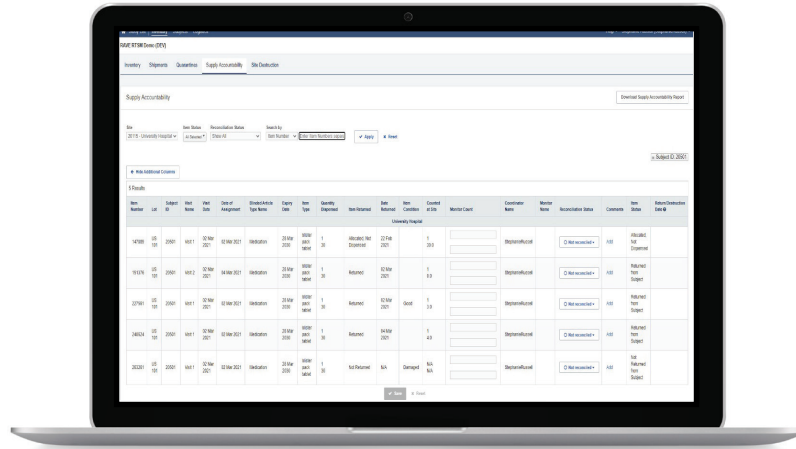# Take the Right Approach to Supply Accountability



Supply Accountability is the tracking and management of supply distribution, return and reconciliation/destruction in clinical trials. The FDA lists Supply Accountability compliance as one of the top 5 issues encountered during drug sponsor audits. Improper Supply Accountability can cause painful regulatory audit findings, study complications and delays in study closeout.

The unified Medidata Clinical Cloud™ is an ideal platform for Drug/Supply Accountability as it already tracks the product by its location as well as by lot/ label/ID and subject allocation and dosing. Medidata's Rave EDC + Rave RTSM unified process is pre-validated, highly flexible and can be significantly streamlined ensuring efficiency, timeliness and accurate data by eliminating the need for separate logs (sometimes done on paper), on multiple systems.
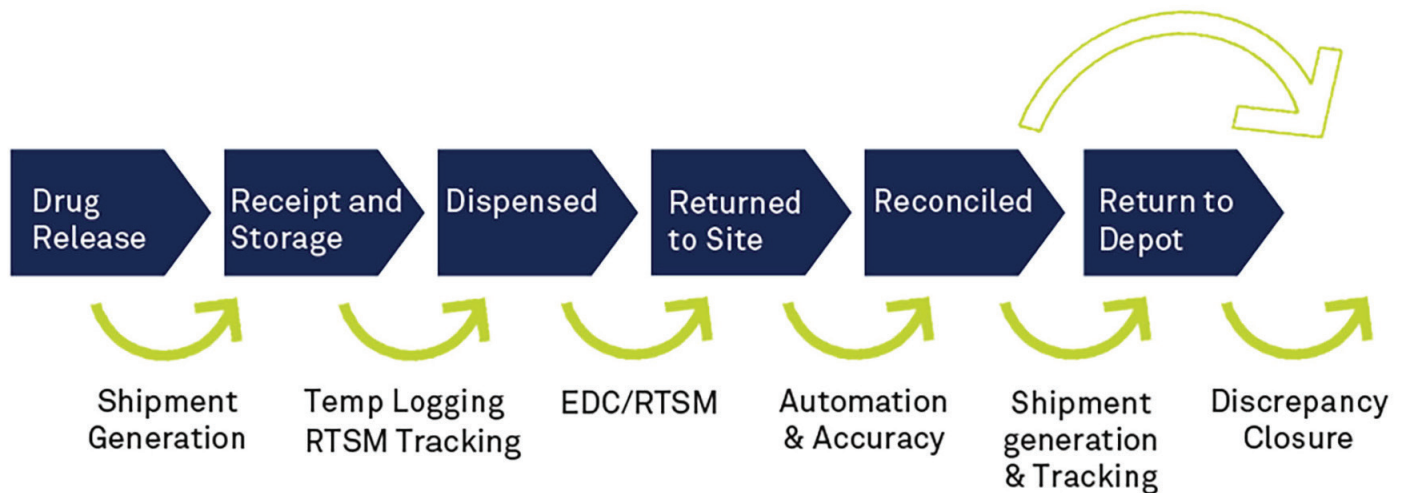
## Unified eSupply Accountability (eSA)

Using a unified Supply Accountability technology benefits the site, subject and site monitor, as seen below. Ultimately, this process results in a reduction in the cost and time spent on reconciliation.

| Site Options | Subject level Accountability | Site Monitor Reconciliation |
|---|---|---|
| Ability to identify sites as points of destruction | Information automatically populated on accountability form | Information automatically populated |
| Option to enable or disable a site for eSA | Site users stay in the same application | Monitors can reconcile items of all statuses on a single page |
| SIte Users alerted of discrepancies in real-time | Column titles configurable | Comments shared across the platform |
| Ability to create a return/ destruction shipment or select to destroy at site | Configurable Column displayed optional | SIte Users updates to the patient log update the reconciliation page |
|  |  | Ability to create a return/ destruction shipment or select to destroy at site |
| Eliminates major pain point different settings for different sites | Efficiency gains and better data quality | Reconcile items of all statuses in one location, using the same flow |

# Supply Accountability with Rave EDC and RTSM

Medidata's approach automates much of the data aggregation and uses Rave EDC to simplify how sites enter data regarding returns and reconciliation. Monitors then log into the platform to create return shipments and to close out the process at the site. Sites have the option to "destroy at site" if local processes allow for this. The figure below describes the supply accountability process using Rave EDC and RTSM.



| Drug Release | Receipt and Storage | Dispensed | Returned to Site | Reconciled | Return to Depot |
|---|---|---|---|---|---|
| Shipment Generation | Temp Logging RTSM Tracking | EDC/RTSM | Automation & Accuracy | Shipment generation & Tracking | Discrepancy Closure |

# The Medidata Advantage

Only the Medidata Clinical Cloud has a fully unified electronic supply accountability (eSA) experience. eSA is pre-validated, truly plug and play and provides quick and simple training for sites and monitors. All of the IP data is in one system to be reported on for study closeout requirements.

No vendor can match the Medidata advantage with the vital requirements and regulations of supply accountability:

- Out of the box eSA leads to reduced implementation/UAT timelines
- Data entered into EDC 25% faster
- Complete view of inventory in one system
- Ability to create return shipments or destroy on site
- Time savings for database lock/analysis