MediLedger

2018 Progress Report

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Executive Summary

The MediLedger Project was started in 2017 with the intention to demonstrate the value of blockchain to solve some of the upcoming life science industry interoperability requirements laid out by the Drug Supply Chain Security Act (DSCSA). Based on positive outcomes (reference MediLedger 2017 Progress Report), our work continued with discussions and analysis of blockchain based solutions for the life-sciences industry. **The 2018 work focused on three distinct topics:**

1. How to establish product verification to meet 2019 DSCSA regulatory requirements, as well as industry operational requirements
2. Use cases beyond DSCSA: evaluation of Revenue Management processes (Contracts and Chargebacks)
3. What governance and principles should be evaluated in establishment of an industry network

These topics represented a shift in focus from our previous efforts to understand and test the validity of blockchain technology for the achieving the 2023 Interoperability requirements of DSCSA to addressing the most immediate business problems where there were poor or no clear solutions in the industry today. The resulting activities provided a framework and an approach to further develop blockchain based networks in enterprise applications.

From this work, we concluded the following:

- Blockchain enabled industry networks have the potential to improve efficiency and capabilities in commerce between trading partners.
- Blockchain will be an element of industry solutions, not the solution by itself.
- Blockchain should only be used in solutions where it provides capabilities not found in traditional technologies:
    - An immutable record of transaction proofs
    - Sharing of public industry master data
    - Enforcement of cross-industry business rules
- Blockchain should not be used as a database solely for the purpose of sharing data
- Industry solutions need to focus on business problems to be solved and then identifying the appropriate technology to address the problem, rather than starting with technology and looking for business problems to solve.
- Once the network is established, it can be used to solve many business problems and network effects are expected to drive substantial and accelerating value for companies.
- Blockchain technology allows solutions to be built in an open and highly collaborative forum with the ability for innovative solution providers to directly connect applications into the established ecosystem.
- Broad industry adoption requires companies to come together to establish and adopt standards that have value (albeit different value) for all the participants in the business process.

Acronyms

API - Application Programming Interface
DSCSA – Drug Supply Chain Security Act
GPO – Group Purchasing Organization
GTIN – Global Trade Item Number
HDA – Healthcare Distribution Alliance
LD – Lookup Directory
NDC – National Drug Code
PVS – MediLedger's Product Verification System
VRS – Verification Router System

2018 Working Group Approach

Our 2018 working group consisted of companies in the life sciences industry, with a focus on Pharmaceutical Manufacturers and Wholesaler Distributors, along with industry supply chain and standards experts. Our main focus was DSCSA regulation compliance solutions: the near-term requirements in 2019 to conduct product identifier verification on all returned prescription medicines for resale by distributors.

We were encouraged to see solution providers begin to understand the evolutionary nature of MediLedger and its ability to serve as a cross solution provider collaboration ecosystem. Several solution providers joined the efforts by agreeing to utilize the initial lookup directory functionality for 2019 Product Verification for DSCSA.

We have also seen a growing interest and participation from 3PL service providers, GPOs, and Payers as the understanding of our vision and the potential of a blockchain platform evolved. Their participation will depend on the use cases that are chosen for experimentation and commercialization.

Our goals laid out at the beginning of the year were as follows:

1. Establish framework for Solution Provider participation (use of the open protocol to serve their customers)
2. Determine the IT architecture for Product Verification / Saleable Returns solution
3. Determine the financial model for open protocol solutions
4. Finalize Pharma industry governance for blockchain solutions
5. Stand up nodes in the MediLedger Network and conduct testing
6. Create specifications and instructions for deploying IT infrastructure and software

Based on success against our goals, we also began work to establish solutions in Revenue Management, with the intention of designing architecture such that many protocols can operate on the same infrastructure, obviating the need for companies to access multiple blockchains.

MediLedger Protocols

Protocol Philosophy

We believe the power of blockchain will come as industries are connected in decentralized networks that allow them to easily communicate with all parties in the network. Protocols will be established that groups of companies benefit from participating together, enabling enforcement of cross-industry business rules. Our vision is that these protocols are not in principle controversial agreements; on the contrary, they simply put in place the pipes that allow industry improved capability and reduced friction to do business with their trading partners in any way they best see fit.

