PharmaChain 2.0: A Blockchain Framework for Secure Remote Monitoring of Drug Environmental Parameters in Pharmaceutical Cold Supply Chain

Presenter: Anand Kumar Bapatla

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Outline

- Counterfeit in HealthCare
- Blockchain Technology
- PharmaChain
- PharmaChain 2.0
- Working Flow of PharmaChain 2.0
- Implementation and Validation
- Conclusions & Future Work

Counterfeit in Healthcare

Counterfeit Medicines is a Problem

Tamiflu is an antiviral drug for the treatment of the flu.

Daflon 500 used to treat gravitational (stasis) dermatitis, and dermatofibrosclerosis

- Drug Components: Active Pharmaceutical Ingredient (API) + Excipients or inactive ingredients
- Counterfeit Drugs: Less API or no API or wrong API drugs produced in sub-standard conditions

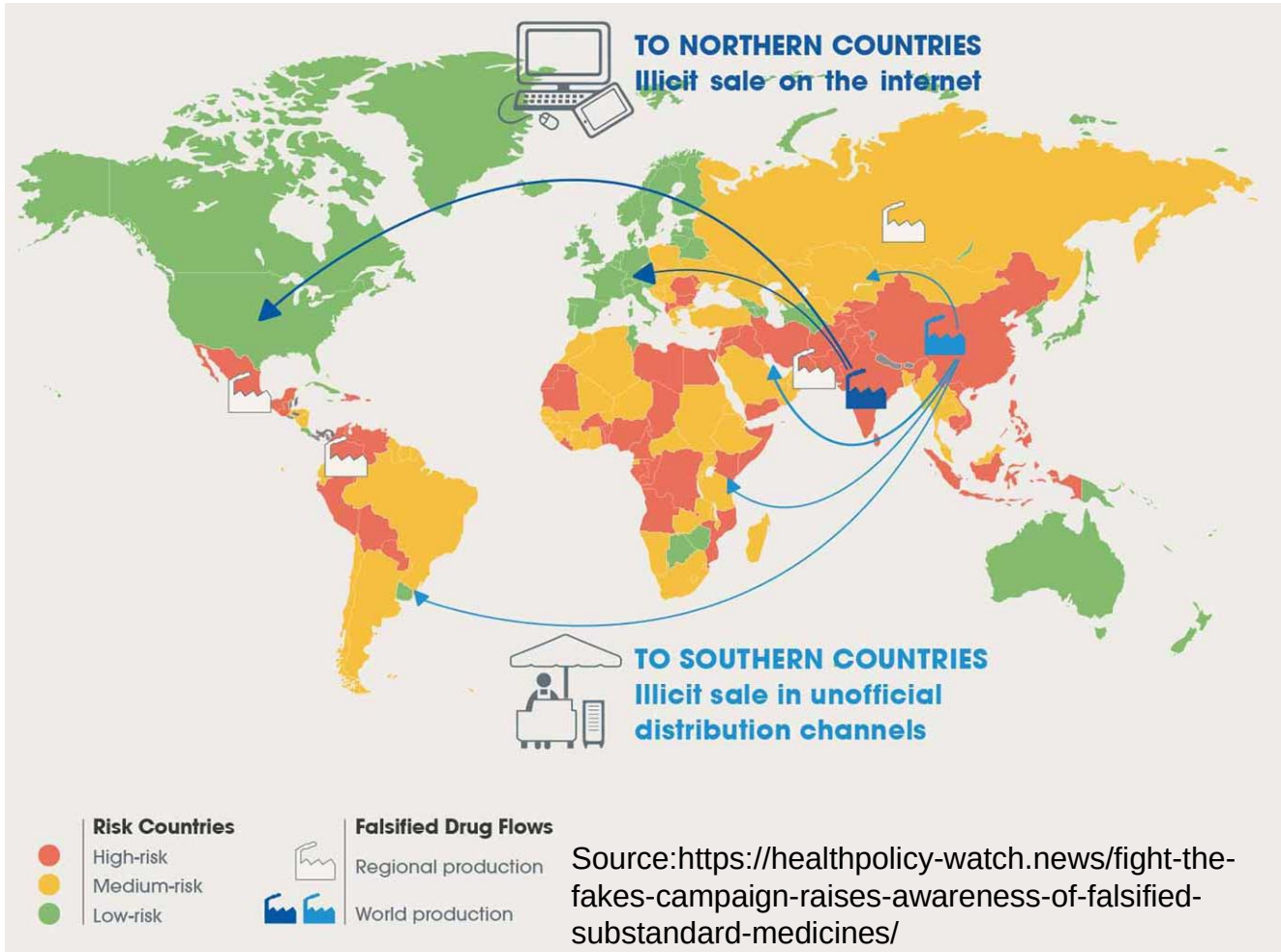
Image Source: https://www.stabroeknews.com/2019/09/06/business/ga-fdds-occasional-fake-drugs-disclosures-may-be-tip-of-the-iceberg/

Fake Medicine - Serious Global Issue

- It is estimated that close to $83 billion worth of counterfeit drugs is sold annually.
- One in 10 medical products circulating in developing countries are substandard or fake.
- In Africa: Counterfeit antimalarial drugs result in more than 120,000 deaths yearly.
- USA has a closed drug distribution system intended to prevent counterfeits from entering U.S. markets, but it isn't foolproof for many reasons, including illegal online pharmacies.

Source: https://fraud.org/fakerx/fake-drugs-and-their-risks/counterfeit-drugs-are-a-global-problem/

Source: https://allaboutpharmacovigilance.org/be-aware-of-counterfeit-medicine/



Source:https://healthpolicy-watch.news/fight-the-fakes-campaign-raises-awareness-of-falsified-substandard-medicines/

Counterfeits in Healthcare → Severe Direct Impact

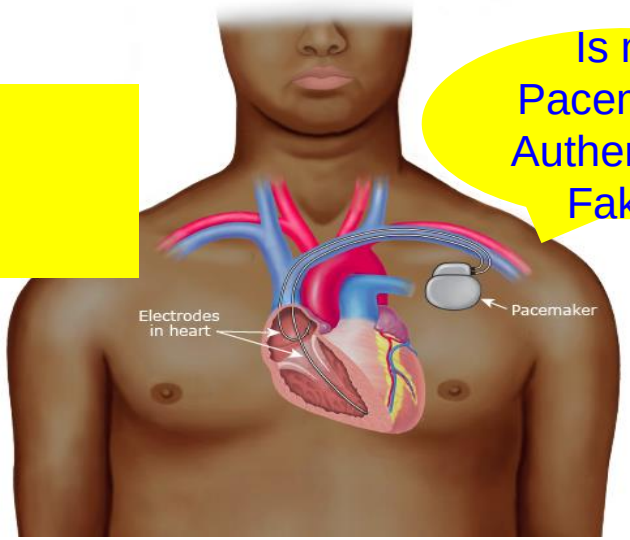
Authentic

Fake

An implantable medical device

Fake data by adversaries

- Consumers are always in dilemma
- Health Security issues



Typical Pharmaceutical Supply Chain

Source: Bapatla, A.K., et al.: PharmaChain: a blockchain to ensure counterfeit-free pharmaceutical supply chain. IET Netw. 1– 24 (2022). https://doi.org/10.1049/ntw2.12041

Issues in Traditional PSC

08/22/2022

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11/12/2021

A federal grand jury in Beaumont has returned a three-count indictment charging nine individuals in drug trafficking conspiracy in the Eastern District of Texas, announced Acting U.S. Attorney Nicholas J. Ganjei today

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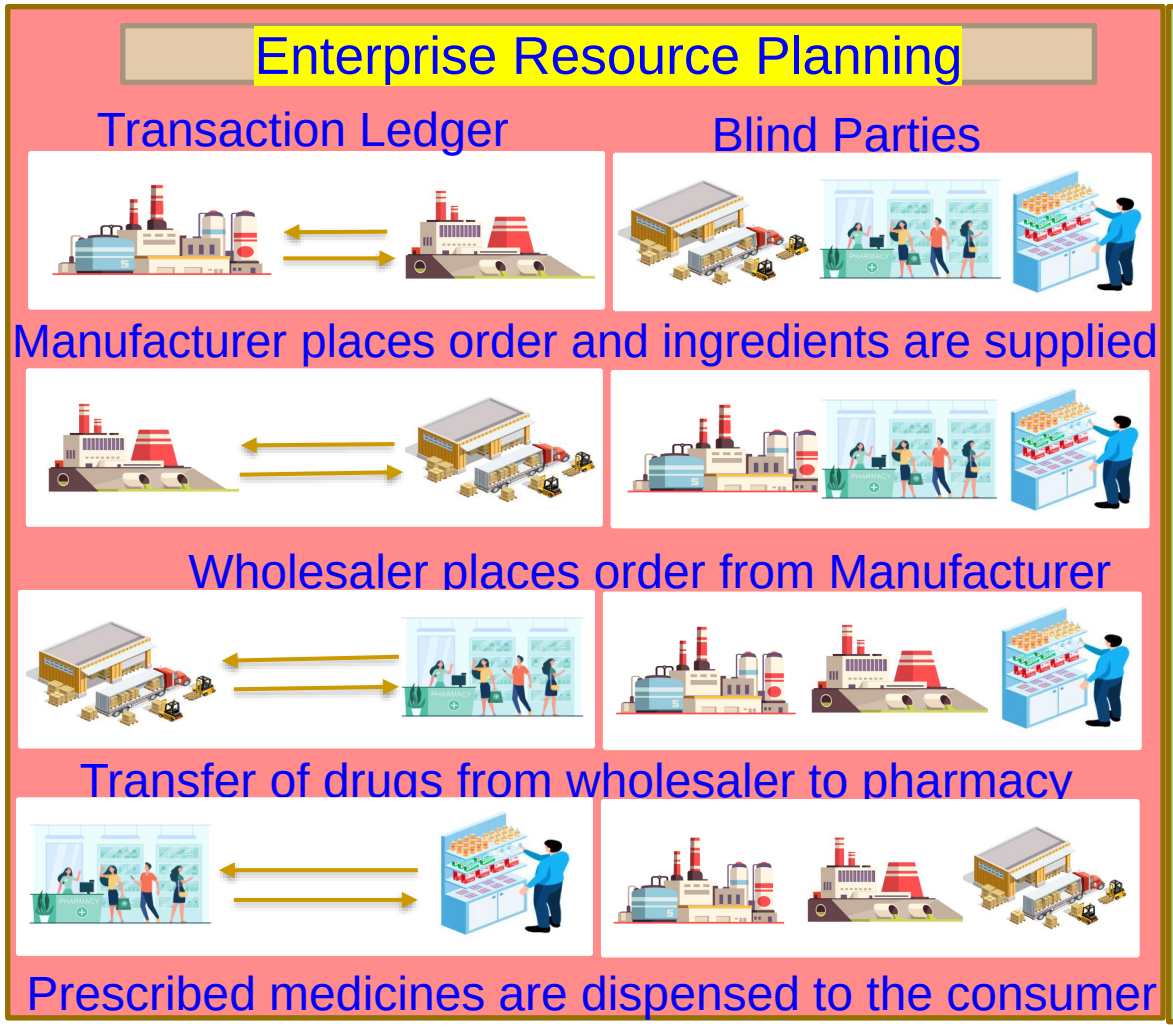
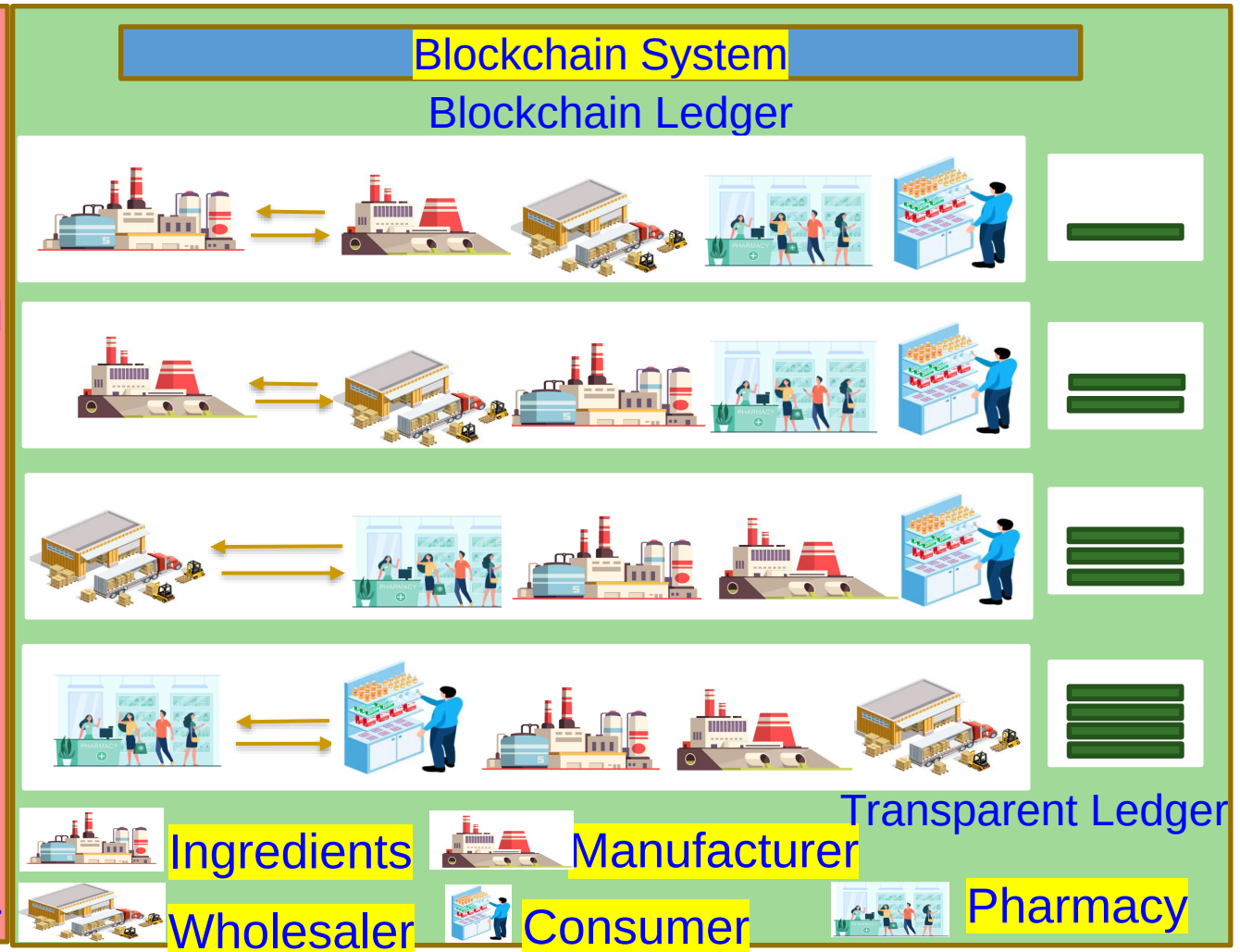
ALEX NDRIA, Va. – An Inverness, Florida, man was sentenced today to three years in prison for selling hundreds of thousands of counterfeit prescription drug pills through the Internet.

