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Innovative Healthcare Systems for Clinical Trials and Drug Delivery in Pharmaceuticals

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PHARMACEUTICALS AND LIFE SCIENCES

An integral piece of healthcare is supporting a patient's recovery which often involves the use of medication and clinical research. Healthcare providers and governments employ the services of pharmaceutical companies to solve a seemingly endless number of health-related issues from global pandemics to rare conditions. Time is a critical component for pharmaceutical success, yet the technology supporting these businesses tends to be archaic, hindering the ongoing research, assessment, and delivery of life-saving medication.

While the obvious priorities in healthcare have been to digitally transform claims processing and health record management systems, the businesses of researching, creating, and delivering drugs have not received enough attention. Pharma is no stranger to operational complexity with a drug's multi-year, multi-stakeholder lifecycle starting at clinical research, where companies develop innovative routes to solve complex medical problems, and ending with supply chain management, where pharmacies can deliver medication properly to patients. From on-going audits to supply chain logistics, the entire pharmaceutical industry runs on disparate platforms that cause data islands, increasing error-prone manual processes, and inhibiting drug innovation and research.

Before diving into potential solutions, two key areas must be addressed to fully understand the state of pharma and life science operations, i.e. clinical research and pharmaceutical supply chain management.

CLINICAL RESEARCH CHALLENGES

The clinical research process starts at drug creation, where it is assessed for safety and measured for implications on absorption, metabolism, and excretion. Every drug must go through manufacturing, trial research, and FDA applications before reaching the shelves of local pharmacies. The entire drug creation process from a clinical research perspective is plagued with process complexities.

RECRUIT AND RETAIN TRIAL PATIENTS

Once a drug is created, pharmaceutical companies must - often through intermediaries - recruit and retain patients to properly test drug effectiveness, manage and analyze the clinical patient data, and upload any applicable billing information to the patient portals. The patient trial experience goes in two waves: first the blinded study for testing drug efficacy and then the global scale testing across thousands of patients. In both cases, patient retention, data integrity, and data quality are at risk, as patient consent, drug usage, and more must be tracked and distributed to permissioned external entities.

TRACK PATIENT CONSENT

Beyond the recruitment, retainment, and tracking of clinical trial patients is the tracking of patient consent - another process intensive aspect of the clinical research lifecycle. Patient consent tracking is essential for tracing fraudulent activity, providing auditors data, and filing lawsuits. Patient consent at the clinical trial tends to be completed through paper signatures that are then faxed to research entities managing the trial experience. The cost of compliance is high for pharmaceutical entities, as any drug that causes high-risk complications can result in legal ramifications. The technology supporting compliance processes compounds the cost even more, as legacy pharmaceutical systems lack the ability to interoperate and share data in an effective manner.

Additionally, the trial participant's medical history usually involves a paper trail of signatures and physician visits. This medical history is a vital puzzle piece to the trial experience, as drug interactions or previous medical conditions must be documented. With no full patient history registry or patient records system interoperating across segregated domains, pharmaceutical companies have no way to accurately identify pre-existing conditions, past trial engagements, medical history, etc. This means pharma operations proceed by the word of their patient. And to make an already complex situation more burdensome, all of this information must be gathered in a HIPAA compliant manner and follow strict regulations as it relates to PII.

DISTRIBUTE CLINICAL TRIAL DATA WITH SEVERAL PARTIES

As previously mentioned, healthcare systems are historically segregated which makes the gathering, sharing, and analyzing of trial data across parties a time consuming and manual process. Many businesses use a provider or researcher to gather clinical trial data, and then input the patient's trial results into a designated system of record. This data must be shared with participants/patients, physicians, trial sponsors, service providers, CROs, research coordinators, regulatory agencies, investigators, ethics committees, and data analysts for establishing trust, security, and visibility. Many of these systems are separate, as multiple physicians and patients will participate in a clinical trial, so researchers must combine all the disparate data points.