A simple example:

Current drug manufacturers register for GS-1 company prefixes and labeler codes that become part of the numbering system used in GTIN and NDC structure. By using the business rule enforcement that only the company with the matching prefix can manage and control master data on the blockchain that contains that prefix, we can accomplish two things: 1. We limit the ability of counterfeit activity as only the originating manufacturer can control activities associated with creation of products with that company prefix; 2. Manufacturers become incentivized to keep that data accurate as others in industry will start to rely on this master data set as the most current "truth" regarding these products. We have also created the business rule functionality such that when molecules are sold to other companies, the change in ownership and accountability can be seen on the blockchain prior to the company prefix changes in the NDC/GTIN.

We are currently in development and testing of two key protocols:

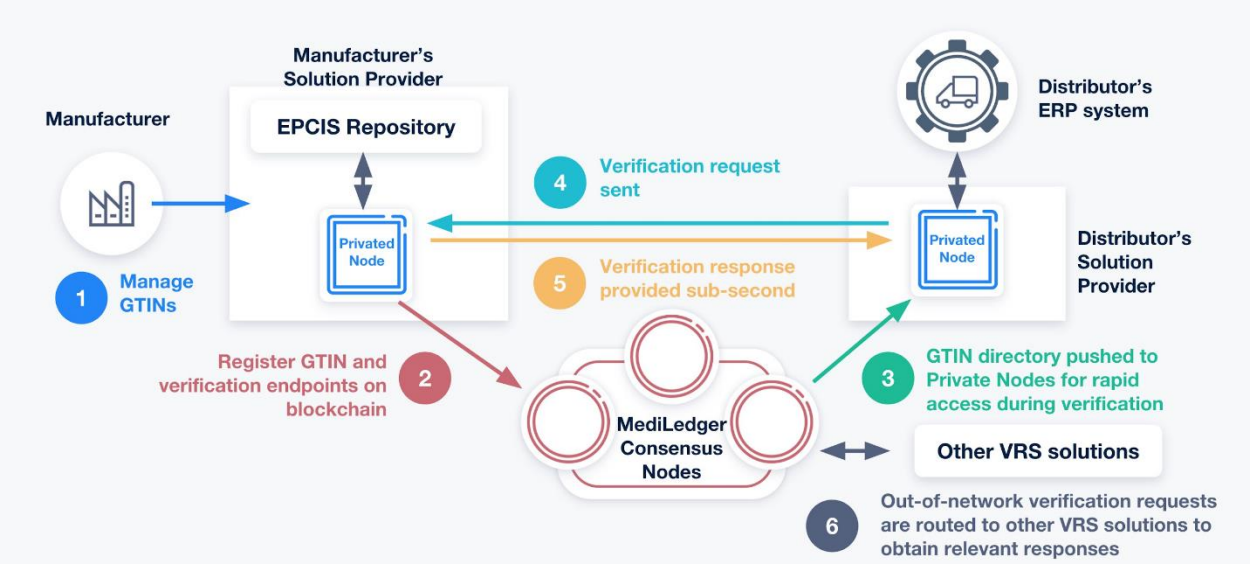
Protocol #1: Product Verification System (DSCSA 2019)

The Drug Supply Chain Security Act (DSCSA) outlines a series of industry milestones between 2015 and 2023 with progressive regulations designed to improve the security of the prescription medicine supply chain in the US. One of the milestones takes effect on November 27th, 2019, when all drugs that are returned to wholesalers for resale will need to be checked to ensure that Product Identifier (defined as GTIN, serial number, lot number, and expiration date) are authentic as per the originating manufacturer's data. The current expectation in industry is this can be accomplished in one of two ways: either the wholesaler will have a copy of that product identifier information when it was originally sold to them, or the wholesaler will be connected to a solution/s that will allow them to access the manufacturers data for verification.

Based on industry developed requirements (HDA Reference) for global messaging standards from GS1, we designed a decentralized solution to provide appropriate cross-industry GTIN lifecycle management (an identified gap in the industry), look-up directory capabilities to know where to send verification requests, and secure messaging capabilities for requests and responses.

We designed a simple solution that takes advantage of the following blockchain attributes:

- Master Data Management: Manufacturers can self-manage public master data related to their products on the blockchain - enabling others in the process to access the latest and most accurate product data.
- Business Rule Enforcement: The smart contract can manage the life cycle of the product master data, ensuring the originating manufacturer is the only one that can put product master data on the blockchain, and ensuring authorized transfer and acceptance in the case of change of ownership of a drug.



To note, the solution does not rely on speed in interactions with the blockchain. The Lookup Directory information is pushed to companies' private nodes for rapid reference, and verification requests and responses go through companies' local private nodes based on secure internet messaging. This has resulted in our response times well under one second, allowing the remaining time for warehouse scan to private node and private node to serial number repository in order to meet the industry's operational requirements.

