

Recommendations, conclusions & thoughts for the future.

This topic and the content have been covered (in part) in report D6.6, the Evaluation Report, and D6.7, the Dissemination Report, but because of the level of interest in the Pilot findings, the WP6 Team felt that these recommendations and conclusions, with some additional thoughts for the future, should be included here for easy access and maximum distribution.

Overview

This section describes a number of key conclusions and recommendations that the WP6 Team reached as a result of this Pilot. We hope they are beneficial to those parties seeking to implement similar traceability systems, whether they reflect the traceability model adopted by the project, be it in part or in whole.

They are not in any order of priority.

An over-arching conclusion of the pilot is that full supply chain traceability systems in the open, cross border supply chain in the European Pharmaceutical sector (and undoubtedly other continents too) is entirely feasible.

The use of open systems information standards together with the hybrid environment of data carriers (GS1 Data Matrix and RFID) enables maximum interoperability.

The data set used (product code, serial number, batch number/Lot code and expiry date), coupled with the EPCIS, not only offers the required traceability for electronic pedigree but also

- recall systems
- enablement of electronic flow of information to back office systems
- with resultant efficiency gains for inventory management and
- financial reconciliation systems.

However all this doesn't come cheaply! Not only is technology investment required by all supply chain parties, not least of all for the manufacturers, but also significant effort and focus on trading partner collaboration and stringent adherence to robust processes and their management. This necessitates high levels of training and education across the business and positive enterprise-wide communications. Total commitment by the most senior levels of management is essential if success is to be maximised!

Key Conclusions and Recommendations

- For full supply chain traceability systems to operate effectively, trading partner co-operation and collaboration is a fundamental prerequisite. This does not mean they necessarily have to adopt identical technologies but they must adopt interoperable systems based on open standards principles
- To enable the necessary levels of co-operation, first-class communications both between trading partners, and as importantly, within trading partner organisations are essential. This includes attention to all parts of the enterprise impacted in any way by the traceability system, including shift personnel.
- It is essential that robust processes are put in place for all related activities and systems that play a part in the traceability system and stringent management procedures deployed to enforce adherence. This not only requires focus on communications aspects but emphasis on all levels of personnel education and training.

- It is clear that this Pilot has successfully demonstrated the deployment of a hybrid data carrier environment. Both types of data carrier, GS1 Data Matrix and RFID, have a role to play, each implementation will determine what carrier best serves the traceability functions required. This point demonstrates that the important element of focus is *not* the data carrier but the data itself. This pilot successfully proved the effectiveness of the SGTIN (product code and serial number) with batch number and expiry date all encoded within the carrier. We see this dataset as the optimum dataset to be deployed for future traceability systems – it fulfils the needs of all prospective traceability requirements we currently know about.
- A traceability system such as the one we have deployed will inevitably touch almost every aspect of an organisation's business. Accordingly the project must command total commitment and buy-in of management at the most senior level. Excellent project management skills are a prerequisite of the project's success.
- Technology systems supporting the traceability system must be intuitive, efficient in operation and highly robust. Operatives in the business with little or no IT skills will be required to process the relevant systems whatever time of day or night in line with often demanding timescales. There will be no room for error – not least to deliver the required levels of customer service but to maintain the traceability trails.
- We have proven the feasibility and effectiveness of encoding and printing product packs directly on the production line at high speed. The subsequent Centre of Excellence in The Netherlands has further built on our BRIDGE work by additionally printing on blister packs and even unit dose packaging levels.
- We have reported that the deployment of highly sophisticated hardware and software systems together with quality assurance processes is a highly complex and time consuming activity. It is therefore essential that sufficient time and resources are applied to the task, including realistic production schedules.
- The pilot deployed all relevant data and system standards available at the time. Given the global nature of the Pharmaceutical sector, it was imperative that a set of standards was selected that would operate in all markets. It was also important that where the industry used existing standards, these were built upon where possible in order to ensure ease of adoption. Based on these elements, the project team identified that the emerging EPCIS standard, based around the GS1 data standard, held promise as an enabler of supply chain security, chain of custody, and in the future, meeting the various local, regional, and global laws.
- Further, as the project developed, we input where possible to the standards making processes, particularly of EPCglobal and their ePedigree and Track and Trace working groups. We would recommend that these groups take note of this traceability pilot implementation and build on the lessons, experiences and our findings into their work, as deemed appropriate. Of particular relevance we would cite our traceability dataset deployed (see 5.2.4 above).
- We have already made the point that full supply chain traceability systems require a high degree of trading partner collaboration. The desire to implement will not necessarily be at the same levels for all trading partners – the business case and return on investment differs significantly dependent upon the stakeholder's supply chain role. Accordingly we recommend that Governments and other Authorities will need to regulate traceability deployment at the community or national levels for sector wide adoption. The case for this is evident in California, and some 30 other US states, as well as in Turkey, Italy, Belgium, Portugal, Greece, France and Brazil.

