

RFID Journal Live! 2006

May 1-3, 2006
MGM Grand Conference Center
Las Vegas, Nevada



Putting RFID to Work

May 3, 2006



The Benefits of Standardized EPC Data Formats

Bob Celeste, Director, Action Groups
EPCglobal US

Ted Ng, Director, Emerging Technology
McKesson



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May 3, 2006





RFID Journal LIVE

State of Pedigree and EPC/RFID Standards

May 3, 2006

Ted Ng, McKesson Corp

Bob Celeste, EPCglobal US





Agenda

- Definitions
- Pedigree
- Track and Trace
- Standards Progress



EPCglobal Healthcare And Life Sciences Business Action Group

- Standards Requirements Methodology
- Current Use Cases





HLS BAG Update

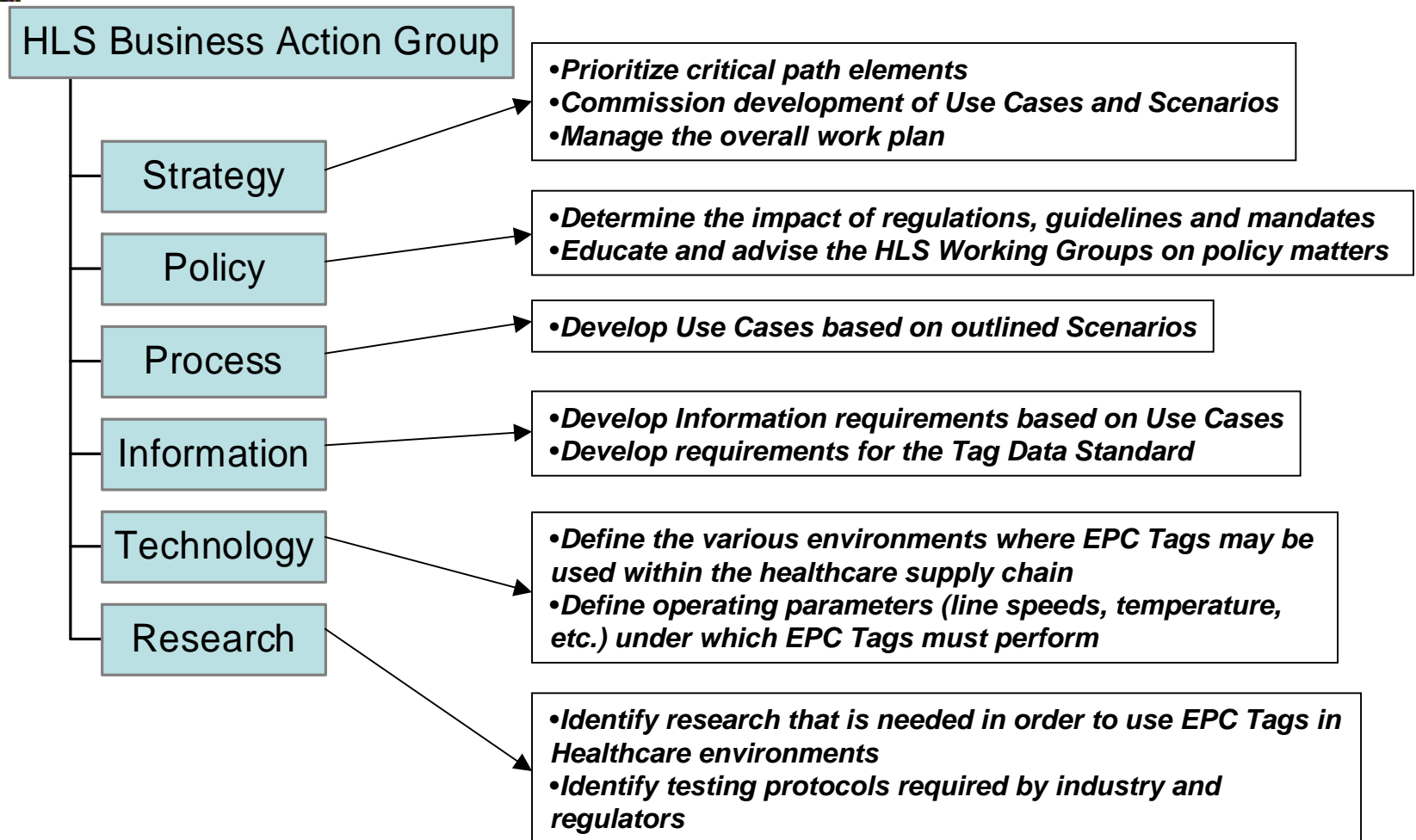
History

July 30, 2004 – Official Kickoff

- 300+ Participants from 150 companies
- Developed Charters for each Working Group
- Coordinating with Industry Groups
(NACDS, HDMA, PhRMA, BIO, NABP, NACDS, EHI)
- Coordinating with Regulatory bodies
(FDA, States, EU Commission)
- Regular Working Group conference calls
- European Meetings

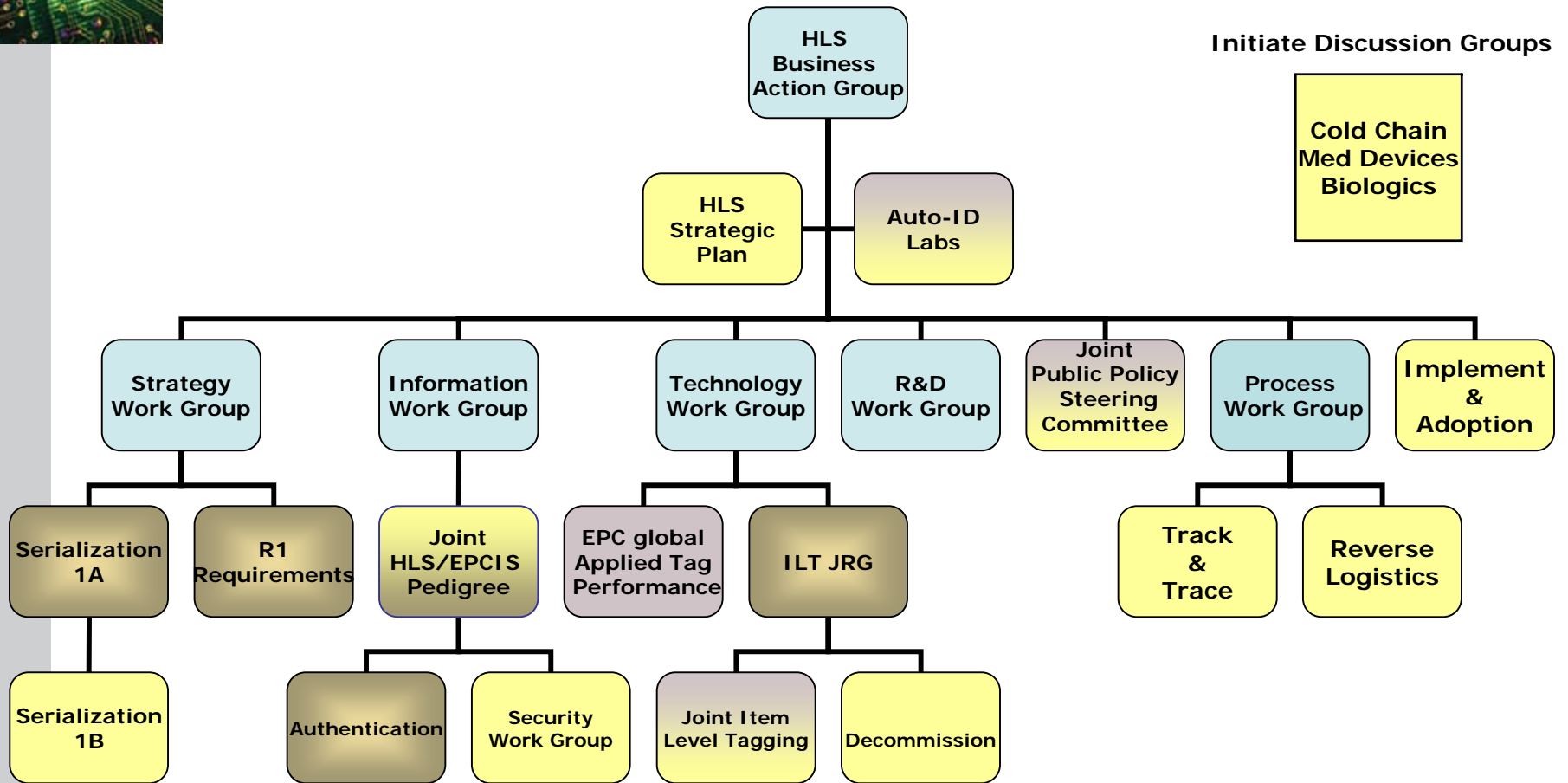


HLS BAG – The Initial Foundation





HLS Work Group & Task Force Alignment



- HLS Top Priorities – 2006
- On-Going EPC Working Groups
- On-Going HLS Working Groups
- HLS Top Activities – 4Q05