Maintaining the security and privacy of this data is also vital for a successful clinical trial. HIPAA regulations make the sharing of data extremely strict and require frequent compliance audits. This means data must be shared with permissioned parties in a highly secure format with full confidence in the application and underlying technology. Enhancing data integrity, secure sharing, capturing aggregation, and ownership of sensitive data is essential to protect from misuse and improve operating efficiency.

After these processes result in successful outcomes, the research team can submit a New Drug Application to the FDA for review with the fully documented research and findings. If the submission is accepted, the FDA will provide a response within six to ten months. At that point, the drug manufacturing process may begin.

SUPPLY CHAIN MANAGEMENT CHALLENGES

Another high risk operation within the scope of pharma and life sciences is the tracking of drug ingredients, manufacturing processes, and recall operations. Securely tracking drugs through the entire supply chain from supplier to point of sale (OTC or prescription) is likely to incur error as pharma track and trace processes are outdated. Whether it is confirming the source of goods or automating supply chain processes to improve data movement between parties, the current systems that support the tracking of drugs is outdated and risky for pharmaceutical organizations.

DRUG QUALITY AND MANUFACTURING INTEGRITY

There have been many technological advancements to support the globalization of drug supply chains. These advancements allow for active primary ingredients (APIs) shipping across borders. While these advancements democratize the ingredients necessary to manufacture and distribute medication and lower overall drug costs, there is a high risk for contamination which often leads to drug recalls by the manufacturer. In addition to drug contaminants, bad actors may disrupt the supply chain and use look-alike products that result in counterfeit drug production and consumption.

Pharmaceutical companies and supply chain operators must develop a single source of truth that tracks goods from source to manufacturing to consumer. This solution would have to start from the actual shipment of ingredients to manufacturers and provide complete traceability, otherwise businesses will continue to see wide-ranging drug recalls by government regulatory agencies. These recalls not only disrupt the distribution of medication to patients, they also interrupt the business operations within the pharmacy and require physicians to notify patients of other drug options.

DRUG RECALLS

The entire drug recall process involves participants utilizing different systems. When a drug needs to be recalled, the following parties must be notified: patients, healthcare providers, legal entities, pharmacies, insurance companies, manufacturing facilities, and more. Once those entities have been notified, an extensive list of tasks ensue. Each entity who had some participation with the drug during its pre-recall life will be obligated to provide data, receive data, or participate in a process with an external business entity.

To date, the entire recall process is long and burdened with manual, error-prone processes that put pharmaceutical companies in danger of greater legal action among patients, providers, and regulatory bodies.

Pharmaceutical supply chain operations must digitally transform and create interoperable systems of record, so companies can stop contaminated drug production, eliminate counterfeit drug consumption, and minimize the number of time consuming and expensive drug recalls.

Addressing Pharma and Life Sciences Challenges through Smart Contracts

In general, the entire data sharing aspect of pharma and life sciences is slow due to HIPAA compliance, FDA regulation, and data sensitivity, along with historically segregated systems. To improve pharmaceutical innovation, speed, and efficiency, and ensure accurate and insightful supply chain and patient data sharing, a complete and total digital transformation must take place. Through the use of smart contracts, businesses can digitally transact in a highly secure and permissioned environment.

DAML AS A SOLUTION TO TAMING COMPLEX CHALLENGES THROUGH DIGITAL TRANSFORMATION

Smart contracts enable multi-party workflows and communication between segregated systems. A common theme across pharma and life sciences is the number of external entities participating in a drug's end-to-end lifecycle. Each entity differs in their rights and obligations regarding highly sensitive data and transactions. Through the use of DAML, a powerful, open source smart contract language and runtime for modeling business logic into distributed applications, patients, providers, insurers, researchers, and pharmaceutical entities can view and share data as it relates to their permissioned role.

SMART CONTRACTS ON DATABASES AND DISTRIBUTED LEDGERS

DAML differentiates itself by giving businesses the power of smart contract technology to solve complex business processes without requiring investment in blockchain technology, i.e. DAML is fully portable, interoperable, and vendor agnostic. DAML supports both blockchain technology and traditional databases. Businesses can deploy DAML on their PostgreSQL v9.6 database or higher. They can also use DAML on distributed ledgers like Corda and VMware Blockchain. Since DAML is fully portable and vendor-agnostic, businesses can deploy on any infrastructure and move when business needs change. The entire mission for DAML-driven applications is to connect global operations and create seamless, accurate, and smart business transactions.

