

Traceability Data Exchange Architecture (TDEA) White Paper



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TDEA Objectives

- Advance the dialogue around serialized data exchange and data architecture models
- Encourage input from all industry stakeholders
- Establish a common understanding of existing models
- Determine if consensus views exist and if harmonization of models may be possible
- Assess the need for additional pilots/proof of concept work
- Identify desired aspects of future pilot/proof of concept work
- The White Paper documents the workgroup comments on all of these topics.



Goals of White Paper

- Delineate choreography types and other considerations
- Establish a common understanding of the various models
- Document the merits (pro's and con's) of the various models as seen by the work group participants
- Discuss harmonization opportunities or define a hybrid approach to be assessed
- Advance the work effort required in order to make decisions regarding the desired choreography for future mandates (U.S. and other)



High Level Questions

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



Individual Market Requirements

- Differences in market requirements illustrate different data choreography models.
- Done in template format: Mandate status/Serialization/Key Dates/Supply Chain Data/Data Repositories/Funding/Governance.
- Markets covered: Brazil, China, US, EU, Turkey, South Korea, Argentina,



Data Storage & Choreography Model

Fundamental Model Aspects:

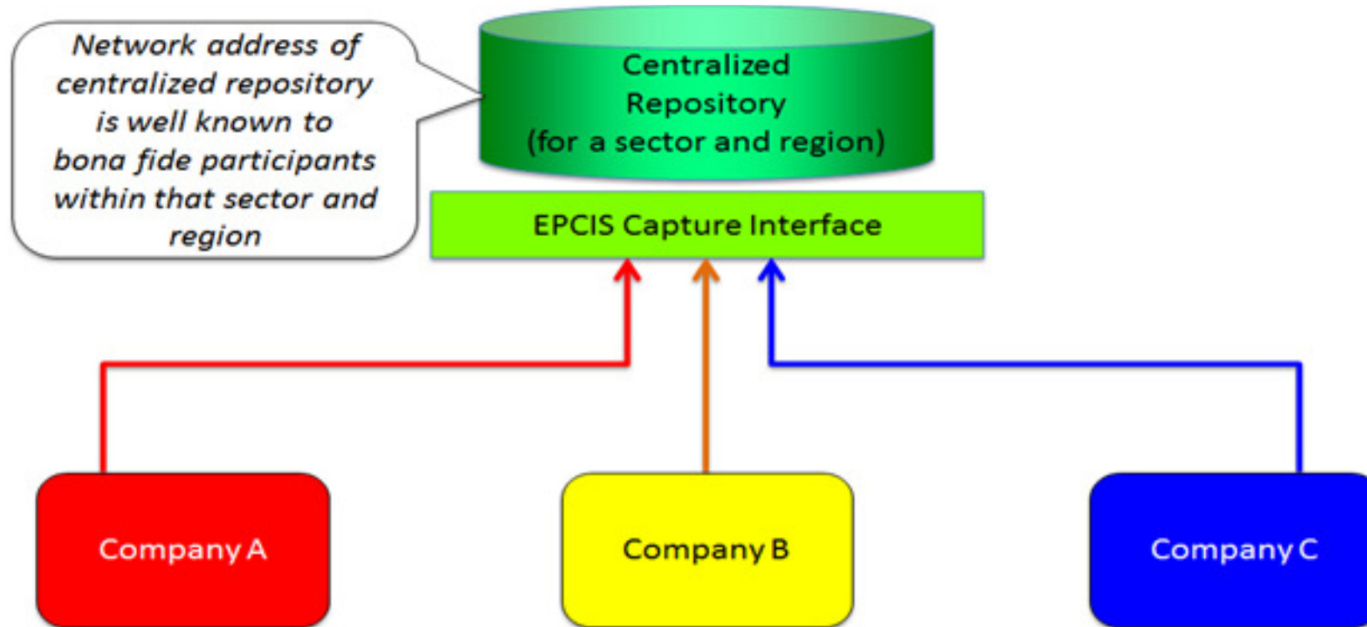
- **What data is needed?**
 - Master Data
 - Transaction Data
 - Event Data
- **Where does the data reside?**
 - Centralized
 - Semi-Centralized
 - Distributed
- **What is the data choreography?**

Choreography is the sequence of steps and movements needed to operate the model and define the process.

