



## DSCSA and Blockchain Phase 2 Study - Proof of Concept Pilots

### PoC Structured Walkthrough Meeting Reference Material

***Welcome to the DSCSA and Blockchain Phase 2, Proof of Concept walkthrough meeting!***

We created this guide to help you better understand the work of the Study team, the PoC Sub-Teams and the Structured Walkthrough Meeting.

***Please use the links above to explore the material***

*If you have any questions about the material, study or meeting, please contact Bob Celeste at [rceleste@c4scs.org](mailto:rceleste@c4scs.org)*

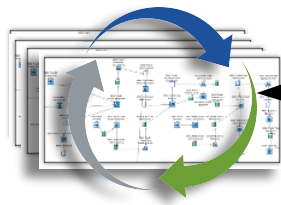
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## Phase 1

Exploration --> Experimentation --> ReferenceModels™



## Phase 2

ReferenceModels --> Proof of Concepts --> Roadmaps



We are Here!



## Phase 3+

Roadmaps --> Consensus --> Industry Pilots



### Phase 1: Exploration and Experimentation

With the team's initial understanding of working with many unknowns, our Phase 1 Study was chartered as an exploratory examination of three complex subjects:

- ▶ *The US Pharmaceutical Supply Chain and the nuanced relationships of its stakeholders*
- ▶ *The Drug Supply Chain Security Act (DSCSA) and the varying interpretations of its language*
- ▶ *Blockchain platforms, their existing and evolving capabilities*

Working together, the team established a set of **seven goals** (or challenges) outlined [here](#).

As weekly team meetings and discussions unfolded, several test scenarios were explored. In fact, at one point, we conducted nine separate experiments.

Ultimately, this resulted in the Study's **three final working ReferenceModels™** that be viewed [here](#).

### Phase 2: From Exploration to Proof of Concept

Chartered as a Proof-of-Concept (PoC) Pilot Study, Phase 2 was launched with the understanding that few supply chain participants are currently capable of exchanging serialized product data or connecting to a blockchain.

#### Creation of the PoCs

The PoCs were implemented in each team's test environment. PoC teams presented their work at Johns Hopkins University on April 30th – May 1st, 2018. The PoC presentations can be viewed [here](#).

#### Value beyond compliance

During this Phase 2 stage, PoC teams also have been working to identify potential benefits for the industry *beyond* DSCSA compliance. PoC teams were encouraged to present some of this work in their PoCs at the Walkthrough Meeting.

#### An industry call for DSCSA Roadmaps

A key take-away from the PoC Walkthrough Meeting was the stakeholders' desire for roadmaps that focus on achieving industry goals to support DSCSA compliance for 2019 & 2023 and separate roadmaps for value added uses.

### What comes next?

#### The work continues

Throughout Study Phases 1 & 2, both teams worked to balance DSCSA requirements with supply chain best practices and individual stakeholder B-to-B opportunities.

This approach will continue as teams create and implement the roadmaps and will proceed at a pace aligned with the industry.

#### New explorations ahead!

The discovery and experimentation that took place in Phases 1 & 2 generated a wealth of new ideas that may ultimately benefit supply chain stakeholders and patients.

Those concepts with the highest levels of interest and viability will be chartered as new Studies open to all stakeholders.

## DSCSA &amp; Blockchain: Phase 2

## Proof-of-concept pilots



**Day 1** was dedicated to deep dives into the activities and learnings of the individual PoC teams. Each team discussed their strategy and implementations as they related to the three Reference Models developed in the Phase 1 Study as well as their individual added value ideas and concepts.

**Day 2** was dedicated to understanding common challenges encountered by all the PoC teams and the industry stakeholders in general. We also devoted time to understanding how analytics can aid the Studies and implementations. The Blockchain for Cold Chain team also provided an updated.

DAY 1: April 30, 2018	
Time	Topic / Presentation
8:00 – 9:00 am	Registration & Continental Breakfast
9:00 – 9:10 am	Welcome & Introduction
9:10 – 10:00 am	"Extending Master Data Management Practices for DSCSA Compliance" and audience Q&A <i>Andrew Nail, ValueCentric / Bob Celeste, C4SCS</i>
10:00 – 11:00 am	<b>BLUE TEAM DEMO:</b> "Using a distributed blockchain network for compliance & innovation" <i>Susanne Somerville &amp; Maurizio Greco, Chronicled</i>
11:00 – 12:00 pm	<b>PURPLE TEAM DEMO:</b> "Creating a 360° View of the Biopharma Supply Chain with Digital Ledger Technology" <i>Darryl Glover, iSolve / David Houlding, Intel / Caitrin O'Shea &amp; Salvatore Paparone, Excellis</i>
12:00 – 12:55 pm	Buffet Lunch
1:00 – 2:00 pm	<b>GREEN TEAM DEMO:</b> "Blockchain: A viable end-to-end solution for pharma supply chain" <i>Joseph Lipari, Systech / Dwight DeVera, RxTransparent</i>
2:00 – 3:00 pm	<b>ORANGE TEAM DEMO:</b> "The Power of Many: Blockchain interoperability and portability for DSCSA Compliance" <i>Catherine Woneis &amp; Peter Ebert, Cryptowork</i>
3:00 – 3:10 pm	Break (coffee, snacks)
3:10 – 4:10 pm	<b>AQUA TEAM DEMO:</b> "Answering the 'Where's My Stuff?' question for the pharma supply chain" <i>Rahul Shah &amp; Aadesh Brahmhatt, Axium Technology Group</i>
4:10 – 5:10 pm	<b>YELLOW TEAM DEMO:</b> "Beyond Compliance: DLT Implementation Lessons Learned & Supply Chain Optimization Potential" <i>Stuart Corby &amp; Rob Torti, Authentag / Nishant Modi, Accenture</i>
5:15 – 6:30 pm	<b>COCKTAIL RECEPTION</b> (in same location)

