# Supply Chain Finance in Pharmaceutical Industry with DLT

## Section 1 Summary

| Use Case Summary | | | |
|---|---|---|---|
| **Use Case ID:** | HLC-001 | **Use Case Type:** | Vertical |
| **Submission Date:** | October 30, 2018 | **Is Use Case supporting SDGs** | Yes |
| **Use Case Title:** | Supply Chain Finance in Pharmaceutical Industry with DLT | **Domain:** | Industries |
| **Status of Case** | Pilot | **Sub-Domain** | Pharmacy |
| **Contact information of person submitting/ managing the use-case** | Full Name: Michael Dong Job Title: CEO<br>E-mail address: dongning@chainnova.com<br>Telephone number:+86 13511068330<br>Social media: WeChat Account: immdong<br>Web site: www.chainnova.com | | |
| **Proposing Organization** | ChainNova Data Technology (Nantong) Co. LTD, PRC. | | |
| **Short Description** | This use case is a proposal to trace the logistics of medicines and provide lower-cost financial support for the trader on pharmaceutical industry chain. | | |
| **Long description** | This use case is a proposal to trace the logistics of medicines and provide lower-cost financial support for the trader on pharmaceutical industry chain. In traditional pharmaceutical supply chain, we see the issues like fake medicines, fragmented medical logistics, untransparency of trading processes and restriction of credit grantees for SMEs. In this use case, ChainNova built a pharmaceutical supply chain financial platform based on DLT technology which can make the whole trading process traceable and increase trust among the participants on the supply chain. | | |
| **SDG in Focus (when applicable)** | 3: Good Health and Well-Being | | |
| **Value Transfer:** | No | **Number of Users:** | |
| **Types of Users:** | Pharmaceutical companies, medicine distribution companies, banks, hospitals | | |
| **Stakeholders** | Government, Pharmaceutical companies, medicine distribution companies, banks, hospitals doctors, patients | | |
| **Data:** | The medicine data, logistics data, sales date | | |

| | |
|---|---|
| **Identification:** | Full identification of all the participants |
| **Predicted Outcomes:** | The predicted outcomes are:<br>- Increase the transparency of the trading processes<br>- Integrate the pharmaceutical industry deeper with finance<br>- Increase the transaction efficiency on the supply chain<br>- Strengthen the credit of medicine distribution companies and lower the cost of financial due diligence for banks<br>- Facilitate the development of medicine distribution companies with greater support from financial institutions<br>- Prevent fake medicine circulation |

**Overview of the Business Problem or Opportunity**

➢ In traditional supply chain finance area, there are restrictions of credit grantees for medicine distribution companies

- Since the national credit information systems is not complete, there is information asymmetry for medicine distribution companies in the supply chain and banks can't directly grant credits to them. The bank credit is based on the credit of core companies.

➢ Limitations of information integration on the supply chain

- The core enterprises own IT system is difficult to integrate the upstream and downstream companies' transaction information on the supply chain, the authenticity of the transaction information is hard to verify and tell if the transaction information has been tampered.

➢ The transaction information is untransparent in the trading process

- Supply chain finance integrates business flow, logistics and cash flow. If the online business flow and offline logistics cannot achieve information transparency and full visibility, the bank's right to control the collateral may create risk and directly affect the business development.

**Why Distributed Ledger Technology?**

The DLT technology can ensure all the information on the supply chain transparent and reliable as they can't be tampered. This will help the financial institutions to access and grant credit to the medicine distribution companies which can lower the cost for their credit investigation and stimulate the development of medicine distribution companies in return. In addition, the smart contract of DLT can automate the trading process with efficiency greatly improved.

## Section 2 Current process

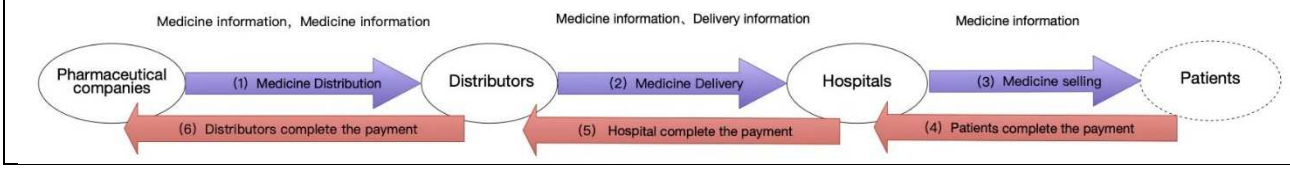
**Current Solutions**

On ChainNova's supply chain finance platform, the credit based on the digital certificates become authentic and transferrable to help medicine distribution companies get more financing support from

banks. The digital certificates will be supervised and granted by the core enterprises on the supply chain and all the information of the certificates is transparent to every participant.

| **Existing Flow (as-is)** | | |
|---|---|---|
| **Step** | **User Actions** | **System Actions** |
| 1. | Pharmaceutical companies provide medicines for distributors on credit | Pharmaceutical companies will supervise the delivery and account receivable of the medicines |
| 2. | Distributors re-sell the medicine to hospitals with large amounts of accounts receivable | Distributors manage the medicines from different factories by batch with details recorded for further analysis. |
| 3. | Hospitals sell the medicine to patients | Hospitals record the source, logistics and inventory of the medicine as the reference for future procurement plan |
| 4. | Patients trace the source of medicines | Patients trace the logistics of the medicines |
| 5. | Hospitals pay the due account , distributors collect the payment and pay the pharmaceutical companies | Hospital update the inventory and account information<br>Distributors update the inventory and account information<br>Pharmaceutical companies update the inventory and account information |

**Process scheme (as-is)**




| **Data and information (as-is)** | | |
|---|---|---|
| **Data** | **Type** | **Description** |
| **1** | Medicine Logistics | All the information during the trading process |
| **2** | Sales data | The sales data includes the amount, inventory, sales volumn etc. |

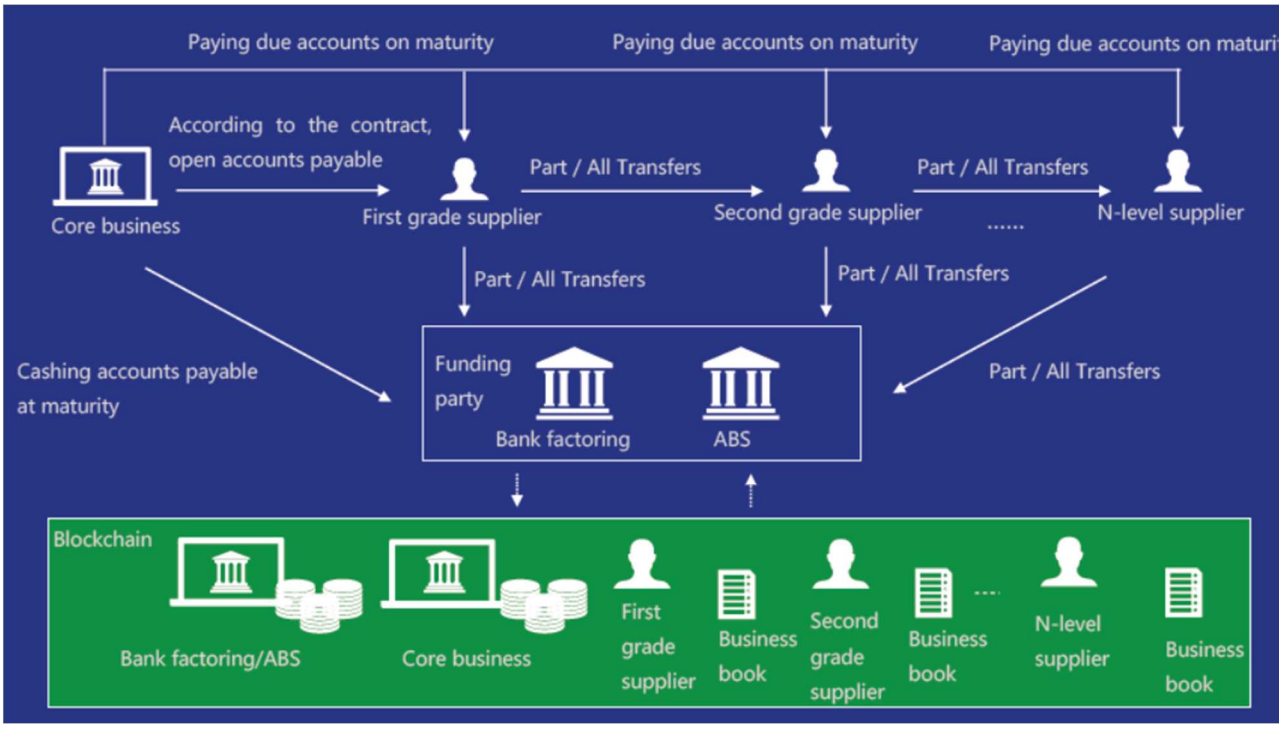
| Participants and their roles (as-is) | | |
|---|---|---|
| **Actor** | **Type/Role** | **Description** |
| **1** | Pharmaceutical companies | The medicine production factories |
| **2** | Medicine distribution companies | The medicine distributors, this may include the first-layer distributor, second-layer distributor etc. |
| | Banks | Provide loan to the traders especially the distributors |
| | Hospitals | Provide the medicine for the patients |

| Other Notes |
|---|
| N/A |

## Section 3 Expected process

| Expected Flow (to-be) | | |
|---|---|---|
| **Step** | **User Actions** | **System Actions** |
| 1. | The pharmaceutical companies sell the medicine to distributors with account receivable generated | The distributors' system generates the electronic certificate for account payable for pharmaceutical companies |
| 2. | Pharmaceutical companies digitalize the accounts receivable and make it transferrable | The electronic certificates will be transferred,split,held and financed. |
| 3. | The pharmaceutical companies pledge accounts receivable to banks to obtain credit lines and financing | The electronic certificates for accounts receivable will be circulated online as an asset |

**Process scheme (to-be)**




| Participants and their roles | | |
|---|---|---|
| **Actor** | **Type/Role** | **Description** |
| **1** | Pharmaceutical companies | The medicine production factories |
| **2** | Medicine distribution companies | The medicine distributors, this may include the first-layer distributor, second-layer distributor etc. |

| Participants and their roles | | |
|---|---|---|
| **Actor** | **Type/Role** | **Description** |
| | Banks | Provide loan to the traders especially the distributors |
| | Hospitals | Provide the medicine for the patients |

| Data and information | | |
|---|---|---|
| **Data** | **Type** | **Description** |
| **1** | Medicine logistics | The medicine logistics information from end to end will be accurately recorded and can not be tampered |
| **3** | Sales data | The sales data includes accounts receivable and payable, inventory, electronic certificates etc will be recorded onto blockchain with full transparency |

**Security and privacy**

1.Since transparency is the main requirement, the ideal information visibility is public;

2. If business privacy prevent public visibility, this critical subset of data can be encrypted or protected;

3. DLT system should be able to provide mechanisms of DLT data integrity control;

**Main Success Scenario + expected time line**

1. The distributors and pharmaceutical companies can get loan from banks in easier way
2. Banks will lower the cost for investigation before providing loan
3. The hospitals and patients will have more trust on the medicine

**Conditions (pre- or post-)**

1. All parties are connected to DLT network

**Performance needs**

N/A

**Legal considerations**

N/A

**Risks**

1. Risks related to DLT immaturity.

| **Special Requirements** |
| --- |
| N/A |

| **External References and Miscellaneous** |
| --- |
| N/A |

| **Other Notes** |
| --- |
| N/A |

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**Appendix 1**

## Domains and subdomains for use cases categorization

**Vertical**:

1. Finance
    a. Financial management & accounting
    b. International & interbank payments
    c. Clearing and settlement
    d. Reduction of Fraud
    e. Financial messaging
    f. Asset lifecycles and history
    g. Trade finance
    h. Regulatory compliance & audit
    i. AML/KYC
    j. Insurance
    k. Peer-to-peer transactions
2. Healthcare
    a. Pharma
    b. Biotechnology
    c. Medicine
3. Industries
    a. Manufacturing
    b. Energy
    c. Chemical
    d. Retail
    e. Real estate
    f. IT and telco
    g. Supply chain management
    h. Transportation
    i. Agriculture
4. Government and public sector
    a. Taxes
    b. Government and non-profit transparency
    c. Legislation, compliance & regulatory oversight
    d. Voting
    e. Taxation and customs
    f. Intellectual property management
    g. Land Registries