Guiding Principles - Scope Hierarchy

HLS Development methodology

| Term | Description | Examples | Output From | Input For |
|-------------------|--|---|-------------|--------------------------------------|
| Capability | Defines high level strategic imperative to be addressed | Pedigree Management, Reverse Logistics, etc | Strategy | Process |
| Scenario | Describes alternative product flow paths | Manufacturer to Wholesaler to Retailer to Pharmacy, etc | Process | Information, Technology, Policy, R&D |
| Use Case | Defines a step in the process | Commission, Ship, Receive, etc | Process | Information, Technology, Policy, R&D |
| Variant | Defines how a use case or scenario could vary based on unique characteristics of the supply chain or product | Biologics, cold chain, medical devices, etc | Process | Information, Technology, Policy, R&D |



HLS BAG Use Cases

Pharmaceutical Supply Chain

- **Manufacturer Commissions**
- **Receiving Party Authenticates incoming pedigree**
- **Receiving Party Registers receipt of item**
- **Distributor Commissions Repack Item**
- **Distributor Commissions Tote w/Loose picked items**
- **Distributor registers Cases and Items to Party**
- **Distributor ships cases and items to Party**

- **Manufacturer Commissions Case**
- **Retail Pharmacy registers receipt of totes and items**
- **Retail Pharmacy authenticates incoming Pedigree**
- **Hospital Pharmacy registers receipt of Totes and items**

- **Hospital Pharmacy authenticates incoming Pedigree**
- **Retail and Hospital Pharmacy Decommissions**
- **Manufacturer Commissions shipping pallet**
- **Distributor Commissions shipping pallet**

- **Retire EPC tags**

- **Re-associate EPC**
- **Manufacturer picks and packs mixed cases**

- **Overt/Covert security confirmation**
- **Manufacturer picks and packs mixed pallets**
- **Manufacturer registers cases and items sold**

- **Decommission internal pallet**



EPCglobal Architecture Review

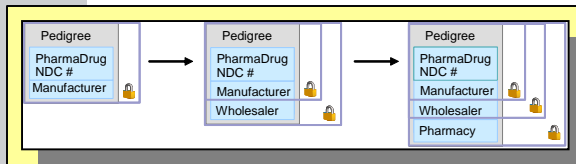
Definitions and Keys



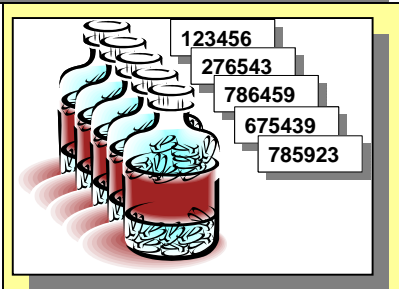


Definitions

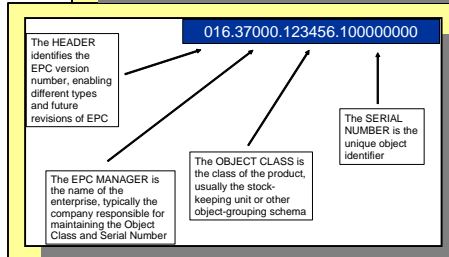
Pedigree, Serialization, EPC, RFID



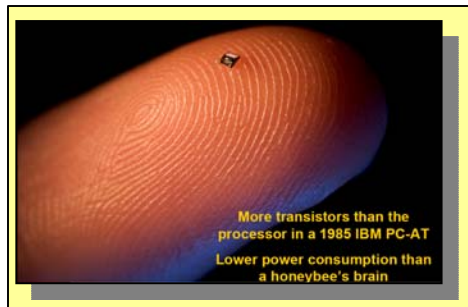
- **Pedigree:** The document, electronic or paper, which communicates the custody history for a particular medication.



- **Serialization:** A unique number assigned and affixed to a particular unit of item. Used to identify the particular bottle.



- **EPC:** Electronic Product Code – A globally and multi-industry acceptable identifier standardized by EPCglobal used to serialize items in many supply chains around the world.

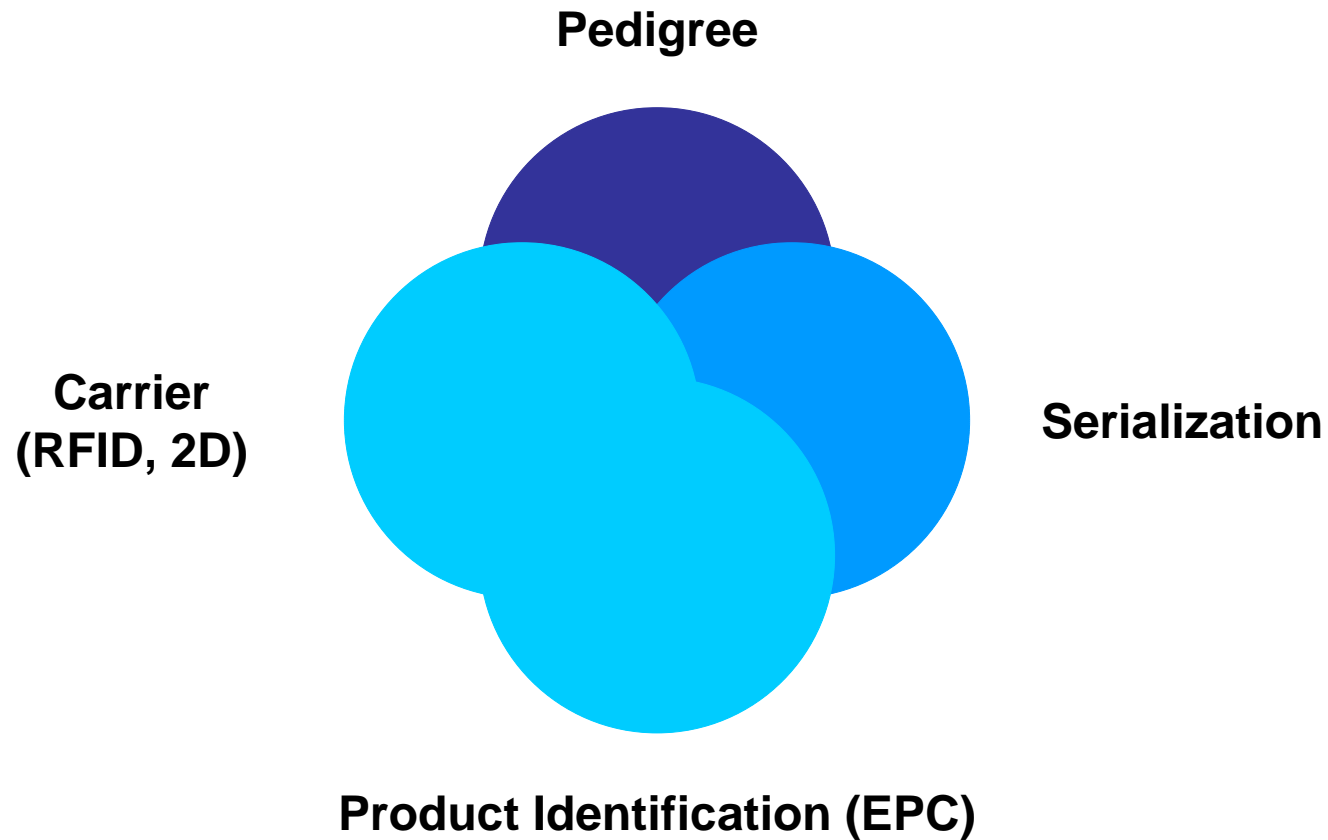


- **RFID:** The technology that can carry an EPC. Made up of a tag (computer chip), antennae and substrate.