DAY 2: May 1, 2018	
Time	Topic / Presentation
8:00 – 9:00 am	Registration & Continental Breakfast
9:00 – 9:15 am	Welcome & Introduction
9:15 – 10:00 am	"DSCSA & Blockchain: The Analytics" <i>Swamy Narayanaswamy, CalQLogic</i>
10:00 – 10:45 am	PANEL DRILL DOWN #1: Confidence & Trust
10:45 – 11:00 am	Break (coffee, snacks)
11:00 – 11:45 am	PANEL DRILL DOWN #2: Elements of the Production-Ready System
11:45 – 12:30 pm	PANEL DRILL DOWN #3: Funding the Architecture
12:30 – 1:25 pm	Buffet Lunch
1:30 – 2:15 pm	"Blockchain for the Cold Chain" – presentation of initial Study Team findings <i>Mohamad Abdo &amp; Mike Rush, TempTime / Jim Sabogal, T-Systems</i>
2:15 – 3:00 pm	PANEL DRILL DOWN #4: Is a 'Governance-Less' System Possible?
3:00 – 3:15 pm	Looking Ahead / Closing Remarks



The purpose of the Phase 2 Proof of Concept effort was to advance industry's knowledge of DSCSA, blockchain and the US pharmaceutical supply chain by attempting to create reference implementations of the simulated ReferenceModels™ developed in the Phase 1 Study.

Although the Phase 1 ReferenceModels provided a great deal of insight into the challenges and benefits of blockchain use for DSCSA, quite a bit more can be learned by actually attempting to implement the designs and concepts. In fact, many challenges remain in blockchain technology strategies, supply chain stakeholder needs and DSCSA language interpretation.

With only a few months from start to finish, some of the teams implemented in their test environments, while others provided solution ideas to some of the more pressing challenges such as interoperability, confidentiality and data provisioning. All teams shared their insights on how they worked around these obstacles.

The analysis of these efforts will provide the whole Study Team with insight into:

- ▶ Interoperability (between solutions and blockchains)
- ▶ Confidentiality and privacy technical options
- ▶ DSCSA 2019 vs 2023 requirements
- ▶ Remaining misconceptions of the language of the law vs general track and trace concepts
- ▶ Issues that require industry-wide consensus
- ▶ Opportunities for standardization
- ▶ Specific roadmaps for 2019 and 2023
- ▶ Potential for separate, non-DSCSA compliance efforts

**Blue Team**  
Presented by:  
Chronicled

**Purple Team**  
Presented by:  
iSolve, Intel and  
Excellis

**Green Team**  
Presented by:  
RxTransparent &  
Systech

**Orange Team**  
Presented by:  
CryptoWerk

**Aqua Team**  
Presented by:  
Axiom Technology

**Yellow Team**  
Presented by:  
Authentag &  
Accenture

**Master Data  
Management**  
Presented by:  
ValueCentric

**Analytics**  
Presented by:  
CalQLogic

**Cold Chain for  
Blockchain**  
Presented by:  
TempTime and  
T-Systems

Team presentation materials are attached to this document. Also, more info can be found [here](#).



### Welcome to the DSCSA and Blockchain Phase 2, Proof of Concept walkthrough meeting!

Our Phase 1 Study team explored many avenues for using blockchain to support compliance with the Drug Supply Chain Security Act (DSCSA). In doing so, the team took a deep look into the complexities of the DSCSA, US pharmaceutical supply chain and blockchain concepts and platforms. To aid discussions, they established a framework for discussing complexities which mapped the interactions between data governance, supply chain stakeholders, service stakeholders and an industry blockchain.

The team also established categories for data, data access rules, processes and functionality. They identified data, process and rules associated with DSCSA, supply chain practice and individual trading partner processes. These categories allowed experimentation to continue without confusing the reason for design elements. Lastly, the team defined three ReferenceModels or system designs that could support DSCSA compliance. Each ReferenceModel included design graphics and supply chain simulations implementing product and information flow through defined scenarios.

These experiments allowed the team to experience simulated interactions between stakeholders, data creation and exchange under a number of typical and abnormal circumstances, testing the assumptions, rules and capabilities applied to the simulated scenarios. These simulations led the team to discover nuanced issues with implementing a system that must support interoperability, data sharing, confidentiality and perform at a level that will not cause supply interruptions of critical medicines. The models also provided insights into little examined issues such as mergers and acquisitions, declared emergency recovery and efficient processing.

The work of the Phase 1 team was the starting point for this Phase 2 effort. The Phase 2 team sought to trial implement key design elements, scenarios and techniques defined in the Phase 1 Study and continued refinement of those models. Often addressing new challenges uncovered during the exploration process. Phase 2 team members formed a series of Proof of Concept Pilot teams in order to move ReferenceModel designs and concepts from the simulation environment to the proof of concept stage.

As this was a time-constrained effort and the stakeholders are at an early stage of exploring traceability and interoperability mechanisms, the data in the PoCs were self-generated or created from the ReferenceModel simulations. As design elements continue to mature and gain acceptance amongst the stakeholders, we expect future PoCs will include direct stakeholder and stakeholder system participation.



