RFID in Life Sciences Series: Part 3

RFID in Clinical Trials

Accelerating the Process

EXECUTIVE SUMMARY

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The Learning Chain:

RFID in Life Sciences Series:

- Part 1: Cold Chains are Hot—Mastering the challenges of Temperature
  www.chainlinkresearch.com/research/detail.cfm?guid=49189262-B102-0E02-9EAC-24A8B4B3F899
- Part 2: RFID in Clinical Settings—New Dimensions in the Chain of Care
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About ChainLink Research

ChainLink Research, Inc. is a Supply Chain research organization dedicated to helping executives improve business performance and competitiveness through an understanding of real-world implications, obstacles and results for supply-chain practices, processes, and technologies. The ChainLink Inter-Enterprise Model is the basis for our research. It is a unique, real-world framework that describes the multi-dimensional aspects of the links between supply chain partners.

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Executive Summary

Since early times man has searched for life-saving compounds, and has found magical elixirs in the minerals, plants and animals he saw around himself. His more recent efforts include the creation of chemical combinations, matching the corresponding effects of those combinations with the symptoms he is hoping to cure.

Today, this process has been formalized, and is the fundamental purpose of the pharmaceutical industry, with collective eons and dollars resulting in drugs that extend and save lives.

The discovery of a 'block buster drug' brings rewards for manufacturers and investors alike.

WHY A REPORT ON THE USE OF RFID IN THE DISCOVERY PROCESS*?*

Estimates for the true cost of drug manufacturing, from drug discovery to commercialization, range from hundreds of millions to billions of dollars. Irrespective of the financial considerations, finding a cure and improving the quality of life for those suffering from disease has immeasurable value. This report shows that reducing the cost of developing drugs, from discovery to the marketplace, translates into a win for everyone in the Life Sciences supply chain.

Monitoring the complex and lengthy business processes, as well as capturing and disseminating critical data and information in a highly regulated industry are critical to the success of this industry. This report, the third in the series related to the use of advanced technology enablers in the Life Sciences Industry, explores using technology to streamline the entire business process. In particular, this report evaluates the use of wireless networks, coupled with auto-identification technologies – sensors, RFID and bar-codes – to identify both current levels of adoption as well as future areas of opportunity.

In addition, this report identifies some of the key constraints, as well as potential process improvements that could be supported by technology, enabling the industry to streamline the discovery, clinical trials, and commercialization processes – reducing both time to market and, optimistically, time to cure!

How this Report is Organized

In this report, we have included survey responses from both the practitioners and the solution providers, as well as additional information that may be new to both. Our goal is to provide each constituency with a frame of reference that is relevant, while stimulating thought and innovation in the use of auto identification technology in the early stages of pharmaceutical discovery, clinical trials and ramp up to manufacturing.

We have broken this report into a review of each of the three major steps required in order to transform laboratory experiments into viable products, outlining within each step some of the key issues and areas of opportunity for technological solutions.

This report is addressed to two audiences:

Practitioners	Enterprises engaged in the discovery and approval process for new pharmaceutical and life sciences products. This community is familiar with the processes and procedures that are necessary to take a new compound from 'potential wonder drug' to approved commercial product. The level of understanding of technology and solution components for the capture and dissemination of data by this community is limited.
Solution Providers	Enterprises that have products and services that can be used to manage and control the information gathered during the discovery and approval of new pharmaceutical and life sciences products. Their level of understanding of the issues, processes and procedures involved in the 'discovery and approval' process is limited. Their experience and expertise relates to the use and introduction of auto identification technology to manage information, streamline manual processes, and diffuse this across a diverse community.

Table 1 — Technology Expertise Levels

WHO SHOULD READ THIS REPORT

The material in this report is of interest to the following groups of people:

- Pharmaceutical and Biotech manufacturers — research and development personnel
- RFID Vendors — wireless technology providers across the medical spectrum
- Software/Solutions providers — companies across the medical spectrum
- Contract Research Organizations
- Suppliers — of goods and services to the Life Sciences Industry
- Government, Policy and Trade Associations

cific disease, only to be re-activated and found to work well on another disease or medical condition. Another twist relates to the approval of a specific compound for one condition, only to discover that this compound is a potential cure for additional diseases. For example, a specific drug which is in Phase IV approval for one condition may also have begun the approval process for additional applications.

