Rx-360 White Paper on Traceability Data Exchange Architecture

14 March 2015
Introduction and Scope of Rx360 TDEA White Paper

With the quickening pace of global pharmaceutical regulatory drug serialization and traceability mandates, the Rx360 Traceability Data Exchange and Architecture Workgroup (TDEA) began its activities in August of 2014 hosting a series of weekly conference calls to gather information and opinions from participants on supply chain data architecture and choreography models. This white paper is the first step in the process of identifying characteristics of different data architecture and exchange models, leading to proof of concept work within multiple organizations working to create solutions for their markets.

According to GS1 Healthcare\(^1\) data, as of January 1, 2015, there are more than twenty markets, including the U.S., who have present or pending pharmaceutical serialization requirements. Putting aside individual, country-specific product identification requirements, overall there is a lack of standardization or harmonization across these regulations on fundamental issues such as:

- Where the data resides
- How the data moves
- Who owns and manages the data
- Who has access to the data

We are hopeful that the process begun here will ultimately result in an improved private sector understanding of how to meet the regulatory requirements in the most efficient and patient-focused manner. Ideally, we see this effort as driving alignment or convergence on a preferred data architecture and data exchange model.

Accordingly, this white paper will not provide an answer or recommendation on the characteristics of an ultimate model. We view stakeholder consensus around a preferred model as a process, longer in duration than the scope of the TDEA workgroup. We intend this white paper to level-set on the basic choreography types and to provide context from the markets discussed herein. In addition, we hope to build on this information by identifying characteristics and discussing attributes and risks associated with each model.

Rx-360

Rx-360 is a membership consortium of supply chain participants which strives through inspections and other means, to protect patient safety. The Rx-360 organizational mission statement is to
“Protect patient safety by sharing information and developing processes related to the integrity of the healthcare supply chain and the quality of materials within the supply chain.”

In establishing the TDEA workgroup, Rx-360 opened the group to all interested organizations, including companies who are not currently members of the Rx-360 organization. This was done to get the broadest possible industry perspective on future data choreography. For those readers who would like information on becoming an Rx-360 member, please visit:


Approach and Assumptions

As a workgroup, we used the following assumptions in the course of our discussions and in this white paper:

- This paper represents a collaborative effort among all participants
- The paper considers only models requiring serialized data
- The paper is not intended to rank or select a preferred market-specific model. Individual market requirements are included to provide readers with a background understanding and document the various models known today

Within this document, we assume that we know and understand each of the market requirements – and we consider the data requirements equal for comparison purposes, thus permitting us to address aspects of choreography independent of specific content requirements. The international models that TDEA workgroup members presented during teleconferences, and discussed later in this paper, were selected as illustrations of certain characteristics of the defined choreography models. These discussions of international requirements are not intended as a definitive guide to specific country requirements. Instead, they are intended to offer examples of model characteristics being implemented in global markets.

We recognize the benefit to the discussions on the strengths and weaknesses of each model from the shared insights of those who have worked on implementation, and we appreciate that the unique and diverse perspectives of those who participated in the TDEA workgroup added credibility and value to this body of work. Workgroup participants included pharmaceutical manufacturers, distributors, dispensers, third party logistics providers, trade associations, consultants, software service providers, regulatory bodies, and standards groups.
Recap of TDEA Workgroup Activities

Below is a brief summary of the TDEA workgroup’s discussions. The tri-chairs of the TDEA workgroup would like to thank all participants for their valuable feedback and all presenters and reviewers for their work.

The TDEA workgroup opened its activities with an overview of traceability models which served to establish a baseline of understanding.

The TDEA workgroup then began a series of market-based discussions in which knowledgeable volunteer participants presented individual country requirements and choreography models. These specific markets and models included the European Union (EU), Brazil, Argentina, China and Turkey.

At the conclusion of these country specific market and model presentations, the workgroup performed a second review and discussion of choreography types and structure. This work was followed by a presentation by GS1 Healthcare on the GS1 Event Based Traceability (EBT) standards development work group efforts, defining the necessary standards framework and toolset to interface with all the model types discussed.

The TDEA workgroup then dedicated the balance of the work on the weekly teleconferences, participant discussions and feedback to key issues for inclusion in this white paper. The issues listed and discussed during the meetings are all reflected in the content of this white paper. The weekly teleconferences were highly interactive and intended to discover preferences, differing opinions, concerns, priorities, and industry-desired next steps. The teleconferences were supplemented by a discussion session at the well-attended, US Healthcare Distribution Management Association (HDMA) Traceability Seminar held in Arlington, Virginia, November 2014.

Individual Market Requirements Overview

As was done during the first few weeks of the TDEA workgroup calls, this portion of the white paper provides a high-level overview of a subset of the current market requirements for several countries with serialization and tracing mandates and is provided for the purpose of understanding the choreography and architecture. This does not represent an exhaustive or complete list of all the various market requirements. This overview captures the prevailing interpretation of regulations and common practices as of the publication date of this paper. In many areas, these requirements and industry approaches are evolving and significant changes are expected as governments and companies define, develop and deploy their serialization solutions.
Brazil

**Mandate Status:** Evolving - Many essential details are pending, including the data interface to the government ANVISA system.

