RFID: The Cure for the Clinical Trial Blues

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Introduction

It seems like we've been moving to a paperless society for years. Going paperless has been touted for the last 20 years, since email became a major form of communication.

Yet, paper chains are alive and well in many industries. But as we move rapidly into a highly digitalized world, signs of a long-predicted paperless society re-birth are becoming evident.

Newspapers seem to be a dying breed, with more and more people opting to receive their news online. As e-readers like the Nook and Kindle become more popular, the future of printed books is in question.

And with the maturation of RFID technology, paper trails that have been required to document the movement of products through the supply chain could become a thing of the past, as chips capable of holding more information and being read from greater distances penetrate the market.

While some will always prefer a paperback book over a Nook, and a newspaper over an Ipad, nobody likes the status quo when it comes to the manual data capture process prevalent within the complex clinical trial industry. RFID technology stands to make monumental change when it comes to how clinical trials are conducted, the costs involved, and the archaic ways in which critical information is gathered and documented during the lengthy clinical trial process.

The primary reason that retailers, healthcare providers and the aerospace industry are embracing RFID is to remove the inaccuracies that result from manual data collection. Retailers are on the way to improving in-store inventory levels from 65 percent on average to the high 90s. The aerospace industry is embedding thousands of RFID tags on planes to simplify maintenance and document reporting.

Imagine the gains that pharma companies and clinical trial providers could see by deploying the same technology to track storage, time stamp and environmental data.

Why RFID?

RFID is making its way into more and more industries as the technology matures and enterprises discover new use cases with solid ROIs. With a strong customer base in the life sciences sector, we see new markets developing rapidly for the technology.

That's especially true in the world of clinical trials, where RFID could help speed drugs to market and sharply reduce drug development costs by making trials more efficient and accurate. Greater visibility into the entire clinical trial supply chain is essential for a process that results in pharmaceutical firms often spending hundred of millions – if not billions – to get drugs to the stage where they are ready for regulatory approval.

Accountability for investigational drugs and devices in development during clinical trials are not only required by regulations, but also confirm study data integrity and accuracy. Almost always this

accountability is completed manually with pen and paper. Frequently this critical documentation is incomplete and contains errors.

Recently there has been a flurry of interest in RFID-enabled solutions for use in clinical trials, such as temperature-controlled cabinets and other products that can be used to track, trace and monitor drug samples. RFID can provide frequent verification of the clinical drugs at each stage during a trial, and the ability to not only account for who removed (or dispensed) the product from storage, but also accounts for subject assignment, time stamp and environmental conditions. Currently, these required pieces of critical information are documented and maintained through separate procedures.

"It's a burgeoning area because one small error in their data could throw off the entire product roadmap for getting a product into production and accepted by the FDA," Drew Nathanson, director of research operations at VDC Research, recently told RFID 24-7. "Drug companies have billions invested in these products, so there is a lot at stake."

Why Clinical Trials?

A lot can go wrong during the long road a drug travels during the clinical trial process, especially in an industry that still relies on pen and paper to record each step of the clinical trial.

The retail supply chain, often regarded as complex and elongated, seems relatively short and clear-cut compared with some clinical trials. A trial conducted on a Parkinson's population could continue for seven years or longer and include thousands of patients from all over the world. Miles of complex documentation occur in such a trial.

Here's a brief look at some of the steps that must be tracked during the clinical trial supply chain. A drug going through trial must have full chain of custody from the minute it leaves the manufacturer. Aside from tracking the quantity of what is being shipped from the source, storage conditions such as temperature must be monitored during the shipment at all times, an ideal application for RFID-based solutions.

Once the drug arrives at its destination – be it a clinic or university – it must be inventoried and deposited into a refrigerator or locked cabinet. If it's a product that requires refrigeration, the holder of the drug must perform daily monitoring of the environmental conditions, which can be accomplished quickly with RFID-enabled storage equipment.

