

Reference Implementation: Hypertrust Patient Data Care X-Chain for Personalized Medicine

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BACKGROUND

Personalized treatments, like autologous cell therapies, are based on a concept that involves a single patient's input, either in the form of physical raw material (e.g., blood or tissue cells) or of data based on the patient's analysis to produce a medicine specifically for this patient. This results in a batch size of one for production and thus has very little potential for productivity increases that may be achieved by core manufacturing improvements.

As it is commonly known that the manufacturing process of personalized medicine starts with the input generation and ends with the application of the final product/medicine, the whole supply chain is a heavily distributed manufacturing process, which provides many starting points for productivity-increasing measures.

The described manufacturing process is quite similar for related treatments, like allogenic therapies, where the input is generated from a donor and the output can be used for different patients. The production output there can be higher than one.

Many different parties, including transport service providers, treatment centers and hospitals, own and handle a variety of processes and data during the personalized treatment manufacturing process. The number of commercially available drugs that need to be personalized has grown beyond 60 in recent years. This includes cancer treatments and drugs against viral infections. During the manufacturing process, drugs and patient data are handled through different institutions.

According to pharma and biotech companies, assuring the chain of identity and custody is hard to achieve due to the high degree of process distribution. Also, the orchestration of many external parties is a challenge for these innovative treatments, still leading to very high treatment costs today.

CHALLENGES OF PERSONALIZED MEDICINE

DATA PROTECTION

The data of the whole supply chain process cannot be shared with all parties. The closed-loop supply chain of personalized treatments involves many parties, often even competing parties of the same branch. For instance, in cell therapies, an apheresis step is involved, to extract the raw material for the manufacturing process from the patient. In certain countries (e.g., the U.S.), these apheresis centers are run privately and are thus competing businesses. When such parties are contributing to the supply chain of one pharma company, it is critical for them to not share data with a central party or storage that could be abused by their competition or even by a business partner (the buyer/seller relationship).

The blockchain-based supply chain management solution Hypertrust X-Chain addresses these challenges. It can allow any party in the network to share its information with only the required parties.

CHAIN OF IDENTITY

An Integral part of a closed-loop supply chain is to ensure that the final product is returned to the correct patient from whom the raw material was extracted. Any deviation could result in severe consequences, physical injury or even death. So, the chain of identity and its correctness is of utmost importance for the manufacturing process of personalized medicine.

CHAIN OF CUSTODY

The chain of custody refers to the chronological documentation that records the sequence of custody, control, transfer, analysis and disposition of physical or electronic evidence. Of particular importance in the supply chain of personalized treatments, it assures the traceability and quality of the final medicine. In many legislations, a consistent chain of custody is a requirement to get commercial approval to sell a new medicine.

The blockchain-based supply chain management solution Hypertrust X-Chain creates and preserves a trustworthy and immutable chain of custody for personalized treatments.

ORCHESTRATION AND AUTOMATION

The manufacturing process of personalized medicine starts with the input generation and ends with the application of the final product/medicine. The whole supply chain is a heavily distributed manufacturing process involving many different external parties. From a final product producer's point of view, this process is difficult to manage.

CONDITIONAL CHECKS AND DEPENDENCIES

Furthermore, due to the high interdependency of some production steps, additional repetitions or quality checks may be required before the final product can be released. This calls for flexible rules-based conditional checks between process steps based on parameter assertation.

To address these requirements, the blockchain-based supply chain management solution Hypertrust X-Chain implements a novel workflow engine fully relying on the resilience and stability of blockchain smart contracts.

HYPERTRUST PATIENT DATA CARE X-CHAIN

SOLUTION DESCRIPTION

The blockchain-based supply chain management solution Hypertrust X-Chain orchestrates a distributed manufacturing process by using a workflow engine implemented through a series of smart contracts acting on a custom workflow model stored on the ledger.

The system provides an end-to-end solution to automate, streamline and secure supply chains for personalized treatments. It also includes an event system to inform affected parties about upcoming actions to take.

Due to the highly modularized implementation, the system can easily be expanded:

- External APIs can be connected
- Additional services can easily be added
- The addition of new members or stakeholders is a simple confirmation process carried out with a click of the mouse

The system can easily be configured to manage the supply chain steps of personalized medicine, including:

- Patient enrollment
- Scheduling and tracking of apheresis and treatment appointments
- Scheduling and tracking of hospital pick-up appointments
- Tracking the position and temperature of raw materials and final products throughout the whole transportation process
- Production plant scheduling support
- Workflow orchestration for decentralized production processes
- Monitoring of treatment outcomes after administration
- Production planning and optimization, including raw material stock management

SOLUTION BENEFITS

By decentralizing the aforementioned processes, it is finally possible to provide the required level of trust between multiple parties to securely handle personalized treatment data. The system provides transparent, immutable and trustworthy patient data security.