- For many of the reasons already covered above, there are significant issues and challenges to be addressed before any significant deployment of open, full scale, supply chain traceability systems become a reality. Accordingly, an interim approach adopting the “in / out” data model – mass serialisation deployed by the manufacturer (the “in” phase) and verification of the patient pack by the pharmacy at the point of dispense (the “out” phase) is perhaps a practical model for today. This can of course be supplemented by the inclusion of additional trading partners as and when the need arises for more complete traceability systems’ implementation.
- As we have already reported, we had difficulties – in some instances significant difficulties – locating appropriate physical space for the GS1 Data Matrix code on the patient pack. This was not due to physical size constraints per se, but because the packaging design (layout and colours used) did not readily accommodate appropriate space and colour background (white for contrast) for the code to be applied in a quality manner. We would thoroughly recommend that in future packaging design at the pack level should be such that the GS1 Data Matrix code can be easily accommodated - in other words, the allocated space for printing designed into the overall packaging design.
- Further, there may be benefits in the pharma industry agreeing in a collaborative manner the most appropriate space (e.g. on the top, edge or side of the carton) for different forms of packaging.
- When printing GS1 Data Matrix codes pack handling is critical. When GS1 Data Matrix codes are printed it is essential that the pack is presented to the printing device in a consistent and controlled manner. Too much ‘wobble’ or vibration on the conveyor or handling system results in unreadable codes.
- As discussed in the business case sections in this report, difficulties were faced determining accurate quantifiable forecasts of potential efficiency benefits to be gained by inventory holders/owners in the supply chain, e.g. wholesalers, distributors. We are convinced significant benefits can be accrued not least for inventory management by the integration of the traceability data into back-office systems that exploit the availability of encoded batch numbers and expiry dates. Accordingly, we recommend that further research is undertaken by relevant parties in these areas.
- Whilst we found that our implementation of EPCIS and its distributed ‘database’ model operated entirely satisfactorily for our traceability system, we recognise that due to its distributed nature, any ‘search and locate’ functions required say for online verification of product (as per the ‘in/out’ data model already discussed) and instantaneous recall could incur unacceptable response times. We recommend therefore that if the EPCIS concept is to be widely adopted for these data models. Where instant response times are a mandatory requirement, which appears to be a developing trend in the European market, relevant standards should be enhanced or created to accommodate a system design requiring faster responsiveness.
- It is clear that a practical working solution to the automated scanning of the high speed picking and tote assembly process required of the wholesaler is a fundamental requirement if they are to play their part in supply chain traceability systems. Whilst some experimental work has been done to RFID-enable the scanning process within the A-Frame environment, it should be remembered that current coding strategies – and we cannot see them changing in the near or medium term – are not based upon RFID implementation at the pack level but upon GS1 Data Matrix codes. A solution is required that supports this either as a separate process following on from the A-Frame pick or as a facility incorporated within it. We are not qualified to judge but we do feel that the first vendor system to market will gain a considerable competitive edge.

- As we have fully covered here and in other project deliverables, our product traceability extended only from the point of manufacture to goods-in at the hospital pharmacy. We fully recognise, however, that further significant benefits are to be had – not least of all patient safety – by extending the traceability trail *inside* the hospital to the patient’s bedside and the point of medicine administration. By association of the medicine to the patient’s electronic patient record, the “5Rs” can be positively assured, saving peoples’ lives as a result. These cannot be valued. Costs of getting something wrong can be radically reduced.

We would strongly recommend therefore that healthcare authorities and regulators undertake further pilots to demonstrate this potential. The fundamental building block of such capability is the positive identification of medicines at the manufacturing point as demonstrated by this Pilot – this now needs to be extended to the ultimate stage where significant benefits to patient safety can be realised.