Once the drug is dispensed, the clinic must track who it was dispensed to, when it was dispensed, who dispensed it, how much was dispensed. Most often, all those steps to document drug accountability inventory is done on paper. Typically, some of the work is done at very small clinics, and in some cases so there is not a lot of capability for the monitoring of accountability for some products.

In many cases, a study nurse is assigned to record the quantity of drugs arriving in a shipment, the daily temperature, and who received the drugs. In addition, an associate from a contract research

organization (CRO) is usually assigned to monitor a clinical site. Syncing up data can take at least eight hours or longer if data is not documented accurately. In cases where drugs are not reconciled accurately, it can take much longer, resulting in greatly increased labor expenses.

In the clinical trial process, an accurate accounting of drugs begins when a company ships products to the physician who will be using the product in the clinical trial. The physician must document drug receipt, inventory, dispensing to subjects and returns of used and unused supplies, as well as the daily storage conditions. Clinical trial providers must also reconcile any returns with the records of the physician. An RFID system that not only tracks inventory but also monitors storage conditions could provide for more accurate accountability and potential cost savings to the clinical site in general.

The View from a CRO

Laura Douglas is President & CEO of Next Generation Clinical Research, a contract research organization based locally in Madison. As part of the clinical trial management services her firm offers, Next Generation works on behalf of pharmaceutical companies to review trial documentation and make sure all samples are accounted for.

As she explains, it's crucial to collect accurate data. If the trial is botched by poor record keeping, the timetable for approval can be delayed, requiring additional investment into the trial. In some cases, faulty record keeping can even lead to criminal investigations.

"We send people in to review all that documentation, reconcile it, make sure they didn't lose anything," says Douglas. "If something was lost, or somebody removed something from a cabinet, we have to account for it and retrieve anything that is unused. If there are things missing or not documented, those are serious issues.

"Depending on the type of drug, it could be very serious if something was stolen. If you don't have any documentation and you have a missing drug, you need to ask if that drug was given to a subject that we haven't accounted for, or did someone receive an overdose or a dose that they shouldn't have received according to the protocol they are participating in? It is very concerning. Did someone receive the drug that is not even participating in the trial? These are serious compliance deficiencies in clinical trial conduct."

It's Not Just About Managing Data

Aside from manual record keeping mistakes, other issues can contribute to inaccurate data collection. In a clinical lab environment, bar codes attached to drug samples can become difficult to read after being handled multiple times during the clinical trial. Additionally, if the trial drug is stored in a temperature sensitive environment, bar codes might become unreadable over time because of frost buildup or condensation from refrigeration. In a best-case scenario, that means that additional time and expense will be required to document those samples. However, that also opens the door for inaccurate data

collection, or entirely missing a data collection event. RFID, which requires no line of sight to read, eliminates both of those issues.

RFID can also play a major role when it comes to track and trace and storing of drugs, especially those deemed high security risks. For example, special attention must be paid during the development of "scheduled drugs," or drugs that have special controls as to who can prescribe, access, and be administered the medication.

Usually, these are narcotic or anesthetic medications. When studying scheduled drugs in clinical trials, special requirements for restricting access and dispensation must to be adhered to and demonstrated – and, of course, documented. The usual procedures for managing these medications include locking them in cabinets within a locked room, with keys provided only to designated personnel.

In most cases, the check-in and check-out of these drugs is documented manually, as opposed to electronic systems. Again, this can lead to faulty record keeping, loss of records, and even loss or theft of the trial drug. In this case, RFID-enabled storage cabinets that track who checked out a drug, and when, can provide secure and documented access to high-risk drugs. Using secure access, each inventory transaction is automatically captured and processed — in real-time. The resulting data can be analyzed to track product usage, improve workflows, and make better business decisions.

Conclusion

RFID for use in clinical trials might not be for everyone. Some of the smaller and emerging pharmaceutical firms might only have $1 million in their budget to bring a drug to development. In those cases, there may not be much room to invest in technology gains, despite the obvious ROI. However, for some of the bigger companies or very large trials where huge amounts money are invested on a clinical trial, RFID provides an opportunity to secure better documentation, tracking and monitoring during the clinical trial phase.

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