CAPSTONE FINAL PRESENTATION

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Team 2

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BLOCKMED
SUPPLY CHAIN SOLUTIONS

1 Executive Summary

Companies in the pharmaceutical industry must increasingly have a thorough understanding of their supply chain and provide transparency to their partners, government agencies, and consumers. Spurred by online pharmacies and globalization, counterfeit pharmaceuticals are an increasing problem. According to a study published by the American Health and Drug Benefits "counterfeit drugs account for $75 billion in annual revenue and have caused more than 100,000 deaths worldwide" (Erwin A. Blackstone, 2014). Determining drug provenance is not only critical for identification of counterfeit drugs, but it is also vitally important for manufacturers to track the source of pharmaceuticals for identifying quality control deficiencies.

Incidents involving counterfeit or low-quality drugs result in significant costs to the healthcare system and lower consumer confidence. Governments have responded to these challenges with legislation. The Drug Quality and Security Act (DQSA), which requires actors in the pharmaceutical supply chain to provide electronic tracking capabilities, was passed in 2013. Enforced by the Federal Drug Administration (FDA), the DQSA imposes significant overhead costs on companies in the supply chain, from manufacturers to dispensers, who need to implement compliance by the deadline. Companies that prove to be out of compliance face heavy fines and consumer backlash.

With revenues of approximately $200 billion per year, our parent company is one of the largest actors in the U.S. pharmaceutical supply chain and is ideally positioned to introduce a technical solution for DQSA. To that end, our parent company has formed the BlockMed division, tasked with developing a solution to meet the drug supply chain security requirements outlined in Title II of the DQSA.

In the current environment, meeting the requirements of Title II is very costly and labor intensive, potentially taking weeks to track down the source of a drug. Our solution will make it possible to track the pedigree of a pharmaceuticals down to the individual package with near real time results. The benefits of our solution will extend to automatically flagging products for recall and detecting potential counterfeit pharmaceuticals, thus enhancing consumer confidence. By providing our solution to our partners, we will not only save money but be a market differentiator for our organization.

BlockMed's Track and Trace solution uses Blockchain-as-a-Service (BaaS) and can be easily integrated to the existing systems and workflows of our partners using standard APIs. Our platform is hosted in the cloud, is highly available, scalable, and easily accessible. Our partners will want to use our solution because it will save them money and help them avoid compliance penalties.

2 Business Requirements

2.1 Business Context

The Drug Quality and Security Act (H.R.3204)[1] requires manufacturers, wholesale distributors, dispensers, and repackagers to track and provide all prior transaction information at each transfer of ownership. The timeline below shows the major implementation milestones.

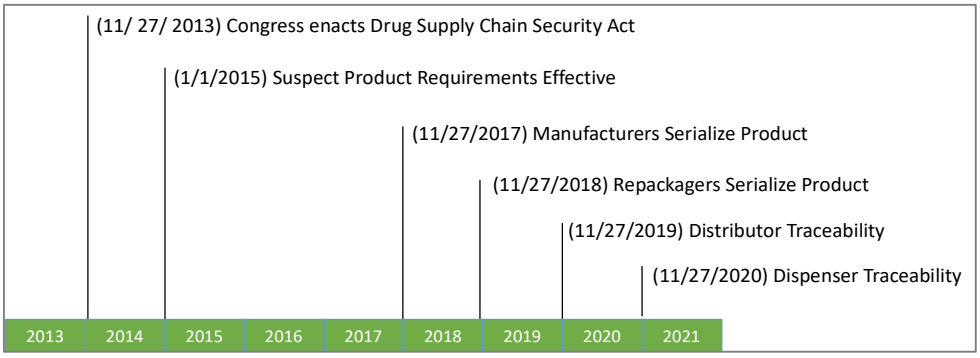

Figure 2-1. DQSA Implementation Timeline

2.1.1 "As-Is" Business Context

In the current environment, changes in drug ownership between the participants in the pharmaceutical supply chain are tracked in multiple disparate systems hosted by the individual participants (drug manufacturers, wholesalers, pharmacies, health care providers). Each transaction is usually accompanied by significant paperwork to record issues and receipts of goods, as shown in Figure 2-2. As a result, end-to-end visibility of the origin of a drug is simply not available.

2.1.2 "To-Be" Business Context

Blockchain technology provides an immutable, unhackable, and virtually distributed ledger to record transactions. Since blockchain is distributed, there is no central database to hack or shut down. Each transaction (block) in the blockchain is linked to the previous transaction and includes a digital signature that guarantees the validity of the entire chain of transactions.

In the to-be model, shown in Figure 2-3, each change in drug ownership will continue to be recorded in the participants ERP/Inventory Management systems. However, using APIs,

[1] https://www.congress.gov/bill/113th-congress/house-bill/3204

transactions will also be recorded in the blockchain. The use of blockchain will virtually eliminate the need for paper records and make all drug transactions readily available.

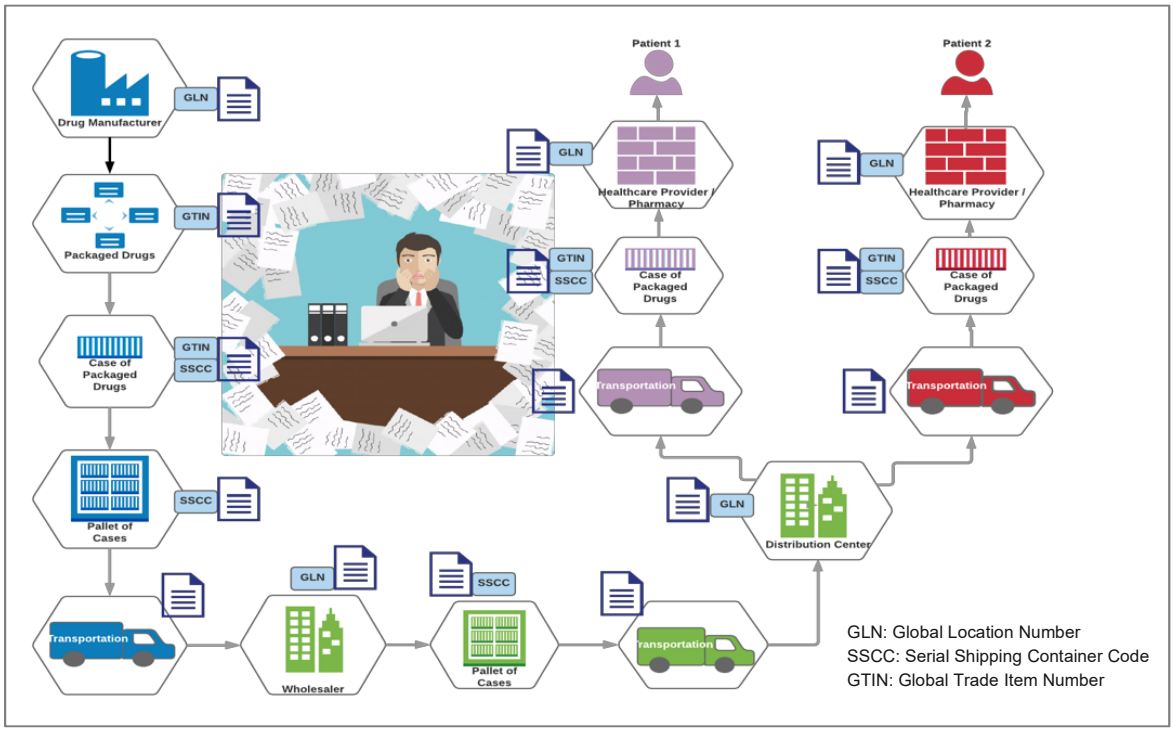

Figure 2-2. As-Is Pharmaceutical Supply Chain

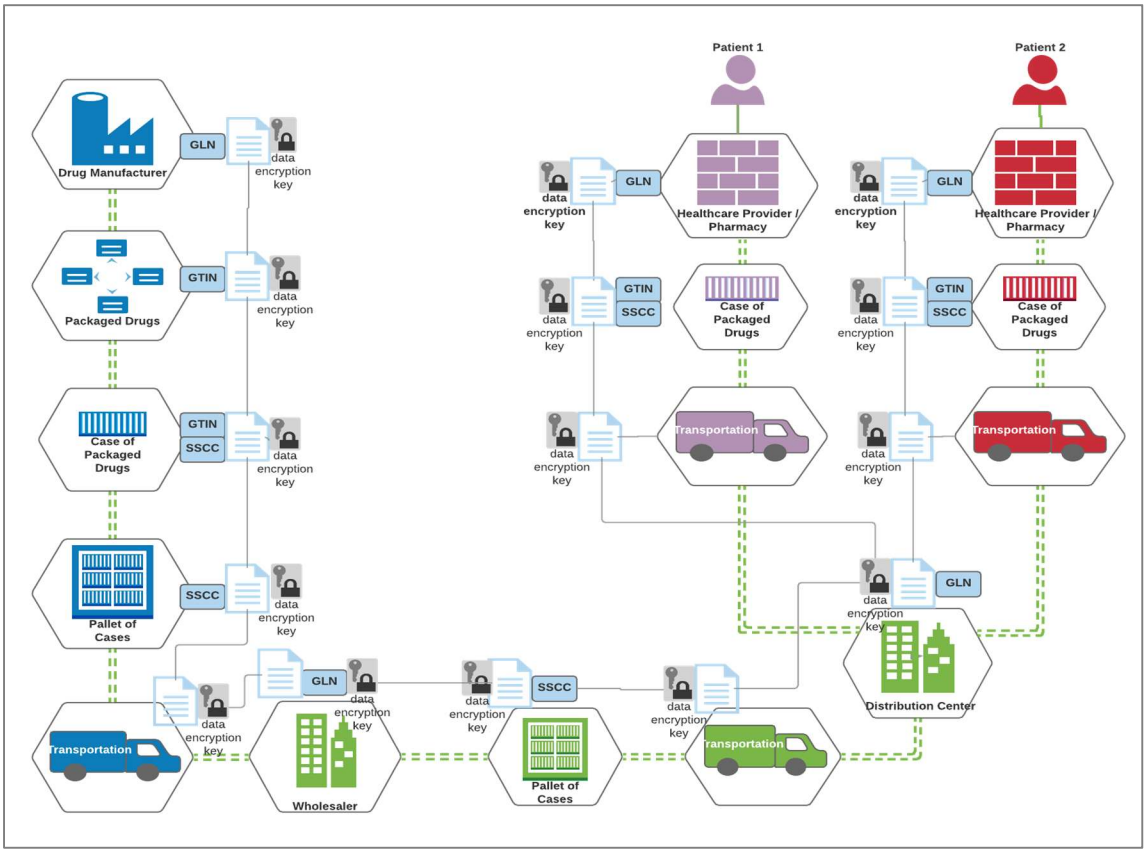

Figure 2-3. To-Be Pharmaceutical Supply Chain

2.2 Product Platform Functional Requirements

2.2.1 Epic 1 - Track and Trace

This epic establishes requirements to facilitate the tracing of prescription drug products through the pharmaceutical supply chain. Features included in the Track and Trace epic include:

- Record transfer of ownership throughout the supply chain
- View ownership history for a package
- Integrate with existing supply chain distributor systems of record for Global Location Number (GLN), Serial Shipping Container Code (SSCC) and Global Trade Item Number (GTIN)

Table 2-1. User Stories

USER STORY	ACCEPTANCE CRITERIA
As a member of the pharmaceutical supply chain*, I want to scan pharmaceuticals that I ship, or that are received by me, so the	• Scan the GTIN of a received pharmaceutical shipment/order. The system will record the transaction to the blockchain.

transaction can be recorded to the blockchain.	• Scan the GTIN of a container that is being shipped from a location. Go to the system and run a report for the GTIN to confirm that it shows that it has been shipped from the Location at the correct time. • Scan the GTIN of a pharmaceutical(s) that has been received at a location. In the system, run a report for the GTIN to confirm that it shows that it has been received at the location at the correct time.
As a member of the pharmaceutical supply distribution chain, I want to trace the history of a received pharmaceutical so that I can know its source of origin.	• Run a report in the system for a GTIN to track location history. View a chronological list of the locations, the pharmaceutical(s), the supply chain member, and the transaction type (packaged, shipped, received, etc.). Confirm the data is correct.
As an admin user in the pharmaceutical supply distribution chain, I want to know where pharmaceuticals from a given source are located so I can issue a recall on those pharmaceuticals.	• Enter a batch ID representing a specific product batch in the system. The system displays the GTINs and current Location for all containers for products in that batch.

*Pharmaceutical supply chain members include manufacturers, wholesale distributors, dispensers (e.g. pharmacies, physicians), and repackagers.

2.2.2 Product Platform Non-Functional Requirements

Table 2-2. Non-Functional Requirements

REQUIREMENT	DESCRIPTION
Security	• The transaction history records are immutable. • The APIs will be accessible over TLS encryption. • The system will not store any patient data.
Scalability and Reliability	• IBM's BaaS offers 'always-on, high availability' with seamless software and blockchain network updates. • IBM's BaaS offers a security stack that blocks malware. • IBM's BaaS offers 24/7/365 support with built-in monitoring.
Usability	• The implemented system will build on the existing scanning capabilities within the current supply distribution chain. • Due to the seamless integration into the current system, there will be no need for additional training of shipping and receiving personnel.

2.3 Business Benefit Justification

BlockMed's Track and Trace provides numerous benefits for all players in the pharmaceutical supply chain. In addition to compliance with the DQSA, other benefits are achieved by improving areas of the pharmaceutical industry itself. These industry benefits include enhancing patient safety and trust, as well as better information security and cost savings.

2.3.1 Compliance with the Drug Quality and Security Act

The DQSA calls out several legal requirements for companies in the drug supply chain. These include requiring manufacturers to:

- Serialize (track) the product at the item or lowest saleable level
- Provide information about a drug and who handled it each time it was sold in the U.S. market
- On request, provide the FDA with transaction information, history, and a statement within 48 hours
- Respond to notifications of an illegitimate product and notify trading partners and the FDA within 24 hours

Accomplishing compliance presents challenges in the current environment because traceability requires connecting multiple partners in the supply chain who must push information from multiple disparate systems to each other. “The unspoken challenge of track-and-trace solutions is to enable ad hoc connections and provide a means of verifying the newly connected partner” (Celeste R. , 2017). BlockMed’s Track and Trace can enable low-cost, efficient compliance by providing visibility for transactions across the many independent companies who are involved in the pharmaceutical supply chain.

2.3.2 Patient Safety

Since BlockMed’s Track and Trace provides transparency in the supply chain, it enables patients to have more confidence and know they are receiving an authentic product. It also enables much more effective detection of fraudulent transactions and counterfeit drugs.

Patient safety is further realized by the capability of faster recalls. If there is a need to have a recall, BlockMed’s Track and Trace will enable quicker identification of the affected lots, thus removing them from the supply chain faster and limiting risk to patients.

2.3.3 Cost Savings

The DQSA was enacted in part because many states were implementing differing versions of e-pedigree or “tracking and tracing” laws. These laws were being implemented in varying ways and creating significant overhead for the supply chain partners to track transactions and still meet delivery schedules. Further, the distributors in the pharmaceutical supply chain were using different systems for tracking and tracing, making the exchange of information tedious (Celeste R. , DQSA, 2015).