Definitions

Confusion over related topics

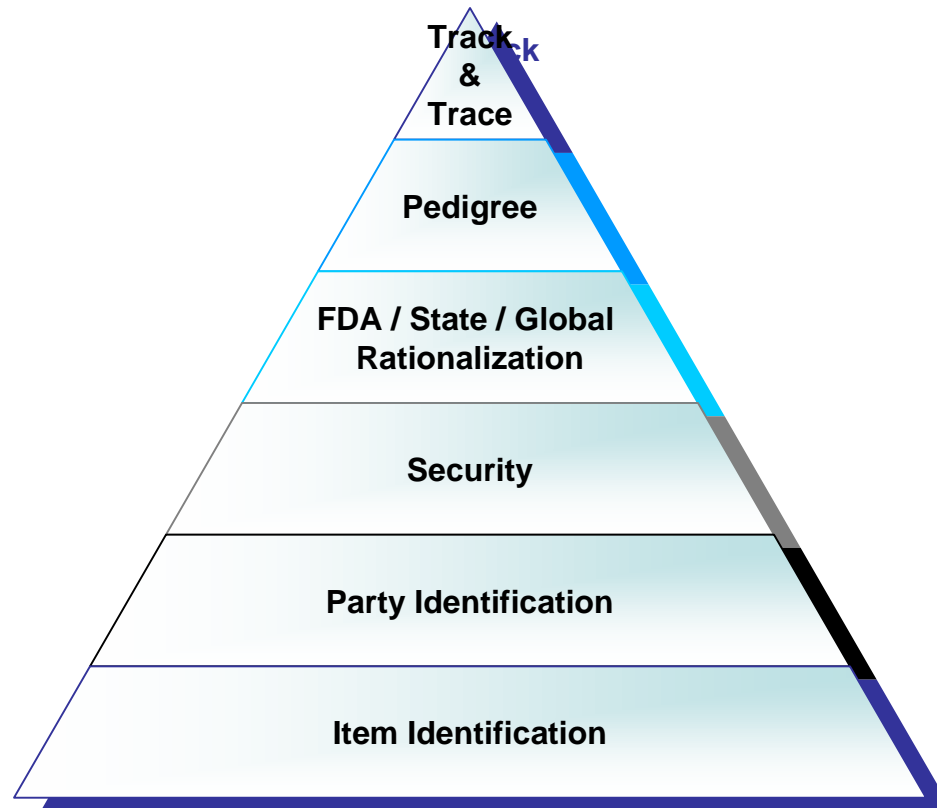


What is Authentication???



E-Pedigree Standards

Data Pyramid

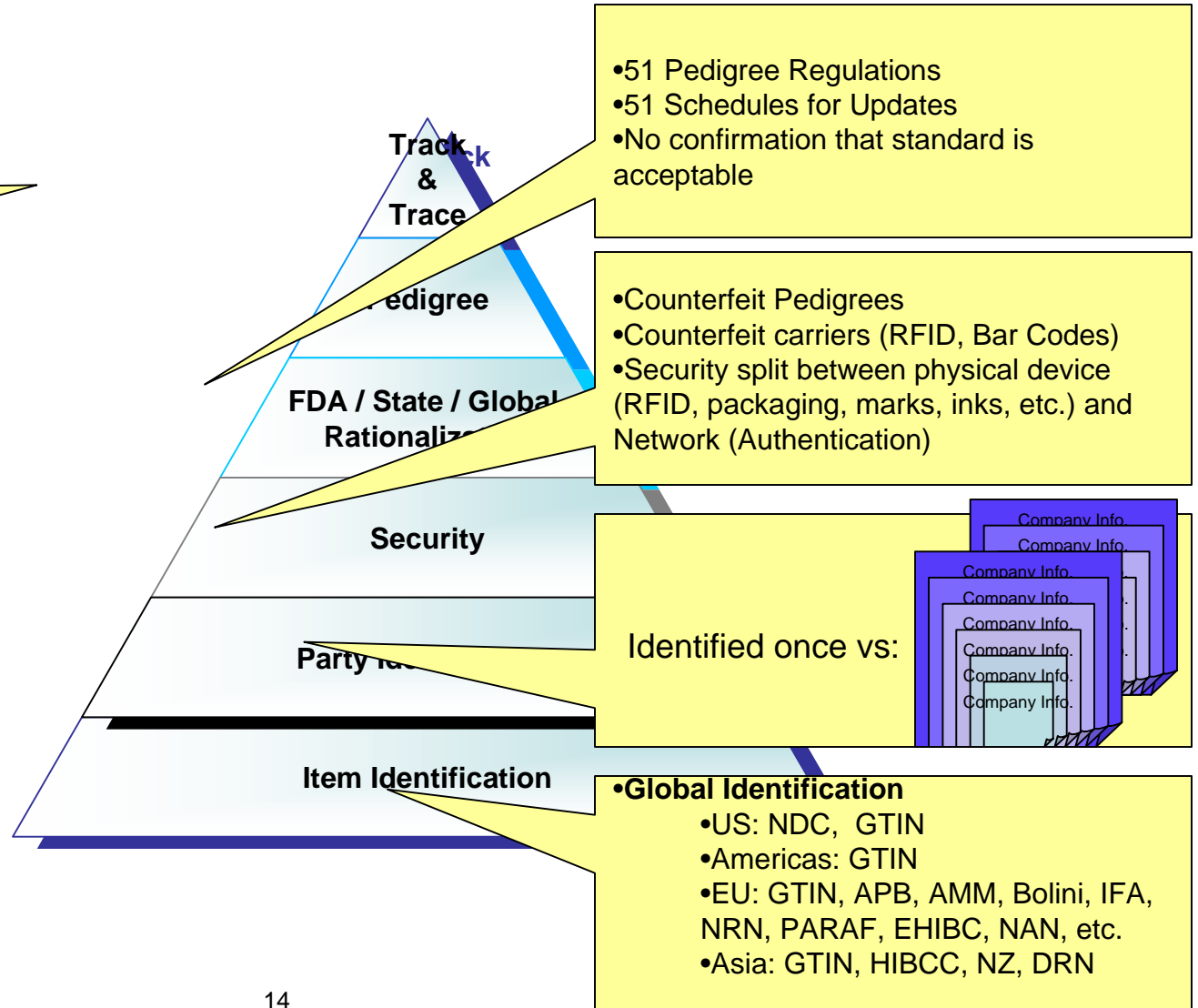
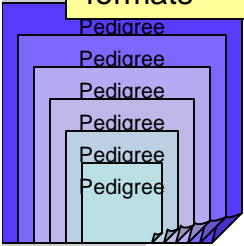




E-Pedigree Standards Issues

- Delays due to Pedigree Activity
- Data Sharing Issues

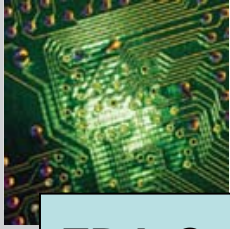
- Pedigree Parsing
- Data Management
- Incorporation of non-standard formats





Pedigree





Definitions of Pedigree

FDA Counterfeit Drug Task Force Interim Report

“A pedigree is a statement of origin that traces the drug from the point of manufacture and contains information about all transactions that the product undergoes until it reaches the end user.”

Florida Statute Chapter 499.003

“Pedigree paper means ... a document in a form provided by the Department of Health and containing information that records each distribution of any given legend drug, from sale by a pharmaceutical manufacturer, through acquisition and sale by any wholesaler or repackager, until final sale to a pharmacy or other person administering or dispensing the drug.”

NABP Model Rules for the Licensure of Wholesale Distributors

“Pedigree means a document in a form, written or electronic, approved by the State Board that records each Distribution of any given Drug, from the sale by a Manufacturer through acquisition and sale by any Wholesaler Distributor or Repackager...”



E-Pedigree Standard

Objectives for a E-Pedigree Standard

- A Standard must address two key challenges in pharmaceutical industry:
 - Provide a **universal interchange format** to express pedigree requirements of varied state regulations as drug products **flow from one state to another**
 - Enable trading partners to send and receive pedigrees in a **secure and interoperable** manner that leverages existing B2B technologies and processes



E-Pedigree Standard

E-Pedigree Requirements

- Support for **all** required **data elements** for PDMA and states
- Support for **non-serialized and serialized** items
- Support for **repackaged** products
- Support for **sales, transfer, and return** transactions
- Support for creating **electronic pedigree from paper** pedigree
- Support for **digital signatures** and **electronic authentication**
- Representation of pedigrees in a **common portable format**
- Exchange using **existing business data transfer mechanisms**
- **Participation by all parties in Supply Chain**



E-Pedigree Standard – Florida Only

Pedigree Data Elements

- **Product Information**
 - Drug name
 - Manufacturer
 - Product NDC, dosage form, strength, container size
- **Item Information**
 - Lot number and expiration date
 - Quantity of units by lot
 - Product serial number (if serialized)
- **Transaction Information**
 - Transaction identifier (e.g., PO, Invoice) and date
 - Transaction type (e.g., sale, transfer, return)
 - Date received
- **Trading Partner Information**
 - Business name, address, and license of seller
 - Alternate ship-from location of seller
 - Seller contact information for authentication
 - Business name, address, and license of recipient
 - Alternate ship-to location of recipient
- **Signatures/certifications**
 - Digital signature of seller
 - Digital signature of recipient