- Whilst the construction of an electronic track and trace system is not exclusive to the EPCglobal network concepts, and indeed there are a number of alternative architectures available today, we opted for the EPCglobal approach in the context of the original project brief. This proved to be successful, although the lack of availability of a full Discovery Service made the pilot implementation more difficult. It is clear that availability of the Discovery Service standard is a priority for EPCglobal - we believe the work of the BRIDGE WP2 and WP3 projects is important in this context.
- We have already commented that the currently available low cost Gen 2 tags do not at present accommodate the four-string dataset used (product code, serial number, batch/lot number, expiry date). To overcome this, some traceability projects have deployed two data carriers to symbolise the four-string data set which creates confusion and inefficiencies of use within the user community. There is a need therefore to formalise the means to encode all four data elements within the Gen 2 tag. This work is currently being undertaken by the EPCGlobal Tag Data Translation and Standards (TDTS) Working Group – it is well advanced and will set the standards for user memory encoding on the Gen 2 chip within the EPCglobal Framework. Documentation is not yet publicly available. Our recommendation is that priority should be given to the completion of this work by EPCglobal.
- We have made the point earlier that many pharmaceutical companies may not wish to be early adopters of the technology and work required to implement traceability systems based on mass serialisation techniques, particularly in the early days. Nonetheless, regulatory pressures and market trends (e.g. California, EFPIA) will drive them to do so. Accordingly, we see an increasing trend towards pharmaceutical manufacturers outsourcing the packaging and encoding operations to those specialists who have already made the investment.

Thoughts for the Future

Electronic Pedigree - Recommendations for Future Work

Pedigree and Electronic Pedigree regulations for pharmaceutical products have been an evolving set of global requirements and laws since the start of the BRIDGE project in mid-2006. The Work Package 6 participants recognised at the start of the BRIDGE project that the emerging EPCIS standard held promise as an enabler of supply chain security, chain of custody, and in the future, meeting the various local, regional, and global laws. The start of the BRIDGE project pre-dated the ratification of the EPCglobal Pedigree Messaging Standard by six months, and the EPCIS ratified standard by approximately a year. The goal of the Work Package 6 pilot was to show the *potential* of the EPCIS standard to provide a chain of custody of the movement of pharmaceutical products, which in the future could be standardised to provide a more proactive and comprehensive approach to help identify and remove counterfeit pharmaceuticals from the supply chain.

As of December 2008, the GS1 Healthcare US industry group has a sub-team that has been working on providing guidance and an update to the EPCIS standard to support various E-Pedigree laws and regulations within the United States. While there has been a considerable amount of work accomplished to date, a standard requires broad consensus and still has further work until an update is completed. Unfortunately, Work Package 6 was unable to take advantage of the work in this team in time to implement in the pilot, although some pilot participants (VeriSign) have contributed to the work in that group.

As a recommendation for future pilots that may utilise the EPCIS standard to provide Pedigree compliance, the following additional steps that were not addressed in the BRIDGE pilot should be considered.

1.) Updated Data Vocabulary

The EPCIS standard has a related Data Vocabulary in which different industry groups specify data elements that are required. Similar to how the Pedigree Messaging Standard defined the mandatory and optional fields for an electronic pedigree, the Data Vocabulary should provide guidance to supply chain members choosing to use the EPCIS standard in a like manner. This will ensure that a common set of data elements will be based specific to electronic pedigree guidelines.

As mentioned below in point 4, it is conceivable that the future EPCIS Core Business Vocabulary standard could include additional optional data fields such as 'Shipped-To:' and 'Received-From:' in order to express a double-linked chain of custody, to enable easy detection of discrepancies, which may indicate injection into the legitimate supply chain

2.) Non-Repudiation

Non-repudiation is defined as "the inability to deny the integrity and authenticity of a document." In the electronic word, this applies to underlying transactions. While legal definitions may vary between jurisdictions, specific technologies and processes can be adopted to the set of data held and transferred between EPCISs to ensure that an entire chain of custody for a given product cannot be in doubt.