## ***DSCSA & Blockchain Study Goals***

*The team identified the following unresolved challenges facing the development of an industry-wide interoperable system defined in the Enhanced Drug Distribution Security section of the DSCSA law.*

- 1. Establish an electronic connection between adjacent and non-adjacent trading partners,*
- 2. Establish trust between these trading partners to support DSCSA requirements,*
- 3. Share required data without inadvertently exposing proprietary and confidential information,*
- 4. Reduce potential activities required of trading partners,*
- 5. Design for expansion beyond DSCSA compliance,*
- 6. Fund the architecture, and*
- 7. Reduce risk and confusion.*



The PoC Teams

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Team Blue: (Chronicled)

**Overview:** The Blue Team developed a distributed platform to be \*owned and operated by industry\* (including trade partners and service providers) to demonstrate its ability to meet all track & trace requirements, as well as be a platform for future business process innovation. It covers all movements of the drug up to the point where it is removed from the manufacturer's packaging/ unique identifier, and its design is based on the initial commissioning, then change-of-ownership, of those identifiers. Pilot demonstrates how the industry can use the blockchain to 1) execute salable returns verification, 2) meet the interoperable 2023 system requirements, and 3) block/eliminate counterfeits.



Full Overview



Presentation Slides  
(attached)

All team PoC videos are in editing/post-production stage. We will send you an update when they are live. Alternately, you can check for updates [here](#)

Presentation Video

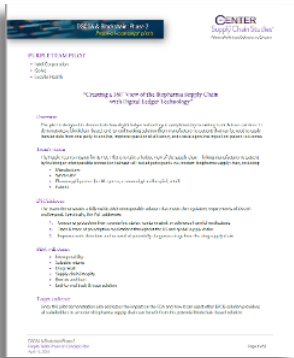


The PoC Teams

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Team Purple: (iSolve, Intel and Excellis Health)

**Overview:** This PoC demonstrates how digital ledger technology is *complimentary* to existing track & trace solutions. It demonstrates a blockchain-based, end-to-end tracking solution (from manufacturer to patient) that can be used to easily transfer data from one party to another, improve operational efficiency, and create a positive impact on patient outcomes. The Team demonstrates a fully viable 2023 interoperable solution that meets the regulatory requirements of DSCSA and beyond. Pilot will demo *interoperability, saleable returns, drug recall, supply chain integrity, and borrow & loan*.



Full Overview



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(attached)

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Presentation Video

The PoC Teams

[< Back](#)

Team Green: (RxTransparent and Systech)

**Overview:** Systech and RxTransparent represent both ends of pharma supply chain manufacturers and dispensers, respectively. With their unique industry insights and perspectives, they came together as a team to build a pilot platform that demonstrates blockchain as a viable solution for compliance with upcoming DSCSA interoperability system requirements. The presentation is designed for a broad audience of stakeholders across the entire life sciences and healthcare spectrum including manufacturers, wholesalers, dispensers, regulators and logistics providers.



Full Overview



Presentation Slides  
(attached)

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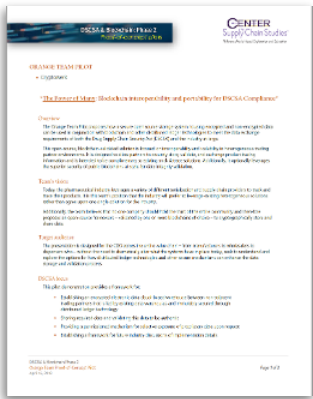
Presentation Video

The PoC Teams

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Team Orange: (Cryptowerk)

**Overview:** This PoC proposes how a secure open source storage system housing encrypted and non-encrypted data can be used in conjunction with blockchain and other distributed ledger technologies to meet the data exchange requirements of both the DSCSA and the industry at large. This open-source, blockchain-validated solution is focused on interoperability and scalability in heterogeneous trading partner environments. It is designed to allow partners to securely store, validate, and exchange product tracing information and is intended to be complimentary to existing track & trace solutions. Additionally, it optionally leverages the superior security of public blockchains at scale for data integrity validation.



Full Overview



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(attached)

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Presentation Video

The PoC Teams

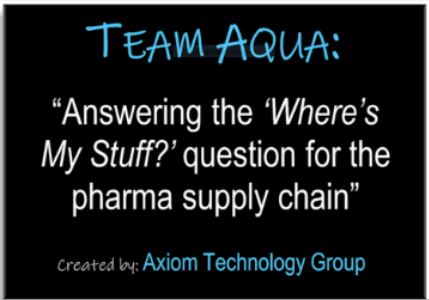
[< Back](#)

*Team Aqua: (Axiom Technology Group)*

**Overview:** The team has designed an enterprise-wide blockchain solution for asset traceability and data transparency that allows unrelated parties to have end-to-end visibility across the value chain regarding transfer of ownership, business events and transactions. Participants can share pertinent business information via a distributed system, allowing them to share cryptographically assured data across a secure supply chain network. Business logic will be applied and implemented via chain codes (Smart Contracts) and combined with analytics to dashboard the asset information. Utilizing the “product-centric” ReferenceModel #3 developed in “DSCSA & Blockchain Phase 1” Study, the team employs an Oracle BCS-based blockchain infrastructure to *augment* existing business systems.



