



Building **R**adio frequency **I**Dentification for the **G**lobal
Environment

Pharma Traceability Pilot Requirements analysis

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About the BRIDGE Project:

BRIDGE (**B**uilding **R**adio frequency **I**dentification for the **G**lobal **E**nvironment) is a 13 million Euro RFID project running over 3 years and partly funded (€7,5 million) by the European Union. The objective of the BRIDGE project is to research, develop and implement tools to enable the deployment of EPCglobal applications in Europe. Thirty interdisciplinary partners from 12 countries (Europe and Asia) are working together on : Hardware development, Serial Look-up Service, Serial-Level Supply Chain Control, Security; Anti-counterfeiting, Drug Pedigree, Supply Chain Management, Manufacturing Process, Reusable Asset Management, Products in Service, Item Level Tagging for non-food items as well as Dissemination tools, Education material and Policy recommendations.

For more information on the BRIDGE project: www.bridge-project.eu

This document:

In the Pharma Traceability project, the Problem Analysis report discussed the market context of the pilot and outlined the overall vision and solution for tracking via mass serialisation of pharmaceutical products enabling full supply chain traceability. This Requirements Analysis builds on this first document, discussing the requirement in more detail with an emphasis on the functionality required and the technologies to be deployed.

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1. Introduction

This is the second deliverable of WP6 and defines the requirements for the ‘Pharma Traceability Pilot’ (also known as Drug Pedigree). Deliverable 1, the Problem Analysis, discussed the market context of the pilot and outlined the overall vision and solution for tracking via mass serialisation of pharmaceutical products enabling full supply chain traceability. This Requirements Analysis builds on this first document, discussing the requirement in more detail with an emphasis on the functionality required and the technologies to be deployed.

With reference back to the Bridge project ‘Description of Work’ for WP6, deliverable 2 is defined as:

“...Based on the work undertaken in (the problem analysis) a set of requirements will emerge that identifies the tools, standards and policies that need to be addressed in order to meet the aim of this WP.

Across the supply chain: There is a physical and information infrastructure (network) requirement imposed on the RFID system for efficient track and trace of RFID tags across multiple organisations and multiple geographical locations. The speed of movement of tags and the sheer volume of tags that need to be read within a particular time frame will determine the type of RFID systems that need to be implemented.

Across the supply chain: There is a distributed infrastructure (network) requirement imposed on the system for the efficient track and trace of healthcare/pharmaceutical products across multiple organisations and multiple geographical locations. These healthcare/pharmaceutical products will be tagged by both RFID and non-RFID means, depending on the physical nature of the product. The speed of movement of products and the subsequent volume of various tags that need to be read within a particular time frame, together with the cost of implementation will determine the type of system that is to be recommended for each product type.

The deliverables for this work package is in the form of a requirements document that outlines the business requirements and the subsequent specifications of the hardware and software that are needed to meet the business requirements. Workflow documents will also be produced to support the ‘Pilots and Development’ work package which will need to cover the end to end supply chain including the varying requirements of each supply chain participant e.g. stock management at goods issue and receipt, financial management, information transparency, in addition to the ePedigree data...”

To fulfil the requirements of this document, it has been constructed to first debate and discuss the various considerations taken into account for this pilot and then to list in tabular form the specific requirements of each business function embraced by the solution.

2. Explanations and Considerations

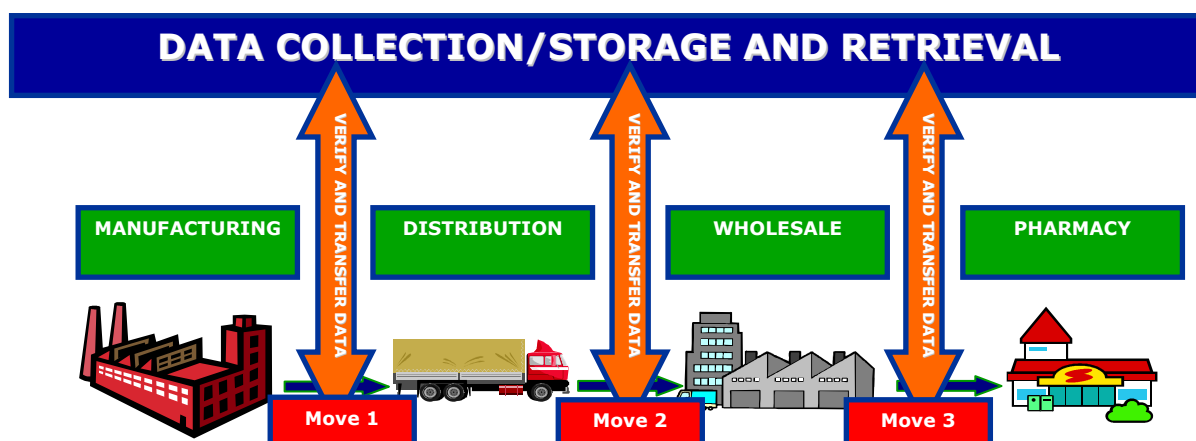
2.1. *Track and Trace – the critical element.*

Much discussion is taking place about the concepts of product track and trace, information management, electronic pedigree (ePedigree), supply chain efficiency, and product authentication. During these discussions, the view of this work team has changed. When this project started we were minded to see the need for an ePedigree as the ‘ultimate requirement’. However the term ePedigree has been used in such a way recently (2005/2006) that our original interpretation of it has been lost. The main reason for this is that the term has been used within the US to define an electronic document encapsulation system where successive electronic documents, used in the drug supply chain are authenticated at each stage and digitally signed (and thus provided with an electronic form of ‘tamper evidence’) to provide a nested series of authenticated electronic documents. This is not what this work team had envisaged for an electronic pedigree and therefore, in order to provide more insight into our work, without the inevitable distraction of comparison with the US system, we have re-considered our objectives and subjugated ePedigree (our interpretation thereof) to an application that flows from a far more fundamental supply chain track and trace requirement. Hence the current naming of the project as the ‘Pharma Traceability Pilot’.

Applications such as those mentioned above can only be realised if a complete ‘object history’, in terms of manufacture and logistics movement (in both forward and reverse supply chain), of specific items is known. We define the ‘object history’ as being access to information that can inform a user of system of the attributes of a specified item, the point of manufacture and, if required, all nodal points along a particular supply chain in which a transaction has been undertaken, whether the transaction be physical or informational. A networked system approach provides more symmetric access to the information held along and across the supply chain and thus provides the potential for all trading partners to have far greater visibility of the products and associated data than say, a document centric approach. The ideal system would involve ‘noting’ the location of each item, together with time and date (plus other environmental considerations if required such as temperature) at every point where the item either changed ownership/custodianship or where a significant activity occurred.

To achieve such a system realistically, each object to be tracked needs its own unique identifier, a serial number or ‘licence plate’. This is in essence the whole rationale behind the EPC (Electronic Product Code) as promoted by EPCglobal via the GS1 organisation. The EPC associated with each object is its ‘licence plate’, its unique identifier. The EPC identifies the object identifier type (e.g. SGTIN-96, GRAI-96, GLN-96 etc.), the manufacturer / originator of the product, the product and the individual unit. The EPC, by uniquely identifying the individual object in this detailed manner, enables any relevant information regarding the individual object to be obtained via the EPCglobal network, wherever that information maybe located globally and irrelevant of the relationship between the organisations whose systems hold information regarding the individual object, provided one has the right to access the information. This kind of access and functionality can only be realised when the EPCglobal network is more complete than it is today, for example by the availability of an open standard interface for Discovery services. However for the pilot being undertaken by this work package, sufficient of the network is either available or can be made available to enable the project. By undertaking such a detailed approach it should be easy to see how an application, that was able to access all data relating to the life activity and movement of a product/object, could provide very quickly, a dynamic track and trace item pedigree and an authentication check or a manufacturers validity check or even a simple ‘where are the goods?’ enquiry.

The concept of a full supply chain track and trace system can be visually represented by the simplified diagram below.



In this diagram we can see a simplistic view of a supply chain (involving only the major object movement events of receiving and shipping). What the diagram does however allow us to show is the way in which a product tracking history is built up.

A discussion of the detailed requirements at each stage is presented in later sections.

Assume that at the first stage the drug items are manufactured and appropriately coded. When the drugs are shipped a number of data transactions and exchanges occur. These can be summed up broadly as follows:

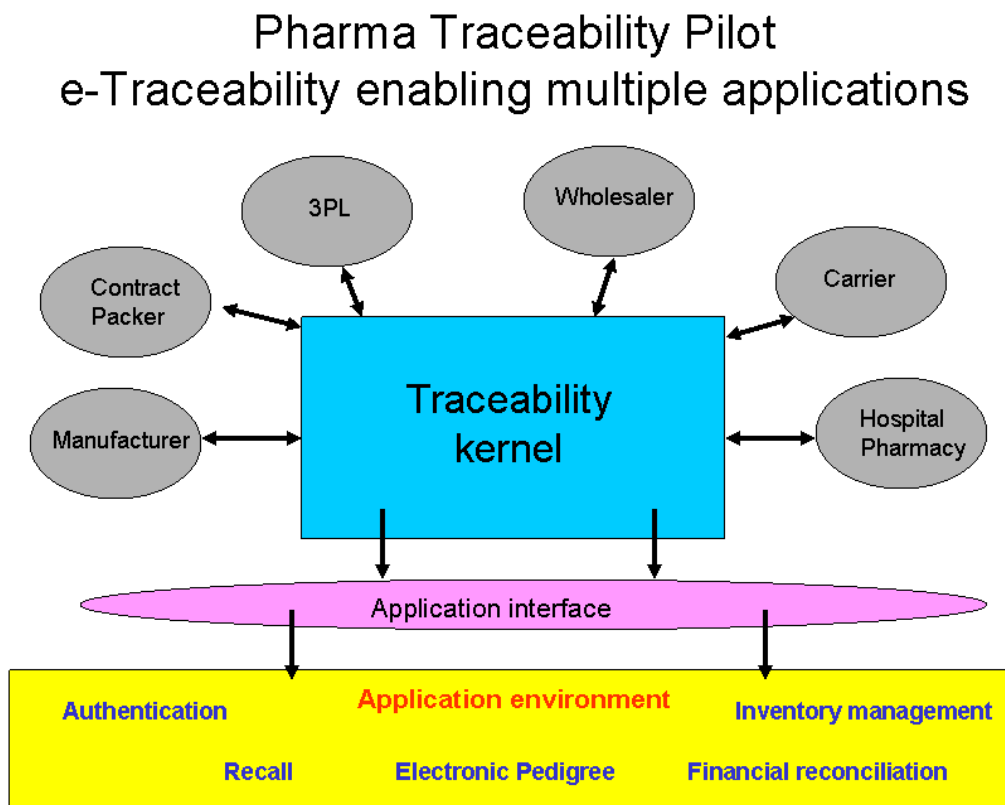
- The individual detailed product descriptions are linked to externally accessible individual unique ID's which in our case will be an EPC number. At this point, as far as the 'outside world' is concerned, the product has now been released into circulation.
- As the items are moved through the internal process chain and eventually shipped to the distribution provider (a transporter or 3PL provider), further transactions occur at each nodal point to 'tell' the system that the specified items have been moved from one activity zone to the next and ultimately shipped to a specific receiver. Each identified transaction is accompanied with time, date and zonal location information.
- On receipt of the items, the receiver 'tells' the system that it has received, from the specified manufacturer, a specified list of items:
 - Note that there is no reliance on system knowledge that the manufacturer has just handed over specific items – each party handling the items has to say what they have shipped or received, or the transaction that has taken place at a particular nodal point.
- When the distributor ships them to a wholesale organisation, the same high level pattern of transactions occur, namely:
 - As items move through the distributors internal process chain, further transactions occur along the internal process chain at each nodal point to 'tell' the system that the specified items have been moved from one activity zone to the next and ultimately shipped to a specific wholesaler
 - Distributor ships specified items (EPC's) to a wholesale organisation.
 - Wholesale organisation warehouse receives the specified items.
- The wholesale organisation then delivers to a pharmacy giving a high level transaction pattern such as:
 - As items move through the wholesalers internal process chain, further transactions occur along the internal process chain at each nodal point to 'tell'

- the system that the specified items have been moved from one activity zone to the next and ultimately shipped to a specific pharmacy
- Wholesale organisation ships specified items to a specified pharmacy.
- Pharmacy receives specified items.

