MediLedger
2019 Progress Report

Executive Summary

In our third year evaluating how blockchain can transform operations of the pharmaceutical / life sciences industry, we have advanced the conversation past POC and pilot to commercial implementations and demonstrated governance. Much speculation has existed since the beginning of Bitcoin on how blockchain will impact the way businesses operate, and our work this year has delivered one possible roadmap on how that can take place.

Key 2019 accomplishments and conclusions:

- The commercial launch of the **Product Verification** solution to meet DSCSA saleable returns compliance demonstrated the capability of blockchain-based solutions to meet industry needs and gain broad adoption
    - Decentralized, no intermediaries
    - Solving problems that could not be solved via traditional technologies
    - Run by the industry themselves, or the solution partners they choose
- The progress of a **Contracting and Chargebacks** solution is demonstrating more complex process automation can serve the industry
    - Exchange real time secure messaging to replace EDI
    - Enforce both network level and trading partner business rules
- We have formulated a working group and **governance model** that can be reproduced for future use case development, and we believe is scalable regardless of number or variety of participants / stakeholder
- We are committed to an open platform to ensure maximum potential for participation and innovation
- The roadmap of potential solutions shows the opportunities that can benefit all parties, as well as new business models that can emerge as the technology is established

We are appreciative of all participating companies who have come together, seeking out areas of alignment in the spirit of overall gains for the industry and patients. In the last three years they have been instrumental in the formation of these solutions and the vision for how this technology can be architected and implemented to enable capabilities not previously possible without manual efforts, interventions, and disputes. We are excited at the expected learnings in 2020 that will continue to bring capabilities to commercialization and advance the dialogue of problems that can be solved, and welcome additional industry participation to ensure broad perspectives are incorporated.

2019 Overview

The MediLedger Project commenced in January 2017 as an industry-led initiative to address the new regulatory requirements associated with the Drug Supply Chain Security Act (DSCSA). The MediLedger project started out with the idea that protocol- and network-driven applications could deliver maximum efficiency for regulatory solutions where all companies in the industry needed to connect into an interoperable process.

At the conclusion of 2019 and the dawn of 2020, the scope of potential value from industry interoperability has grown. There are regulatory, consumer transparency, digital transformation, and cost pressures interacting to create a perfect mix of strategic and operational issues impacting the pharmaceutical supply chain, by which cooperation among industry trading partners and competitors could deliver value back to all players in the industry, as well as improve healthcare for patients.

Our work in 2019 focused on both regulatory and direct ROI use cases, while advancing the conversation on how decentralized solutions can be architected and executed in the Life Science industry. The three primary streams of activity undertaken under the umbrella of the MediLedger program in 2019 were as follows:

1. **DSCSA / Supply Chain Workgroup** - industry collaboration to conduct industry-wide testing and carry the MediLedger Product Verification System (PVS) Saleable Returns solution live into production with multiple service providers and industry firms active in the network.
2. **Contracting & Chargeback Workgroup** - industry collaboration to refine and confirm system specification requirements and commence commercial solution development to automate the chargebacks workflow.

BOX 1: The Power of Protocols

Everyone is familiar with the need for cross-company business communication. The SMTP protocol and the modern email client were created to solve this problem of routing electronic messages between IP addresses in a standard way with standard functions such as To:, From:, Cc:, Bcc:, Subject, Date, etc. The first email client, Hotmail, created by Sabeer Bhatia, was released as a non-business solution. However, the adoption and power of the protocol-driven solution was so obvious that quickly Microsoft picked up on the idea with its purchase of Hotmail, which they also re-released as an enterprise offering, MS Outlook. Today, it would be unimaginable to conduct business communication without the usage of email. Yet, few people recognize that the true power underneath of email lies in everyone running a standard protocol called SMTP.

3. **FDA Pilot Workgroup** - industry collaboration to review Chronicled's 2017 pilot, provide feedback on the substance of the work, and report to the FDA on the pilot methodology and findings.

In addition, conceptual and operational progress has been achieved throughout 2019 in defining a "lifecycle" model for MediLedger working groups, combining technologies to deliver a robust platform, articulating the governance and operating model for the platform, and defining the 2020 thru 2024 MediLedger strategic roadmap. The opportunity ahead is enormous, and the expectation in 2020 is to continue to deliver functional capability along with refinement to what a governance and operating model can and should deliver.

2019 Working Group Approach

When the MediLedger Project was originally launched, there was one initial working group with five founding members: AbbVie, AmerisourceBergen, Genentech, McKesson, and Pfizer. In 2019 the program grew to encompass three distinct working groups involving nearly 30 companies and industry organizations actively participating.

