WHITE PAPER

Electronic Drug Accountability through IRT Systems

Study drug accountability is crucial for monitoring patient compliance and ensuring study data integrity. Accountability should be demonstrated by full traceability of IMP (investigational medicinal product) from initial release, ordering, allocation, and dispensation through return-to-site, accountability, reconciliation, and eventual destruction.

The traditional, paper-based methods increase the risk for human error, as well as illicit activity in clinical trials. Failure of an FDA site audit due to insufficient or inaccurate paper-based drug accountability records is common. A failed federal audit leads to costly trial delays to the sponsor, and may result in non-approval of the investigational drug, or criminal liability for the investigator. Electronic drug accountability managed through an IRT system is a cost-effective way to ensure compliance with federal regulations, reduce inefficiencies, preserve the integrity of data and increase patient safety in clinical trials.

mIRT applications , allows a real-time drug accountability and compliance, any time the study drug is dispensed to patient, by through the combination of data from the returned medication with the date of dispensation of new medication, the system will immediately calculate the patient's compliance rate to the experimental drug.

Real time accountability and compliance data will provide transparency through the entire chain of IMP supply and management and will complement the interpretation of study drug efficacy and safety.

Challenges of paper based drug accountability management

Paper-based drug accountability systems are inherently complex, making them rife with the potential for error and obfuscation. The process begins upon receipt of the investigational drug at the site. Site staff must verify that shipment records match the contents of the shipping container. Once verified, authorized personnel must sign, date, and file the shipping record in a regulatory binder. Authorized personnel then store the investigational drug in a secure area according to the requirements of the protocol. A staff member must enter the shipment information into the drug

accountability log. If IRT is employed in the trial, site staff must place the call to confirm the receipt of the drug shipment, and then return the proof-of-receipt to the sponsor. If a paper-based system is used, site staff must send paper documentation of proof of receipt to the sponsor. When the trial commences, detailed drug dispensing records must be written and updated across multiple documents in a timely manner.

The drug accountability paperwork does not end at study termination. When the trial is complete, the accountability logs must be updated, and discrepancies reconciled. Copies of the accountability logs need to be made and returned along with the original drug shipment record; copies are filed on site, as well. The reconciled log must be included in the shipping container with the returned investigational drug and shipped back to the sponsor. It is easy to understand how one moment of inattention by a staff member can result in an audit failure.

Reconciliation data in the IRT system

A good clinical trial supply chain management system includes tracking for not just allocation and dosing, but also management of returns, reconciliation and destruction. The return and destruction process should be defined in the beginning of the study with the integration of technical solutions. Best practice takes advantage of interactive response systems to manage the supply chain, reduce storage and dosing errors, manage multiple expiry dates, and account for final reconciliation, recycling and destruction. This phase should also include the elements that involve study closure and data transfer. A good system that provides dispensing and inventory logs should also provide query resolution functionality and full audit trailing ensuring the integrity and transparency of drug accountability data. When the trial is completed, returns depot personnel should be able to provide the link to destruction certification, meaning that the site, monitor, depot and destruction facility information is completely integrated into comprehensive drug accountability requirements.

mIRT system provides advanced management of returns, reconciliation and destruction

Regulatory Compliance

As regulators increase scrutiny to ensure patient safety, many issues arise involving the transport, storage and distribution of medical products. Sponsors and clinical supply companies need to ensure that the product remains safe and accountable during transportation and storage, while evaluating product handling requirements, transportation lanes to be used, container availability and cost.

As per ICH-GCP sponsor is responsible to deliver of investigational product(s) to the investigator(s) on time. Maintain records that document shipment, receipt, disposition, return, and destruction of the investigational product(s). Sponsor has to maintain a system for retrieving investigational products and documenting this retrieval (e.g. for deficient product recall, reclaim after trial completion, expired product reclaim). Sponsor has to maintain a system for the disposition of unused investigational product(s) and for the documentation of this disposition.

Solutions to drug accountability management through electronic system (iRT)

A technological solution to the problems central to paper-based drug accountability already exists. Interactive response technology (IRT) systems are used in many clinical trials for a myriad of tasks, from patient randomization to drug supply management and allocation. IRT is ideal for drug accountability because it tracks drug dispensing units by depot, and site location, and by batch, bulk lot, packaging step, and patient allocation. All trials can benefit from using IRT for drug accountability management. However, some types of trials may realize greater benefit than others.

IRT is an ideal system for management of drug accountability because it was designed with safeguards that reduce the risk of human error. It automatically time-stamps dispensing information, automatically flags entries that do not adhere to protocol, enforces compliance by mandating that staff write summary statements for potential protocol deviations, and creates an audit trail with electronic signatures that helps preserve the integrity of the trial data. IRT also allows for remote, site-level monitoring of drug accountability logs. Finally, to meet the unique needs of every trial, some vendors offer a fully customizable IRT.

These inbuilt features give electronic drug accountability many advantages over the manual, paper-based process. The safeguards involved with electronic drug accountability management make it a more accurate and efficient method than its paper-based counterpart. For instance, IRT links records, eliminating time-consuming collating of files at the end of the trial.

This timesaving feature is also cost-effective, because it reduces the necessity for costly site visits by the clinical trial monitor. On-site monitoring can account for up to 30 to 40% of the overall cost of a Phase III trial. IRT centralizes information, reporting it in a uniform format that is available for review at any time.

This is a vitally important feature for trials investigating drugs with the potential for abuse. For such trials, the FDA mandates that sponsors provide all information, including case report forms and final outcomes, on all instances of drug diversion, discrepancies in inventory of the clinical supplies of the study drug, and noncompliance and protocol violations.

The availability of centralized trial information afforded by an IRT system is invaluable for this and other tasks, including reconciling inventories of investigational drug supplies at study termination. A centralized accountability system allows sponsors to easily track trial drugs from manufacture to shipping, and use, return, or destruction. IRT also provides site-level, real-time tracking of investigational drug supplies. This reduces the possibility of drug diversion or inappropriate drug assignment by clinical staff, as well as patient noncompliance.

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