Optionally the system could be further enhanced by specifying the delivery vehicles as 'known' objects with a unique global returnable asset number (GRAI) thereby associating on which vehicles goods were transited. Indeed, in order to more fully secure the supply chain, this step is likely to be necessary. However, the data transaction elements will be exactly the same as those used by the rest of the system, i.e. logistics movement and aggregation, and thus the system will need no extra enhancement to accommodate this aspect. For this pilot however, the investment and management issues are out of scope and thus this will be left as a potential to trial in the future.

By now it is hoped that a picture is emerging where the custodianship of the items throughout their existence has been recorded as a series of events. Given access to this data and an EPC number, it would be possible to determine precisely where the item had originated from and how it got to where it currently is. In essence, this ability to look back at the transit history, the custodianship of the product is what we have dubbed an ePedigree.

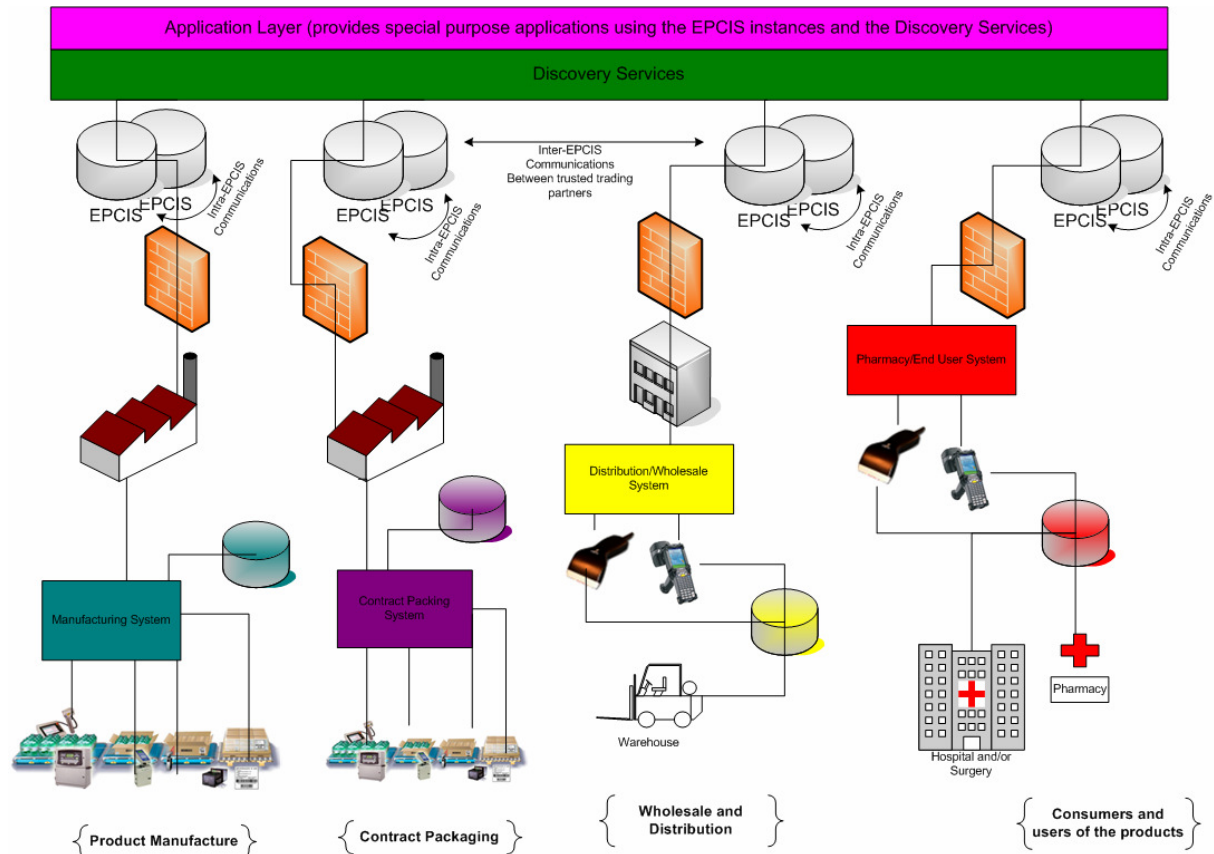
The team have found the following diagram useful when trying to understand how the idea of a 'Traceability System' works.



Essentially the whole system hinges on a central 'Kernel'. Within the context of the EPCglobal Network, this 'Kernel' represents the EPC Information Service and Discovery Service elements. Each partner, represented here by the grey circles, is an instance of an individual or multiple partner EPCIS instances and the API (Application Programming

Interface) is used as the link from the EPCIS and Discovery Services into a variety of applications and tools that are additional to the basic infrastructure that the kernel represents. Thus the API is able to make queries of the Traceability kernel (Discovery Service) to find all the sources of information across the supply chain and is also able to **directly** query the EPCIS of each provider. Over time we would envisage the number and capability of the applications available to increase dramatically for it is here that users of all varieties will gain benefit from the track and trace capabilities whether this be via EPCIS' as players within the supply chain for instance, or via EPCDS' as players external to the process chains (i.e. consumers or regulatory / government bodies).

To provide an insight into the way in which we will utilise the EPCglobal Network, the diagram below shows a simplified supply chain in more detail and how the 'Traceability Kernel'/discovery service links with EPCIS instances for each partner together with the need for each partner to have a degree of 'system software' or 'applications' running within their organisation to 'feed' the traceability system at the most appropriate points (as will be discussed later). Also, applications such as e-Pedigree and track and trace are 'by-products' of the EPCglobal Network. The network itself provides observations of each EPC submitted and does not, by itself provide the application solutions that many discuss freely. As part of the project that this work package is undertaking, lightweight, e-Pedigree and track and trace applications will be used that are external to the EPCglobal Network but that will make extensive use of the Discovery Services



The diagram above shows a number of different concepts and capabilities of the proposed system using the EPCglobal Network. Within any given organisational unit, many instances of EPCIS will be present and each of these EPCIS instances are able to interact with each other in user defined ways.

EPCIS instances between different organisations that have trusted trading relationships are also able to interact and communicate with each other in pre-defined ways that have been agreed by the trading partners.

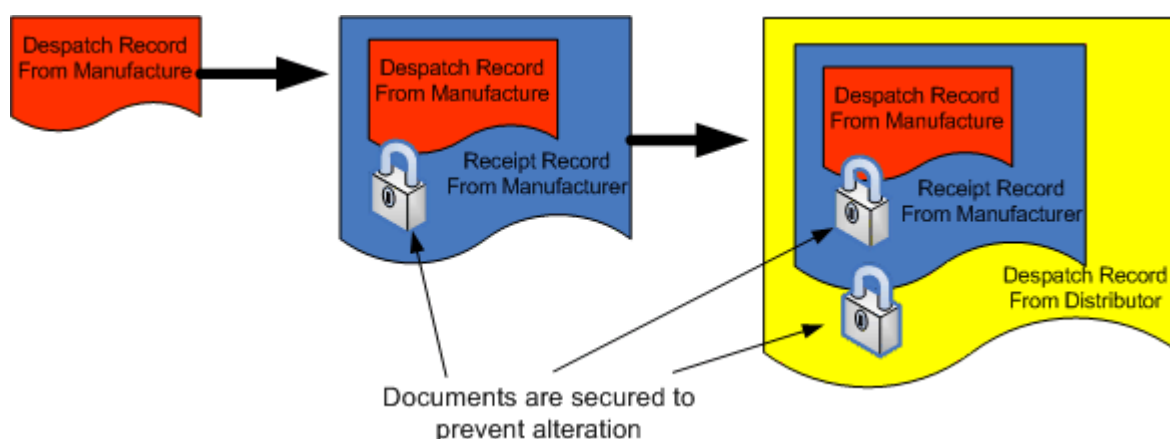
If the trading partners do not have a trusted relationship or one of the partners requiring access to certain information is from outside the trading relationship (e.g. members of the public, trade bodies and regulatory bodies), access could be gained to certain restricted information by means of an EPC Discovery Service and where necessary using an ONS (Object Naming Service) to assist in identification of EPC event that may have occurred on a separate network, not managed by the Discovery Service to which the user is currently subscribed. The ONS instances and potentially Discovery Services could be held at a national level to identify the object manufacturer / originators identity, and therefore the relevant EPCIS instances, provided that access to the information was allowed.

2.2. Electronic Pedigree – What is it?

The previous section built up a picture of our definition of an ePedigree. However, as defined earlier in this document, the term ePedigree has been somewhat adopted via EPCglobal, (as directed by end-users and systems integrators who participate in the HLS Drug Pedigree Action Group and are predominately US based) to mean something very specific in order to meet in part, the requirements of the FDA directive.

Mindful of the lack of a global data network and also mindful of the potential lack of ICT infrastructure in place within the pharmaceutical supply chain, the US interpretation of an ePedigree is more of a nested collection of secured electronic documents.

We can visualise this in the following diagram.



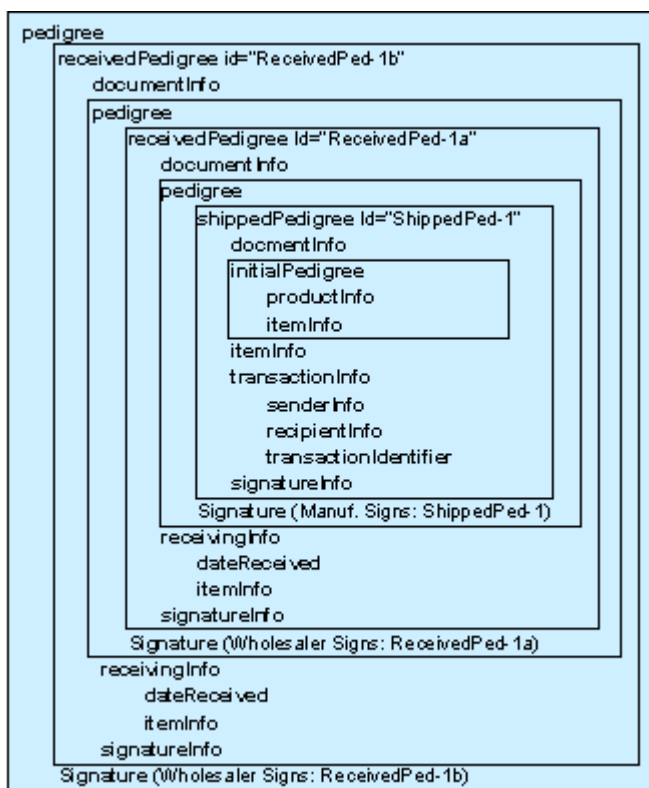
What the diagram shows is as follows:

- The manufacturer ships a series of items (ideally specific items – i.e. carrying unique id's such as EPC numbers) to a distributor. The goods are accompanied by an electronic document, such as a PDF document or more likely an XML document, stating what the goods are and the provenance of the goods.
- The distributor receives the goods and the manufacturers shipping record, which is suitably 'digitally signed' by the manufacturer and thus locked from modification and viewable only by select partners. The distributor places this together with a receipt record. In essence, one electronic document becomes embedded within another.
- The distributor then ships the product, produces paperwork for the shipment, embeds the receipt documents for the goods (which now may be manifold) and digitally signs his element of the document to restrict access to its content.
- The 'layering' of these documents is defined as an XML schema which provides a portable and open means of interfacing with the system.