E-Pedigree Standard – Known Requirements

Process Requirements

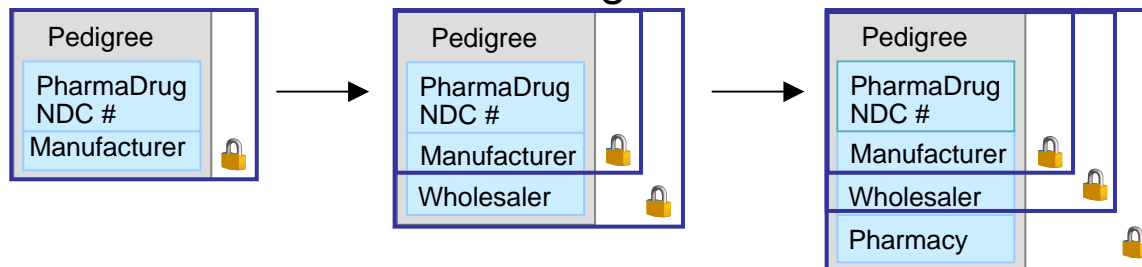
- Each party engaged in the **Wholesale distribution** of prescription drugs must **provide a pedigree** to the recipient for sales, returns, and transfers of prescription drugs
- Pedigrees must contain a **certification** (via signature) by the sender that the information is true and accurate
- Pedigrees must be **authenticated** by the recipient prior to receipt of drugs
- Recipient must add **receipt and authentication signature** to pedigree
- A pedigree received by or provided by an organization is a **subject to recordkeeping requirements** for record retention and record availability

What should be the process?



E-Pedigree Standard – Florida Only Signatures and Authentication

- Use of digital signatures to electronically sign (certify) the pedigree
 - Provides document integrity, authentication and non-repudiation
 - Recognized as extremely secure electronic signature
- Authenticate pedigrees electronically
 - Electronic verification of the signature and the signed transaction content for each transaction
 - Ensures that the signatures are valid and the transaction information has not been altered since signed



Paper based approach... can it be better ?



E-Pedigree Standard

Interchange Standards Working Group

- **E-Pedigree format for the pedigree data elements required by regulation**
 - Product information, transaction information, distributor and recipient information, and digital signatures
 - Item information to describe the specific non-serialized or serialized products in the transaction
- **E-Pedigree envelope for sending pedigrees to trading partners**
 - Identifying information about the envelope
 - Optional information about the relationship of pedigrees to products in cases to facilitate product-to-pedigree matching
 - Pedigrees for the products in the shipment



E-Pedigree Standard

Interchange Standards - “Completed”

- **Common format that meets PDMA and state needs**
 - ✓ Supports all required data elements for PDMA & one state
 - ✓ Extensible format supports future state requirements
- **Addresses regulatory and business requirements**
 - ✓ Support for non-serialized as well as serialized items
 - ✓ Support for repackaged products
 - ✓ Support for sales, transfer, and return transactions
 - ✓ Support for creating electronic pedigree from paper pedigree
 - ✓ Support for digital signatures and electronic authentication
- **Enables interoperability among trading partners**
 - ✓ Representation of pedigrees in a common portable format
 - ✓ Exchange using existing business data transfer mechanisms

What are the changes or additions for a National or FDA Standard?



ePedigree and RFID Challenges

Industry Challenges:

- **Data Sharing Issues**
- **Non-serialized Items**
- **Patient Privacy**
- **Public Policy**
- **Regulatory Considerations**
- **Cost/Benefits Differ by Stakeholder**
- **End-to-End Supply Chain Implementation Essential for Mass Adoption**
- **Lack of Universal Pedigree Agreement**

Technology Challenges:

- **Serialization**
- **Tag Frequency**
- **Performance**
- **Package Size**
- **Physical Characteristics**
- **Event Vocabulary**



EPCglobal Architecture Review

Track and Trace Platform





E-Pedigree Standards

Pedigree Data Elements

- **Product Information**

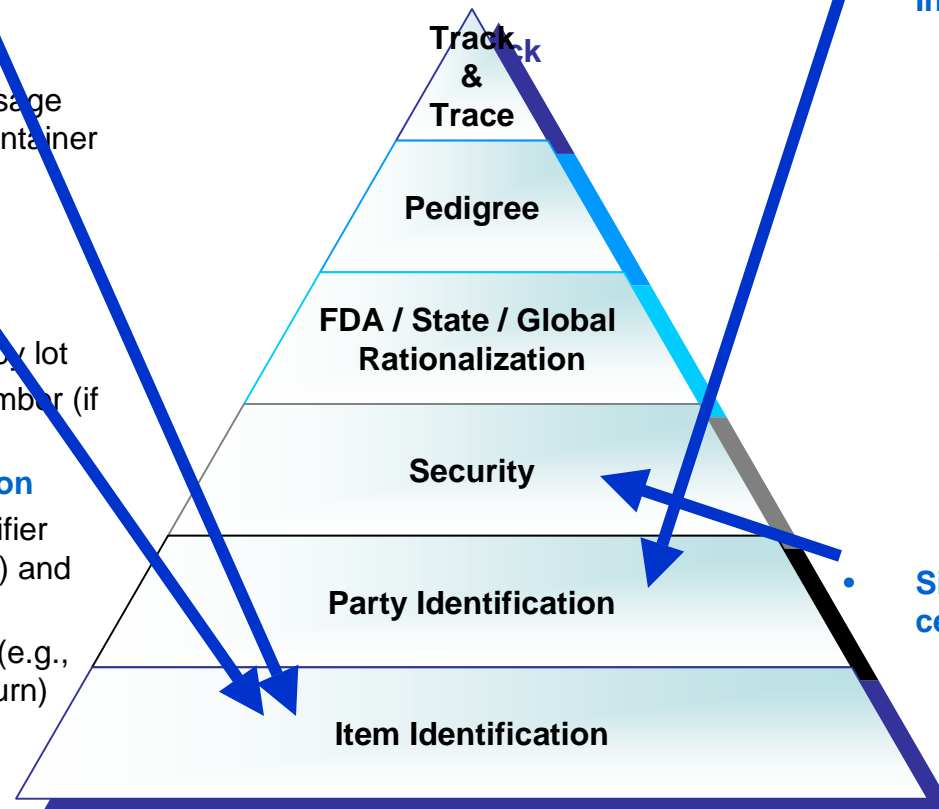
- Drug name
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- **Transaction Information**

- Transaction identifier (e.g., PO, Invoice) and date
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- **Trading Partner Information**

