BRIDGE – WP6: Dissemination

Purpose of this document

A requirement of the EU for the BRIDGE Project is the dissemination to the widest possible audiences across Europe of information regarding the experiences gained and the lessons learned by the various BRIDGE work packages in the fulfilment of their project obligations.

Accordingly the WP6 Team have developed a Dissemination Plan which has identified a number of items of collateral – such as White Papers, presentation materials, a video, press releases and articles – all promoting various aspects of the Pharma Traceability Pilot for public use. All of these items will be posted on the WP6 Dissemination Website, currently under development, which itself will be widely publicised.

The article below is one component of this set of collateral. It has been written for general purpose use.

We ask all project participants – our Users as well as the Partners – to actively exploit it. It may be modified and amended as required.

GENERAL PURPOSE ARTICLE

User community and Solution Providers collaborate in EU BRIDGE project

The Pharma Traceability Pilot - building a complete item-level traceability system within the pharmaceutical supply chain.

Finding strategies that improve patient safety is a hot topic for pharmaceutical companies and healthcare providers alike. With errors in medication administration and the problem of counterfeit drugs entering health services both increasing, it's essential that technologies which can track drugs and monitor their progress throughout the entire supply chain are implemented as soon as possible. Getting the correct, authentic drugs to patients quickly and accurately is an essential component in reducing medical errors and increasing patient safety. Implementing systems that support the traceability of products also help ensure product recalls are effected thoroughly and swiftly, preventing patients being exposed to sub-standard, or dangerous drugs.

Quite apart from improving patient safety, having the means to automate key elements of the global pharmaceutical supply chain and receive live information about the location of products significantly improves visibility, reduces administrative overheads and consequently delivers tangible efficiencies.

Piloting traceability technologies in the pharmaceutical industry
For the past two and a half years, members of the pharmaceutical supply chain user community and a group of innovative IT solution providers, together with GS1, the global standards organisation, have been participating in the BRIDGE (Building Radio frequency IDentification solutions for the Global Environment) project, a 3-year research and development project part funded by the EU. One of its Business

Application work packages was the Pharma Traceability Pilot, which aimed to demonstrate full item-level traceability in a live operating environment.

The project's overarching objectives were to implement a complete supply chain traceability system for pharmaceutical products to improve patient safety and increase supply chain efficiency. Additionally this would facilitate the development of related supply chain applications such as electronic pedigree, authentication, recall, inventory management and financial reconciliation.

Implementing the traceability trial

The project - the operational pilot having been completed in May 2008 - is the only one of its kind in the world to involve the trialling of such a comprehensive standards-based tracking and tracing system within a live, end-to-end supply chain spanning drug packaging, their distribution, right through to their receipt at the hospital pharmacy.

Pilot participants included:

- Drugs companies, Althone Laboratories, Actavis and Sandoz
- Dutch contract packer, Tjoapack
- Distributors, Kent Pharmaceuticals and CPG Logistics
- Transport provider, Movianto
- Wholesaler, UniChem
- Recipient/customer, Barts and the London NHS Trust
- Equipment and printing solution vendors, Domino
- Project management and business consulting, JJ Associates
- Technical design and software development, Melior Solutions
- EPCIS database provision, VeriSign Inc
- Provision of coding structure, standards and RFID consultancy, GS1 UK

A range of technologies and standards were implemented to allow fifteen different types of drugs to be tracked from the start of their journey at the packaging plants – one in Ireland, one in the Netherlands - to the end, at Barts' and the London hospital.

Technology and standards

Data Matrix symbology was used on all levels of product packaging from individual items to product bundles, cases, pallets and even transport lorries. It was chosen for its cost effectiveness and robustness and its ability to carry a 4-string data structure, which was first deployed by GS1in Ireland during the "The Blood Derivative Proof of Concept Trial" of early 2006. In this case the structure comprised the GTIN, serial number, expiry date and batch number.

In addition, RFID tags were employed on cases and pallets in hybrid labels, with printed bar codes. Selected pallets were also fitted with active devices to allow GPS tracking across the international supply chain. Every single pack of each product involved was assigned a unique serial number. Using this and the process of aggregating the contents to other packaging levels that were also assigned unique serial number identifiers allowed full traceability of every single item from the packaging line to the final destination. Printing systems were installed that enabled the required codes to be assigned, printed and checked within the production line. EPCIS, EPCglobal's network standards for supply chain-wide data collection was also implemented to capture data at each 'handover' point in the journey.