The greatest benefit of this solution comes from the trustworthy and highly customizable workflow process engine for personalized medicine supply chains, which supports the patient's treatment and recovery. During proof-of-concept implementations together with leading global pharma companies, a production cycle roundtrip time improvement of up to 25 percent could be observed, compared to traditional processes and tools.

FRICTIONLESS AND AUTOMATED SUPPLY CHAIN PROCESSES

The system guarantees a smooth and automated supply chain process through all manufacturing steps for personalized medical treatments. Because of the shared ledger, all participants can retain their own processes, yet the overall progress is still orchestrated by a leading pharma provider. Also, since the defined workflow is fully distributed and therefore transparent for all participants and since the engine and the workflow model are immutably stored on the blockchain, it makes the solution highly secure against tampering, attacks and outages.

DATA PROTECTION

Traditional blockchains are not equipped with data protection features. In contract, the blockchain-based supply chain management solution Hypertrust X-Chain offers a concept called SBDXL (Secure Blockchain Data Exchange Layer) that enables parties to share their data with only specific participants of the network. Since the data is not centrally available, it therefore cannot be abused or shared with unauthorized parties.

In addition to this, X-Chain optionally implements Camelot Trusted Computing Appliances to process private patient data in a trustworthy manner in order to derive truthful insights from it. The key advantage is that this is done without revealing any sensitive data to any other party: an algorithm agreed on beforehand by the data owners processes the private data and returns only specific results to legitimately requesting parties.

A more detailed explanation of the concept of Camelot Trusted Computing Appliances can be found in a joint case study of Dell Technologies, Intel, Camelot ITLab and SAP.

PAPERLESS AND COMPLETE PATIENT-CENTRIC AUDIT LOG

All important steps of the manufacturing process as well as the complete chain of identity and custody are immutably stored on the blockchain, being constantly validated by the network. Applying changes or malicious manipulations of the data is impossible, which leads to increased trust, security and reliability.

AUTHENTICITY AND SECURITY MECHANISM

All parties involved in the distributed manufacturing process are clearly identified and authenticated. Data being contributed to the chain of identity and custody is uniquely signed by the respective network participant, thus making manipulations impossible on a system level.

ARCHITECTURE

The SAP Cloud Platform is the cloud extension platform for SAP. It enables developers to securely develop applications based on loosely coupled services, thereby implementing additional workflows or modules on top of their already existing solutions.

SAP Cloud Platform Blockchain services (using the Hyperledger Fabric framework in this specific case) enable the creation of nodes, networks and channels on an intuitive cloud-based user interface. Here you can make use of service and network dashboards to deploy and analyze chaincode, grant network and channel permissions, and connect externally hosted Hyperledger Fabric networks to the platform. SAP Cloud Platform Blockchain Services (Hyperledger Fabric) lets you provision a Hyperledger Fabric node and join it to a network of nodes. Hyperledger Fabric supports enterprise-ready blockchain with smart contracts.

Figure 1 depicts a proposed reference architecture to implement the blockchain-based supply chain management solution Hypertrust X-Chain by connecting a blockchain network to an SAP backend and by onboarding external parties to the blockchain network.