DISCOVERY PROCESS								
Major Steps	1—Discovery		2—Clinical Trials				3—Approval	
PROCESS STEP	Discovery Computer clues, mother nature, experimental compounds	Animal Testing	Phase 1 20 – 80 participants	Phase 2 100 – 300 participants	Phase 3 1000 – 3000 participants	Phase 4 Optimal use, doseage, storage and packaging	Approval	Manufacturing ramp up and general distribution
CONSTITUENTS	Manufacturer's scientists Suppliers of raw ingredients	OHRP, scientists and biologists, IRB, FDA	CRO OHRP IRB – doctors Nurses HHS FDA	CRO OHRP IRB – doctors Nurses HHS FDA	CRO OHRP IRB – doctors Nurses HHS FDA	CRO OHRP IRB – doctors Nurses HHS FDA	FDA/ Manufacturer Suppliers	Manufacturer and supply chain partners
DATA REQUIRED	Compounds and interactions	Interactions and results	Safety, Dosage, Side effects	Effectiveness and safety issues	Specific use, side effects, comparison with existing treatments	Optimal use and results – dosage, dispensing configuration, packaging and labeling	All info obtained during previous stages	All data related to Supply Make Store Ship

Table 2 — The Discovery Process

RFID Auto-Identification in the Clinical Trials Process

CONCEPTUAL VIEW

All parties engaged in the discovery and clinical trials process need access to detailed data and information. Having this available in a single 'system of record' or 'single version of the truth' (SVOT) would facilitate timely and accurate data capture and sharing, reducing time to market – and to cure!

