ICON INDICES
Incredible Ingenuity

DSCSA Pilot Project Program

Final Report

Company Name: ICON INDICES

Industry Sector: Software and Technology

Company URL: www.iconindices.in

Project Title

Web 3.0 based on Identifier system

An autonomous system for electronic tracing of product for pharmaceutical

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1. Pilot Key Objectives

The pilot is to design a electronic, interoperable system for drug product traceability, enabling information flow as required by the DSCSA guidelines with the product moving to next custodian the most efficiently, interoperable with other, disparate systems of the pharmaceutical ecosystem members.

The pilot key objectives are to test the electronic, interoperable system on the following metrics:

1. Is interoperable with the legacy system of pharmaceutical ecosystem members
2. Is the most efficient
3. Delivers accurate result for 100% instances
4. Operates at the minimum cost
5. Has high adoptability
6. Is greatly robust

2. Description

2.1 System Overview

Web 3.0 is the decentralized records of transaction events through manufacturer-to-patient supply chain. Web 3.0 facilitates the gathering of information which essentially builds the transaction history for a product on receiving a request to return an automated response to the entity making the query instantaneously, to comply the section 582(g)(1)(E).

Identifiers system for object as well as recording transaction events which has the ability of routing and switching, enabling self-driven navigation through decentralized record of transactions for multiple stakeholders collectively to approve a transaction without the need of centralized controlling authority, referred to as the web 3.0. Location based Identifier system with underlying algorithm facilitates point-to-point navigation through decentralized records of events.

Features

1. Data light system, no duplication of records elsewhere
2. Most efficient search, identifiers having ability to drive the routing and switching
3. Location based identifiers, Non-cloneable, data immutability, data irreversibility
4. Encrypted identifiers, ensuring confidentiality and security

Web 3.0 based on location based identifiers, creating directory of decentralized records of events which is found unbeaten on efficiency, scalability and cost than any other decentralized database technology.

Web 3.0 allows movement of legitimate product by legitimate trading partners through manufacturer-to-patient supply chain to comply the product tracing requirements of the Drug Supply Chain Security Act (DSCSA).

2.2 System Components

The Web 3.0 System consists of the following components:

1. **Data repositories**

    a. Master data repositories
        i. Pharmaceutical ecosystem members
        ii. NDC Master
        iii. Packaging hierarchy Master

    b. Events repositories
        i. Manufacturers
        ii. Distributors
        iii. Pharmacies

2. **Identifier generator**

        i. For item level
        ii. For packaging hierarchy
        iii. For repackaging
        iv. For transaction events

3. **Events processing system**

    Events processing system consists of the following:

    a. Authentication mechanism, verifying product authenticity on every event as it occurs anywhere in the supply chain in real time

    b. Record updating mechanism, updating product movement status into all the respective event repositories of participating stakeholders, simultaneously and in real time

c. Reporting mechanism, generating reports as needed in real time and notifying to the participating stakeholders

d. Navigation mechanism, enabling record discovery at the ultimate speed in the repositories by,

   i. Finding record in the repository by moving direct to cell-address of the repository by decrypting Identifiers to find address of the record in the repository

   ii. Minimizing navigation path at the shortest for the record discovery into the repositories of respective participating stakeholders by moving cell-to-cell among the repositories of respective participating stakeholders by using identifiers

4. Services

a. Product recall

5. User interface

2.3 System Security

1. Data immutability

The records are kept in a chain in the distributed events repositories, making the system immutable.

2. Data irreversibility

The records are to be placed at specified location in the events repository, making the system temper-proof.

3. Data security

The records stored in the data repositories are in encrypted format by using algorithms which are impossible to decipher.

4. Data privacy

The access to data is made unidirectional only which protects data privacy.

3. Methods

The methodology to test the electronic, interoperable system on the metrics, as planned, is by simulation of the real world events which are carried out among the pharmaceutical ecosystem members in the drug product movement in the supply chain.

The data sets, to populate the repositories on to the Web 3.0 System, are given as below:

1. Pharmaceutical supply chain members

Data that has been simulated for the supply chain members is as follows:

1. Manufacturers 2 nos.,
2. Distributors 5 nos.
3. Pharmacies 5 nos.

2. NDC

Data is simulated for NDC 6 nos.

1. 5 nos. NDC are used as good products
2. 1 no. NDC is used as suspects
3. Out of 5 nos. NDC, 1 no. NDC is used to the repackaged product.

3. Unit-level packaging

Identifiers have been generated for around 300,000 nos. from NDC.
Identifiers have been varying between 40,000 to 60000 nos. per NDC.

4. Case level packaging

Identifiers have been generated for case level packaging, one case containing 15 units.