We started and continue our work from a working group construct because the benefits of blockchain come from delivering a multi-company, decentralized, networked, protocol-driven platform to solve a ***shared*** business problem. When workflows are shared due to individual company business processes being nested in larger end-to-end industry-level business processes, then there are cost, performance, and time-saving benefits to be realized by working together. Collaborating in a consortia format is a very efficient way to define a jointly-agreed solution specification (i.e. protocol), test and deploy the software solution, and monitor performance. The working group will stay in place through the point where the system is operational and there are clearly no issues end-to-end and all of the kinks and edge cases have been worked out.

Today, MediLedger has become a coordinating body that oversees several working groups. A working group is kicked-off when a set of companies who share a common business problem approach Chronicled and express a desire to collaborate together on a solution. Chronicled plays the role of neutral convener, to help the companies in the working group determine if it is an appropriate problem for a blockchain powered solution, define the requirements of the workflow, protocol, and solution, and then specify, mock-up, develop, test, and assist the companies in launching the solution on a decentralized basis.

In terms of size, a workgroup might be as narrow as one wholesaler and two upstream manufacturing partners. Or, a workgroup might be more extensive with multiple wholesalers coming together to streamline and automate key areas of "industry plumbing" where everyone

across the board gains benefit from process automation, and there is no longer a basis for competition on manual processes.

The life cycle of each MediLedger working group unfolds according to the phases depicted in Figure 1, below. Phase 1 represents R&D to create a new multi-company solution, Phase 2 involves commercialization, and Phase 3 is about steady state system operation.

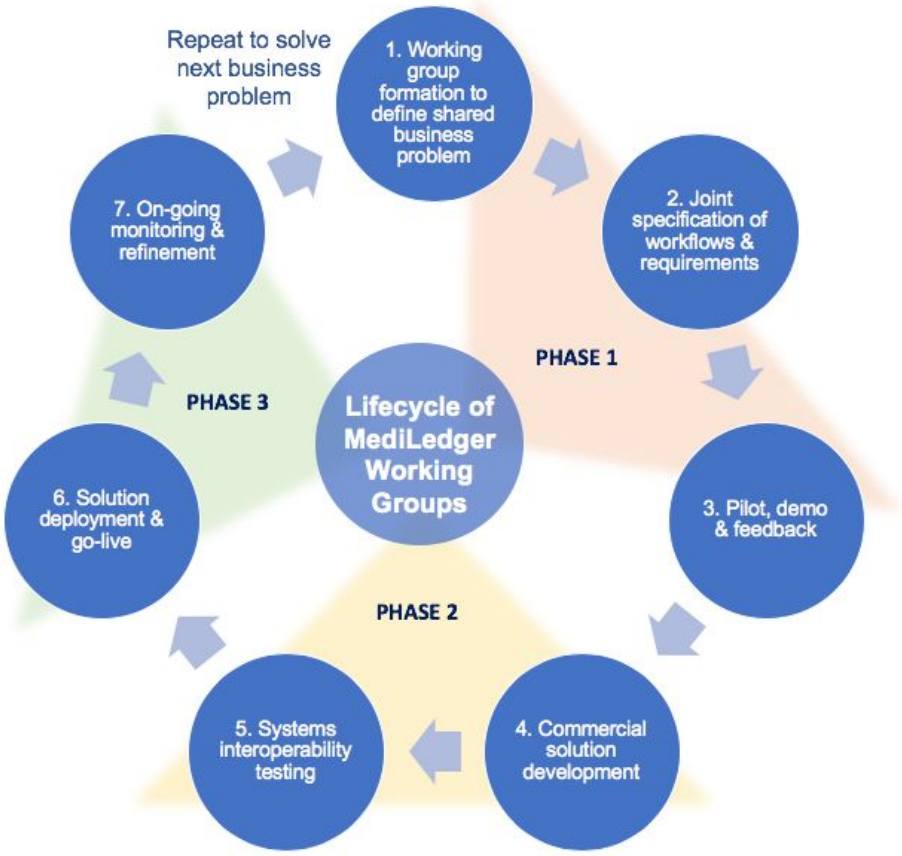

Figure 1. Life Cycle of MediLedger Working Groups

In 2019, the three MediLedger working groups that were active were as follows:

- **DSCSA / Supply Chain**: The working group was collaborating on production release of the PVS solution in order to meet the November 2019 saleable returns milestone of the DSCSA regulation, which involved crossing from Phase 2 to Phase 3 within Figure 1.
- **Contracting & Chargebacks:** The working group was active in defining system specification and inter-company workflows (Phase 1) and beginning commercial solution development (early Phase 2 activities), geared towards a mid-year 2020 go-live date for a multi-company chargebacks automation solution.
- **FDA Pilot**: This working group grew to more than 25 companies in response to an FDA call for pilot submissions, and was engaged in review and submission to FDA of findings

of Chronicled's 2017 pilot to develop an approach to meeting the DSCSA 2023 interoperable system requirement (Phase 1). We found it especially important for this group to be representative of industry wide viewpoints - spanning manufacturer to dispenser, large and small size entities, as well as industry trade organizations, logistics companies, and standards bodies - to gather a wide variety of viewpoints to ensure a robust evaluation could be made.