This pattern continues until the goods reach their final point of use where it will then be possible to read through the various documents, if required, to check and test the provenance of the goods. In simplistic terms, this collection of digitally signed and restricted access electronic documents is what the US has dubbed an ePedigree. The digital signing of the documents provides layers of 'tamper evidence' and also provides the ability to restrict access to documents contained within the stack from parties who have no need or requirement to view them. It is this system (currently in a few guises) that is required by state law in key territories within the US.

One of the major drawbacks with this form of ‘non-networked’ system however is the data replication that occurs. At each point where an addition to the pedigree is required, the entire collection of previous documents (suitably signed and restricted) has to be added to the new document. Thus, by the time the pedigree is complete there may be many duplications of earlier stage documents in existence. This problem then multiplies if the goods have to be returned along the supply chain for any reason. The data payload associated with the pedigree simply keeps on growing. It can of course be argued that having all of the pedigree data in one ‘document’ that travels with the product is beneficial because there is no reliance on an external system. This is true however the overhead of providing such a system and the data payload associated with it for the millions of medication movements that will occur over time is neither efficient nor workable in the longer term. Too many benefits that can be associated with a networked approach are unavailable using the document encapsulation method.

The diagram below is the representation of an ePedigree from EPCglobal SAG Drug Pedigree Work Group.



The example shown is a logical representation of a pedigree after the shipment from the manufacturer to the wholesaler arrived in two separate sets requiring two receiving signatures.

It is not the intention of this work package to implement the approach adopted in the US. What we intend to pilot and test is a track and trace system that is capable of providing all of the information quality sought from this style of ePedigree without the need to embed electronic documentation. We intend to pilot an overall system that can provide an ePedigree by means of access to critical logistics event data and that is also able to provide a richness of capability beyond just ePedigree using the same data infrastructure and same basic logistics event data.

The use of a networked approach allows us to demonstrate some of the advantages that this approach can bring. These can include automated anti-counterfeit alerting, predictive monitoring of logistics movements (monitoring transport methods and processes to provide, for example, alerting if a common transport system suddenly deviates from a known and expected norm – i.e. the shipment arrived late or went via the wrong route). A networked approach means that access to the basic event data is near real-time and therefore requirements such basic product authentication, efficient product recall, simply being able to

identify where specific products are ⁽¹⁾, counterfeit surveillance, financial reconciliation, inventory management and patient care administration systems are some of the applications we envisage being developed as an essential part of delivering value from such a traceability system.

When this proves successful we will need to define some specification criteria for testing and verification of the ePedigree produced to ensure that it meets the need, provides an accurate result and can be embodied by other providers.

Note:

⁽¹⁾ During a recent (Feb '06) FDA workshop in Washington USA, a speaker commented that one of the biggest perceived threats in terms of emergency healthcare provision (the comment being made in the wake of the various hurricane disasters of 2005/2006) was the inability to quickly locate stocks of any specific medicine. Knowledge that there was enough in stock was one thing, knowledge about the location of the stock was another. This also has implications when nations need to prepare for potential pandemics such as avian flu.

2.3. EPCglobal and GS1

It is the purpose of EPCglobal to provide multi-industry, user-driven standards for collaborative commerce utilising the Electronic Product Code (EPC) and EPCglobal Network. The intention of EPCglobal is to provide standards which cover all potential areas of applications processes by:

1. defining a universally acceptable and usable code framework/standard, (the EPC),
2. providing the ability to use all types of required carrier as defined by user organisations (e.g. RFID)
3. providing a network via which players can communicate information (the EPCglobal Network), and
4. providing standards to cover all areas of the above entities and interfaces, enabling interoperability and completely open systems.

EPCglobal is an independent, neutral, trusted advisor to its members, with no commercial agenda and the belief that the only successful path to achieving the concept of EPCglobal, is via a cross industry global approach by industry for industry, where subscribers determine priorities and initiatives.

GS1 is a global standards organisation with the mission to bring benefit to its members by the global commercialisation, promotion, deployment and support of GS1 standards and related services. This includes the promotion and development of the GS1 identifier types and support for the development of the concept of EPCglobal.

GS1 is an independent, not-for-profit association, formed by the coming together of EAN and UCC in February 2005. It employs over 1,500 staff in 104 national organisations operating across 133 countries, and has over a million member companies world-wide. More than eight billion transactions are undertaken everyday using GS1 standards.

2.4. Coding constructs

As will be described in the later sections, the system we intend to use will recognise the various stages of packaging in to which the items we want to track are placed. The actual areas of use will be described in later sections of this document.

For this pilot and trial we will be using GS1 standard data identifier types. Detailed reference to the structures can be found by reference to GS1 General Specifications and EPCglobal tag data standards version 1.3.

- SGTIN – (serialised global trade item number) will be used to uniquely identify individual revenue objects.
- SSCC – (serial shipping container code) will be used to uniquely identify individual shipping consignments.
- GLN – (global location number) will be used to uniquely identify fixed asset locations such as factories, warehouses goods inwards/goods out locations. Use of the GLN spares us having to communicate location address information for transactions.
 - Note, consideration has been given to the use of the SGLN identifier, however at present, the use of this identifier has not been fully determined and therefore, this project will use instances of the GLN instead.
- GRAI – (global returnable asset number) will be used to uniquely identify individual transit objects that are returnable/reusable. An example would be the tote bins often used within wholesale and distribution for the delivery of mixed drug loads to retail and pharmacy outlets.

- GIAI – (global individual asset number) will be used to uniquely identify fixed organisational assets that remain owned by a single organisation – items such as transport vehicles or scanning/reading stations, or leased objects such as fleet cars etc.
- GSRN – (global service relationship number) will be used to uniquely identify organisational relationships such as the identification of a patient within a hospital.
- GDTI – (global document type identifier) will be used to uniquely identify document types where required such as insurance or bond documents.
- NOTE: This work package team acknowledge that there are currently no EPC standards for a GSRN EPC or a GDTI EPC.

2.4.1. Manufacturing

In the manufacturing section we will need numbers to define the items themselves, we will need numbers associated with the packs into which the items are placed, the cartons the packs are placed into, the boxes the cartons are packed in and finally the pallets onto which the boxes are loaded. In addition we will need to identify the facility locations along the supply chain, the vehicles used for transportation of the objects and their transit units, and scanning / reading stations. In general, the manufacturing part of the system can be undertaken using a mix of SGTIN, GLN, GIAI, GRAI and SSCC identifiers.

We acknowledge the work being undertaken within EPCglobal to promote a potential new identifier type, the GSIN which is being promoted as a means to address potential patient privacy concerns. In its current form the GSIN proposal amounts to an SSCC for unit pharmaceutical objects, thus has no embedded indication of the product identity. Whatever the merits/demerits of the GSIN may be, we have elected not to use the GSIN for two basic reasons:

- 1) the GSIN is not currently a ratified identifier type.
- 2) the full specification for the GSIN is not yet available. The GSIN is mentioned here only because it was debated during the review of this work packages earlier submission

2.4.2. Distribution

As organisations grow and combine it is becoming increasingly difficult to draw a clean line of differentiation between the distribution function and the wholesale function in terms of pure logistics. As such, we intend to use the same basic system design for both distribution and wholesale operations and allow ourselves the flexibility to choose the system components that best match the operation of each partner we work with.

2.5. The Carrier Debate

There is much industry discussion about the merits and demerits of the various carrier technologies available today. Specifically bar code or RFID tag.

This project will utilise these two carrier types with possible sub division of each type into a further two different representations.

2.5.1. The Bar Code

The bar code is today the predominant machine readable symbol used throughout the world. GS1 has provided a wealth of standardisation in this area and as such, the GS1 bar code system will be employed by this pilot project.

Bar codes have a number of advantages over RFID tags, however in many cases these advantages can be equally argued as disadvantages compared to RFID. The bottom line is that the carrier technology should be chosen to fit the need. Careful assessment of the business problem to be addressed should always be the first issue. Once this is fully understood, the most appropriate carrier technology can be selected. “Problem first, solution second.”

Where we need to use bar codes within this pilot, we will use predominantly one type, but reserve the ability to use a second should the need occur.

Data Matrix Code

The Data Matrix code is a highly compact ANSI/AIM standard code symbology that has been adopted by GS1 and has the capability of high data density and high data capacity. It can be printed by a variety of printing technologies and has the ability to utilise error-correction technology to ensure that codes remain readable even following a high degree of destruction. In this pilot program, we will use the Data Matrix code extensively and will use it with ECC200 error correction enabled.

The code is capable of being printed at a very small physical size making it ideal for non-obtrusive use on pharmaceutical packaging where the data payload needs to be quite high, yet the available space on the packaging is only very small.

When using the code, we will encode the data using GS1 application identifiers to delineate the various aspects of the encoded data. We will not use the Data Matrix code to encode the EPC number in the same way that it would be encoded within a tag.



A sample Data Matrix Code



The same code more realistically sized

Data Matrix is recommended by EFPIA; it has also been selected by the IFAH (International Federation of Animal Health) for its global roll-out of a traceability system for animal health products.

GS1-128

Unlikely to be employed but mentioned here in case it is required as the carrier for the SSCC codes on pallets etc. The GS1-128 (better known as the EAN/UCC 128 code) is a linear code symbology that allows the encapsulation of multiple data elements and uses the GS1 application identifiers mentioned above to define the data elements within. The code is in widespread use within logistics operations worldwide.

2.5.2. The RFID Tag

The RFID tag has a huge potential appeal for transforming logistics operations and processes of organisations worldwide. While RFID has been around for many years, as with all technologies, the technology within some forms of packaging is still evolving. This is both a curse and a blessing. On one hand the technology offers some fantastic opportunities today and given that it has more development potential, is likely to offer more opportunities later. On the other hand, when technology is still at a developing stage (albeit developing at a pace), the decision criteria regarding adoption is often confused and potentially risky. However there are still some technical challenges at certain frequencies to overcome when attempting to use RFID at the item level. These include (at some frequencies) 100% readability and reliable read range control. These challenges will be overcome and are not strong enough reasons to ignore the potential that RFID can offer.

One potential disadvantage however with RFID at the item level is in fact the biggest advantage of RFID when used with higher order packaging levels, namely the ability to read the device in a non-line of sight manner. Current concerns, especially with high value goods or high sensitivity items such as pharmaceuticals revolve around the areas of privacy and potential targeted theft. The privacy argument is that with RFID at the unit item level, it would be possible to read the device from the outside of a shopping bag or coat pocket to reveal the product being carried. This way it would be possible to discover the medicinal product being carried by a person without their knowledge or consent. The targeted theft argument is that thieves would be able to scan packages to determine the actual content and then only steal the ones with a high enough value. Both of these arguments have hypothetical merit in terms of pharmaceuticals.

We will adopt the use of the SGTIN at the item level and if the GSIN is ever ratified and becomes a US requirement we will consider the use of the GSIN at a later phase of the project after GS1/EPCglobal has fully specified its use. The scope of this pilot is such that the issues of privacy or targeted theft are unlikely to become a factor. We do however note the potential and hope that RFID technology can be developed sufficiently fast that these issues can be overcome at a hardware (tag) design level rather than having to utilise a new identifier scheme that will lose some of the advantages sought by logistics and healthcare manufacturers/users.

We will use RFID technology that is most appropriate to the task. In essence this will involve the use of two frequency ranges which RFID passive tags are permitted to operate in.