News Source: Affairs, O. of R. (n.d.). *Press releases*. U.S. Food and Drug Administration. Retrieved November 15, 2022, from https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/criminal-investigations/press-releases

PharmaChain - Counterfeit Free Pharmaceutical

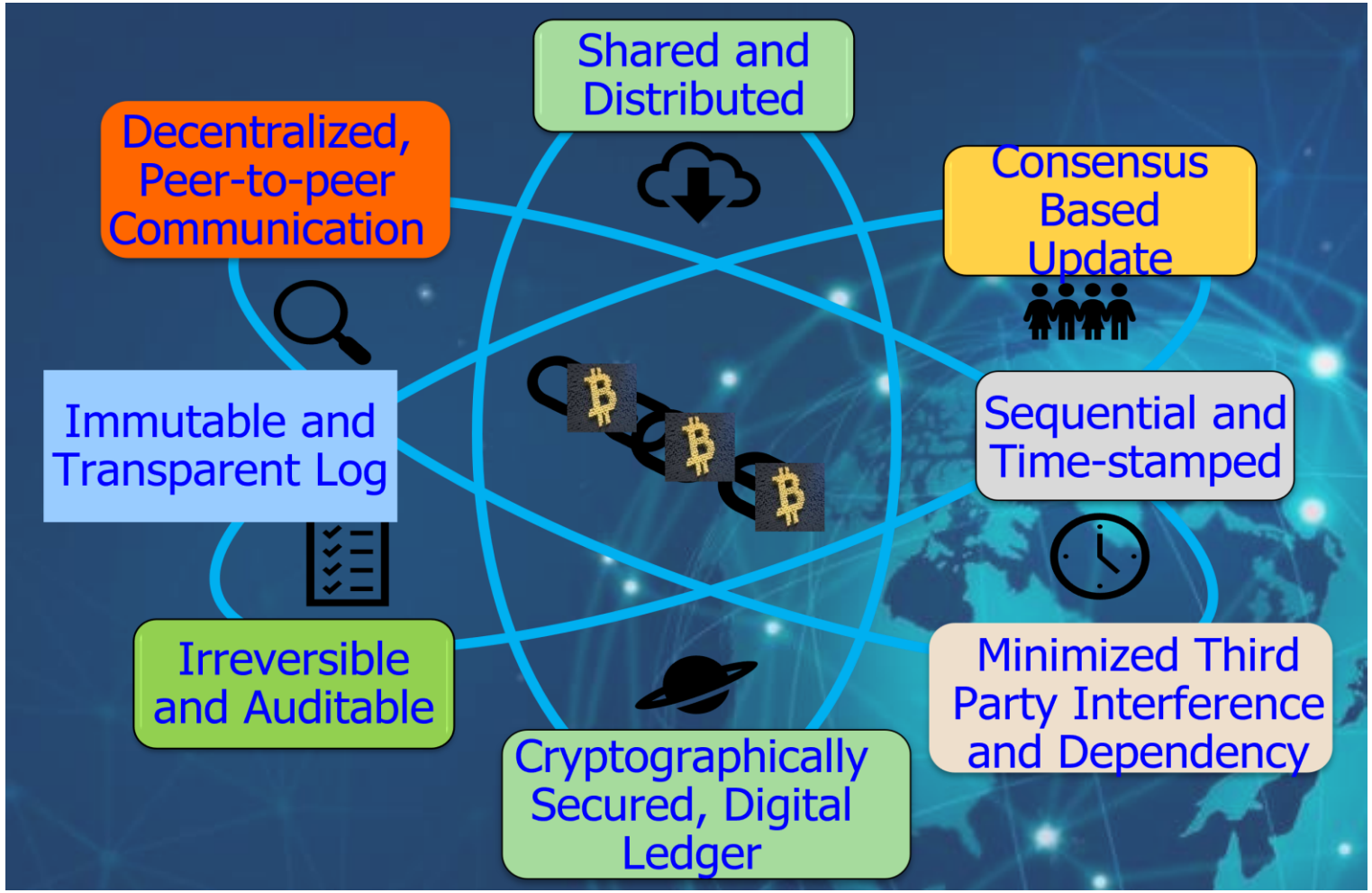




Source: A. K. Bapatla, **S. P. Mohanty**, E. Kougianos, D. Puthal, and A. Bapatla, "PharmaChain: A Blockchain to Ensure Counterfeit-Free Pharmaceutical Supply Chain", *IET Networks*, Vol. XX, No. YY, ZZ 2022, pp. Accepted on 24 June 2022, DOI: https://doi.org/10.1049/ntw2.12041. (Dataset for Research: GitHub)

Blockchain Technology

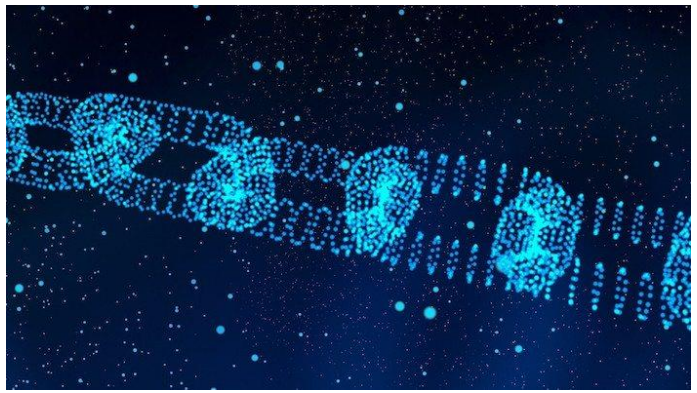
Blockchain Definition

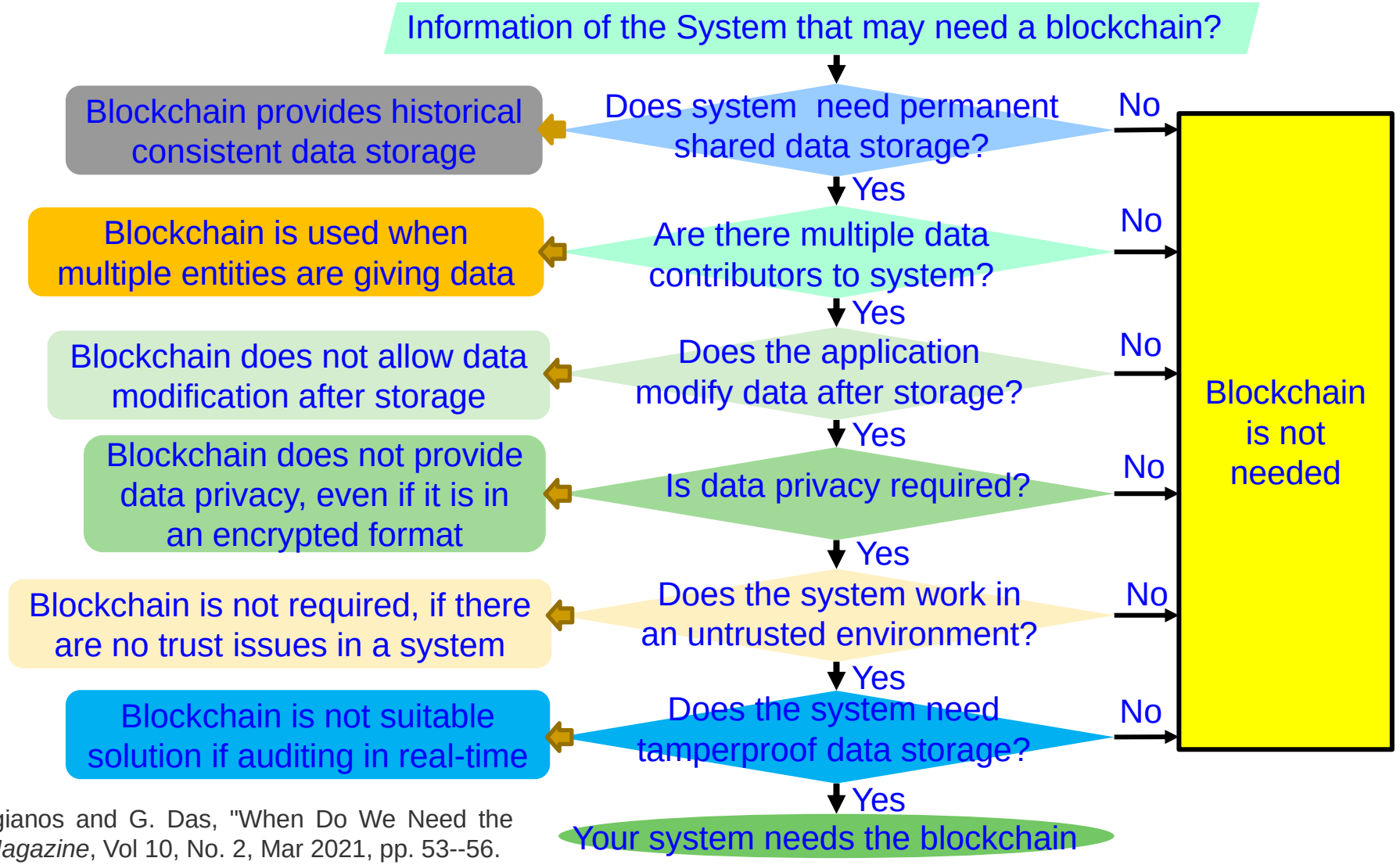


Technical Definition: A blockchain is a linked list that is built with hash pointers instead of regular pointers.
Socio-Political–Economic Definition: A blockchain is an open, borderless, decentralized, public, trustless, permissionless, immutable record of transactions.
Financial – Accounting Definition: A blockchain is a public, distributed ledger of peer-to-peer transactions.

Source: D. Puthal, N. Malik, S. P. Mohanty, E. Kougianos, and C. Yang, "The Blockchain as a Decentralized Security Framework", *IEEE Consumer Electronics Magazine (CEM)*, Volume 7, Issue 2, March 2018, pp. 18--21.

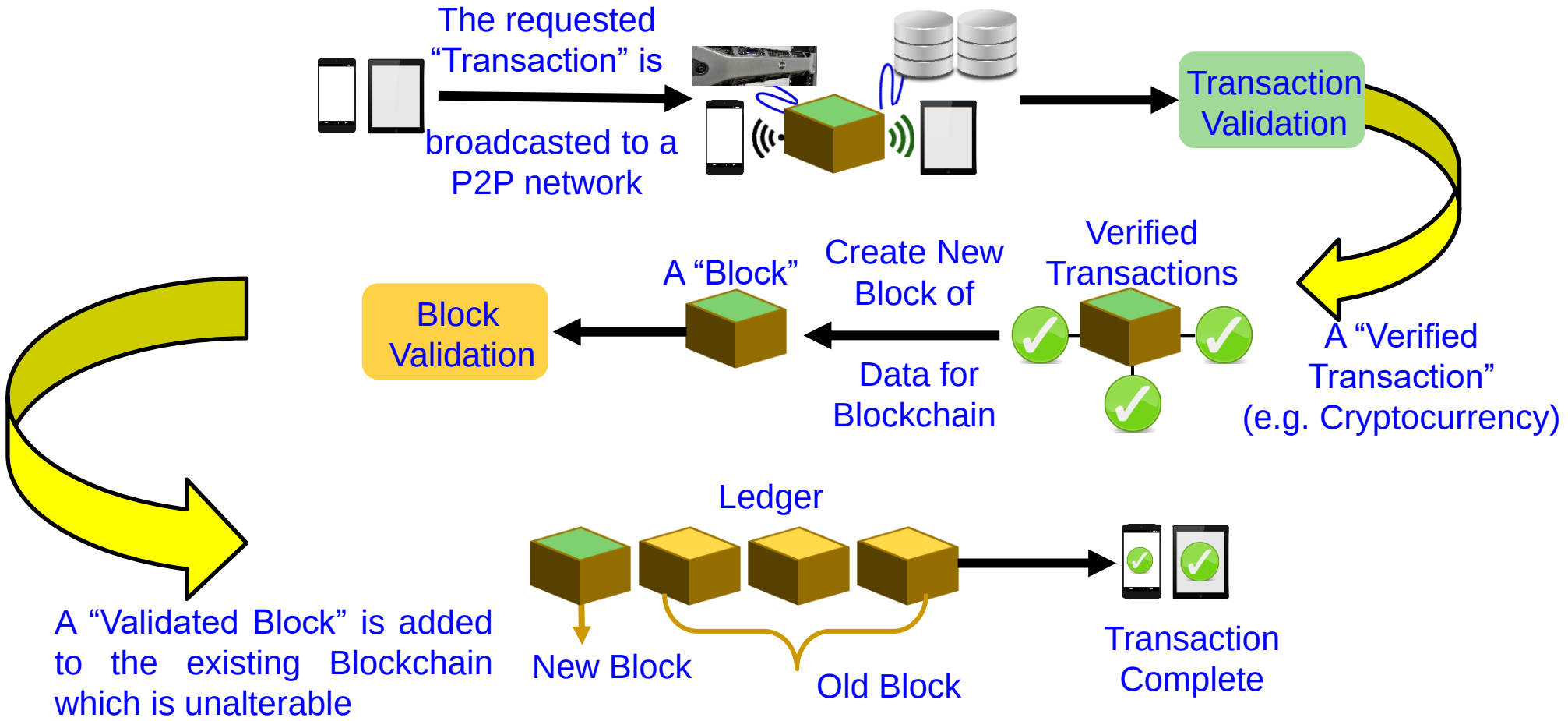
When do You Need the Blockchain?





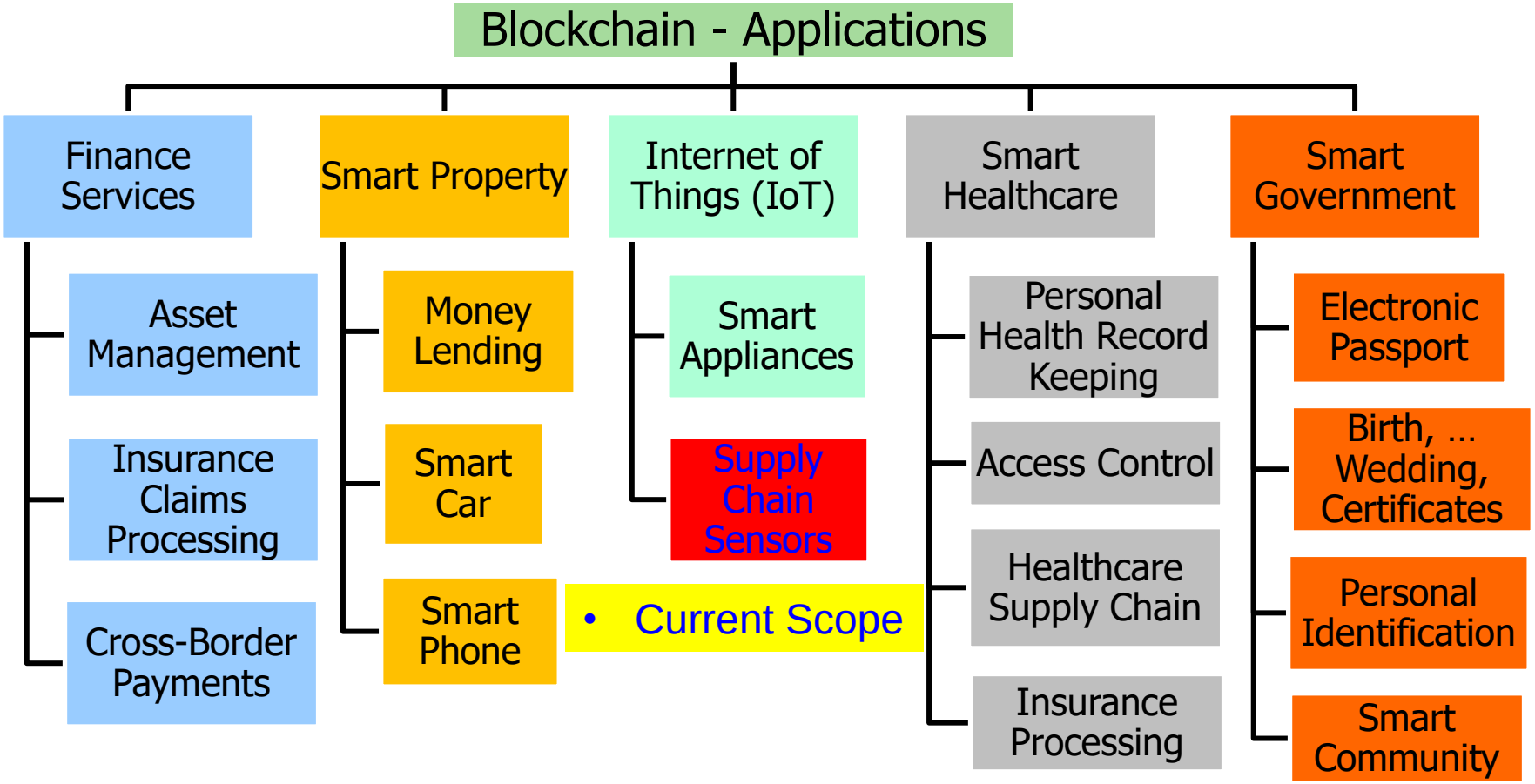
Source: D. Puthal, S. P. Mohanty, E. Kougianos and G. Das, "When Do We Need the Blockchain?," *IEEE Consumer Electronics Magazine*, Vol 10, No. 2, Mar 2021, pp. 53--56.

Blockchain Transaction Steps



Source: Deepak Puthal, Nisha Malik, Saraju P. Mohanty, Elias Kougianos, and Gautam Das, "Everything you Wanted to Know about the Blockchain", *IEEE Consumer Electronics Magazine*, Vol. 8, No. 4, pp. 6--14, 2018.