**Serialization**
In Brazil, all registered medications are required to be serialized, including samples. Serialization is required at the item and case level with manufacturer assigned serial numbers. Transport container identification requirements are not yet fully defined. The product code is based on the National Health Surveillance Agency (ANVISA) registry number and introduces a 5th data element to be encoded on the product packaging if a GS1 Global Trade Item Number (GTIN) is also used. The serial numbers are required to be 13 digits, which does not align with the GS1 standards used in many other markets where serial numbers are “up to” 20 alphanumeric characters in length. A 2-dimensional (2D) Data Matrix carrier/barcode is used at the item-level, and item to case aggregation is required.

Manufacturers must randomize the serial numbers and cannot repeat them across any of the products from that manufacturer. This approach differs significantly from the GS1 standard approach, which contemplates a serialized identifier being a combination of the GTIN plus the serial number.

**Key Dates**
- Legislation passed on 10th December 2013
- 3 lots must be serialized and traced by 10th December 2015
- All products to be serialized by 10th December 2016

**Supply Chain Data**
Data collection requirements for the supply chain include information about the product itself as well as its movement via shipments and receipts. A specific set of transactions also must be captured, including purchase, return, donation, etc. Dispositions will be used to describe the status of an item, and there will be a mechanism to correct previously captured data. Some details related to data collection requirements are not yet fully defined.

**Data Repositories**
Each supply chain member must capture product data related to their business and retain it for one year beyond the product expiration date. In order to do so, the supply chain member must have its own systems in place. In addition, the registration holders (e.g. manufacturers) must also receive and store all product events related to their products which have been generated by any supply chain participant. Manufacturers must then make data available to ANVISA for reporting purposes.

Advanced functionality for reporting suspicious activity is planned, including identification of product data that was not generated by the manufacturer, detection of product instances
appearing multiple times in different locations, and observation of serialized product previously reported to have left the supply chain. The requirements for these advanced functions in the future ANVISA system are currently being defined.

The various data repositories in use in Brazil combine several database models, and as such, may be considered a hybrid of existing models.

**Funding**
All supply chain stakeholders will fund the development of their own systems used to meet the country requirements. The funding related to the development and operation of the central ANVISA system has not yet been defined.

**Governance**
The central ANVISA system requirements will be governed by the Brazilian government, with input from public sector subcommittees. The development and management of the central system will be the responsibility of the industry stakeholders, and the registration holders have the additional responsibility of collecting and storing all trading partner data related to their products.

**China**

*Mandate Status: Initial serialized product shipments have occurred and a phased implementation is underway*

**Serialization**
China’s serialization requirements apply to all pharmaceutical products at all packaging levels, except primary and pallet. The product identifier is a non-standard format; it is encoded in the Chinese Electronic Drug Monitoring Code (EDMC). The serial number can be up to 20 digits. It need not be random, but it must be non-sequential. The data carrier is the 1-dimensional (1D) barcode 128C, and aggregation is required at all packaging levels. Unique to China is that the allocation of serial numbers is done by the Chinese Food and Drug Administration (CFDA) and is allocated to manufacturers through a proprietary software interface.

**Key Dates**
- Legislation initiated: December 2012
- Phased implementation by product
- All products complete by: 31st December 2015

**Supply Chain Data**
Data collected in the supply chain includes product information (termed “activation data”) and shipment data (warehouse in / out). Transaction and status data are also captured, including sale, return, destroy, replace, allocate, etc. Each supply chain participant is responsible for
reporting its own data, of which the content and format are strictly specified utilizing a proprietary XML format. Data retention requirements are not currently defined.

**Data Repository**
The China database model is centralized, with the data collected by each supply chain member uploaded to the central database via a hardware key. This centralized system is developed and operated by the Chinese government.

**Funding**
The central database is funded entirely by the Chinese government. Supply chain participant systems required for compliance are funded by the companies themselves.

**Governance**
All aspects of China serialization are specified and governed by the Chinese government.

**United States**

*Mandate Status:* Evolving – Food and Drug Administration (FDA) guidance regarding the details of electronic product tracing is mandated by law over the implementation period. The FDA also has the legal authority to define alternative methods of compliance with the law.

**Serialization**
In the U.S., all human-health prescription drugs, with some exceptions, are required to be serialized at the item and case level, with serial numbers assigned by the manufacturer. Aggregation is not specifically required. The data carrier is a 2D Data Matrix barcode at the item-level; a 1D or 2D Data Matrix barcode may be used at the case level. A standard numerical identifier (SNI) is specified by law, and is comprised of the National Drug Code (NDC) and a serial number of up to 20 alphanumeric characters. Industry direction is moving toward embedding the NDC in a GTIN along with a 12 digit *numeric* serial number. Randomization is not required.