UHF Tags 860MHz to 960MHz Frequency Range

The UHF 860MHz - 960MHz frequency range for passive tag applications is the first frequency range for which EPCglobal has defined standards covering the whole system application and enabling complete interoperability and open systems throughout the operation. The EPCglobal UHF Class 1 Gen2 standards, published by EPCglobal are therefore inherently tailored around 860MHz to 960MHz UHF passive tags. However in terms of packaging, the UHF tag is the 'new kid on the street'.

UHF has a generally longer read range and a higher data rate than HF tag technology. This is generally an advantage however this is, as always, application specific (as the longer read range can be disadvantageous when reviewing item level tagging issues). A UHF tag placed on a pallet can be read in a non line of sight manner over several metres (note, the tag cannot be read in all orientations easily depending on its antenna design and that of the antennae associated with the reader equipment) and its abilities are greatly dependent on the structure and material of the object to which the tag is attached and environment in which it is operating. Due to the high frequency of operation, the rate at which data can be extracted or sent is also, theoretically high. However, UHF tags have some disadvantages.

They do not work well in native form when placed against items with a high electrical conductivity, – such as metal stillages, items packed in foil wrappers or indeed damp or wet surfaces where the ‘wetness’ is a conductive liquid such as water. The common factor being the electrical conductivity of the material against which the tag is being placed. Some plastics also show the same issues. This is because the electrically conductive substance attenuates the radiated electric field from the tag in such a way as to result in destructive interference of the radiated waves. How much of an issue is caused depends on many factors, including the electrical conductivity of the surface and the proximity of the tag to the electrically conductive material (often an air gap between the two can make a big difference) It is however now possible to design a tag that mitigates these effects and that does not require a specialised antenna design for different product designs. A further disadvantage in some territories is that UHF tag based systems have to employ a ‘listen before talk’ system to overcome limitations on the bandwidth legally available for use.

During our program we will assess the effect of using some of these RFID tag constructions when used in conjunction with either high water content product or high metal content packaging, such as blistered tablets. It is likely that use of UHF tags in this environment will require the use of ‘near-field’ UHF tags which have a very small, single turn antenna and result in a very small, low RF propagation distance tag potentially suitable for use within caps/lids of pharmaceutical product. This project, at least within phase 1 however, will only utilise RF tag technology when applied at the item level, in conjunction with the pack outer (e.g. pack of two blisters etc).

HF 13.56MHz Tags

HF tags do not suffer to the same degree from the same physical affects of packaging and environment that native UHF tags do. The longer wavelength makes them easier to use and are generally less affected by environmental factors such as the reflection and absorption of the RF energy They do however have a generally much shorter read range than comparable UHF tags (as they work on induced magnetic field, not propagated electric field). However they have been in use with packaging for a longer period than UHF tags and therefore represent a longer established technology. (not necessarily a better technology, just more established)

EPCglobal have recognised the importance of this frequency to industry in addition to the UHF frequency discussed above, and in response to this, are now developing standards for HF based on current existing HF ISO standards (to be termed Rev 2), to provide the same level of interoperability and open standards that now exist for passive 860MHz to 960MHz UHF applications.

HF demonstrates a number of advantageous characteristics, namely:

- i) a relatively short read distance (potentially good for reasons of operational control and security management),
- ii) it is an established technology with numerous formats (including very small formats) and applications,
- iii) there are existing global standards (ISO 18000-6A/B) for the areas around the tag – reader interface – however this could also be cited as a disadvantage given that currently these are incompatible with EPC Gen 2,
- iv) equipment is widely available at relatively low cost,
- v) radio fields created are generally easier to control and define than those of higher frequency,
- vi) the effects of reflection and absorption etc., tend to be less pronounced than those of higher frequency and consequently, aqueous solutions, metallic environments etc. have less effect and applications.

There are however a number of potentially negative characteristics namely:

- i) the short read range results in an inability for the technology to operate in situations when for instance, portal readers covering the area of a dock door are required.
- ii) a degree of line of sight is required for reading and issues can be experienced reading some tags in situations such as one tag being placed on top of another
- iii) Global standards exist around tag and reader but are lacking across the whole potential application (hence the EPCglobal focus on producing Rev 2 standards to enable this).

3. Solution Requirements

3.1. Manufacturing Environment

3.1.1. Scope

Essentially, the manufacturing environment is where the track and trace capability begins. If it were not possible to apply unique identification to product at this stage, the track and trace system that we want to trial simply would not work. In order to provide the key benefits that we seek, the top level benefit being increased patient safety (ref deliverable 6.1) it is essential that the unique EPC number is applied to the product at the point of manufacture and at the exact point at which it comes into existence as an object – the point at which it is under tightest control and can be 100% understood to be the authentic product.

It is impractical however to expect the forward supply chain to read every single unit item that passes through the various level of distribution and wholesale control. Except where the product is picked for delivery to end use pharmacies, in general the product will flow through the supply chain packed as pallets and cases. Therefore what is essential is to ensure that during the packaging processes within manufacturing, we provide a system that can accurately aggregate and associate unit item unique ID's into the packs they are packed in, the cases and pallet they are shipped in. It is essential that the tracking system knows which items are contained within any given shipping unit. It is also essential, given that we may read the item level tags and codes as infrequently as the points where they items have been disaggregated, that each carton has a form of tamper evident seal associated with it to provide a visible indication of interference. (It should be noted that the intention of the project is to read the item level tags/codes more frequently than this, ideally a minimum of one per custodian change, however we are cognisant of the potential issues surrounding the accurate mass reading of item level tags within cartons and on pallets) We are also intended to build in other security measures to help combat this potential deficiency.

The manufacturing facilities we employ will vary from raw product manufacture (capsule and powder antibiotic manufacture) through to the contract packing required for blister packing a variety of other partner's product. The IV fluid partner we seek (but not yet found) will be involved only at a case level and not the unit of use. This decision has been made to prevent an undesirable level of 'scope creep' occurring at this stage while being able to provide further benefit to the pharmacy.

3.1.2. Detail

The diagram and description below will use the expression ‘coding’ to mean the application of either a bar code containing a suitable EPC identifier or an RFID tag containing a suitable EPC identifier.

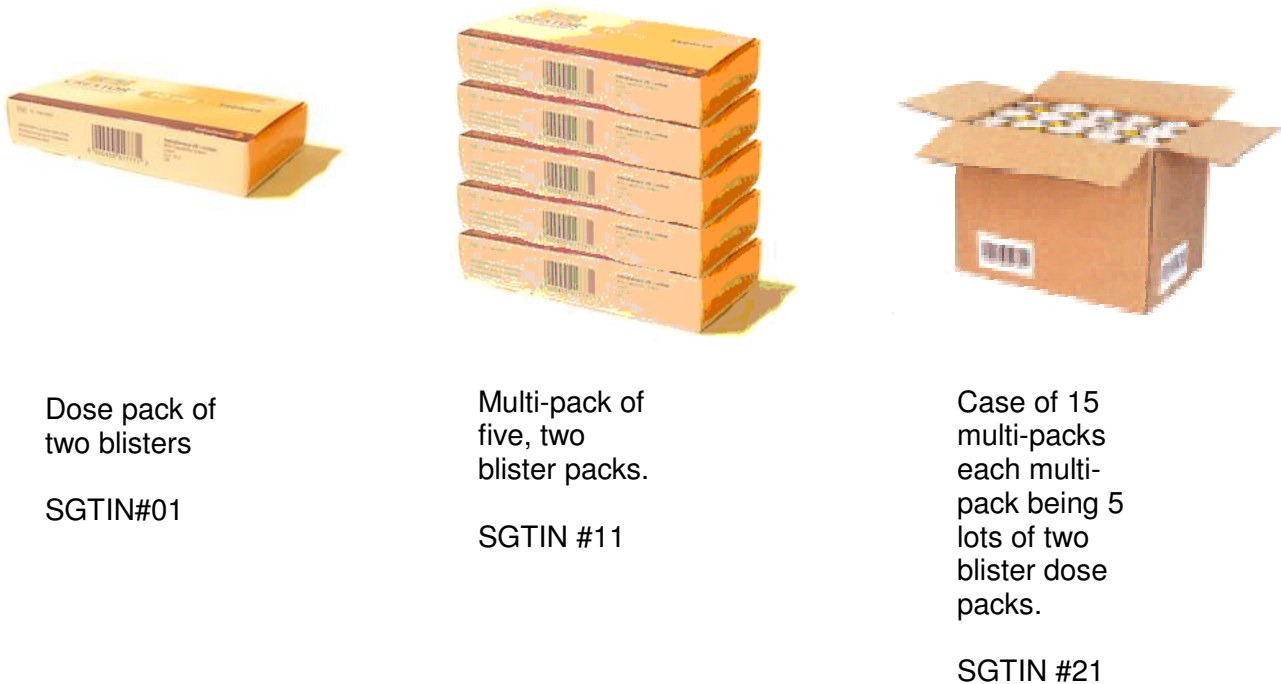
The key issues for the manufacturing environment are:

- a) Serial number management
- b) Accurate aggregation and association of product manufactured.

Clearly there are issues surrounding the secure transfer of data and user/operator access to the numbering and aggregation system, however we believe these to be straightforward issues to resolve whereas the numbering and aggregation are critical to system operation and performance.

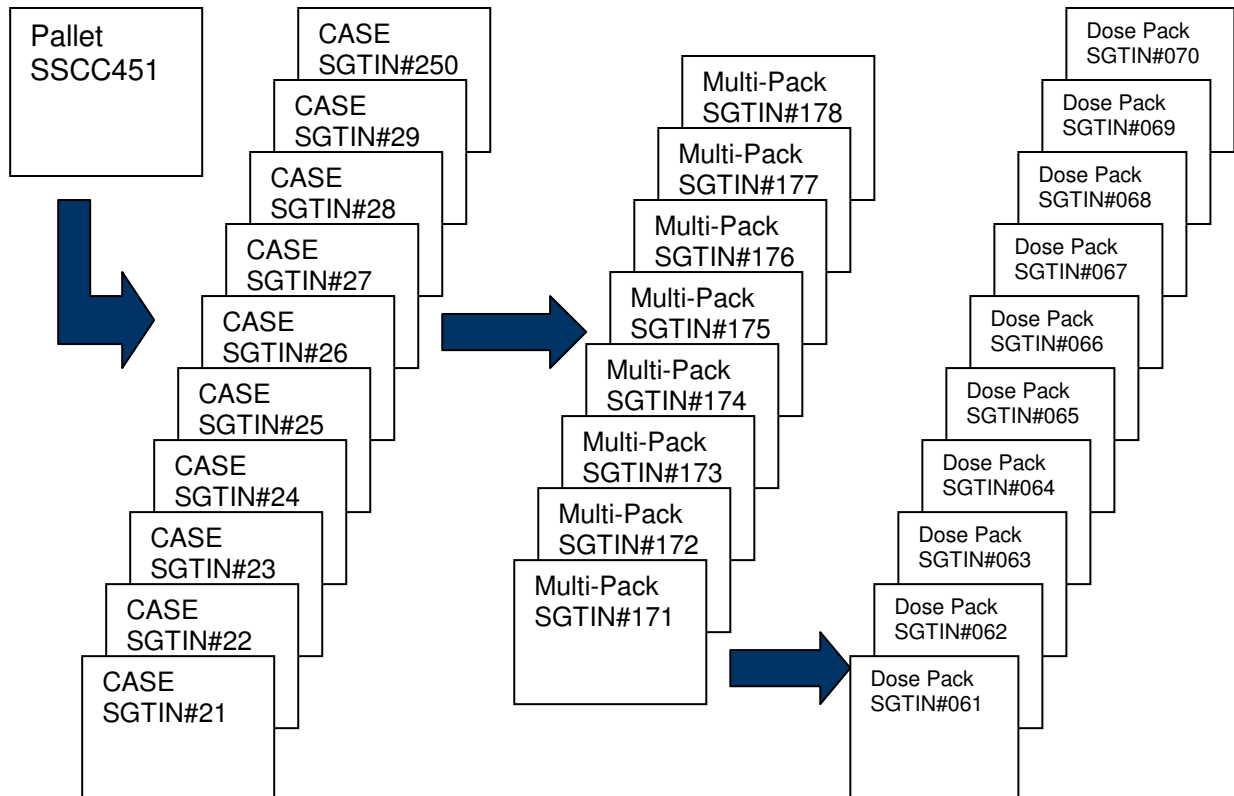
The systems that we install as part of this pilot program will be as non-invasive to the current manufacturing process employed by our partners as is practically possible. It is not our intent to add unnecessary risk to the manufacturing operation by the addition of unreliable or process critical systems. It is also a pilot program and therefore imperative that we install systems that allow the partners manufacturing process to proceed at normal operating speeds and throughput. We do not, unless absolutely necessary, want to rely on sub-optimal performance of the manufacturing facilities in order to provide the coded product our pilot requires.

