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 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. 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 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.		

	SDG 9. Indicator 9.1
	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.
	SDG 17. Indicator 17.18
	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.

Value Transfer:	The Application will generate assets for transactions on the blockchain. The proof of concept involves three counties in Kenya	Number of Users:	1000
Types of Users:	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		
Stakeholders	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		
Data:	*What data are expected to be stored in distributed ledger in terms of types, record structure, privacy*		

The application has both human actors and what we call IoT actors. Both actors have different data sets.

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

2. GS 1 data matrix codes data scanned from the vaccines and hold each vaccine details

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

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.

The NVIP plans to set up its own data centre but meanwhile the data will be stored in the DHIS2.

	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.* 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. 2. Every vaccines potency is known from the time it comes to the country to the time it is used on a child 3. Every transaction done receives consensus from the participants permissioned hence ensuring transparency and accountability 4. Every transaction is immutable and so traceability is achieved. 5. Provision of high-quality reliable data 6. Every vaccine can be accounted for. 7. Data on who was vaccinated, how many, by region, by gender is made available. 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:

- Stock-outs

- Potential administration of ineffective vaccines

- Avoidable wastage

- Expirees

- Inadequate cold-chain capacity

- 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

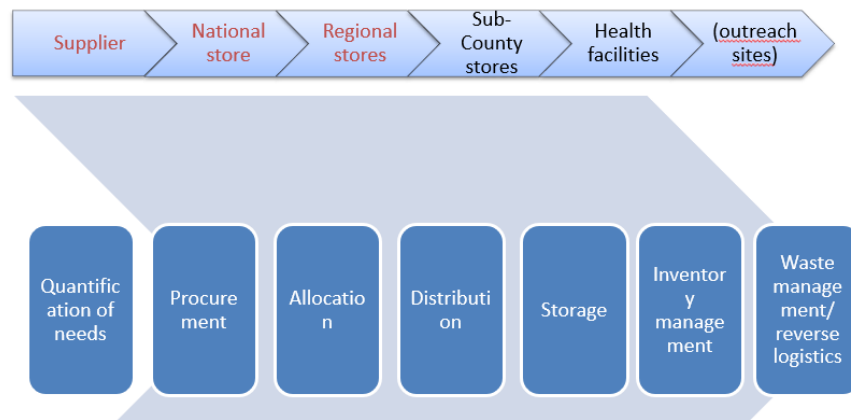| Current Solutions |
|---|
| Chanjo system that is used for stock management. Manual registers for recording vaccine arrival and dispatch/distribution and administration. Fridge tags for temperature monitoring which have no real time streaming of data capabilities. |
| Existence of data in silos and 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.	

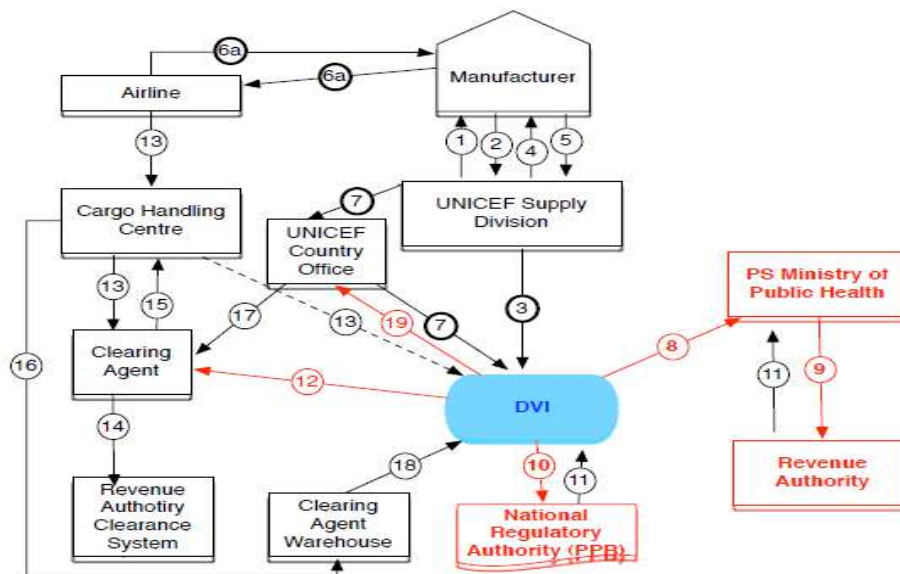| Existing Flow (as-is) Without DLT		
Step	**User Actions**	**System Actions**
5.	Storage; Stringent SOPs have to be followed during storage and transportation at all levels. The temperatures has to be at acceptable ranges. Every store must record the vaccine details including conditions e.g temperature, 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)

