward, access is determined and strictly enforced by predetermined access privileges and expectations of users within each function are clear. The simplicity and user-friendliness of the tool enhances the likelihood that site staff, in particular, will comply with all protocol entry requirements, avoiding the downstream hassles of incomplete, incorrect, or inconsistent data that put a trial at risk.

ART™ is not just a tool for supply management and monitoring. It is vital for sites to achieve compliance, essential for CRAs to streamline their operations, and key for Clinical Operations to monitor, audit and produce records.



Get the control you need of your accountability and returns management process through a fully configurable, streamlined, and error minimizing platform.

Get the conversation started today by emailing us at:
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