The pilot process goes live

Prior to the pilot commencing, all participants received in-depth training on the systems they would be responsible for, or operate. During the pilot's operation, all technology partners provided on-site and phone-based application support, recording issues and rectifying glitches.

Step 1

At the patient pack level, each item was coded with a unique SGTIN (serialised Global Trade Item Number), in the form of a 2-D Data Matrix code together with the expiry and batch information.

Step 2

Packs were aggregated into a case coded with an SGTIN correctly identifying the contents as a grouped trade item. The case label was a hybrid, or multi-format type, capable of storing the SGTIN code and expiry/batch information as a Data Matrix code, GS1-128 linear barcode and human readable text. The SGTIN was also encoded into the RFID tag. This ensured that the case label would be readable no matter what system was used downstream.

Step 3

Finally cases were scanned as they were aggregated onto pallets. The RFID tag was also scanned to provide alternative data that could be compared to the data read by bar code scanners. This would later allow full evaluation of the technologies used in this process. Each pallet was given an SSCC identifier which was encoded on the pallet label as a 2-D Data Matrix code, GS1-128 barcode and onto an EPC Gen 2 standard UHF RFID tag.

Step 4

Upon despatch, each pallet was scanned onto a vehicle, each of which was assigned a unique GS1 GRAI (Global Returnable Asset Identifier) code number that was also scanned so that all its contents were associated to it. For those pallets implanted with a GPS tracking device, their unique codes were linked to the EPCIS system via mobile tracking and read at regular intervals to check their progress which was recorded as part of the chain of custody process. Data was sent back to a central server for display on a map.

Step 5

At each stage of the journey to the wholesaler, pallets were scanned as they were removed from one vehicle and scanned again as they were loaded onto the next vehicle. This was carried out using mobile phones, loaded with decoding software that scanned the Data Matrix code and sent the data via SMS to an EPCIS database, so that each transaction or movement was recorded.

Step 6

When the pallets reached the wholesaler they were scanned with a barcode scanner (and the data sent to the respective EPCIS database). Then each pallet was moved through an RFID portal, data from which was stored separately to enable easy comparison between the two methods.

Step 7

Warehouse staff picked the required products for delivery to Barts, scanning the products into a tote box, which was uniquely identified using a GRAI code. The tote was labelled, bearing a Data Matrix code and an SSCC label applied on the folded lid to act as an anti-tamper device. As they were loaded for delivery, each tote was again scanned.

Step 8
Once at the hospital pharmacy, staff scanned the SSCC code to record receipt of the goods and all contents were checked against the tote manifest which was generated from the EPCIS record.

Drawing positive conclusions
Currently, all the data collected during the pilot is being evaluated and key learnings are being developed. However, what is clear is that the pilot was an overall success and that the technology required to implement full international supply chain traceability systems is available today.

Good communication and collaboration between trading partners was vital to the success of this project. The use of open systems information standards with the hybrid environment of data carriers – GS1 Data Matrix and RFID – supported this by maximising system interoperability.

Coupling the 4-string data set with the EPCIS system delivered complete traceability. As each participant in the supply chain recorded the movement of the products in and out of their custody, the data that was sent to their respective EPCIS databases formed the necessary traceability information. Cumulatively, and in a live scenario, this could deliver significant efficiencies and reduce costs. Having the product code, serial number, batch number and expiry date aligned to the EPCIS system also supports future recall capabilities, inventory management and financial reconciliation, which will generate further process efficiencies.

In the context of Bridge project collaboration, the traceability data collected has been shared with the Bridge work packages, notably Work Packages 2/3 (supply chain serialisation software) and Work Package 5 (counterfeit product analysis) to supplement their project findings.

The real-world nature of the pilot of course highlighted issues that will require solutions prior to future implementations. For example, the complexity of coding and printing within the production line environment requires meticulous planning. Packaging design may have to take into consideration the space required to print Data Matrix symbology. Staff training and robust intuitive applications will also play a crucial role in the success of any traceability solution implementation.

Regardless of these concerns, traceability systems will have an incredibly positive impact on improving patient safety and reducing the scourge of counterfeit drugs.

For more information about this pilot and to access all the reports pertaining to the BRIDGE project visit: www.bridge-project.eu/.

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