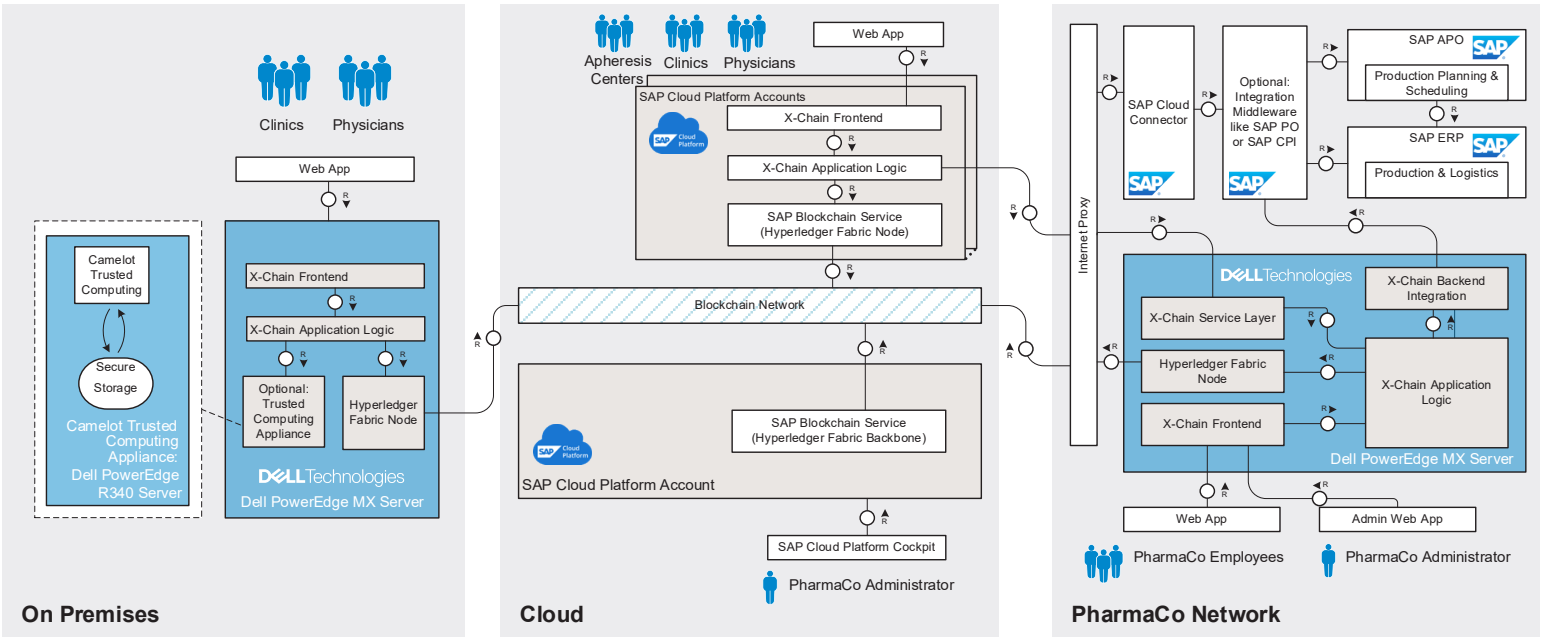


Figure 1. A proposed reference architecture to implement the blockchain-based supply chain management solution Hypertrust X-Chain.

THE REQUIRED COMPONENTS

To implement the reference architecture, the following components are needed on top of an existing SAP backend (like SAP ERP and connected systems):

- SAP Cloud Platform Blockchain Service Hyperledger Fabric (Backbone plan)
- SAP Cloud Platform Blockchain Service Hyperledger Fabric (Node plan) — for every party that wants to be onboarded to the network via a Hyperledger Fabric node running in the SAP cloud
- Camelot Hypertrust Platform and Hypertrust X-Chain provisioned on SAP Cloud Platform Cloud Foundry — for every party that wants to be onboarded to the network via a Hyperledger Fabric node running in the SAP cloud
- Dell EMC™ PowerEdge™ MX Servers with Camelot Hypertrust Platform and Hypertrust X-Chain application — for every party that wants to be onboarded to the network via an on-premises Hyperledger Fabric node
- Optionally: Camelot Trusted Computing Appliances on Dell EMC™ PowerEdge™ R340 servers (Intel SGX ready) — for every party that needs to trustworthily process sensitive data (e.g., patient health records)

AN EXAMPLE: CELL THERAPIES

An example implementation of Hypertrust X-Chain can be depicted on top of the autologous T-cell therapy use case (famous product example: Gilead Yescarta).

These treatments can be used to treat patients suffering from a blood cancer characterized by diffuse large B-cell lymphoma and certain types of leukemia, after previous treatments have failed. The costs for such treatments are quite elevated, in the region of several hundred thousand U.S. dollars.

The closed-loop supply chain of such a treatment displays some of the most common attributes of a personalized medicine product, as shown in Figure 2.