**Key Dates**
- Legislation signed: 27th November 2013
- Lot-level tracing: 1st January 2015
- Serialized products: 27th November 2017
- Full item-level traceability requirements: 27th November 2023

**Supply Chain Data**
Transaction Information (TI), Transaction History (TH) and Transaction Statement (TS) documentation must be provided, captured and maintained with each change of ownership, beginning 1st January 2015 for all supply chain stakeholders, except dispensers who must comply with the requirements by 1st July 2015. Product owners must verify TI/TH/TS and
provide it to the FDA or other government official in the event of an investigation. Records must be retained for six years.

The FDA is expected to issue future requirements as guidance related to unit-level tracing and interoperable data exchange in advance of the 2023 regulatory date. FDA has the ability to define alternative methods of compliance from that which is stated in the statute.

Data Repository
The data repository model has not yet been determined and may be influenced by industry pilots and input.

Funding
Supply chain participants will fund the systems necessary for compliance. No government funding for systems was provided in the law.

Governance
Any current implementation activity is based on supply chain member’s interpretation of the Drug Supply Chain Security Act (DSCSA) statute. Neither the statute nor the FDA has specified a specific data architecture or governance model, although FDA has enforcement authority, and by law, must provide guidance documents on these topics. The pharmaceutical industry has the ability to participate in pilots, provide input at FDA workshops, and respond to calls for comment on draft guidance documents. Trading partner collaboration is necessary to achieve interoperability and an optimal data architecture and governance model.

European Union (EU)

Mandate Status: The Falsified Medicines Directive (FMD) is published but most individual country requirements (i.e. Delegated Acts) are not yet published. Approved infrastructure necessary for implementation is under development.

Serialization
All pharmaceutical drugs in the EU are subject to serialization regulations, however, there are exempted prescription drugs which are enumerated on a “whitelist” and a separate list, the “blacklist”, for non-prescription drugs which are subject to the regulations.

Manufacturers must assign serial numbers at the item level, and are not required to aggregate. The data carrier is a 2D Data Matrix, which includes a GTIN (or in some markets a country-specific product ID) and a serial number with up to 20 alphanumeric characters. Randomization of serial numbers is required, and specific rules exist that define parameters for how randomization is achieved. Data retention requirements are still to be determined and may be country specific.
3/14/2015

**Key Dates**
- Legislation initiated: 2006
- Publication of Delegated Acts: Q4 2015
- Implementation Date: Q4 2018
- Inventory Cleanout Period: Q4 2020

**Supply Chain Data**
The EU is a “point of dispense verification” system. Manufacturers post serial number and product master data to a database when the product enters into the supply chain. That data is routed to the individual market of sale based on serialization information. Dispensers are able to verify the product serialization data against the data in their individual country database. Risk-based verification is also an option at other points along the supply chain. Each EU country is able to specify their individual risk-based reporting requirements.

**Data Repository**
In the EU model, each country will operate its own repository that will hold serialization data for all of the products in its supply chain. There is also a European Hub system which provides interconnection between the different national systems.

All data posted in a data repository is owned by the creator. Access to another party’s data is allowed only for verification purposes, or pursuant to an agreement between the parties.

**Funding**
The EU Hub and the national repository systems are funded by manufacturers. The systems that interact with serial numbers and are used for verification are funded by wholesalers and pharmacies.

**Governance**
The EU Hub is governed by the European Medicines Verification Organisation (EMVO) which sets the system standards and engages with national system owners.

The national systems are governed through the National Medicines Verification Organisation (NMVO). Industry stakeholders will also play a critical role in the Governance of the EU model.

**Turkey**

*Mandate Status: Implemented - Turkey has been in production with serialization for several years.*
Serialization
All prescription drugs are required to be serialized, except for drugs imported by the Turkish Pharmaceutical Association. Items, cases, and pallets are all required to be serialized, with manufacturer-assigned numbers. Item-level serialization utilizes a 2D Data Matrix, while cases and pallets use a 1D GS1 128. Product codes are GTINs, but are only used at the item level, all other levels use a serialized shipping container code (SSCC). Serial number length is up to 20 alphanumeric characters, and randomization is not required.

Key Dates
- Legislation published: 2005
- Serialized products: 2010

Supply Chain Data
Manufacturers post serial number data to a database when the product enters the supply chain and dispensers verify individual serial numbers. Movement and transactions are also captured in the supply chain, including ship, receipt, sale and decommission. Turkey does not specify a data retention period. In addition to improving patient safety, Turkey uses this system to ensure accurate reimbursements.

Data Repository
In Turkey, the data resides in different repositories based on the specific events captured. The Package Transfer System (PTS) is used to route package shipment data to the appropriate trade partner, and the Drug Tracking System (DTS, previously called iTS) database is used for commission event data. For reporting, the government directly queries the DTS repository for verification of product and PTS to determine which trade partner received transfer data.

Funding
The Turkey database is government owned and funded. The company-owned systems that enable serialization and interact with the government database are funded by the individual supply chain participants.

