



ART™ - Accountability & Reconciliation Tracking
Fact sheet for Contract Research Organizations (CRO)

ART™ by Almac.
"Tracking by the numbers."





Tired of paying the price when sites don't have an easy way to comply with accountability procedures? The time that your monitors spend reconciling incomplete, inaccurate and inconsistent records of returned supplies could—and should—be better spent.

With Almac Clinical Technologies' Accountability & Reconciliation Tracking (ART™) found within Almac's Interactive Response Technology (IRT) known as IXRS® 3, your monitors can be more productive, preserving your margins. And, you can speed study close out, making you a hero with trial sponsors.

Improve project profitability by staying on top of reconciliation

The traditional tools that sites have relied on to account for drug returns still fall short in delivering a comprehensive solution that suits all protocol needs, align with site and sponsor procedures, and are intuitive so that users can reliably enter all required data.

Those shortcomings force some sponsors and CROs to still rely on paper records either completely or as a supplement to electronic record keeping that still doesn't go beyond being a data entry system.

The use of disparate systems result in effort duplication, missing data, and errors and discrepancies that all need to be discovered, explained, and resolved during the reconciliation and closeout phases.

Now, Almac makes it easy for sites to record complete, accurate information, and for your monitors to ensure compliance with Good Manufacturing Practices (GMP). This extended functionality of IXRS® 3 provides:

Standardization using one IRT vendor

CROs don't need to use different IRT systems for different trials anymore, or maintain different SOPs for each of the vendors used. ART™ is fully configurable to account for the great variations among protocols and supply packaging designs.

From kit- or unit-level accountability, one- or two-step reconciliation, site-level destruction capabilities, or depot returns, this tool can be set up quickly to accommodate a variety of workflows and variations for accountability, reconciliation, and 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 reflect changing or unforeseen needs. Training of Clinical Research Associates (CRA) and site staff is streamlined with the use of one comprehensive toolkit.

Improve your margins!

IXRS® 3 optimizes monitors' use of time by enabling a risk-based approach and by facilitating site compliance.

IXRS® 3 enables the adoption of a risk-based approach to monitoring, and, therefore, drastically reducing billable hours of costly resources.

Site monitors can receive alerts when accountability discrepancies appear (for example, if investigational product return counts do not sync with drug assignments). Monitors can then immediately access site records and comprehensive reports to remotely assess discrepancies, perform root cause analysis, prioritize and plan their site visits, and prepare timely remediation plans, if necessary.

IXRS® 3 guides site users through an intuitive workflow that allows them to catch errors and self-correct. The built-in 'smart-logic' greatly reduces the overall volume of site queries for CRAs and depots, thus reducing monitors' time on resolving discrepancies throughout the trial and mostly at closeout.

IXRS® 3, in effect, optimizes monitors' use of time and preserves or improves the CRO margins.

Real-time access, continuous visibility and trial monitoring

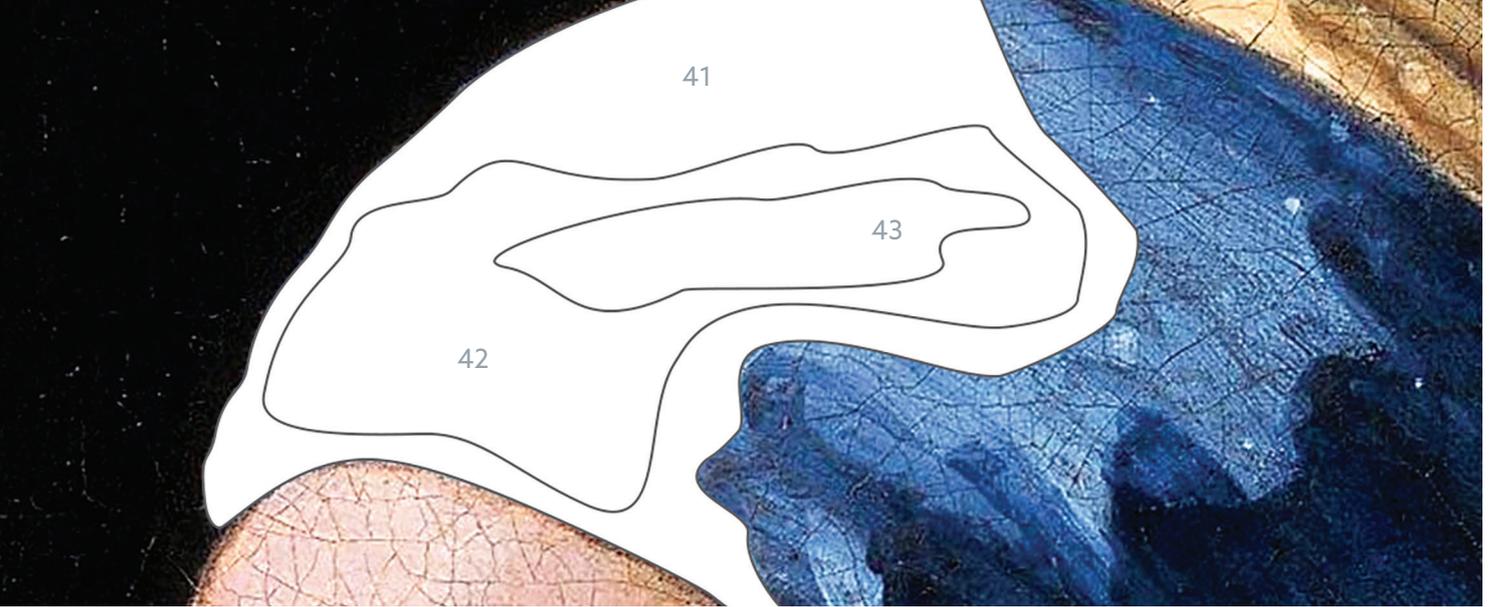
The ART™ toolkit provides continuous data along the entire supply chain including patient supply events. This way the clinical and supply operations that operate in silos are able to exchange data thus gain the ability for early on intervention and prevention of costly errors.

Having data under one unified platform enables users to have real time access and visibility along the entire chain of custody and history of supply and patient events.

Chain of custody status reports at the site, country, and trial levels are available on demand to give you real-time visibility on trial progression at any location or globally.

When you deploy Almac Clinical Technologies ART™ to sites, the benefits are immediately apparent to your monitors and directly impact the efficiency of your operations. The toolkit provides:

- **Streamlines trial operations activities.**
Your staff can define Standard Operating Procedures (SOPs) for accountability and reconciliation tasks across studies; they don't have to change processes and documentation for different study designs. The tedious and time-consuming steps in reconciling discrepancies that appear in paper records or records kept in multiple systems, are all but eliminated.
- **Reduces the number of discrepancies.**
Site users are "forced" to complete all of the required fields, and logic checks prevent basic data entry errors and can be more compliant due to cross-referenced patient and supply records. Monitors have far fewer discrepancies to reconcile and can remotely prioritize their site visits based on system-generated discrepancy alerts they receive.
- **Speeds study close-out.**
Configurable alerting conditions notify monitors early on about events that can potentially cause compliance issues, errors, and discrepancies, rather than letting them pile up to be addressed at site visits or until the end of the study. By the time the study closes, reconciliation should be just a formality that adds no additional time and significantly reduces trial costs.



A power tool for CROs!

Users—whether at sites, depots, 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 defined 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. IXRS® 3's ART™ reduces inefficiencies in the accountability and reconciliation process—inefficiencies that eat into your margins.

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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