Annex A details the industry participation in the three MediLedger working groups in 2019.

BOX 2: Business Protocols on Steroids

A problem with older protocols such as the SMTP email protocol is that each party can delete messages and/or pretend they didn't receive or didn't send the message. As consequence, the courts have been reluctant to accept email as evidence in some legal cases, and business solutions can not automatically settle contracts based on emails without human verification. We have pushed the frontier by creating protocols whereby each peer to peer message or transaction that happens in the application causes a cryptographic proof to be recorded on a shared blockchain ledger (as required), which all of the parties who are using the solution are passively maintaining. This secure record-keeping enhances trust. It also means that parties outside of a particular p2p message or transaction workflow can now trust that a particular event between two third-parties did in fact occur, as they can verify the proof on the ledger, and they can automate their subsequent response, whatever that may be.

Protocol #1: Product Verification System (PVS)

The MediLedger Product Verification (PVS) protocol was developed following appropriate industry specifications to enable both verification routing as well as industry interoperability to ensure an open, competitive environment of solution providers to serve the industry. The protocol offers the functionality shown in Box 3, and follows the core workflow depicted in Figure 2.

The PVS application leverages the blockchain component as an industry utility in the following way:

BOX 3: PVS Protocol Functionality

- Member Registration
- Verification Endpoint Management
  - Register, Modify
- GTIN Management
  - Register, Modify, Transfer
- Look-up Directory Synchronization
- Full Returns Verification
  - Verify in under a second
- Hosting options
  - Self-hosted (on-prem or cloud)
  - Service-provider hosted

- **Data Synchronization**- Master data is self-managed by each participant on the network, propagated to all network participants, and synchronized on the blockchain under proof of authority consensus rules, ensuring a single source of truth for all network participants. This guaranteed synchronization prevents errors and delays caused by one company having out of date master data.
- **Digital Asset Exchange** - Product identifiers (GTINs) registered on the blockchain function both as digital IP and as an end-point in an operational messaging system. The GTINs can be transferred under the M&A scenario when a buyer buys a molecule from a seller without interrupting the operational performance of the system, with a simple GTIN transfer event managed through the UI, so that verifications can continue even before packaging with new GTINs have been updated in real-world, which can take up to a year or more.

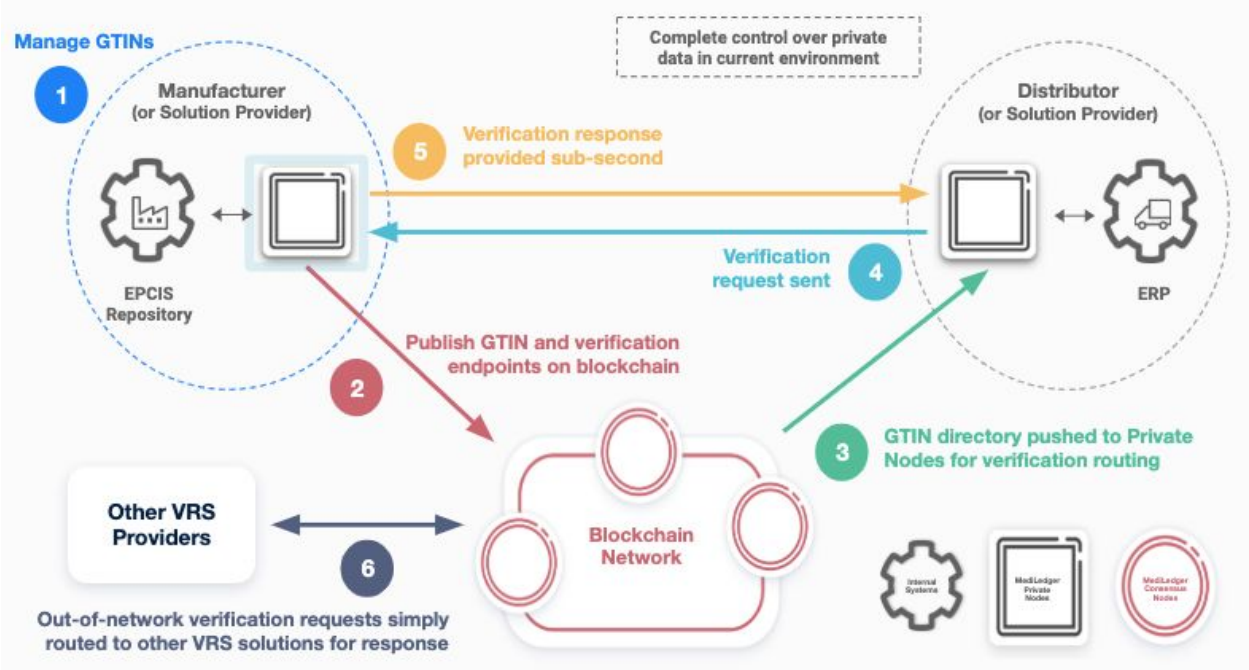

Figure 2. PVS Protocol Workflow

During 2019, Chronicled coordinated the **pharma industry testing for the verification ecosystem**. Chronicled documented the test cases for the MediLedger Product Verification System (PVS) and the larger verification ecosystem. The objective was to document the key business processes which must be tested as part of this test phase, describe the process to track deficiencies, and to document the test's exit criteria.