Governance
The Turkish government administers all serialization efforts and controls the government-owned database.

South Korea

Mandate Status: Evolving. Phase 1 Implemented. Many essential data requirements are pending.

Serialization
All prescription drugs are subject to South Korean serialization requirements, with certain documented exceptions. Serialization is required at the item and case levels using manufacturer
assigned serial numbers. Manufacturers affix a 2D Data Matrix to items and a 1D barcode to cases. GTIN-14 is utilized for the item product code while SSCC is used for cases, and the serial number length is up to 20 alphanumeric characters. South Korea will likely require item to case aggregation but does not require serial number randomization.

**Key Dates**
- Amendment to regulation: 2011
- Phased Implementation
  - 30% of products (including some specified products) to be serialized by 1\textsuperscript{st} January 2015
  - All products to be serialized by 1\textsuperscript{st} January 2016

**Supply Chain Data**
South Korea has not yet determined the data to be collected in the supply chain or the reporting requirements.

**Data Repository**
South Korea has not yet determined the data repository model.

**Funding**
Manufacturers are responsible for costs associated with their serialization systems. The South Korean Ministry of Health (KMOH) is responsible for funding a data repository.

**Governance**
The KMOH governs all serialization efforts, many of which are still being developed.

**Argentina**

*Mandate Status*: Implemented for specified drugs - Systems have been in production since 2012.

**Serialization**
All current drugs and samples that contain an Active Pharmaceutical Ingredient (API) on the lists published by the Argentina Health Authority (ANMAT) are subject to serialization regulations, plus all new drugs which are introduced to the market.

Secondary packaging is required to have a machine-readable GTIN and serial number; the manufacturer may choose the data carrier format, with 2D Data Matrix being commonly used. The GTIN and serial number follow GS1 standards, with the serial number assigned by the manufacturer and comprised of up to 20 alphanumeric characters. Randomization is not required. There are no requirements for case or pallet level serialization or aggregation, but aggregation is typically used (with SSCC barcodes) for logistical efficiencies.
Key Dates
- Initial law passed requiring serialization of specified products: 23rd May 2011
- Updated law passed requiring serialization of additional products: 28th March 2012
- Implementation dates: 2011 and 2012; additional products to follow

Supply Chain Data
All changes of ownership must be recorded by the corresponding supply chain participant in the central government database. Many types of transactions are also required to be captured, including ship, receive, return, dispense, recalled, etc. Data captured includes timestamp, invoice ID, transaction ID, locations, lot/batch number and expiration date. Event data must be sent to the central system at the time it occurs (in real-time).

Data Repository
In the Argentina model the data captured by each supply chain member is uploaded to the central database in a specific file format. The centralized system is developed and operated by ANMAT, and no data retention requirements exist for supply chain members.

Funding
All supply chain partners are responsible for costs associated with their serialization systems, ANMAT is responsible for funding related to the central data repository.

Governance
ANMAT is responsible for the rules and policies associated with data capture and communication.

Data Storage and Choreography Model

Now that we have detailed the ways that several different countries intend to implement their serialization and traceability requirements, we will turn to an overview of data storage and choreography models.

Serialization and traceability requirements are intended to address a specific purpose or objective, some examples of which include reimbursement fraud reduction, counterfeit protection, or supply chain security. While it is important to understand the business driver (use case) behind the models chosen to support these objectives, we must also focus on what each model has in common, an intention to create a new level of visibility and allow access to authorized stakeholders. As such, every model shares three critical process aspects that must be defined, created, and practiced.
Fundamental Model Aspects:

1. What data is needed? Here we consider which stakeholders create the data, how they create it, and the integrity of the data. The data needed can vary greatly by the intended purpose and use of the model.
2. Where does the data reside? Here we consider security and access needs for reporting.
3. What is the data choreography? Choreography is the sequence of steps and movements needed to operate the model and define the process.

General comments related to the three aspects: Upon discussion of these three model aspects, multiple topics, including cost, data rights, and ownership, among others, emerge for consideration.

Commentary related to what data is needed? Every effort to create a model involves stakeholders who define the required data elements needed to obtain the desired results. From the perspective of the TDEA workgroup, our aim is to develop a workable choreography model for known, prescribed data. For purposes of this white paper, we begin with the foundational aspects of data, and a good starting place when considering the foundational aspects of data is data standards. GS1 standards are configured to work with three data types, which can all be shared.

1. Master data: associated with the product, static and seldom changes
2. Transaction data: shared between two trading partners in the purchase process
3. Event data: created based on activities which occur as product moves through the supply chain and designed to support answers for the primary questions of what (product), when (time/date stamp) where (location), and why (the business context, including what happened to the product and links to relevant transaction data)

Event data includes commissioning events, created at the origination of an encoded product, packing events, created following the commissioning step and reflecting relationships between commissioned products (these data sets are also commonly referred to as aggregations), and additional events which reflect supply chain steps and movements pertinent to a commissioned product. Shipping and receiving events are generally leveraged by all models, regardless of regulatory jurisdiction; aggregation and disaggregation may also be utilized. Likewise, queries against commissioning events are also created and leveraged by several models, in order to verify the chain of custody.