Response Times	Response Time
Verification Request/Response within MediLedger (west coast nodes)	<50 ms
Verification Request/Response within MediLedger (geographically diverse nodes)	200-300 ms
Verification Request/Response with external VRS (VRS 1)	3097 - 5021 ms
Verification Request/Response with external VRS (VRS 2)	612 - 1172 ms
Verification Request/Response with external VRS (VRS 3)	655 - 788 ms

In order to facilitate use in the industry, all protocols are designed as open protocols, available to anyone who wants to run them. We are currently working with solution providers who offer serial number management services to the industry and are in process of testing the verification protocol, which will be based on GS1 standards, with them to understand performance and to allow the industry to assess the different configurations available to them to deliver verification request and response capabilities.

Testing of the MediLedger Network and then the industry interoperability testing should be complete by end of Q3 2019.

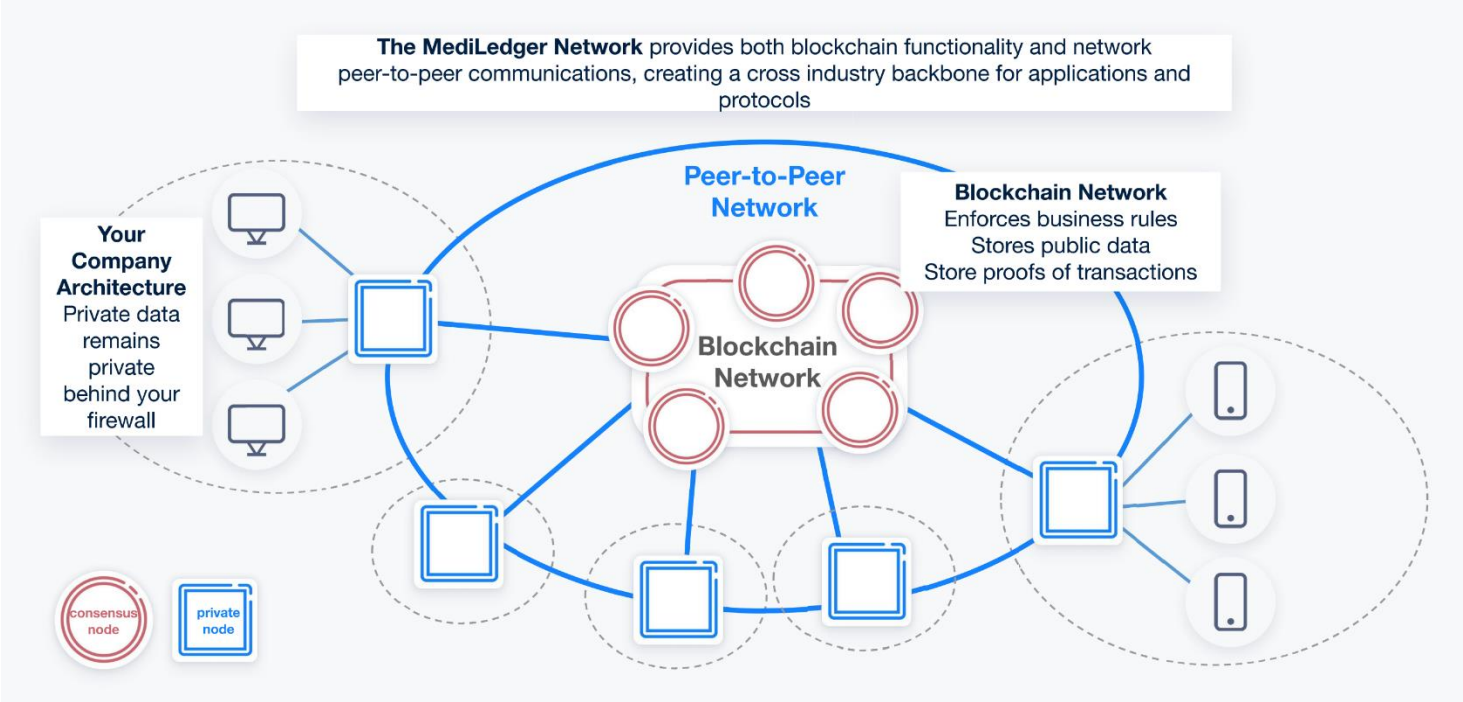
MediLedger Network Participants

The MediLedger network for PVS will be hosted by Chronicled, Life Sciences companies, and Solution Providers who support the Pharma industry's efforts to comply with DSCSA. Additional Life Sciences companies and Solution Providers are still evaluating participation.