**Horizontal**:

1. Identity Management
2. Security Management
    a. Public Key Infrastructure

3. Internet of Things
4. Data processing, storage and management
    a. Data Validation  (includes provenance)
    b.

# Blockchain Web/Mobile Application for Vaccine Supply Chain

## Section 1: Summary

| Use Case Summary | | | |
|---|---|---|---|
| **Use Case ID:** | HLC-002 | **Use Case Type:** | *Vertical* |
| **Submission Date:** | January 9, 2019 | **Is Use Case supporting SDGs** | *yes* |
| **Use Case Title:** | Blockchain Web/Mobile application for vaccine supply chain | **Domain:** | *Healthcare* |
| **Status of Case** | *Pilot Implementation* | **Sub-Domain** | *Pharma* |
| **Contact information of person submitting/ managing the use-case** | Dr. Agnes Naliaka Mindila<br>amindila@icsit.jkuat.ac.ke | | |
| **Proposing Organization** | *Jomo Kenyatta University of Agriculture and Technology (JKUAT), KENYA* | | |
| **Short Description** | The application seeks to achieve visibility, transparency and traceability of the vaccines along the supply chain and ensures that each vaccine can be isolated, analyzed and all activities associated with it identified. | | |
| **Long description** | Developing countries face challenges in the vaccine supply chain. The Challenges threaten vaccine access, availability, and quality. As countries adopt newer and more expensive vaccines and attempt to reach people at different ages and in new settings, the supply chain must be optimized. Information about demand, stock-levels and timely use of vaccines is poorly kept affecting timely supply leading to expirees and/or lack of needed vaccines. There is also the risk of poor product quality and counterfeiting that countries face and avoidable wastage. Accurate data collection, secure data storage and a flow of trusted information between parties is required.<br>Development of Permissioned Blockchain-based web/mobile application will enable incorporation of Identity Management technologies, achieve end to end visibility with the incorporation of BLE iBeacon technologies, GS 1 data matrix codes and map the physical to the digital. The application will achieve transparency and traceability within the vaccine supply chain through the use of immutable record of data and transactions, distributed storage, rules enforcement, and controlled user accesses. This will ensure every vaccine in the supply chain can be isolated, analysed and all activities associated with it identified. Data analytics and creation of dashboards for decision makers will be possible. | | |
| **SDG in Focus (when applicable)** | SDG 3. Indicator 3.2 and 3.8<br>The application aligns to SDG 3 indicator 3.2 and 3.8 by ending preventable deaths to children under five and access to quality essential health-care services such as vaccines. | | |

<table>
<tr><td></td><td colspan="3">SDG 9. Indicator 9.1<br><br>The blockchain application aligns with SDG 9. Indicator 9.1 in that it will provide a reliable and resilient infrastructure that will support human well-being by enabling access to vaccines.<br><br>SDG 17. Indicator 17.18<br><br>The blockchain application aligns with SDG 17. Indicator 17.18 by increasing significantly the availability of high-quality, timely and reliable data disaggregated by gender, age, geographic location and other characteristics relevant in national contexts concerning immunization.</td></tr>
<tr><td>Value Transfer:</td><td>The Application will generate assets for transactions on the blockchain. The proof of concept involves three counties in Kenya</td><td>Number of Users:</td><td>1000</td></tr>
<tr><td>Types of Users:</td><td colspan="3">Manufacturers of vaccines, Manufacturers of cold chain equipment, UNICEF Supply Division, National Vaccine and immunization Programme (NVIP), MoH Head, National Logistician, Logisticians, National Primary Store Managers, Regional Store Managers, Sub-County store managers, hospitals, health centres, Cold chain equipment technical officers, community health workers and Mothers/care givers, Kenya Regulatory Board</td></tr>
<tr><td>Stakeholders</td><td colspan="3">Donors, Government of Kenya specifically Ministry of Health (MoH), the citizens who need the vaccines, NVIP, UNICEF, Manufacturers of Vaccines, Manufacturers of cold chain equipment, Kenya Regulatory Board</td></tr>
<tr><td>Data:</td><td colspan="3">What data are expected to be stored in distributed ledger in terms of types, record structure, privacy<br><br>The application has both human actors and what we call IoT actors. Both actors have different data sets.<br><br>1. IoT actors include data from the (a) ibeacons that have temperature sensors that send temperature readings for vaccines in storage and those on transit (b) ibeacons that send location data for vaccines on transit and storage (c) identification data that uniquely identifies the different devices involved (ibeacons, smart phones, coldchain equipment, gateways<br>2. GS 1 data matrix codes data scanned from the vaccines and hold each vaccine details<br>3. Human actor’s data that includes (a) identification data of participants in the blockchain network since it’s a permissioned blockchain (b) assets in the form of messages that are exchanged between the participants (c) Transactions performed along the supply chain (d) Mother-child data for last mile monitoring<br><br>Privacy is ensured by the blockchain structure of creation of different channels, where one needs authorisation to access any specific channel in the blockchain network achieved through the Certification Authority(CA) of the blockchain architecture.<br><br>The NVIP plans to set up its own data centre but meanwhile the data will be stored in the DHIS2.</td></tr>
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| | |
|---|---|
| | Interaction with external data and other systems will be though authorization through the CA of the blockchain architecture in what can be termed as Personal health trains (PHT) that 'knock' and are given access after necessary vetting by the CA according to the rules. |
| **Identification:** | *Identification mechanism and rules; ability of participants to be anonymous, etc.*<br>Identification Mechanism is achieved by the Certification Authority that is implemented as a chain from the root CA to Intermediary CA to the normal users according to allowable rules for authorization. Participants in a specific channel are known because it's a permissioned blockchain. |
| **Predicted Outcomes:** | 1. Every vaccine is visible from the time it comes to the country to the last step when it is used on a child.<br>2. Every vaccines potency is known from the time it comes to the country to the time it is used on a child<br>3. Every transaction done receives consensus from the participants permissioned hence ensuring transparency and accountability<br>4. Every transaction is immutable and so traceability is achieved.<br>5. Provision of high-quality reliable data<br>6. Every vaccine can be accounted for.<br>7. Data on who was vaccinated, how many, by region, by gender is made available.<br>8. Creation of dashboards and maps to decision makers made possible. |

| **Overview of the Business Problem or Opportunity** |
|---|
| Existing systems are unable to cope with the changing landscapes of national immunization programme and as a result they experience:<br>• Stock-outs<br>• Potential administration of ineffective vaccines<br>• Avoidable wastage<br>• Expirees<br>• Inadequate cold-chain capacity<br>• Risk of poor product quality and counterfeiting |
| **Why Distributed Ledger Technology?** |
| The DLT solution will improve data capture by introducing automatic data capture through GS 1 data matrix codes and ibeacons. It will provide dashboards allowing stakeholders to see a country wide view of the stock levels. It will enable stakeholders to transact in a secure manner and offer consensus seamlessly to transactions they are required to with all stakeholders in the picture hence offering transparency. It will enable stakeholders in every process have the same data at the same time. It will enable immutability of records that concern vaccines from the time it comes to the |

country to the time its administered and hence every step is verifiable. It will enable stakeholders to accurately ensure potency of vaccines administered. It will offer guidance on redistribution of vaccines in cases of shortages.

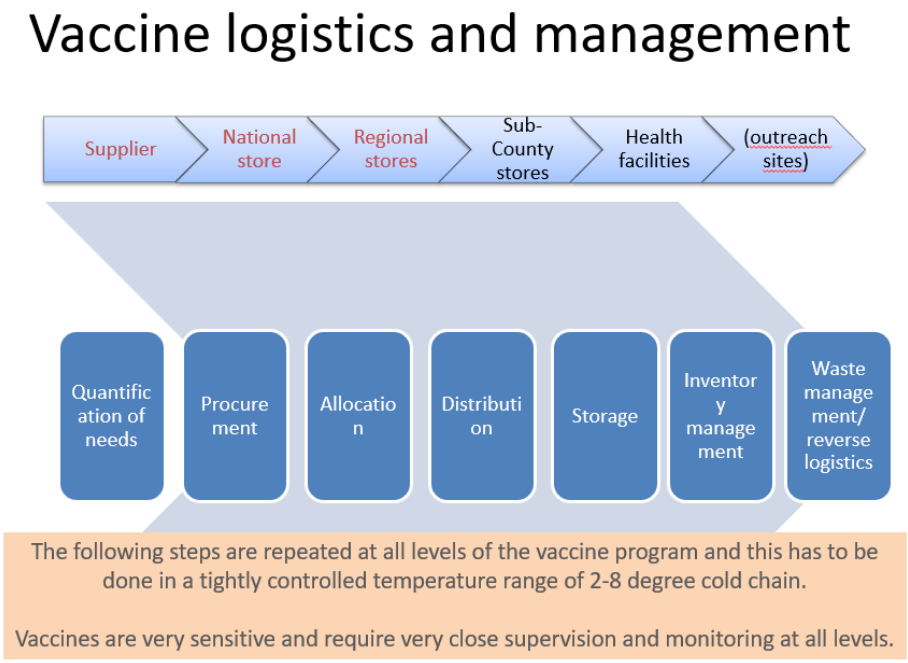
## Section 2: Current process without DLT

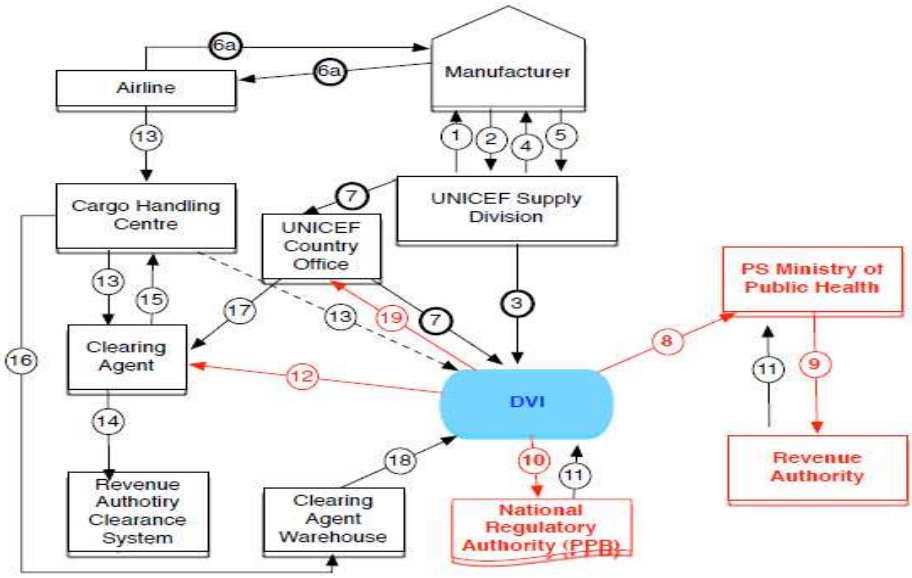
| **Current Solutions** |
|---|
| Chanjo system that is used for stock management. Manual registers for recording vaccine arrival and dispatch/distribution and administration. Fridge tags for temperature monitoring which have no real time streaming of data capabilities.<br>Existence of data in silos and untimely and/or unavailability of data along the supply chain. |

| **Existing Flow (as-is) Without DLT** | | |
|---|---|---|
| **Step** | **User Actions** | **System Actions** |
| 1. | Quantification of needs; concerned personnel fill the information on paper order sheets | In A few places they key in the the chanjo system. |
| 2. | Procurement: The NVIP head send the procurement order to UNICEF Supply division which sets in motion the arrival and clearance process once approved. This process is shown in process scheme | |
| 3. | Allocation: The National store allocates to Regional stores, Regional stores allocate to subcounty stores, which allocate to health facilities according to their needs, they fill in paper based vaccine order sheets | In few places this data is again filled in the chanjo system |
| 4. | Distribution; Transporters are engaged to distribute to the regional stores and subcounty stores and health facilities pick their supplies from the subcounty stores. | |

| Existing Flow (as-is) Without DLT | | |
|---|---|---|
| **Step** | **User Actions** | **System Actions** |
| 5. | Storage; Stringent SOPs have to be followed during storage and transportation at all levels. The temperatures has to be at acceptable ranges. Every store must record the vaccine details including conditions e.g temperature, wastages and FIFO rules must be followed. The recordings are done on paper-based forms | |
| 6. | Inventory management | A mix of electronic and manual registers is used for inventory management |
| 7. | Waste Management and Reverse Logistics: use paper.based forms to fill in the forms | |

**Process scheme (as-is)**




Source: NVIP, MoH Kenya

| Data and information (as-is) | | |
|---|---|---|
| **Data** | **Type** | **Description** |
| **1** | Vaccine order sheet | Paper- forms that contain number of doses requested for each vaccine type, quantities in stock, date, last order date, current date. In few centres Chanjo stock management system used |

| Data and information (as-is) | | |
|---|---|---|
| **Data** | **Type** | **Description** |
| **2** | Purchase order | Paper-based form that captures vaccine type, quantity of doses, price per unit |
| **3** | UNICEF shipment documents | Five Documents that accompany the shipment of vaccines that enable clearance of vaccines |
| **4** | Tax exemption Document | Paper. Based permit |
| **5** | Permit from the regulatory body | Paper-based permit |
| **6** | Vaccine Details | Antigen type, manufacturer, Batch Id, lot number, expiry date, Temperature |
| **7** | Vaccine arrival report | Filled form |

| Participants and their roles (as-is) | | |
|---|---|---|
| **Actor** | **Type/Role** | **Description** |
| **1** | NVIP head | Head of the entire immunization supply chain and administration of vaccines |
| **2** | National Logistician | Oversees the processes |
| **3** | UNICEF Country office | Receives the Vaccine arrival report |
| **4** | UNICEF Supply Division | Supplies the vaccines |
| **5** | Clearing agent | Handles clearance of vaccines from customs on behalf of NVIP |
| **6** | Airline | Transports the vaccines into the country |
| **7** | Customs | From where the vaccines are cleared |
| **8** | Store managers | Receive vaccines, store them, separate wastes from good and dispatch the vaccines and confirm potency |
| **9** | Health Workers | Administer the vaccines |
| **10** | Mothers and Children | Child is vaccinated |
| **11** | Distributors | Contracted to transport vaccines on behalf of NVIP |
| **12** | Cold chain equipment Technicians and engineers | Make sure the freezers, fridges, cold rooms and all cold chain equipment works well |

| Participants and their roles (as-is) | | |
|---|---|---|
| **Actor** | **Type/Role** | **Description** |
| **13** | National Regulatory Authority | Clears vaccines as safe to be administered in Kenya |
| **14** | Ministry of Health | Seeks tax exemption for vaccines from KRA |