When creating a model for serialized product, all three data types should be considered in the design, including the best ways to leverage the data. For example, how can a model leverage the different event data types?

The data will need to be routinely generated by integrated and ongoing operational processes, created by pertinent stakeholders across the supply chain. As such, each supply chain
participant should create and store the data needed for any model in an individual database it owns. Such an arrangement is therefore considered distributed at its genesis, regardless of the repository in which the data eventually resides.

Commentary related to “where the data resides?” The event-based traceability work group overseen by GS1 considered three primary types of database structures\(^2\): central, semi-central, and distributed. The three types – which represent an agreed, but non-normative common denominator designed to address multiple scenarios – differ in the location of the databases storing the captured supply chain events.

In this context, the centralized model is based on the assumption that all event data from all supply chain parties are stored in one central repository. The following, simplified illustration was drafted by the aforementioned GS1 work group, to facilitate discussion of requirements and development of suitable standards:

![Figure 1](image)

In the semi-centralized model, all Electronic Product Code Information System (EPCIS) event data for a given item (i.e. at class level, represented by GTIN) and its serialized instances, is stored in one of the nominated repositories. The following, simplified illustration was drafted by the aforementioned GS1 work group, to facilitate discussion of requirements and development of suitable standards:
In the distributed model, EPCIS event data is stored by each data creator (i.e. the party in whose custody or ownership the corresponding EPCIS events occur) in its own repository. The following, simplified illustration was drafted by the aforementioned GS1 work group, to facilitate discussion of requirements and development of suitable standards:

The above models differ in the locations of the captured event data. Reviewing each model from a reporting access perspective helps understand the models from a different perspective.

- In a central database model, the central repository where all participants store their event data is queried in order to obtain data required for reporting.
- In a semi-central database model, each repository nominated to store a given GTIN’s event data is queried in order to obtain data required for reporting.
- In a distributed database model, each repository which was used to store a given product instance’s captured event data along each step of the supply chain path is queried in order to obtain data required for reporting.
One way to understand these database models is to ask the following question. *Is the required data stored in one place or many?*

If your answer is just one place, then it is a central database rather than a distributed or a semi-central.

If everyone keeps the data they create, the database is distributed.

For a semi-central model, the data moves to a place other than a single central database. Two examples below help explain this. However, it is important to remember that there could be many other variations.

1. For this first example, the data moves with the product to a specific end repository of the last trading partner handling that product. This semi-central repository type was proposed in the California ePedigree model.
2. A second example of a semi-central repository is one in which the repository is nominated by the item owner, who is commonly the brand owner/manufacturer. Events created for given GTINs would be sent to that GTIN specific repository.

As we have discussed during TDEA work group calls, hybrid database structures are also a possible option. A hybrid model may be a combination of the database model archetypes drafted by the aforementioned GS1 work group. It is assumed that the EU model may be considered differently from one person to the next and could be considered a hybrid. However, because all product data for a particular country is maintained in a country-specific central repository to facilitate product verification by the pharmacies of that country, it may be considered as a central repository model. However, under the EU model, event data for a specific product may be stored in multiple databases, which may be more similar to a semi-centralized or distributed model. When stakeholders place staged data in the “Hub”, the data remains there until it is certain which country will ultimately receive the product. As product moves across national borders in Europe (parallel trade), the process is acknowledged and the data is allocated to the appropriate database which is again used by all stakeholders. At all points in time, for the EU model, the data for any given product will be stored in a repository for use by stakeholders to achieve the objective needed for that step in the process.

*Commentary related to the data choreography:* Ideal model choreography is achieved when alignment of created data allows appropriate access for the intended purpose. A whole host of questions arise when stakeholders discuss the process. The process by which the data is handled once created is very important and can have cost and complexity implications. It is also important that the process facilitates interoperability for the stakeholders to achieve the desired purpose. In the GS1 white paper titled *The Need for Global Standards and Solutions to Combat Counterfeiting*, a safe and secure supply chain framework is shown as follows:
Figure 4

The above framework represents the basic secure supply chain model objectives. Can the product identification features be verified as authentic? Can the product be tracked to where it is currently held in the supply chain and/or can the product be traced from where it came?

The GS1 white paper titled “The Need for Global Standards and Solutions to Combat Counterfeiting” notes that proprietary solutions are not the answer if users intend to achieve interoperability. See the diagram (Figure 5) below for how GS1 standards can be leveraged for purposes of product identification, data capture and data exchange.

Figure 5
While a great deal of time and effort has been invested by the industry to leverage a standards-based approach for the identification and capture of data from a 2D DataMatrix, thus far very little time and effort has been dedicated to a standard method of data exchange. Stakeholders typically discuss EPCIS, which is a language that enables disparate applications to exchange visibility data. The EPCIS standard is a GS1 standard which enables trading partners to share information about the movements and whereabouts of products and assets through the supply chain. EPCIS is a key component of the framework for sharing supply chain visibility event information.