Chronicled, Life Sciences companies, and Solution Providers will host a consensus node and one or more private nodes for their customers. The private node provides an up-to-date lookup directory and interfaces and APIs for managing the lifecycle of the GTINs (on behalf of their customers).

An X509 certificate will be stored on the blockchain for each authorized trading partner. These certificates will be established during the on-boarding process, which will include a manual verification of each company's state license or other documented proof that they are allowed to be part of the network.

The peer-to-peer messaging network will be the path for the request and response for verification. The certificates will be exchanged for purposes of authentication.

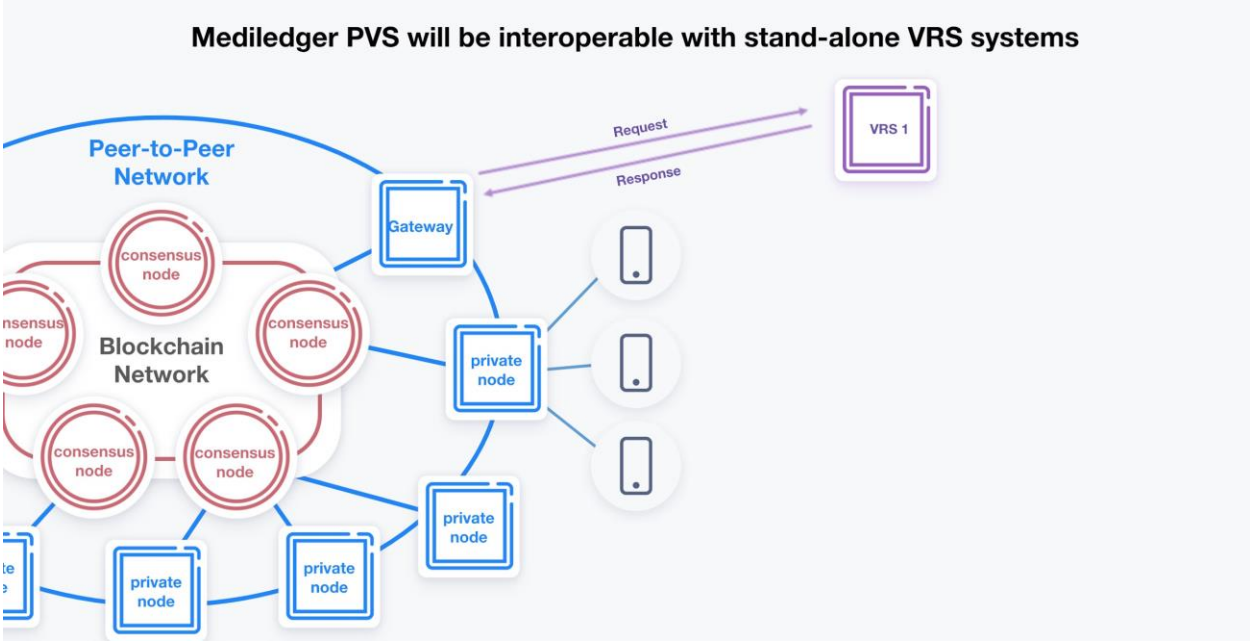


Interoperability

The MediLedger network for PVS will also be interoperable with stand-alone VRS solutions. The primary capabilities of interoperability will be:

- A mechanism to synchronize lookup directories
- The ability to exchange request and response messages

Both of these functions have been delivered for the MediLedger PVS using HDA and GS1 standards.



Industry testing will continue through Q2/Q3 this year in preparation for compliance with the November regulation dates.