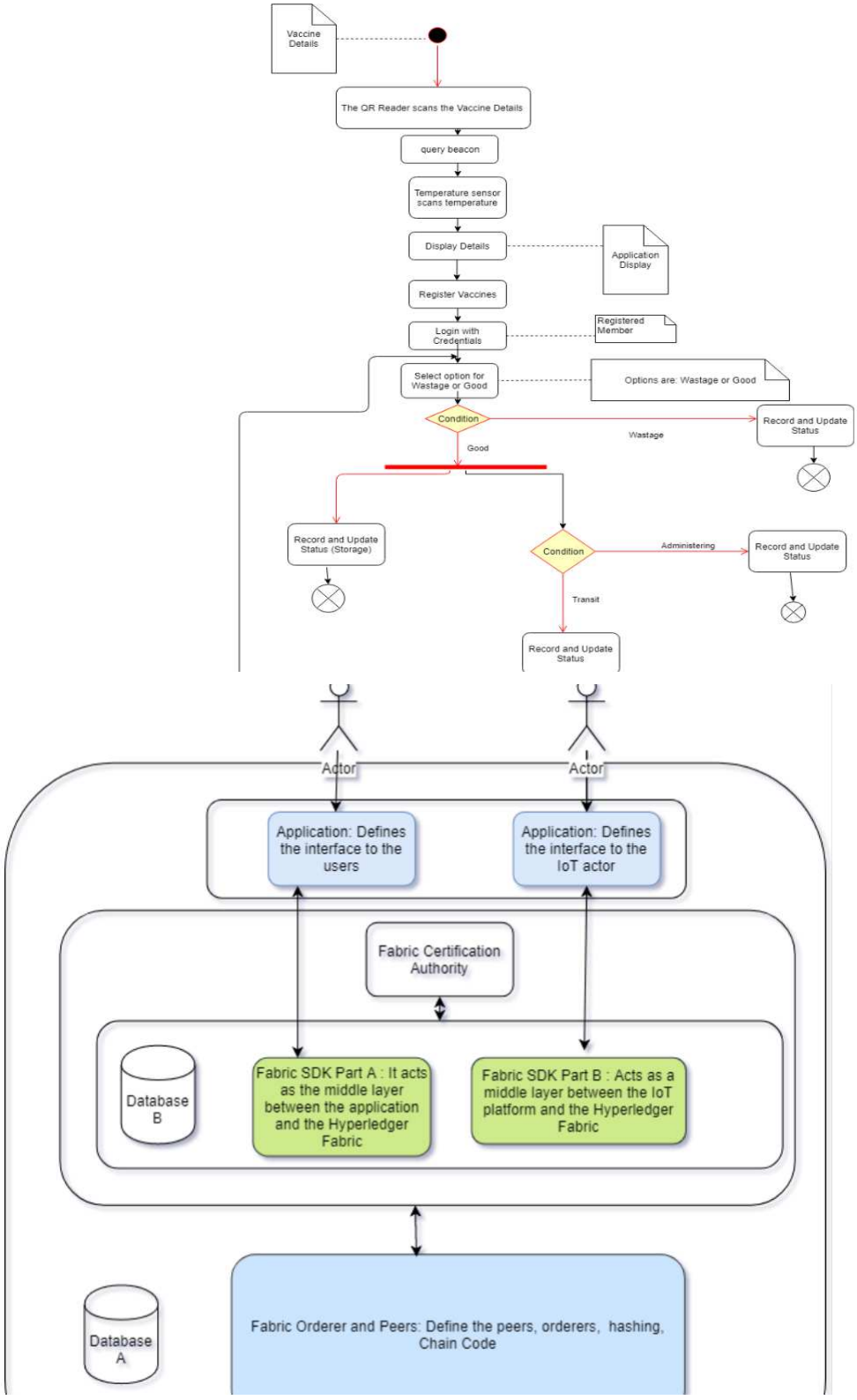
| Other Notes |
|---|
| *N/A* |

## Section 3: Expected process : VacTrace Blockchain Application (With DLT)

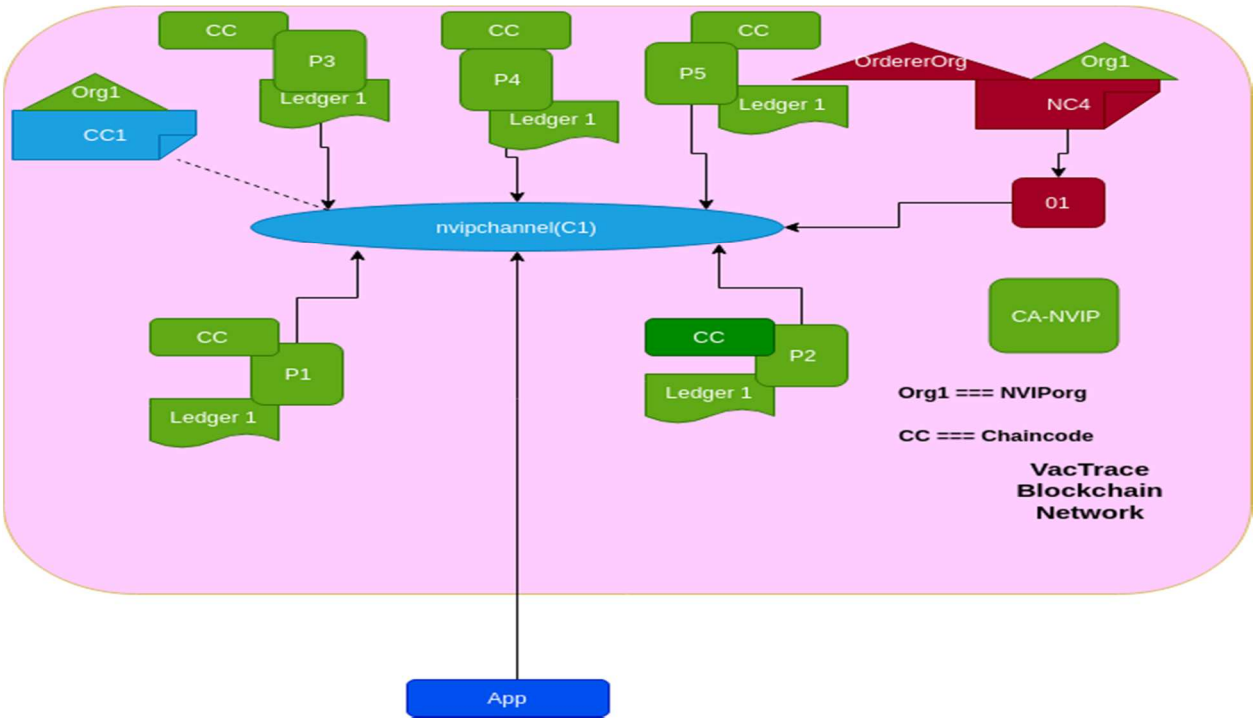
| Expected Flow (to-be) | | |
|---|---|---|
| **Step** | **User Actions** | **System Actions** |
| 1. | Quantification of needs: concerned persons key in the required data into the system | Calculates target population, calculate minimum and maximum doses, get stock available, estimate vaccines needed and generate vaccine order sheet, Submits data into a database, the system submits the data on the blockchain channel for quantification of needs, the concerned participants are prompted by the system for confirmation to reach consensus and the block of data is added on the chain. |
| 2. | Procurement: Fill requestor details, input delivery instructions, fill donor details | Generates procurement order, submits to UNICEF, all participants on the procurement channel give consensus to the data and transactions involved and the block is appended to the chain. |
| 3. | Primary store officer receive arrival dates notification, upload pre-shipment documents,receive pre-shipment documents, sent permit request to National Regulatory board, Tax exemption request sent to MoH, | System sends assets in terms of messages and acknowledgements of receipt. It gets and sends pre-shipment documents, permit and tax exemption signed for authentication by the senders and acknowledge messages send for receipt. The transaction after consensus is appended to the blockchain. |

| Expected Flow (to-be) | | |
|---|---|---|
| **Step** | **User Actions** | **System Actions** |
| 4. | Primary store officers receive, record vaccines. Separate the good and bad vaccines and update in database<br>Fill the Vaccine arrival report | Scanner used to update the database of vaccines that arrive. The data matrix form in the system provides a new holder for arrival temperature.<br>ibeacons with temperature sensors in place to read the temperature of vaccines in storage into the system<br>database updated<br>generate the vaccine Arrival Report and submit to UNICEF Country office. The participants in the clearance channel of the blockchain provide consensus to the data and block is appended |
| 5. | Store officers at all levels Arrange vaccines on shelfs following FIFO principles | Location ibeacons deployed on each shelf and continuously broadcasting the temperature of vaccines and their details on each shelf. Gateway in place and sends that to the cloud and application. The real time temperature monitoring participants have access to same data and consent and block is appended after agreed time frame |
| 6. | Distribution; Dispatch done according to set SOPs. Use scanners to confirm those dispatched. Ibeacons and gateway are placed in the vehicles | The database updates . the vehicles transmit location, vaccine details and temperature conditions to the transit channel, participants in the channel consent and block added to the block. |
| 7 | Administering vaccine to the children. Use scanners to update database. Update data matrix on the mother child card/book | Append the transaction on the administer channel |

## Process scheme (to-be)



**VacTrace Network Structure**




**Peer Organization**

i) Name: NVIPorg (Org1)

ii) Ledger 1

iii) Nvipchannel

iv) 5 Peers nodes (P1,P2,P3, P4,P5)

**Orderer Organization**

The Ordering service serves as the network administration point for the VacTrace network and uses the system channel

i) Name: OrdererOrg

ii) Solo Orderer for the testing

iii) System channel(genesis.block)

iv) The ordering service also supports dashboard nvipchannel linked to a Vactrace client application, for transaction ordering into blocks for distribution

**Fabric Certificate Authority**

For NVIPorg, there is one **Certificate Authority (CA-NVIP).** Certificates issued by CAs are at the core of the transaction generation or validation process. For instance, X.509 certificates are used in client application transaction proposal and smart contract transaction responses to sign the transactions digitally. Certificates issued are used to ***sign transactions*** to show that NVIPorg organization endorses the transaction result – a pre-condition of it being accepted onto the ledger (Ledger1). Different components of the VacTrace Blockchain network use certificates to classify themselves to each other as being from a specific organization. The mapping of certificates to the member organizations is realized by via a structure called a **Membership Service provider (MSP).**

**CA-NVIP**

The vacTrace network is a resource, accessed by a **set of users** defined by a Certificate Authority **CA-NVIP**, who have a set of rights over the resources in the vaccine safety network as defined by policies contained inside a network configuration **CA-NVIP**. This is made real when the ordering service node is constituted and started. **CA-NVIP** plays a crucial role in the VacTrace network because it dispenses **X.509 certificates** that can be used to identify participants or nodes as belonging to organization OrdererOrg. Network configuration **CA-NVIP** uses a named MSP to identify the properties of certificates dispensed by **CA-NVIP** which associate certificate holders with organization NVIPorg. The **Network Configuration (NC)** can then use this **MSP** name in policies

to grant actors from NVIPorg special rights over network components. An instance of such a policy is to find the administrators in NVIPorg who can add new member organizations to the network.

**Network Configurations and Channel Configurations**

1) Network Configuration **NC** - The VacTrace network is governed according to policy rules specified in network configuration, the network is under the control of organizations **NVIPorg** and **OrdererOrg**.
2) Channel Configuration (C1) with the name; **nvipchannel,** is governed according to the policy rules specified in channel configuration; the channel is under the control of peer organization NVIPorg only.

In VacTrace Network, the ordering service comprises of a single node, **O1**, which is configured according to a network configuration (**NC**), which gives administrative rights to the orderer organization (OrdererOrg). At the network level, Certificate Authority CA-NVIP is used to **dispense identities** to the administrators and network nodes of the OrdererOrg organization.

The Orderer node is initially configured and started by an administrator in organization NVIPorg and hosted in ordererOrg. The configuration **NC** contains the policies that describe the starting set of administrative capabilities for the network. Initially, this is set to only give ordererOrg rights over the network. In the configuration file, the ordererOrg is the first member of the network. The Orderer node is initially configured and started by an administrator in organization NVIPorg and hosted in ordererOrg. The configuration **NC** contains the policies that describe the starting set of administrative capabilities for the network. Initially, this is set to only give ordererOrg rights over the network. In the configuration file , the ordererOrg is the first member of the network.

**Adding a Network Admin from NVIPorg**

NC is initially configured only to allow ordererOrg users administrative rights over the VacTrace network. An admin from NVIPorg should have similar privileges over the VacTrace network. This

means that the ordererOrg through its root admin should update the network configuration to make the peer organization (NVIPorg) an administrator too. In this way, even though ordererOrg is running the ordering service, and NVIPorg has full administrative rights over it. Ordering services are usually **multi-node**, and can be configured to have different nodes in different organizations. For example, we might run O1 in ordererOrg and connect it to another O2. This way, the VacTrace Network would have a **multi-site structure**.