The most important take away from the GS1 System of Standards and the Global Traceability Standards for Healthcare (GTSH) shown in Figure 6 is that all elements (identify, capture, share) must be accounted for when considering the design of a traceability model. The circled elements are used to illustrate an example of chosen standards to enable a given model.

- How will things be identified?
- What is used for data capture?
- How will data exchange and discovery be performed?
- What is the process that assures needed objectives are met?

Summary of data storage and choreography models: Stakeholders must agree on the three aspects of a model in order to create one. The stakeholders must define what data is needed to meet the model objective, where the data is stored, and how it moves and can be accessed. Additionally, to achieve model objectives, stakeholders must define the process of who has to do what and when it needs to be done.
Advancing the Industry Dialog

Proactive Collaboration

As this white paper details, there are many factors that regulators and industry must consider in the creation of a model. The consensus of the TDEA workgroup participants is that industry must align on a proactive path forward to determine a deliverable, efficient data choreography model. To meet this goal in a timely manner, an industry dialog that furthers development and adoption of a broad strategy for determining an eventual model must begin very soon. Industry must collaborate on the key characteristics of an eventual model, including the distribution of the cost burden, responsibilities, risks, security considerations and reporting of information. The model should offer flexibility, allowing some important characteristics to be harmonized among existing and prospective global requirements.

Understanding the priorities and concerns of each pharmaceutical supply chain stakeholder

In order to realize the most efficient data choreography model possible for the entire supply chain, it is imperative that all pharmaceutical supply chain stakeholders and sizes of companies participate in the discussion. The perspective of representatives from different parts of the supply chain will be critical to the creation, participation and evaluation of proof-of-concept (POC) work. This Rx-360 TDEA workgroup has been open to any and all participants with an interest, and we further anticipate that similar opportunities will be made available through feedback and reporting to the various groups and associations like the Asia-Pacific Economic Cooperation (APEC), the Pharmaceutical Distribution Security Alliance (PDSA), and the Healthcare Distribution Management Association (HDMA) that work on POC.

Timing

In order to have an impact on the characteristics of a prospective model, it is imperative that the industry begin work in 2015 to determine POC strategies. These strategies, which will be discussed in the next section of this white paper, include concepts such as:

- What characteristics should be tested?
- How would pilot results be evaluated against one another?
- On what scale would the testing take place so as to get a more accurate idea of operational challenges?
- Is it possible or feasible to run more than one industry pilot concurrently?

While it may seem to some that there is plenty of time remaining before requirements become effective in certain markets, we need only look at the EU model and the past decade of work to see how long a stakeholder-determined model can take to develop to a finished state. In order to have impact on global harmonization efforts, as well as definition and implementation of US-based unit traceability models, the POC efforts should be defined in 2015 with a go-forward
POC plan in place by the end of the year. For this to happen, much like the consensus experience PDSA has enjoyed with respect to the U.S. mandate, there is a critical need for broad stakeholder involvement and engagement in 2015.

**Future Harmonization and Implementation Impact**

Through discussion and deliberation across the full range of supply chain participants, stakeholders can present industry consensus choreography model characteristics to governmental and regulatory bodies. Industry alignment can maximize the influence on the requirements and help drive desired outcomes. Ideally, this would include harmonization of certain aspects of data choreography in different markets. Participation in this important process will require that stakeholder work is completed and evaluated within an appropriate timeframe, and, in order to accomplish this, industry dialog and efforts at alignment must begin now.

**Assessment Criteria**

Moving forward, it will be important for industry to align on a common set of criteria against which the various models will be assessed and to agree on objective metrics to evaluate the performance of each model. The most fundamental criterion for any model will be its ability to comply with varying global regulatory requirements, and the question for industry is whether a single model can be flexible enough to comply with point-of-dispense requirements as well as full supply chain traceability mandates. As we focus on model aspects such as where the data resides (the architecture) and how it moves (the choreography), we believe that we can achieve this level of flexibility; a single model that can enable compliance with the various mandates, whether they require point-of-dispense verification or traceability. Other criteria to be considered when assessing the models may include (but are not limited to):

- Cost-effectiveness
- Ease of Use/Access
- Complexity
- Scalability
- Flexibility
- Reliability
- Operational Impact
- Interoperability
- Security
- Governance
- Data Access and Ownership
- Standards-based

Each of these criteria is discussed briefly below:
Cost Effectiveness – We recognize that serialization solutions are costly to implement and will require investment from all supply chain stakeholders. The ideal model is one that has the lowest cost to implement and maintain while still realizing the desired benefits. The cost must not be prohibitive for entities (large or small) to comply with the minimal regulatory requirements. All aspects of the process should be taken into account including both normal handling and exception processing.

Ease of Use/Access – In order to minimize any adverse impact on operations, the model must be easy to access with minimal disruption to operational processes. We must not disrupt or delay the efficient flow of product to patients. Models that do not allow efficient access to the data required to move product forward in the supply chain would not meet these criteria.