General discussion of the three aspects highlighted multiple topics including; cost, data rights, and ownership



Centralized Model Archetype

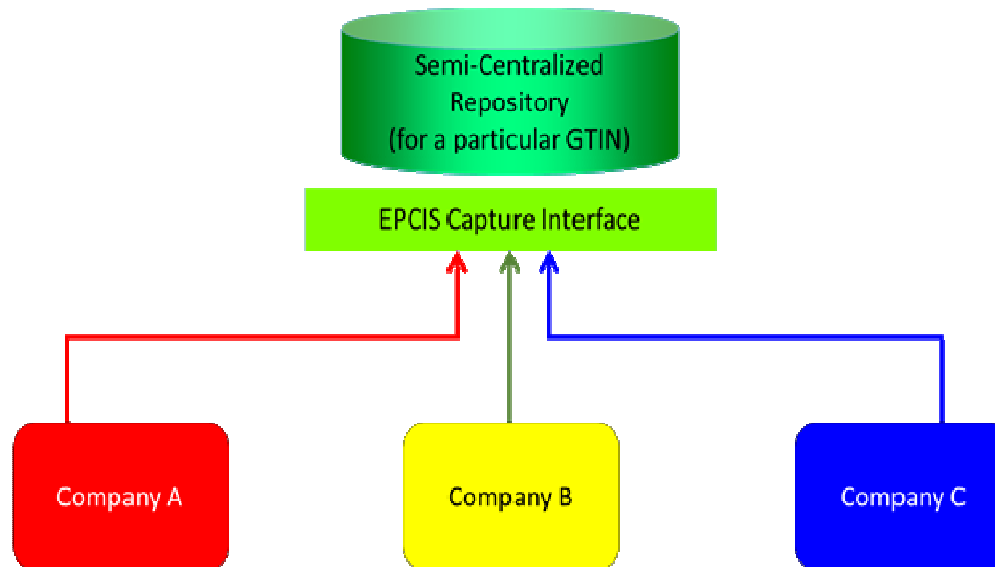


Model graphics used with permission from GS1 Global.

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.



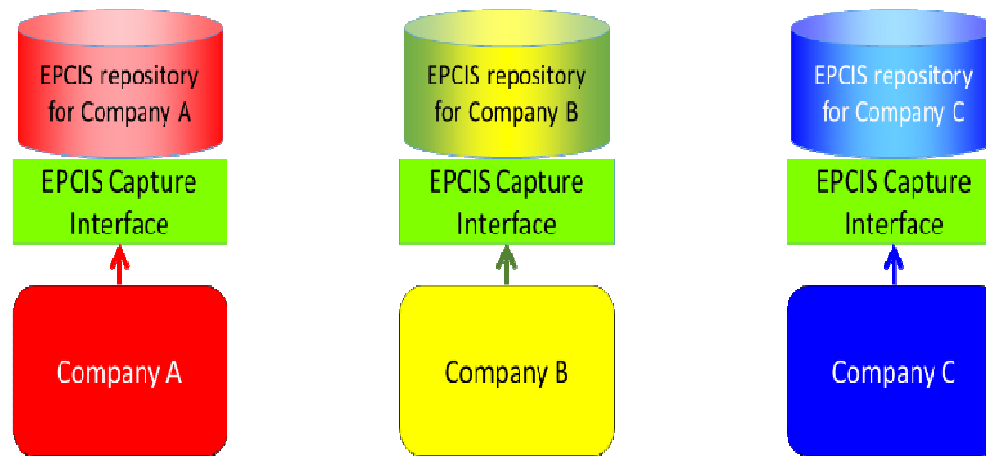
Semi Central Model Archetype



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.



Distributed Model Archetype

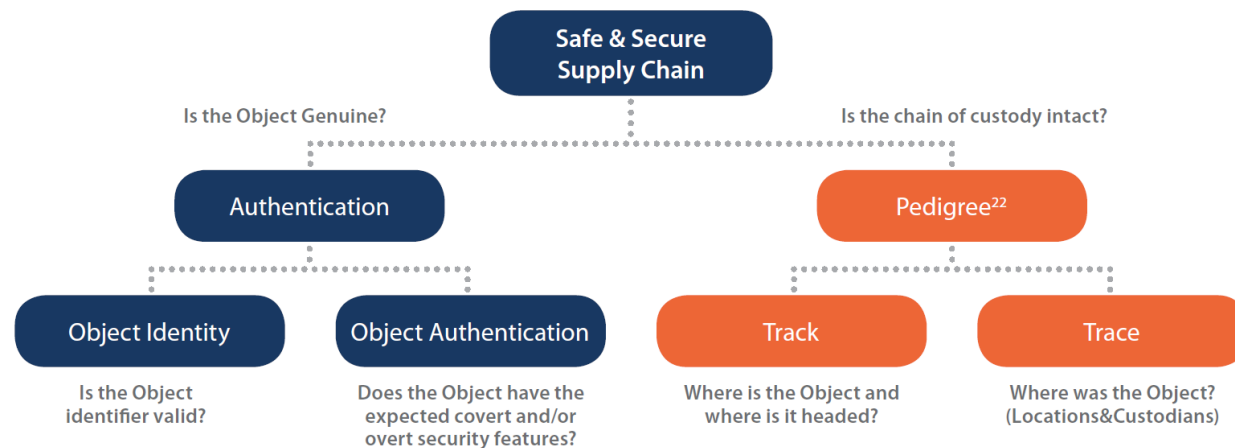


In a distributed database model, each repository which was used to store a given product instance's captured event data along each step of the supply chain path is queried in order to obtain data required for reporting.