Blockchain Applications



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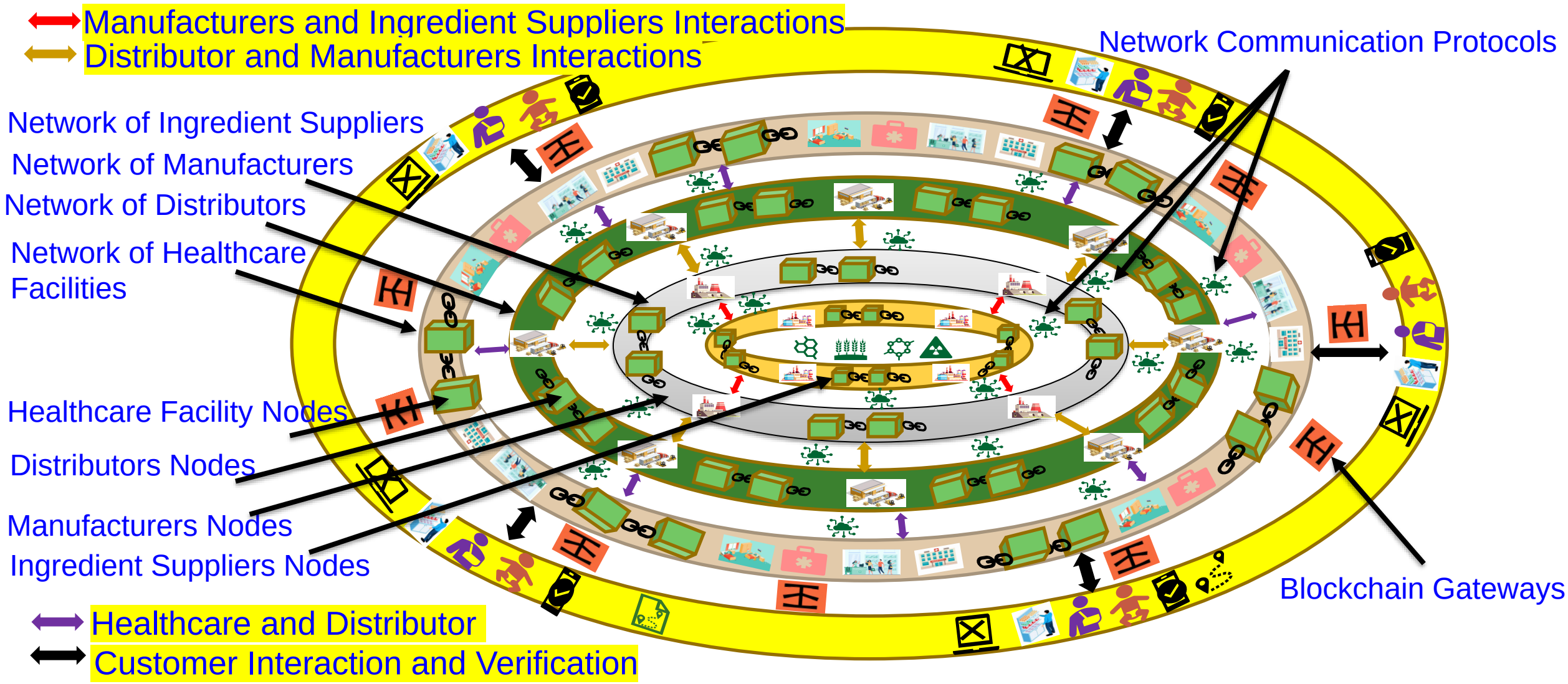
Blockchain Leveraged Healthcare CPS



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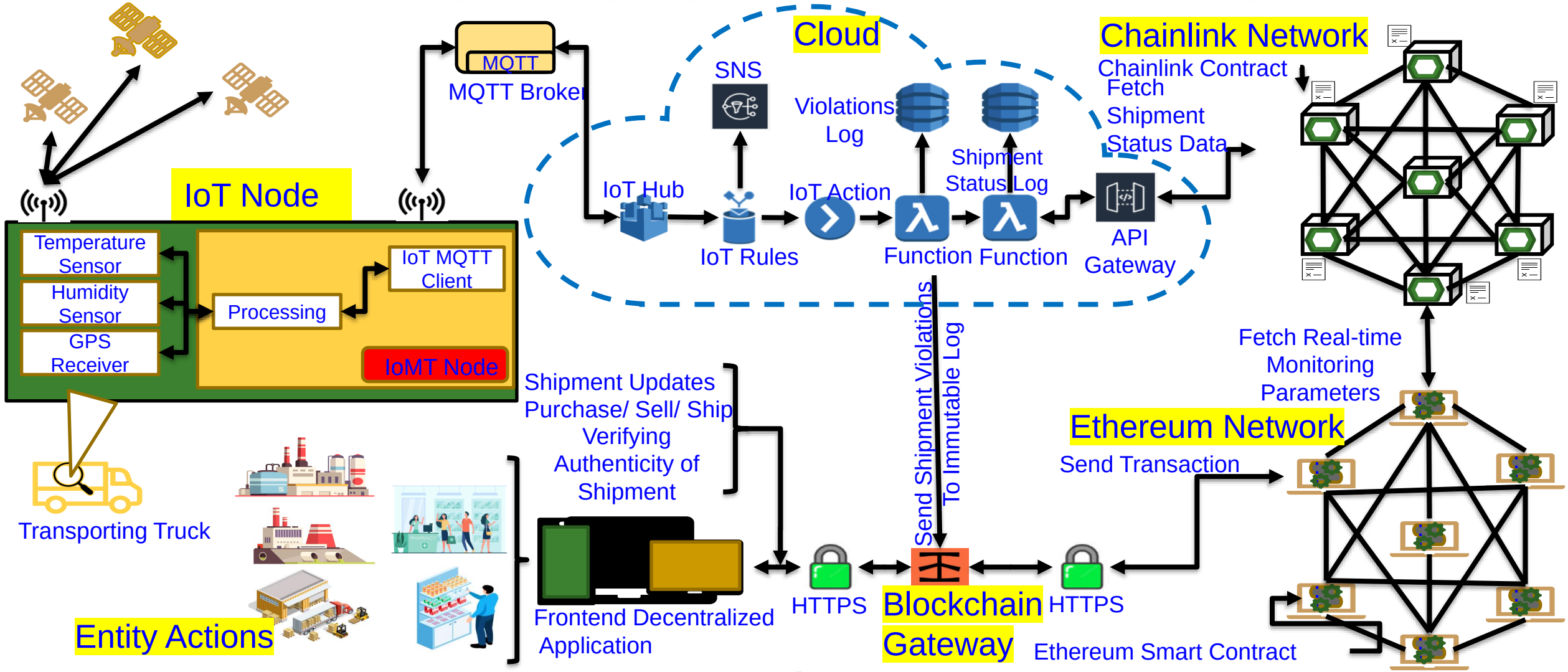
Our First Work to Transparent Pharmaceutical Supply Chains

PharmaChain: A Blockchain to Ensure Counterfeit-Free Pharmaceutical Supply Chain

Architectural Overview of PharmaChain



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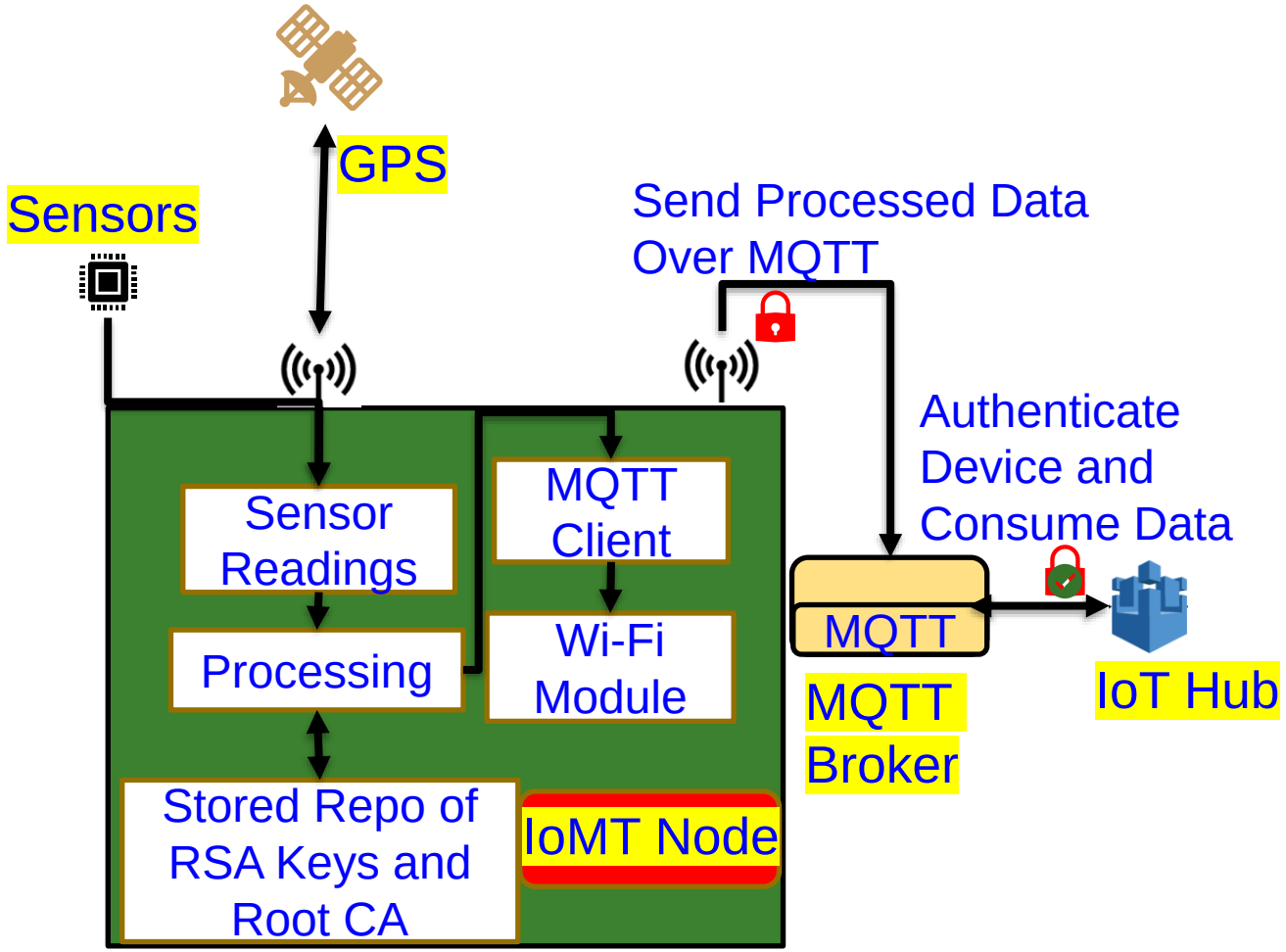
Novel Contributions

- Expedite the order processing and prompt decision making
- Information fragmentation issue is addressed
- Detecting counterfeits easily in the supply chain
- Increasing accountability of participating entities
- Drug recall process made easier
- Real-time decision support tool is provided for pharmaceutical supply chains

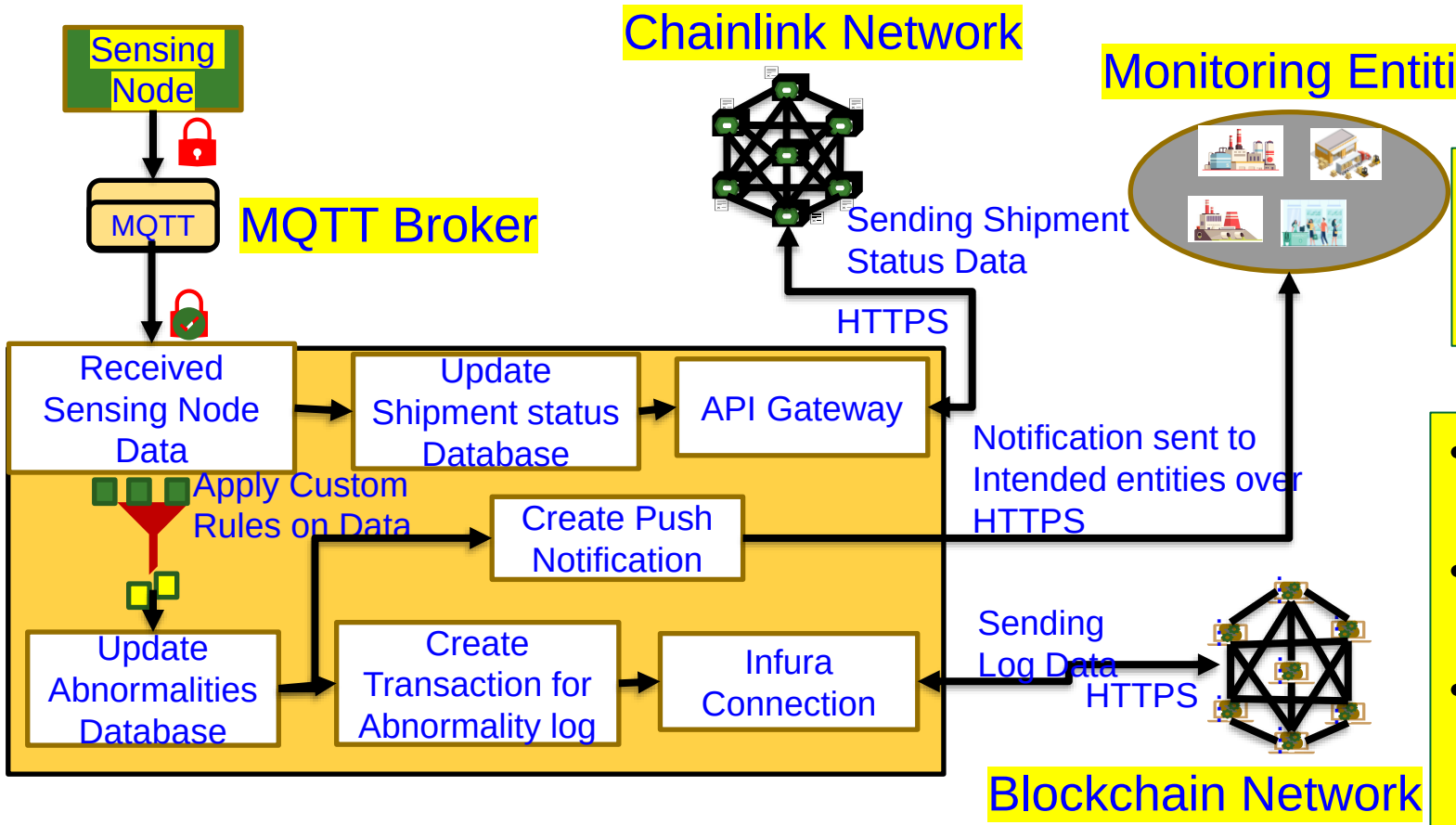
PharmaChain Sensing Node



- Designed to monitor important parameters for pharmaceutical shipment which include temperature, humidity along with GPS coordinates of the shipment
- Monitoring data from sensing nodes will be processed and formatted into a JSON file before being sent to the cloud component
- Lightweight Message Queuing Telemetry Transport (MQTT) protocol and topics are used

Source: Bapatla, A.K., et al.: PharmaChain: a blockchain to ensure counterfeit-free pharmaceutical supply chain. IET Netw. 1– 24 (2022). https://doi.org/10.1049/ntw2.12041

PharmaChain Cloud Component

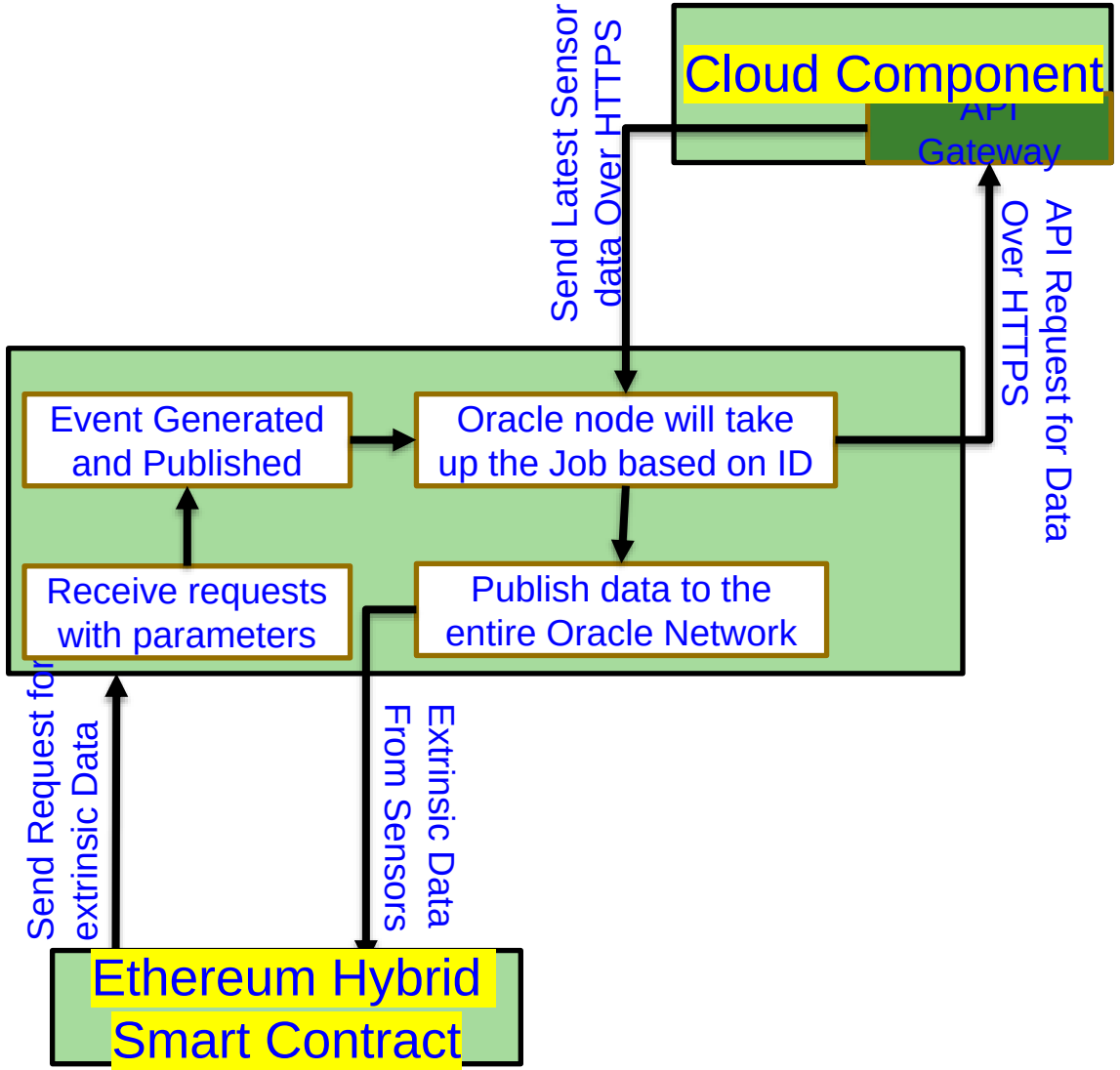


- Smart contracts cannot interact with API or external environmental data

- Cloud component used for designing data provider for Oracle.
- Data feeds to the smart contracts are done by Oracles.
- It is simply decentralized verifiable data to integrate smart contracts with external data feeds.