- Business name, address, and license of seller
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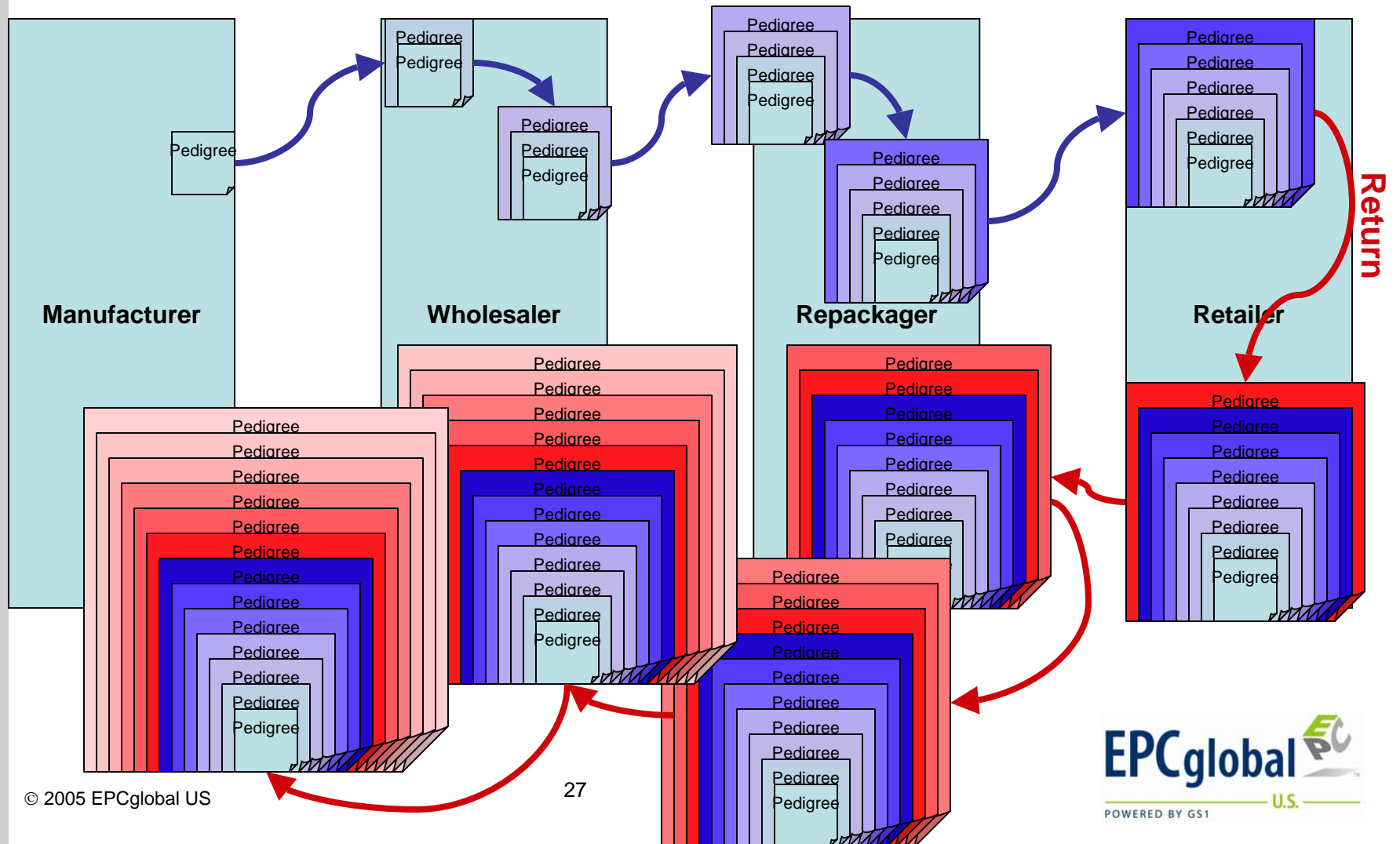
- **Signatures/ certifications**

- Digital signature of seller
- Digital signature of recipient



Pedigree Data

Passing Large amounts of redundant data



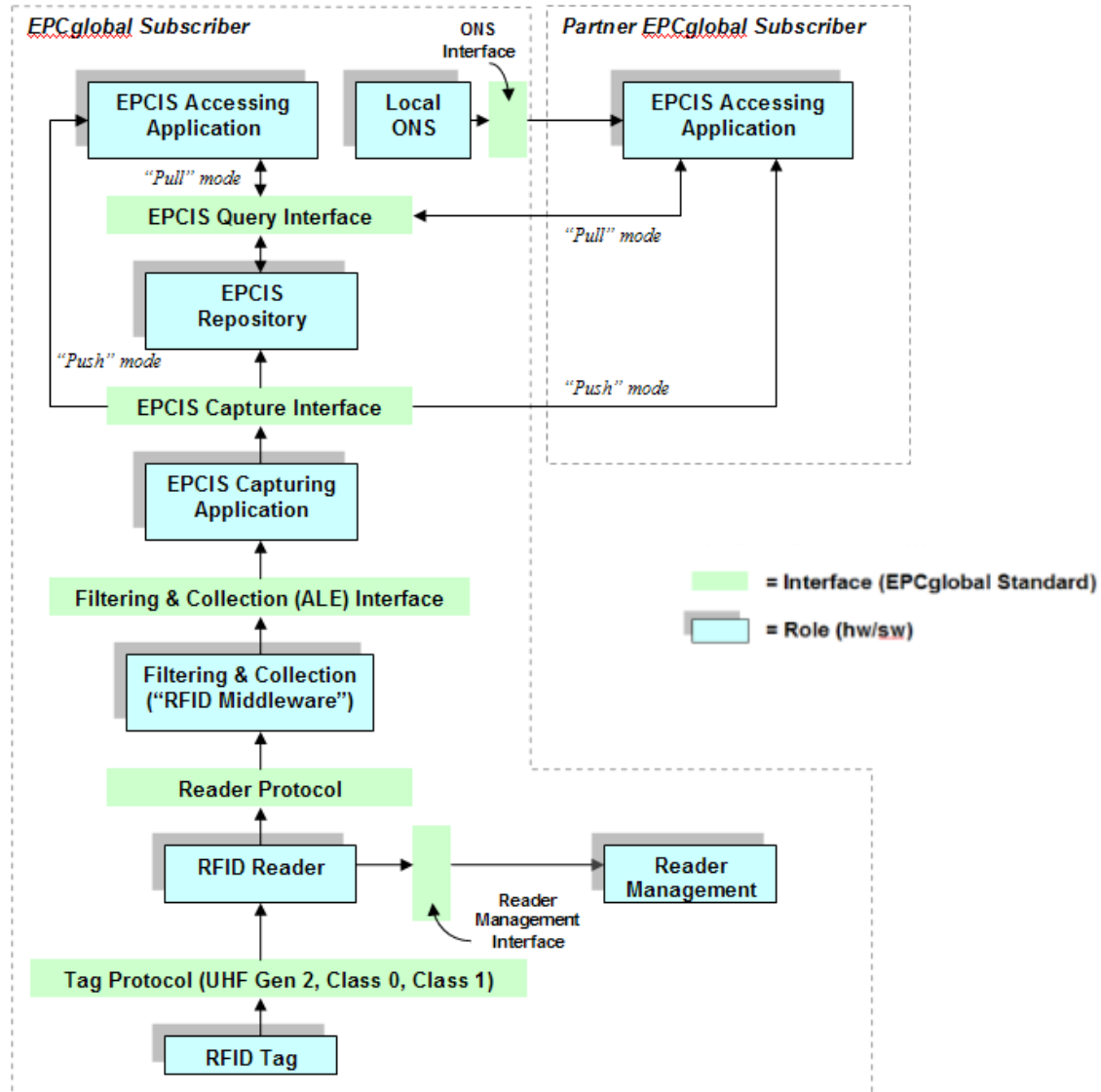


EPCglobal Network Architecture





Key Portions of the EPCglobal Architectural Framework





Objective of EPCIS

EPCIS is aimed at enabling disparate applications to leverage EPC via EPC-related data sharing, both within and across enterprises.

EPC Information Services

- Focused on data Capture/Query approaches using defined “services”/operations performed by request
- Not specifically tied to a particular technology
- Not tied to any particular industry