**Defining a Consortium**

A consortium defines the set of participants in the network who share a necessity to transact with one another – in this case, peer members of NVIPorg. A network administrator from either NVIPorg or ordererOrg defines a consortium NVIPConsortium only contains the organization NVIPorg for now. This consortium definition is stored in the VacTrace network configuration NC. We use consortium NVIPConsortium to create an essential part of a Hyperledger Fabric blockchain a channel.

**VacTrace Blockchain APP**

**Peers and Ledgers**

Peer nodes are the network components where copies of the blockchain ledger are hosted. A peer node P1, P2, P3, P4 and P5 can join the channel C1. Peers physically hosts a copy of the ledger L1. Peer nodes and Orderer nodes can communicate with each other using nvipchannel. P1's purpose in the network is purely to host a copy of the ledger L1 for other participants to access. We can think of L1 as being physically hosted on peers but Logically hosted on the nvipchannel. A key part of a peers configuration is an X.509 identity issued by Certificate Authority which associates peers with NVIPorg organization.

Once peer nodes are started, it can **join channel** the **nvipchannel using** the Orderer O1. When O1 receives this join request, it uses the channel configuration **nvipchannel** to determine P1's permissions on this channel. For instance, **nvipchannel** determines whether peers can read and write information to the ledger L1. Once channel **nvipchannel has a ledger on it**, we can start connecting

**client applications** (back-end or Front end) to consume some of the services provided by workhorse of the ledger, **the peers**.

**Chaincode**

**ChainCode (CC)** can be installed onto **the peers.** VacTrace client application in organization NVIPorg can use **CC** the to access the ledger via peer nodes P1, P2,P3, P4, and P5. The VacTrace client application, peer nodes and the orderer node are all joined to the nvipchannel, i.e., they can all make use of the communication facilities provided by that channel.In this case, VacTrace client application can connect to the peer nodes and the orderer node.

NB: In thiscase, VacTrace client application is associated with organization NVIPorg; and although it is outside the Fabric blockchain network, it is connected to it via the ***nvipchannel***. All VacTrace client application access is managed via the Chaincode. For now, the critical thing to understand is that to get to this point two operations must have been performed on the Chaincode; it must have been **installed in Peers** and then **instantiated in*nvipchannel*** using **Peers** by **an** administrator in organization NVIPorg.

Specifically, Peers can see the **implementation logic** of **a** Chaincode – the program code that it uses to access the ledger L1. After instantiation, **every component** on ***nvipchannel*** is aware of the existence of the Chaincode but it is not able to see its program logic. Chaincode can now be invoked by vacTrace client application **application.** The most important piece of additional information supplied at instantiation is an **endorsement policy** that describes which organizations must approve transactions before they are accepted by other organizations onto their copy of the ledger. In our *VacTrace Network*, transactions can be only be accepted onto ledger L1 if NVIPorg endorses them. The act of instantiation places the endorsement policy in **channel configuration** ***nvipchannel***; it enables it to be accessed by any member of the channel.

**NB:** We contrast this to the Chaincode **interface,** which only describes the inputs and outputs of **CC** Chaincode, without regard to its implementation. Also, when an organization has **multiple**

**peers in a channel**, it can choose the peers upon which it installs ChainCodes; it **does not** need to install a ChainCode on every peer.

Once a chaincode has been installed on a peer node and instantiated on a channel, it can be **invoked** by a VacTrace client application.

**Summary.**

Conclusively, NVIPorg and the VacTrace client application can access the ledger L1 through **CC** Chaincode, to generate transactions that will be permitted by NVIPorg, and therefore **accepted onto the ledger** because they conform to the endorsement policy. **The VacTrace Network** grows through the addition of infrastructure from organization NVIPorg. Specifically, NVIPorg has peer node P1, P2, P3, P4 and P5, where each peer host a copy of ledger L1 and Chaincodes. The five peers Join the ***nvipchannel***, which has the VacTrace client application. VacTrace client application are identified using certificates from CA-NVIP. All of this means that the VacTrace client application invoke the **CC** Chaincode on ***nvipchannel*** either using peer node P1, P2, P3, P4 and P5.

| **Participants and their roles** | | |
|---|---|---|
| **Actor** | **Type/Role** | **Description** |
| **1** | IoT actor | GS 1 Data matrix, location ibeacon, temperature ibeacon, gateway, smart phones |
| **2** | Human actor | As-is in above table |

| **Data and information** | | |
|---|---|---|
| **Data** | **Type** | **Description** |
| **1** | Vaccine details scanned | Digital identifier,Digital twin of the antigen |
| **2** | Assets transferred | Information, messages and approvals |
| **3** | Real time Temperature readings | ibeacons write to the blocks directly |
| **4** | Location readings | Ibeacons in stores transmit location data/ibeacons on transit transmit location data to the block |

| **Security and privacy** |
| --- |
| Achieved by the CA as shown in the process scheme |

| **Main Success Scenario + expected time line** |
| --- |
| Prototype scheduled to be complete in April 2019 |

| **Conditions (pre- or post-)** |
| --- |
| Post; to be scaled up for the entire country Pre; adopted in the NVIP strategic plan |

| **Performance needs** |
| --- |
| At any instance of time a child is being vaccinated in the country. Interoperability achieved via permissioning |

| **Legal considerations** |
| --- |
| 1. Need for standardization of the blockchain and Distributed Ledger Technology<br>2. Learning Institutions to be deliberate in incorporating DLT education into curiculum |

| **Risks** |
| --- |
| It would be privacy issues, but the very nature of the architecture that is permissioned, the risk is mitigated |

| **Special Requirements** |
| --- |
| Training of staff and establishment of data centers and definite platform that integrates smoothly the IoT module, Blockchain and data analytis |

| **External References and Miscellaneous** |
| --- |
| Use GS 1, Provenance Data Model, Hyperledger Fabric, Cloud services |

| **Other Notes** |
| --- |
| *N/A* |

# Drugs Distribution Ledger

## Section 1 Summary

| Use Case Summary | | | |
|---|---|---|---|
| **Use Case ID:** | HLC-003 | **Use Case Type:** | Vertical |
| **Submission Date:** | May 28, 2018 | **Is Use Case supporting SDGs** | No |
| **Use Case Title:** | Drugs Distribution Ledger | **Domain:** | Healthcare |
| **Status of Case** | PoC | **Sub-Domain** | Medicine |
| **Contact information of person submitting/ managing the use-case** | *Full Name* Vadim Likholetov *Job Title CTO*<br>*E-mail address:* vadikas@setere.com *Telephone number:*+7-921-417-99-55<br>*Social media: none* *Web site: http://www.setere.com* | | |
| **Proposing Organization** | *Limited Liability Company "Tech Medical Group", INN 7841019901* | | |
| **Short Description** | Drug distribution ledger based on DLT can make the distribution process trustworthy and transparent. | | |
| **Long description** | Main conditions of success scenario:<br>• All the medical centers and pharmacies are connected to DDL<br>• Patients can get treatment reports via the internet<br>• All the necessary drugs distribution reports are being provided by DDL<br>The implementation of DLT solution, which allows tracking medical treatments and provides the necessary reports can reduce paperwork and increase common efficiency. | | |
| **SDG in Focus (when applicable)** | NA | | |
| **Value Transfer:** | No value transfer | **Number of Users:** | 1000+ |
| **Types of Users:** | Medical centers, Patients, Federal and Local Government (as auditors) | | |
| **Stakeholders** | Medical centers, Patients, Federal and Local Government | | |
| **Data:** | Information about treatment sheets, prescriptions and associated with them drugs distribution should be stored in DLT. | | |
| **Identification:** | Identification for inserting data to DLT is required. Reports can be provided to anonymous users depending on report type. | | |
| **Predicted Outcomes:** | Implementation of open DLT for collecting transactions connected with drugs distribution processes will provide transparency of the process. Also every patient can get possibility of tracking their treatment. | | |

| **Overview of the Business Problem or Opportunity** |
|---|

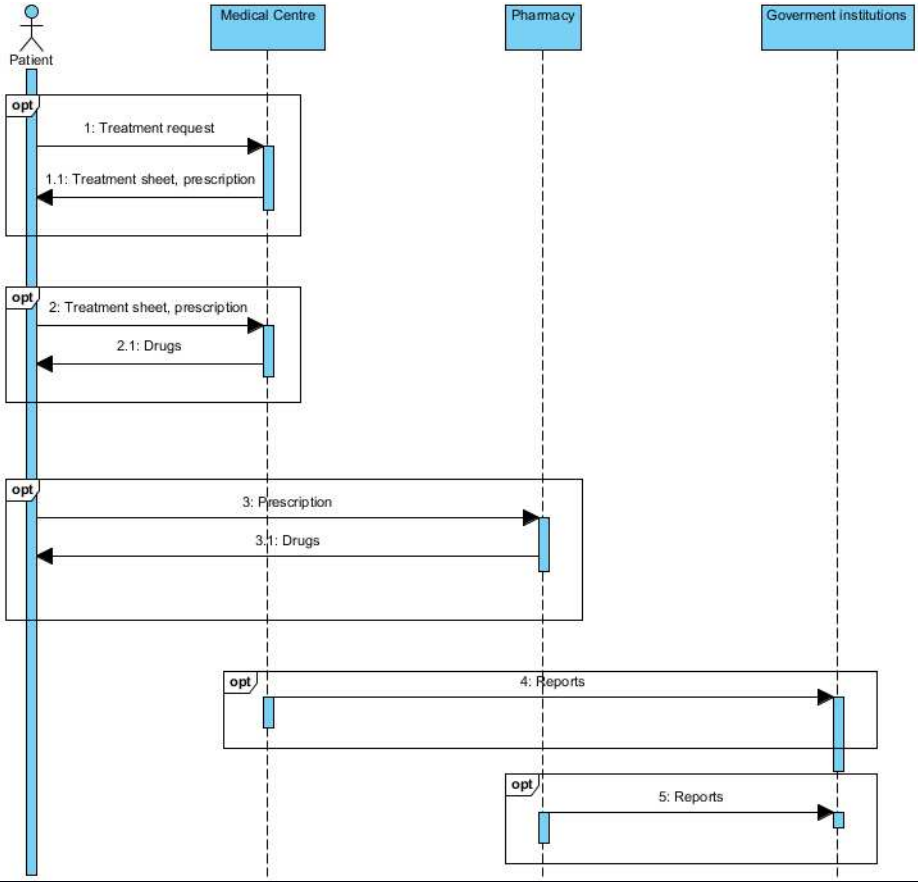
| |
|---|
| There is no information system for collecting all the treatment sheets, prescriptions and connected with them drugs distribution. Every medical centre makes own reports and then send it to government institutions. Patients cannot track their treatment. |
| **Why Distributed Ledger Technology?** |
| The Blockchain and smart-contracts make this process trustworthy and transparent. The implementation of DLT solution, which allows tracking medical treatments and provides the necessary reports can reduce paperwork and increase common efficiency. |

## Section 2 Current process

| **Current Solutions** |
|---|
| Medical centres have local Medical Information systems (issuing treatment sheets and prescriptions). Pharmacies have local Drugs distribution systems. Patients cannot track medical treatment. The necessary reports are being provided separately by every organization. |

| **Existing Flow (as-is)** | | |
|---|---|---|
| **Step** | **User Actions** | **System Actions** |
| 1. | Medical Centre issues treatment sheet or prescription | n/a |
| 2. | Patient get treatment or drugs according the treatment sheet or prescription | n/a |
| 3. | Medical Centre or Pharmacy creates report | n/a |