Source: Bapatla, A.K., et al.: PharmaChain: a blockchain to ensure counterfeit-free pharmaceutical supply chain. IET Netw. 1– 24 (2022). https://doi.org/10.1049/ntw2.12041

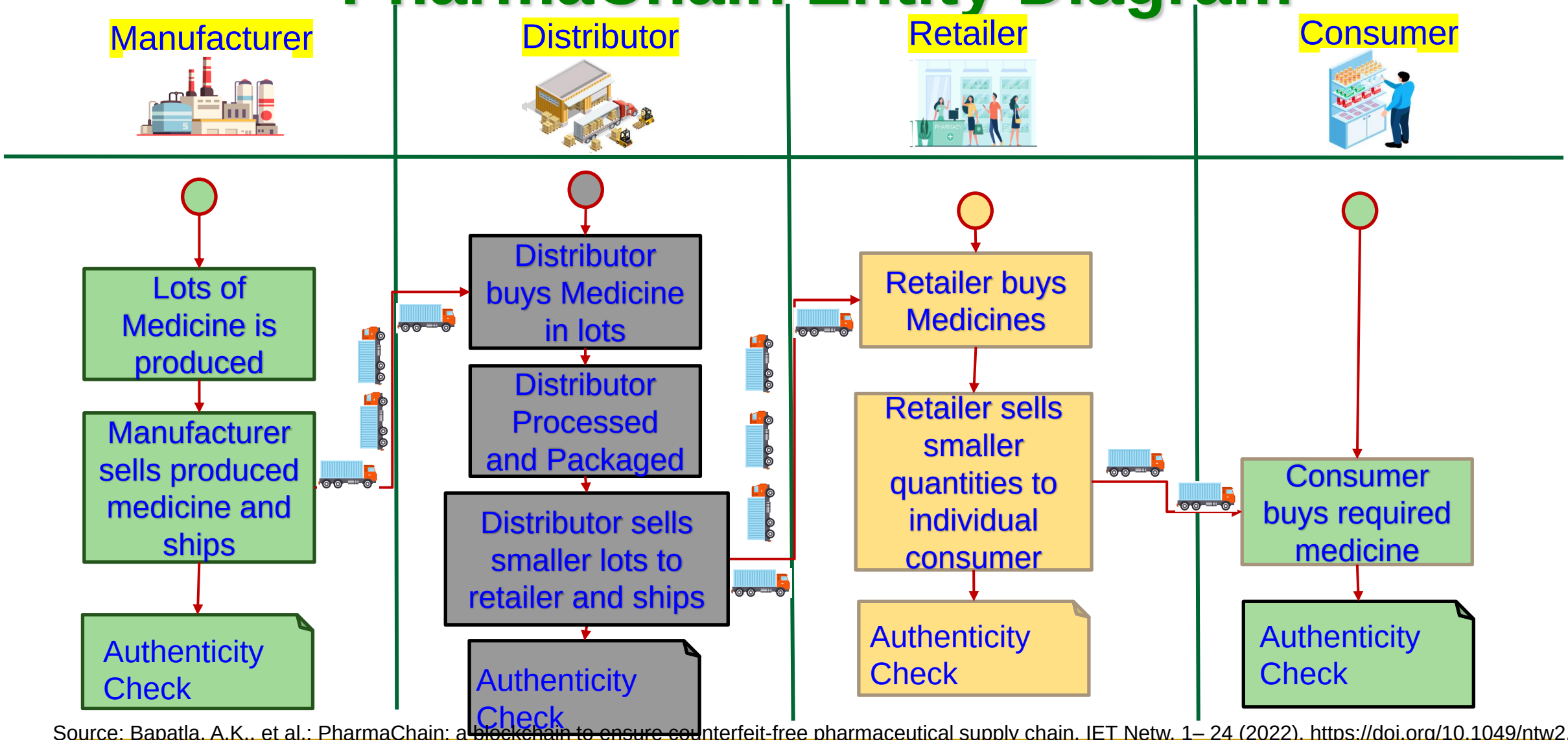
PharmaChain Oracle Component



- Multiple jobs are executed to fetch the data instead of a single job
- Results from multiple jobs are aggregated
- Aggregated data is published to hybrid smart contract

Source: Bapatla, A.K., et al.: PharmaChain: a blockchain to ensure counterfeit-free pharmaceutical supply chain. IET Netw. 1– 24 (2022). https://doi.org/10.1049/ntw2.12041

PharmaChain Entity Diagram



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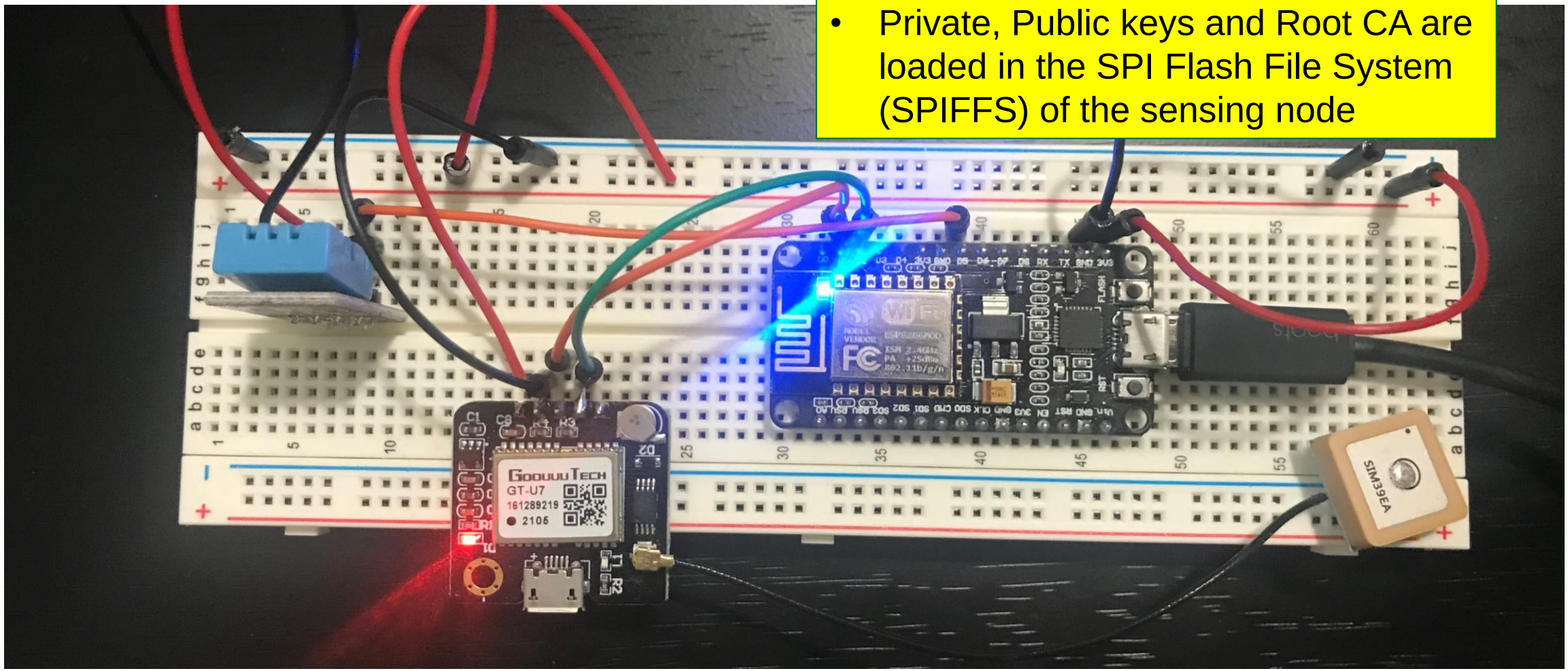
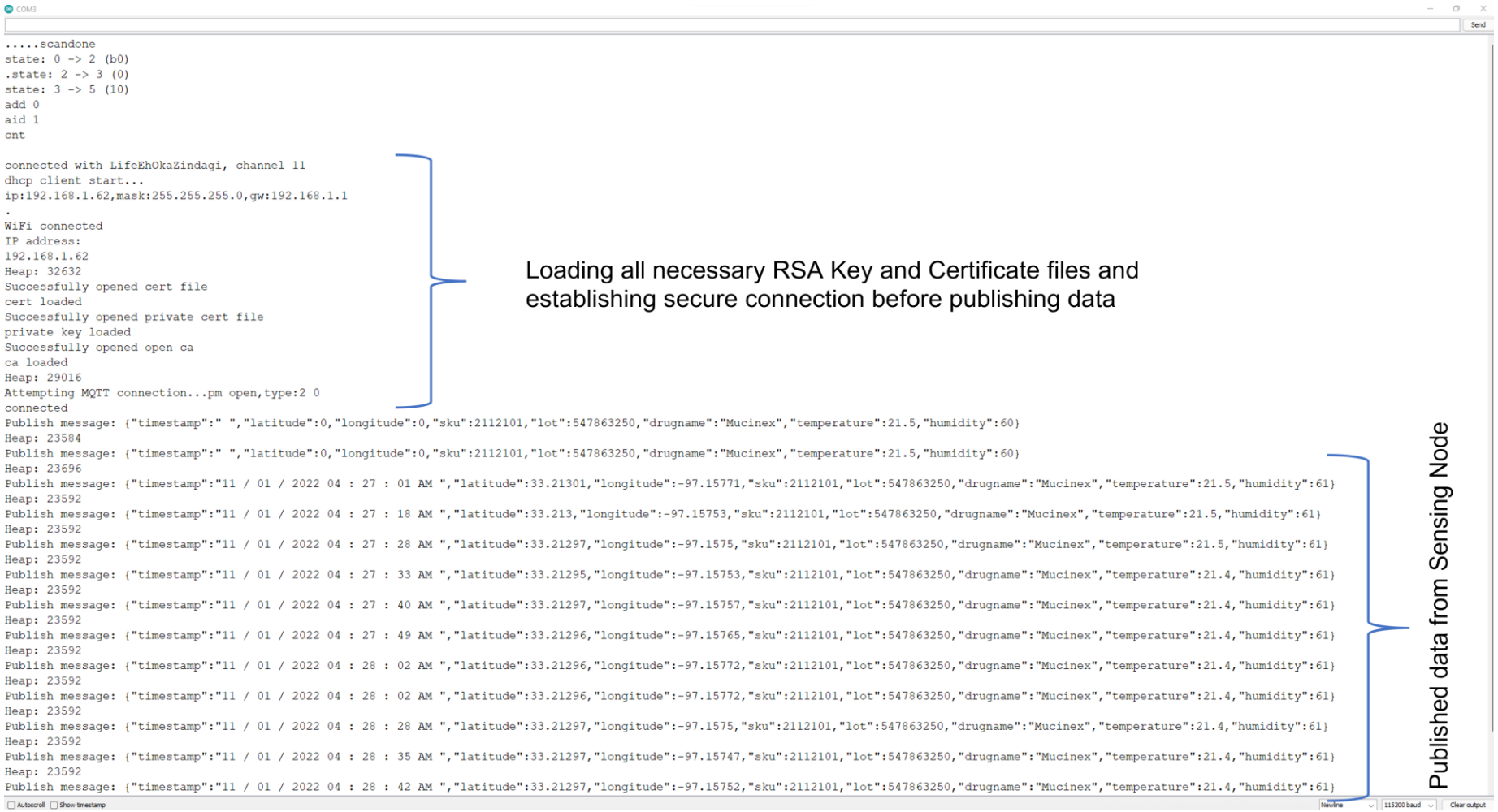
Designed Sensing Node



- Private, Public keys and Root CA are loaded in the SPI Flash File System (SPIFFS) of the sensing node

Source: Bapatla, A.K., et al.: PharmaChain: a blockchain to ensure counterfeit-free pharmaceutical supply chain. IET Netw. 1– 24 (2022). https://doi.org/10.1049/ntw2.12041

Sensing Node Data



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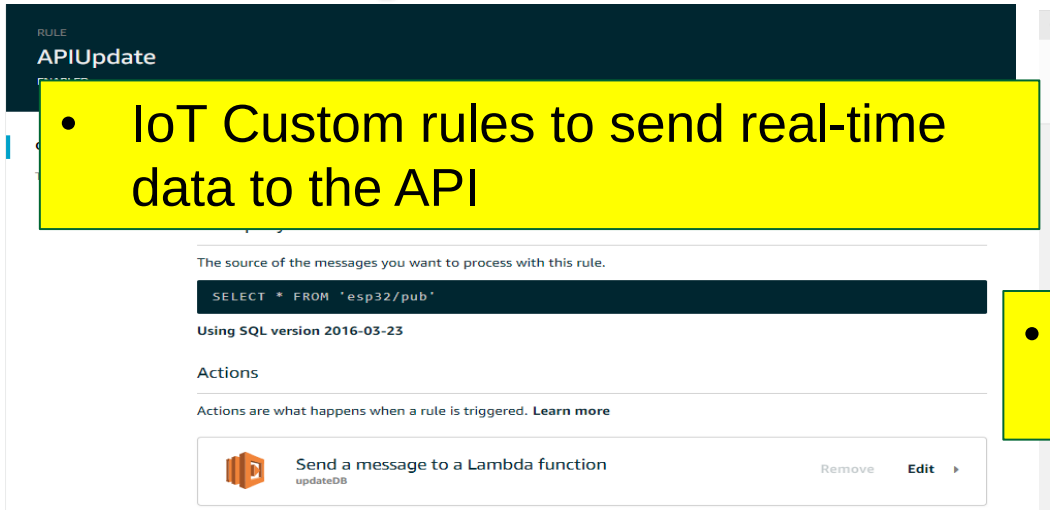
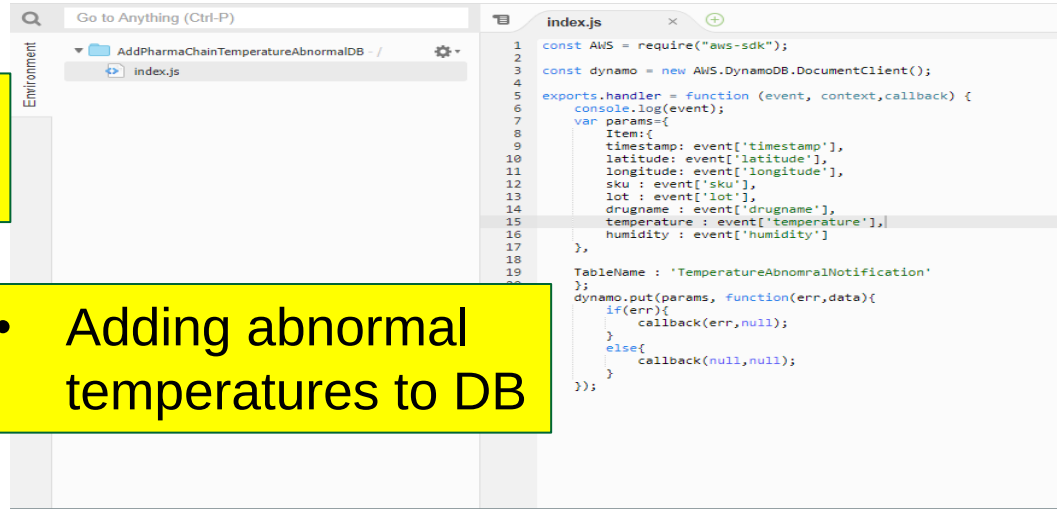
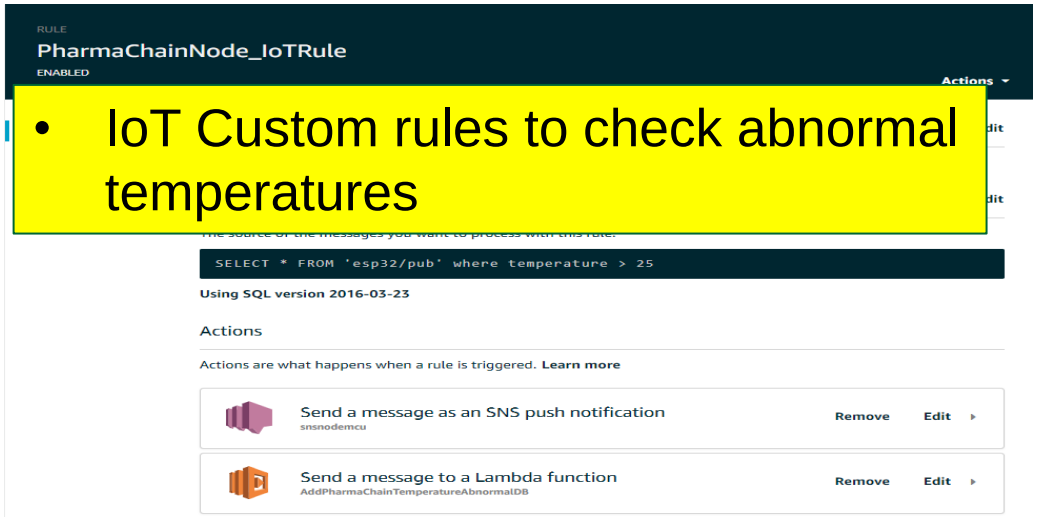
Implemented Cloud Component