These business processes were tested:

- Create GTIN by manufacturer

- Transfer GTIN to another manufacturer
- View lookup directory
- Synchronize lookup directory with each standalone VRS
- Verify PI
- Error conditions

Test pre-requisites were achieved before the test started and they included:

- Nodes were set up and the MediLedger California release deployed
- Integration with the serial number repositories were created
- Credentials for each participant were created in the appropriate node
- GTIN master data was defined
- Test PI information was created in each Solution Provider's system. Chronicled created a tracker with the PI data for each of the valid and invalid test scenarios. The tracker was shared with all of the test participants.

The coordinated tests occurred during the MediLedger face-to-face meeting in October 2019. Working group members participated in the tests and were joined on the phone by representatives from other standalone Verification Router Service (VRS) providers and some of their key customers. Test execution took place over two meetings for a total of four hours. Each test scenario was tested and the results were documented. Chronicled shared these test results with all of the participants along with a detailed list of action items to resolve a small number of failed tests.

This coordinated test illustrated the challenge of testing between multiple solution providers with varying degrees of readiness. Testing of the MediLedger platform was successful overall with no significant technical failures identified for the software. Most of the failures during the test in October were the result of infrastructure set up, data set up at service providers and from pharma industry participants, and requests coming in to the network from external, non-MediLedger Network sources. While the tests were successful from a MediLedger product perspective, the outcome of the test showed exactly how much work was required before these systems could be used to support production verification of returned products. Ultimately, the FDA chose to delay enforcement of some of the 2019 DSCSA requirements. This means that the industry has until November 27, 2020 to ensure that this complex ecosystem, which includes MediLedger PVS and standalone VRSs, is thoroughly tested and functioning as the industry expects.

Protocol #2: Contracting and Chargebacks (CBK)

BOX 4: Contracting & Chargeback Protocol Functionality

- Fully validated communications:
  - Roster from GPOs to Mfgs & Wholesalers
  - Customer Status from Mfgs to GPOs
  - Contract updates from Mfg to Wholesalers & GPOs
  - Chargebacks from Wholesalers to Mfg and GPOs
- Product management (including WAC price management)
- Automated Customer Class of Trade & Eligibility determination via business rule engine
- Hosting options
  - Self-hosted (on-prem or cloud)
  - Service-provider hosted

Our second dedicated workgroup in 2019 focused on reviewing business requirements and building out the commercial enterprise protocol to automate the process of Contracting and Chargebacks for the Life Sciences industry associated with the sales of prescription medicine. This solution leverages the network architecture we have previously described of both blockchain capability and peer to peer messaging to transform the ability of trading partners to share data, and have assurance of business rule enforcement on that data exchange and associated transactions.

The solution, depicted in Figure 3, enables the real time communication of contract updates - both pricing and customer eligibility - between parties. We are using a business rule engine to enable manufacturers to tailor their customer eligibility criteria, enabling automation of roster assessment and evaluation, without the need to share proprietary information about specific class of trade interpretation. By storing a proof of the latest state of contract on the blockchain - which certifies which products, prices, and customers are eligible under the contract - wholesalers can at time of sale check that eligibility is current to ensure the seamless execution of the chargeback. The solution will enable the elimination of EDI 845, 844, and 849.

Questions frequently arise as to the need for blockchain in this solution - isn't the data in the EDI messages trusted? Aren't a company's trading partners trusted? Our vision for intercompany automation is that by enabling rule enforcement during messaging, recipients can be assured that data rules are followed, and specific trading partner rules are enforced which can enable the "trust" that can truly automate processes that require review and support today.