The DQSA mandates a level of standardization, which should on its own reduce some costs in contrast to disparate state-by-state solutions. BlockMed’s Track and Trace enables implementing the standards in a very cost effective and efficient way. While various supply chain members could provide their own systems, a single platform used by all will be far cheaper, minimizing the cost of compliance and reducing existing costs for tracking and tracing drugs.

A blockchain solution has an advantage in pricing models when compared to alternative technologies. Because a per-transaction, tokenized charging system is built into the model, partners can pay as they use it, and there is not necessarily a need to negotiate subscription fees or licenses (Celeste R. , The Value of Blockchain: And It’s Application to the Drug Supply Chain Security Act, 2018).

The cost of a drug recall can vary greatly due to the following factors: number of packages affected, the cost of the drug, and the seriousness of its impact. Studies done by the International Pharmaceutical Industry, indicate that up to 84% of the cost in a recall are operational—business disruption and recall costs. BlockMed’s Track and Trace can have a significant impact by streamlining the critical operations of locating drugs, issuing recalls, and notifying affected supply chain partners.

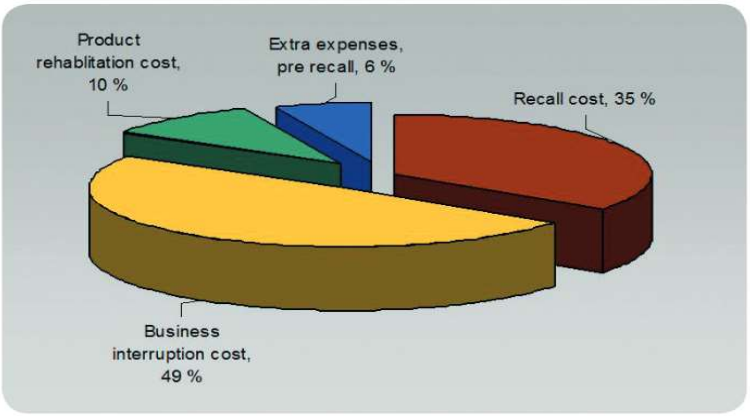

Figure 2.4 International Pharmaceutical Industry Breakdown of Recall Costs

2.3.4 Security

As a blockchain solution, BlockMed's Track and Trace can provide superior security for transactions to protect against fraud or hacking. Any single database will be susceptible to a clever attack, but blockchain employs an encrypted, immutable, distributed database that is nearly impossible to corrupt, because all the copies cannot be affected simultaneously (Pharmaceutical Technology Editors, 2017).

2.4 Performance Indicators

The table below shows performance indicators that can be used to measure the system. These tie to the business benefits mentioned in the previous section.

Table 2-3. Performance Indicators

NAME	DETAIL	TARGET
Net Promoter Score	A Net Promoter Score (NPS) is a measure of customer loyalty calculated by subtracting the percentage of customers who are Detractors from the percentage of customers who are Promoters. NPS values can range -100 (everybody is a detractor) and + 100 (everybody is a promoter). BlockMed can improve user satisfaction for all members in the supply chain.	> 80
Reporting time	The DQSA calls for responding to FDA requests within 48 hours. Currently, reporting likely takes several weeks. Monitoring this reporting time metric will ensure the system is meeting performance expectations and enabling compliance.	< 24 hours, over 99% of the time
Cost savings	Reduce the cost of paperwork and manual labor to track the supply chain.	Savings of over 25%

3 Technical Specification and Prototype

3.1 Architectural Approach

3.1.1 Main Components of BlockMed

BlockMed provides a wraparound fabric to the existing ERP / Inventory Management systems in the pharmaceutical supply chain. The main components that make up the BlockMed application are as follows:

1. **BlockMed Mobile App -** BlockMed has a read-only web/mobile app that allows authorized BlockMed users to easily query drug pedigree and perform other interactive track and trace functions.

2. **BlockMed Admin** - A management portal used by partner admins (a trusted subset of partner users with the ability to manage data). In addition to track and trace functions similar to those offered by BlockMed app, this interface provides access to restricted functions such as:
   - Onboarding other users for the partner.
   - Executing special operations, such as flagging recalls.
   - Viewing historian data for data transparency and accountability.

   BlockMed Admin also supports the ability to manually manage pharmaceutical data via the BlockMed Admin interface (though this data will primarily be recorded using partner ERP integrations). Authorized users can manage Product, Item, Batch, or Location information here. They can also manually record transactions such as Shipping and Receiving events.

3. **BlockMed Entity Management APIs** - These REST APIs allow authorized integrating systems to add or update entity information. They also provide a convenient mechanism for admins to perform batch data loads. In addition to the ability to manage reference data, the APIs provide access to the Hyperledger Fabric Historian.[2] The historian provides a detailed, immutable view of all changes issued to the blockchain. It is this view that provides the transparency and accountability that makes BlockMed a trusted solution.

4. **BlockMed Transaction APIs** - These REST APIs provide the hooks to capture important events registered in the participant ERP systems as they occur in the supply chain (such as packaging, shipping, receiving, etc.)

5. **Peer ERP / Inventory Management Systems** - Participant members are permissioned who can generate and record supply chain transactions, through Smart Contracts, in their

[2] Hyperledger Composer Historian - https://hyperledger.github.io/composer/reference/historian.html

ERP / Inventory management systems. BlockMed does not impose any requirements on how these transactions are captured.

3.1.2 BlockMed Architecture

BlockMed builds on existing infrastructure and integrates existing ERP/Inventory Management systems from each participant with a shared distributed ledger. This is accomplished through an EPCIS[3] compliant API. This way, transactions generated in the participant's ERP systems will also be recorded in the blockchain, providing increased security, information access, traceability, and virtually eliminating the need for paper records.

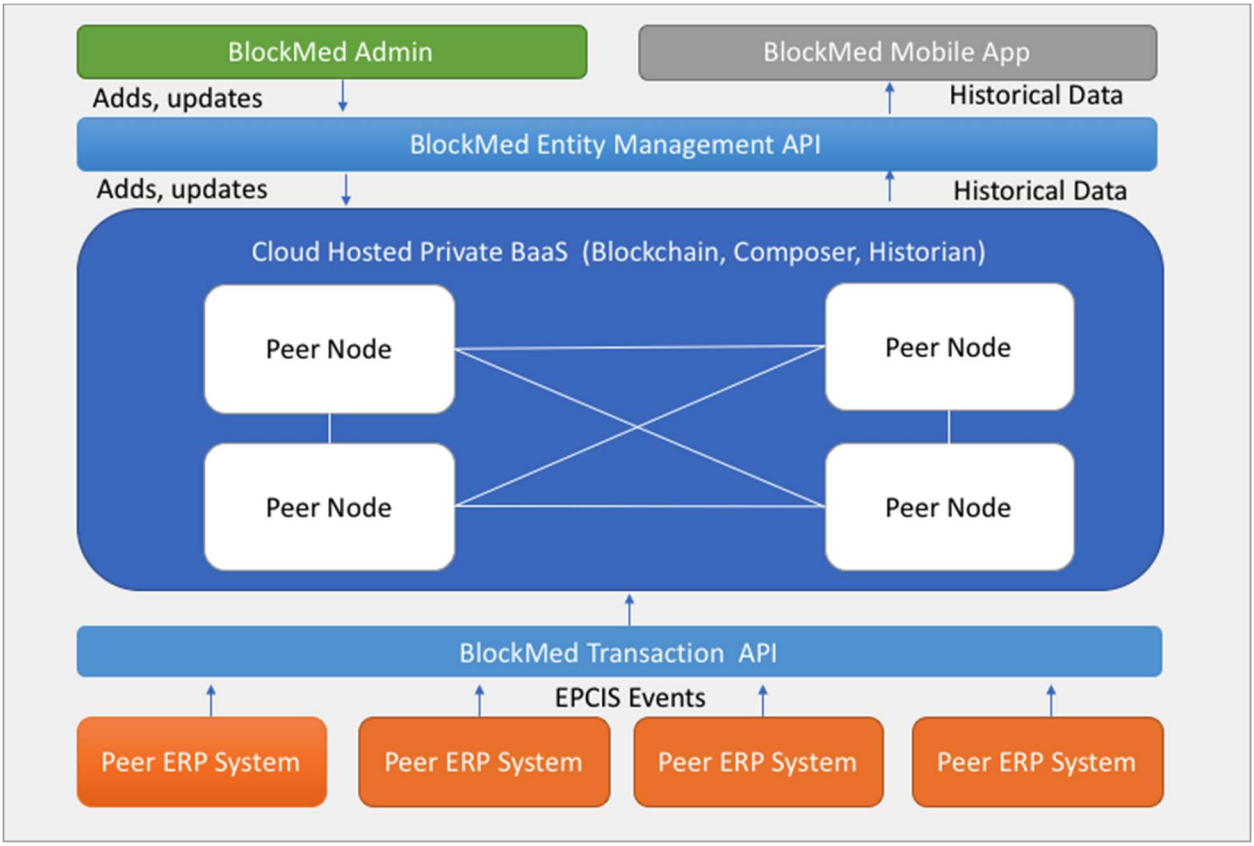

Figure 3-1. BlockMed Solution Architecture

[3] https://www.gs1.org/epcis/epcis/1-1

3.2 Software Solution

3.2.1 Platform and Tool Selection

Platform Vendor - BlockMed utilizes permissioned, shared ledgers on a private blockchain network hosted as a cloud service. A permissioned distributed network rather than an open network platform that allows membership control in the BlockMed blockchain is required. BlockMed leverages IBM's blockchain-as-a-service (BaaS) cloud which uses Hyperledger Fabric to implement BlockMed's permissioned network. Utilizing the flexible as-a-service model, allows BlockMed to bypass internal hardware procurement regulations, network staffing requirements, hardware maintenance, updates and security, future hardware disposition and upgrades. As part of this service platform, IBM Cloud manages the high availability infrastructure and provides the Hyperledger fabric features and capabilities, Hyperledger composer, as well as various levels of compute, reliability, scalability, security and protection technologies depending on the plan selected.[4]

Hyperledger Fabric Distributed Ledger Technology (DLT) Architecture - Hyperledger is an open initiative hosted by the Linux Foundation, with a goal of promoting blockchain technologies for business use.[5] Hyperledger Fabric is a project within the initiative, which implements core blockchain functionality with a modular architecture which allows for architectural flexibility of features, such as pluggable consensus algorithms.[6] Fabric provides modular and extensible architecture that is ideal for BlockMed's healthcare supply chain solution. Fabric complies with federal statutes and regulations, supporting verified identities, and private and confidential transactions.

Hyperledger Fabric is comprised of the following key components:

- **Peer and Orderer Nodes -** These nodes comprise the Hyperledger Fabric and are responsible for adding data to the distributed chain and ordering transactions, respectively.
- **Authentication and Authorization -** Certificate Authorities built in to the fabric are used to secure access to the blockchain, secure channels between nodes, and to issue identities to users. Membership Service Providers link identities to organizations and provision access to resources.
- **Chain and State Databases -** The immutable chain database and the "World State" database, which represents the current status of entities in the system, are implemented as NoSQL databases.

[4] https://www.ibm.com/blockchain/platform/

[5] Hyperledger Home - https://www.hyperledger.org/

[6] Hyperledger Fabric - https://www.hyperledger.org/projects/fabric

Hyperledger Composer - Hyperledger Composer is a suite of tools that allow developers to rapidly create applications for the Hyperledger Fabric[7]. The architecture is shown in Figure 3-2.

Smart Contracts - BlockMed will eliminate the hassles and delays inherent in contracts by building the contract into the transaction block. BlockMed smart contracts will define how communications (API calls or BlockMed app) and data transfer will occur between partner ERP applications and the BlockMed blockchain. It serves as the conduit between users and the BlockMed blockchain.

In Blockchain for Business, the term "Smart Contract" is typically used to refer to business logic that runs on the network peers and is automatically applied based on the changing state of the data. For example, a BlockMed smart contract could be a change of pricing that is applied when a shipment is late or exceeds a certain temperature. In Hyperledger Composer, all transaction logic is considered a smart contract.

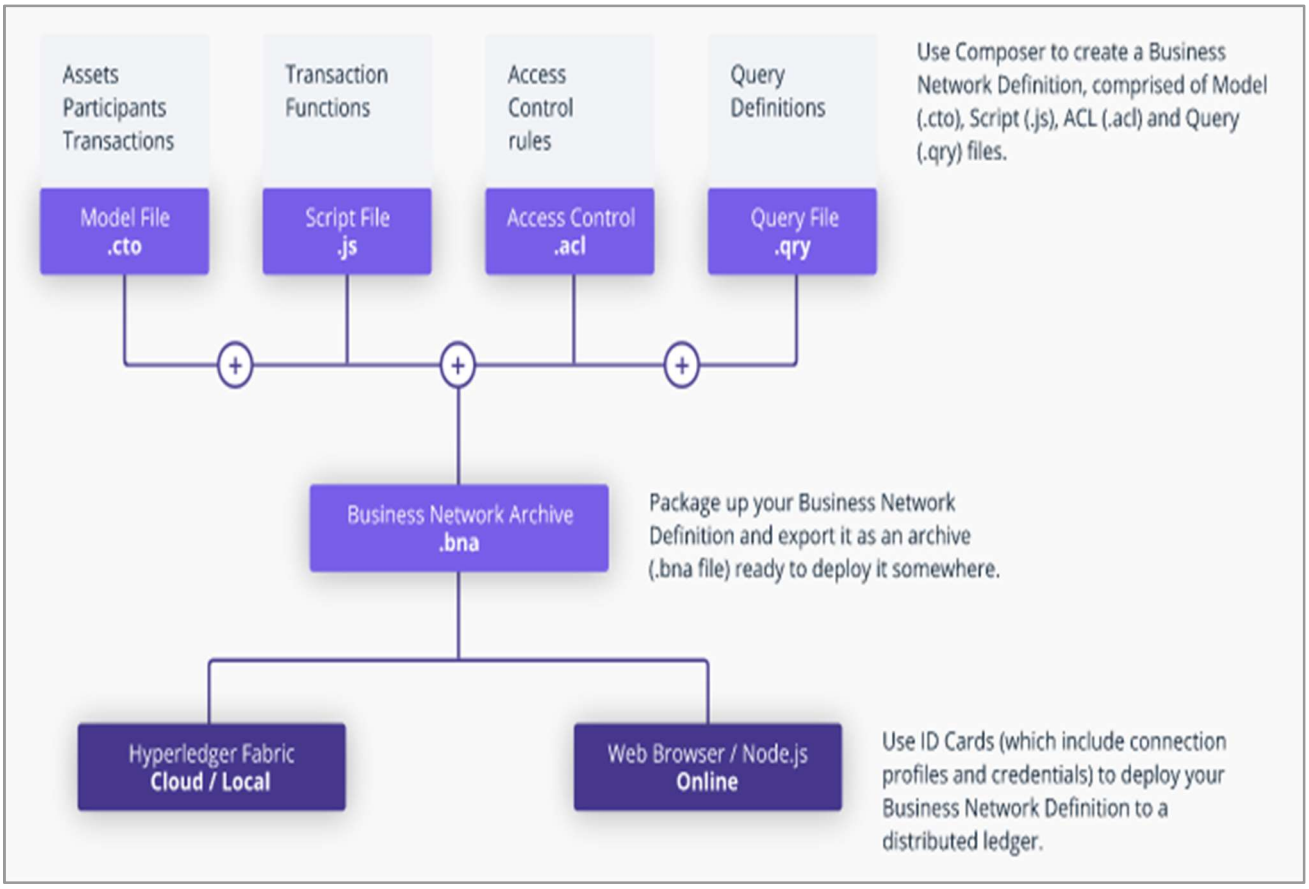

Figure 3-2. Artifacts of a Hyperledger Composer Application[8]

[7] Hyperledger Composer - https://hyperledger.github.io/composer/latest/introduction/introduction.html

[8] Diagram source: https://hyperledger.github.io/composer/latest/introduction/introduction.html

Hyperledger Composer Tools - The following tools enable developers to rapidly create blockchain applications using Hyperledger Composer:

- **Hyperledger Composer CLI / shell scripts** - The Composer command line tools and provided shell scripts simplify installation of the Hyperledger Fabric for local development. The Hyperledger Fabric components are installed as local Docker containers that can be quickly set up and torn down.
- **Composer REST Server** - Composer scaffolds an API layer (using the LoopBack NodeJS framework)[9] based on the developer's business network, providing an easy way for applications to interact with the Blockchain.