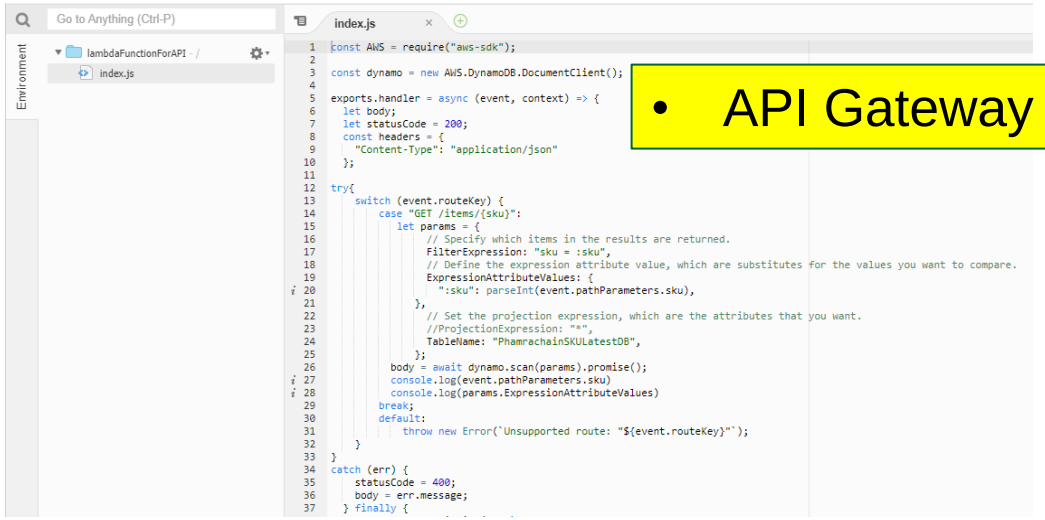
- IoT Custom rules to send real-time data to the API



- Adding abnormal temperatures to DB



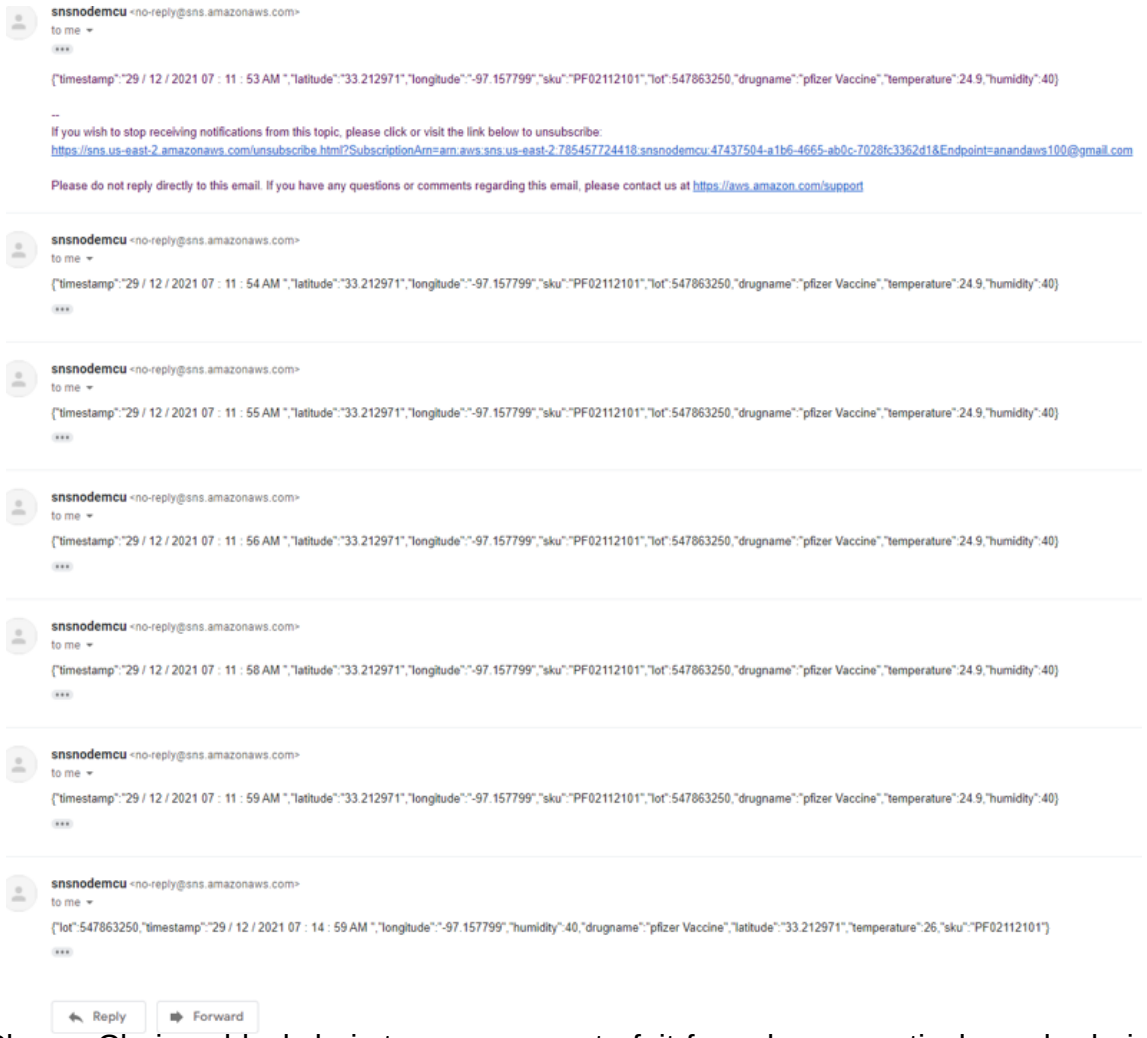
- IoT Custom rules to check abnormal temperatures



- API Gateway

Source: Bapatla, A.K., et al.: PharmaChain: a blockchain to ensure counterfeit-free pharmaceutical supply chain. IET Netw. 1– 24 (2022). https://doi.org/10.1049/ntw2.12041

Alerts Generated



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to me

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to me

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to me

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to me

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to me

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Reply Forward

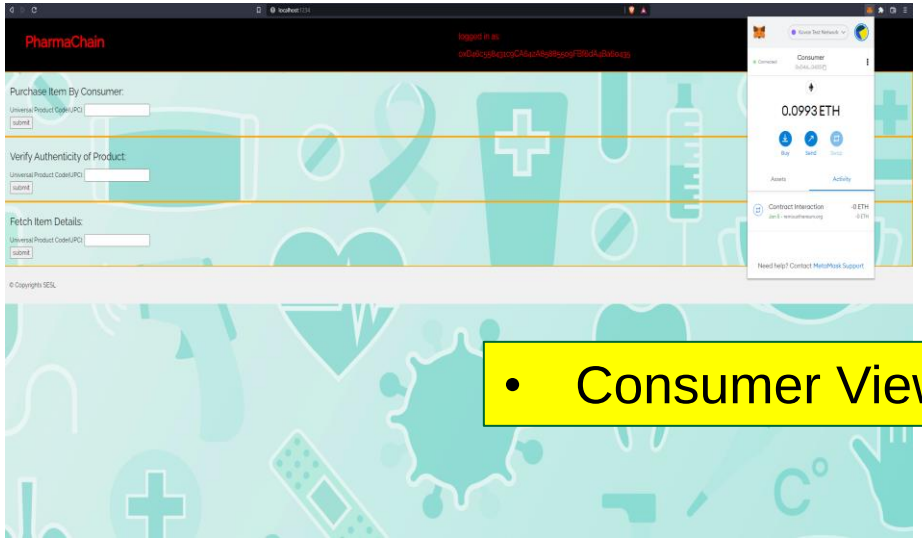
Source: Bapatla, A.K., et al.: PharmaChain: a blockchain to ensure counterfeit-free pharmaceutical supply chain. IET Netw. 1– 24 (2022). https://doi.org/10.1049/ntw2.12041

Web DApp Interface

- Manufacturer View

- Distributor View

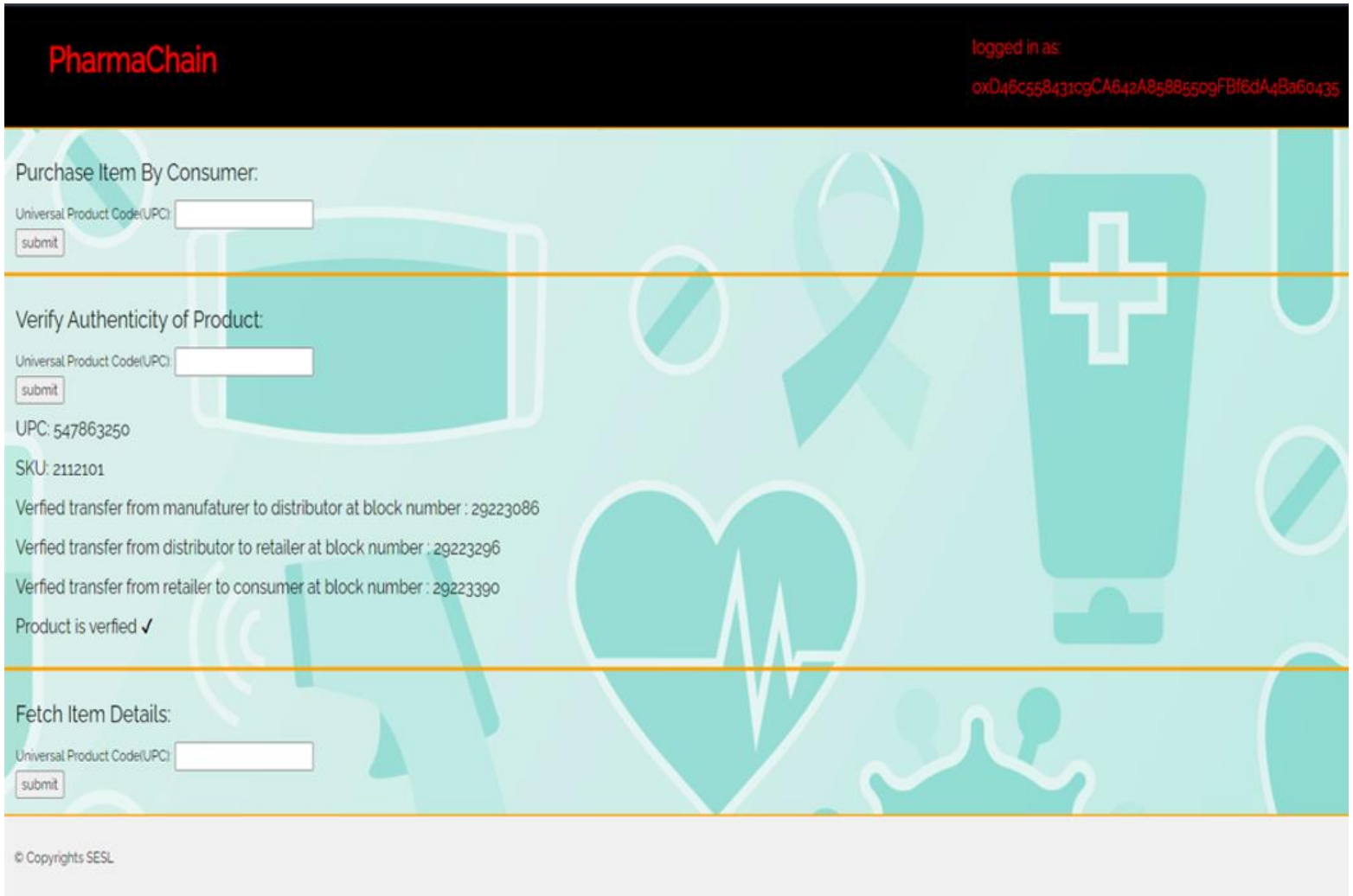
- Retailer View



- Consumer View

Source: Bapatla, A.K., et al.: PharmaChain: a blockchain to ensure counterfeit-free pharmaceutical supply chain. IET Netw. 1– 24 (2022). https://doi.org/10.1049/ntw2.12041

Consumer Verifying Authenticity



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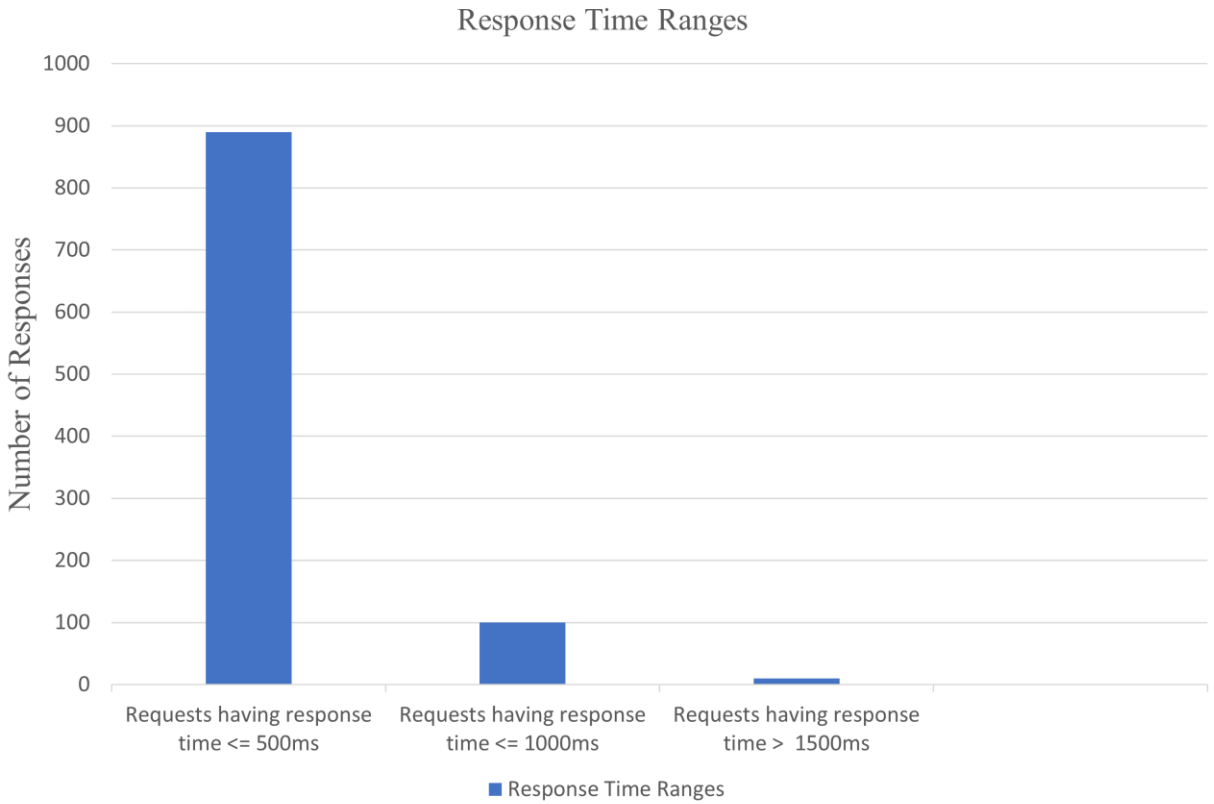
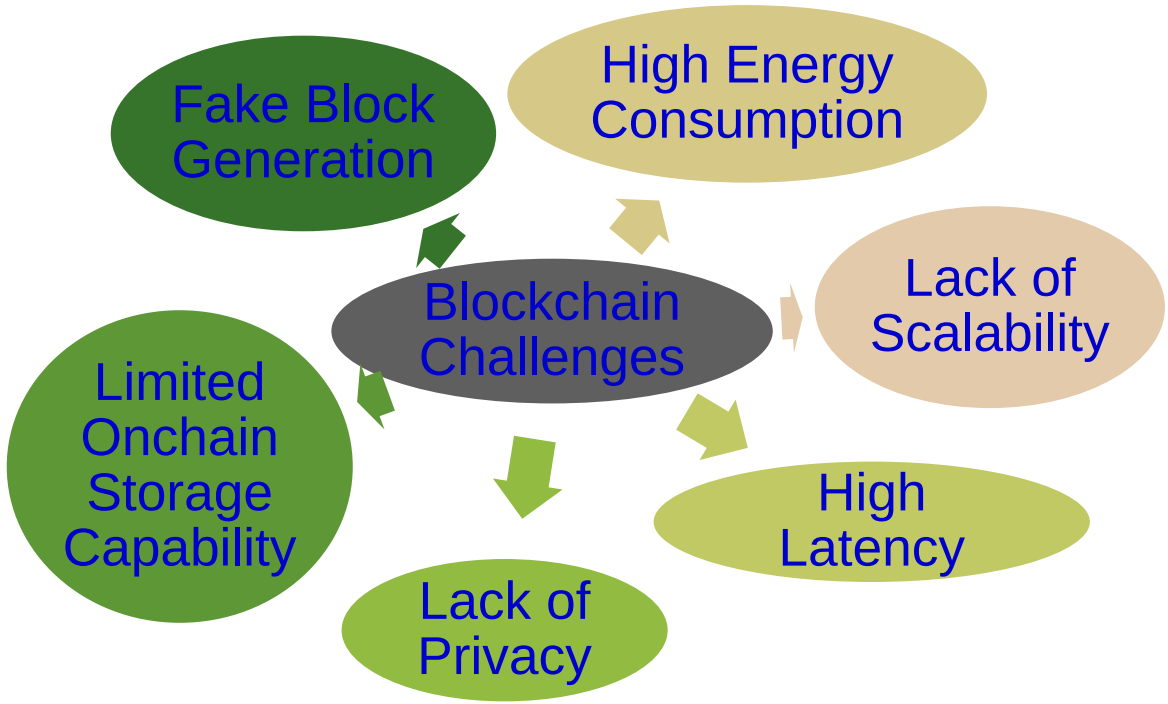
Performance and Cost Analysis