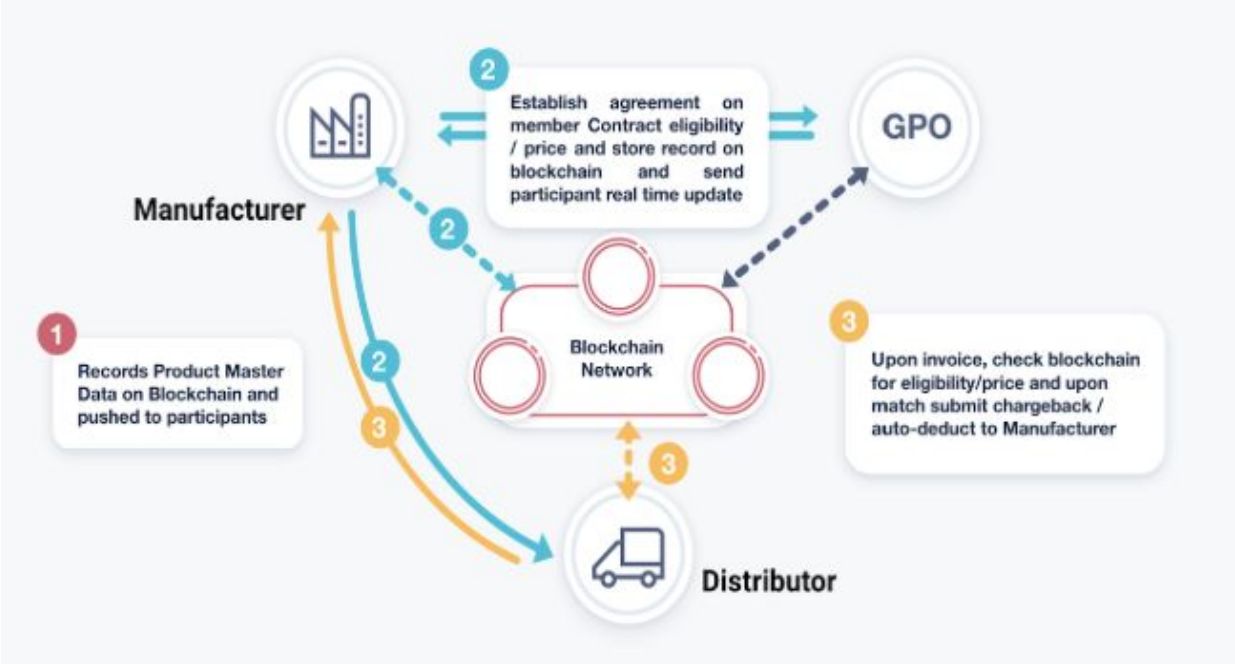

Figure 3. CBK Protocol Workflow

The working group has been instrumental in not only outlining the business requirements and business rule capability necessary for such a solution, but has also enabled dialogue around industry practices and where lack of capabilities has driven “bad” behavior that can now be eliminated.

Current timelines have our test environment going live in Q2 of this year, with commercial functionality available starting at the end of Q2/ start of Q3, and additional functionality going live in Q4. We intend to build upon our learnings of network operations from our PVS work, and add learnings from the CBK go-live into our governance framework.

FDA Pilot

On February 8, 2019, FDA requested pilot programs to help in the development of the electronic, interoperable system that will identify and trace certain prescription drugs as they are distributed within the United States, as outlined in the Drug Supply Chain Security Act (DSCSA). Leveraging Chronicled’s work from 2017, we requested participation of companies across the industry, as well as industry groups to participate in our evaluation of our ideas of how this electronic interoperable system could work. The report was issued on Feb 4th, 2020, and can

be accessed on the MediLedger website, as well as via this link. The FDA pilot outcomes included the following:

- Shared blockchain knowledge, separating reality from hype
- Modeled material flow events in a serialization data exchange environment for prescription drugs using a blockchain-distributed ledger system
- Developed and proposed a business and financial model that allows for the participation of the different industry stakeholders
- Identified potential issues with system performance and capabilities
- Defined the potential IT architecture of an electronic interoperable system
- Demonstrated how blockchain technology may be better suited than others to respond to 2023 DSCSA interoperable requirements and how it can provide other strategic advantages
- Identified industry standards in use for the solution, and standards that would benefit the industry
- Outlined how the system could facilitate solving system and process errors and identify nefarious behavior
- Defined human factors that could present implementation challenges
- Identified a process for onboarding and managing authorized trading partners
- Described possible governance of the system
- Showed how the MediLedger solution could be interoperable with other technology solutions like EPCIS

We intend to continue working with FDA and industry organizations to advance the conversation in 2020 on the potential to meet the regulations and improve patient safety.

Platform and Technology

The MediLedger platform (see Figure 4) was developed combining modern technologies to meet the business, regulatory, and operational requirements of the pharmaceutical industry. For example capabilities include GTIN lifecycle management, master data synchronization, item level tracking, three- and four-party contract automation, business rule enforcement, regulatory compliance, and data privacy for every trade partner. The platform creates the ability to form a network enabled to automate the routine business processes between companies.

By leveraging new technologies including blockchain, libp2p, Docker, Kubernetes, zk-SNARKS, and a micro-services architecture to deliver these capabilities, the platform enables applications with more capabilities than conventional SaaS or cloud applications.