The following diagram explains the concept of aggregation.



Cases are then formed onto a pallet which will be given a unique SSCC code. Thus, knowing a specific dose pack SGTIN would allow the system to readily identify the pallet on

which that dose pack is contained and also, given a specific pallet SSCC, the reverse operation would be possible, to identify all the individual dose pack SGTIN's contained within it. Thus if an item range is found to have goods that need to be recalled, it is possible to determine exactly which pallets, case and multi-packs are affected, and thus target the recall process very precisely. As will be demonstrated, the system will also be able to identify the exact location of any given package ID to make the concept of recalls not only highly precise in nature, but also extremely thorough, less costly and less invasive/worrisome to the customers.



By way of example only, we can see from the partial view of goods packed on this pallet above that reference to:

- Pallet EPC ID SSCC451 will reveal fifty Case EPC ID's (SGTIN#21 thru SGTIN#250).
- Anyone of those fifty case ID's will reveal a further eight Multi-Pack EPC ID's (in our example, case EPC ID SGTIN#27 has revealed Multi-Pack EPC ID's SGTIN#171 thru SGTIN#178).
- Each Multi-Pack will reveal the presence of ten Dose Packs (in this example, Multi-Pack SGTIN#171 has revealed that it contains the ten Dose Packs, SGTIN#061 thru SGTIN#070 inc.)

Thus it is a simple process, knowing the higher order packaging ID to display the precise ID's of every unit item and outer packaging unit contained within it. The pallet in our example when interrogated will return fifty cases, each case will return eight multi-packs and each multi-pack will return ten dose packs. Thus in this example there are 4000 (50 x 8 x 10) uniquely coded dose packs on each pallet.

This process of precise aggregation and later in the distribution and wholesale section, de-aggregation and re-aggregation is critical to understanding how a serialised supply chain can

be expected to function. When a pallet of product such as the example is despatched, we do not expect the despatch unit or receiving transport vehicle to scan and confirm 4000 individual unit dose packs. We expect them to confirm despatch/receipt of one pallet. The system will tell us what is on that pallet.

With the manufacturing system, although the despatch unit will scan one pallet and despatch one pallet, the manufacturing system will have already placed the aggregated items/multi-packs and cases into 'containers' that the pallet ID will reference. At the point of shipping, the manufacturing system will inform the information service that these items are now 'live' and will post them to the manufacturing EPCIS. Until this point, none of the product that is held in stock by the manufacturer is available to the 'outside world' or EPCglobal network for inspection. The EPCglobal Network has no knowledge of the existence of any EPC's that it has not been 'informed' of. Thus, if an EPC number goes live at this point and some unscrupulous organisation has guessed the EPC numbers for product belonging to this manufacturer and already (somehow) managed to insert them into their EPCIS instance that was receiving their aggregated EPC data, an external application running at a security centre and taking a feed from a discovery service (and if required ONS where cross discovery service interaction is required) can be configured to provide an instant alert to warn of the potential duplication and a stop placed on all potentially rogue product. This is one reason why the management of the unique ID's is so critical. The scope of this project will include some of the concepts surrounding automated duplicate detection.

The system to collect data and provide the aggregated output will only function correctly if the products (items, cases, pallets etc.) are marked/coded with suitably unique codes. This project will use a mix of RFID and bar code technology, therefore the manufacturing system will need to have the ability to provide unique identification data, in the form of EPC's, to the various coding devices.

The aggregation system will therefore be enhanced to enable items or cases to be dual coded where required allowing us to examine and understand the relative benefits of the printed code versus the RFID tag and how these benefits weave into the cost implications for industry.

One of the critical aspects of the coding system will be the generation of the unique serial numbers. The aggregation system should be capable of catching and rejecting duplicate id's and potential rogue reads (ref phantom RFID reading issues – further reading available from many of the tag and tag reader manufacturers. However in short, it is possible for reading equipment to 'apparently' read a tag that simply is not), however it is critical that any system used to apply unique identification to product is supplied with unique data in the first place. There are many ways to provide such unique data. In the main these split into two methods

- a) the provision of sequential id's from a maintained list – guaranteed to provide a unique output but has the side effect of code predictability.
- b) the provision of a random id. Requires extra processing before issue to ensure uniqueness but decreases the likelihood of detecting a series or number pattern for the coded product. Random id's can be either pseudo random (generated by some mathematical algorithm) or truly random which requires some hardware to generate the randomised number 'root' initially.

For this trial we will utilise a combination of both sequential and pseudo random numbers to provide the easy of use of a sequential number with the added robustness of a pseudo random number.

The numbering scheme we will adopt will pre-allocate a series (range) of sequential numbers to a manufacturing facility or line. These will be appended with a pseudo random element which will then be further enhanced by the addition of a CRC or checksum. It is accepted that the number used could be simply encrypted using a private CRC algorithm known only to the manufacturer. This would allow (as would the system we are intending to adopt)

trusted affiliates of the manufacturer who either know the algorithm or have been issued with equipment that knows the algorithm, to undertake in field 'plausibility' checking of the product. We are not advocating this as a replacement for full network integration and 'proper' authentication of the product, however it could provide a very quick means to at least verify the 'likelihood' of the product being genuine.

It should also be noted that where product is marked using a code, be that in addition to a tag or instead of a tag, the code will also include the batch/lot number and product expiry date. This has been requested by our industry partners to allow extra benefit to be derived from the system, especially in the earlier period of adoption where dynamic product look-up using the network (to verify the batch/expiry) will not be readily available.

3.1.3. Requirements

The following table details the basic requirements needed within the manufacturing facilities in order that this pilot program can operate.

Requirement Number	Description	Priority
MAN-001	The system shall use EPC numbers	
MAN-002	The system shall provide a means to manage the EPC numbers used	
MAN-003	The system shall use appropriate GS1 identifiers	
MAN-004	The system shall use appropriate, AI based constructs within the printed codes.	
MAN-005	The system shall aggregate all items into higher order packaging as dictated by the manufacturing process.	
MAN-006	The aggregation system shall provide the 'manifest' for any packaging level requested and be able to produce the 'manifest' to item level regardless of packaging hierarchy. (Manifest could be substituted by BOM, Bill of Materials)	
MAN-007	The system shall date and time stamp all item records.	
MAN-008	The system shall interface with line based equipment designed to read/program the RFID tag technology selected.	
MAN-009	The system shall interface with bar code reading equipment	
MAN-010	The system shall interface with bar code and human readable code marking equipment as required (anticipated to be a mix of laser, inkjet and thermal transfer technology)	
MAN-011	The system shall provide local capability to review and administer aggregation records	
MAN-012	The system shall provide capability to scan and release items for transit	
MAN-013	The system shall interface with a hosted EPCIS based at Verisign	
MAN-014	The system shall be designed such that it provides a minimal impact on existing ICT infrastructure at the manufacturing/packing facility	
MAN-015	The system shall be able to operate within facilities without detrimentally affecting production throughput. The system therefore will not operate at reduced production speeds just to enable this trial.	
MAN-016	The system shall provide the ability to re-work packaging stages (to allow for the removal of QA samples and to allow for manual re-packing before despatch)	
MAN-017	The system shall be capable of using both bar code and RFID tag information at any packaging level and storing these records in such a manner that the tag and bar code data is clearly linked together.	
MAN-018	The system shall allow for the inclusion of part filled cases and pallets.	
MAN-019	The system shall not be restricted with respect to item numbers per parent container.	
MAN-020	The system shall provide clear, unambiguous alerting	

Requirement Number	Description	Priority
	when goods readied for despatch are found to have EPC numbers that are already known to the discovery service (indicating a host of potential problems!)	
MAN-021	The system shall use unique identification in the form of a GLN for the location of the manufacturing facilities.	
MAN-022	The system shall enable the manufacturer to view traceability information for their own product(s) as they transit down the chain as far as supply chain privacy rules allow.	
MAN-023	Provide a means of tamper evidence to use packed carton	

3.2. Distribution and Wholesale Environment

3.2.1. Scope

The distribution and wholesale environment have been pulled together under one section because, so far at least, the implications on system requirements appear very similar. The aim here is to provide a functional solution that will allow product to be confirmed as received and later, confirm as despatched, regardless of what occurs to the packaged item while in the possession of the distributor/wholesaler.

3.2.2. Detail

The distribution and wholesale environment provides potentially the most challenging environment for this project team. The partners for this section of the trial have differing IT systems and thus different requirements in terms of overall integration. To overcome these issues and to prevent the need to make our pilot program too invasive to the various distribution and wholesale partners business, we will adopt a scheme that is essentially portable and is able to operate in parallel with the existing IT systems used by the partners. Our system will be able to provide reports showing item receipt and despatch and thus overall item movement. The system will require the double entry of some vital information such as supplier/customer details, shipping methods etc. However we will aim to keep this to an absolute minimum to reduce the overall potential for human error (which is often an issue when entering duplicated information).

We envisage a trolley mounted or a rucksack mounted reader system being used at both the goods inwards section and also the goods despatch section. For this trial we will not be monitoring item movement within a facility, this will remain the function of any existing WMS (Warehouse Management System) currently employed by our partners. Where possible, the portable system will be connected to a local internet connection. Where such a connection is not possible, we will employ a mobile internet link.

Each partner will have access, via suitable security means, to an EPCIS instance. Each partner will have access to a portable software system that will be able to receive items from suppliers and ship items to customers. The system will be able to provide new numeric designations for any new packing items used in the process (e.g. totes and SKU's) The system will handle both processes of de-aggregation and re-aggregation as items are removed from original manufacturer shipping cartons and re-packed into new, customer specific carriers. This practice is anticipated to occur primarily within the wholesale area. This is an ideal point in the process for any tamper evident seals applied to the cartons and cases to be visually checked for integrity

Rules will be defined to describe the system behaviour when items are unpacked from larger shipping entities. For example, when a case of ten packs of tablets is removed from a pallet of 100 cases, the system within the distribution/wholesaler will 'know', because the IT associated with the aggregation and dis-aggregation processed will be configured to observe all aggregation events, that the original pallet of 100 cases is now a split pallet and record that the pallet id provided is no longer valid as the pallet integrity has been removed. Thus a subsequent attempt to ship the remains of the pallet using the same SSCC code will cause an alert within the distribution/wholesale system and thus prevent shipment. The pallet will need to be re-coded or re-authenticated prior to shipment.