Protocol #2: Contracting and Chargebacks

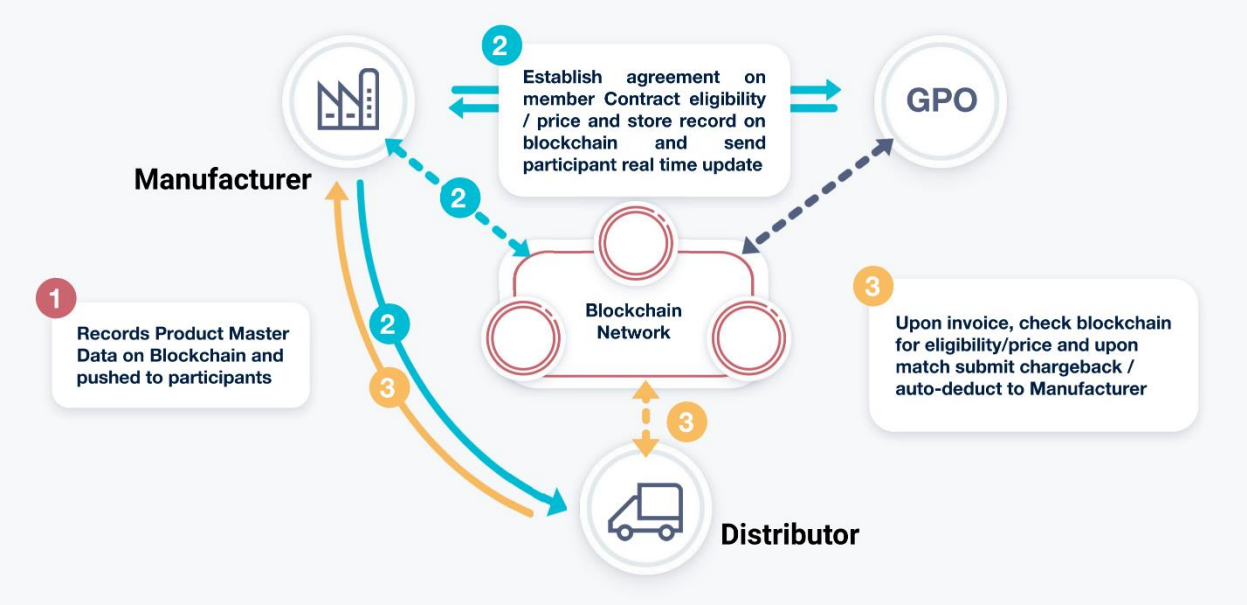
The sale of prescription medicines is complex, with the flow of goods and associated financial transactions involving the Manufacturer, the Wholesale Distributor, and the Pharmacy / Healthcare Provider. Group Purchasing Organizations work on behalf of Pharmacies and Healthcare Providers to negotiate beneficial contracts with the Manufacturers, but then the Distributor who is moving the actual product completes the financial transaction based on the contract terms, and works with the Manufacturer on the "chargeback" between the price they purchased the product for and the contract price.

Today, most transactions execute correctly, but due to the high volumes, the resulting issues and errors prove to be a costly burden to all parties involved. This process has issues due to a variety of

root causes, including ambiguity around member eligibility for contracts, or contract master data differences due to either timing offsets or system errors.

This business process, with multiple parties involved in contract agreements and different parties involved in execution of those contract terms, is an ideal use case for a blockchain based solution. In this case, we have again designed a simple solution that takes advantage of the following blockchain attributes:

- Master Data Management: Manufacturers can self-manage public master data related to their products on the blockchain - enabling others in the process to access the latest and most accurate product data.
- Business Rule Enforcement: The smart contract identifies the continuously updated contract terms and member eligibility, obfuscated so competing companies don't have visibility, but engineered to ensure that all parties to the contract are able to verify the latest terms and prices are correct before executing their portion of the process.



Another conclusion we reached is that by using secure identification of network participants on the blockchain, we can eliminate the need for EDI messaging and utilize truly modern peer-to-peer messages, reducing the need for unnecessary services and infrastructure, and potentially allowing current batch processes to move to real time.

We have a working group participating in the commercial solution development, with expected testing and commercial release targeted for later in 2019.

Governance and Operating Principles

Framework

In last year's report, we outlined a basic framework based on four components:

- Private client nodes where participant's private data is accessed (either stored in the private client or accessing private company data via APIs) and acts as the channel for communication to either other companys' private clients or the consensus nodes that hold the blockchain ledger.
- Consensus nodes that are run by a limited set of trusted companies, which include companies that are incumbent Solution Providers, Manufacturers, or Distributors, that are connected to Private nodes and that contain the shared blockchain ledger
- The system would be overseen by a utility function we are now designating as a Network Manager role. The basis for this construct still holds true in that we do not believe the industry's solutions can exist on public blockchains (too slow, too costly) and for a permissioned network there needs to be a role overseeing onboarding and compliance with the network terms and conditions.
- Governance will be required to guide the overall management of the network, as well as defining the protocols and any required modifications, especially after go-live.

This still appears to be the basic construct for a decentralized industry-wide network, and is our continued planned framework.