Full Overview



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(attached)

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Presentation Video

The PoC Teams

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Team Yellow: (Authentag and Accenture)

**Overview:** This PoC demonstrates how an immutable chain of custody and granularity of ownership can reshape logistics, and shows current advances enabled by FDA led GS1 GTIN and PI labeled unique identification and demonstrate full 'creation to end use' traceability through all parties in the supply and use network. Team analyzed current real usage of FDA Regulated GS1 GTIN + PI uniquely labeled traceability and how full traceability is already being used for more than just FDA compliance. Real examples then illustrate why a distributed ledger and blockchain are necessary and suitable as part of a traceability solution for the pharma industry.



Full Overview



Presentation Slides  
(attached)

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Presentation Video

## Additional Presentations

&lt; Back

**Master Data Management** (ValueCentric)

**Overview:** Master Data management is a core best practice for ensuring quality data, reducing risk and improving delivery accuracy.



Presentation Slides  
(attached)

*All team PoC videos are in editing/post-production stage. We will send you an update when they are live. Alternately, you can check for updates [here](#).*

Presentation Video

Additional Presentations

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*Analytics* (CalQLogic)

**Overview:** Study ReferenceModels produce a large amount of data. The DSCSA and Blockchain ReferenceModels contain thousands of records in fifteen datasets. CalQLogic provides the Center's Studies with access to their Triggerware product, which enables Study teams to better manage and analyze the ReferenceModel data sets and detect unwanted patterns in the data.



Presentation Slides  
(attached)

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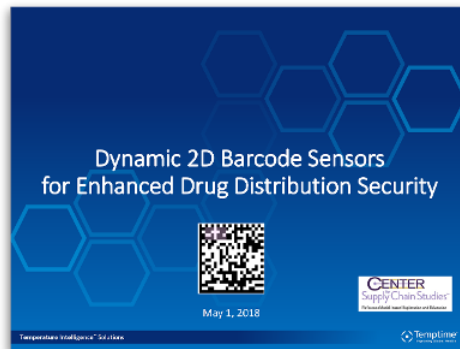
Presentation Video



## Additional Presentations

[< Back](#)**Blockchain for Cold Chain Study** *(Temptime and T-Systems)*

**Overview:** The Blockchain for Cold Chain Study builds upon the DSCSA and Blockchain Study ReferenceModels by exploring ways blockchain could be used to better manage the temperature experience of cold chain products, provide timely alerts and temperature excursion investigation support. These presentations address new temperature indicators and sensors that provide an electronic connection.

Presentation Slides  
(attached)

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Presentation Video

- 2017
- Serialized Product
  - Electronic TI.TH.TS
  - 2D barcode (NDC, Sn, Lot#, Exp Date)

- 2019
- Transact only Serialized Product
  - Saleable Returns Verification

- 2023
- Serialized TI Sharing
  - Interoperable System, TI gathering



Requires Increase Process Accuracy of all Stakeholders



To trace an item, we must trace the logistics units that the item has been traveling in



The system doesn't yet exist

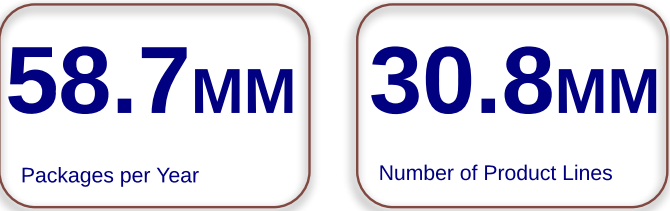
Although manufacturers are not required to share the unique identification (SNI) of individual packages that are placed into commerce until the DSCSA 2023 deadline, wholesalers must verify the identification of saleable returns with the manufacturer by November 27, 2019.

- 2017
- Serialized Product
  - 2D barcode (NDC, Sn, Lot#, Exp Date)

- 2019
- Saleable Returns Verification

- 2023
- Serialized TI Sharing
  - Interoperable System, TI gathering

Saleable Returns\*



\* HDA

Manufacturers and Repackagers



- Ship serialized products
- Continue to share TI, TH, TS at Lot level
- Aggregation of packages to logistics units not required at this time
- May be contacted by many wholesalers to verify ~ 59MM saleable returns / yr
- What if the verification request comes from a wholesaler the manufacturer doesn't do direct business with?

Wholesalers



- May not know the SNI of packages that are sold through in full cases
- Need to document that the SNI was placed into commerce by the manufacturer

Dispensers



Q: in 2023, if you receive a shipment and are provided information that a certain package is in a particular case and it isn't there ...

... did you actually ever own it?

- 2017
  - Serialized Product
  - 2D barcode (NDC, Sn, Lot#, Exp Date)
- 2019
  - Saleable Returns Verification
- 2023
  - Serialized TI Sharing
  - Interoperable System, TI gathering

Manufacturers and Repackagers



- Provide customer with shipping hierarchy
- Aggregation required (by customers)
- May need to provide TI for any legitimate request
  - Who is the Requestor?
  - Are they Legitimate?
  - Have they had ownership of the Package?

Wholesalers



- Large customers require full unopened cases
  - Need to "infer" SNIs in the case from manufacturer's aggregation Info
- May need to provide TI for any legitimate request
  - Who is the Requestor?
  - Are they Legitimate?
  - Have they had ownership of the Package?

Dispensers



- Must know who they purchased each package from (for returns)
- May need to request TI from previous owners
- How do they know who to request TI from?