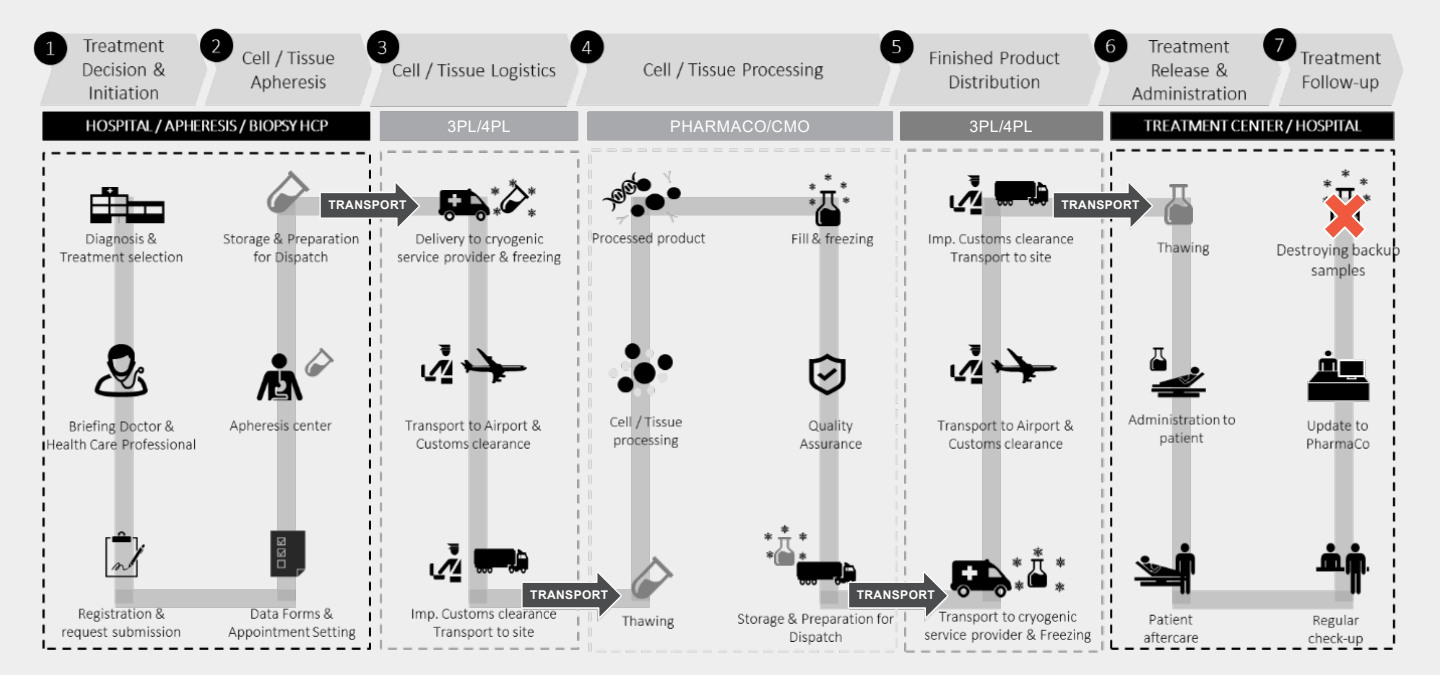


Figure 2. An example closed-loop supply chain for a personalized medicine product.

KEY TAKEAWAYS

As we noted in the introduction to this paper, many different parties, including transport service providers, treatment centers and hospitals, own and handle a variety of processes and data during the personalized treatment manufacturing process. During this process, drug and patient data are handled through various institutions. With so many parties involved and such a high degree of process distribution, assuring the chain of identity and custody is hard to achieve. In addition, the orchestration of many external parties is a challenge for these innovative treatments, leading to higher treatment costs.

The Hypertrust X-Chain solution on blockchain technology addresses all of these challenges. It enables full orchestration of the closed-loop supply and distributed data chain, as well as real-time traceability, notifications and secure exchange between stakeholders. By using a workflow engine implemented through a series of smart contracts acting on a custom workflow model stored on the ledger, the system provides an end-to-end solution to automate, streamline and secure supply chains for personalized treatments.

TO LEARN MORE

For more information about the technologies discussed in this paper, visit the following sites:

SAP HANA

SAP Blockchain as a Service

Hypertrust Patient Data Care X-Chain

Camelot Hypertrust Platform

Camelot Trusted Computing Appliances

Dell EMC Ready Solutions for SAP HANA

Dell Technologies – Solutions for SAP



Camelot IT Lab GmbH

Camelot IT Lab is the leading SAP consultancy for digital value chain management, with more than 20 years of experience. Camelot guides clients in their digital transformations from strategy to the implementation of innovative solutions. The company's blockchain journey started in 2015, and today Camelot offers a comprehensive portfolio of blockchain products and services leveraging Camelot Hypertrust Platform and SAP Cloud Platform Blockchain Services.

Hypertrust Patient Data Care GmbH

Founded in 2018 as a spin-off of the broader CAMELOT Consulting Group, this is Camelot's dedicated brand for supply chain solutions in the area of Pharma and Biotech. Especially new and innovative treatment concepts that require mindset and paradigm shifts on many levels are the focus topics of this Munich-based start-up company. The core of the Hypertrust X-Chain solution is Camelot ITLab's Hypertrust Platform.

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Dr. Marten Neubauer is Dell Technologies Field Director Healthcare in Germany. A former CIO for a national German healthcare provider himself and a Ph.D. for system integration into OR theaters, Marten has a breadth of experience in the healthcare and life sciences segment. Marten is driving several thought leader initiatives to support solutions in the healthcare and life sciences space with Dell Technologies infrastructure.

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