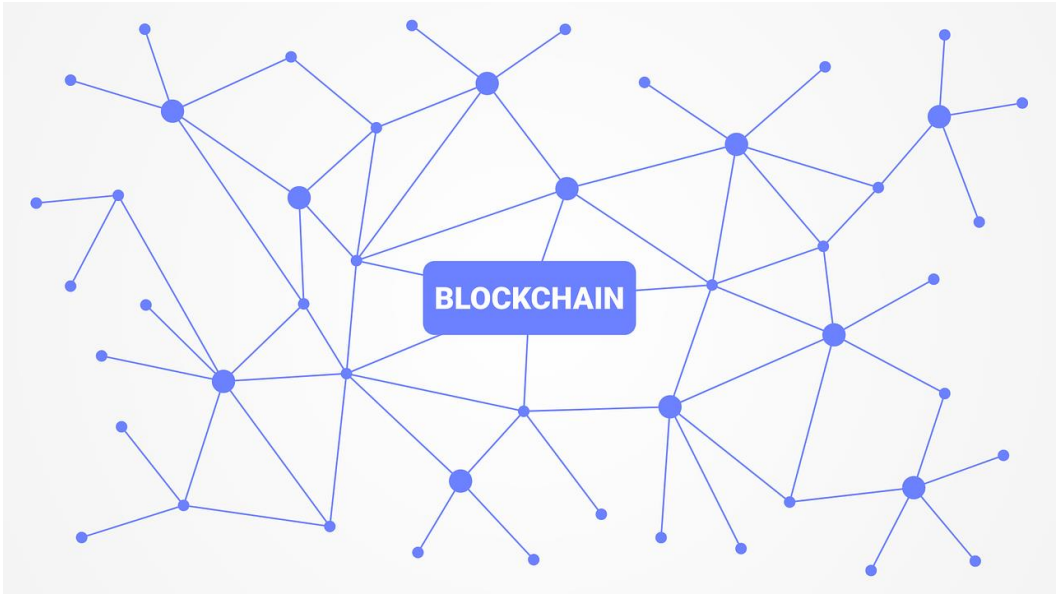


Parameters	Value
Number of Oracle Requests sent	1000
Load Duration	2 Seconds
Failed Requests	0
Percentage of Error	0%
Average Response Time (ms)	285.196 ms
Maximum Response Time (ms)	78ms
Throughput (requests/sec)	16.66

Source: Bapatla, A.K., et al.: PharmaChain: a blockchain to ensure counterfeit-free pharmaceutical supply chain. IET Netw. 1– 24 (2022). https://doi.org/10.1049/ntw2.12041

Blockchain has Many Challenges





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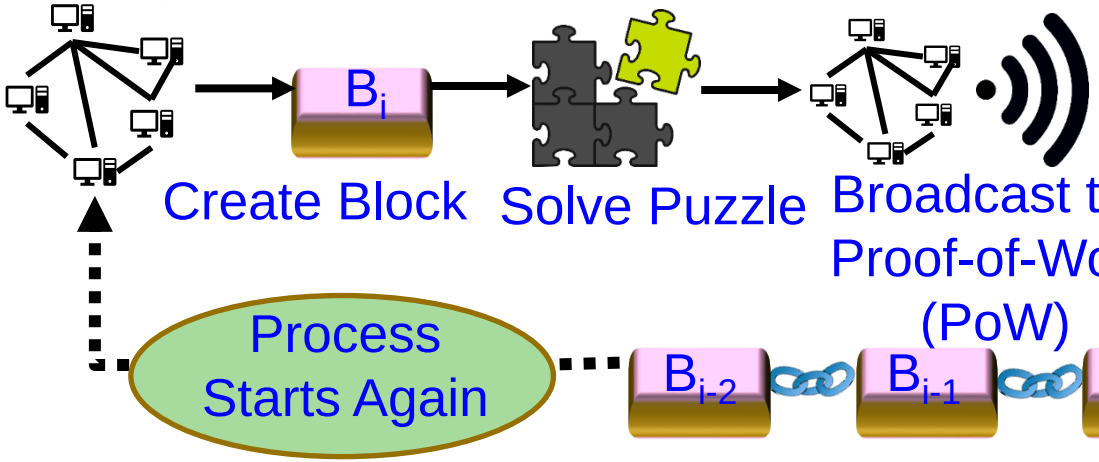
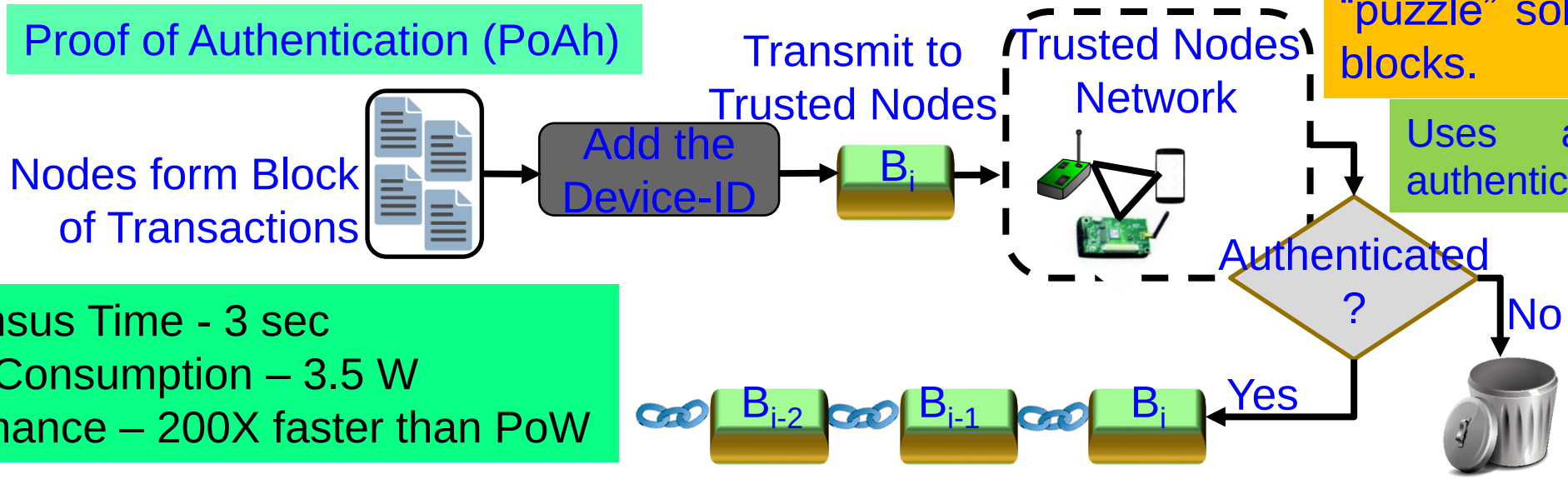
Our EasyChain: Proof-of-Authentication (PoAh)



Proof-of-Work (PoW)

Eliminates cryptographic "puzzle" solving to validate blocks.

Proof of Authentication (PoAh)

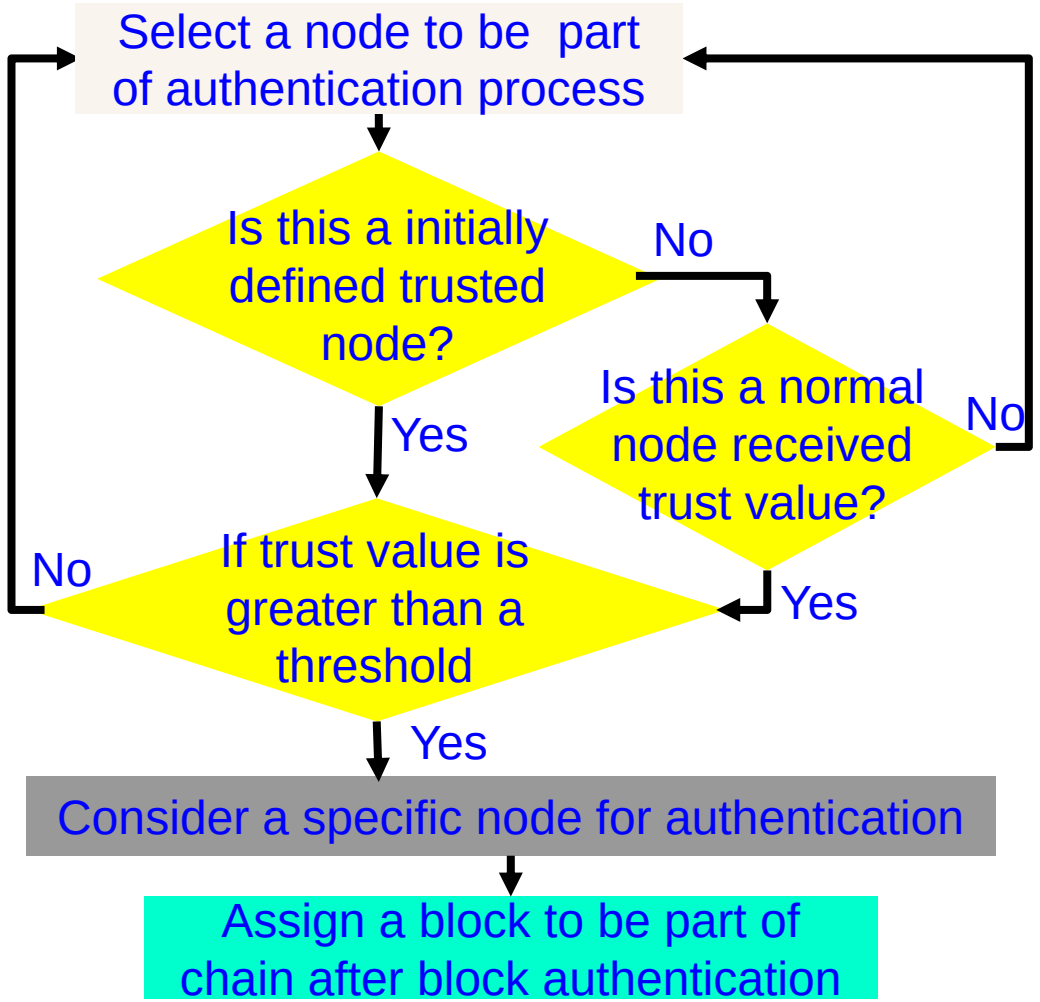


Uses a cryptographic authentication mechanism.

Consensus Time - 3 sec
Power Consumption – 3.5 W
Performance – 200X faster than PoW

Source: D. Puthal and S. P. Mohanty, "Proof of Authentication: IoT-Friendly Blockchains", *IEEE Potentials Magazine*, Vol. 38, No. 1, January 2019, pp. 26--29.

Our EasyChain: PoAh Authentication Process



Algorithm 1: PoAh Block Authentication

Provided:
All nodes in the network follow SHA-256 Hash
Individual node has Private (PrK) and Public key (PuK)
Steps:
(1) Nodes combine transactions to form blocks
  (Trx^{+}) → blocks
(2) Blocks sign with own private key
  S_{PrK} (block) → broadcast
(3) Trusted node verifies signature with source public key
  V_{PuK}(block) → MAC Checking
(4) If (Authenticated)
  Block||PoAh(ID) → broadcast
  H(block) → Add blocks into chain
(5) Else
  Drop blocks
(6) GOTO (Step-1) for next block

Steps to find a Trusted Node which will Authenticate a Block.

Source: D. Puthal and S. P. Mohanty, "Proof of Authentication: IoT-Friendly Blockchains", *IEEE Potentials Magazine*, Vol. 38, No. 1, January 2019, pp. 26--29.

Addressing Blockchain Scalability Issues and Control During Transport

PharmaChain 2.0: A Blockchain Framework for Secure Remote Monitoring of Drug Environmental Parameters in Pharmaceutical Cold Supply Chain

Issues in Traditional PSC

08/22/2022

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News Source: Affairs, O. of R. (n.d.). *Press releases*. U.S. Food and Drug Administration. Retrieved November 15, 2022, from https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/criminal-investigations/press-releases

Motivation

- Temperature-controlled drug's life cycle includes:
  - Monitoring and controlling the temperature during the storage of medicines in warehouses.
  - Maintaining the temperature ranges during the transportation of drugs.
  - Packaging should be taken care of following all recommended procedures.
  - Pharmacies and care sites should be properly equipped to maintain the medication temperature until dispensed.

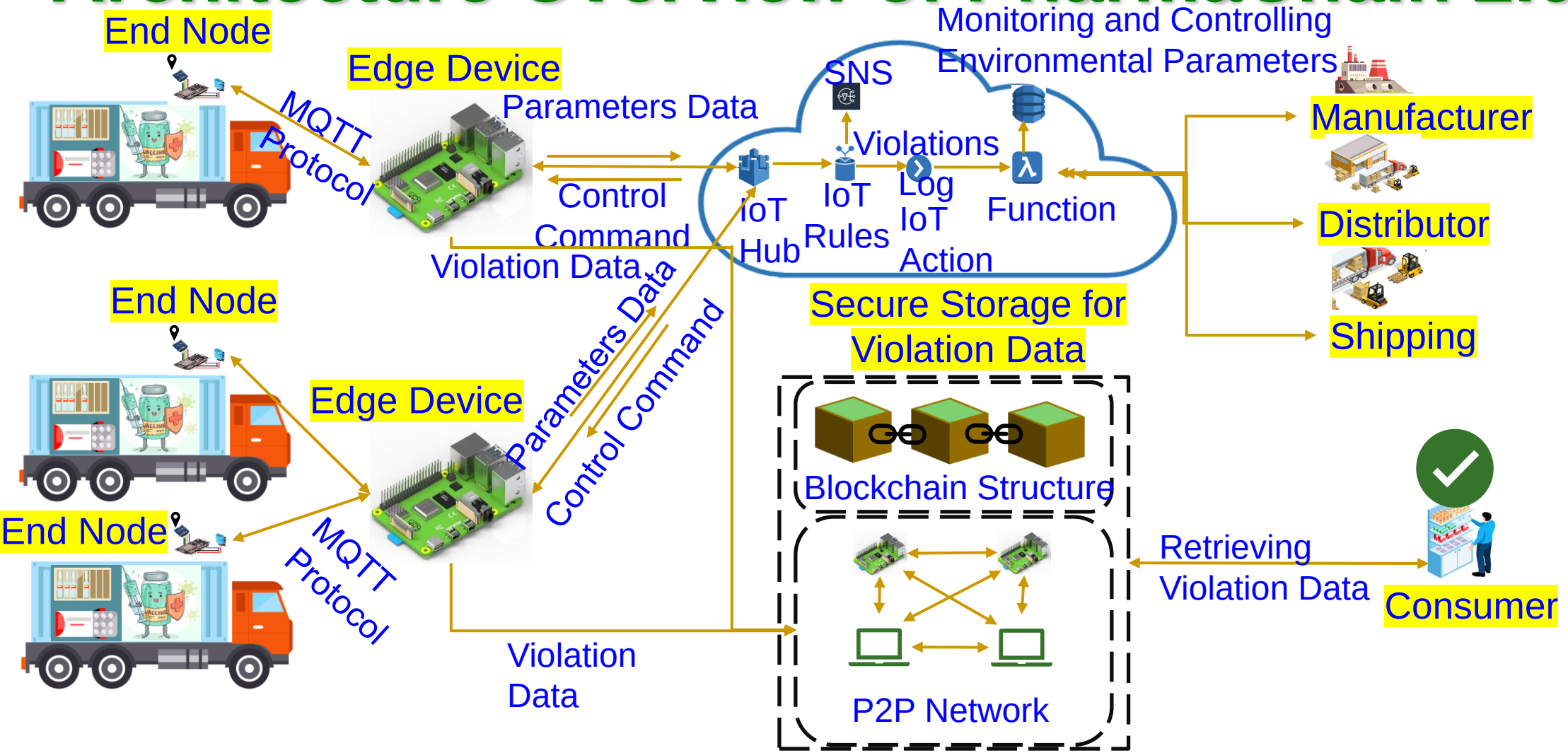
Novel Contributions

- Near real-time data will be propagated in the P2P network. Hence, prompt action can be taken to prevent decreases in drug efficacy.
- Consensus in the proposed P2P network will make the system more robust to different security threats.
- PharmaChain 2.0 makes use of IoT systems to provide continuous monitoring and control throughout the drug life cycle in the supply chain.
- Data security is provided by using the immutable characteristic of blockchain.
- PharmaChain 2.0 provides a cost-efficient infrastructure that can be adapted on a large scale as cold supply chains are huge.