3.3. Requirements

Requirement Number	Description	Priority
D&W-001	The system shall use EPC numbers	
D&W-002	The system shall be capable of reading either, or both, bar code and RFID data carriers as appropriate.	
D&W-003	The system shall, where required for de-aggregation and re-aggregation purposes, provide a means to manage the forming and generation of new EPC numbers	
D&W-004	The system shall provide a means of inspection, to the item level, any product that is within the distributor/wholesale possession, using the EPC number associated with any given package.	
D&W-005	The system shall provide a means to display product currently held using EPC numbers.	
D&W-006	The system shall be able to provide reports to indicate product received.	
D&W-007	The system shall be able to provide reports to indicate product shipped.	
D&W-008	The system shall be able to provide information for use by the next trading partner to assist with order reconciliation.	
D&W-009	The system shall be able to capture ASN (Advance Shipping Notice) information and use this to pre-emptively download expected product receipt information to streamline the goods in process	
D&W-010	The system shall provide means to scan product at receipt	
D&W-011	The system shall provide means to scan product at despatch.	
D&W-012	The system shall operate in such a manner that it is, for this trial, independent of existing partner ICT infrastructure.	
D&W-013	The system shall be configured to be portable wherever possible.	
D&W-014	The system shall interface equipment designed to read and if required, program the RFID tag technology selected.	
D&W-015	The system shall interface with bar code reading equipment	
D&W-016	The system shall interface with bar code and human readable code marking equipment as required (anticipated to be primarily desktop thermal transfer technology)	
D&W-017	The system shall interface with a hosted EPCIS based at Verisign	
D&W-018	The system shall be able to operate within facilities without adversely affecting distribution throughput where possible. It is accepted that this may not be entirely possible without integration with the partners ICT system.	
D&W-019	The system shall provide the ability to re-work packaging stages (to allow for the removal of QA	

Requirement Number	Description	Priority
	samples and to allow for manual re-packing before despatch)	
D&W-020	The system shall be capable of using both bar code and RFID tag information at any packaging level and storing these records in such a manner that the tag and bar code data is clearly linked together.	
D&W-021	The system shall allow for the inclusion of part filled cases and pallets.	
D&W-022	The system shall not be restricted with respect to item numbers per parent container.	
D&W-023	The system shall provide clear, unambiguous alerting when goods that cannot be authenticated or that do not have a reconcilable pedigree are either received or readied for despatch.	
D&W-024	The system shall use unique identification in the form of a GLN for the location of the logistics facilities.	
D&W-025	The system shall enable the logistics provider to view traceability information for their own product(s) as they transit down the chain as far as supply chain privacy rules allow.	
D&W-026	Ensure that stages are provided where the tamper evident seals are checked and confirmed as intact.	

The system will initially rely on each participating party being issued with a ‘participant ID’ (Manager Number). For the pilot we will only be issuing manager numbers to licensed participants, however this is an area of future system enhancement where the manager numbers are validated against correctly licensed participants.

If required, this ‘Distribution/Wholesale’ model will be used to accommodate the use of NHS (National Health Service in the UK) repackaging points which serve hospitals / wards in hospitals as these also require the ability to receive product, have product broken down and re-packaged, and re-deliver product.

3.4. Pharmacy Environment

3.4.1. Scope

This pilot currently terminates its scope at the hospital pharmacy. Once the items have been delivered to the pharmacy and our system has confirmed their receipt, our data collection essentially completes. The intended phase 2 of the pilot program (to be defined at a later stage) will extend the data capture from the pharmacy receipt point through to ward level and ultimately to the point of patient administration. However, there are a number of features that the system, even in this sub-optimal state of completeness, can provide that is of great value to the pharmacy.

3.4.2. Detail

The system will be able to indicate, in real-time that the product just received is from an authentic source and that the product has an acceptable trail of provenance (i.e. Pedigree). Simply knowing that the drug was made by an authentic manufacturer and has been transported through the supply chain intact and passed through licensed providers en route, allows the Pharmacist to know that the product is authentic.

The system will be able to generate exception alerts and reports if any of the products received do not have an acceptable trail of provenance or cannot be regarded as authentic. With the added benefit of tamper evident seals on cases and cartons that have not been broken down to item level, the overall system should provide a high degree of confidence that the items in hand are the genuine product. The system will also be able to generate post delivery alerts should the EPC number on a product already received be discovered again in the supply chain without a trail to show it being returned from the Pharmacy. This will protect against bulk duplication of drug packaging.

During this trial we will deliberately insert safe medication bearing duplicate EPC numbers to test the system ability to provide means to alert potential users of the product and longer term, the licensing authorities. Great care will be needed to ensure that we do not provide alerts where no problem exists (false positives) as well as ensuring that there is little to no possibility to practically insert counterfeit or duplicated product without an alert being generated. We will also test the insertion of safe medications in the incorrect tote or case to allow for a 'system' level check of incoming tote contents and to ensure that in the event where a tamper evident seal has been carefully compromised, the incorrect contents of the tote would still provide evidence of an issue requiring investigation.

3.4.3. Requirements

Requirement Number	Description	Priority
PHA-001	The system shall use EPC numbers	1
PHA-002	The system shall operate independently of any existing hospital IT system	1
PHA-003	They system shall provide item level and case level authentication of product entering the pharmacy stores.	1
PHA-004	The system shall cause a system alert, prominent enough for an operator to easily recognise, when a drug product is scanned that cannot be authenticated or does not have a complete reconciled pedigree.	1
PHA-005	The system shall allow recalled product to be identified	2

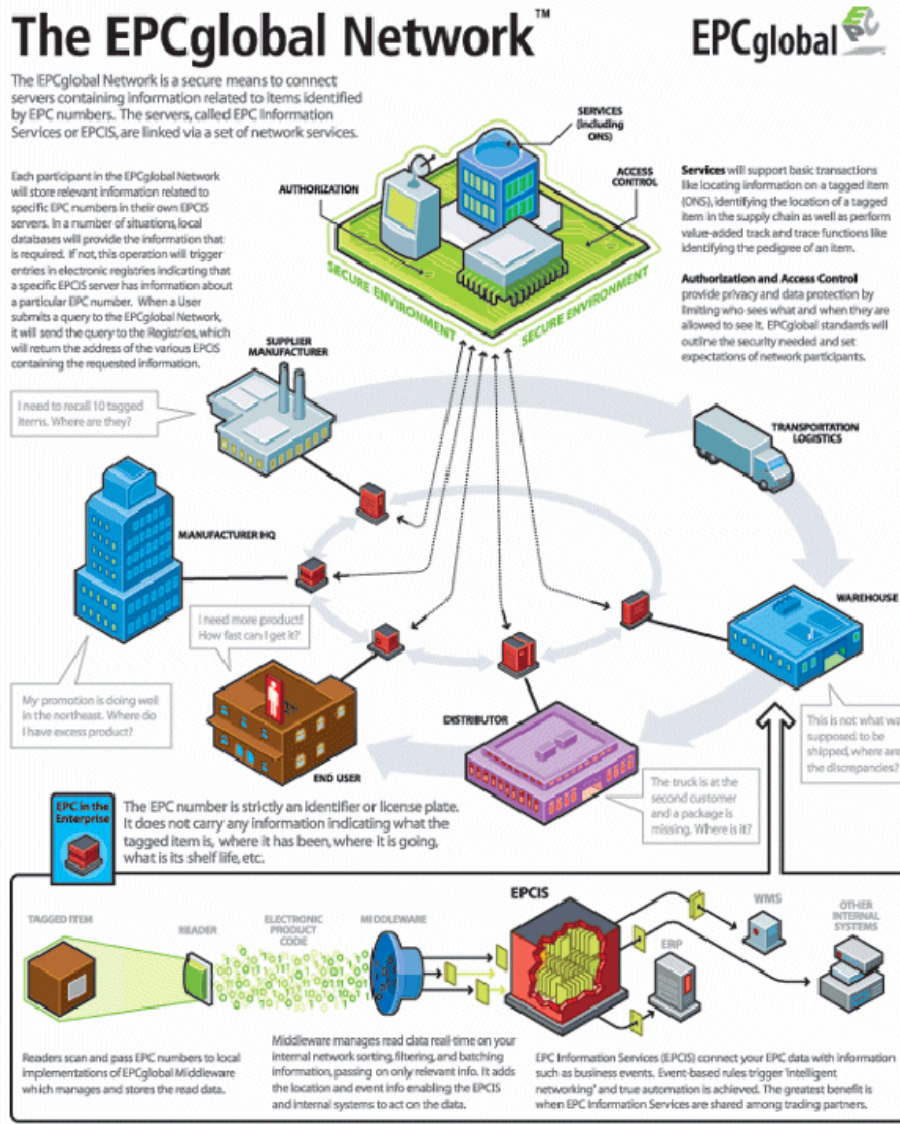
Requirement Number	Description	Priority
	immediately as soon as the items are scanned in	
PHA-006	The system shall allow hospital to more easily reconcile order placed with goods received	3
PHA-007	The system shall provide reports regarding goods received.	1
PHA-008	The system shall (assuming the order information can be easily integrated) provide reports regarding order fulfilment and order shortages	3
PHA-009	The system shall provide a means for the pharmacist to easily report any suspicious packaging	3
PHA-010	The system shall use appropriate EPC identifiers to identify the pharmacy location, internal pharmacy storage/distribution locations and any other critical nodal points where event based activity data will need to be collected.	
PHA-011	Ensure that stages are provided where the tamper evident seals are checked and confirmed as intact.	

3.5. Infrastructure Requirements

A critical aspect of the tracking system that this project discusses and utilises is the availability of the ICT infrastructure to enable the product event data to be managed.

The EPCglobal network, currently is the basic network infrastructure used by this program. For this project we will be using EPCIS, discovery services and potentially ONS provided by Verisign. It is not essential that this implementation be used, however currently this system represents one of the most developed infrastructure we have available today. It is also an infrastructure that certain partners within this program have used to great effect in the past.

The EPCglobal Network follows a distributed model. At each point of data interaction (goods movement) there is a local event database, an EPCIS. The security of each EPCIS is the responsibility of the owner, however the essential security layers have been encapsulated by design in the implementation used by this pilot program. The Verisign implementation that we will use will be a hosted model (the EPCIS instances will be held by Verisign not the trading partners)



Each EPCIS instance will record the event data appropriate to the part of the supply chain that it affects. For example, the manufacturer's EPCIS will contain the static product data as well as the dynamic EPC data associated with each product item. This is the only place within the network where the actual product data will be stored. Thus, access to the product information is under the control of the manufacturer.

As an extension to this, the contract packer will be viewed as an 'outpost' from the manufacturer. The contract packer will in essence be an outsourced supply point for the manufacturer's product and thus will be represented as a node in the supply route for the product as a 'pseudo-manufacturer'

The system we will adopt for this trial will be a hosted model using the Verisign infrastructure. Each trading partner will be provided with an EPCIS at an offsite location by Verisign. The software systems used at each trading partner location will be provided by the WP6 team where this was an agreed element of the initial deliverable. Where extra partners have been included or extra scope added, the costs will be borne by other means.

Each software system will employ suitable security means to ensure that only valid connections are made to each EPCIS and that only data reflecting real item movements is provided to the EPCIS system.

Verisign will provide the necessary ONS, discovery services and information services. These will be used extensively by both the software systems employed at each partner location for item movements and also by the various application modules, described later, that utilise the item movement data to provide the system value sought by this pilot.

3.6. Availability

The system will be available via secure link over the internet. The system design will be such that should the system be unavailable at any time, data will be buffered, correctly time/date stamped and sent to the system when a connection is available. This will be particularly useful with the portable systems used by the distribution and wholesale partners.

We believe it to be impractical to conduct system based item lookups in real time as product is received from a supplier. Therefore, we intend to test this theory by using both a real time item look up system as well as a system design that will rely on knowledge of the anticipated deliverable ahead of physical receipt. This will allow us an opportunity to pre-download information with which we can verify and authenticate an item movement event without needing to rely on an active and responsive uplink to the EPCIS or discovery service.

Availability is required 24x7 to ensure that the system does not provide a means to adversely affect operations at any point. However, the aspect defined above where pre-delivery knowledge is required will be employed not only to speed system response but also to provide a buffer to design for potential system availability issues. In the event that the system is unavailable or the buffering provided does not allow for the goods to be inspected, a quarantine process will be employed. The nature and function of this quarantine process will be identified during the process mapping phases of the project.