**Process scheme (as-is)**



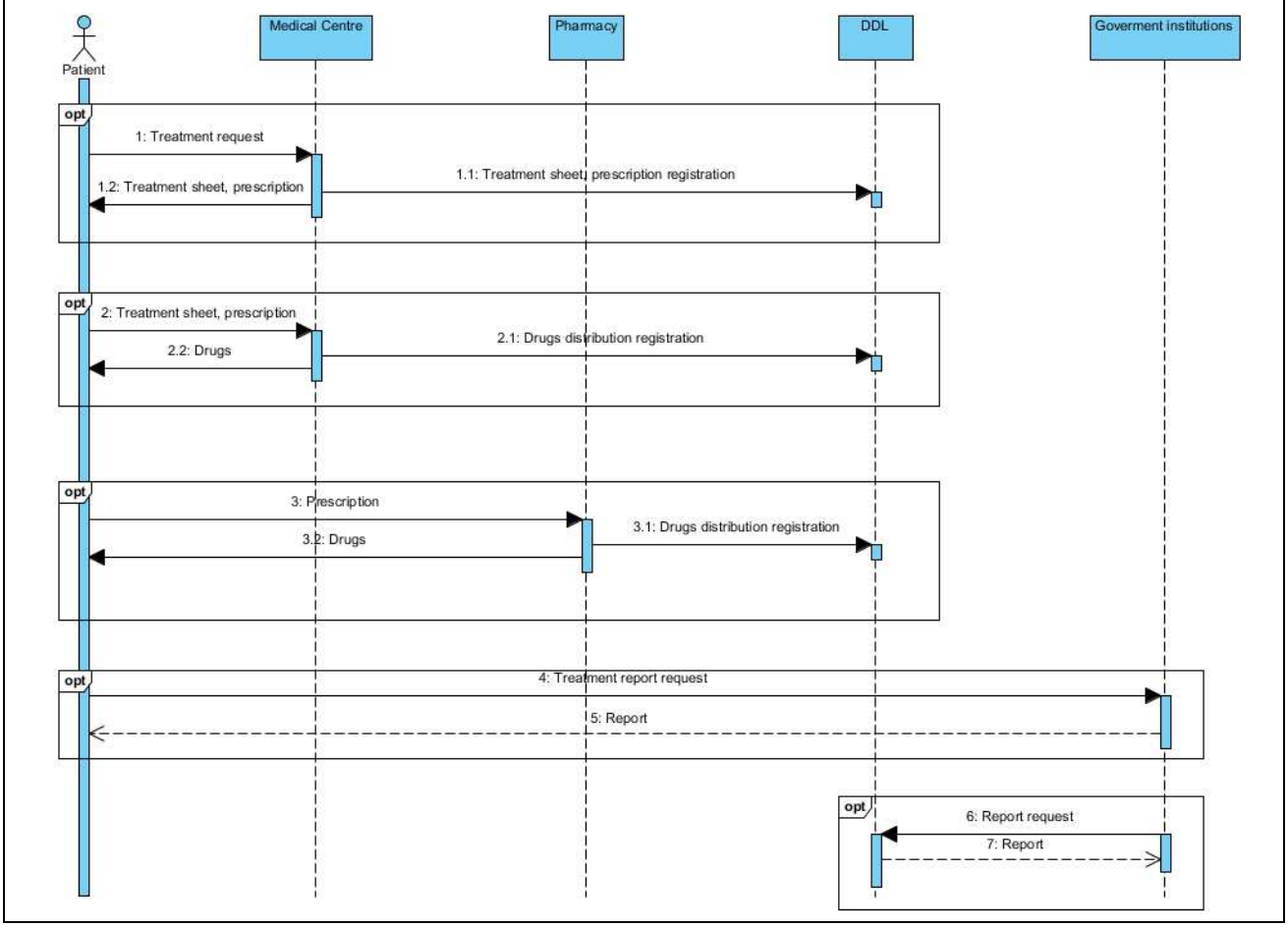

| Data and information (as-is) | | |
|---|---|---|
| **Data** | **Type** | **Description** |
| **1** | Treatment sheet | List of medication and medical procedures |
| **2** | Prescription | List of medication |
| **3** | Report | Reports of Medical Centers and Pharmacies |

| Participants and their roles (as-is) | | |
|---|---|---|
| **Actor** | **Type/Role** | **Description** |
| **1** | Medical Centre | State or private medical centre |
| **2** | Pharmacy | State or private pharmacy |
| **3** | Patient | Client of medical center or pharmacy |
| **4** | Government Institution | Regulatory or audit functions |

## Section 3 Expected process

| Expected Flow (to-be) | | |
|---|---|---|
| **Step** | **User Actions** | **System Actions** |
| 1. | Medical Centre issues treatment sheet or prescription | Registration the treatment sheet or the prescription in DDL(DLT) |
| 2. | Patient get treatment or drugs according the treatment sheet or prescription | Registration the drugs distribution event in DDL(DLT) |
| 3. | Patient get a treatment report | DDL(DLT) provides the treatment report |
| 4. | Governmental Institution get drugs distribution report | DDL(DLT) provides the drugs distribution report |

**Process scheme (to-be)**




| Participants and their roles | | |
|---|---|---|
| **Actor** | **Type/Role** | **Description** |
| **1** | Medical Centre | State or private medical centre |

| Participants and their roles | | |
|---|---|---|
| **Actor** | **Type/Role** | **Description** |
| **2** | Pharmacy | State or private pharmacy |
| **3** | Patient | Client of medical center or pharmacy |
| **4** | Government Institution | Regulatory or audit functions |

| Data and information | | |
|---|---|---|
| **Data** | **Type** | **Description** |
| **1** | Treatment sheet | List of medication and medical procedures |
| **2** | Prescription | List of medication |
| | Treatment Report | Report for Patient |
| | Drugs Distribution Report | Report for Government Institution |

| Security and privacy |
|---|
| Identification for inserting data to DLT is required. Reports can be provided to anonymous users depending on report type. |

| Main Success Scenario |
|---|
| 1. All the medical centers and pharmacies are connected to DDL<br>2. Patients can get treatment reports via the internet<br>3. All the necessary drugs distribution reports are being provided by DDL |

| Conditions (pre- or post-) |
|---|
| 1. All the local information systems can interact with DDL<br>2. All the transactions needed for DDL correct working are being posted by connected information system |

| Performance needs |
|---|
| Communication channel capacity |

| Legal considerations |
|---|
| *1.* |

| Risks |
|---|

| |
|---|
| Legal risks (possibility to avoid connection of a information systems to DDL) |

| **Special Requirements** |
|---|
| |

| **External References and Miscellaneous** |
|---|
| |

| **Other Notes** |
|---|
| |

## Appendix 1

## Domains for use cases categorization

**Vertical**:

1. Finance
    a. Financial management & accounting
    b. International & interbank payments
    c. Clearing and settlement
    d. Reduction of Fraud
    e. Financial messaging
    f. Asset lifecycles and history
    g. Trade finance
    h. Regulatory compliance & audit
    i. AML/KYC
    j. Insurance
    k. Peer-to-peer transactions
2. Healthcare
    a. Pharma
    b. Biotechnology
    c. Medicine
3. Industries
    a. Manufacturing
    b. Energy
    c. Chemical
    d. Retail
    e. Real estate
    f. IT and telco
    g. Supply chain management
    h. Transportation and logistic
4. Government and public sector
    a. Taxes
    b. Government and non-profit transparency
    c. Legislation, compliance & regulatory oversight
    d. Voting
    e. Taxation and customs
    f. Intellectual property management

**Horizontal**:

1. Identity Management
2. Security Management
    a. Public Key Infrastructure
3. Internet of Things
4. Data storage (Inter-organizational data management)

# LifeBlocs - Bone Marrow, Blood, and Organ Donation

## Section 1: Summary

| Use Case Summary | | | |
|---|---|---|---|
| **Use Case ID:** | HLC-005 | **Use Case Type:** | Vertical |
| **Submission Date:** | January 3, 2019 | **Is Use Case supporting SDGs** | Yes |
| **Use Case Title:** | LifeBlocs | **Domain:** | Healthcare |
| **Status of Case** | PoC | **Sub-Domain** | Bone marrow, blood, and organ donation |
| **Contact information of person submitting/ managing the use-case** | *Full Name:*<br>Cathy Chen<br><br>*E-mail address:*<br>cathy.chen@lifeblocs.com<br>*Social media:*<br>N/A | *Job Title:*<br>Co-Founder & CMO & Head of Government Relations<br>*Telephone number:*<br>+1 805 304 5849<br>*Web site:*<br>www.lifeblocs.com | |
| **Proposing Organization** | LifeBlocs | | |
| **Short Description** | LifeBlocs endeavors to reinvent the donation value chain for bone marrow, blood, and organs globally by utilizing the blockchain technology. In doing so, it aims to reduce the number of lives lost as a result of inefficiencies in the donation and matching processes. Moreover, LifeBlocs strives to increase the number of donations amongst the population.<br><br>Our first use case and current primary focus is bone marrow data storage and matching. | | |
| **Long description** | LifeBlocs is a start-up that aims to increase blood, bone marrow, and organ donations, and optimize the matching process between donors and receivers. Powered by the Ethereum blockchain, LifeBlocs hopes to optimize supply chain efficiency by equipping each actor in the donation supply chain with a data storage and matching process, from donors and donor organizations to hospitals and patients. It hopes to give patients their much-needed access to healthcare essentials by offering a secure data storage and higher rate of match compatibility, thereby enabling timely availability of life-saving material.<br><br>In executing its mission, LifeBlocs aims to save human lives by providing the following solutions:<br>1. An easy-to-integrate, decentralized data storage and matching platform that enables greater access for patients, and fosters collaboration between organizations and nations;<br>2. An incentive system that rewards blood and bone marrow donors through a non-monetary incentive, and through which donors can visualize the impact of their donation; | | |

| | | | |
|---|---|---|---|
| | 3. Spreading awareness and increasing the participation of donors worldwide.<br><br>Finally, through the implementation of LifeBlocs' system in multiple smart cities and the learnings gathered in this process, it also plans to provide its system in countries where existing donor systems do not exist. | | |
| **SDG in Focus (when applicable)** | SDG 3, indicator 3.8.<br>LifeBlocs aligns with SDG 3, indicator 3.8, in that it seeks to achieve universal access to a quality essential healthcare services and access to safe, effective, quality and affordable essential bone marrow, blood, and organs for all. | | |
| **Value Transfer:** | LifeBlocs will not generate a token or an asset for transactions on the blockchain. | **Number of Users:** | N/A |
| **Types of Users:** | Donors, Donor organizations, Hospitals | | |
| **Stakeholders** | Individual donors, donor organizations, hospitals, patients. | | |
| **Data:** | ***What data are expected to be stored in distributed ledger in terms of types, record structure, privacy, etc.***<br>- The method of storage can be adjusted to comply with specific countries' privacy and health data storage laws. Outlined below is a general description of the default structure.<br>PII (Personally Identifiable Information)<br>- PII will be stored separately on a conventional, secure database.<br>Medical Data<br>- Medical Data, specifically HLA (Human-Leukocyte Antigen) types, will be stored on IPFS (Inter-Planetary File System).<br>Links to PII and Medical Data<br>- The links that provide access to the two sub-sets of data will be stored on the blockchain. Given increased computing power and storage capacity prove to be quite expensive on the blockchain, we aim to utilize blockchain as the technology for the facilitation of storage and matching of health data.<br>***How DLT solution would interact with external data and other systems.***<br>- The DLT solution interacts with bone marrow registries, IPFS (Inter-Planetary File System), and a conventional, secure database. The DLT stores the separate links to the PII and the Medical data and facilitates cross-border matching. | | |
| **Identification:** | When bone marrow registries register new donors, PII and HLA lab results are stored. Bone marrow registries only have access to the PII of individuals that they have registered themselves. | | |
| **Predicted Outcomes:** | Donors:<br>Individual donors will be able to visualize their individual impact as the LifeBlocs system provides a transparent and up-to-date overview of where | | |

| | |
|---|---|
| | their donation has been located along the supply chain. Moreover, those who are not donors yet will be encouraged to donate through the non-monetary incentive system.<br><br>Donor organizations:<br>Organizations that manage donations along the supply chain will become visible and traceable. Furthermore, the data storage and matching process will become more secure.<br><br>Hospitals:<br>Hospitals will benefit from increased success rates of match compatibility, and face lower administrative costs as a result of the system.<br><br>Patients:<br>Personal and health data will be stored securely on the system, and patients will have timely availability of life-saving material. |

**Overview of the Business Problem or Opportunity**

- Technological advancements are lacking in the current tissue and organ donation systems, and lives are lost as a result of inefficiencies in the value chain. As of today, major issues prevent universal access to essential blood, bone marrow, and organs for patients. For example, issues include individuals that are not incentivized to donate, donation registries that are not integrated seamlessly, and large, centralized players in the donor value chain that prevent transparency and traceability.

**Why Distributed Ledger Technology?**

- DLT will seamlessly integrate data siloes across countries without centralizing and harbouring all data in one centralized location. This is essential as many bone marrow registries would be hesitant to share and centralize all of their data into one location. Each of the features listed above (immutability, security, verifiability, transparency) are valuable for our use case of blockchain. For example, having a verifiable source of truth for tracking blood transfusions can be invaluable in countries such as India where, in the past 10 years, 20,000 cases of HIV transmission from blood transfusions have occurred.