Complexity – Similar to Ease of Use/Access above, the effort required to provide, capture and maintain data must NOT be complex, and the effort required to implement the model should be minimized. Complexity must be eliminated from the system design and implementation whenever possible. Errors and exceptions should not be introduced into the process as a result of the complexity of the given model. Markets requiring traceability as well as those with distributed models are inherently more complex than point-of-dispense authentication models. The ideal data architecture and choreography model is one that complies with the given regulatory requirements (with the least complexity) and is actually flexible enough to enable additional business value. Stakeholders should consider whether data will be pushed, pulled or stored for retrieval and reporting.

Scalable – Ideally, the model will be scalable in order to transition from non-serialized to serialized product or from lot traceability to item-level traceability, as necessary. The model must also be able to accommodate large volumes of data and increasing number of supply chain participants.

Flexible – It will be important for any given solution to be flexible enough to enable additional business value beyond what is mandated by the given regulations and to comply with the various reporting requirements.

Reliable - All models must be reliable in order to ensure timely access to required data. Will data be available 24/7? Is a centralized system more vulnerable with all data stored in a single location? In a distributed model, what happens when trading partners leave the supply chain (cease to exist)? What model affords the most reliability? What about response time-- is the model expected to operate in real time or within another acceptable time period? Consider the ESM (European Stakeholders Model) response requirements. In that model, the objective is to verify that the product is authentic at the point of dispense. The process requires the dispenser to scan the product and software to verify the captured serial number against a repository holding a replication of commission data at a known network address which delivers a response in less than a second. The requirements for such a system are very fast due to the process that needs the response. The requirements for other process models may not need to be as fast and
therefore could be designed differently. The speed of sending, receiving and processing is an important system design consideration.

Operational Impact – As noted above, the ideal model is one that has the least adverse impact on operational processes and the efficient movement of product through the supply chain. Exceptions and errors associated with the preferred model should be minimal. How does exception processing impact the normal process? In general, a desirable model will quickly identify exceptions and then accurately permit correction. The model should also minimize impact on “good” product and focus more extensively on exceptions that identify suspect or illegitimate product. Business processes today leverage inference to facilitate trade. Stakeholders should fully understand and define the choreography and exception processes for inferring contents of a package, if utilized, in a model.

Interoperability – Any model will need to ensure that stakeholders are able to locate the required data (efficiently) when needed and exchange it seamlessly (accurately and consistently). When generated, reports should be done in a standard interoperable manner. Again, consideration must be given to the capabilities of all supply chain stakeholders to access and use the model. Will the selected model have the functionality to access data stored in different models or created by previous versions of software as newer releases occur (backward and forward compatible)? Reporting requirements also assume interoperability as various regulatory bodies must have or be given access to product data in a timely manner, particularly in risk-based event situations. What kind of reporting or ad hoc querying capability should be present in a prospective model to allow regulatory agencies the ability to access and process traceability data? Is this a separate capability, as Brazil is considering, or is this capability part of the overall choreography model, perhaps with different security permissions? What are the considerations and potential risks in each approach?

Security– Although we are not exchanging and storing patient-level information, it is important that only legitimate and authorized users are able to access the model and its associated data. Any model must have the required security controls necessary to ensure the integrity of the data and to prevent unauthorized use/access. Security can be addressed both by system attributes and facilitation of sound security processes. Does one architecture type (central, semi-central or distributed) offer greater security than others? Does adopting one architecture lead to greater security risks? In terms of overall data integrity, are there benefits or additional security risks to sending data downstream as opposed to leaving it in a repository and allowing authorized access to it? Access to data must be available to those legitimate users to satisfy their own requirements, and thus other considerations include:

- Thorough analysis of threats
- The risk of a model experiencing service outages
- The need for any prospective model to allow trading partners to locate and exchange data with a high level of interoperability and
- A robust authentication system related to levels of access, plus adequate reporting and detection built in to identify possible suspicious activity

**Governance**- Who has oversight and control? Will it be governed by regulators, by stakeholders or a combination of both? Decisions around governance can significantly impact model complexity, architecture, financing considerations and speed-to-implementation. As discussed earlier, some markets (Turkey, Argentina, and China) have well-defined database structures with strong governance processes. Alternatively, markets such as the EU and the US require stakeholders to develop and govern a model. Other markets such as Korea have not yet specified the governance structure. Each market should clearly define its governance structure.

**Data Access and Ownership** – Who will own what data, and how will access to the data be determined? Does this change at any point in the choreography model? In a prospective choreography model, how is master data differentiated from transactional data from event data? Is there any choreography point where a trading partner has access to another company’s master data? Is it possible to exchange data necessary to achieve our patient safety objectives and not raise concerns of downstream trading partners to visibility of data?

**Standards-based** – In order to facilitate interoperability, standards-based solutions are necessary. A preferred model is one that is based on globally harmonized standards and NOT on proprietary solutions. Foundational elements should be extensible from market to market even if there are operational differences between the models.