3.7. Security

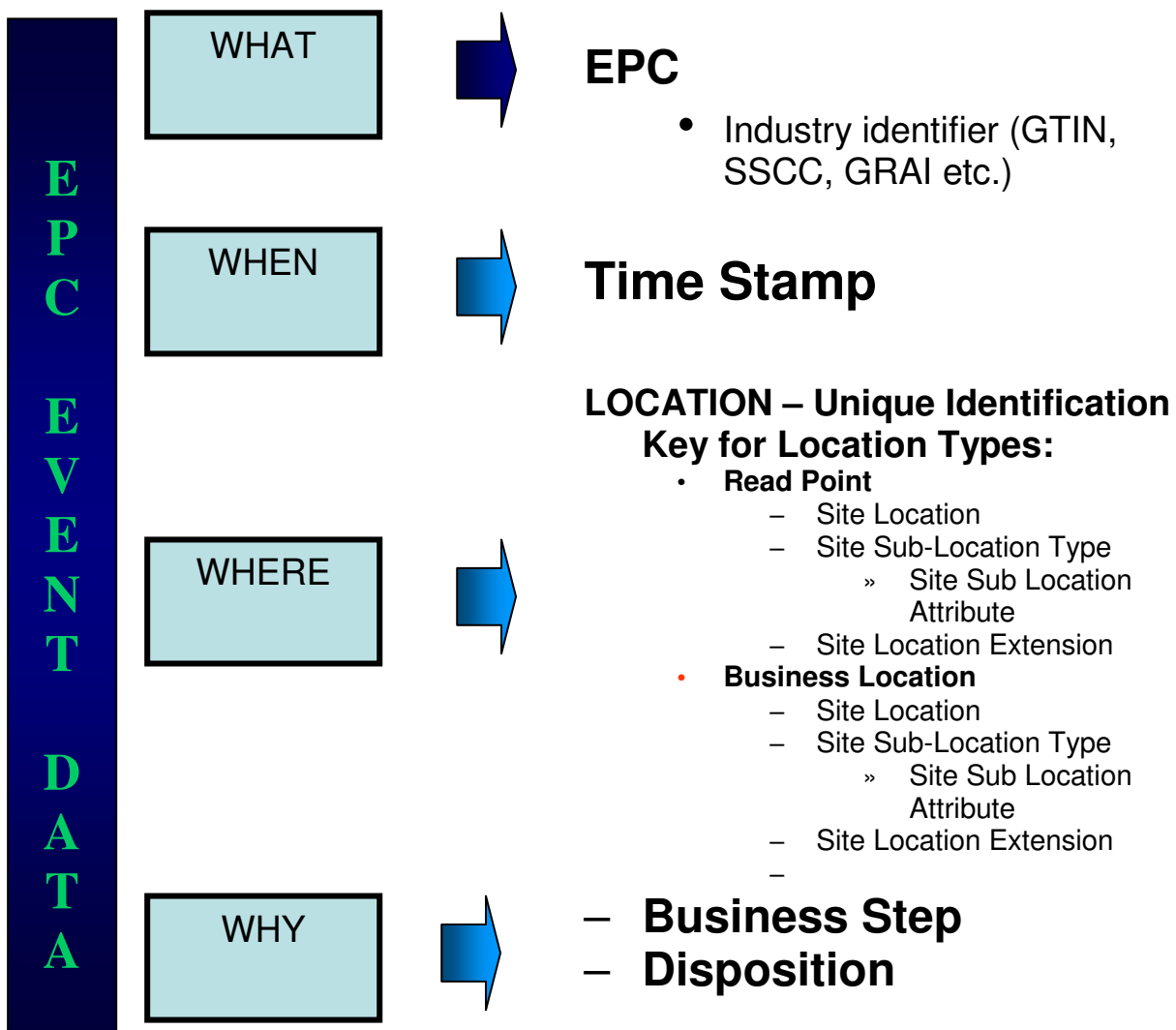
The security associated with the overall system design is critical to the long term success of a globally available infrastructure such as the EPCglobal Network. This work package will employ a basic security system to avoid use of the system by unauthorised individuals. Because of the closed nature of the trial, it is not our intention to introduce a level of security

'overkill'. For a full system implementation with many involved partners, we accept that the security of the system will have to be tighter and at the same time, more flexible than the system we will employ. We will employ a username/password scenario in order to gain access to either an EPCIS or the discovery services/ONS. Each transaction will be logged together with the user id of the person/system undertaking the activity. Thus it will be possible to audit not only the movement of individual EPC numbers (items) but also to audit the activity of each user/system that interacts with either an EPCIS. We will attempt to build in additional security measures (such as digital signing of recorded events and holding the digital certificates in escrow) to provide means of authenticating the EPCIS contents for accuracy (and alteration) or to provide a means whereby the EPCIS contents are manipulated on a WORM basis (Write Once, Read Many) thus providing an explicit means of detecting potential EPCIS tampering.

3.8. The Data

3.8.1. What Data Constitutes an Event?

To best define this we refer to work currently being undertaken by the EPCglobal HLS Track and Trace work group. They recently published (Dusseldorf JAG Meeting September 2006) a slide that clearly demonstrates the basics of an item movement event.



What is described by this diagram is the need to have four basic information elements transferred and thus recorded during an item movement event. These are described as WHAT, WHEN, WHERE, WHY. The diagram is reasonably self-evident however each of these basic information elements can be described as follows:

- WHAT – here we are referring to a specific unique ID on a product item. An EPC.
- WHEN – is an explicit time and date stamp using a standardised form denoting the year month and day of the event together with the time in hours, minutes and seconds plus a time zone offset value to enable globally synchronised timing events (referenced to GMT)
- WHERE – is the site location of the object at the time of the event, which at the highest level is a GLN. However this is taken further with the addition of sub-location ID's to describe where within the site the location is/was e.g. storage yard, stock room etc, further sub-divided with a further location attribute denoting location still further e.g. storage yard – store shed #3
- WHY – a description of the event itself and the item status – e.g. the business step for the event could be 'SHIPPING' the disposition/status of the item could be 'available for sale'.

On reflection of this description, which is currently a work in progress, this work package is considering the additional basic data element of WHERETO to define the forward logistical movement of the product. This is considered to be a valuable addition when applying item movement algorithms to the track and trace data to permit the use of intelligent alerting to further enhance supply chain security and in the specific case of this pilot, provide further substance to the arguments regarding increased patient safety.

3.8.2. Centralised versus Distributed

For the purposes of this pilot, we will adopt a distributed model in line with the EPCglobal network design. However, all of the EPCIS instances will be hosted by Verisign and thus, the whole system will be centralised on a Verisign server/system. This is not the typical method of operation however it does reflect a potential real-life use case scenario where a partner organisation wishes to outsource the IT support requirements for an EPCIS to a 3rd party.

3.8.3. Practical considerations

For this trial one of the main practical considerations for the interface with the EPCglobal Network will be the availability of an internet connection with a bandwidth in excess of 0.5Mbps (broadband would be fine) and an ability to be available on-demand, ideally always-on; however, use of a dial-up or GSM (G3) connection will be acceptable

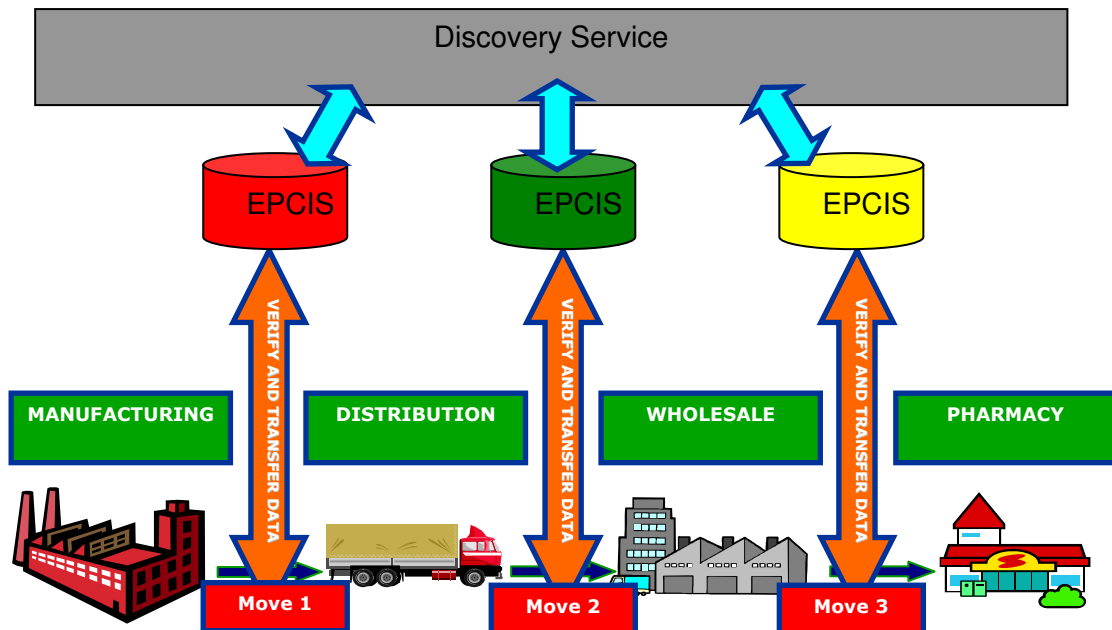
3.9. Application Requirements

The following section outlines key application provision that can be provided using the basic tracking system implementation used under this program. The list of applications provided is not exhaustive and does not represent a list of the applications that will be provided as part of this project. However where we can we will use the data collected by the tracking system to highlight how such applications could be engineered to provide significant extra advantage from a suitably widespread tracking system. They are overviewed below in no particular order.

3.9.1. Counterfeit Surveillance

To understand how this might work it is important to understand that an EPC assigned to a pharmaceutical item only becomes known of when the manufacturer ships the item and publishes the existence of the item to their EPCIS. It is at this point that the manufacturer publishes the EPC numbers to Discovery Service thus making the system ‘aware’ of the new EPC numbers injected into the system.

We will use a hypothetical scenario to describe how a counterfeit surveillance application might work. (In the example, a re-packer is made out to be the ‘bad guy’ – this is no reflection on re-packers in general, this is simply a hypothetical example)



Assume that the manufacturer ships an item with serial number 202. At the point he ships it to his chosen distributor, item 202 becomes ‘live’ within the tracking system. The distributor moves the item in the normal manner and as he receives it and then ships it on to a re-packer, he makes a number of item movement events available to the trading system via his own EPCIS. The re-packer receives the item and he too makes a goods movement event available to his EPCIS. If we now assume that the re-packer has some ‘other product’ that he believes he can pass off as a copy of the item just received from the distributor. Let us assume that he copies the packaging the real item is in, including the EPC number. The item being cloned as the real thing might indeed be a real alternative to the drug being

copied – that’s not the issue. The re-packer now has in stock numerous ‘copies’ and one original of the item received from the distributor. When he ships the first item, he will make a goods movement event available via his EPCIS. As soon as the re-packer ships the second item with the same EPC number, the goods movement event generated will cause an exception to occur. The tracking system knows that an item bearing the EPC number 202 has already been shipped from the re-packer. The tracking system will have the ability to find out where the item was shipped to. It also is easily able to detect the apparently same item being shipped a second time from the same re-packer. This logistical discrepancy can be flagged by the tracking system as a possible item authenticity breach and the system can be programmed to prevent any item with EPC number 202 being verified as genuine – there are too many items bearing the same EPC number in the system for the system to be able to authenticate any of them. The system could then be set up to inform the original product manufacturer or licensing authority of the breach.