EPCIS in a Nutshell

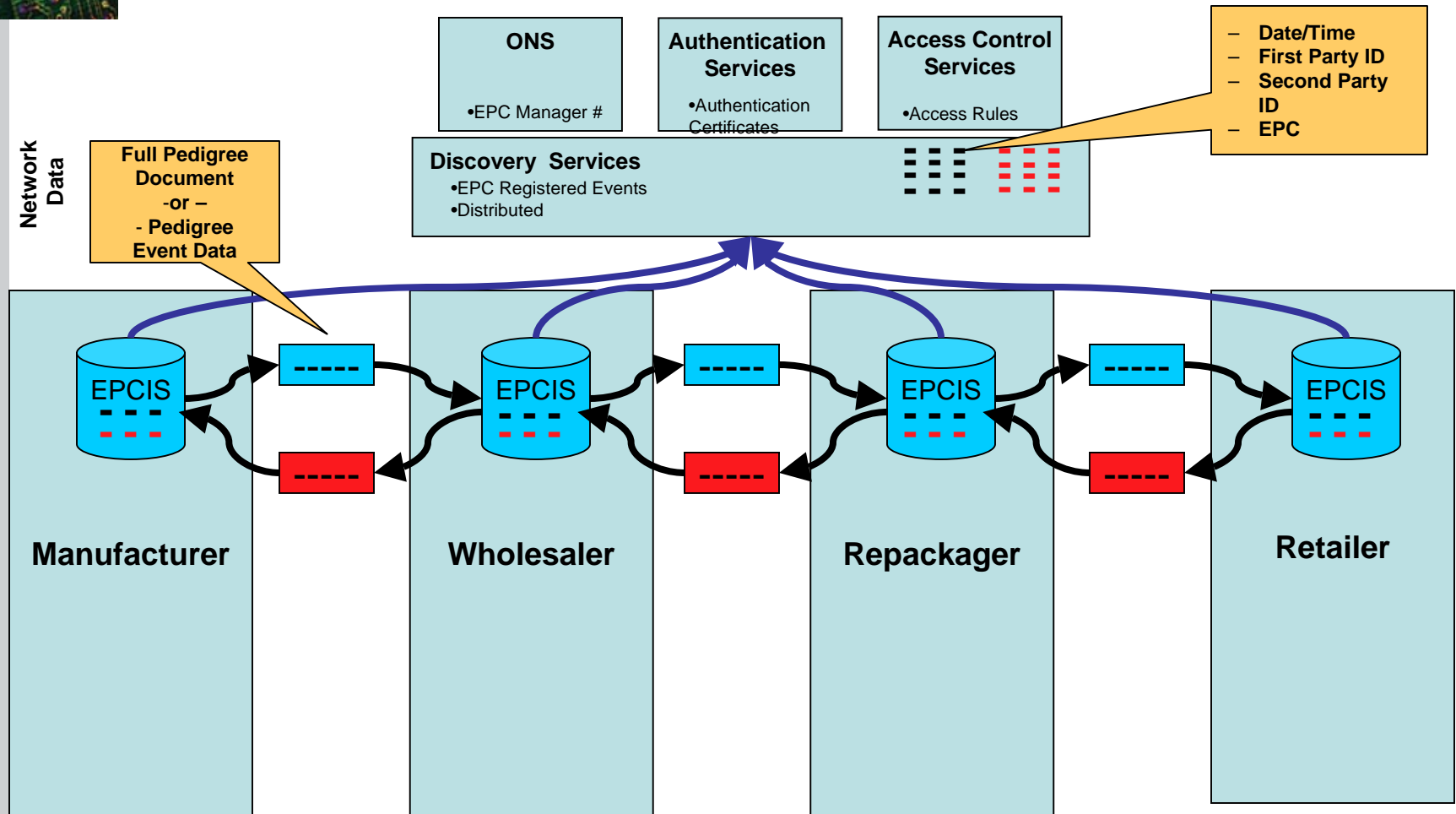
EPC Information Services

- **Service Interface** for Capturing/Querying EPC-related data
 - **EPC-related data standards** for sharing past and present data
 - **Services standards** for capturing/exchanging the data
 - **Security standards** to protect capture/exchange
- **Modular and extensible** for industry variation
- **Discrete EPCIS Instances**, no “Master EPCIS”



Track and Trace Data

Passing keys to pre-existing data





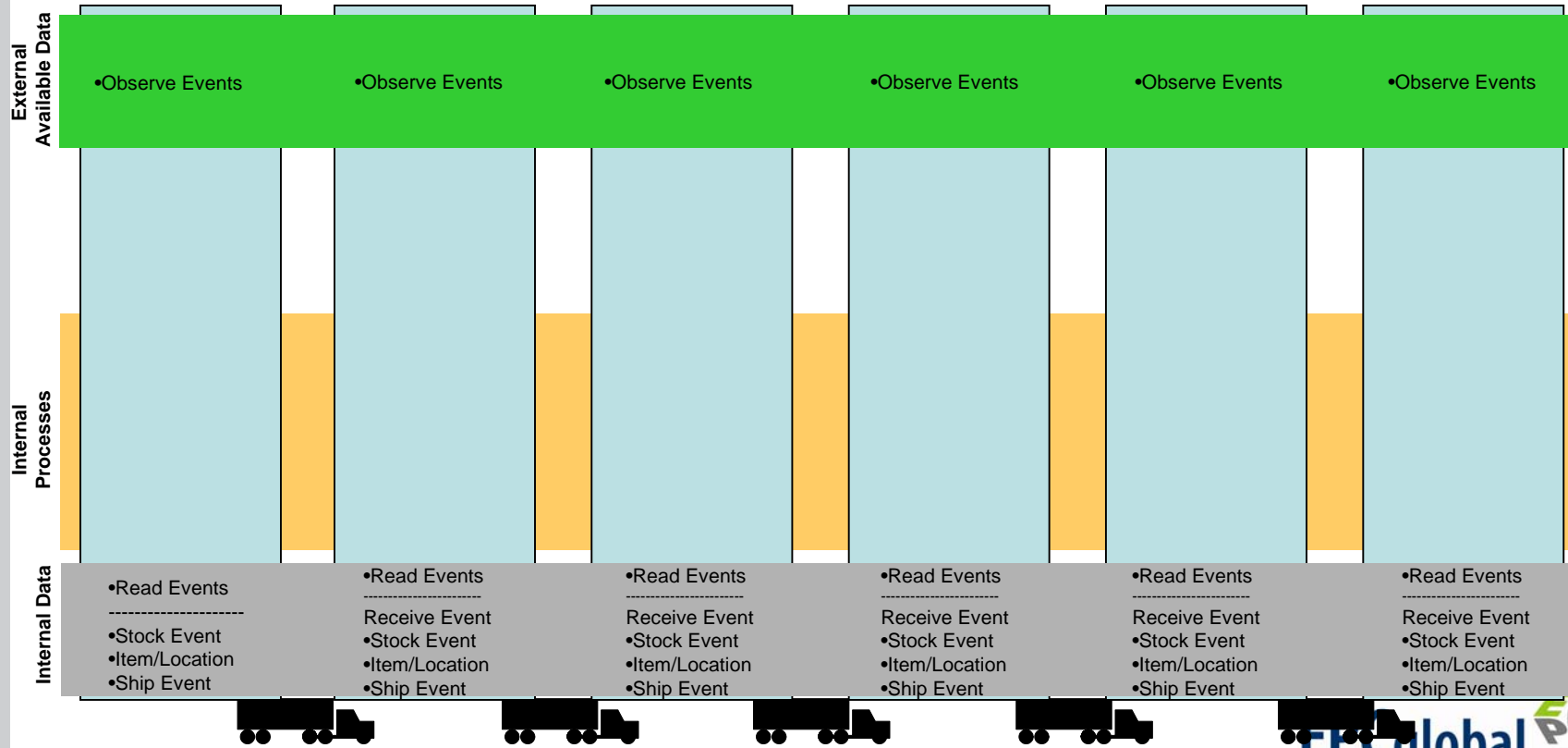
Using the EPCglobal Network Architecture for Track and Trace