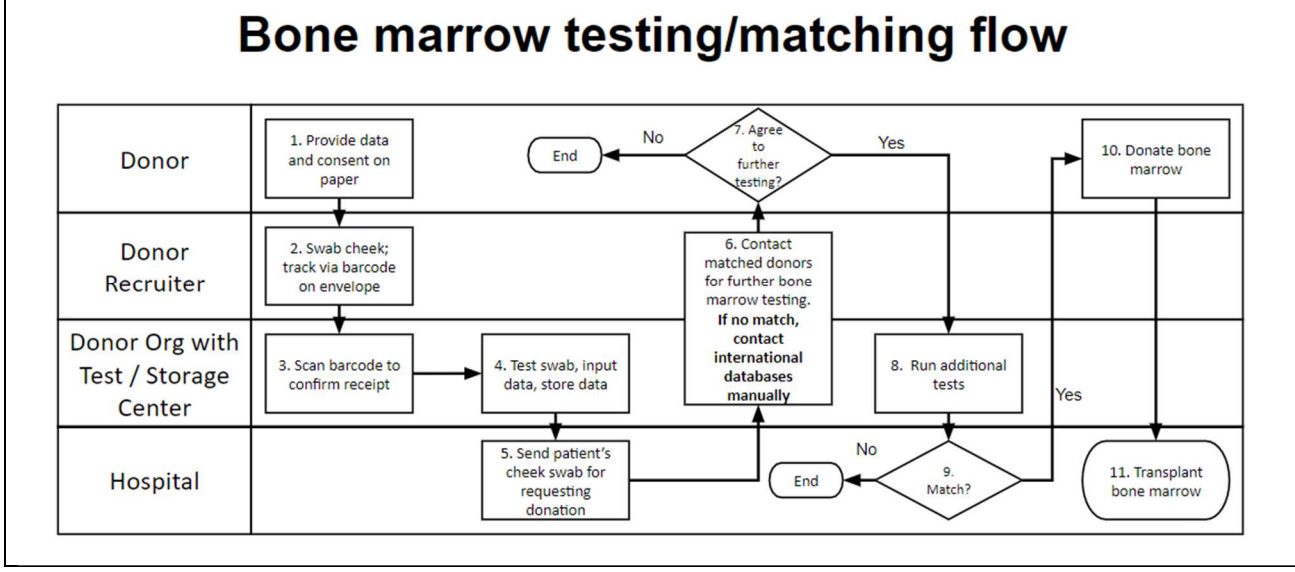
## Section 2: Current process

**Current Solutions**

- World Marrow Donor Association currently utilizes a centralized server for matching internationally. DKMS has set up offices in multiple different countries. Neither of these organizations/systems have decentralized/distributed databases. Although, both strive to develop as large of a database as possible.
- Aside from the issue of having siloed data, the administrative processes for registering donors is quite inefficient. Many organizations still use manual paper registration without immediate electronic data or consent storage.

| Existing Flow (as-is) | | |
|---|---|---|
| **Step** | **User Actions** | **System Actions** |
| 1. | Donor elects to sign up as donor (fills out paperwork manually) and provides DNA sample | |
| 2. | Donor recruiter swabs cheek and sends sample via envelope mail with barcode | |
| 3. | Donor organization lab scans barcode to confirm receipt | System logs receipt |
| 4. | Lab conducts tests and inputs data | System stores lab results |
| 5. | Hospital send DNA sample of patient | |
| 5.1 | Repeat Step #4 for patient | System stores lab results |
| 6. | Match patient data against donor database, if no match, manually contact international databases | System matches patient data against database |
| 7. | If there is a match, does the potential donor agree to further testing? | |
| 8. | If so, donor provides blood and doctor runs additional tests | |
| 9. | If additional tests prove positive, donor is eligible to donate | |

**Process scheme (as-is)**




| Data and information (as-is) | | |
|---|---|---|
| **Data** | **Type** | **Description** |
| **1** | *PII Data* | Personally Identifiable Information such as name, email, phone number, address, ethnicity, country, etc. |

| Data and information (as-is) | | |
|---|---|---|
| **Data** | **Type** | **Description** |
| **2** | *Medical Data* | Human Leukocyte Antigen genotypes |
| **3** | *Other Medical Data* | Not currently designed into the bone marrow use case, but for the blood and organs use cases, additional medical data will be necessary such as height, weight, age, sex, sexual orientation/history, recently traveled countries, etc |

| Participants and their roles (as-is) | | |
|---|---|---|
| **Actor** | **Type/Role** | **Description** |
| **1** | *Donor* | Individual that is willing to donate bone marrow or peripheral blood stem cells (PBSC) to save a patient's life |
| **2** | *Donor recruiter* | Organizations that focus on increasing the number of donors by running bone marrow drives and facilitates the spread of education and knowledge |
| **3** | *Donor organization / test center / storage center* | Organizations that consolidate donors' information to build a database of potential donors |
| **4** | *Hospital* | Provides cheek swab of patient in need of bone marrow transplant |

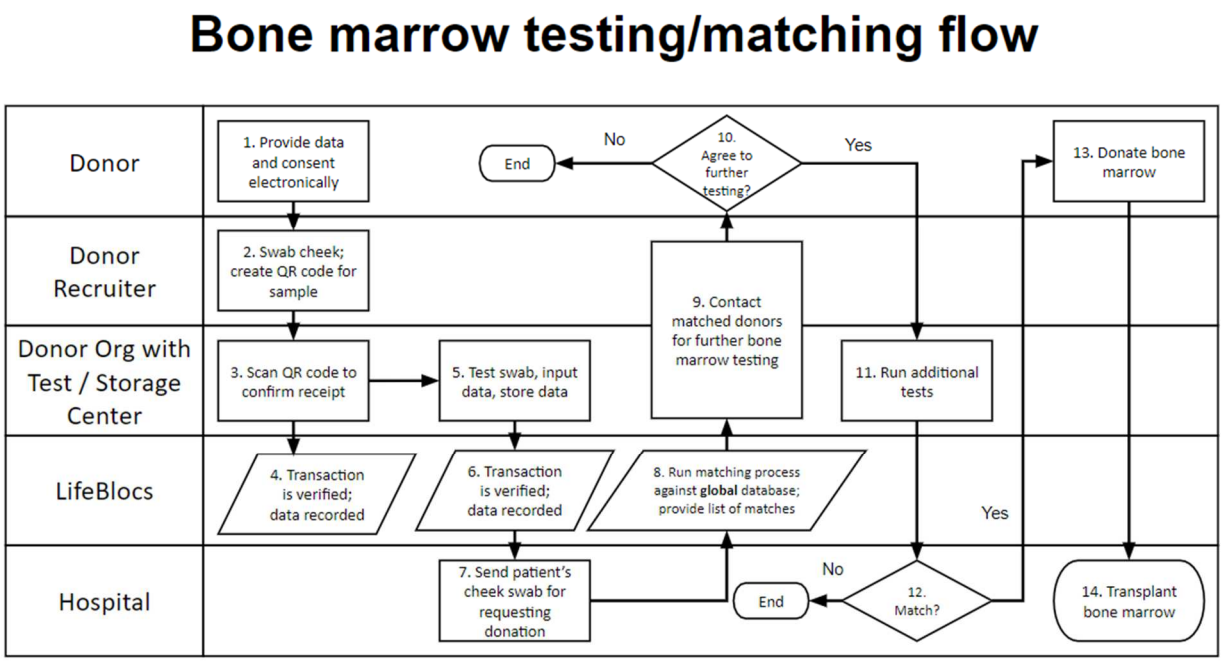
| Other Notes |
|---|
| - *N/A* |

## Section 3: Expected process

| Expected Flow (to-be) | | |
|---|---|---|
| **Step** | **User Actions** | **System Actions** |
| 1. | Donor elects to sign up as donor (provides necessary information electronically) and provides DNA sample | |
| 2. | Donor recruiter swabs cheek and sends sample via envelope mail with QR code | System logs sending of cheek swab with a PII link generated stored on secure database |
| 3. | Donor organization lab scans QR code to confirm receipt | System logs receipt |
| 4. | Lab conducts tests and inputs data | System stores lab results to Inter-Planetary File System (IPFS) |

| Expected Flow (to-be) | | |
|---|---|---|
| **Step** | **User Actions** | **System Actions** |
| 5. | Hospital scans QR code and sends DNA sample of patient | System logs sending of cheek swab with a PII link generated stored on secure database |
| 5.1 | Repeat Step #4 for patient | System stores lab results to Inter-Planetary File System (IPFS) |
| 6. | Match patient data against global donor database | System matches patient data globally |
| 7. | If there is a match, does the potential donor agree to further testing? | |
| 8. | If so, donor provides blood and doctor runs additional tests | |
| 9. | If additional tests prove positive, donor is eligible to donate | |

**Process scheme (to-be)**




| Participants and their roles | | |
|---|---|---|
| **Actor** | **Type/Role** | **Description** |
| **1** | *Donor* | Individual that is willing to donate bone marrow or peripheral blood stem cells (PBSC) to save a patient's life |

| **Participants and their roles** | | |
|---|---|---|
| **Actor** | **Type/Role** | **Description** |
| **2** | *Donor recruiter* | Organizations that focus on increasing the number of donors by running bone marrow drives and facilitates the spread of education and knowledge |
| **3** | *Donor organization / test center / storage center* | Organizations that consolidate donors' information to build a database of potential donors |
| **4** | *Hospital* | Provides cheek swab of patient in need of bone marrow transplant |
| **5** | *LifeBlocs* | Provides participant #3 with a system that allows a more seamless solution for searching for bone marrow matches globally |

| **Data and information** | | |
|---|---|---|
| **Data** | **Type** | **Description** |
| **1** | *PII Data* | Personally Identifiable Information such as name, email, phone number, address, ethnicity, country, etc. |
| **2** | *Medical Data* | Human Leukocyte Antigen genotypes |
| **3** | *Other Medical Data* | Not currently designed into the bone marrow use case, but for the blood and organs use cases, additional medical data will be necessary such as height, weight, age, sex, sexual orientation/history, recently traveled countries, etc |
| **4** | *Links to Data* | The current infrastructure is built in a way that the blockchain stores the 2 separate links 1. To the PII data and 2. To the medical data. |

| **Security and privacy** |
|---|
| - N/A |

| **Main Success Scenario + expected time line** |
|---|
| - Global adoption with every major bone marrow registry as a member. Best practices and learnings will be applied to create bone marrow registries in countries where registries do not yet exist. We plan to have our pilot implementation completed by end of 2019. Each year, we'd like to have additional implementations in different countries with all countries onboarded by 2030. During this time, we also plan to expand our solution to the blood and organ use cases. |

| **Conditions (pre- or post-)** |
|---|
| - N/A |

**Performance needs**

- For the bone marrow use case, frequency or load is not of primary concern as bone marrow matching is with a relatively much smaller volume than many other DLT use cases. The current standards should suffice.

**Legal considerations**

1. USA: HIPAA
    a. PII and Health data will be stored separately on authorized/certified databases.
2. EU: GDPR
    a. We will build in a mechanism for breaking the links that provide access to the PII and health data. By destroying the hash, the data becomes inaccessible and unreadable.
3. Korea: Health Data Privacy Consent
    a. Korean law requires disclosure of what legal entities will have access to / ownership of the data collected. Our current approach to address this is to either 1. Build onto a permissioned/private blockchain or 2. Conduct private transactions on public blockchains.

**Risks**

Legal risks

- Cross border PII and health data privacy

Business risks

- Limited number of potential revenue channels to sustain the business. Potential to sustain the business through charitable donations

Technical risks

- As with any other DLT use case, advancements in quantum computing poses a risk in the security of the technology

**Special Requirements**

- N/A

**External References and Miscellaneous**

- A detailed document with descriptions can be provided upon request.

**Other Notes**

- We assume all stakeholders in the value chain prioritize increasing the number of lives saved through a more efficient, globally integrated process

# My Health Data

## Section 1: Summary

| Use Case Summary | | | |
|---|---|---|---|
| **Use Case ID:** | HLC-006 | **Use Case Type:** | *Vertical* |
| **Use Case Title:** | My Health Data | **Is Use Case supporting SDGs** | *Yes* |
| | | **Domain:** | ***2*** Healthcare |
| **Status of Case** | *Proof Concept* | **Sub-Domain** | *a – Pharma*<br>b – Biotechnology<br>c – Medicine |
| **Contact information of person submitting/ managing the use-case** | *Valeria Queiroz* *Idealizer*<br>*E-mail address: valfqueiroz@gmail.com*<br>*Telephone number:55 21 99327-5080*<br>*Social media: https://myhealthdata.github.io/*<br>*Web site: **www.myhealthdata.com.br*** | | |
| **Proposing Organization** | *My Health Data, Brazil* | | |
| **Short Description** | *My Health Data is born, with the purpose of constructing a system where patient is the sole detector of his/ her data, a system which enables not only unified repository, but, above all, ease of access and portability, once the information holder is the user and not the third party.* | | |
| **Long description** | *My Health Data using the Blockchain technology, we invite everyone, through our interactions, to create a health data network, in which we will be the agents capable of generating solutions, which bases should be:*<br>1. *Empowerment of people, where the individual is not the patient, but the agent, the generator and the owner of their information;*<br>2. *User centralized data generation capable of providing the network with reliable and faithful information;*<br>3. *Generation and transmission of consistent information, capable of assisting in medical, pharmaceutical and wellness research and remunerating the parties involved;*<br>4. *Creation of an "anti-fragile" system, supported by multiple nodes of the network, encryption, anonymity and database not corruptible and, at the same time, generic capable of adapting to multiple situations, people and cultures easily;*<br>5. *User-focused solution, in which the Individuals will always be at the forefront of institutions, whether they are governments or for-profit entities.* | | |

| | | | |
|---|---|---|---|
| **SDG in Focus (when applicable)** | *1 – No Poverty*<br>*3 – Good Health and Well-being*<br>*5 – Gender Equality*<br>*8 – Decent work and Economic Growth*<br>*9 – Industry, innovation and infrastructure*<br>*17 – Partnership for the goals* | | |
| **Value Transfer:** | *Data, tokens* | **Number of Users:** | *0* |
| **Types of Users:** | *Patients, Partners (hospitals, clinics, doctor office, laboratories)* | | |
| **Stakeholders** | *Government, Researchers, …* | | |
| **Data:** | In My Health Data the information is always stored under this primary key and with the permission of the key owner. The system, based on the patient's permissions, controls access to medical records, permits the inclusion, removal and reading of medical records by the patient or third parties, makes the sale of such data available to third parties, where negotiation is done directly between interested parties, but always preserving the identity and anonymity of those who make them available. | | |
| **Identification:** | *Identification mechanism and rules; ability of participants to be anonymous, etc.* | | |
| **Predicted Outcomes:** | | | |

| **Overview of the Business Problem or Opportunity** |
|---|
| *The platform that consists of a smart contract that not only validates operations, but also stores and creates a patient-centred health data network that can be used in a variety of applications such as academics surveys, hospitals, laboratories and the pharmaceutical industry.* |
| **Why Distributed Ledger Technology?** |
| *Due to the characteristics of the DLT, such as immutability, transparency, security, distribution, verifiable, technology can take these characteristics to medical data ensuring safety, ensuring that the patient knows who is accessing their data and ensuring universal access from anywhere in the world, anytime.* |