Vaccine logistics and management

Supplier › National store › Regional stores › Sub-County stores › Health facilities › (outreach sites)

| Quantification of needs | Procurement | Allocation | Distribution | Storage | Inventory management | Waste management/ reverse logistics |

The following steps are repeated at all levels of the vaccine program and this has to be done in a tightly controlled temperature range of 2-8 degree cold chain.

Vaccines are very sensitive and require very close supervision and monitoring at all levels.

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 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. ibeacons with temperature sensors in place to read the temperature of vaccines in storage into the system database updated 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)
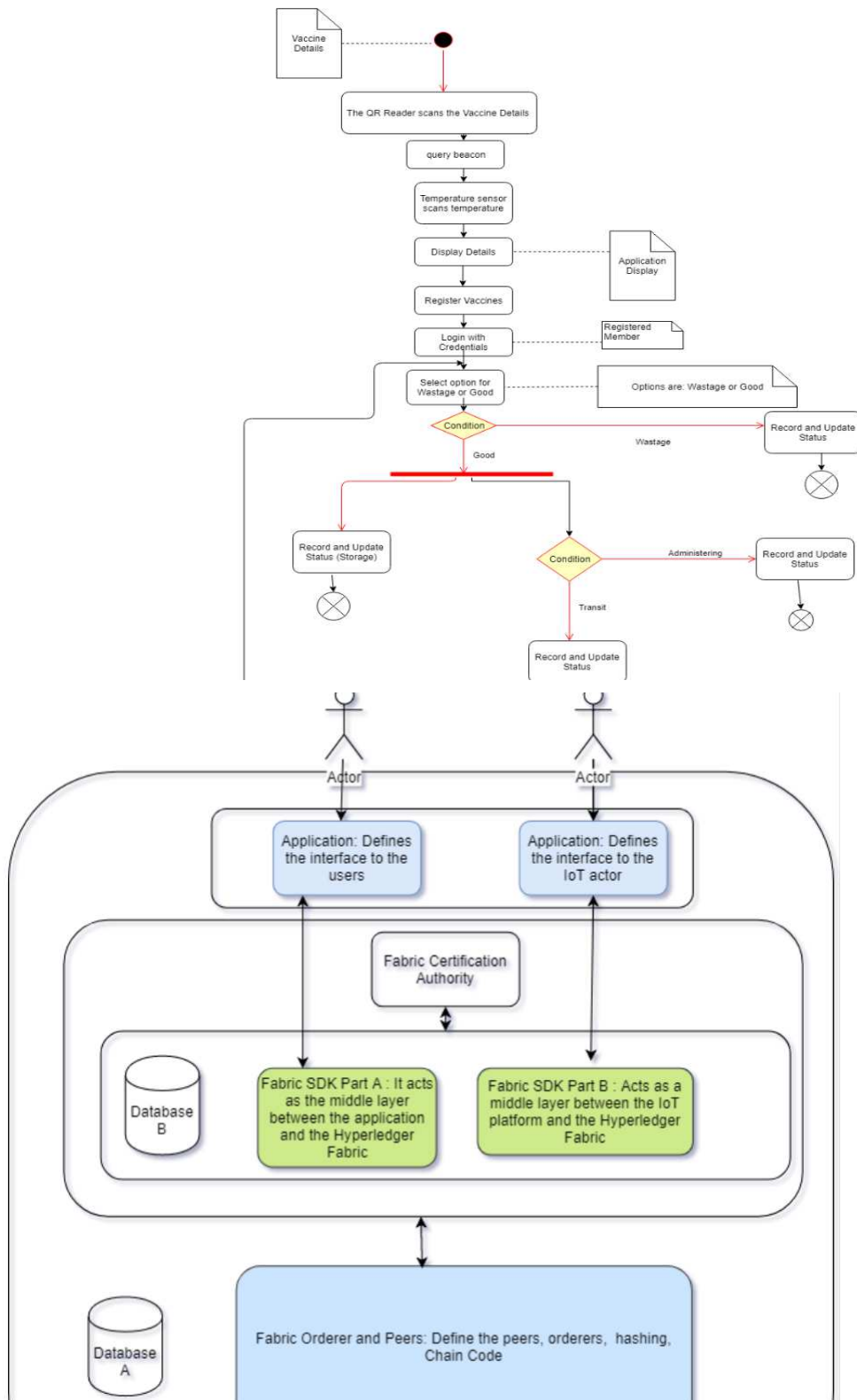
VacTrace Network Structure
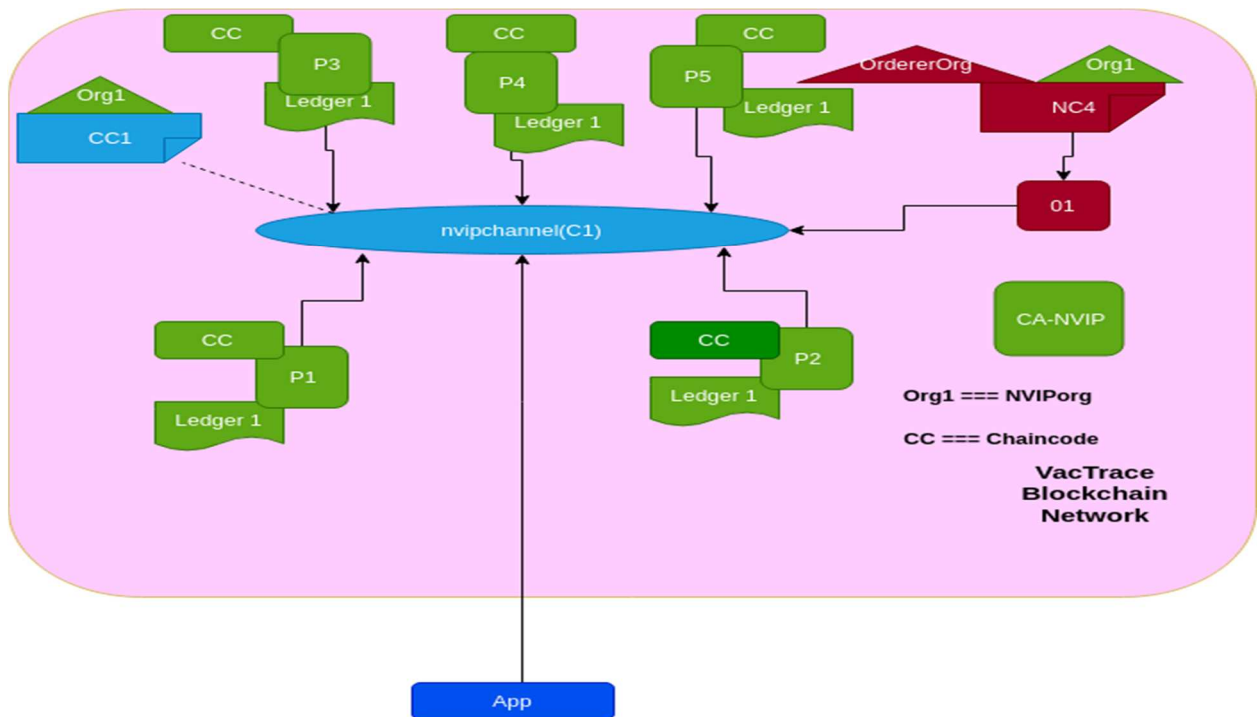
Peer Organization

  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 th*e* 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 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