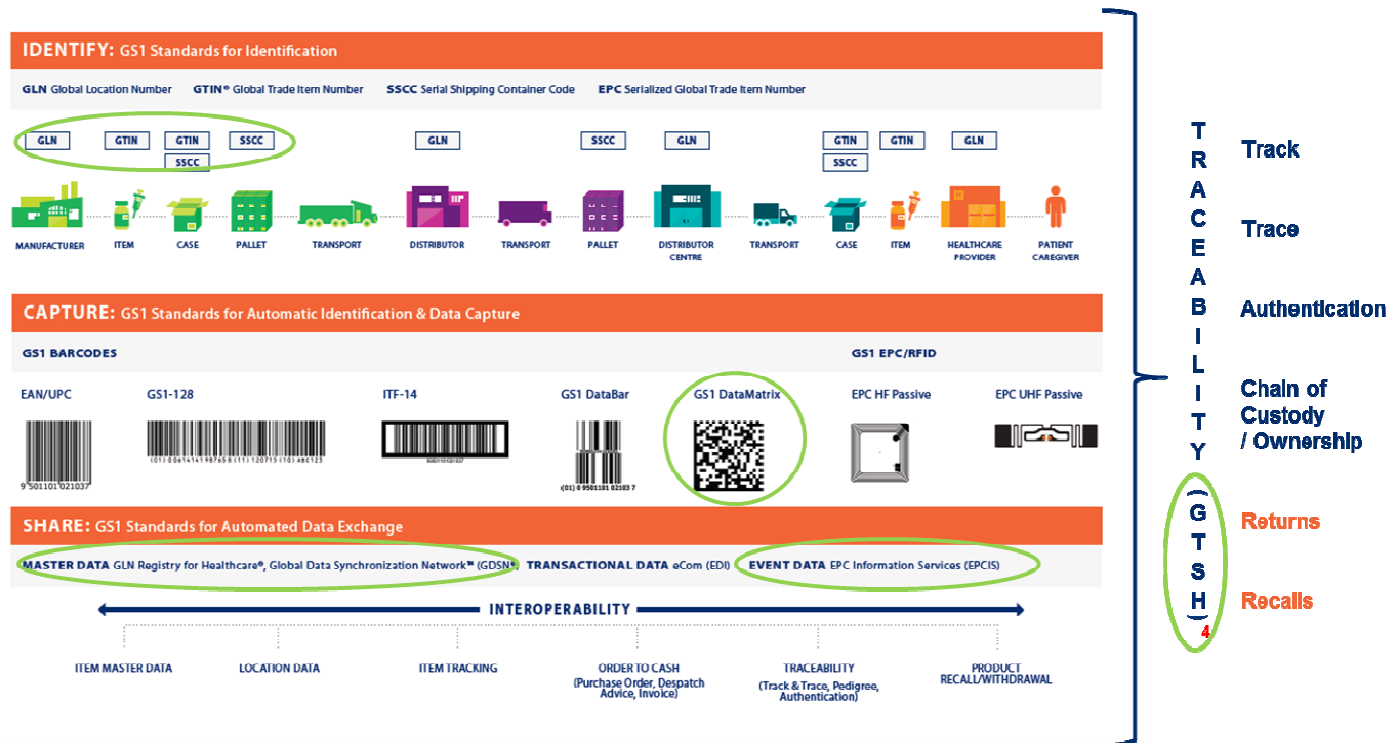
Data Choreography

- Ideal model choreography is achieved when alignment of created data allows appropriate access for the intended purpose.
- Can the product identification features be verified?
- Can the product be tracked to where it is – or traced to where it came from?



Identify, Capture, Share

- How will things be identified?
- What is used for data capture?
- How will data exchange be performed?
- What is the process to ensure objectives are met?



Summary of Data Storage & Choreography Issues

Stakeholders must agree on:

- What data is needed to meet the objective?
- Where is the data stored?
- How does the data move and who has access to it?
- How to define the process of “who has to do what – and when does it need to be done?”



Advancing the Industry Dialog

- Proactive collaboration among all sectors.
- Understand the priorities and concerns of each sector.
- Timing of POC work.
 - What characteristics should be tested
 - How would results be evaluated against each other.
 - Can we test on an appropriate scale to determine real operational impact?
 - Can more than one industry pilot run concurrently?
- Future Harmonization and Implementation Impact.



Assessment Criteria for Characteristics

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



POC Work

The TDEA participants labeled these as a list of characteristics requiring POC work:

- Aggregation & Inference
- Operational Impact of Serialization
- Errors and Exception Handling
- Data Movement
- Transaction Data v. Master Data
- Cost Comparisons
- Data Access & Ownership
- Inventory Visibility
- Test Semi-centralized model



Next Steps and Timing

- PDSA Assessment Criteria & Evaluation
- HDMA POC Work
- US FDA and ABAC (APEC Business Advisory Council) Pilots
- Industry call to action.
 - Industry must engage in 2015 to have impact on developing requirements.



Thank You