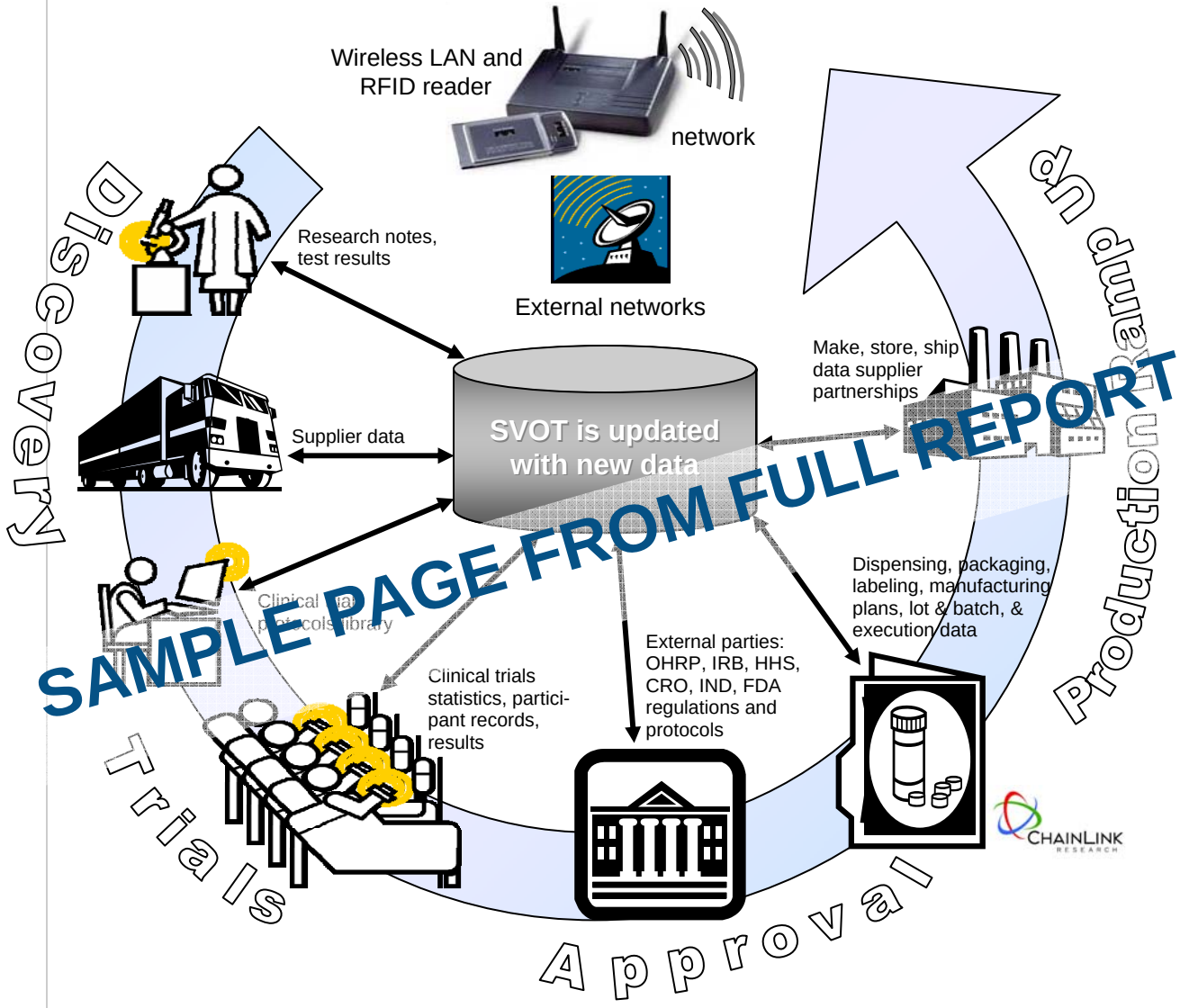


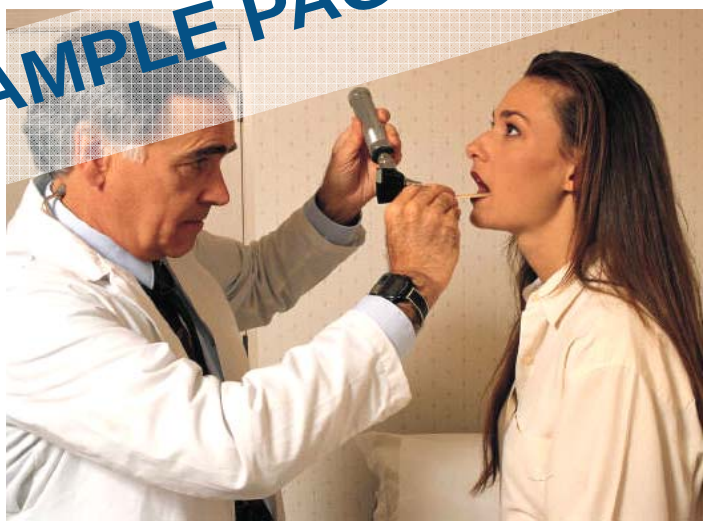
Figure 2 — RFID in Clinical Trials Conceptual View

How RFID could be used to improve the Clinical Trials Process

The introduction of auto-identification technologies – in particular RFID and sensors – would facilitate the capture of digital data related to the specific location and state of materials, at the unique item level. It would also enable the tracking of placebo versus active compounds, with the immediate correlation between item and patient/subject. This data, in digital format, could be integrated into existing information systems, creating a 'single system of record' in critical data that could be shared by all participants. (See table 3, page 17)

How would it actually be used and how would the process change?

One of the biggest challenges in Clinical Trials is ensuring the efficacy of the compound as it moves from point of manufacture to point of consumption in the test environment. In addition, there is concern that the subjects consume the compound in the correct dosage level at the correct time intervals. RFID/sensor tags could be applied to external packaging, bran materials and finished compounds. As they are moved through the 'chain of custody', all activities could be recorded, linked to the specific incidence of the item, ensuring that the compound has not been compromised due to environmental factors. The key activities at each point in the process could be monitored and recorded – for example, using RFID and sensor technology in unit level packaging to record the time and date each patient consumed the test compound.



The data captured would create a digital audit trail, less prone to human error than the current process that includes manual data capture and secondary entry into information systems.

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