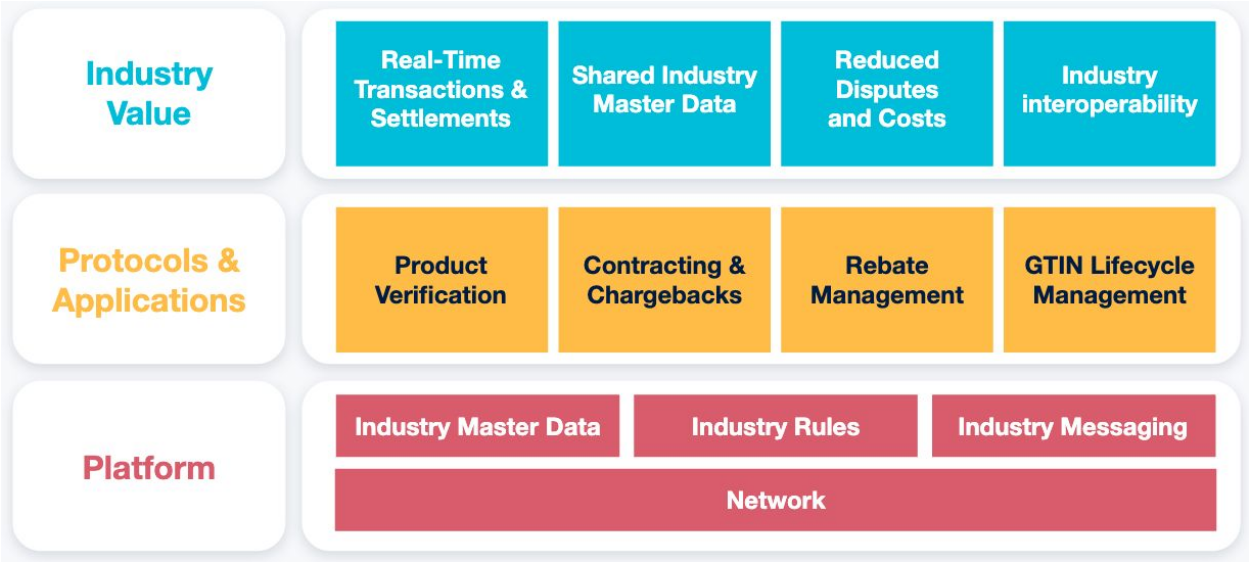

Figure 4. MediLedger Platform

In the future, the MediLedger platform can power many additional value-added applications to both streamline and automate legacy multi-company business processes and to create new solutions that address the new (and old) challenges confronting the pharmaceutical supply chain today.

The platform is designed to be “Open” in three key ways:

1. **Open Source Standards (OSS)** - the platform leverages OSS where they exist and if/as it is value-added for the industry to create new standards. For example, the industry interoperability requirement of the DSCSA law is a situation where an industry-endorsed specification that is released as a standard can ensure efficient and effective cooperation for everyone. Chronicled, in development of the MediLedger platform, actively maintains alignment via industry trade organizations and standards bodies and defers to these groups in the publishing of standards, but is comfortable to support with technical leadership.
2. **Open APIs** - MediLedger customers can connect to existing MediLedger protocols through the Open API that is released for each protocol. This enables the customers to build new Apps on top of the existing solutions easily, as demonstrated with service providers offering their own customized Apps on top of the PVS protocol already.
3. **Open SDK** - in 2021, Chronicled intends to deliver a Software Developer Kit (SDK) that will empower software developers to create custom solutions on top of the platform leveraging the platform’s differentiated technical capabilities in creating blockchain-powered, business-rule enforcing, and privacy-preserving protocols and applications. Governance of how solutions can be implemented will need to be

developed to ensure integrity of the existing solutions and network to ensure seamless service to the industry.

Network Values & Governance

The creation of protocol-driven networks on the MediLedger platform is undergirded by a value-based framework as follows:

1. **Industry-First** - Chronicled aims to address industry problems and needs that require collaboration. New protocols and functionalities are prioritized based on the benefits delivered to the trading partners.
2. **Inclusive** – The Network is designed to ensure all qualified healthcare industry companies can participate, with no barriers based on size or subjective criteria.
3. **Fair** - All members have equal opportunities to develop their businesses because the Network facilitates connectivity across all members.
4. **Company Controlled Data** - By leveraging the blockchain and confidential data exchange, the Network is designed to ensure that each participant's private data is owned by such participant, and each participant has full control of who and how it shares its private data.

An actively discussed topic over the first three years of the MediLedger workgroups has been that of governance. While there is likely more to learn, we are currently focusing on developing a practical, scalable, efficient, and sustainable model of governance, and our competence in this area will continue to grow as solutions are launched and governance is tested.