Composer Application Components- Hyperledger Composer applications consist of these components:

- **Models -** Entity definition files lay out participants, assets, transactions, and events in an object-based language.
- **Scripts -** Transaction behavior (chaincode and smart contracts) are implemented in JavaScript (NodeJS) syntax.
- **Query Definition Files -** Hyperledger Composer supports the ability to use predefined searches and filters in query definition files. For example, a query could be defined to retrieve all product records that were added prior to a parameterized date.
- **Access Control Lists (ACL) -** ACL rules define the types of operations different participants can perform and data participants can access [10]. For example, BlockMed could ensure that only Supply Chain Partners can update product data owned by them.
- **Business Network Archive -** CLI tools are used to package the Composer solution into a Business Network Archive file, which can be deployed locally for development, or to a cloud host.
- **Business Network Card -** Clients connect to a Composer app using a Business Network Card. A Business Network Card is a file that contains a connection profile defining the peers that it connects to and user identity information.

3.3 Deployment

BlockMed has selected IBM as the cloud provider for the BlockMed Network. IBM Cloud provides tools which eases provisioning and managing of Hyperledger Fabric implementations11, including those written using Hyperledger Composer.

Each organization that wishes to fully participate in the network will create one or more peer nodes on the IBM Cloud.

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[9] LoopBack - https://loopback.io/

[10] Hyperledger Composer ACL Language - https://hyperledger.github.io/composer/reference/acl_language.html

[11] IBM Cloud Blockchain Hosting - https://console.bluemix.net/catalog/services/blockchain

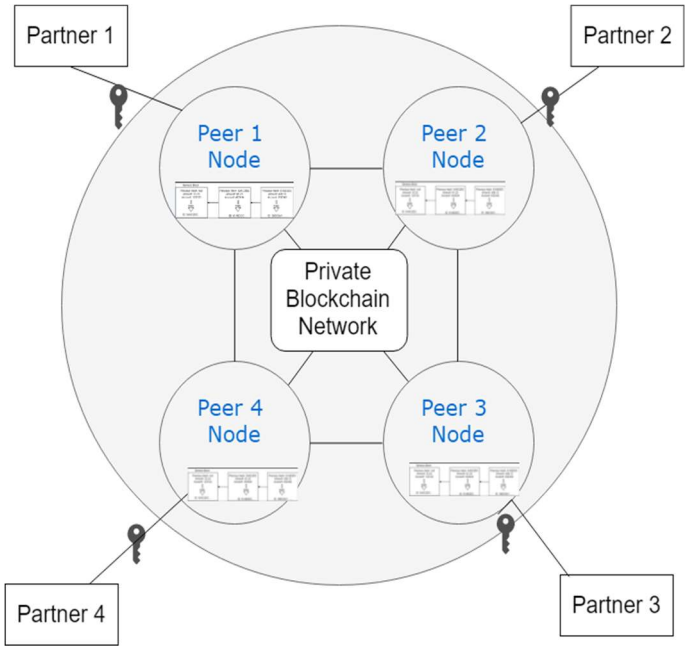


Figure 3-3. Peers in a Private Blockchain as a Service Network

3.3.1 Deployment Process

There are two main deployment scenarios that must be considered: deploying the BlockMed business network itself and adding partners onto the network.

Deploying the Business Network - A Network Initiator performs the following actions to deploy the initial network.[12]

1. Create an IBM Cloud Blockchain Enterprise Account
2. Define the network including:
    a. Peer & Orderer nodes
    b. Endorsement policy
    c. Certification authority
3. Export a Business Network Card that Composer uses to access the network.
4. Deploy the Business Network Archive (.bna) for the application (see above)
5. Deploy the REST APIs that will interact with the network.
6. Deploy web UIs which layer on top of the REST APIs.
7. Set up initial participants, which includes:
    a. Creating participant records for the Supply Chain Partner.
    b. Create Peer Admin identities and link them to the participant
    c. Invite participants to join the network via the IBM Cloud console.

[12] Deploying a Composer application to IBM Cloud - https://ibm-blockchain.github.io/platform-deployment/

d. Invited partner creates peer nodes and adds them to the BlockMed Blockchain.

Adding partners - Step 7 above is repeated for each new partner that joins the network after initial deployment.

3.4 System Metrics

The system metrics provide the objective basis for the system's performance. Critical ones for a cloud-based blockchain like BlockMed are summarized below[13].

Table 3-1. Technical System Metrics

NAME	DESCRIPTION	TARGET METRIC
Uptime	The % of time system is up and operational	99.999%
No. of Records	The number of records the database can hold.	Unlimited
Transaction	The maximum transactions per second once the	3000 tps
Latency	The latency from when an package or container is	10s
Scalability	How quickly a new node can be added.	1 hour
Average Cost per	The cost for the partner of hosting a partner node.	$5000
Fault tolerance	Time to recover a failing node.	5 mins

3.5 Integration with Partner Applications

BlockMed will integrate primarily with ERP/Inventory management systems. Integration will be achieved by leveraging EPCIS compliant REST APIs via hooks and batch processes that enable CRUD activities.

Integration with the BlockMed network uses public key cryptography. Membership is provided by the Certificate Authority. All entities in the network must have an identity to communicate, authenticate and transact. Identities exist in the form of x509 certificates[14] which are required for any direct participation in the blockchain network.[15] Client ERP systems, either directly, or via a service bus, translate their supply chain state changes into secure REST API

[13] Guiding Metrics. The Cloud Service Industry's 10 Most Critical Metrics. URL: https://guidingmetrics.com/content/cloud-services-industrys-10-most-critical-metrics/ Accessed: March 22, 2018.

[14] https://en.wikipedia.org/wiki/X.509

[15] https://console.bluemix.net/docs/services/blockchain/index.html#ibm-blockchain-platform

calls (this can be done in real time or via batch processes). BlockMed will provide adapters for common ERP to simplify the onboarding process.

Integration requires customers to present transactions generated in their ERP systems as EPCIS events. For optional functionality, customers can build their own applications and subscribe to Hyperledger events emitted by Hyperledger Composer.

3.6 Data Design and Management

3.6.1 Data Entity Model

BlockMed's architectural solution will integrate as a layer on top to the client's already existing enterprise system. It will collect the necessary information from transactions to store in the blockchain ledger. These entities comprise the initial BlockMed data model shown in Figure 3-4 and are required to support features to be delivered in the first phase of deployment. Hyperledger refers to these entities as Participants and Assets.

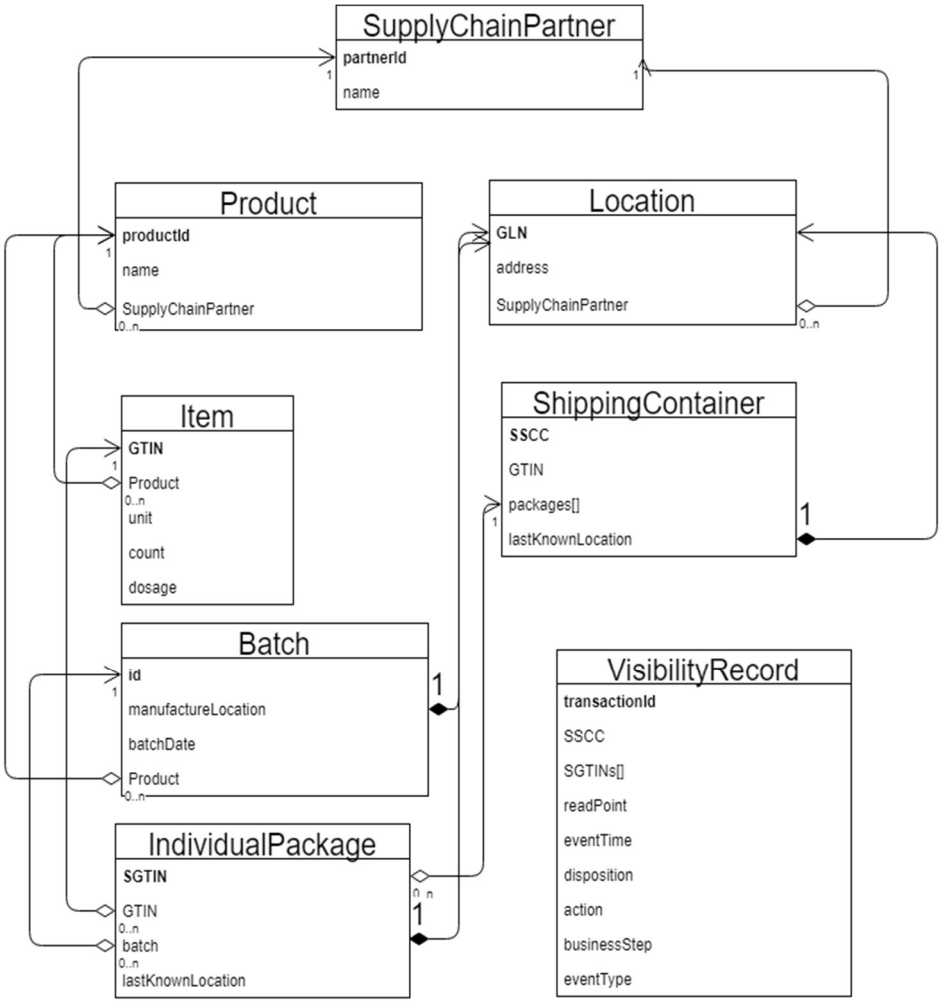


Figure 3-4. BlockMed Data Entity Model Diagram

These data model entities are as follows:

- **SupplyChainPartner –** A producer, shipper or receiver of pharmaceuticals. All users of the blockchain represent a SupplyChainPartner.
- **Location –** A physical address, identified by the Global Location Number (GLN). The location is that of the Supply Chain Partner.
- **Product –** The branded name of the pharmaceutical product produced by a manufacturer. A SupplyChainPartner has their own Product record in the case of generic brand names.
- **Batch –** The manufacturing lot of a pharmaceutical product. References expiration dates and recalls at the lot-level.
- Item – Unique identifier number, known as the Global Trade Item Number (GTIN), for a stockable package (e.g. a branded case of 500 Curitol pills, 50 mg each).
- **IndividualPackage –** A unique and specific instance of an item (e.g. case of 500 Curitol pills). BlockMed APIs' smallest trackable unit identified by the Serial GTIN (SGTIN).
- **ShippingContainer –** a shipping unit such as a pallet. Referenced by the Serial Shipping Container Code (SSCC).
- **VisibilityRecord –** A data record produced by each transaction in the BlockMed ledger from EPCIS visibility event (see sub-bullet). The EPCIS visibility event record provides a record of a business step (i.e. shipping, packing, packaging, receiving, etc.). A collection of these EPCIS visibility events provides a detailed record of business steps over time and place with information organized among the four dispositions of what, when, where and why. The BlockMed system integrates with these events to record transaction updates to its blockchain.

3.6.2 Data Transactions

The BlockMed Transaction API layer is on top of the Hyperledger REST API and provides the ability to submit transactions. These transactions run blockchain code that triggers CRUD behaviors and implements smart contracts.

Phase 1 of BlockMed's implementation will have transactions loosely mapped to EPCIS supply chain visibility events. The EPCIS guidelines minimize work needed for partners to integrate their existing ERP systems into BlockMed's APIs. The following are phase 1 transaction record types:

- **PackageTransaction –** individual packages that are added to a shipping container
- **ShipTransaction –** shipping container in transit from a partner location
- **ReceiveTransaction –** shipping container in transit to a partner location
- **UnpackTransaction –** individual packages removed from a container

The transaction logic can apply complex behavior to add significant value to the BlockMed implementation. Examples may include:

- Automatically notifying partners and taking other actions when a Batch is flagged for recall.

- Setting a “potential counterfeit” flag on IndividualPackages when two or more IndividualPackage records with the same SGTIN are marked as received at different locations without corresponding shipments.

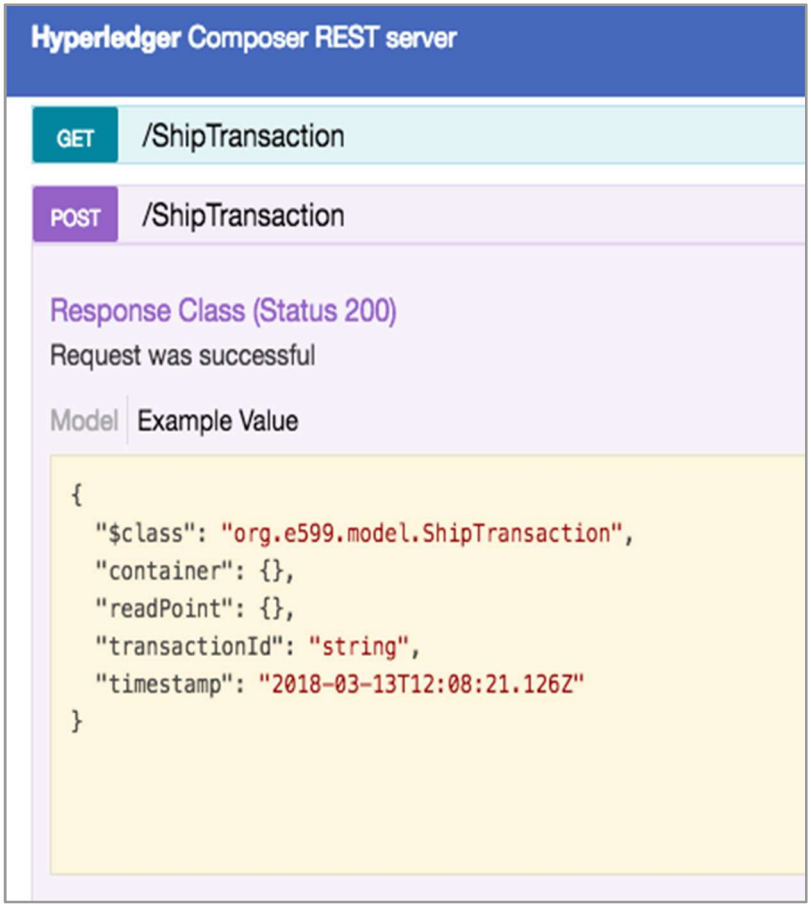


Figure 3-5. Swagger UI Showing a prototypical ShipTransaction API call

3.6.3 Data Provisioning and Maintenance

BlockMed does not support loading of historical transactional or shipment data for a new partner. An initial load of reference data is required to provide context to transactions. Examples of reference data includes products, batches, items, and locations, all of which can be bulk-loaded by the partner admin. The BlockMed network is a permissioned private blockchain. Partners are invited to the network by network administrators. The process looks like this:

- A blockchain business network administrator (ex: a BlockMed Admin) creates a SupplyChainPartner participant record in the network for the new partner.
- The blockchain business network administrator issues an identity card for the partner and maps it to the partner’s participant record (using the Hyperledger Composer REST Identity APIs).
- The partner admin uses this identity card to create additional identity cards for their organization as needed to access the BlockMed systems and APIs.
- Bulk load of reference data

```
# Add products
curl -X POST --header 'Content-Type: application/json' --header 'Accept: application/json' -d '{
  "$class": "org.e599.model.Product",
  "productId": "1",
  "productName": "Curitol",
  "manufacturer": "org.e599.model.SupplyChainPartner#1"
}' 'http://localhost:3000/api/Product'

curl -X POST --header 'Content-Type: application/json' --header 'Accept: application/json' -d '{
  "$class": "org.e599.model.Product",
  "productId": "3",
  "productName": "Gazundisol PM",
  "manufacturer": "org.e599.model.SupplyChainPartner#1"
}' 'http://localhost:3000/api/Product'

```

Figure 3-6, CLI for loading reference data during partner onboarding

After initial onboarding, partners can integrate their ERP systems with BlockMed Entity Management APIs to update their products, items, batches and locations. Data can also be maintained manually via the BlockMed Admin interface.

