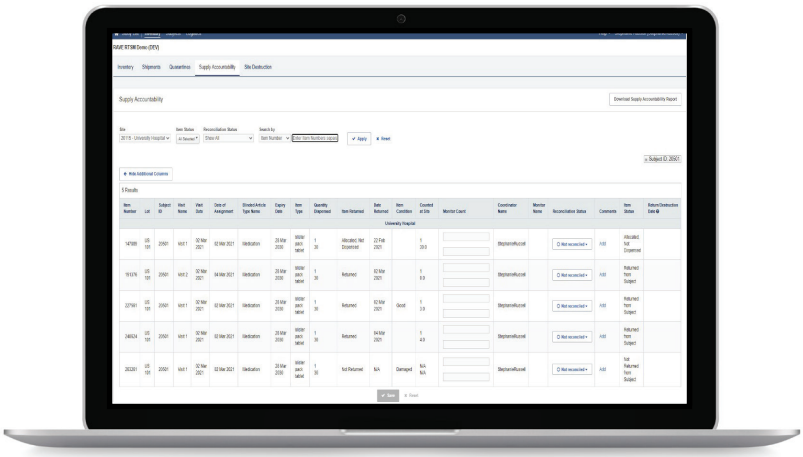
Take the Right Approach to Supply Accountability



Supply Accountability is the tracking and management of supply distribution, return and reconciliation/destruction in clinical trials. It covers the entire life-cycle of the investigative product (IP). 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 Rave 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 solutions 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)

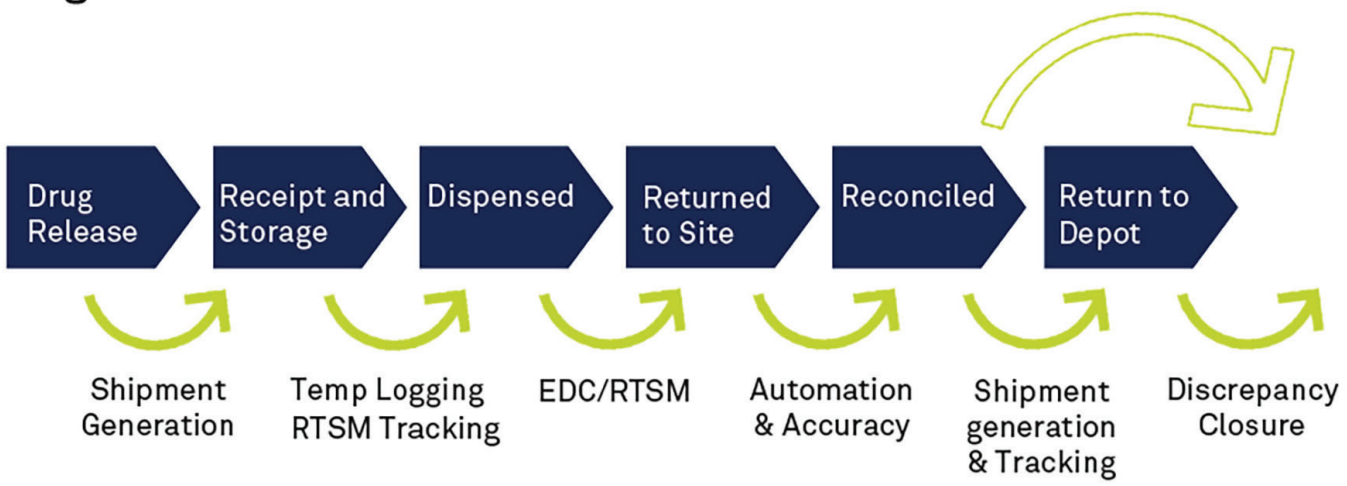
Using a unified Supply Accountability technology delivers benefits at the site, subject and site monitor levels as seen below. Ultimately, this process results in a reduction in the cost and time spent on reconciliation.

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 platform
Ability to create a return/ destruction shipment or select to destroy at site	Column displayed optional	Site Users updates to patient log will update 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 the Rave EDC interface to simplify how sites enter data regarding returns and reconciliation. Monitors then log into the platform to create return shipments and close out the process at the site. Sites have the option to "destroy at site" if local processes allow for this. Figure 2 below describes the supply accountability process using Rave EDC and RTSM.

Figure 2



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 standard functionality which provides quick and simple training for sites and Monitors. IP data automatically populates the accountability form after patient dispensation and the site users enter return IP data directly in Rave EDC.

Monitors record their reconciliation and can send direct messages to sites for discrepancies with the workflow within this unified process. Sites users or monitors can continue the accountability process by selecting to generate a return shipment to a depot or to destroy on site. All of the IP data in one system, all about to be reported on for study closeout requirements.

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

- Out of the box eSA > 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