After a working group is launched -- which happens only when a group of companies have identified cost savings, workflow automation, compliance, or other advantages to developing software in a working group format with business rules enforced by a blockchain -- then a steering committee is formed and meetings begin. The governance is broken down by phase of the project:

- **Strategic Governance.** Goals are fully aligned, as only those companies that share a business problem will join the working group. Moreover, the scope of work is confined to solving only one specific business problem, and not other problems, which keeps the group focused. This first phase is strategic in the sense that the messaging, data privacy, workflow, automation, error-handling, and other design parameters for the shared solution are discussed, debated, and codified. Specs, mock-ups, and pilots are circulated -- and feedback is given. There may be several iterative cycles over the course of several months, until all parties are aligned. It is true R&D, in a group context. Chronicled has a business interest in helping the companies to agree on a protocol and

solution to meet all of the various requirements, and to get the industry as close to an automated solution as possible. To remain consistent with the MediLedger value of 'industry-first', the 'strategic phase' must be driven by industry firms, and service providers typically are not actively involved. Based on our experience to date, this strategic phase will last 6-18 months, and after completion of design, development, and testing, then the protocol and protocol-driven application are ready to go live.

- **Operational Governance.** At the go-live point, the companies who were involved in designing the protocol can opt-in to going live commercially, or dropping out of the group. Therefore, going live is a voluntary step. The need for strategic input in the steering committee is no longer needed. Also, priorities shift from strategic design to operational oversight of the infrastructure supporting the protocol, and therefore from a governance standpoint it makes sense to 'swap out' the composition of the membership of the steering committee to include the set of companies who decide to run the nodes and participate in the protocol-driven solution. This can include the original companies and may now include solution providers also.

Additional governance considerations:

- **Dispute Resolution Mechanism.** Since companies in a working group or running a protocol are coming together on a voluntary basis, with tightly defined goals to solve a common business problem, generally, we do not anticipate disputes. It is in Chronicled's best interest as a neutral convener to facilitate consensus by collaboration so that all participants in the workgroup are satisfied with the solution design prior to go live, and so that all companies want to progress into the operational phase without any attrition. Even with this strong natural alignment of interests, if disputes do occur during either the strategic or operational phase, there is an escalation framework in place--see Figure 5. In our three years of solution discussions and development, we have never required formal escalation as we have enabled requirements through improved solution design (agile methodology).

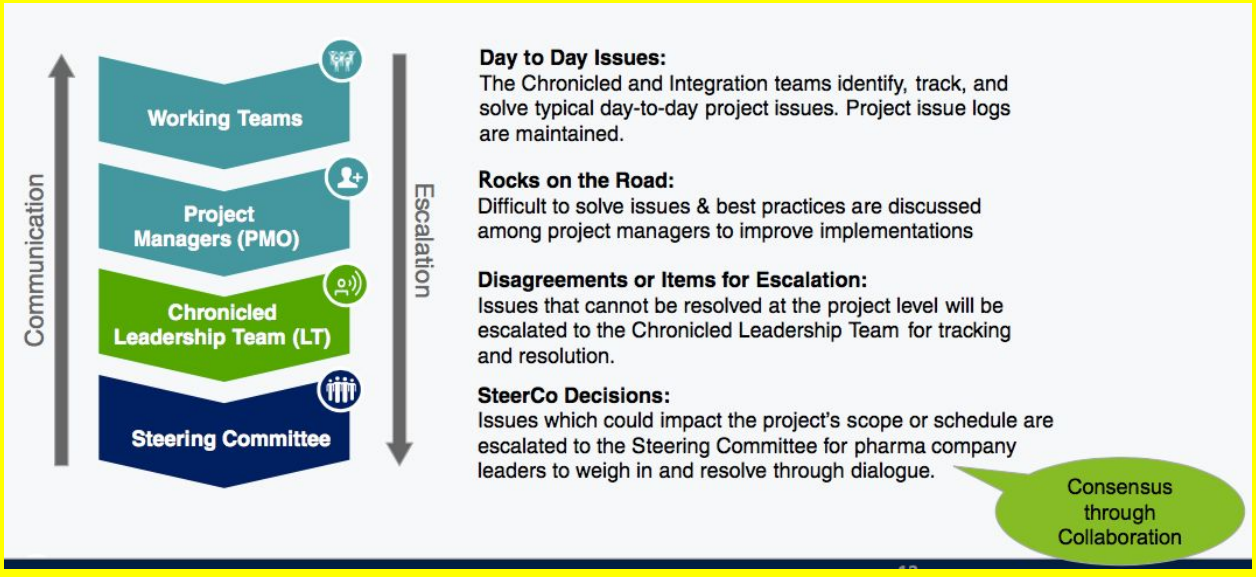

Figure 5. Dispute Escalation Framework

Of note, this protocol governance model does not restrict the growth of the number of protocols or steering committees that can be devised under the MediLedger umbrella. An additional attractive feature of our protocol governance approach is that the membership of each steering committee continuously reflects the domain expertise needed at the table, and we have avoided the issues associated with defined number of seats and voting control that can often stall progress due to conflict over specific industry segment control. As the solutions only work with multi-company participation, it requires all needs to be met in order to be successful, and as such some version of consensus needs to be achieved in order for companies to continue participation and eventual commercial use of the solutions.

