Take the Right Approach to Drug Accountability

Drug Accountability is the uniform tracking and management of drug distribution, storage, use and reconciliation/destruction in clinical trials. It covers the entire life-cycle of the investigative product (IP). Drug Accountability is a regulated and critical activity needed to ensure clinical trial data integrity. The FDA lists Drug Accountability compliance as one of the top 5 issues encountered during drug sponsor audits. Improper Drug Accountability can cause painful regulatory audit findings and study complications. Therefore, it is important to think about the people, processes and technology in planning for Drug Accountability.

The unified Medidata Rave Clinical Cloud is an ideal platform for Drug/Supply Accountability as it already tracks the drug 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 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. Using a unified Supply Accountability technology delivers benefits at the site, subject and site monitor levels as seen in **Figure 1** below. Ultimately, this process results in a reduction in the cost and time spent on reconciliation.

Figure 1

Unified eSupply Accountability (eSA)

Site Options

- Ability to opt sites out of eSA flow
- Option to identify sites as points of destruction

Eliminates major pain point... different settings for different sites

Subject Level Accountability

- Information automatically populated on accountability form
- Site Users stay in the same application
- Column titles configurable
- Column displayed optional

Efficiency gains and better data quality

Site Monitor Reconciliation

- Information automatically populated
- Monitors can reconcile items of all statuses on a single page
- Comments shared across platform
- Site Users alerted of discrepancies in real time
- Site Users updates to patient log will update reconciliation page

Reconcile items of all statuses in one location, using the same flow

Proper Drug Accountability requires:

- Targeted efficient process
- Clear assignment of responsibilities
- Technology to track and manage the IP lifecycle
- Process execution and ability to report on it to auditors

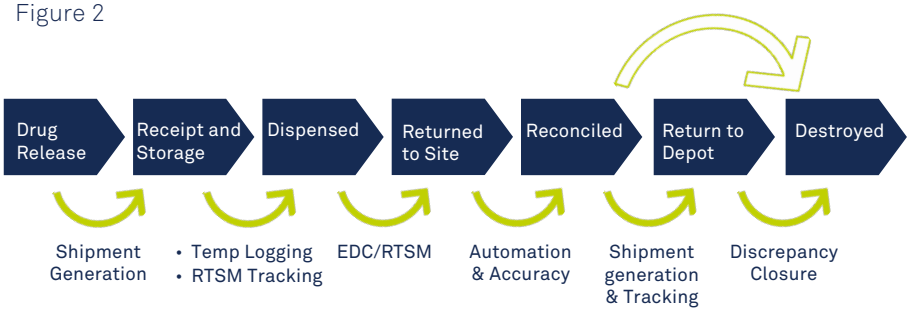
Platform of Choice for Clinical Research

The Medidata Rave Clinical Cloud is the cutting-edge platform that transforms the clinical trial experience for patients, sponsors, CROs, and research sites. Designed with a unified data platform, the Rave Clinical Cloud creates a single source of truth for all study-related data. Simply put, enter data once and let the platform master and populate it throughout the end-to-end suite of Rave applications. Optimize operational execution, decrease the data entry and maintenance burden, and reduce the number of clinical systems across your study teams. Throw away your list of passwords and excel sheets, you are now on a truly unified platform.

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.

Supply Accountability with Rave EDC and RTSM

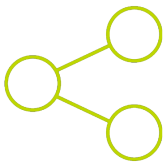
Figure 2



In Conclusion

Rave RTSM with eSA is built on the Mediadta Rave Clinical Cloud's unified platform, which enables a single source of truth for all study-related data across your entire portfolio. This ensures that supply accountability data collected in Rave EDC can be easily compared to data collected in RTSM. This can be accomplished because once data is entered, the platform masters and populates it throughout the end-to-end suite of Rave applications. The right mix of processes, people and technology will help ensure a successful outcome in Drug Accountability.

Consider processes, people, and technology



The right mix ensures a better chance of success

A workable solution is achievable

A suite of unified platform solutions married with flexible processes

Drug Accountability done right avoids study complications

Prevents painful regulatory audit findings

About Medidata

Medidata is leading the digital transformation of life sciences, creating hope for millions of patients. Medidata helps generate the evidence and insights to help pharmaceutical, biotech, medical device and diagnostics companies, and academic researchers accelerate value, minimize risk, and optimize outcomes. More than one million registered users across 1,400 customers and partners access the world's most-used platform for clinical development, commercial, and real-world data.

Medidata, a Dassault Systèmes company (Euronext Paris: #13065, DSY.PA), is headquartered in New York City and has offices around the world to meet the needs of its customers.

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