5. Access control

Manufacturers/ Distributors/ Pharmacies that are simulated are given login ID/ password

6. Master data

Master data repositories are created for,

1. Pharmaceutical ecosystem members
2. NDC that are simulated
3. Packaging hierarchy for NDC

7. Event repositories of the pharmaceutical ecosystem members

Events repositories are populated for around 2000 nos. cases and around 10,000 nos. unit-level packaging among the pharmaceutical manufacturers, distributors and the pharmacies in random selection of the pharmaceutical manufacturers, distributors and pharmacies. The repositories are populated for,

1. Identifiers for each NDC
    a. For item level
    b. For packaging hierarchy
    c. For repackaging
2. Product movement in the supply chain
    a. Identifiers of Case, send by manufacturers
    b. Identifiers of Case, received by distributors
    c. Identifiers of item-level packaging, send by distributors
    d. Identifiers of item-level packaging, received by pharmacies

4. Evaluation Methods

Around 3000 nos. tests are carried out with random selection of Identifiers, distributors and pharmacies for the following test parameters which are listed as below:

1. Interoperable system

Identifiers are selected to populate the events repositories for around 2000 nos. cases and around 10000 nos. unit-level items among the pharmaceutical manufacturers, distributors and pharmacies in random. Tests are conducted for variety of cases.

2. System Efficiency e.g. time to response

Identifiers are randomly selected. Tests are carried out from random selection of distributors/ pharmacies
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3. System Accuracy

a. Master data retrieval

Identifiers are randomly selected. Tests are carried out from random selection of distributors/ pharmacies.

b. Disaggregation

Identifiers are randomly selected. Tests are carried out from random selection of distributors/ pharmacies.

4. Report generation

Identifiers are randomly selected. Tests are carried out from random selection of distributors/ pharmacies.

5. Notifications for suspect/ illegitimate products

a. Identifiers of NDC (1 nos.) for suspect are randomly selected to test suspect/ illegitimate products
b. Identifiers are randomly selected to test supply chain infiltration.

6. Repackaged Item

Identifiers are randomly selected. Tests are carried out from random selection of distributors/ pharmacies.

5. Cost

Pilot project cost US$ 60000

Primary cost head has been on the manpower
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6. Key findings

1. **Interoperable system proved**

   This has been proved as the events repositories are successfully populated among the pharmaceutical manufacturers, distributors and pharmacies and tests have been successfully conducted on 100% instances.

2. **Peak performance delivered**

   This has been accomplished by both the encryption mechanism for Identifiers and the navigation mechanism together.

   Identifiers containing address of the record placed in the specific repositories, facilitating shortest navigation path among the distributed data repository of supply chain ecosystem members on to the Web 3.0 System.

   a. **Time to response**

      Minimized Time to response to absolute minimum which has been achieved by,

      1. Time to search record in the event repository by moving direct to the cell-address in the event repository
      2. Time to navigate among the distributed events repositories by making navigation path at the shortest possible

   b. **Cost to operate**

      Minimized cost to operate which has been resulted on account of having zero data redundancy and with the navigation path at the shortest.

3. **Got accurate results for the following cases on 100% test that are conducted**

   1. **Master Data retrieval**
      This has been accomplished as the master data is retrieved, every time, from the source data which is stored centrally.

   2. **Disaggregation**
      This has been accomplished as the disaggregation data is retrieved, every time, from the source data which is stored centrally.

4. **Reports are produced with zero error**

   This has been accomplished as the report data is retrieved, every time, from the source data on the event as it occurs in real time by using master data repository and events repositories on to the Web 3.0 System.

5. **Notifications delivered instantaneously**

   This has been made possible by the authentication mechanism, verifying product authenticity on every event as it occurs anywhere in the supply chain in real time.

6. **Error free results for repackaged item on 100% test that are conducted**

   This has been accomplished by generating Identifiers to repackaged item with the same address as was found in the Identifiers of original package and using repackaging algorithm for the repackaged items.

7. Lessons learned from the project

Web 3.0 System, emerging unprecedented capabilities for the pharmaceutical ecosystem members to achieve excellence in their operational efficiencies, their sales turnover and their cost to sale. The new capabilities are as followings:

1. Enabling personalization

2. Enabling provenance

3. Driving for zero CapEx enterprise
   Around 1/6th of annual sales is locked up in inventory with the enterprise

4. Developing a marketplace for trade for both purchase as well as sale

Web 3.0 System, helping the enterprise comply the DSCSA traceability regulation requirements in the most efficient manner and also helping the pharmaceutical ecosystem enterprise network achieve excellence in their operational efficiencies, their sales turnover and their cost to sale, alongside.

End of report