The EPCglobal Network

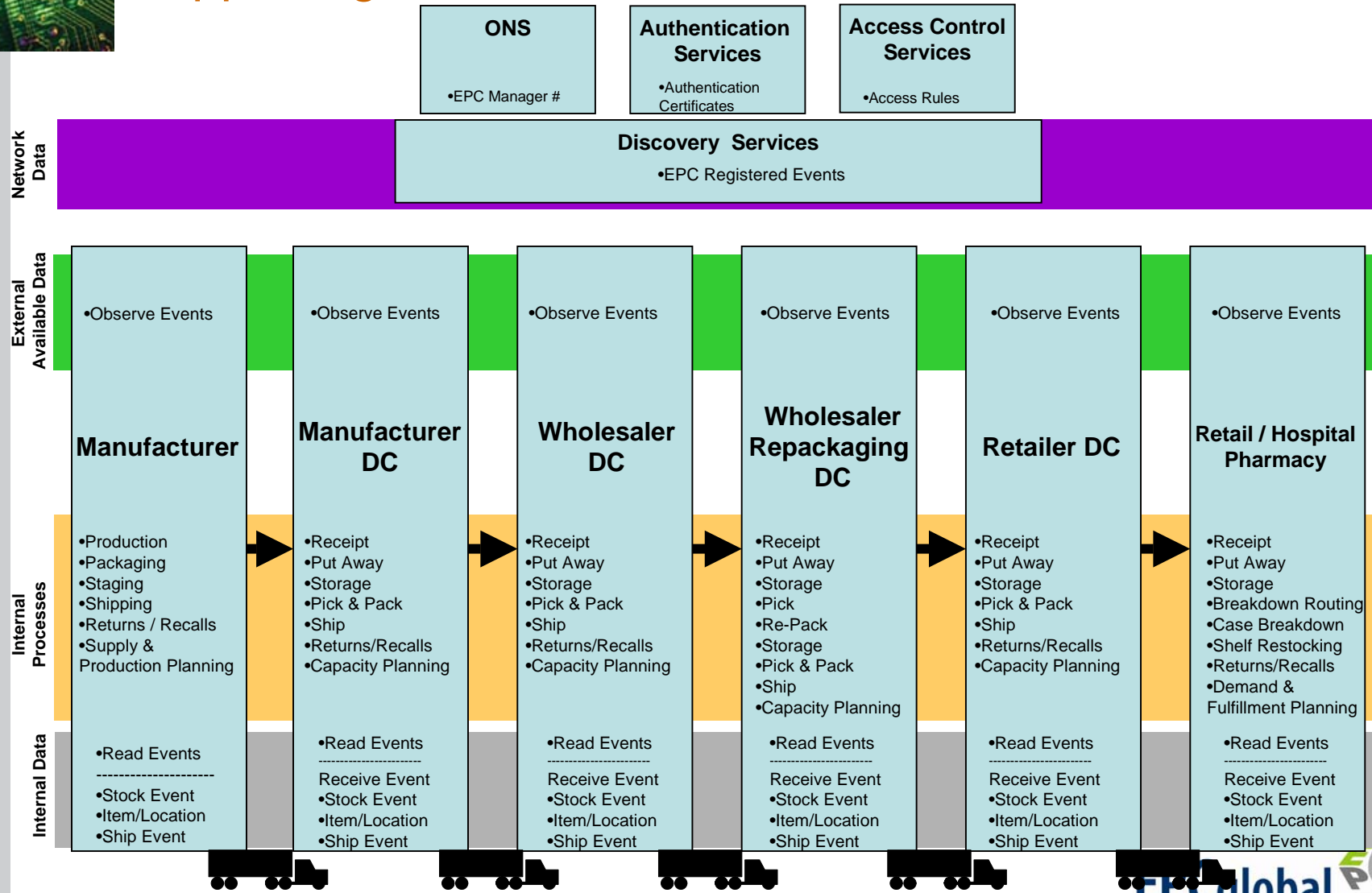
Supporting Track and Trace





The EPCglobal Network

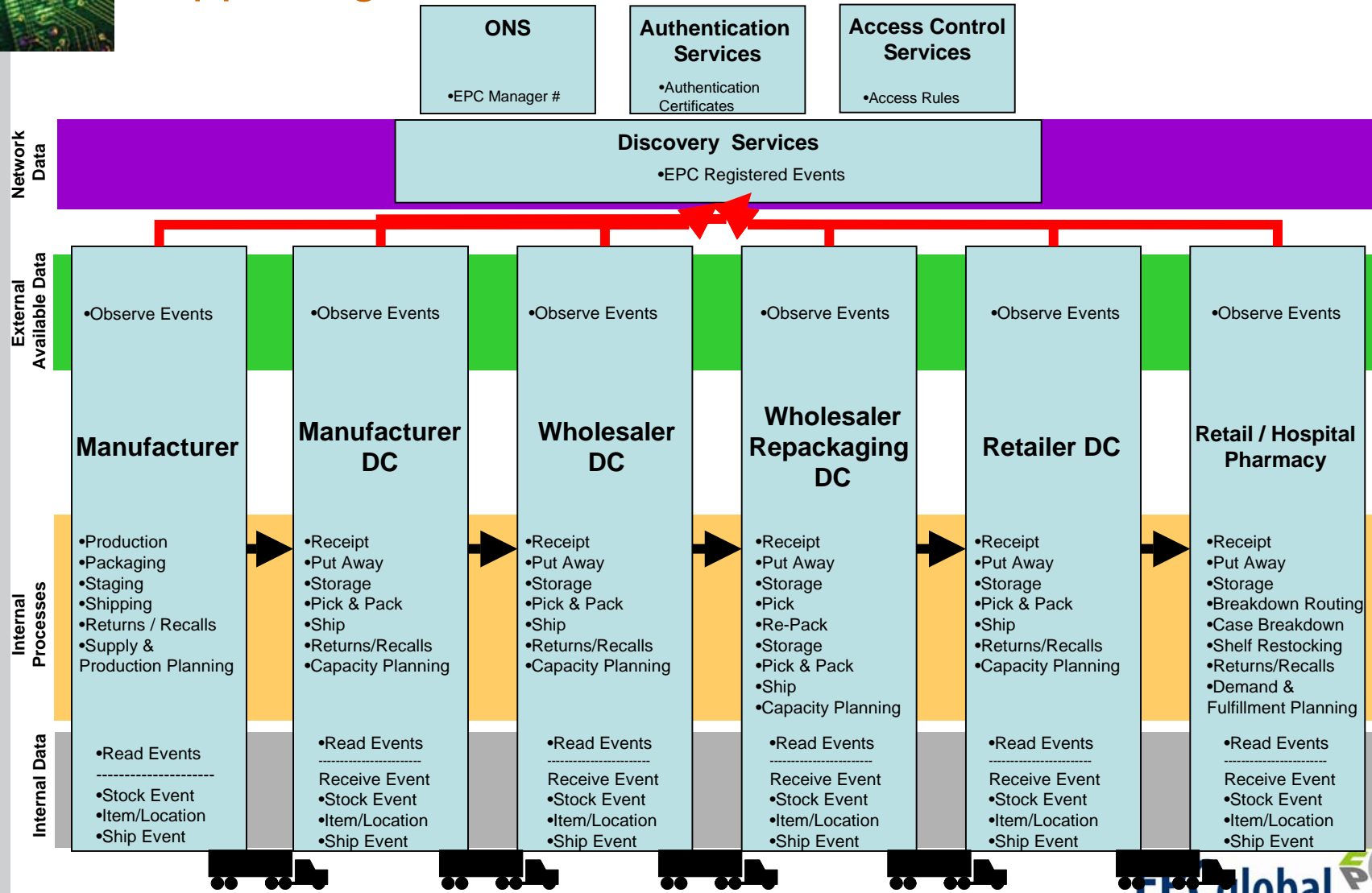
Supporting Track and Trace





The EPCglobal Network

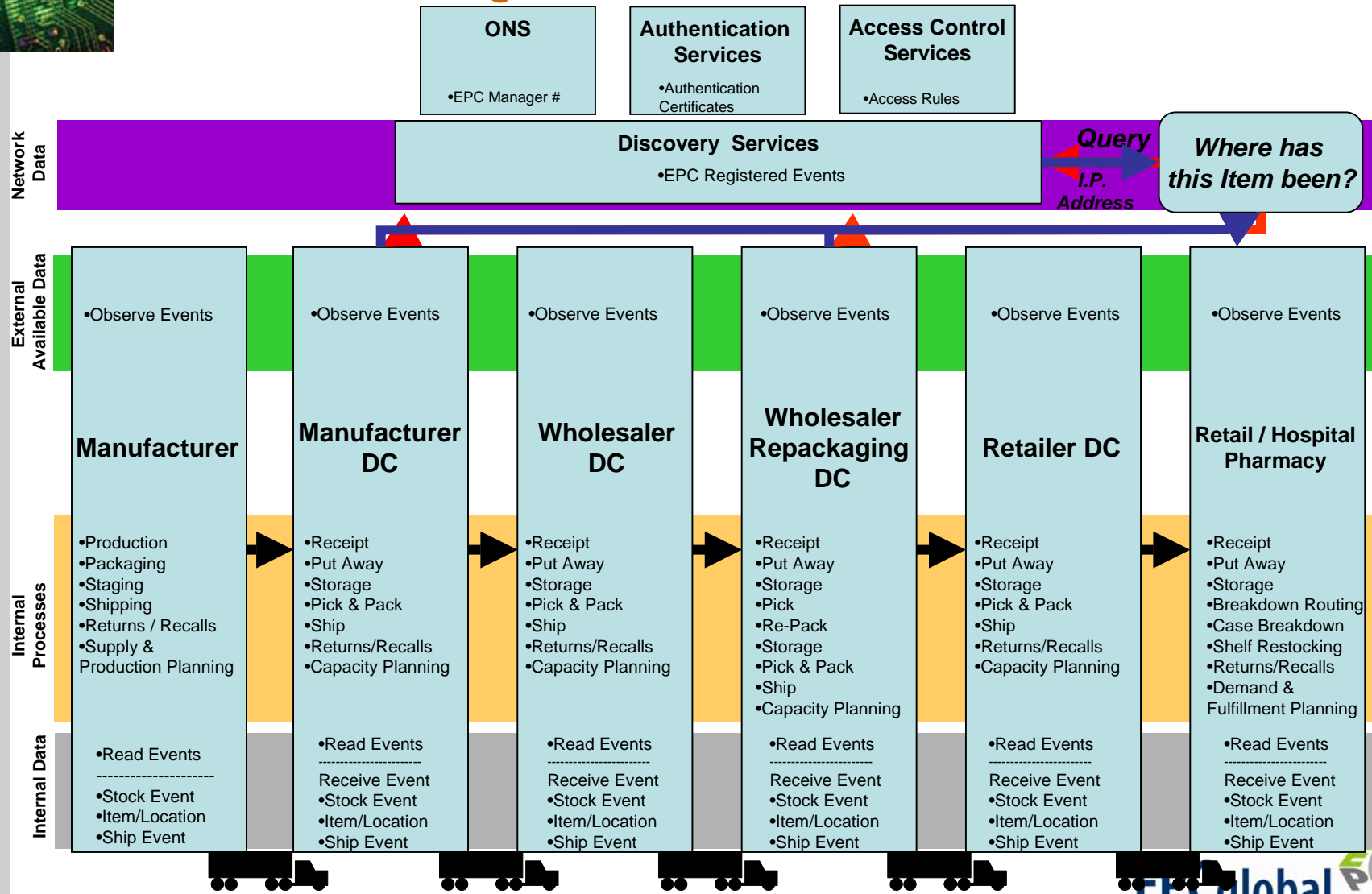
Supporting Track and Trace





The EPCglobal Network

Incident Investigation





Tricky Spots in EPCIS

- **Location**
 - Internal vs External visibility
 - Physically Hierarchical
 - Logically Hierarchical
- **Query Language**
 - Simple vs Rich
 - SQL vs XQuery vs Custom
- **Master Data**
 - Data that helps an accessing application interpret results (e.g. Street Address of a named location)
 - Capturing interface is not provided.
 - Separate Query language may be used to access.
 - Challenging Role in Event Query joins.
- **Discovery**
 - Currently not specified



Key Questions

- Events
 - What extensions may be required?
- Query Language
 - How intelligent would it need to be?
- Security
 - Are current directions sufficient?
- Discovery
 - Is it required?