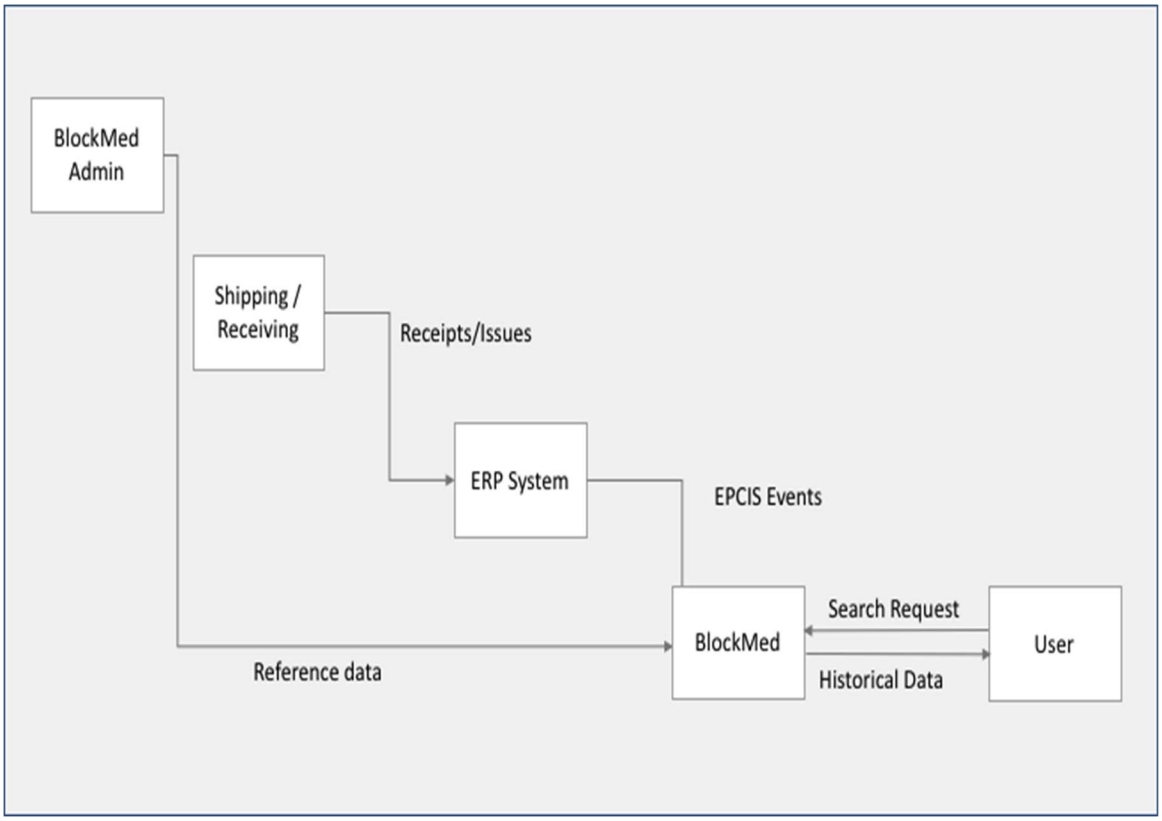


Figure 3-7. Data Flow

3.7 Solution Demonstration

By using APIs, BlockMed acquires transactions from supply chain partners during the routine scanning of containers and packages when doing such activities as packaging, shipping, receiving, and unpacking. This was described in Section 2.1. We can further understand how key roles interact with the system operation in these user stories:

1. Getting the pedigree of package
2. Locating all shipments from a batch
3. Recalling a drug

While a full understanding of the roles is outside the scope of the technical discussion, the following summary will give context to the subsequent sections.

Partner User - A Partner User has read-only access to certain BlockMed entities which allow them to perform track/trace functions.

Partner Admin - A user with privileges that include:

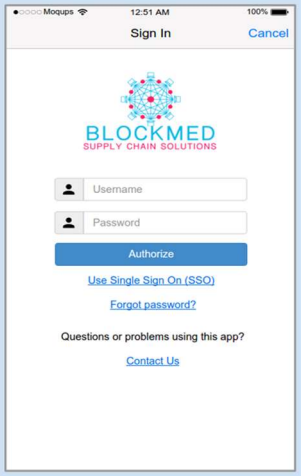
- Issuing identities (Partner Admins / Partner Users) for their SupplyChainPartner.
- Create Transactions on the BlockMed network
- Manually modify World State data.

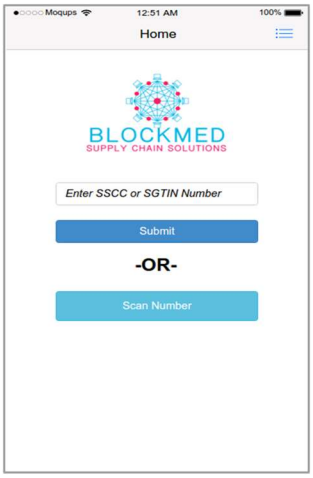
BlockMed Network Admin - A “super user” of the BlockMed network. These users are employees of BlockMed or designated initial partners that have the authority to create participants and issue identities to Peer Admins via standard Hyperledger Composer tools.

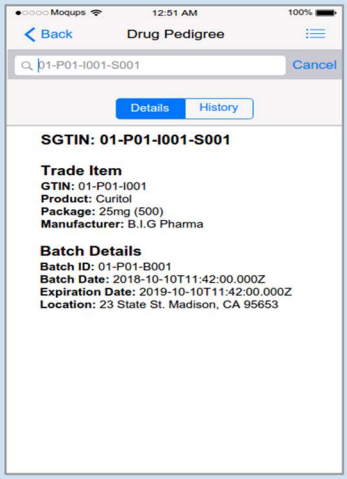
3.7.1 Getting the Pedigree of a Package

In this user story, a Partner User—for example, a pharmacist at local pharmacy or shipping manager at a distributor—wants to determine the transaction history or pedigree, of a package to gain assurance of its authenticity. The pharmacist uses a mobile app called BlockMed, which is connected to their partner node. This mobile app enables searching for visibility events by identifiers such as SGTIN or SSCC. See Figure 3-8 for the flow.

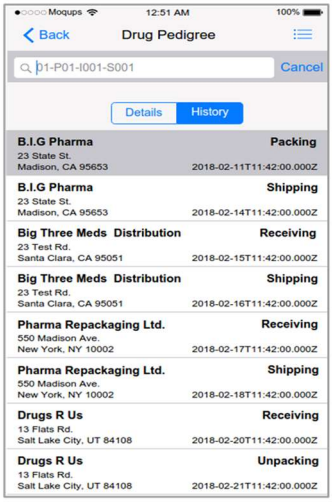
1. **Login.** User can enter BlockMed credentials or company SSO credentials.	2. **Enter Package Number.** User can manually enter or scan the SSCC or SGTIN number.	3. **Results.** The app first displays details about the package. User could enter a different package in the search bar rather than going to the previous page.







4. **The history of visibility events can be displayed.** Clicking on the History button shows the visibility events of the package in chronological order.	5. **View details of a specific visibility event.** When an event is tapped, it highlights (as shown in the previous screen) and then displays the event details.



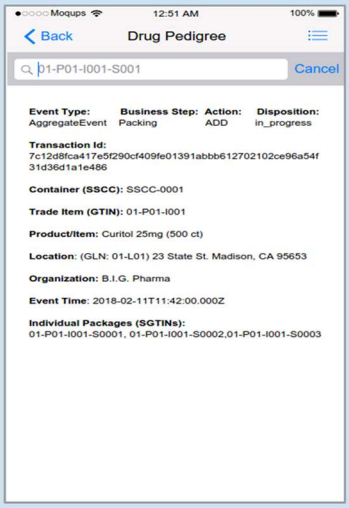


Figure 3-8. Pedigree Search on BlockMed Mobile

A pedigree search could also be done by a Partner Admin, such as an operations manager at a manufacturer, using the BlockMed Admin desktop interface. This interface provides an additional visualization of the trace. To do this, the Partner Admin accesses the UI and enters or scans the SSCC or SGTIN as shown in the figure below.

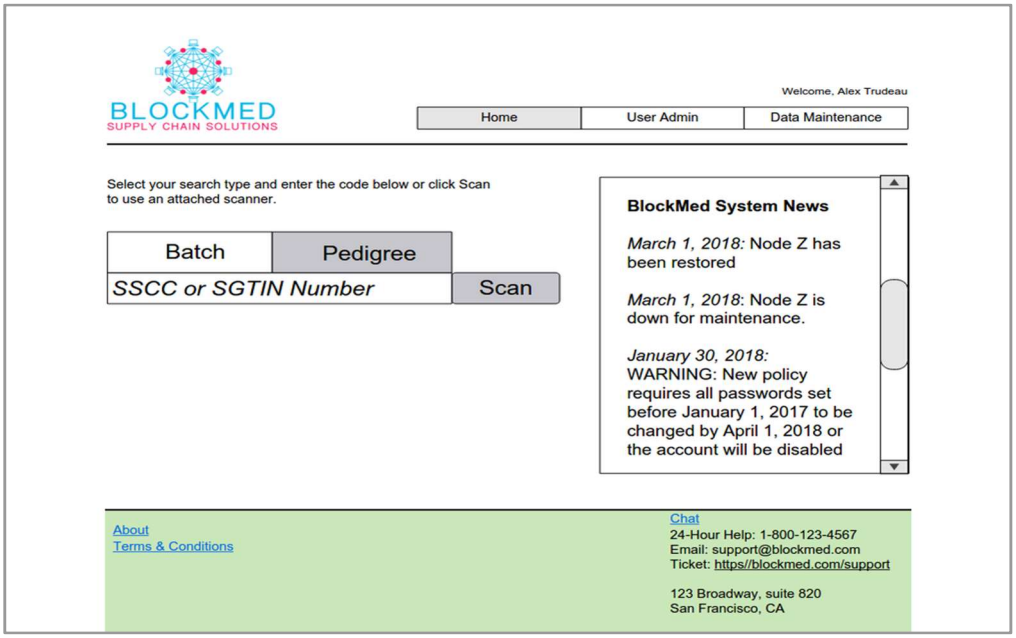


Figure 3-9. Finding Pedigree using BlockMed Admin Desktop UI with Pedigree Selected

This results in a map tracing the visibility events related to the package.

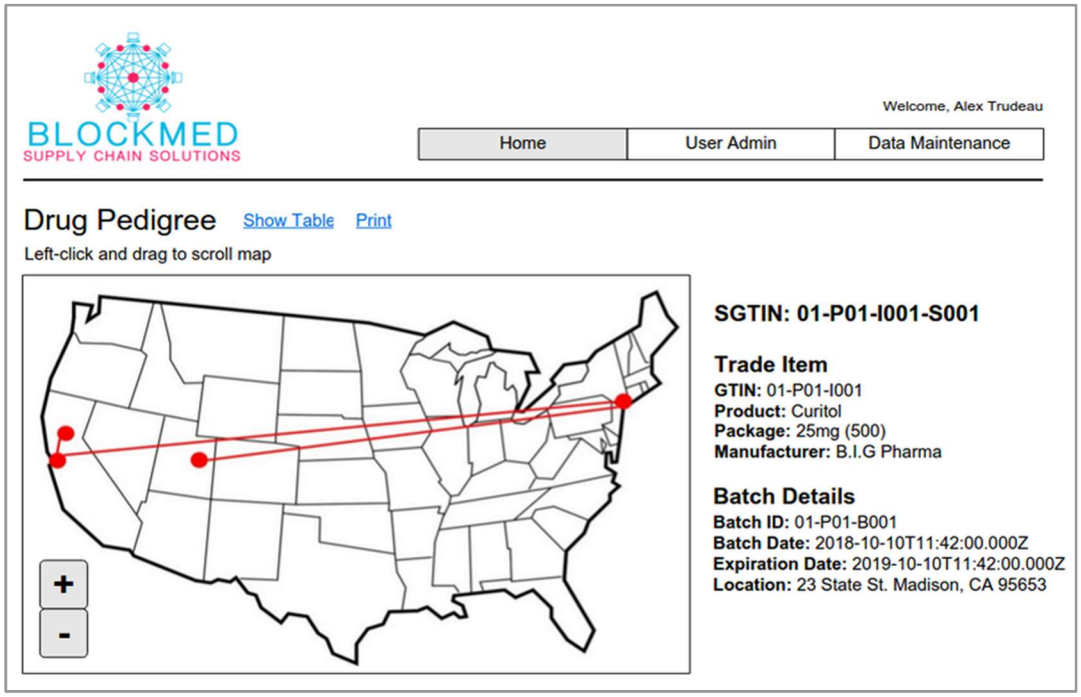


Figure 3-10. Pedigree Trace Visual on BlockMed Admin Desktop

History detail can be shown by clicking “Show Table.”