3.) Digital Signatures

Digital Signatures in the context of electronic pedigrees provide two functions that support non-repudiation:

(i) They uniquely identify an individual who digitally signs a set of pedigree data. In most jurisdictions, the application of a digital signature holds the same legal weight as if the person actually provided a handwritten signature on a paper document. For at least one US state, digital signatures are required to be associated with an electronic pedigree record.

(ii.) Digital signatures are also used to calculate what is called a "hash", which enables a downstream trading partner to identify whether the information that the originator sent was altered or changed in any way.

From a technical perspective, digital signatures are much stronger and difficult to forge or counterfeit than traditional handwritten signatures for two reasons:

a) digitally signatures are intrinsically linked to the data because the actual data content is used in calculating the signature. Unlike a handwritten signature, if a digital signature is copied to a different document of different packet of data, it is immediately obvious to anyone checking the signature that it does not correspond to that data packet or document.

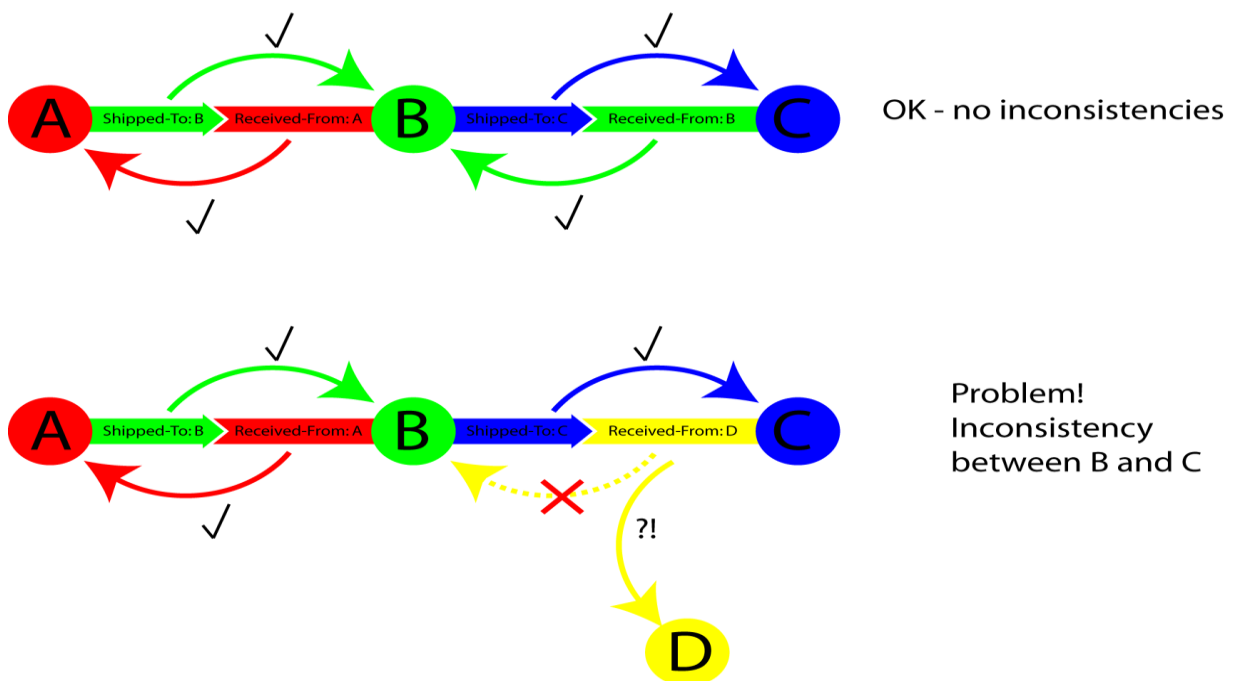
b) we can have a very high confidence that the digital signature could only have been created by the organisation or individual who has the secret private key of the public-private key pair, provided that the signatory has kept their private key confidential.

4.) Specify Intended Recipient

For a recipient of pharmaceutical products to know that it was the intended recipient, and not someone else, it is recommended to list both the "Ship From" and "Ship To" information for each EPCIS transaction. If a complete electronic pedigree is later created from EPCIS records, then both sets of information can be compared to ensure that the product did indeed follow the specified chain of custody.

We have inserted a diagram that you're welcome to use to illustrate this and how it can be used to check for discrepancies that might indicate possible unauthorised injection into the supply chain.

Double-linked chain of custody:



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