Discussion Framework:

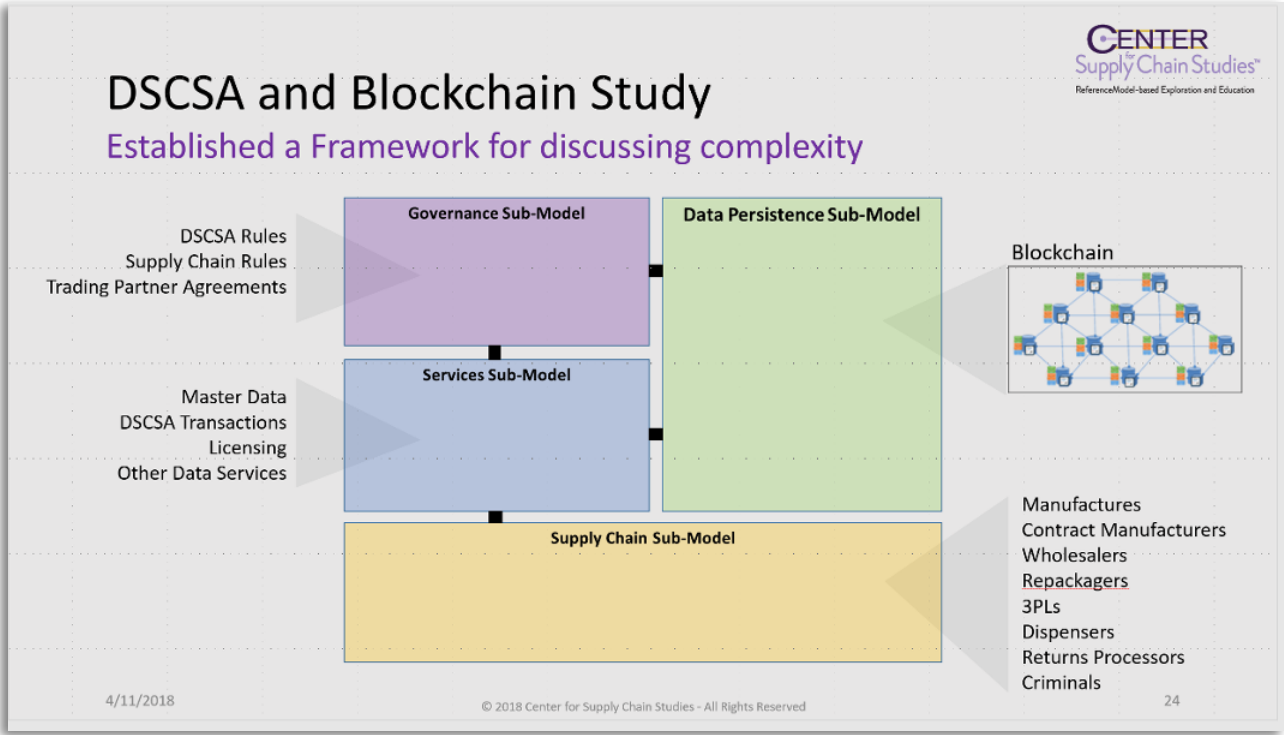
To aid team discussions, we developed several sub-models to represent:

- ▶ **Supply Chain** trading partner activities and information creation and sharing
- ▶ Industry shared **Data Persistence** structure and activities (blockchain platform and services)
- ▶ **Services** that would provide blockchain posting and query support as well as additional data services
- ▶ **Industry Data Governance** - data access rules and support processes

Rule categories:

Knowing this was an exploratory Study that would consider design aspects beyond DSCSA compliance, the team grouped design decisions, data posting and access rules to support:

- ▶ **DSCSA** Compliance
- ▶ **Supply Chain** Practice
- ▶ **Trading Partner** to **Trading Partner** Agreements

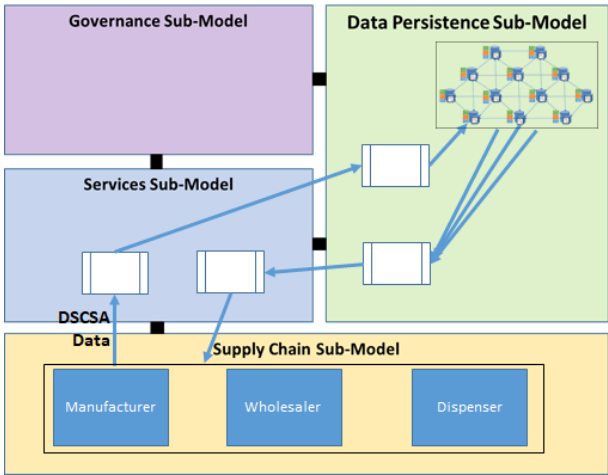


# Study Findings

The Study found three methods for sharing DSCSA data

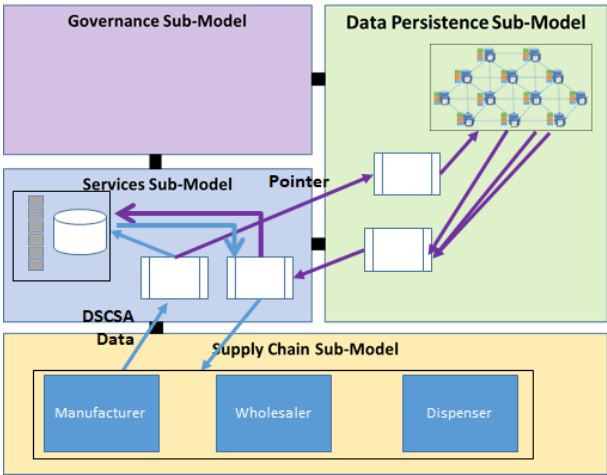
## ReferenceModel 1 (TI Ledger)

In this architecture, the entire TI set of data is posted to the blockchain. This is the simplest architecture, however, as all data is visible, it carries a large governance burden.