PharmaChain Versus PharmaChain 2.0

PharmaChain	PharmaChain 2.0
Ethereum Blockchain Used for Tracking and Tracing in Pharmaceutical Supply Chain	PoAh Consensus Based Blockchain, used for both Tracking & Tracing along with Monitoring and Controlling Temperature Excursions
Proof-of-Authority (PoA) with less throughput compared to PoAh	Proof-of-Authentication (PoAh) with higher throughput
Private Blockchain with only nodes participating from Entities	Private Blockchain with only nodes participating from Entities
Not IoT friendly Consensus	IoT Friendly Consensus with less power and computations
The average transaction processing time is 5.6 sec.	The average transaction time has been improved significantly to 322.28ms

Architecture Overview of PharmaChain 2.0



Source: A. K. Bapatla, **S. P. Mohanty**, E. Kougianos, and D. Puthal, "PharmaChain 2.0: A Blockchain Framework for Secure Remote Monitoring of Drug Environmental Parameters in Pharmaceutical Cold Supply Chain", in *Proceedings of the IEEE International Symposium on Smart Electronic Systems (iSES)*, 2022, pp. Accepted.

Proposed Algorithms – Log Generation

Algorithm 1 Proposed Violation Data Log Generation Algorithm For PharmaChain 2.0

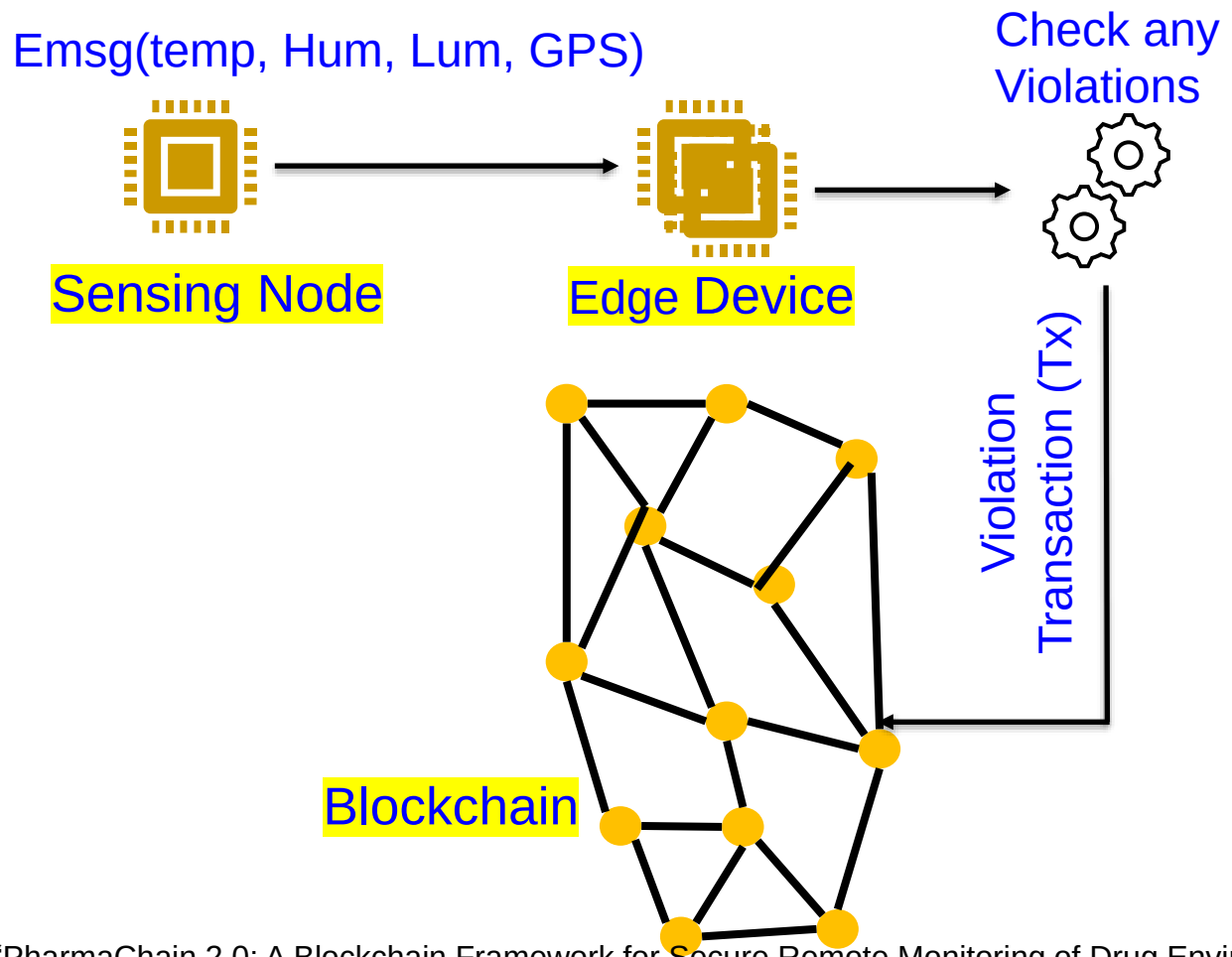
Input: Temperature, Humidity, Luminosity and GPS Position data from End node

Output: Violation data transaction published to blockchain network and cloud layer

1: End node E prepares a message E_{msg} with all the environmental parameters Temperature (temp), Humidity (hum), Luminosity (lum) and GPS position data(gps)
2: Prepared message is published to the topic τ of edge device using light weight pub-sub protocol
3: E.Publish(τ,E_{msg}(temp,Hum,lum,GPS))
4: Edge device E_e consumes the messages sent by the end nodes
5: E_e.consume(τ)

Phase 1 – Edge Device Processing

6: **procedure** EDGE DEVICE PROCESSING
7: **for** Every message E_{msg} **do**
8: Check the pre-defined conditions on Temperature, Humidity, Luminosity
9: **if** Any Violation Detected **then**
10: Publish violation data V_E to both cloud
11: E_e.Publish(V_E)
12: Prepare and send transaction to blockchain network
13: Tx ← E_e.prepareTransaction(V_E)
14: E_e.generateTransaction(Tx)
15: **end if**
16: **end for**
17: **end procedure**



Source: A. K. Bapatla, **S. P. Mohanty**, E. Kougianos, and D. Puthal, "PharmaChain 2.0: A Blockchain Framework for Secure Remote Monitoring of Drug Environmental Parameters in Pharmaceutical Cold Supply Chain", in *Proceedings of the IEEE International Symposium on Smart Electronic Systems (iSES)*, 2022, pp. Accepted.

Proposed Algorithm – Log Generation

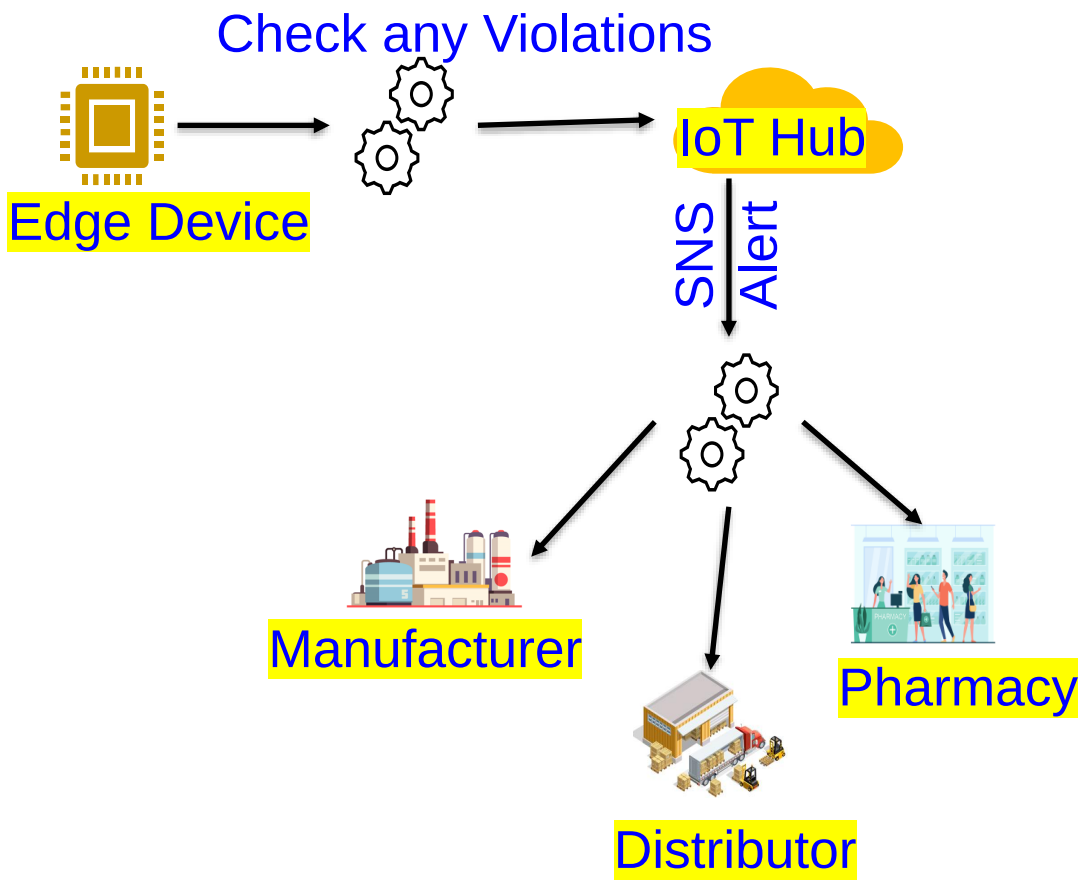
Phase 2 – Cloud Layer Processing

procedure CLOUD LAYER PROCESSING
  for Every Violation Data V_E received **do**
    Consume the message
    IoTHub.consume(V_E)
    Generate an alert using SNS (Simple Notification Service) to the registered entities
    SNS.generateAlert(V_E)
  end for
end procedure

Phase 3 – Blockchain Layer Processing

procedure BLOCKCHAIN LAYER PROCESSING
  Generated transaction is received into unconfirmed transactions pool (UTx)
  UTx.append(Tx)
  Miner picks transaction from UTx pool and creates a block
  Mining performed based on PoAh consensus protocol
  New block is added to the chain at all the participating nodes in the network creating an immutable violation data log

end procedure

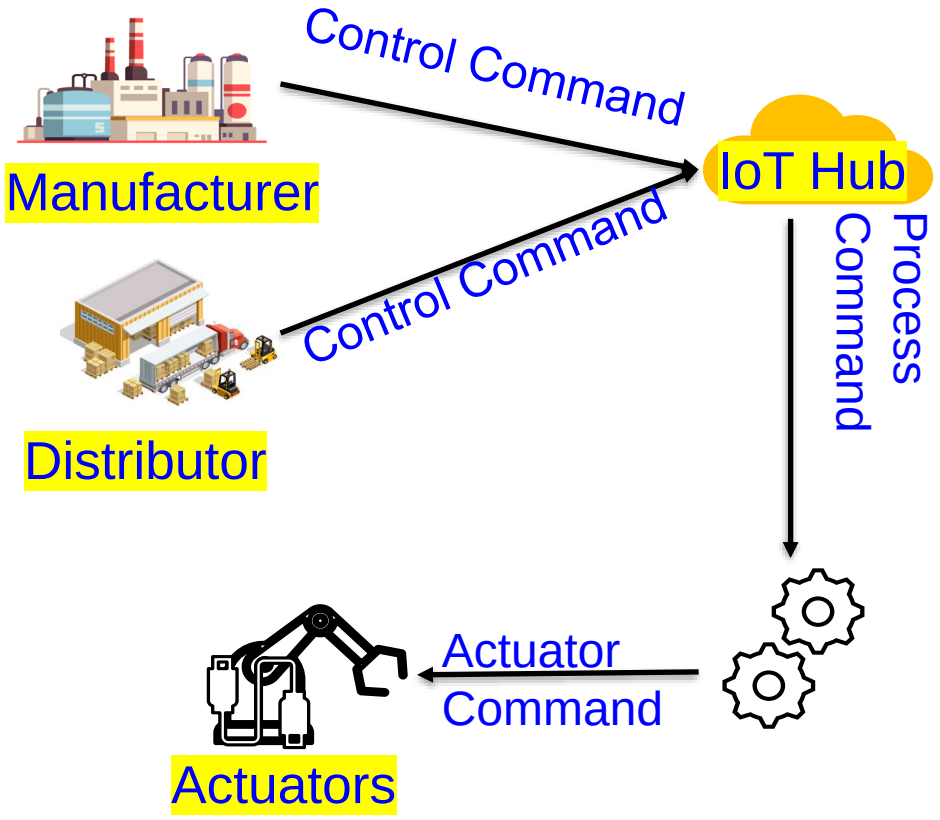


Source: A. K. Bapatla, **S. P. Mohanty**, E. Kougianos, and D. Puthal, "PharmaChain 2.0: A Blockchain Framework for Secure Remote Monitoring of Drug Environmental Parameters in Pharmaceutical Cold Supply Chain", in *Proceedings of the IEEE International Symposium on Smart Electronic Systems (iSES)*, 2022, pp. Accepted.

Proposed Algorithm- Control Algorithm

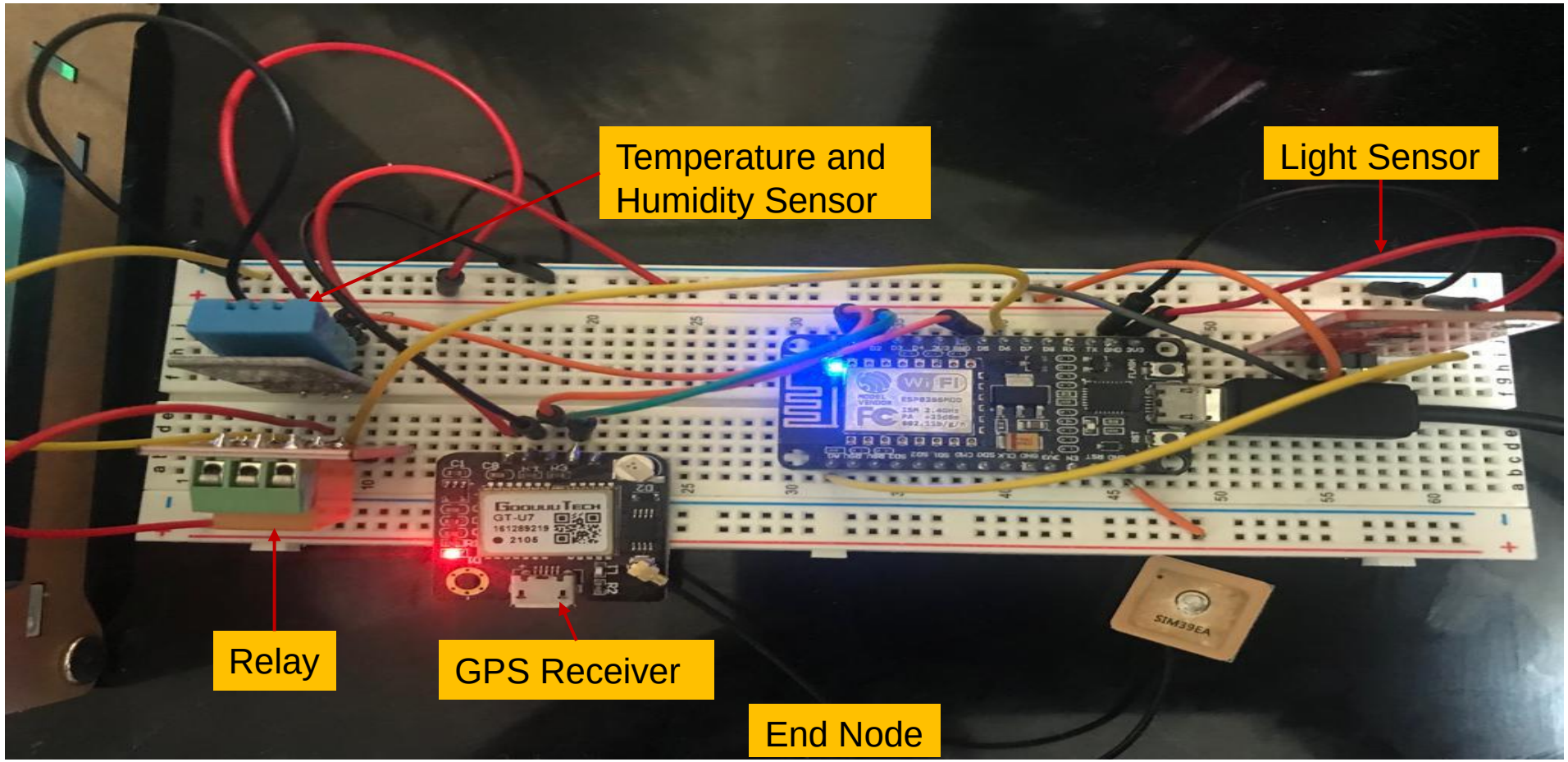
Algorithm 2 Proposed Control Algorithm For PharmaChain 2.0

1: **for** Each violation alert received **do**
2: Alert is reviewed by the responsible entity in the cold supply chain network
3: Control command CC_e for actuator is prepared by the entity
4: $CC_e \leftarrow$ Entity.prepareCommand(Control Instructions)
5: Control command is published to the cloud layer
6: Entity.publish(CC_e)
7: Cloud Layer processes the command and prepares control instructions for end node
8: $CC_e^+ \leftarrow$ IoTHub.process(CC_e)
9: Cloud layer published the processed control command to the edge devices
10: IoTHub.publish(CC_e^+)
11: Edge devices will send control instructions to the corresponding end devices
12: **for** Received Control Instructions by End Node e **do**
13: e.consume(CC_e^+))
14: Process and turn ON/OFF the actuators
15: e.process(CC_e^+))
16: **end for**
17: **end for**



Source: A. K. Bapatla, **S. P. Mohanty**, E. Kougianos, and D. Puthal, "PharmaChain 2.0: A Blockchain Framework for Secure Remote Monitoring of Drug Environmental Parameters in Pharmaceutical Cold Supply Chain", in *Proceedings of the IEEE International Symposium on Smart Electronic Systems (iSES)*, 2022, pp. Accepted.