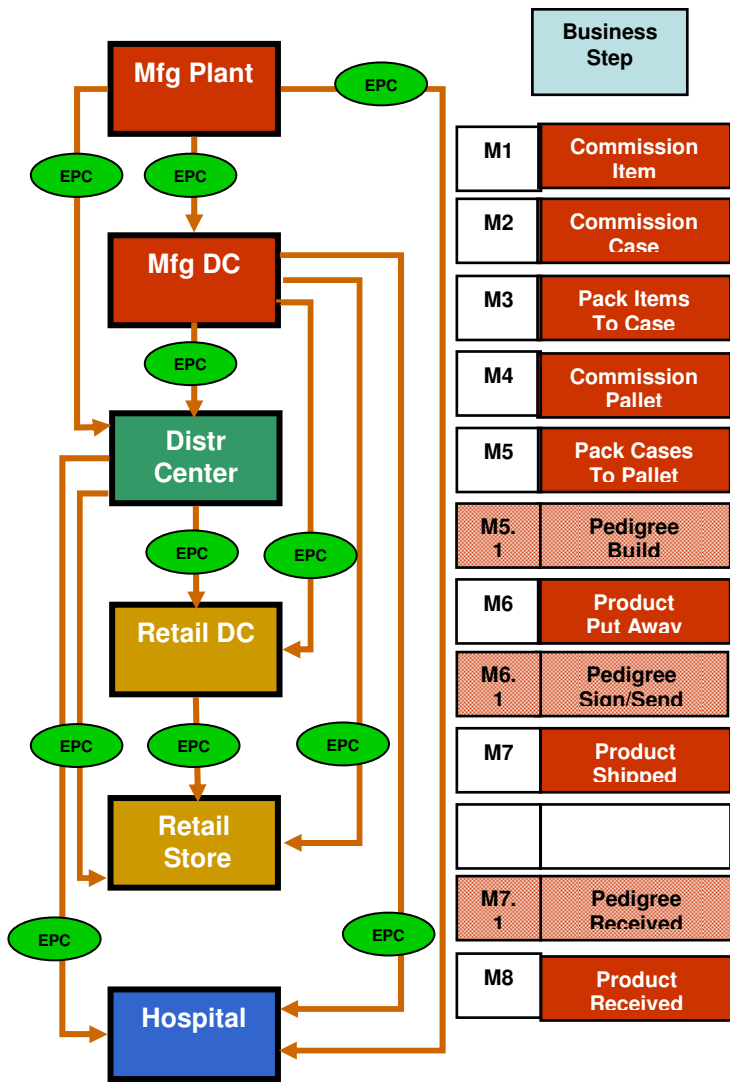
If the re-packer decided to try and ‘outwit’ the system by transferring the stock to an alternate facility without recording the goods movement events, the system would still throw a goods movement exception not however on the second occurrence of the EPC number 202 being shipped, but the first occurrence. This is because the system will be able to ‘tell’ that the item being shipped with EPC number 202 was never received by the organisation shipping it. This can be undertaken by applications working with the system that monitor and observe where goods are scanned and can then determined if the object was being scanned at a point where it should be (geographically speaking)

The principle here is, that regardless of how the items with duplicate codes are moved around, the instant the tracking system notes a movement of the same item from either the same place twice, or an incorrect location once, an alert can be generated. In some cases, the system may be able to identify the real item - in most cases this will have to be forensically determined, however so long as the system ‘sees’ an item movement in the wrong place at the wrong time, achieved by means of our additional WHERETO parameter described earlier, it is possible to increase patient safety by preventing the administration of a potentially non-authentic drug. In the ideal system, each drug would be authenticated prior to administration. This level of extra protection and assurance is to be provided by external applications working in harmony with the Discovery Services and ONS (as required). It is the strong belief of this work package that the Discovery Services and ONS need to be as ‘lightweight’ and ‘thin’ as possible with extra benefit being derived by specialist external applications. This will be a subject of phase 2 of this pilot program.

3.9.2. Electronic Pedigree


Before detailing this section there is need to re-iterate an early comment. The definition of ePedigree, as understood by this work package team is fundamentally different from the understanding held in the US with regard to electronic pedigree. The US pedigree system is a means for bundling together in a secure and auditable manner, a multitude of electronic documentation that in total, would add up to the audit trail of drug product movement from source to point of use.

This system will use a trace and trace system based on the EPCglobal network to provide the pedigree information that we need. With reference to work by the EPCglobal HLS Track and Trace work group, we can see that a pedigree need not contain a reference to every item movement event. Some events are internal to a process and thus can be safely and easily ignored. The HLS T&T work group has defined the series of events within an overall idealised logistics process flow. As an example, one of these is shown below. The remaining diagrams, as they are likely to change, can be seen by reference to the original EPCglobal HLS T&T working group documentation.



The essence of the pedigree is to provide a catalogue of item movement events through legitimate and licensed product providers such that it can be shown (proven) that the article has been produced by an authentic and licensed source, transported and handled by licensed and authentic logistics providers and then finally, when at the level of primary and secondary care, has been stored, selected and administered by licensed and authentic practitioners. The pedigree should show clearly what the trail of item custodianship is, show if any of the custodians were non-authorized and show clearly any item movements that would cause concern over the authenticity of the product (e.g. why it took four weeks to move from one location to another when normally it would only take two days). With careful event data capture, this style of item pedigree can provide far more flexibility and considerably improve richness of data quality than a paper based or electronic document encapsulation system can provide because of the capability to undertake pro-active monitoring of data and alerting of irregularities.

Example screenshots of an electronic pedigree application developed for the purpose described is as follows.



[Help] [Log Out]

E-Pedigree Expiration Recall Alerts Visibility Users

Search Results: Pedigree [Back]

Search Criteria

Status: *	Received from Party: *
Pedigree ID: *	Sent to Party: *
Shipment ID: *	Lot#: *
Manufacturer: *	NDC: *
EPC: urn:epc:id:sgtin:15025.20060329.11	Invoice#: *
Drug Name: *	

	▼ Pedigree ID	NDC	Lot#	Pedigree Status	Available Quantity	Drug Name
<input type="checkbox"/>	8416	0123-4567-00	7887987	sendSuccess	40	CUREITALL

View Pedigree ID: 8416 [Print] [Search]

✓ Pedigree VALID

UID Match: ✓ N/A	Expiration: ✓ VALID
Recall Status: ✓ N/A	Signature Verification: ✓ VALID

Status: SendSuccess

Initial Quantity: 40	Available Quantity: 40
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ACME PHARMACEUTICALS

Shipping Information	
Date: 2006-3-29	Sent To: AAA Wholesalers, Inc.
Sent To Address: 99 Drug Packers Way Tallahassee, FL, 19087	Certified By: Gregory D. Gilbert 102 New Ridgetop Lane Ashburn, VA , 20147
Invoice Date: 2005-06-01	Invoice Number: 78910

EPC

urn:epc:id:sgtin:15025.20060329.11
urn:epc:id:sgtin:15025.20060329.12

CUREITALL



Manufacturer: PANACEA DRUG COMPANY
NDC: 0123-4567-00
Lot#: 7887987
Manufacturer Date: 2006-01-11
Expiration Date: 2009-08-13
Strength: 50MG
Dosage: TAB COATED
Container Size: 2

3.9.3. Authentication

Checking the authenticity of a product is a complex issue. True checking of the product authenticity can only really be achieved by means of forensic analysis however the testing and checking of various covert and overt security features within the product can also be used. However, the issues of counterfeit product can be massively reduced by the use of a system, such as that being advocated by this document, where mass serialisation and use of Unique Identifiers (UID's) are employed and then surrounding the use of UID's with a system capable of checking their provenance. Thus, authentication of the product (more strictly, of the product identifier) becomes essentially a bi-product of being able to produce the pedigree described above. In essence, the product item can be considered as authentic if:

- It emanated from a genuine and licensed source
- It travelled through a wholly licensed supply chain and was monitored on route
- It at no point deviated from its specified (within the track and trace system) logistics transit routes
- At no point did the unique ID associated with the product 'show up' somewhere it should not have been (product insertion and diversion issue described earlier)

An example application output, showing an authentication warning is shown below.

The screenshot displays a VeriSign authentication interface. At the top left, the word 'Authentication' is visible. On the right, the VeriSign logo is present. A prominent yellow warning box contains the following information:

UID Match: ✓ VALID	Expiration: ✓ VALID
Recall Status: ✓ VALID	Signature Verifies: ✓ VALID
Drug Integrity: ✓ VALID	Drug Quality: ✓ VALID
Custody Chain: ✓ VALID	End Point Validity: ✗ FAILED

Below the warning, the supply chain is detailed in three sections:

- AmerisourceBergen Corporation:** Shipping Information. Date: 09/24/2005. Authenticator: Krall, Gary (logistics@amerisourcebergen.com, 303-336-2343 ext. 2346). Sent To: Walgreens. Sent To Address: 223 Centre Road, Brooksville, FL 32541, USA.
- Walgreens:** Receiving Information. Date: 09/24/2005. Authenticator: Krall, Gary (logistics@walgreens.com, 904-445-6723). Received From: AmerisourceBergen Corporation. Recipient Address: 223 Centre Road, Brooksville, FL 32541, USA.
- Shipping Information:** Date: 09/24/2005. Authenticator: Krall, Gary (logistics@walgreens.com, 904-445-6723). Sent To: Wal-Mart. Sent To Address: 4406 Ashton Drive, Ft. Pierce, FL 40567, USA.

On the right side, a product image of TRIZIVIR is shown above a list of product details:

- Manufacturer:** SMITHKLINE
- NDC:** 0173-0691-20
- Lot#:** 75
- Manufacture Date:** 12/07/2005
- Expiration Date:** 08/07/2008
- Quantity:** 1
- Strength:** 300MG
- Dosage:** TAB COATED
- Container Size:** 60

At the bottom right, the 'Associated EPCS' section shows the URL: urn:epc:id:sgtin:0015025.0173.21

3.9.4. Product Recalls

The concept of product recalls is not new. The work within GS1 and EPCglobal identifies a number of reasons for returning goods and describes at length reasons why goods may need to be returned. However, one area that this work does not currently highlight is the need, especially within Healthcare and Lifesciences, to recall product where it has been determined, for whatever reason that the product may in some way harm human life. This issue has been highlighted with recent traceability trials such as the blood disorder medicines trial conducted in January 2006 with GS1, Domino, Verisign, NCHCD, TCP Ireland, Melior Solutions and a large manufacturer of generation three blood factor product. This 'proof of concept' system was conducted to provide added evidence that point of manufacture identification of product can be used to effectively identify the location of any specific product item within the entire supply chain. The system currently employed in Ireland allows the accurate location of any dose of any blood disorder related medicinal product thus allowing the rapid recall of any product found to be suspect or even incorrectly dispensed to specific patients. This project tracks product to the point of administration in the patient's home. It is highly advanced and highly effective.

The pilot program being undertaken by this work package aims to build significantly on some of the concepts and successes of this early trial and prove that a globally operated track and trace system can provide significant benefit to all partners and stakeholders involved, especially the patient.

3.9.5. Inventory Management

The automatic collection of information about stock movements and inventories received as provided by the 'traceability kernel' offers the additional benefit of automated inventory management when integrated with back-office ERP / stock management systems. There is a requirement therefore to ensure that at a future stage of the project that application adapters and integration tools are available to technology and solution providers to build these interfaces offering increased added value to end users e.g. wholesalers, pharmacists.

Whilst this is a future requirement, this capability will be accounted for at this stage of the project's development.

3.9.6. Financial reconciliation

A key issue for the pharmacist is the financial reconciliation and matching process of invoice data to the goods actually received. The administrative overhead incurred by "query chasing" is significant for both pharmacist and wholesaler. Payment delays inevitably occur as a result.

In the same way that inventory management systems can be automated by an interface with the 'traceability kernel', financial accounting systems can also benefit by automated reconciliation.