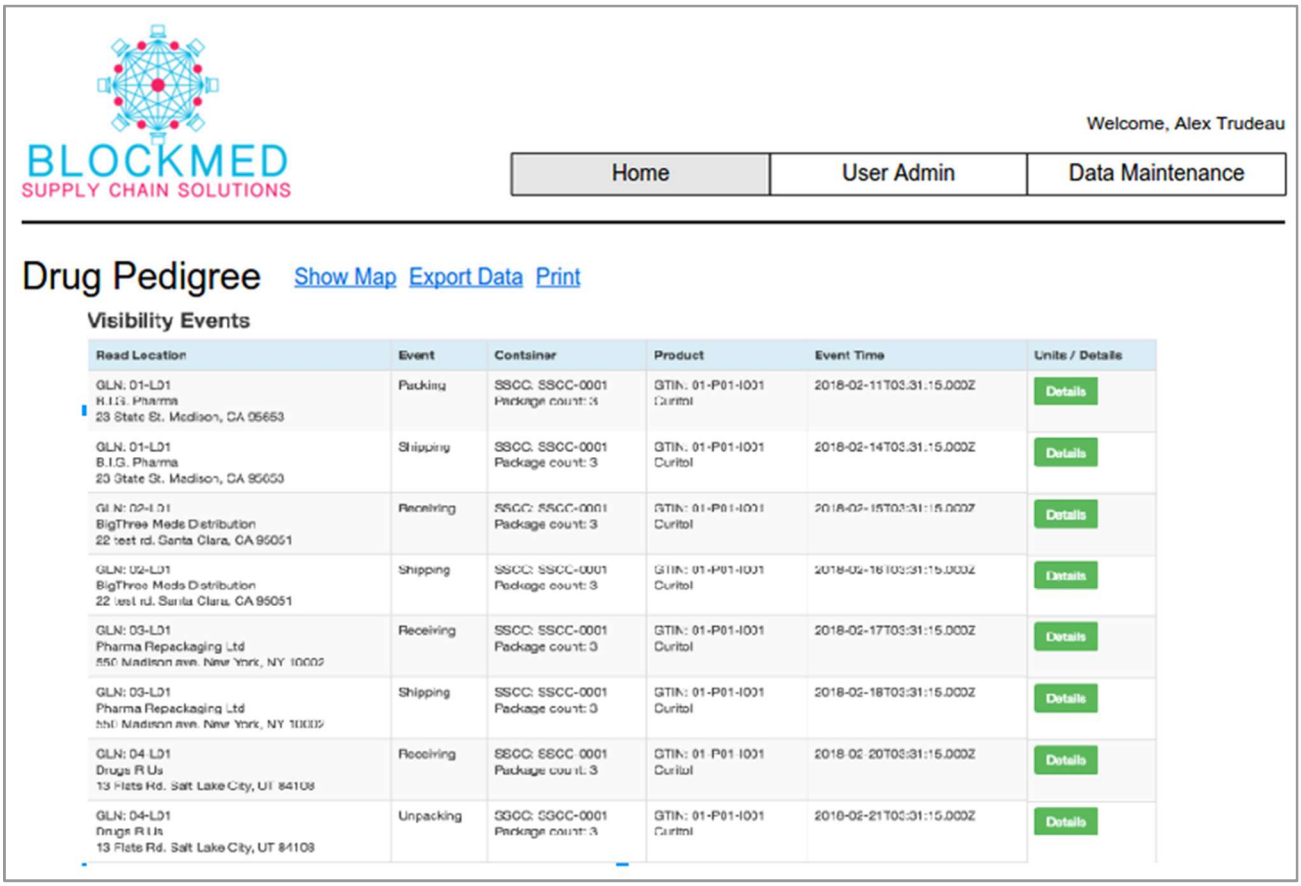


Figure 3-11. Pedigree Trace (Historical) Table on BlockMed Admin Desktop

3.7.2 Locating All Shipments from a Batch

In this next user story, a Partner Admin, such as an operations manager from the manufacturer, receives information that questions the authenticity or quality of a certain batch of drugs. The operations manager wants to know the final location and details of all shipments of that batch so that he can analyze them and determine what to do next.

For this kind of search, he uses the BlockMed Admin desktop site, which allows partner users with proper authorization to perform restricted data management functions. After logging on, he selects the “Batch” search and enters the Batch ID.

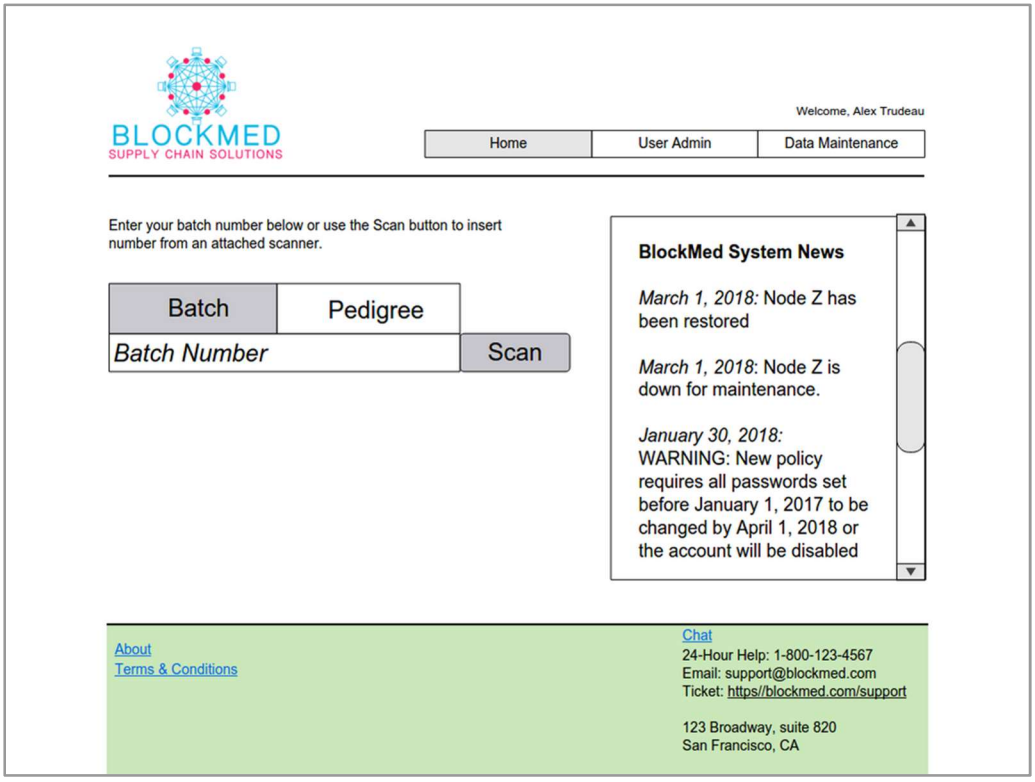


Figure 3-12. BlockMed Desktop Home with Batch Trace Selected

The result shows the final locations of all shipments on a map.

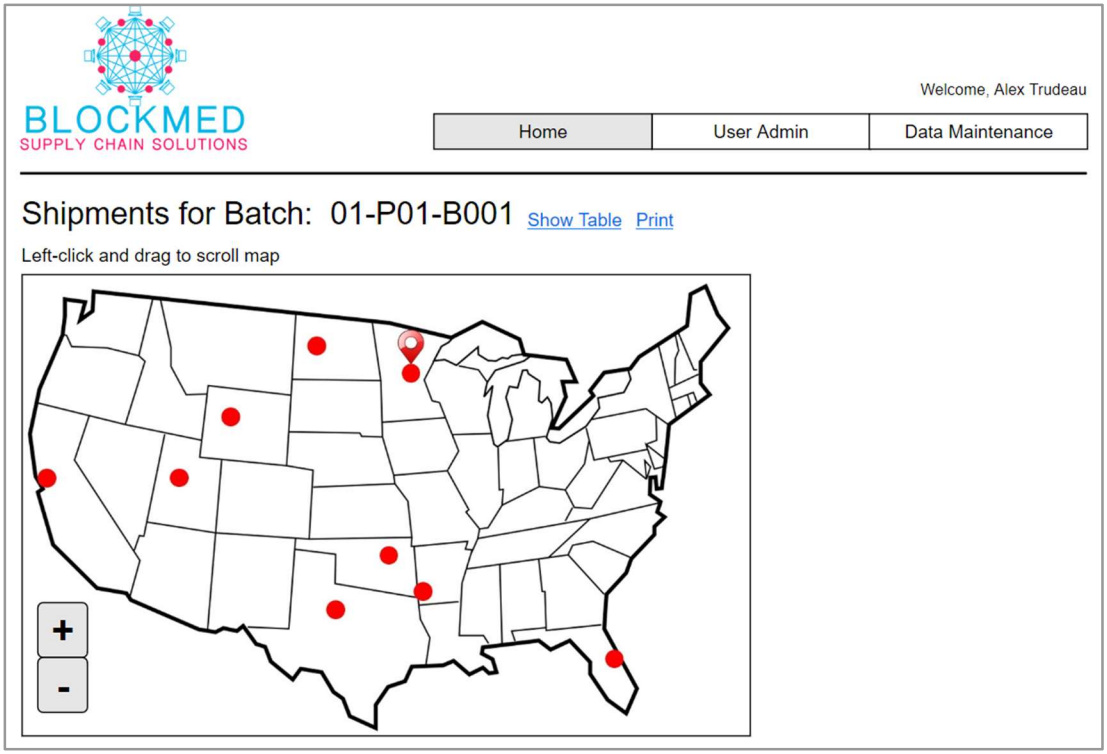


Figure 3-13. Map of BlockMed Batch Shipments

To verify information at the final location, the Admin could click on a node, for example, Madison, Wisconsin, and get a sidebar with more with more detailed information, as shown below.

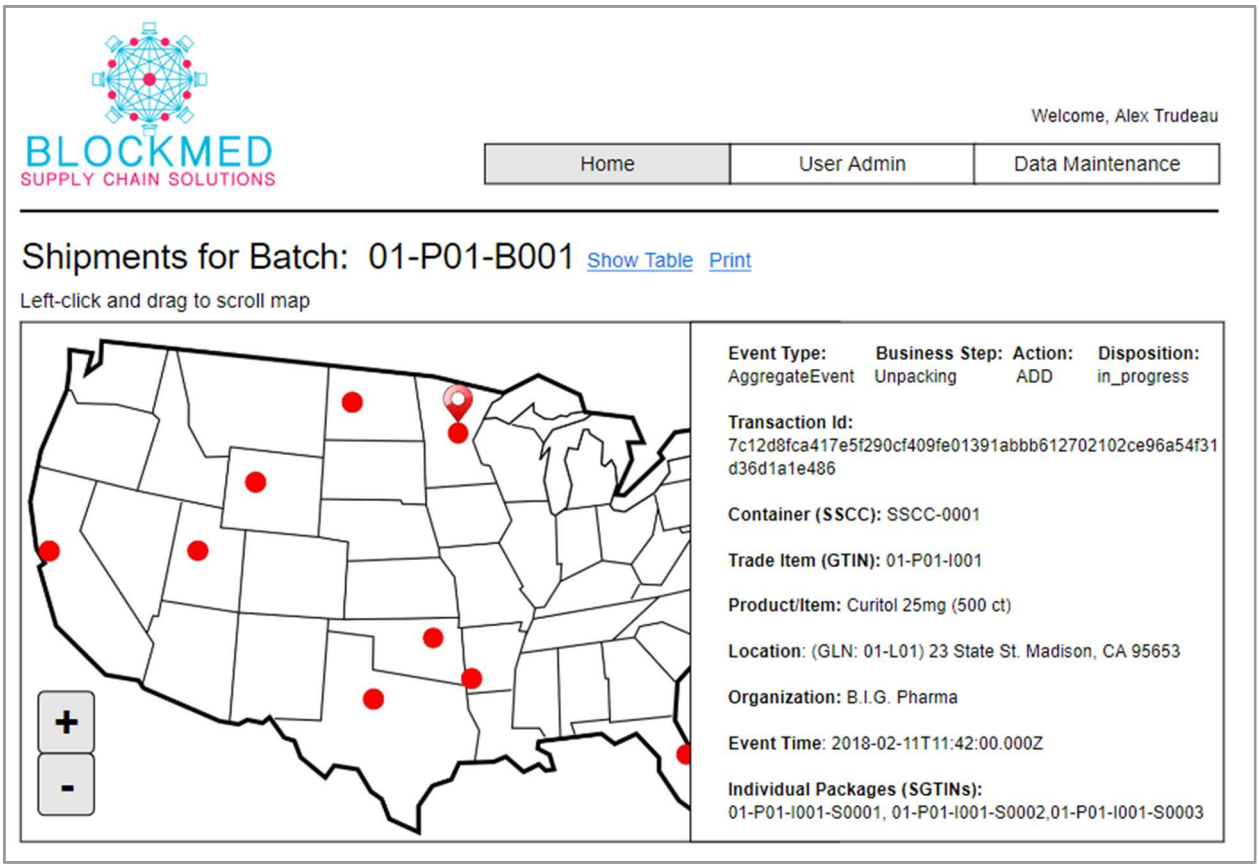


Figure 3-14. BlockMed Shipping Event Trace with Node Details

3.7.3 Recall a Batch

One of BlockMed's key features is helping the supply chain partners efficiently recall a batch and provide required information to the FDA. For example, a Partner Admin, like the operations manager mentioned above, could want to use the results so that he can effectively initiate a recall. Obtaining the final locations of shipments from a batch as shown in the previous user story, the admin can click "Show Table" for further analysis. This provides the screen shown in Figure 3-15.

The Partner Admin can examine the list of last known locations for each shipment. He can use the Details button in the rightmost column to see more information related to the shipment. He can use checkboxes in the left column to include or exclude some locations. When ready, the Partner Admin can choose to send a personalized message or flag the shipment as being recalled.

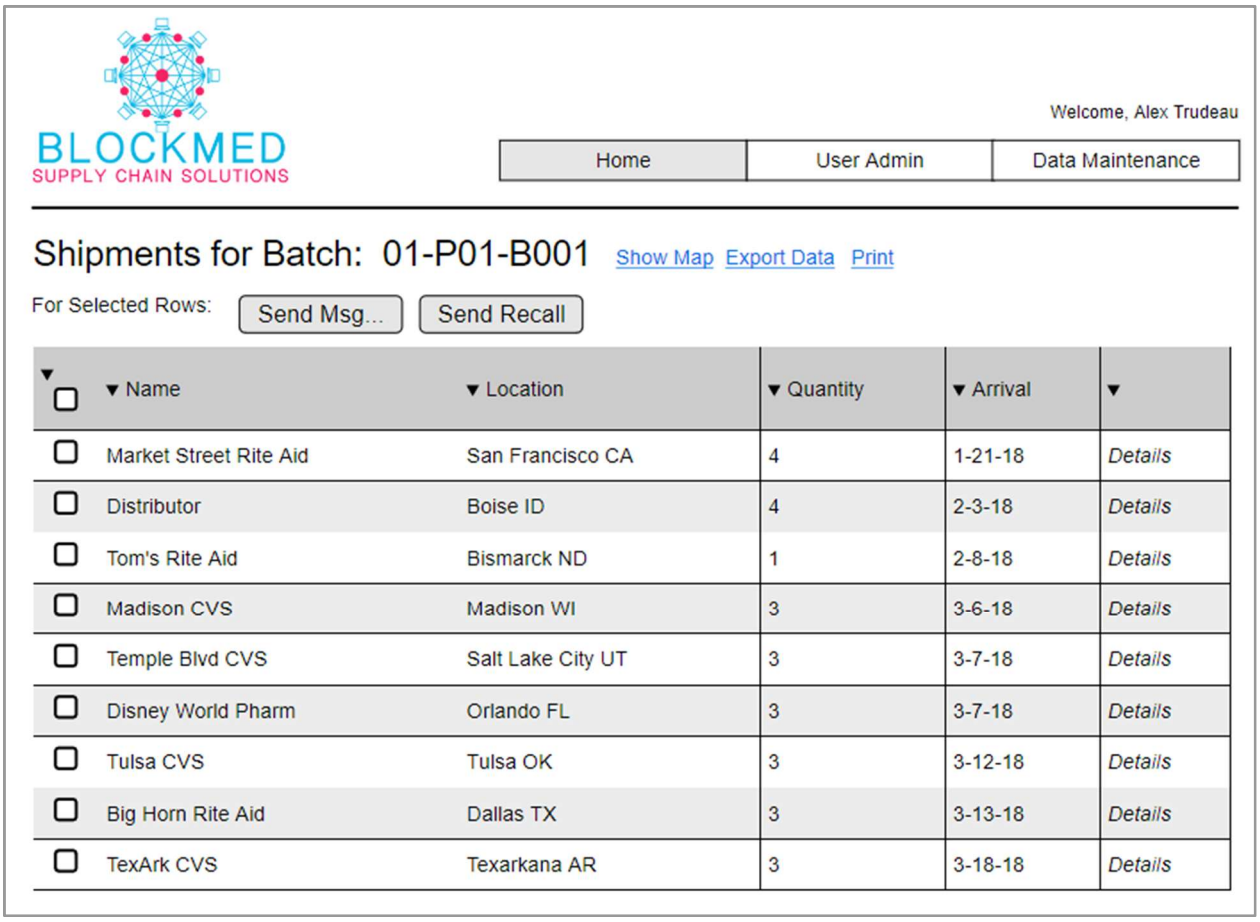


Figure 3-15. BlockMed Shipment Table and Actions

4 Implementation Plan

This section covers the roll out of BlockMed as a pilot system to meet *H.R 3204 Drug Supply Chain Security Act (Sec. 202)* requirements for a core set of users. It discusses how the technical design in implementation will be built and deployed to the BlockMed system and to the initial participant networks, as well as how BlockMed will operationalize the necessary teams, resources, and user enablement activities. The result of the pilot is the network shown in Figure 4-1, below.