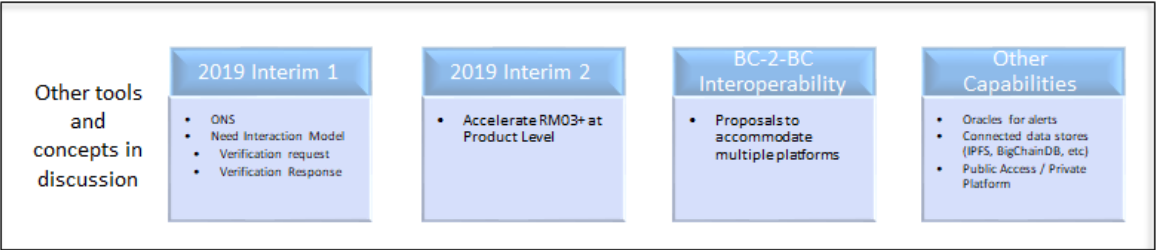
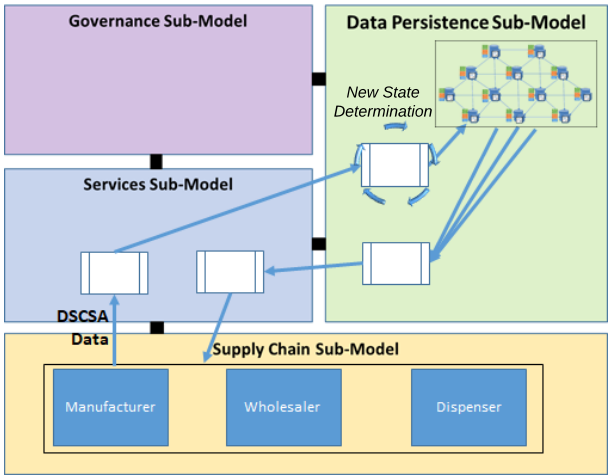
## ReferenceModel 2 (TI Directory)

In this architecture, pointers, or addresses to portals that house TI are posted to the blockchain. This is a more complex model than RM001, however, industry-wide governance is lessened as each trading partner (or proxy) stores their own data.



## ReferenceModel 3 (Package State)

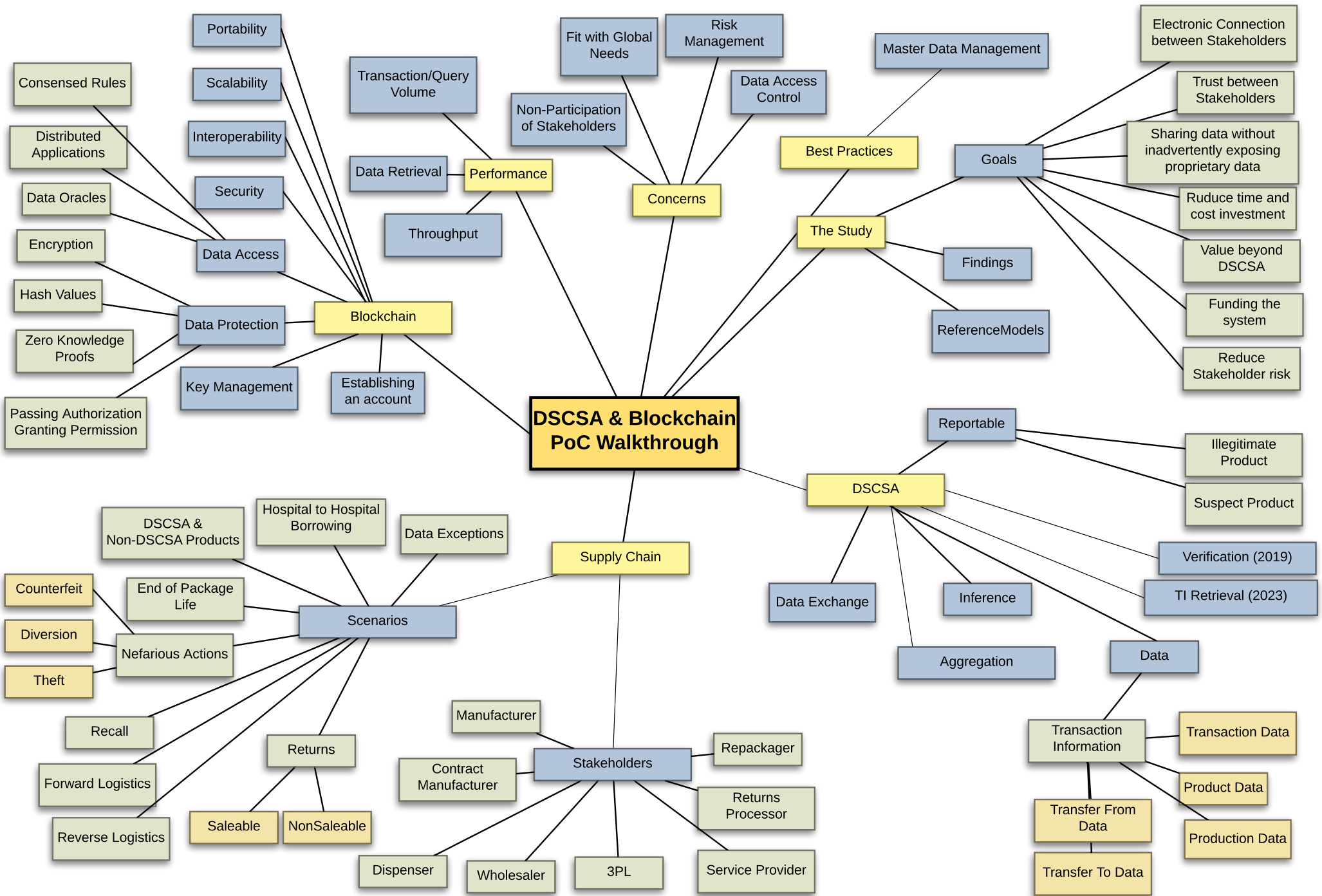
In this architecture, we take advantage of the programming features of blockchain platforms. TI data is provided to an on-blockchain application (DApp) which enforces industry-goverend rules. The TI data is evaluated and a set of "states" or statuses are set for the package.