Through our work we have also come to agree on the specific functionality that benefits from a blockchain construct:

- permissions to ensure only authorized trading partners are participants
- master data management
- cross-industry business rule enforcement
- secure record of transactions
- permissioned messaging between network participants

Additionally, there are specific principles we feel are paramount to distinguishing blockchain based solutions from centralized solutions.

Principles

The current market of companies offering blockchain based solutions holds a wide variety of approaches. We feel strongly that key principles need to be followed to meet the "ethos" of

blockchain, and the value that sets blockchain apart from current centralized solutions. This goes beyond simply decentralized operation. Here are the key operating principles:

1. **Industry-First** - MediLedger aims to address industry problems and needs that require collaboration. New Protocol Primitives are prioritized based on the benefits delivered to the trading partners.
2. **Inclusive** - Work to ensure all qualified healthcare industry companies can participate, with no barriers based on size or subjective criteria. By focusing on protocol and network development, MediLedger also provides solution providers with the opportunity of leveraging the platform to connect their applications, further develop their businesses and more effectively server the industry.
3. **Fair** - All operators have equal opportunities to develop their businesses because the network facilitates connectivity across all participants.
4. **Company Controlled Data** - By leveraging the blockchain and confidential data exchange, MediLedger aims to reduce the need for compromise on data ownership and sharing. Private data is owned by the companies and the Network is designed to allow them full control of who and how they share that data. To note: the Network Manager role (currently played by Chronicled) will not even have access to company private data. As an example, we will have guidelines for key management, but will not offer key management services directly to avoid any potential perceived conflicts with this principle.

Governance

We explored the topic of governance in 2018, with no clear conclusions on an ideal construct. Constructs reviewed:

- ***Network Ownership:*** it became problematic for the Industry to want full control of the Network, because they would be incapable of taking on the accountability and risks, especially with protocols that could impact drug shipments or payments of competing companies. Industry ownership was our vision, but further work needs to happen to establish and mature the network and its processes before we can return to this option.
- ***Voting Rights:*** in discussion and review of establishing a set of voting rights, it is difficult to ensure our network principle of "fair". For example, the governance model needs to be constructed so that industry segments cannot form coalitions to drive decisions that give them an advantage over other trading partners.
- ***Industry Guidance:*** We are currently operating under a construct of the MediLedger working groups acting as industry governance at this stage. As we have cross-functional representation in all of our working groups, we have been able to ensure equity and incentive for all industry segments in the solutions developed. We have observed that the protocols operate at a relatively low level such that we have not experienced any conflict

over design. We believe that the protocols remove friction that exists today and enables companies to execute more efficiently and to do business with their trading partners as they see fit.

We will continue to evolve the conversation on governance as we move into commercial solutions this year and will continue to enhance our construct for change control and enhancements.

Conclusions and Next Steps

Our understanding of the application of blockchain in industry solutions grew in 2018, with progress on two protocols. We have confirmed our initial hypotheses or updated our thinking on system architecture, network framework, and operating principles. We still expect thinking to evolve on governance, and that a governance framework will emerge.

Chronicled is grateful for the partnership and the collaboration of the 2018 MediLedger working group. We would like to say thank you for the leadership and valuable guidance of: ***Genentech*** - Nirmal Annamreddy, Kathleen Antigo, Kathy Daniusis, Jaya Kala, Mark Karhoff, Stephanie Lansang, Mark Mcloughlin, Pablo Medina, Vid Rajaram, David Vershure; ***AmerisourceBergen*** - Jeffery Denton, Matt Sample, Heather Zenk; ***McKesson*** - Matt Langford, Kevan Mackenzie, Scott Mooney; ***Pfizer*** - Byron Bond, Dennis Even, Mack MacKenzie, Michael J. Mazur, Allison Sheldon, Andrew Schmitt; ***Cardinal Health***- Quentin Dittman, Dan Vaught; ***Gilead*** - Rathna Arumugam, Sundar Harini, Sandhya Iyer, Blane Stroh; ***Amgen*** - April Fitzgerald, Nikkhil Vinnakota.

Company participation is as follows:
DSCSA Working Group in 2018 for Product Verification Protocol: Genentech, AmerisourceBergen, McKesson, Pfizer, Novartis, Cardinal Health, Gilead, and Amgen.

Chargebacks Working Group in 2018 for Contract and Chargebacks Protocol: McKesson, Pfizer and AmerisourceBergen.

We look forward to 2019 and the commercial launch of two industry solutions and the continued growth in understanding how blockchain can solve business problems.