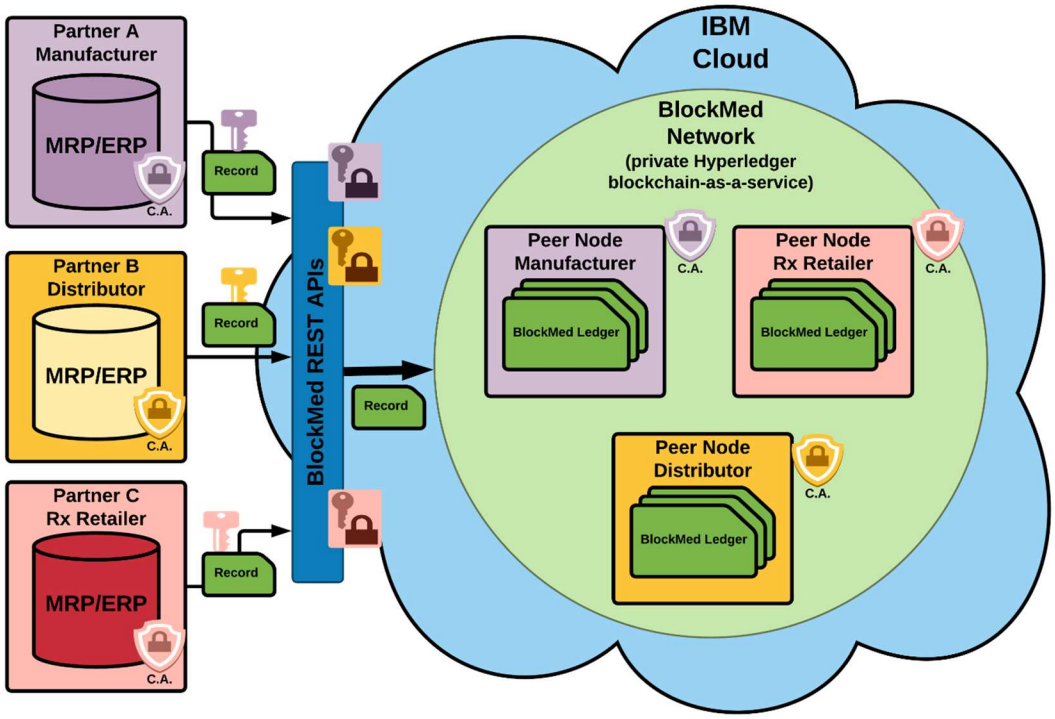


Figure 4-1, The private BlockMed blockchain and initial partners

The pilot build-out is part of a deployment plan that has several phases, as shown in Figure 4-2.

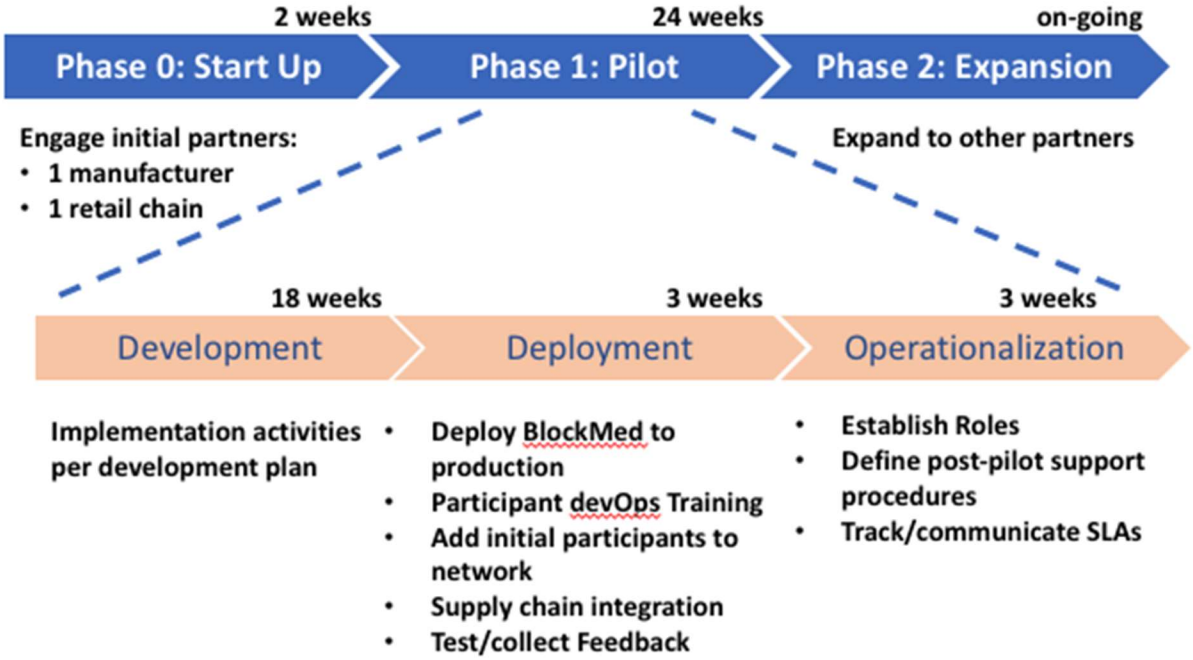


Figure 4-2, Major Phases of the BlockMed Deployment

In Phase 0, a single end-to-end set of supply chain partners is enrolled as clients of the service. This will be a manufacturer, a distributor, and a chain of pharmacies. BlockMed is part of the distributor, which is assumed to manage the logistics services.

BlockMed managers will give a 2-hour overview presentation to the management of each of the targeted supply chain partners to outline the benefits of the service and request their participation in the pilot. The new partners must commit to providing technical and business resources to administer and manage the partner node.

With this agreement in place, the implementation can go to Phase 1, Development, where BlockMed will build and deploy an MVP (Minimum Viable Product) with the supply chain partners to prove out the system before making it available for a wider release.

4.1 Development

In this stage, BlockMed will develop the Phase 1 BlockMed solution and prepare for initial participant integration and deployment. To develop the solution, BlockMed will use the Scrum agile framework[16] for development of the software. Development will be executed in a series of two-week sprints.

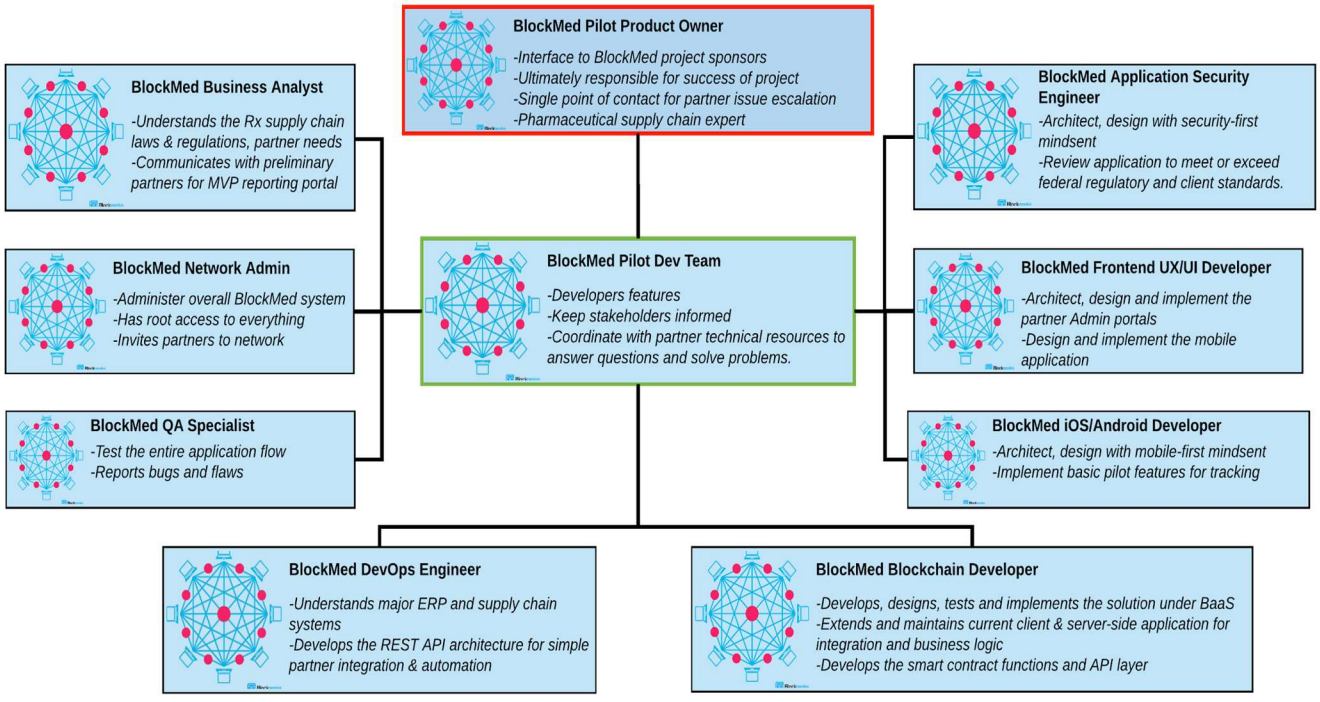


Figure 4-3. BlockMed Development Team

[16] https://www.scrum.org/

The table below lists the sprints and associated themes that are required to deliver the Phase 1 deliverables. The timeline consists of a 4-week ramp-up period when the backlog will be groomed and estimated. During that activity, features may be added or dropped from the Phase 1 release, and the timeline may be altered.

The current plan is an 18-week timeline to deliver features for Phase 1 deployment. (See Appendix A for details.) At the end of these sprints, BlockMed will have created all the necessary components for the pilot.

Table 4-1. BlockMed development team

Sprint (Weeks)	Description
0-1	Project ramp-up. Identify key people and set up development systems.
2-3	Project ramp-up part 2. Connect with partner contacts, train teams, agree on tools.
4-5	System Modeling / User Experience. Install and develop key structures.
6-7	Log transactions to Blockchain. Create scripts and APIs for input and retrieval of data from BlockMed.
8-9	Authentication/Authorization. Implement security and authentication algorithms.
10-11	Display Pedigree. Implement functions to display pedigree.
12-13	Enhanced Admin Track/Trace functions. Implement enhanced tracking and tracing functions.
14-15	Mapping / Recalls. Develop mapping and recall warning functions.
16-17	Partner Integration Modules. Implement code for adapters and analytics.

4.2 Deployment

In this stage, the BlockMed Phase 1 pilot network will be deployed to a secure production environment and integrated with a small set of initial participant member organizations by working with a subset of the partner devOps technical personnel and business users. BlockMed and initial participants will perform end-to-end testing at this stage, but the solution will not be generally available for all business users until the operationalization stage. BlockMed will provide a deployment project manager to help the partner team collect and meet requirements needed to be added to the BlockMed blockchain.

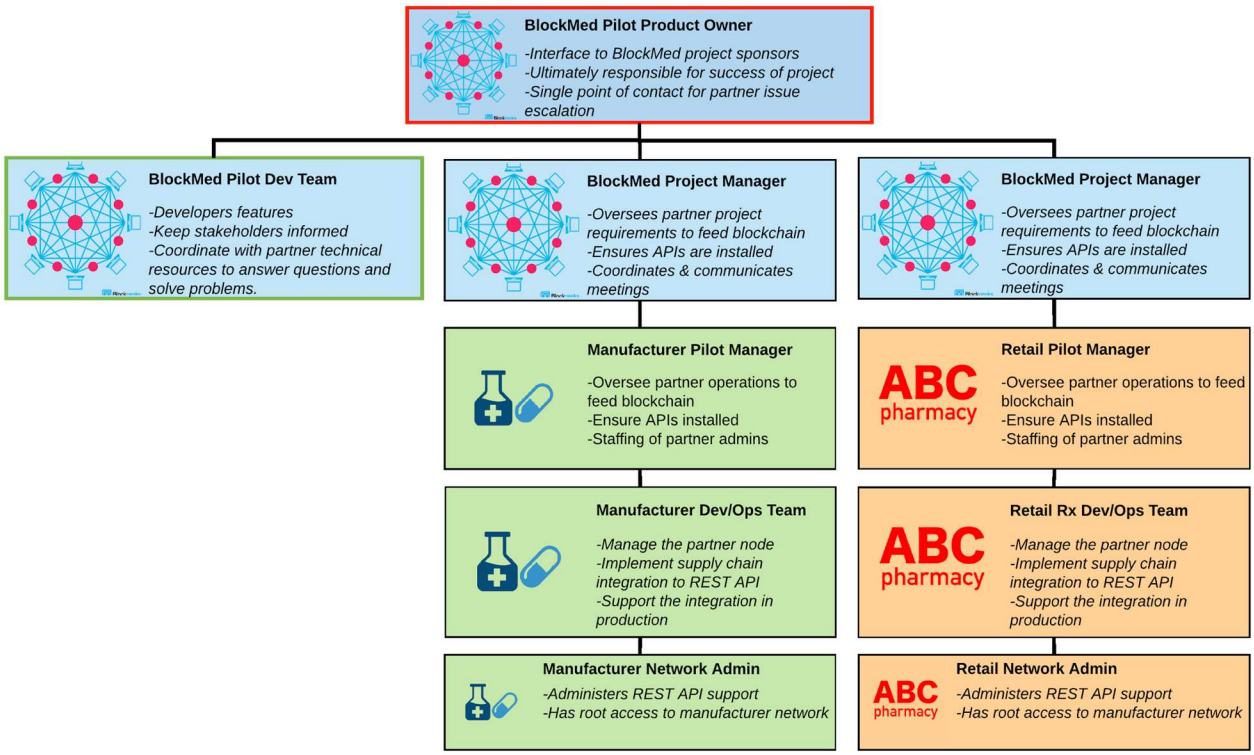


Figure 4-4. BlockMed Deployment and Partner Teams

The deployment stage consists of the following activities:

1. Deployment of the BlockMed network and solution
2. Deployment of initial participant nodes
3. Initial participant supply chain integration
4. Test/collect feedback

4.2.1 Deployment of BlockMed Network and Solution

This operationalization activity involves the deployment of the core BlockMed blockchain network on the IBM Hyperledger platform, along with custom software components that allow systems and users to interact with it. The activity is performed by BlockMed and consists of the following high-level steps:

- Initiate blockchain network on IBM Hyperledger cloud
- Deploy BlockMed blockchain network archive / chain code
- Deploy REST APIs that collect reference & transaction data.
- Deploy mobile/web interfaces to allow users and admins to interact with it.
- Invite partners to join blockchain, as shown in Figure 3-4.