PRIVACY-FIRST FRAMEWORK

This global connectivity is backed by a privacy-first framework that ensures the right people receive the right information at the right time. With fine-grained permissions, DAML specifies who is allowed to authorize a given contract step and who can view the contract data with clearly defined rights and obligations in the code. DAML ensures data is only visible to those who have a right to see the data via sub-transaction level privacy at the API level. It can also support blinding transactions from the network operator (when specific distributed ledger platforms are in use).

NATIVE DISTRIBUTED LOGIC

DAML was also built from the ground up to support distributed logic. This means the code automatically handles distributed concerns, so developers can focus on the business logic only while DAML abstracts away the underlying complexity of the database or distributed ledger.

DAML is also vendor agnostic, meaning developers can write an application once and port it to their platform of choice. This ensures that the infrastructure used today does not hinder future investment for the business. Today, each blockchain platform has its own choice of smart contract language and framework for application development. However, this causes significant vendor lock-in because the applications do not port without code loss and create a migration nightmare. These languages are complex (no abstraction from the infrastructure layer) and do not enable interoperability between systems or other platforms, so businesses end up developing solutions that create more data silos.

INTEROPERABILITY BETWEEN HISTORICALLY SEGREGATED DOMAINS

DAML also created the first global interoperability protocol for smart contracts, enabling integrations with multiple infrastructure providers and communication between segregated domains. This means a pharmaceutical company running on a database and a healthcare provider running on a distributed ledger can share data and transact seamlessly. If both entities are running a DAML-driven distributed application, then the parties can leverage DAML's interoperability protocol to interoperate between networks. With this protocol, business operations will not be slowed down by each party's infrastructure, as DAML integrates with multiple infrastructures and horizontally scales by adding new networks.

Through the use of DAML, pharmaceutical companies can build solutions that solve clinical trial research and supply chain management challenges. The next section will highlight solutions to solve patient consent tracking, patient drug consumption, and drug recalls.

Brillio's DAML-Driven Clinical Research Solution for a Trial Patient Portal

Patient consent tracking must log the patient education and acknowledgment of the procedures, steps, and associated risks involved in the clinical trial. This consent must be obtained and maintained in a secure environment for data security purposes. There also needs to be a place to document the patient trial experience and share results with participating parties.

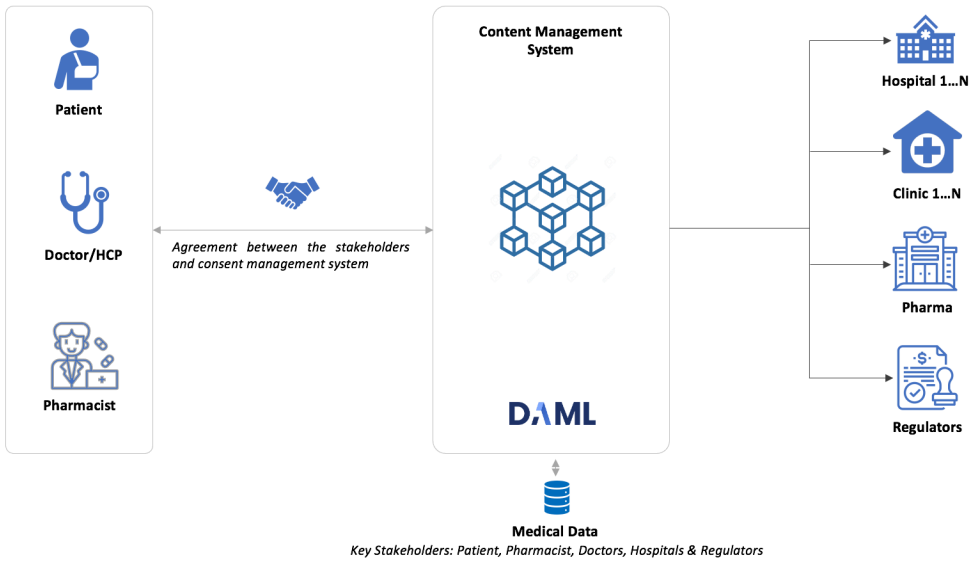
COMPLETE END-TO-END TRIAL PATIENT PORTAL