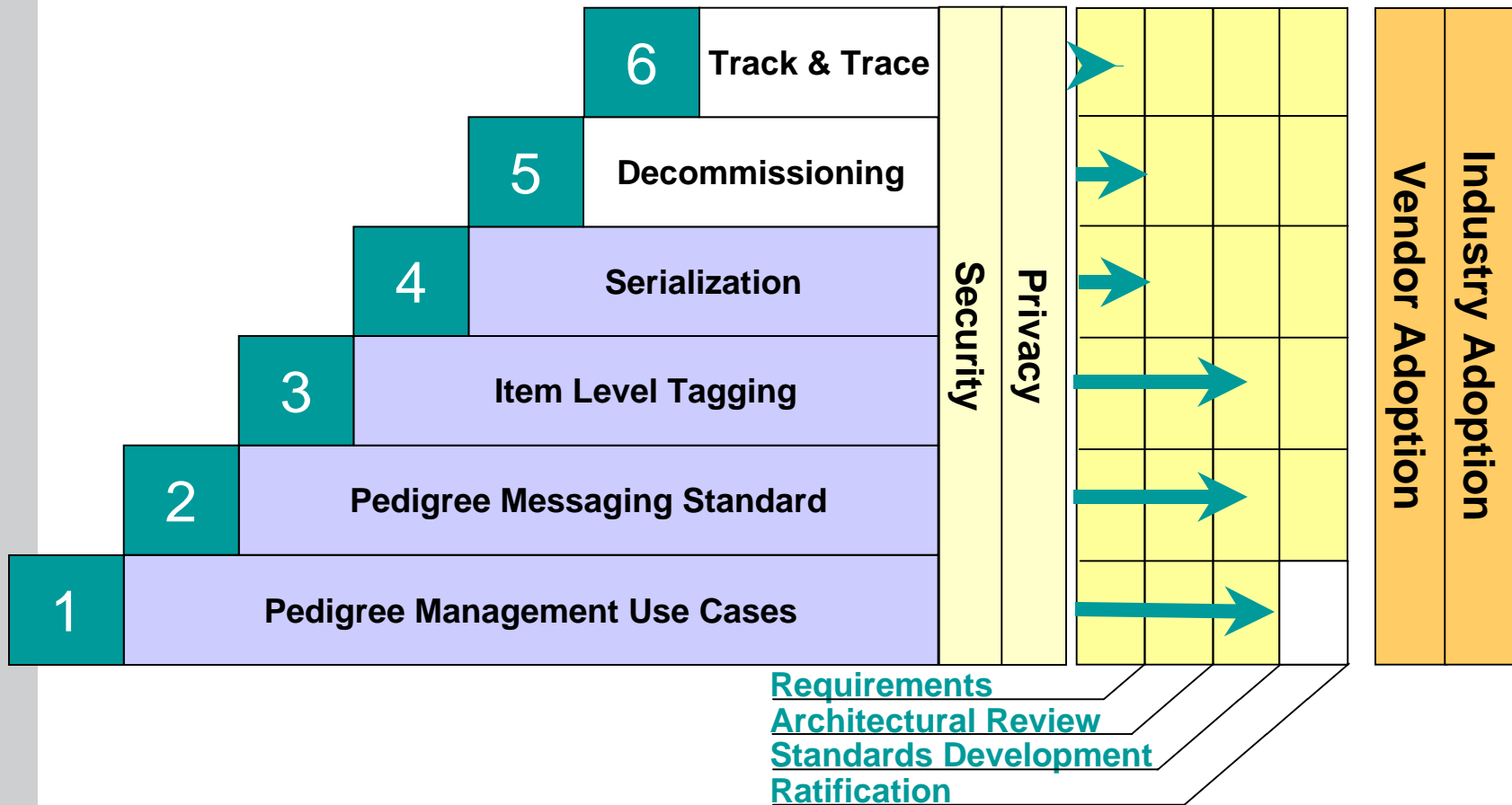
Standards Progress





ePedigree Standards

State of the Standards

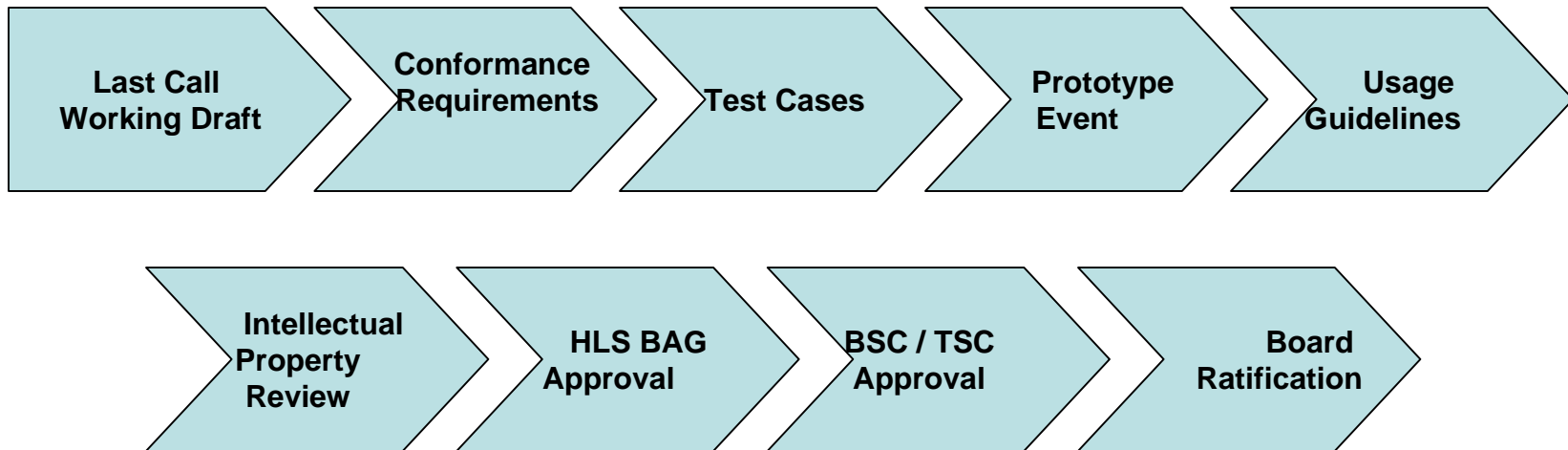




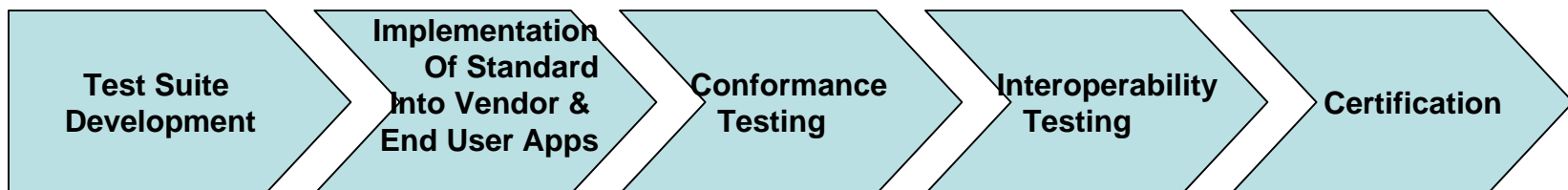
ePedigree

Development and Certification

Standards Development:



Certification Development:





Questions

Thanks....