MediLedger Roadmap

Throughout our industry conversations, we have discussed business pain points that can be solved through automated processes executed in an industry-wide network, operated by the industry, that allow privacy and rule enforcement. Summarizing these findings, Figure 6 presents a potential roadmap for the MediLedger platform, and how it could evolve over the next four years. While many functions are listed here, we do not intend to imply that MediLedger will replace all systems in these areas. Rather, the MediLedger platform will be the link between companies providing business rule enforcement and linking to internal systems within each company. The eventual prioritization will be driven by industry demand, and we will continue to revise opportunities as new working groups form.

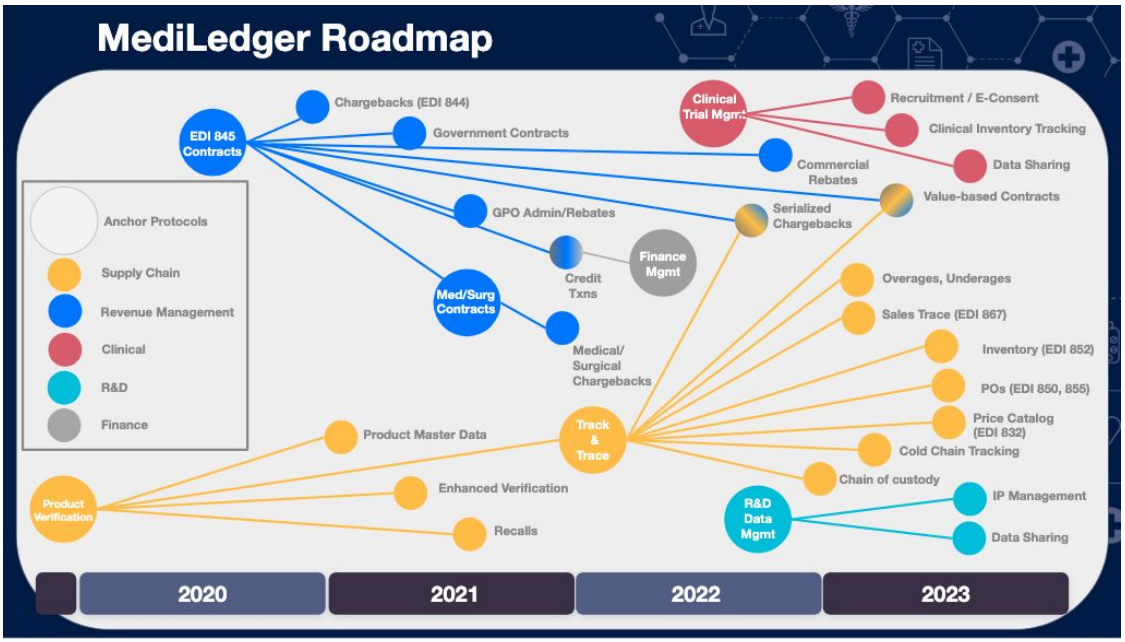

Figure 6. MediLedger Roadmap

Conclusions & Next Steps

MediLedger strives to enable a more collaborative, technology-driven, and results-oriented approach to accelerating value delivery within the pharma industry. Work needs to continue through actual solution implementation and learnings to add to the body of knowledge, and continued improvement is expected to shape the approach in the years to come.

In 2020, we look forward to gaining experience with oversight of decentralized network infrastructure with PVS, refining the MediLedger protocol governance framework in an operational context with PVS and CBK, furthering use case development within the supply chain working group, and exploring additional working groups that have interest to form.

Also in 2020, we look forward to supporting industry efforts as work commences to define interoperability in support of the 2023 DSCSA regulation. The challenge ahead is how to establish an open and competitive playing field for innovation, while ensuring improved services and capabilities for customers and patients as a top priority. Problems previously deemed unsolvable can now be addressed, and we look to be a constructive voice in bringing the industry together for the benefit of all to solve them.

Annex A: 2019 Working Group Membership

DSCSA PVS / Supply Chain	Contracting & Chargeback	FDA Pilot
AmerisourceBergen	AmerisourceBergen	AmerisourceBergen
Amgen	Cardinal Health	Amgen
Cardinal Health	FFF Enterprises	Cardinal Health
Center for Supply Chain Studies	Genentech	Center for Supply Chain Studies
FFF Enterprises	Gilead	Dermira
Genentech	Health Industry Business Communications Council (HIBCC)	Eli Lilly
Gilead	McKesson	Endo
GS1 US	Pfizer	FedEx
McKesson	Premier	FFF Enterprises
Pfizer		Genentech
		Gilead
		GS1
		Glaxo Smith-Kline
		Hikma
		Inmar
		Maxor
		McKesson
		Novartis (Sandoz)
		Novo Nordisk
		Pfizer
		Sanofi
		Vaxserve
		Walgreens
		Walmart