### States Explored:

- ▶ Is DSCSA Product
- ▶ Is Grandfathered
- ▶ Is in Commerce
- ▶ Is fit for Commerce







In 5 slides, you'll know all you need to know about blockchain

## What is Blockchain?

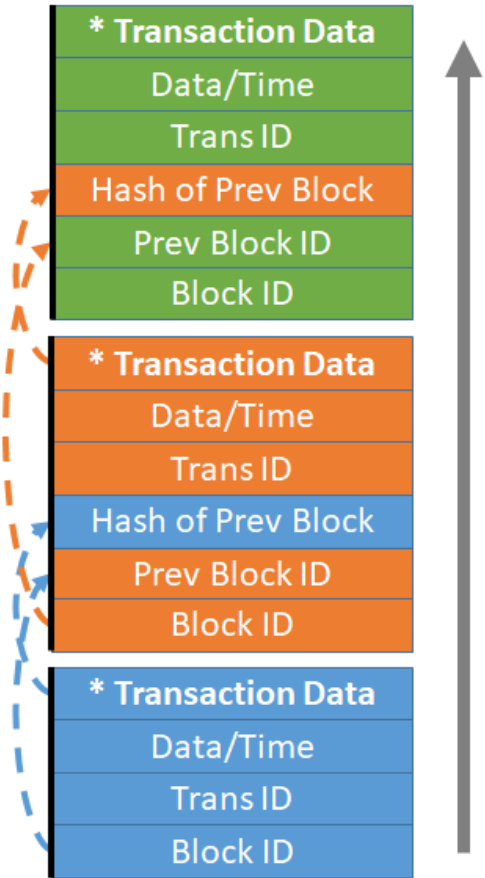
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# What is Blockchain?

*A blockchain is a continuously growing list of records, called transactions. These transactions are gathered into groups called blocks. The blocks of transactions are secured using cryptography.*

*By design, blockchains are inherently resistant to modification of the data held within them.*

*The data is said to be immutable.*



\* Multiple, Unrelated Transactions

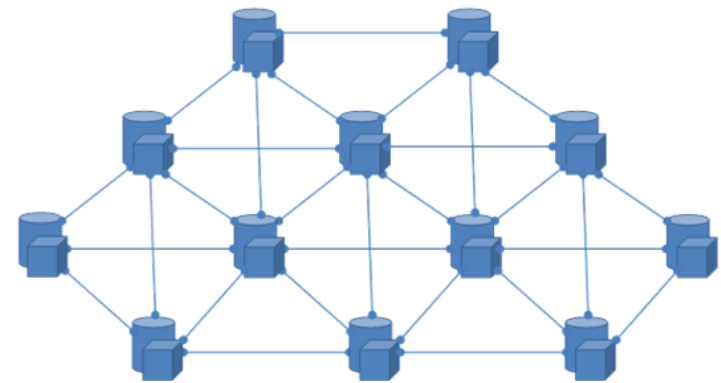
# What is Blockchain?

A blockchain is typically managed by a [peer-to-peer](#) network collectively adhering to a protocol for validating new data blocks.

*It is a utility upon which applications are built.*

*It distributes data securely and ensures all copies are identical.*

*Data can be encrypted to ensure bad actors can't make sense of it.*



**Decentralized**

*nodes are only connected to peers*

# What is Blockchain?

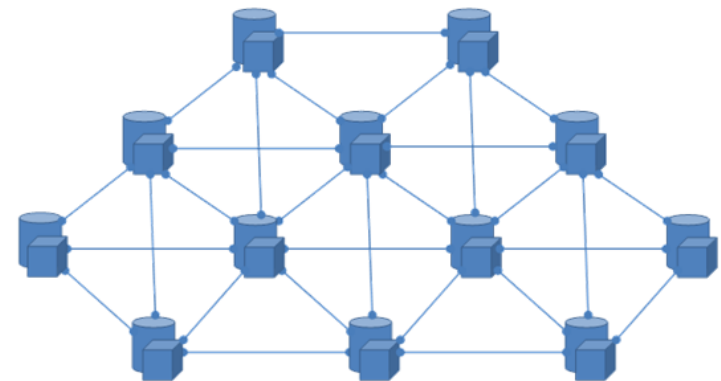
Blockchain platforms contain computer programs, or "Distributed Applications".