Implemented Sensing Node



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Implementation and Validation

```
pi@raspberrypi2: ~/Desktop/Implementation_python
login as: pi
pi[redacted]'s password:
Linux raspberrypi2 5.10.92-v7l+ #1514 SMP Mon Jan 17 17:38:03 GMT 2022 armv71

The programs included with the Debian GNU/Linux system are free software;
the exact distribution terms for each program are described in the
individual files in /usr/share/doc/*/copyright.

Debian GNU/Linux comes with ABSOLUTELY NO WARRANTY, to the extent
permitted by applicable law.
Last login: Tue Feb  1 19:03:56 2022
pi@raspberrypi2:~ $ cd Desktop/Impl*
pi@raspberrypi2:~/Desktop/Implementation_python $ python3 app.py 1234 1
 * Serving Flask app 'app' (lazy loading)
 * Environment: production
   WARNING: This is a development server. Do not use it in a production deployme
nt.
   Use a production WSGI server instead.
 * Debug mode: off
 * Running on all addresses.
   WARNING: This is a development server. Do not use it in a production deployme
nt.
 * Running on http://[redacted]:1234/ (Press CTRL+C to quit)
```

(a) Edge Device Running Proof of Authentication Based Blockchain

```
login as: pi
pi[redacted]'s password:
Linux raspberrypi2 5.10.92-v7l+ #1514 SMP Mon Jan 17 17:38:03 GMT 2022 armv71

The programs included with the Debian GNU/Linux system are free software;
the exact distribution terms for each program are described in the
individual files in /usr/share/doc/*/copyright.

Debian GNU/Linux comes with ABSOLUTELY NO WARRANTY, to the extent
permitted by applicable law.
Last login: Tue Feb  1 22:42:31 2022
pi@raspberrypi2:~ $ cd /Desktop/Implementation_python
-bash: cd: /Desktop/Implementation_python: No such file or directory
pi@raspberrypi2:~ $ cd Desktop/Implementation_python
pi@raspberrypi2:~/Desktop/Implementation_python $ python3 app.py 3456 3
 * Serving Flask app 'app' (lazy loading)
 * Environment: production
   WARNING: This is a development server. Do not use it in a production deployme
nt.
   Use a production WSGI server instead.
 * Debug mode: off
 * Running on all addresses.
   WARNING: This is a development server. Do not use it in a production deployme
nt.
 * Running on http://[redacted]:3456/ (Press CTRL+C to quit)
```

(b) Edge Device Running Proof of Authentication Based Blockchain

```
pi@raspberrypi1: ~/Desktop/Implementation_python
login as: pi
pi[redacted]'s password:
Linux raspberrypi1 5.10.17-v7l+ #1403 SMP Mon Feb 22 11:33:35 GMT 2021 armv71

The programs included with the Debian GNU/Linux system are free software;
the exact distribution terms for each program are described in the
individual files in /usr/share/doc/*/copyright.

Debian GNU/Linux comes with ABSOLUTELY NO WARRANTY, to the extent
permitted by applicable law.
Last login: Tue Feb  1 22:31:44 2022 from 192.168.1.235
pi@raspberrypi1:~ $ cd Desktop/Implementation_python
pi@raspberrypi1:~/Desktop/Implementation_python $ python3 app.py 2345 2
 * Serving Flask app 'app' (lazy loading)
 * Environment: production
   WARNING: This is a development server. Do not use it in a production deployme
nt.
   Use a production WSGI server instead.
 * Debug mode: off
 * Running on all addresses.
   WARNING: This is a development server. Do not use it in a production deployme
nt.
 * Running on http://[redacted]:2345/ (Press CTRL+C to quit)
```

(c) Edge Device Running Proof of Authentication Based Blockchain

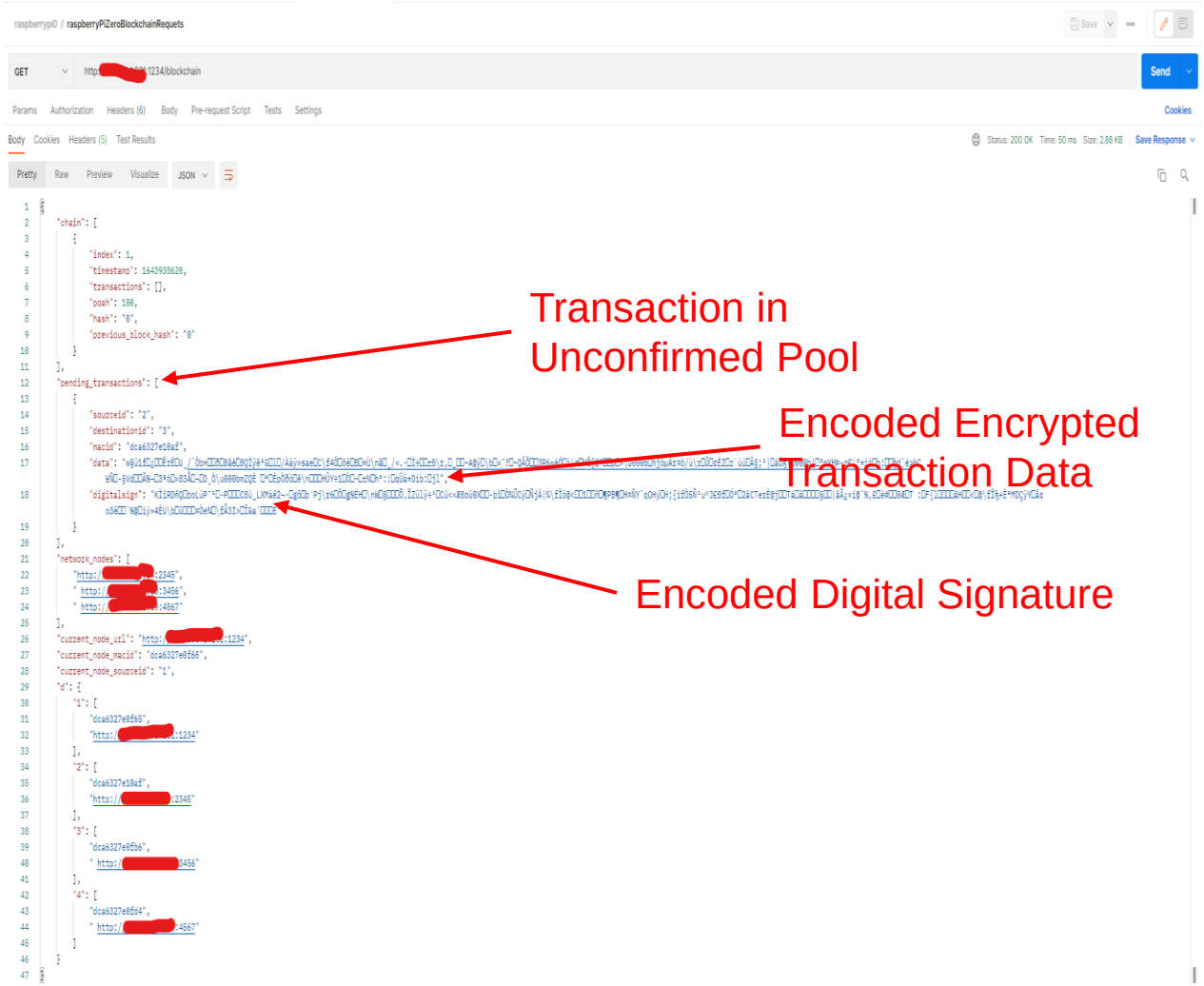
(e) Implemented Four Node Prototype for PharmaChain 2.0

```
pi@raspberrypi3: ~/Desktop/Implementation_python
login as: pi
pi[redacted]'s password:
Linux raspberrypi3 5.10.63-v7l+ #1459 SMP Wed Oct 6 16:41:57 BST 2021 armv71

The programs included with the Debian GNU/Linux system are free software;
the exact distribution terms for each program are described in the
individual files in /usr/share/doc/*/copyright.

Debian GNU/Linux comes with ABSOLUTELY NO WARRANTY, to the extent
permitted by applicable law.
Last login: Tue Feb  1 22:42:32 2022
pi@raspberrypi3:~ $ cd Desktop/Impl*
pi@raspberrypi3:~/Desktop/Implementation_python $ python3 app.py 4567 4
 * Serving Flask app 'app' (lazy loading)
 * Environment: production
   WARNING: This is a development server. Do not use it in a production deployment.
   Use a production WSGI server instead.
 * Debug mode: off
 * Running on all addresses.
   WARNING: This is a development server. Do not use it in a production deployment.
 * Running on http://[redacted]:4567/ (Press CTRL+C to quit)
```

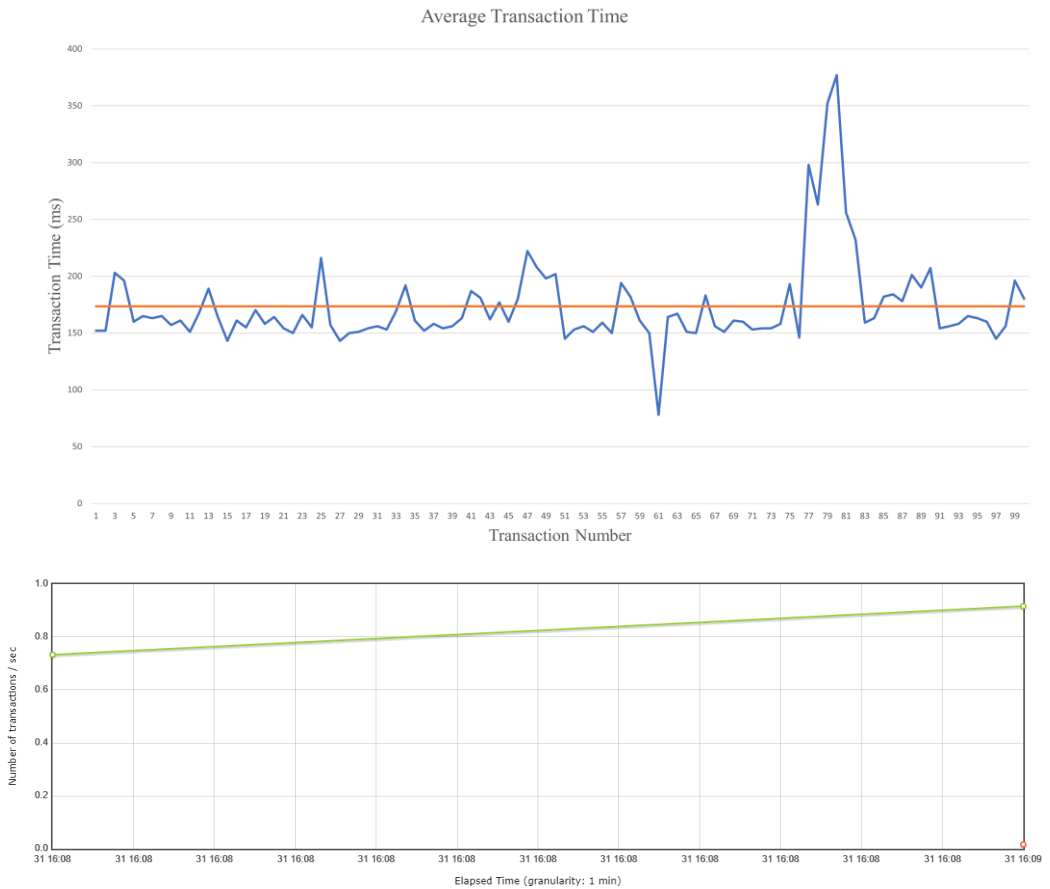
(d) Edge Device Running Proof of Authentication Based Blockchain

- Two nodes act as a miner nodes which are responsible for creating blocks from the unconfirmed

Pharmachain 2.0 Validation

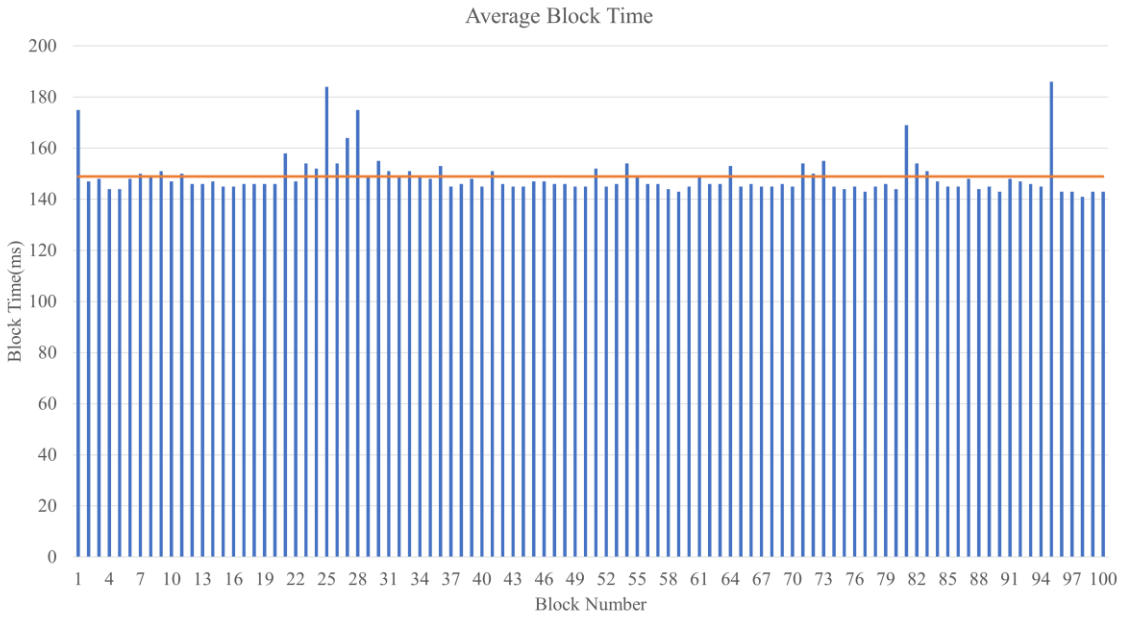


Testbed Evaluation



	Transaction Time	Block Time	Total Time
PharmaChain 2.0	173.39ms	148.89 ms	322.28ms

Analysis Summary of PharmaChain 2.0



Comparative Analysis with Existing Solutions

Comparison of Proposed PharmaChain 2.0 solution with Existing Solutions					
Features	**Blockchain**	**Consensus Protocol**	**Openness**	**IoT Friendly Consensus**	**Average Time**
CryptoCargo [15]	Ethereum	Proof-of-Work (PoW)	Public	No	43.36 sec
PharmaChain [9]	Ethereum	Proof-of-Authority (PoA)	Private	No	5.6 sec
Current Paper (PharmaChain 2.0)	PoAh Consensus Based Blockchain	Proof-of-Authentication (PoAh)	Private	Yes	322.28ms

Conclusion

- This paper presents a novel lightweight blockchain solution to ensure the safe handling of medicines carried in the cold supply chain.
- The proposed PharmaChain 2.0 provides continuous monitoring and control capabilities for different entities in the Pharmaceutical Supply Chain to take prompt actions for shipments.
- PharmaChain 2.0 works based on the lightweight consensus mechanism Proof-of-Authentication (PoAh) which is cost-efficient as no mining fees are involved and not computationally intensive, unlike other established consensus protocols.

Analysis Summary of PharmaChain 2.0

	Transaction Time	Block Time	Total Time
PharmaChain 2.0	173.39ms	148.89ms	322.28ms

Future Research

- In future work, we try to include more complex interaction scenarios between multiple entities in the pharmaceutical supply chains.
- User-friendly UI design can help to navigate through different functions provided by PharmaChain 2.0.
- Increasing the efficiency and throughput of the proposed system by further improving the consensus mechanism.
- Automating the procedures within the pharmaceutical supply chain to reduce latencies.

Thank You !!