As work progresses, it will be important to assess the costs and benefits of the criteria noted above to better understand what is possible and at what cost. The TDEA Work Group discussed the importance of POC work with agreed upon success criteria as an important step in evaluating various aspects of the respective models.

**Proof-of-Concept Work**

The following areas were identified by TDEA participants as requiring additional POC work:

**Aggregation and Inference** – What is the operational impact of serialized product moving through the supply chain with or without aggregation to its logistical container? Is there a difference between models on this issue? Will manufacturers find value in aggregating product (albeit at a greater cost), and are there Good Manufacturing Practice (GMP) implications? Is there a value to distributors in receiving aggregated product, and are there Good Distribution Practice (GDP) implications? How will dispensers perform necessary activities?

**Operational impact of serialization** and the associated point-of-dispense or traceability requirements – how can industry move from “one-off” pilots to integrating serialized products
(and the associated data exchange) into daily operations to better understand the impact? We also need to move from small volume pilots to pilots testing the movement of large volumes of serialized product and involving other industry stakeholders (secondary distributors, 3PL, etc.).

**Errors and Exception Handling** – Are certain models more conducive to quickly and efficiently identifying and correcting errors? Do certain processes within models create additional exception handling requirements as compared with other models?

**Data Movement** – Push vs pull. Is there a preferred approach and alignment across the industry on whether data should be pushed or pulled in the various models? Is there a cost associated with data movement? Which data set would be considered the definitive record?

**Transaction Data vs Master Data** – Should master data, transactional data and event data move in the same manner? If not, where should master data reside and what should be required to access this data when needed? At what cost? It is highly recommended that efficient master data practices be considered when determining a model for use. Industry for example could align on whether or not to utilize tools such as the GS1 GDSN (Global Data Synchronization Network) or master data handling methods enabled by the EPCIS standard.

**Cost Comparisons** – Documented evidence of the difference in the cost of standing up the various models will be important to the discussion going forward.

**Data Access and Ownership** – Who will own what data and how will access to the data be determined? Does this change at any point in the choreography model? Is it possible to exchange data necessary to achieve our patient safety objectives and not raise concerns of downstream trading partners to visibility of data?

**Inventory Visibility** – Is there mutual benefit to greater inventory visibility across the supply chain (similar to that realized in the retail sector)? If so, is there POC work that might move this dialog forward?

**Semi-Centralized Models** – Most pilot work (in some markets such as the US) has focused on distributed models, and industry appears to have a good sense of what’s required to implement a centralized model given the number of existing implementations. However, very limited work has been done with semi-centralized models involving third parties. What would an ideal semi-centralized model look like, and what is the relative cost of such a model?

**Next Steps**

As detailed above, TDEA workgroup participants felt that both evaluating the various models against an agreed upon set of criteria and conducting pilot (POC) work to address the issues noted above would be beneficial. Additionally, the workgroup expressed that some urgency would be required in order to influence emerging mandates and drive potential convergence. To further these goals and continue this positive forward momentum, the following activities are planned:
PDSA Assessment Criteria and Evaluation

The Pharmaceutical Distribution Security Alliance (PDSA), a consortium of companies and trade associations in the US with broad representation from all sectors of the pharmaceutical supply chain, has agreed to further develop the list of assessment criteria noted above during the first half of 2015. Once agreement is reached on the assessment criteria, the PDSA team will work to assess models against these criteria. The possible questions or issues that may result from this process and require further assessment could be fed into the POC work.

HDMA and Proof-of-Concept Work

The Healthcare Distribution Management Association (HDMA), a trade association of wholesale distributors in the US, has agreed to provide a forum and oversight for the POC work identified by the industry as necessary to move the dialog forward on data architecture and choreography. This work will commence during the second half of 2015, following the PDSA assessment mentioned above.

U.S. FDA and ABAC (APEC Business Advisory Council) Pilots

TDEA workgroup participants are aware that the US FDA and the ABAC Global Traceability Pilot will be addressing key topics involving data architecture and choreography during the next few years. Ideally, the model assessment and POC work noted above may help inform the pilot design and be integrated into the planned pilot testing activity.

Industry Call to Action

The ultimate goal of this white paper and the additional work yet to be completed is to move the discussion on data architecture and choreography forward and to gather credible evidence in order to inform future decisions on data architecture and exchange models. Continued stakeholder engagement and dialog will be vital to the design and testing of successful models, alongside active participation in the further development of existing and additionally required GS1 standards, and we hope that this white paper serves as an effective and urgent call to action for industry stakeholders around these efforts. In order to optimize the chances of agreement on and adoption of the criteria and outcomes of this work, a wide range of stakeholders must be aware and engaged in this goal.

REFERENCES

1. GS1 Healthcare www.gs1.org/healthcare
2. EPCIS http://www.gs1.org/gsmp/kc/epcglobal/epcis
3. Event Based Traceability Video  http://www.gs1.org/healthcare/ebt_sc
5. Global Traceability Standard for Healthcare (GTSH)  

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