*They are also distributed among the network.*

*They are also immutable. The applications cannot be tampered with.*

*They enforce data governance rules, controlling posting and retrieval of data.*

*Everyone connected to the blockchain can validate and use the exact same application to add or retrieve data on the blockchain platform.*



## Decentralized

*nodes are only connected to peers*

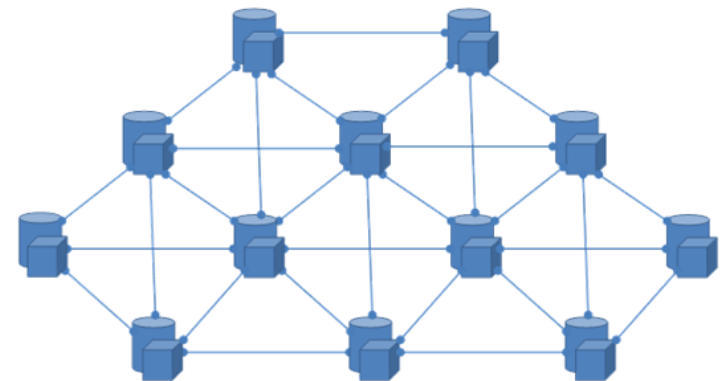
# How are blockchains funded?

Each transaction is assessed a fee to fund the work of the utility.

*The fee is paid whether a transactions is successful or not.*

*Transactions that require more storage or processing resources than funded are canceled.*

*The fee model fairly distributes the cost of the utility, prevents run-on processes from affecting the performance of the platform and deters nefarious activities.*



## Decentralized

*nodes are only connected to peers*

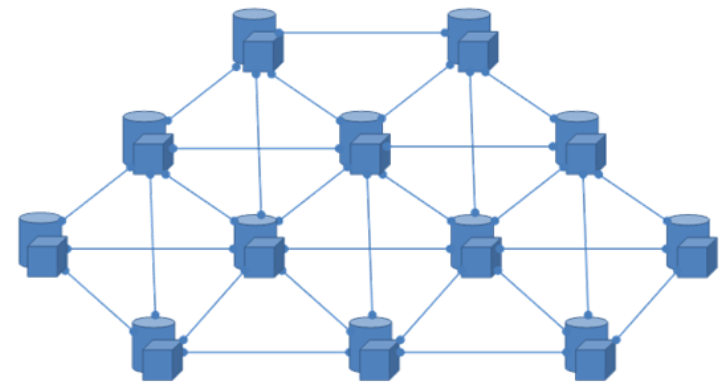
# Why the interest in blockchain technology?

The data is unchangeable, but encryptable so that only the correct parties can interpret and use the data.

*The applications are unchangeable.*

*Anyone registered on the blockchain platform can view and verify the application's behavior.*

*We can trust the applications (once validated) and the decisions they make based on a set input.*



**Decentralized**

*nodes are only connected to peers*

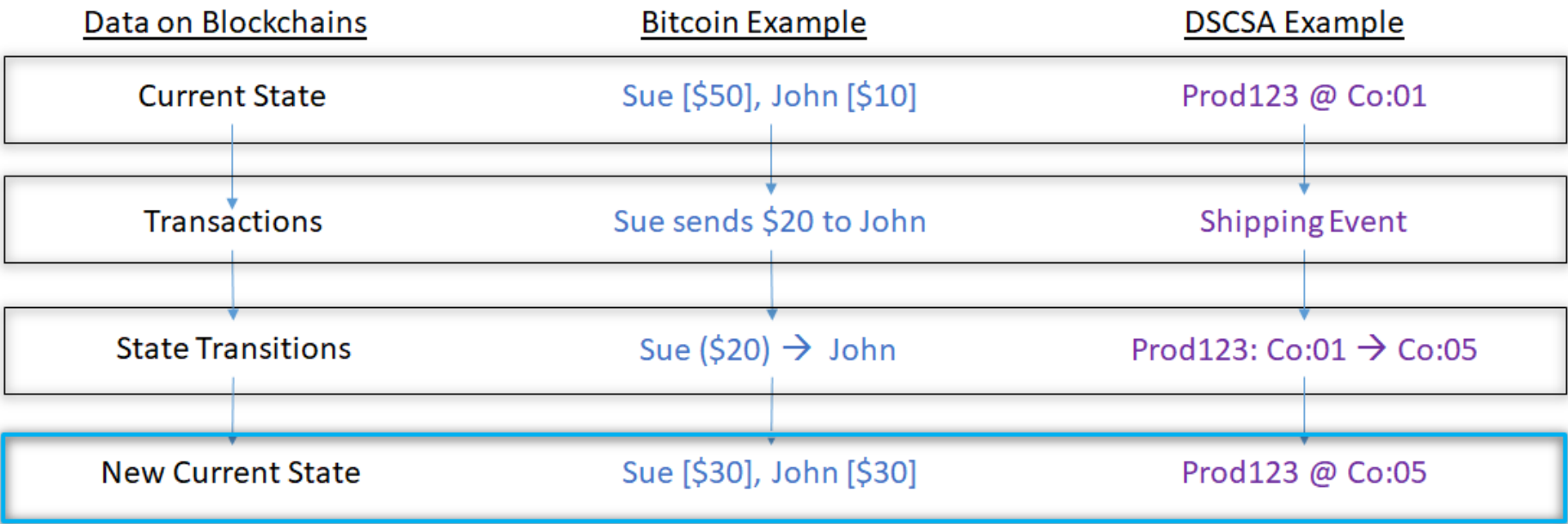
So, now that you know everything there is to know about blockchain, let's try a few examples ...

## Blockchain in use

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# Data managed by a blockchain



The transactions are interesting, however we're most concerned with how things stand (the new state) after each transaction.

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