## Section 2: Current process

| **Current Solutions** |
|---|
| *If there are existing systems which automate the above business problem/opportunity.* |

| **Existing Flow (as-is)** | | |
|---|---|---|
| **Step** | **User Actions** | **System Actions** |
| 1. | *The patients information have been spread out in different silos, which are Labs, hospitals, doctor offices.*<br>*As consequence, the patient does not have access to all his/her information when needed, mostly when they are sick.*<br>*This decentralization generates the lack of interoperability and lack of control over health information, that causes a fact known as asymmetry of information.* | *Decentralization of health data in different silos, such as hospitals, clinics, laboratories, doctors offices.* |
| 2. | | |

| **Process scheme (as-is)** |
|---|
| |

| **Data and information (as-is)** | | |
|---|---|---|
| **Data** | **Type** | **Description** |
| **1** | *Documents: There is no pattern* | *Documents and data spread out in different silos.* |
| **2** | *Payment transactions* | |

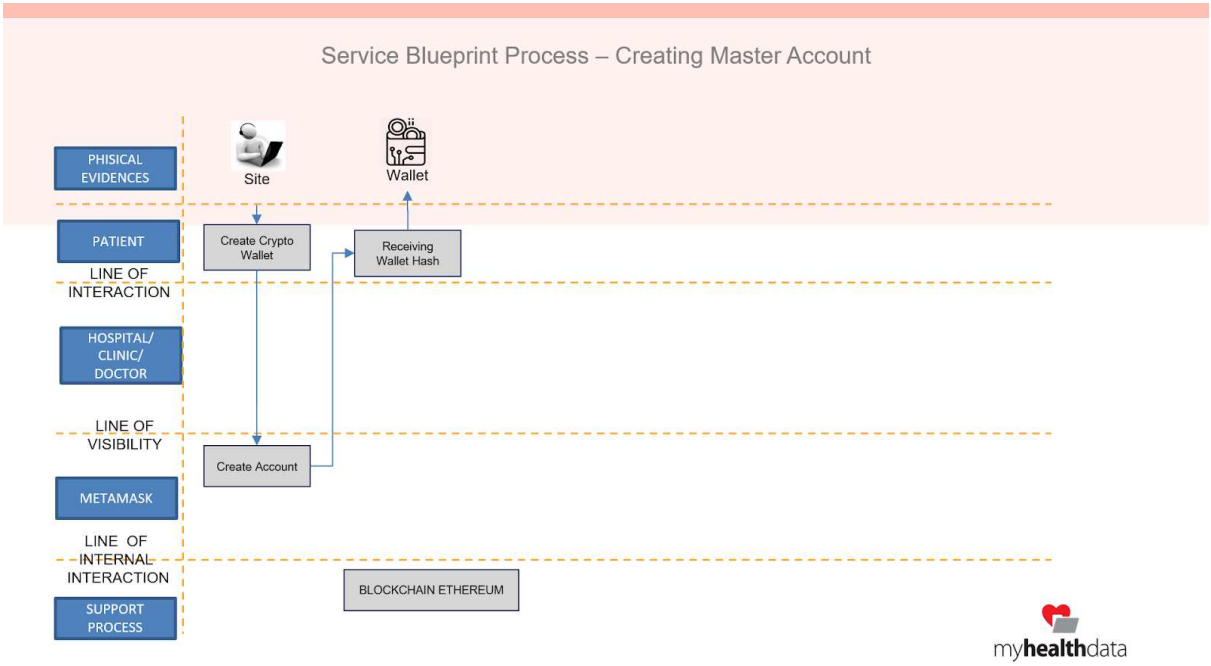
| **Participants and their roles (as-is)** | | |
|---|---|---|
| **Actor** | **Type/Role** | **Description** |
| **1** | *Patient* | Patient has no control or possession over his/her health data. |
| **2** | *Hospital/Clinic/Doctor Office* | Health data are stored in a decentralized way, each entity storing it their respective silos. |

| **Other Notes** |
|---|
| *Any assumptions, issues* |

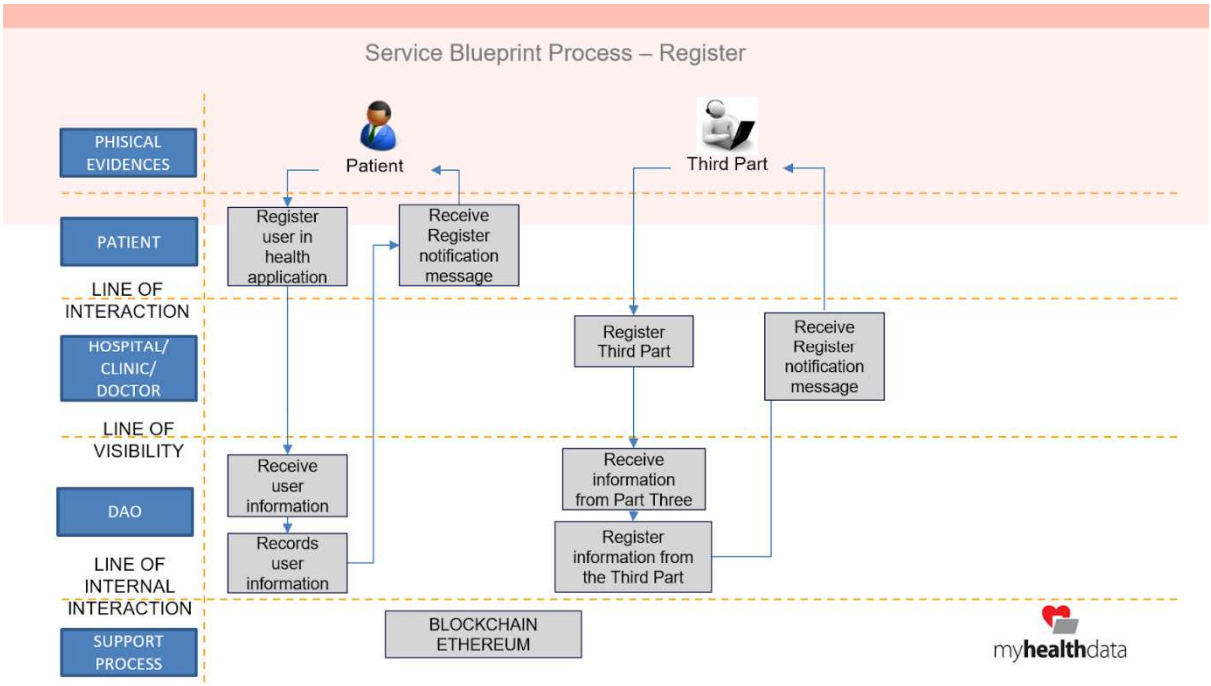
## Section 3: Expected process

| Expected Flow (to-be) | | |
|---|---|---|
| **Step** | **User Actions** | **System Actions** |
| 1. | My Health Data proposes, through the empowerment of the patient, making them the sole owner of their medical data, solving the above mentioned problems of information silos, interoperability and asymmetry of information, having developed, for that purpose, a smart contract, published in the blockchain Ethereum network, which is capable of providing a patient-centered medical data repository system, having as primary key its Ethereum account.<br><br>The My Health Data smart contract has been structured in a way that any entity can develop applications on it, as long as the information is always stored under this primary key and with the permission of the key owner (the patient). Thus, the system, based on the patient's permissions, as described above, controls access to medical records, permits the inclusion, removal and reading of medical records by the patient or third parties, makes the sale of such data available to third parties, where negotiation is done directly between interested parties, but always preserving the identity and anonymity of those who make them available. | Install and create a Metamask application and access https://abezzerrademenezescavalcanti.github.io/saudechain |
| 2. | | |
| **Process scheme (to-be)** | | |