Brillio has developed a solution that tracks clinical trial processes at every level. Through the use of a DAML-driven distributed application, Brillio's solution is able to:

- Securely collect patient data and assure participants of the data usage and trust
- Manage patient consent through DAML's clearly defined rights and obligations between the patient and clinical trial team
- Configure reports to support adherence to industry regulations

The proposed solution would log the informed consent of the patient/ trial participants' consent and the actual drug trial experience (i.e. side effects, medication timing, results, etc.). This solution would act as the trial patient portal to facilitate the sharing of consent, tracking of drug consumption, and results from the drug experience for research purposes, all in one place as a single source of truth. This would then be shared with the proper entities based on their role in the trial. This solution minimizes enrollment challenges and patient participation by providing a secure exchange of data from the trial site to the patient during and after clinical trial enrollment. This solution would create a clinical trial portal on top of a database or distributed ledger that interoperates between the healthcare provider and clinical trial network, so the patient can minimize their contact with the research team and healthcare provider for a seamless clinical research experience.

Trial Patient Portal Solution

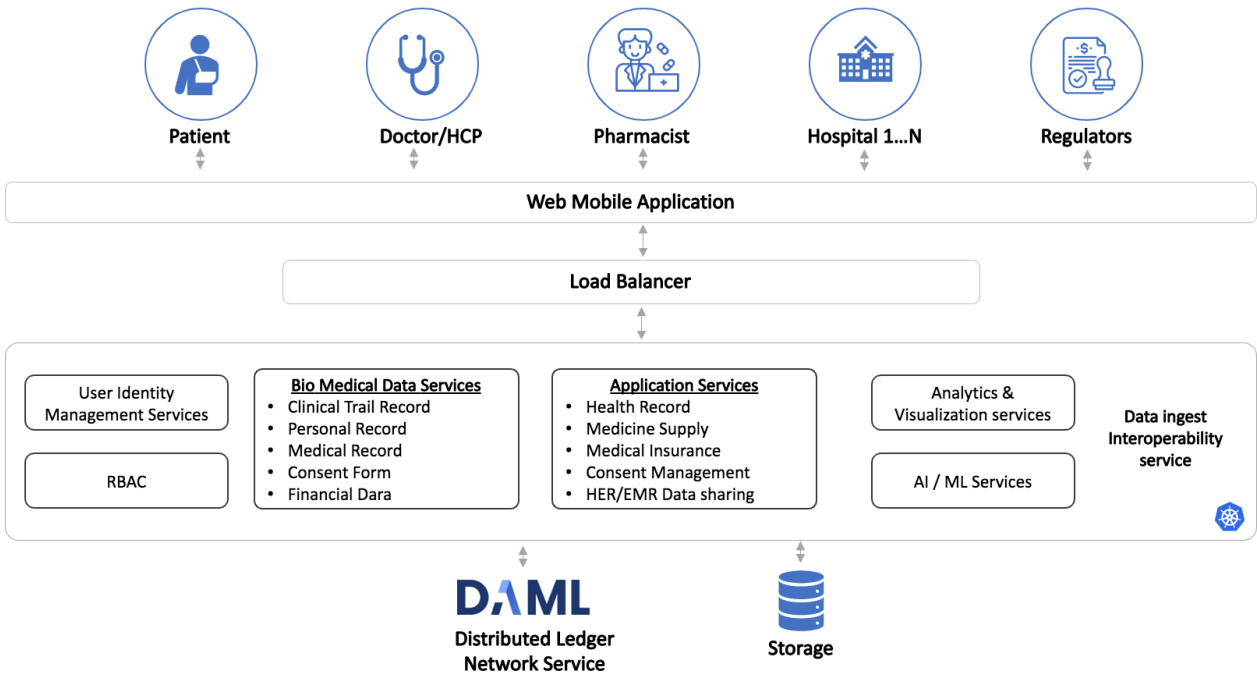


This solution will provide the following for clinical research teams:

- Reduce the burden of trial participation through remote data collection vehicles
- Manage consent tracking for each instance of data collection
- Identify and certify data collection devices independent of the site prior to data collection
- Ensure a data provenance for trail master management Operationalize distributed clinical trial models to improve recruitment and lessen the burden of trial participation
- Comply with regulatory burdens while providing a successful, cost-effective trial

The patient consent tracking would run a distributed application written in DAML across a database or distributed ledger, depending on the need for data immutability and infrastructure investment.

Patient Consent Tracking Solution - Technical Specifications



Brillio's DAML-Driven Track and Trace Solution to Speed Up Drug Recalls

Counterfeit medicine is categorized as drugs that may be contaminated, contain wrong ingredients, incorrect dosage of active ingredients, or have no active ingredients. According to the World Health Organization, over $79 billion in counterfeit medicine is traded annually across the globe and 1 million people die every year due to counterfeit drug consumption. Not only do counterfeit drugs endanger people's lives, but they also negatively impact the pharmaceutical company's brand and ability to continue producing life-saving drugs. Hence it is critical to have a robust process in place to avoid counterfeit drugs in the supply chain, as well as recall the drugs quickly in case of mishaps.

The drug recall process requires businesses to not only stop the manufacturing, shipment, and distribution of medication with healthcare providers and drug stores, but to trace the entire drug's lifecycle to identify the root cause for the drug's deficiency. This requires pharmaceutical operations to review trial data, ingredient quality, and manufacturing facilities. It also requires the team to notify patients using the medication of the risks and discontinued use of the drug. Healthcare providers must be informed and notified of the potential risks associated with the medication. A complete list of the drug's manufacturing and shipment records must be logged for legal purposes. The entire recall process is high risk with many data gaps due to disparate platforms. A transparent track and trace solution

across the supply chain will improve the visibility and process of the tracking and recall.

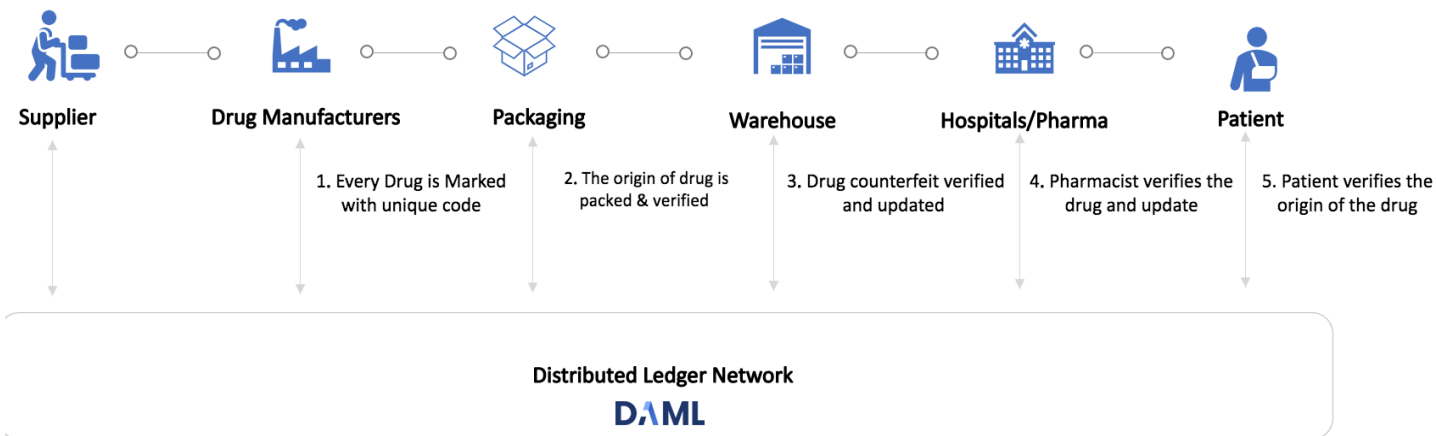
DRUG LIFECYCLE TRACK AND TRACE SOLUTION

Brillio developed a solution to track and trace a drug through the entire supply chain from supplier to point of sale (OTC or prescription) through a DAML-driven pharmaceutical model. This solution helps manufacturers notify all stakeholders, including the regulatory bodies, about contaminated drug batches that must be pulled from shelves at storefronts. This solution also cancels future shipments and notifies patients of the adverse effects of the contaminated drug prior to consumption.