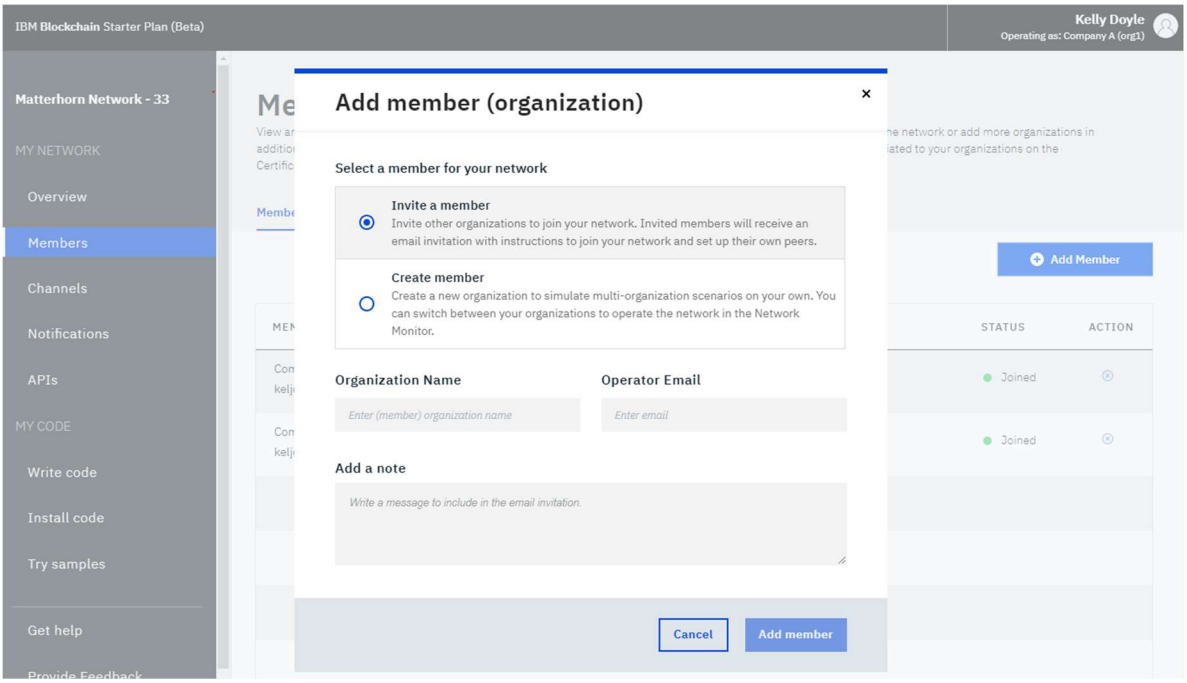


Figure 4-5. The Network Initiator organization invites a member organization to join a blockchain

4.2.2 Deployment of Initial Participant Nodes

Once the partner is formally invited via the IBM Hyperledger portal, BlockMed will facilitate the following activities:

- Initial participant DevOps training on IBM Hyperledger
- Participant creates IBM Blockchain cloud account
- Participant accepts invitation and creates their blockchain nodes on the BlockMed network.

4.2.3 Initial Participant Supply Chain Integration

BlockMed will work closely with initial participants, DevOps and business users that are members of the pilot team to complete the following activities:

- Load reference data via scripts and/or APIs
- Implement integration with Partner ERP systems to collect EPCIS event.
- Testing and deployment of partner nodes and integrations

4.2.4 Collect Feedback

Feedback will be collected from partners during integration, administration and operation of the system to improve it for Phase 2, Expansion.

4.3 Operationalization / User Enablement

The high-level operationalization stages are outlined in this section. This involves working with stakeholders to maintain and use the key system components.

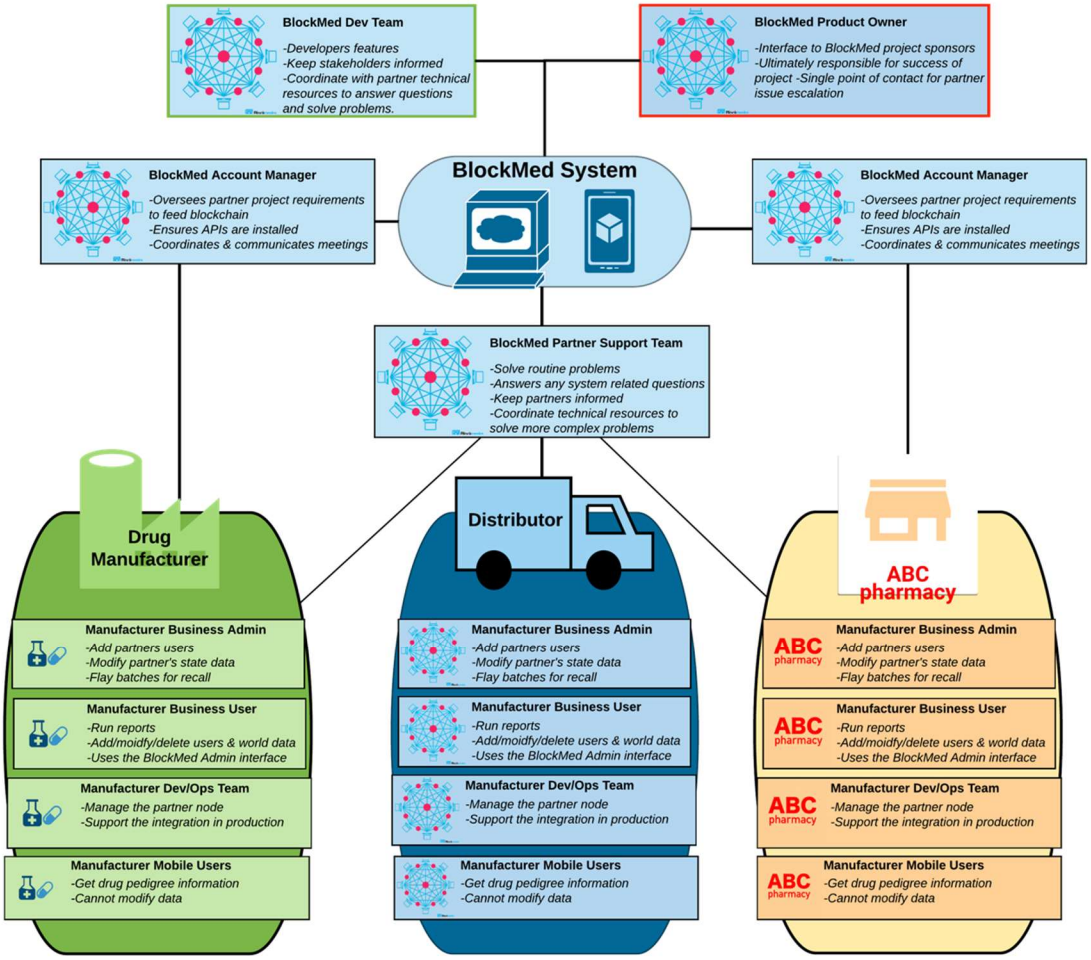


Figure 4-6. Post-deployment maintenance, support and system users

4.3.1 Establish Roles

The BlockMed core staff will develop and administer the BlockMed network, APIs, and user interfaces. Each partner is responsible for administering their own nodes and user base and performing business functions such as track and trace operations and flagging batches for recall.

BlockMed will conduct 3-hour training with the partners' staff on how to perform their roles and use the BlockMed UIs. They will also be given a sample plan and communications template to inform their users how to install and use BlockMed Mobile. The Phase 1 roles and responsibilities are given in the table below.

Table 4-2. Stakeholder Groups and Roles for Pilot Phase

Roles	Responsibilities	Projected Resource
BlockMed Team Roles		
BlockMed Pilot Product Owner	• Interface to BlockMed project sponsors and executives • Ultimately responsible for success of project • Single point of contact for partner issue escalation	1 full-time employee
BlockMed Network Admin	• Administer overall BlockMed system • Has root access to everything • Continues to invite partners to network	1 full-time employee
BlockMed Development Team	• Develop ongoing features • Keep stakeholders informed • Coordinate with partner technical resources to answer questions and solve problems	7-10 team members supporting key functions
BlockMed Partner Account Manager	• Oversees the ongoing success of the partner project • Manages the requirement to maintain feed to blockchain • Ensures new APIs are communicated • Coordinates & communicates meetings with Partner	1 full-time employee (provided by BlockMed)
BlockMed Business Admin	• Can modify state data • Business process expert • Add BlockMed users	1 full-time employee
BlockMed Support	• Keep stakeholders informed • Answer questions • Solve routine problems • Coordinate with technical resources to solve more complex problems	3-4 full-time support admins
Partner Roles		
Partner Manager	• Oversee partner operations to feed blockchain • Ensure APIs installed • Staffing of partner admins	1 full-time business manager
Partner Network Admin	• Administer overall partner network system • Has root access to everything • Invites new members to partner network	1 full-time employee
Partner DevOps Team	• Manage the partner node • Implement the supply chain integration to REST API • Support the integration in production	Multiple team members involved depending on partner resources.
BlockMed Business and User Roles		

Roles	Responsibilities	Projected Resource
Partner Business Admin	• Add partner users • Modify partner's state data • Flag batches for recall	1 part-time admin
Partner Business User	• Run Reports • Add/modify/delete users under partner network • Add/modify/delete world data • Uses the BlockMed Admin interface	Multiple employees from the Partner using the system occasionally
Partner Mobile User	• Install the BlockMed Mobile • Get information about pedigree • Cannot modify data	1000s of occasional users

4.3.2 Track & Communicate SLAs

BlockMed offers three key SLAs for partners. These are described in the table below.

Table 4-3. Service Level Agreements

SLA	Metric	How Measured
Up-time. The percentage of time the system is up and operational.	• 99.99%	Reporting services provided by IBM's cloud platform.
Pedigree Search Max Time. The maximum time that a pedigree search would take.	• 2 minutes (Search for entire batch locations) • 5 seconds (pedigree search for GTIN)	Time from initiation of the search to return of results using either BlockMed Admin or BlockMed Mobile.
Mean-time to Respond. The average time to respond based on 4-level scheme where P1 is critical importance and P4 is low importance.	• P1: 30 minutes any time • P2: 4 hours any time • P3: 1 business day • P4: 4 business days	Time from opening of ticket to when a resource is assigned, based on priority level.

The priority levels are as follows:

- P1: Significant safety or financial risk, system down
- P2: Multiple business users are impacted, a workaround is available
- P3: Small set of users impacted, no mission-critical operations
- P4: Routine changes, non-business impacting

4.3.3 Define Support Procedures

For the Phase 1 pilot, BlockMed will set the expectations with initial participants that issues will be reported and resolved informally between BlockMed and the initial participant development

teams where possible. Initial participants can escalate issues to the BlockMed pilot product owner as needed.

Prior to the Expansion phase, the product owner will define formal support procedures based on ITIL best practices with buy-in from participating partners.

The support procedures that are defined for post-pilot operations will include categorizations for problem, incident, and change tracking. (See the Appendix.)

4.4 Project Risks

The table below shows potential risks identified for the BlockMed Phase 1 project and associated mitigation strategies.

Table 4-4. Risks and Mitigations

Risk	Mitigation Strategy
Partner and user adoption, dependency on reaching critical mass	• Solution mandated by law • Executive buy-in • Communication and training plans. Continuous meetings with partners to get feedback and prioritize action plan
Understanding of blockchain technology	• Training for partner IT teams and end users
Working with IT team of partner members, resource availability and skill set readiness	• Engage partners at management and technical levels • Definition of ready • Statement of work with clear roles, responsibilities, time commitment and expectations
Quality of data provided by partners	• Mock data conversions • Data quality expert provided by BlockMed
Legal agreements, limitation of liability	• In-house counsel to produce standard Master Services Agreement and review proposed changes • Leverage existing agreements between partners • Third party insurance • Limited liability agreement
Different versions and customizations of existing ERP systems may not be compatible with API's	• Discovery process before starting engagement
Cost: pricing and consumption in a production environment.	• $0 cost for pilot partner participation. Post pilot analysis will provide additional insight into monetization strategy.

4.5 Success Metrics

The overall performance of the system from a business perspective will be measured on a "balanced scorecard" (BSC) style format of key performance indicators (KPIs). The balanced

scorecard format, developed by Harvard authors David Norton and Robert Kaplan, posits having KPIs that provide a holistic view of the business and thus counteract tendencies toward sub-optimization of one measure like cost (Kaplan & Norton, 1996).

We use the classic BSC perspectives of customer value, operational performance, financial performance, and innovation and learning. KPIs for the 26-weeks covering the Phase 0 and Phase 1 are shown in the table below.

Table 4-5. BSC-Based KPI's

Perspective	Goal	Measure	How Measured
Partner Value	Satisfied partners	• Net Promoter Score(NPS) > 100 • User satisfaction from weekly meetings • Costs less than $100K for staff and $3K for licensing*	• NPS results • Anecdotal feedback and periodic survey • Report from Partner
Financial Performance	Meet budget	• $800,000 for 10 developers • $300,000 for 4 management staff • $50,000 for equipment & training • $4,000 licensing fees	• Actual expenses
Operational Performance	Meet SLAs	• All of SLAs met	• See SLA section
Innovation and Learning	Regularly improve the system	• % completion of planned user stories	• Actual expenses

*During the Pilot phase, there is no charge to the Partner from BlockMed. Their costs are paid to IBM for licensing Hyperledger and for their own staff to support their node. In the Expansion phase BlockMed will consider licenses or subscriptions for the BlockMed APIs and services.

4.6 Expansion to Other Partners

The Phase 1, the pilot consisted of a "soft launch" to a functional end-to-end solution with limited functionality. In Phase 3, to expand beyond the pilot, BlockMed will have to further institutionalize service operation, on-boarding procedures, and user enablement. Automation would have to be improved, and the ability for clients to bring up their own nodes would have to be improved through providing scripts, documentation, and training. While these activities are beyond the scope of this paper, some initial thoughts are given in the Appendix.

5 References

5.1 Works Cited

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5.2 Supplemental Resources

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3. Sources from System Metrics section Scherer, Matthias. (2017). Performance and Scalability of Blockchain Networks and Smart Contracts. UMEA University. URL: https://umu.diva-portal.org/smash/get/diva2:1111497/FULLTEXT01.pdf. Accessed March 22, 2018.
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6 Appendix

6.1 Technical Standards

6.1.1 Interoperability Standards

Two electronic formats for interoperability are the most common for Blockchain. The first one is the Electronic Data Exchange (EDI) Advanced Ship Notice (ASN)[17]. The second is the Electronic Product Code Information Service (EPCIS)[18] method. EPCIS is a GS1 global standard and is supported by large players including SAP's Track and Trace, Mediledger, and Tracelink Life Sciences Cloud. EDI has limitations for volume intensive applications "the current industry requirement under DSCSA is taxing the systems that use EDI data with Advanced Shipping Notice formats, and it won't be feasible when item-level traceability becomes a requirement" [19] BlockMed, uses the EPCIS standard since it is designed for performance and supported by some of the largest players in the space.