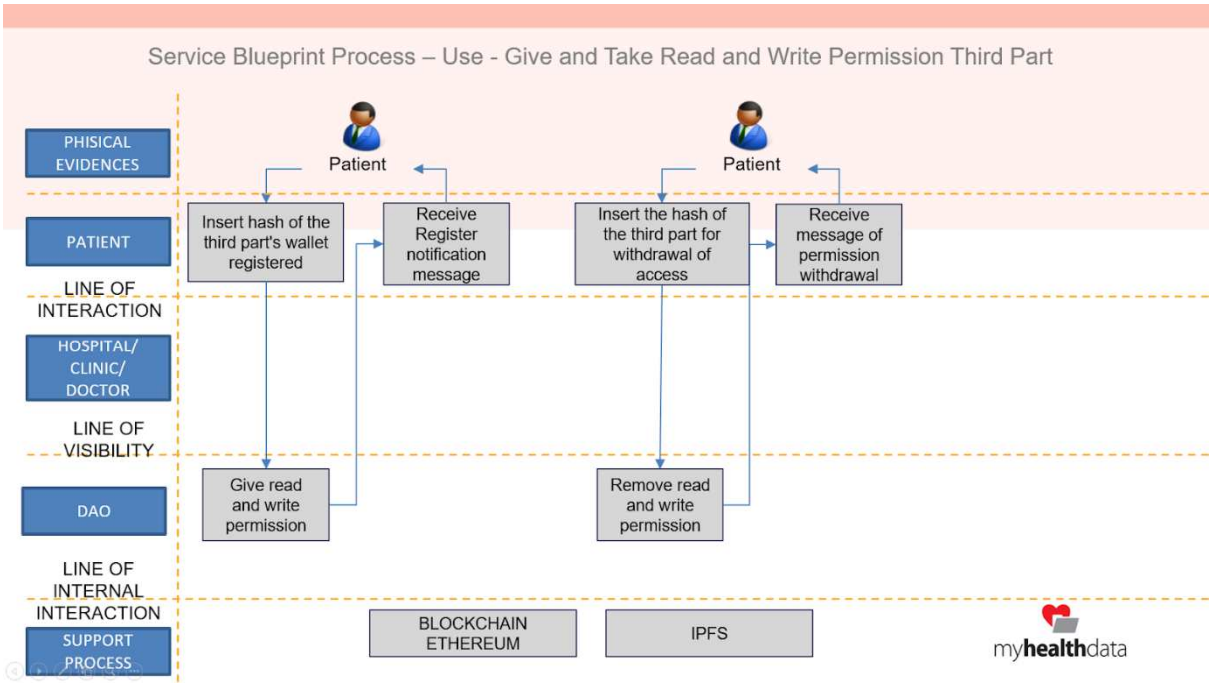
## Master Account Creation



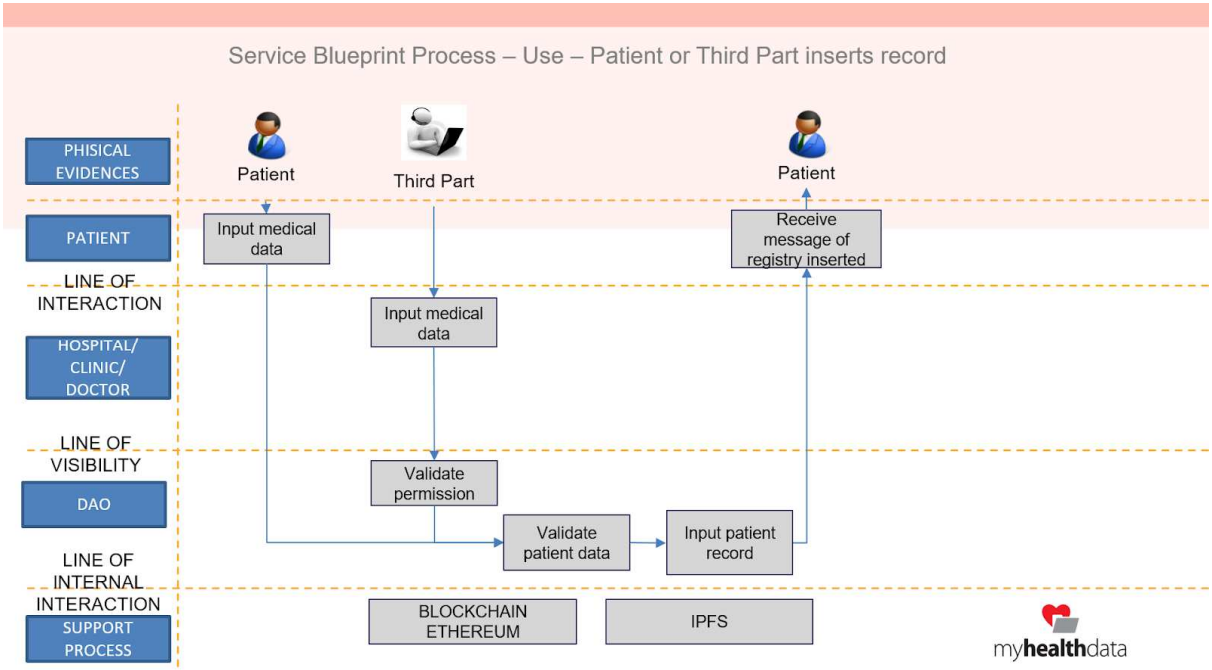

## Patient and Third Part Registration



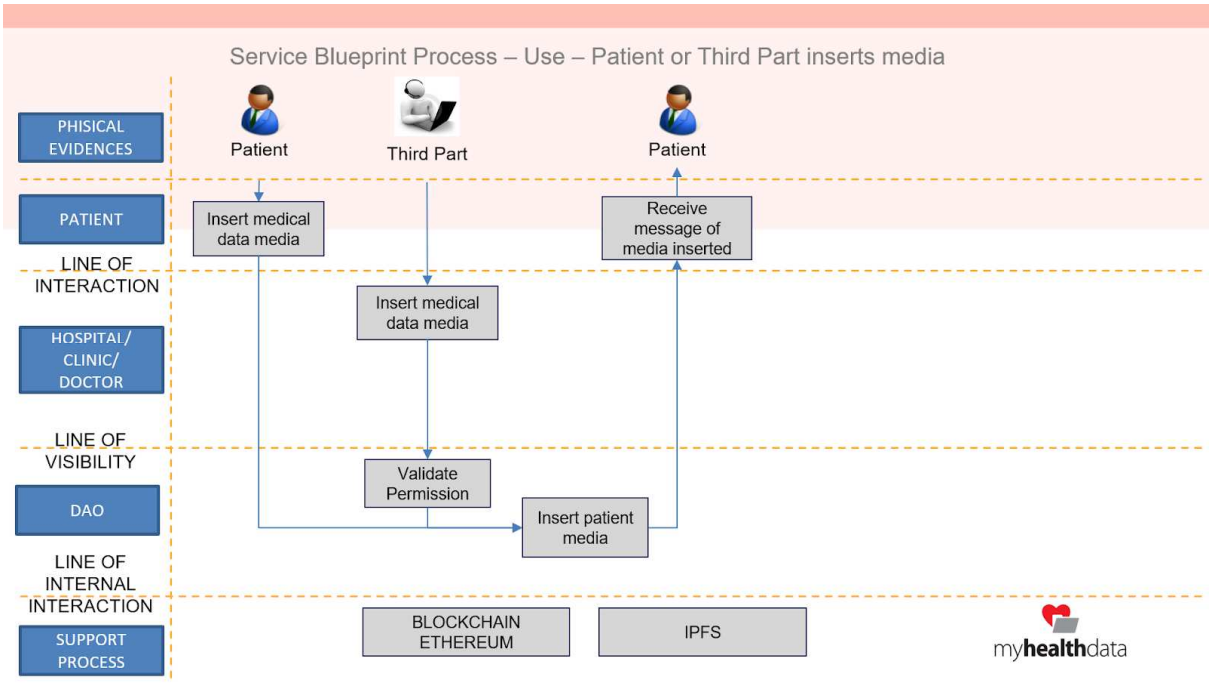

## Use - Third Part reading and writing permission



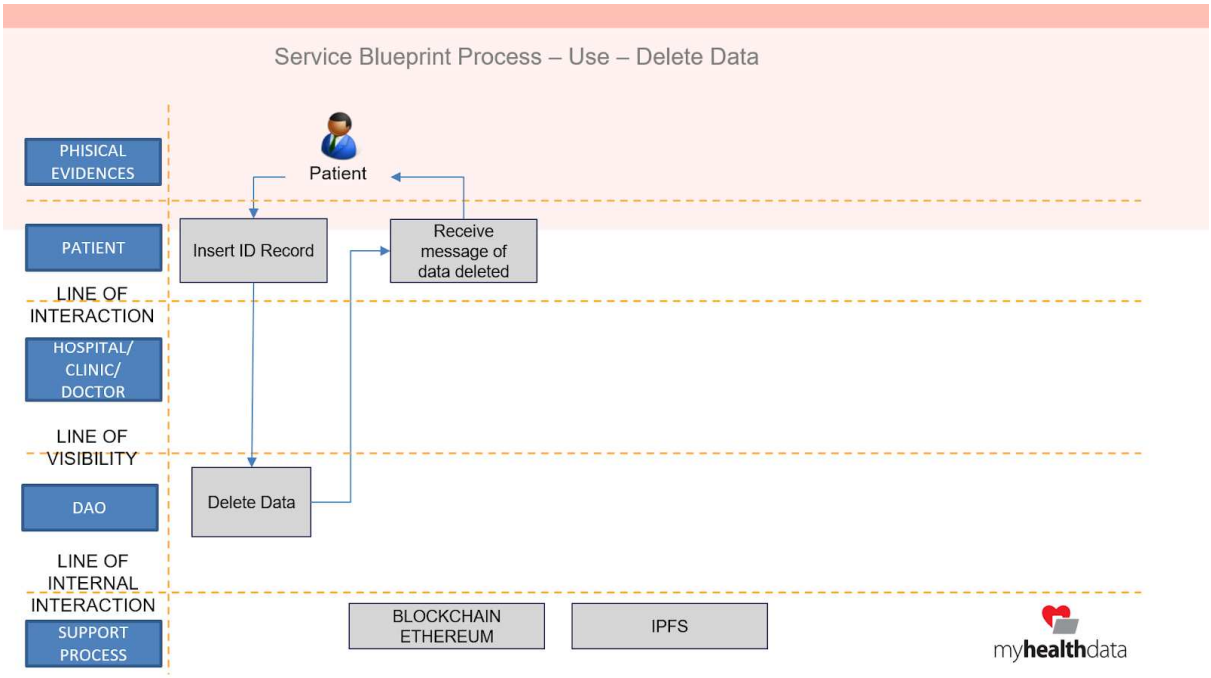

## Use – Patient or Third Part inserts record




## Use - Patient or Third Part inserts media

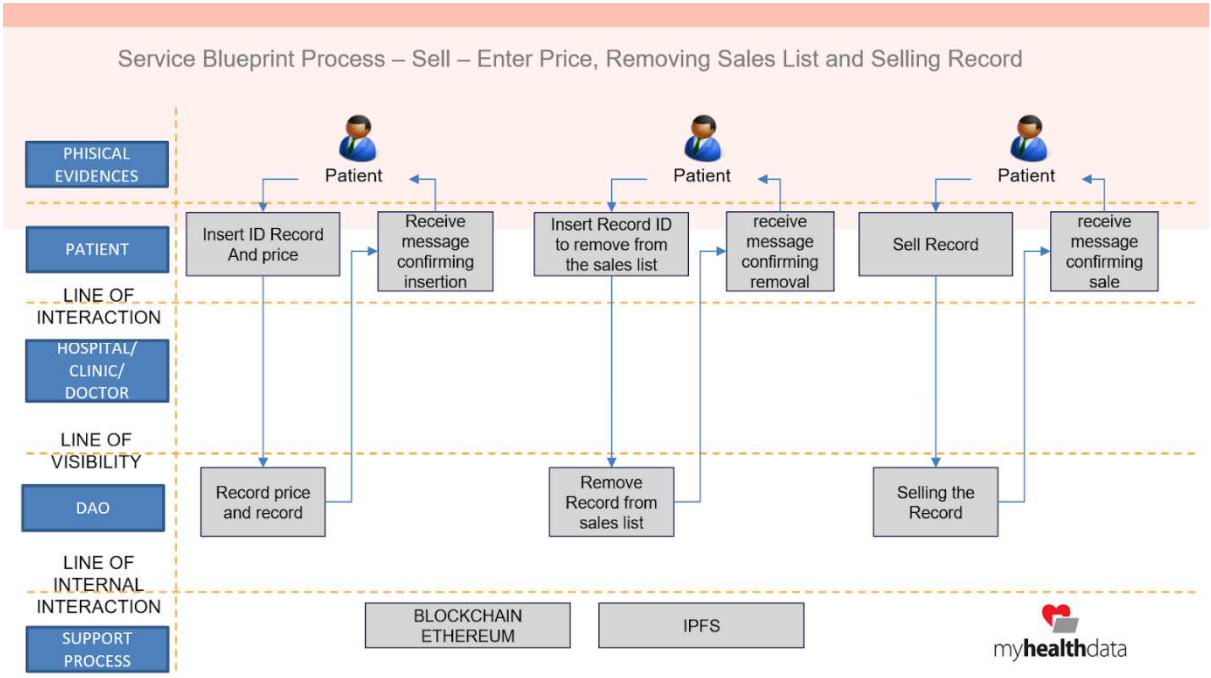



## Use - Delete Data

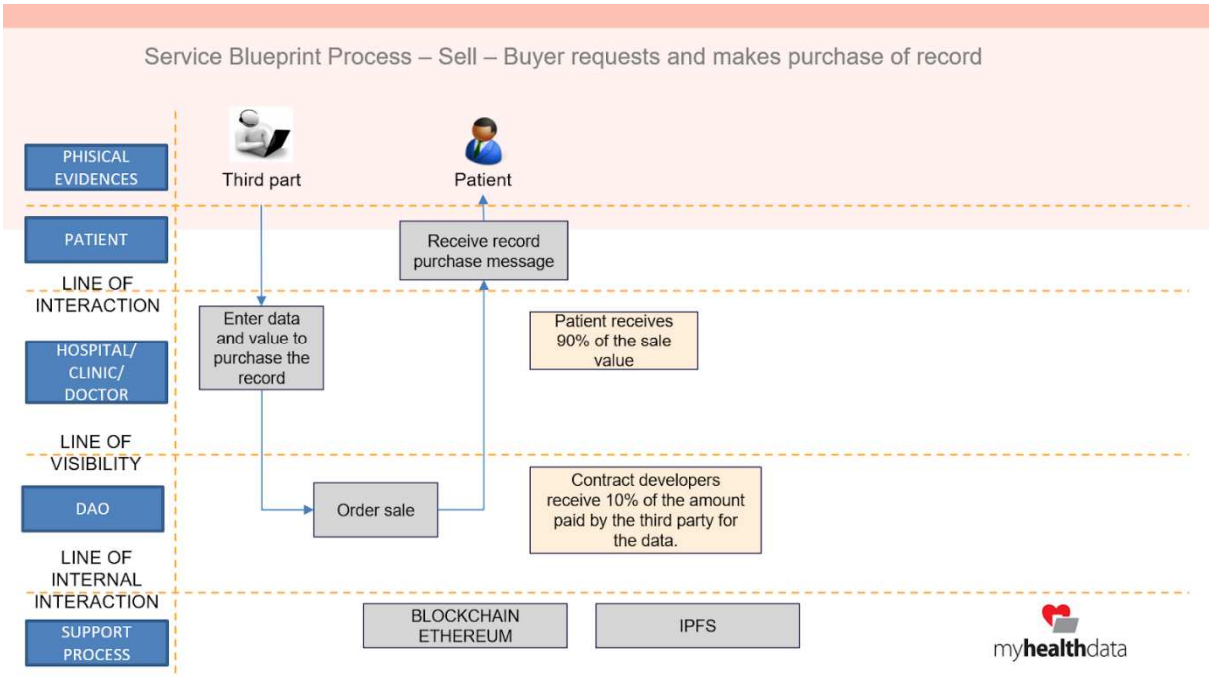



## Sell – Enter Price, Removing Sales List and Selling Record

| Expected Flow (to-be) | | |
|---|---|---|
| **Step** | **User Actions** | **System Actions** |




**Sell – Buyer requests and makes purchase of record**




| Participants and their roles | | |
|---|---|---|
| **Actor** | **Type/Role** | **Description** |
| **1** | *Patient* | Patient can create register, give third party permission to read and insert data, sale permission and delete data. |

| Participants and their roles | | |
|---|---|---|
| **Actor** | **Type/Role** | **Description** |
| **2** | *Hospital/Clinic/Doctor Office* | Receive permission from patient to read and insert data and buy data. |
| **3** | | |

| Data and information | | |
|---|---|---|
| **Data** | **Type** | **Description** |
| **1** | *Documents* | |
| **2** | *Payment transactions* | |

| Security and privacy |
|---|
| *1.* |

| Main Success Scenario + expected time line |
|---|
| *Description of DLT-based solution, which potentially will be created* |

| Conditions (pre- or post-) |
|---|
| *1.* |

| Performance needs |
|---|
| *What potential performance specs (frequency of use, transactions per second, confirmation time, sync time, etc.) are expected. What scalability, interoperability, reliability, accessibility needs exist.* |

| Legal considerations |
|---|
| *For each issue, please describe the name of the legal act containing the identified barrier, what is the negative impact and a proposal to overcome this negative impact.*<br>*1.* |

| Risks |
|---|
| *Legal, business and technical risks related to use case* |

| Special Requirements |
|---|
| *Business and technical requirements of use case* |

| External References and Miscellaneous |
|---|

*List of references for standards or well-defined mechanisms if any of requirements calls for the implementation of a standard or protocol or other well-defined mechanism. If the use case needs non-standard consensus mechanisms or cryptographic tools, such information should be included here. Also such section may be used to provide more information regarding the use case including links to any kind of related materials, terms and descriptions or any other related information.*

| **Other Notes** |
| --- |
| *Any assumptions, issues* |