Brillio's track and trace solution is able to:

- Securely track drugs through the entire supply chain from supplier to point of sale (OTC or prescription).
- Enable a common platform for all third party logistics relationships where manufacturers, logistics service providers, distributors, hospitals, and pharmacies can utilize supply chain records to ensure patient safety.
- Provide direct access to supply chain data for regulators and other industry participants to more swiftly enact drug recalls.

Drug Lifecycle Track and Trace Solution



The Ledger contains connected record of each transaction

- Authenticates it comes from licensed manufacturer
- Validates the unique code does not exist in the system and is being shipped from the rightful stakeholder
- Allow rapid response to counterfeit attempts and recalls
- No confidential information or business intelligence is shared

The application would track each drug via a unique identifier that is used across all parties. The manufacturing facility would verify the origin of the drug ingredients and notify shipping and logistics of its transit. Pharmacists would verify the drug's arrival and update its record. The patient would also verify the purchase of the drug and origin of purchase. In the case that a regulatory body or supply chain entity identifies counterfeit ingredients or contamination, every participating member along the network would be notified and update their data accordingly. This would also provide a complete picture of the drug's lifecycle, where the drug originated, who interacted with the drug, etc.

This solution will provide the following for supply chain participants:

- Authenticate the drug's origin from a licensed manufacturer
- Validate whether the drug's unique identifier exists in the system and is being shipped from the rightful stakeholder
- Ensure rapid response to counterfeit attempts or contaminated ingredients to speed up recalls and lower patient health risk
- Complete confidentiality and privacy between permissioned entities (DAML clearly defines the rights and obligations of each party so only the permissioned entity receives the information and data associated with their data rights)

The proposed solution would use a distributed ledger for the underlying infrastructure and run a distributed application written in DAML. This will ensure more efficient sharing of sensitive data in a highly secure model and privacy-first framework.

To increase visibility and tracking accuracy, Brillio also created a machine learning algorithm that reduces counterfeit drug consumption and production in the supply chain. The algorithm is trained to quickly identify and notify manufacturers of potentially fraudulent ingredients and contaminators to encourage greater visibility into drug production.

CONCLUSION

Every business function and entity participating in the pharma and life sciences industry benefits from the use of smart contracts. When using a platform agnostic solution like DAML, businesses are able to tap into the tech that supports blockchain on both decentralized and centralized models. By doing this, external parties with varying degrees of rights and obligations can participate in a distributed application in real-time. This ensures patient data is more accurately tracked during clinical trials. This helps recalls happen more quickly and notify users to lower health risk from counterfeit medication consumption. It also provides a means to store more data points and build more accurate machine learning algorithms.

A true digital transformation must take place in the pharmaceutical industry and it starts by assessing the clinical research and supply chain model. Once these areas are improved, businesses will be able to expand into the greater patient healthcare journey and provide better patient experiences.

ABOUT BRILLIO

Brillio focuses on delivering design-led solutions to its customers. Brillio focuses on turning technology disruptions into advantages for its customers and provides a unique path to market for every solution. The team strives to bring innovation to the digital world with the best customer experience possible.

https://www.brillio.com/

ABOUT DIGITAL ASSET

Digital Asset helps companies of all sizes and across all industries get distributed applications to market faster, and stay there longer. At the core of Digital Asset's service offering is DAML, an open-source and platform-independent smart contract language that enables developers to write an application once and deploy it anywhere. The global team of professionals at Digital Asset are experts and innovators from technology, engineering, enterprise domains, and many other industries served through DAML applications.

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