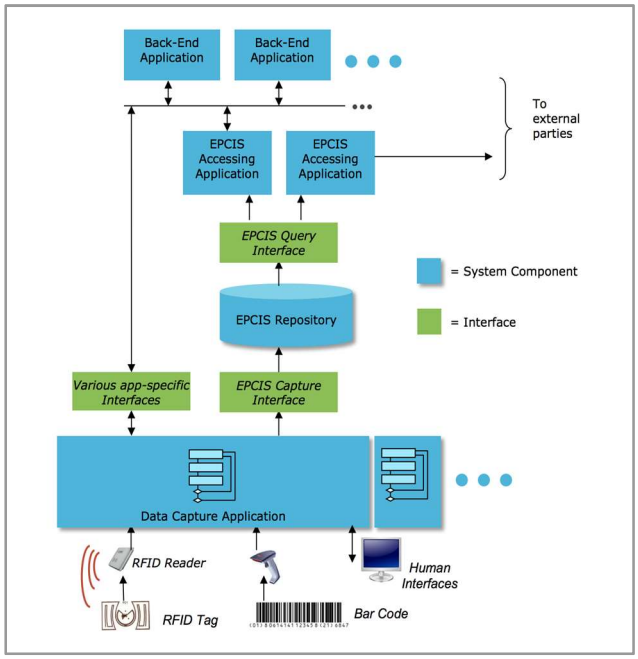

Figure 6-1. How EPCIS information typically integrates into back-end systems[20]

[17] https://en.wikipedia.org/wiki/Advance_ship_notice

[18] https://en.wikipedia.org/wiki/EPCIS

[19] http://pharmaceuticalcommerce.com/supply-chain-logistics/amerisourcebergen-defines-its-path-forward-in-traceability/

[20] https://www.gs1.org/docs/epc/EPCIS_Guideline.pdf

6.1.2 Blockchain Concepts

Business Service Component - BlockMed provides an immutable, unhackable, and virtually distributed ledger to record pharmaceutical supply chain transactions (i.e. changes in ownership). To do this, BlockMed utilizes blockchain technology, where each transaction includes a digital signature that guarantees the validity of the entire chain of transactions.

BlockMed also enhances the existing landscape by providing user interfaces to perform track/trace functions across the supply chain, and with a user facing web app that allows users to track the history of transactions.

A blockchain consists of a sequence (or chain) of discrete data units (blocks). Each block records a transaction, such as a record of goods received, and is identified by a unique value that consists of a cryptographic hash of the contents of the block. All participants on the blockchain network share the transaction record.

A blockchain network has the following key characteristics:

- **Consensus**: For a transaction to be valid, all participants must agree on its validity.
- **Provenance**: Participants know where the asset came from and how its ownership has changed over time.
- **Immutability**: No participant can tamper with a transaction after it's been recorded to the ledger. If a transaction is in error, a new transaction must be used to reverse the error, and both transactions are then visible.
- **Finality**: A single, shared ledger provides one place to go to determine the ownership of an asset or the completion of a transaction.

Blocks that are added to a blockchain reference the ID (hash) of the previous block (which becomes part of the hash of the new block), forming a linked list (See Figure 7.2). Therefore, changing or replacing any block in the blockchain would alter the hash and invalidate the linked list. The blockchain is validated using this mechanism when any record is added to the ledger.

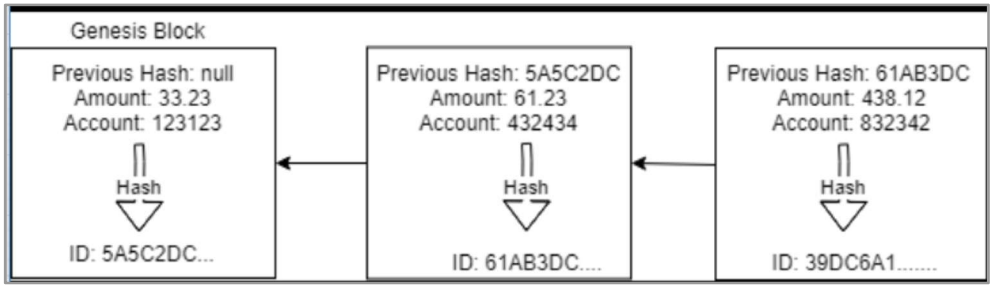

Figure 6-2. Software solution with no blockchain

While the blockchain architecture was introduced as a solution for decentralized electronic payments[21], the general concepts behind blockchain are applicable to many business problems. Blockchain for Business implementations often employ private blockchains, which restrict access to authorized members who are invited to join the network by membership administrators. This process of accepting transactions based in an authenticated peer consensus is termed “selective endorsement” and is a highly scalable mechanism.

Blockchain as a Service (BaaS) - Cloud service providers are introducing Blockchain as a Service (BaaS) solutions, which allow organizations to leverage the benefits of Blockchain for Business without having to implement low-level blockchain details. In this model, each member of a blockchain can “own” one or more nodes which are hosted in the cloud vendor’s network but isolated from other peers and strongly secured.

Examples of BaaS solutions include offerings on Microsoft Azure, Ethereum, and IBM’s Hyperledger Fabric implementation.

Hyperledger Fabric Details - Hyperledger Fabric consists of the following key components:

Nodes - Nodes represent entities that comprise the Hyperledger fabric. Multiple nodes, and nodes of different types, may run on a single host.

Peer Nodes - Peer Nodes are entities which maintain the state and ledger databases (see below). Peer nodes can also participate in the transaction endorsement scheme. Organizations that are part of a blockchain network typically operate their own peer nodes (or a pair of nodes for redundancy), which are secure and isolated from each other. This is what provides organizations with trust in the network.

Orderer Nodes - Orderer nodes listen for incoming transactions from clients, order the transactions, and submit the transactions to Peer Nodes for endorsement and commitment.

Authentication and Authorization - Fabric Certificate Authority (CA) - A Hyperledger Fabric Certificate Authority is a host that can issue identity certificates using public key infrastructure. In addition, the CA provides security for TLS connections between nodes on the network.

Membership Service Provider - A Membership Service Provider (MSP) is an organization-level entity that can identity the appropriate CA that is used to authenticate a user as well as provide role-based authorization services.

It is possible for a single Organization to maintain multiple MSPs for its organizational units. In this manner, a single large organization can maintain one Peer Node set for all of their organizational units, while still having granular control over what actions these units can perform.

[21] Bitcoin: A peer to peer electronic cash system. Nakamoto, Satoshi; 2008 https://bitcoin.org/bitcoin.pdf

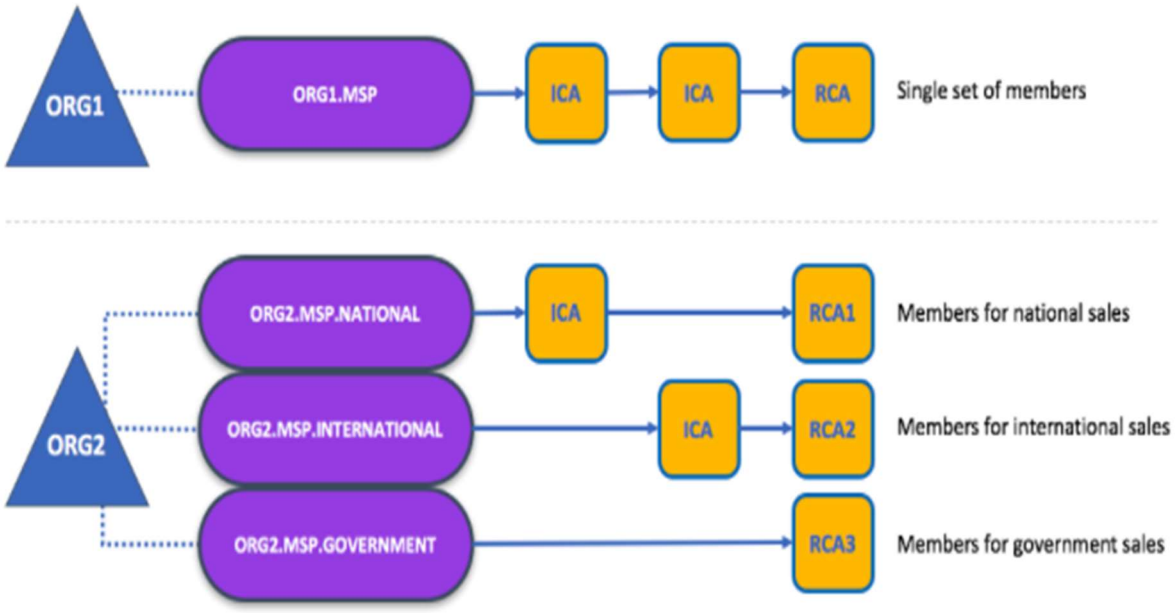

Figure 6-3. An organization may have multiple Membership Service Providers [22]

Databases - Hyperledger Fabric data storage consists of two distinct distributed data storage mechanisms, the chain and the state database. [23]

Chain Database - The chain database is the immutable blockchain ledger. Every transaction that results in an addition, deletion, or modification of business data is recorded as an addition to the ledger. This provides transparency and accountability as any member of the network can see data that was deleted or modified.

State Database - The state database (or World State) represents the current values of business entities. For example, if a record is deleted, the record will not exist in the state database, but a record of the deletion will be preserved in the chain database (along with the original addition and any previous modifications). Hyperledger Fabric supports either the LevelDB or CouchDB NoSQL databases for an underlying state database.

Channels - Hyperledger Fabric supports the concept of Channels[24]. Channels allow a subset of partners in a business network to share data that is not visible to other partners. This is useful for partners that do not wish to leverage the advantages of blockchain without exposing sensitive data where not necessary. Creating a channel generates a new genesis block and chain database, which separates the transactions from the parent chain database.

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[22] http://hyperledger-fabric.readthedocs.io/en/latest/membership/membership.html

[23] http://hyperledger-fabric.readthedocs.io/en/release-1.0/ledger.html

[24] https://hyperledger-fabric.readthedocs.io/en/latest/channels.html

6.2 Development Sprints

Table 6-1. Development Sprints Detailed

STORY/THEME	EPIC
Week 0-1: Project ramp-up	
Identify Subject Matter Experts (SMEs) and internal stakeholders	Ramp Up
Identify Product Owner, Scrum Master, and Development Team	Ramp Up
Set up BlockMed project management (Jira)	Ramp Up
Set up private BlockMed source code repository (Bitbucket)	Ramp Up
Set up BlockMed Confluence Wiki for project info	Ramp Up
Week 2-3: Project ramp-up part 2	
Identify Initial Participants and their contacts for BlockChain Network	Ramp Up
Identify development & testing tools	Ramp Up
Document team agreements & processes	Ramp Up
Review proof of concept (PoC)	Ramp Up
Development team training	Ramp Up
Create BlockMed IBM Blockchain Service Account for Network Initiator	Hosting
Week 4-5: System Modeling / User Experience	
Finalize BlockMed Hyperledger entity models	System Model
Define BlockMed CSS style guide for web and mobile	UI/UX
Create BlockMed logos	UI/UX
Create IBM cloud hosting account for web/API services/resources (non-	Hosting
Create Staging blockchain node cluster for network initiator.	CI/CD
Implement CI/CD build/test/deploy automation for web/API resources	CI/CD
Week 6-7: Log transactions to Blockchain	
Create scripts to automate chaincode deployment process	Deployment
REST APIs for managing entity data	Integration
Complete NodeJS transaction logic for packing/unpacking, shipping, and	System Model
REST APIs for logging EPCIS transactions.	Integration
Create Production blockchain node cluster for Network Initiator (BlockMed)	Hosting

STORY/THEME	EPIC
BlockMed static information web pages	Onboarding
Week 8-9: Authentication / Authorization	
Implement security for REST APIs	Integration
BlockMed Web/Mobile - User Authentication	BlockMed Mobile
BlockMed Admin - admin authentication	BlockMed Admin
BlockMed Admin - Admins can provision new admin/user accounts	BlockMed Admin
Week 10-11: Display Pedigree	
Web UI for manual maintenance of Entity data.	BlockMed Admin
BlockMed Web/Mobile - Display drug pedigree given SGTIN	BlockMed Mobile
BlockMed Admin - display pedigree trace given SGTIN	BlockMed Admin
BlockMed Admin - View details for a Batch	BlockMed Admin
Import initial reference data for Network Initiator entities (BlockMed parent	Onboarding
Week 12-13: Enhanced Admin Track/Trace functions	
BlockMed Admin - list last known locations for all batch shipments	BlockMed Admin
BlockMed Admin - display pedigree trace on an interactive map	BlockMed Admin
BlockMed Admin - show last known batch shipments on an interactive map.	BlockMed Admin
Develop Internal/Partner Training Materials	Onboarding
Week 14-15: Mapping / Recalls	
BlockMed Admin - Flag a batch for recall	BlockMed Admin
BlockMed Web/Mobile display recall warning/info for recalled products	BlockMed Mobile
BlockMed admin: email partner contacts on product recall	BlockMed Admin
Week 16-17: Partner Integration Modules	
EPCIS to BlockMed data adapters for ERP: SAP	Integration
Google analytics for BlockMed web/mobile	Analytics
Finalize BlockMed training materials	Onboarding
Execute BlockMed internal stakeholder training	Onboarding

6.3 ITIL-based support for Expansion phase

BlockMed will adopt ITIL for all Service Management activities:

- **Change Management.** At a given time, BlockMed will maintain two Generally Available (GA) versions. Participants will be expected to migrate to the most current version within 3 months of its release. All upgrades and bug fixes will follow a strict Change Management process to ensure proposed changes are fully tested, have backup plans, are reviewed by a change control board, and communicated to the participants with sufficient notice. To minimize downtime, upgrades will be performed utilizing CI/CD (continuous integration, continuous delivery) principles.
- **Incident Management**. An unplanned interruption or reduction in the quality of the BlockMed service will trigger a formal Incident Management process with the goal to restore service as quickly as possible.
- **Problem Management.** If multiple occurrences of related incidents are observed, a formal Problem Management process will be triggered with the goal of identifying the root cause of the problem and prevent future occurrences.
- **BlockMed Support.** BlockMed's development team will provide support during the pilot phase. Through regular meetings, email, and phone the partner admins can get support as needed.

6.4 Post-Pilot Implementation

As go forward market strategy after the pilot phase, deployment to production operations will be based on Generally Available product versions. A generally available version has set features and functionality that are not likely to change. Since the tasks required to implement a given BlockMed product version for a new participant are known and not likely to change, deployment to new participants will follow a waterfall methodology where initial versions of standard documents will be provided by BlockMed and adjusted as needed in collaboration with the new participants. Implementation of BlockMed will be done in partnership with third party systems integrators.

A typical implementation will last approximately 12 to 20 weeks, depending on the readiness of the participant.

- **Design** (4 - 8 weeks). BlockMed to provision standard initial templates for workflows, interface specifications, reports, data conversion formats and training materials. Participant to review standard templates and work in collaboration with BlockMed to identify gaps and adjust as needed.
- **Build and Test** (4 - 8 weeks). Participant extracts reference data and presents it in the format expected by the API. Extensions to participant's ERP systems are installed to present the transaction date in the EPCIS format. Multiple mock data loads are performed until defects are removed. Unit, Integration and User Acceptance testing.
- **Deploy** (4 weeks). End user training. Service Desk training. Final data conversion and interface activation. Commissioning to production operations.

As previously described, the BlockMed solution per-se is built utilizing an Agile methodology to minimize time to market and maximize product quality. BlockMed will continuously improve the product using scrum and collaborating with a limited set of partners.