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## CoDuBoTeSS: A Pilot Study to Eradicate Counterfeit Drugs via a Blockchain Tracer Support System on the Nigerian Frontier

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### ABSTRACT

The pharma-sector has maintained improved productivity and profitability via a concerted effort to address critical issues such as an unorganized regulatory system, lack of safety data, no standards in manufacture process, non-adaptation to pharma-chain, and no-harmony of inventory supports. Study proposes blockchain trace-support to ensure drugs quality, consumer safety, and its trading as asset. It uses a radio-frequency identification sensor to register manufacture and administration process, and provide a databank to trace drug records. Results notes: (a) presents a roadmap for adoption by the National Agency for Food and Drug Administration and Control (NAFDAC) to ensure a traceable pharmaceutical blockchain, (b) show ensemble is scalable for up-to 7500users to yield a performance of 1138-transactions per seconds with response time of 88secs for page retrieval and 128secs for queries respectively, and (c) yields slightly longer time for increased number of users via its world-state as stored in the permissionless blockchain hyper-fabric ledger. Thus, the framework can directly query and retrieve data without it traversing the whole ledger. This, in turn, improves the efficiency and effectiveness of the traceability system.

**Keywords:** Blockchain, Counterfeit drugs, Healthcare, Nigeria, CORDA, hyper-ledger fabric, HIPPA

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## 1. INTRODUCTION

Drugs have been around and are as old as nature [1] – they are targeted agents and solutions provisioned [2] to help resolve health issues within the human body [3]. Thus, the administration of counterfeit drug to an ailing body, animal or plant [4] – not only yields negative impacts [2] but worsens to causes organism/organ decay within the applied body [5]. Thus, counterfeited drug is not just an enemy to mankind [5]; But, it also have been known to kill, endanger the lives of its recipients, and even damages vital organs within the applied body or organism [6].

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Millions of lives are lost yearly as well as diseases outbreaks from these, both in Nigeria and globally, as a result of such counterfeited (fake and poorly designed) [7]. The fallout from such falsified and substandard drugs includes poisoning, untreated disease, early death, and treatment failure [8]. Today – pharmaceutical companies and their inherent supply chain have since become vulnerable to the threats cum attacks from fake/substandard drugs; And this, have since become a global menace as it has also become a topical issue of discuss in the global health landscape and sectors [9]. While, patient lives cannot be quantified in lieu of the incurred loss; however, the rising cost associated with patient welfare and administration of such fake and substandard drugs that has since become an issue of public health concern, has remained staggering in billions of dollars, both annually and globally [10]–[12].

Pharm companies must thus, secure and constantly scrutinize their supply chains as support frameworks for public health delivery. Mitigating the risks associated with counterfeit drugs – requires a food/drug (pharmaceutical) support supply chains to ensure effective management of drugs as inventory [13], their traceability from manufacturer to target patient [14], [15], resilience of the framework system to ensure operability irrespective of faults encountered [16], and security [17]. Drugs counterfeiting and compromised pharmaceuticals are quite prevalent both in Nigeria and Africa, at large [18]–[20]. The practice of counterfeiting is also quite a difficult feat to detect, investigate, quantify, or stop [21]–[23].

Factors facilitating the occurrence of counterfeit drugs include (but not limited) to weak penal sanctions against such actions [24], and weak/absence of a national drug regulatory authority, etc [25]. The London School of Hygiene and Tropical Medicine in 2017 studied the impacts of fake/substandard drugs [26]. Their results showed that fake anti-malaria drugs were responsible for 158,000 deaths, annually in sub/Sahara Africa [27]. In addition, fake drugs have their fallout impacts, yielding significant risks for patients and their families, and resulting in severe damage that rippled across society over-time with resultant financial loss and death [28]–[30].

The inability to ensure the integrity and safety of pharmaceutical coy global supply chains has led to the proliferation of counterfeit drugs [31]. Uddin et al. [32] record traceability is significantly hampered with the difficulty of effective data sharing and transparency with immutable record-set across its many stakeholders. Additionally, tracing and linking knowledge to materials cum constituents for each drug manufactured, without bias becomes difficult due to the intricacy of stakeholder interactions. The lack of a secure decentralization bank as split across various stakeholders often degrades performance and ensure access difficulty by stakeholders to records [33]–[35]. Song et al. [36] access to medical product records via efficient tracing of drug constituents/composition along its supply chain helps to prevent negative incidents/impacts of counterfeit drugs.

Some measure in place against counterfeiting includes: (a) barcoding and serialization [37]–[39], (b) technology adoption in pharmacovigilance [40]–[42], and (c) post-market surveillance of drugs [43]–[45]. These, however have also posed ill-equipped to effectively handle the issue(s). Thus, the market is constantly besieged by counterfeited drugs/pharmaceuticals [46]–[48].

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Technology can be effectively harnessed to halt the propagation of counterfeit drugs especially with the adoption/adaption of blockchain [49] – as the vehicle to drive pharmaceutical supply chain(s). Production cum use of counterfeit drugs rose by 122-percent in 2010 [50] and by 243-percent in 2023 alone [51]–[53] such that 1-in-10 drugs supplied in many developing nations were detected as fake/substandard. These, had harmful impurities via their manufacturing process, and/or tested positive with improper dosages of active ingredients [54]–[56]. Nartey et al. [57] Over 19.1percent of tested anti-malaria drugs in the low-and-middle-income nations, and in the Organization for Economic Cooperation and Development (OECD) were either substandard or fake; And in 2021, accounted for an estimated loss of over \$900-million in tax revenue annually in the East African Community [58]–[60].

The loopholes were worsened on the Nigerian front; Though, NAFDAC with her vigilance is playing a pivotal role in leading the discuss with her frontier policies cum regulations [61]. In spite of these feats, NAFDAC is yet to attain meaningful strides in the war against drug counterfeiting. In their study, [49] notes that health-care delivery in Nigeria is provided mostly by the private health sector; And, patients often obtain their medications via hospital pharmacies (public/private), and retail outlets (pharmacies, patent medicine shops, illegal vendors, and hawkers). This harsh reality ensures a chaotic distribution network that is managed by both (non)professionals and administered within (un)registered premises [62].

### **1.1. Blockchain Technology and Adoption**

Today's asset market is the epicenter for finance portfolio diversification [63] on 3-major frontiers that impact human existence namely: food/drugs, clothing, and shelter [64]. Focusing on man's basic needs – food/drug via agriculture continues to play a crucial role on the market [65]–[67]. Pharmaceuticals are traded today as assets – and thus experiences the spot-and-futures price direction from market volatility; Thus, optimizing its value-chain structure becomes crucial and imperative [68].

An efficient value-chain must deliver superior values to her customers at reasonable cum lower-cost [69]. It thus uses portfolios of smart-contract policies to drive the value chain framework [70]–[72] to satisfy all stakeholder needs and requirements therein [73]. Furthermore, a value-chain manager must consider the interactions of both (un)known parameters, relations in their limitations as well as minor shifts from which they must yield alternatives that will provide effective results to the value chain [74]–[76].

A typical drugs supply chain can consist of manufacturers, regulate-agency, wholesales or distributors, retailers, and consumers/patients [77]–[79] – with a plethora of technicalities such as package, movement, store, handling, and trading of these goods for finance portfolios [80]–[82]. These stakeholders alongside the inherent processes constitute a dynamic, complex structure such that each also contributes its minor shock to rippled across the entire system [51], [83]. The medical sector has played, and still plays a pivotal cum critical/crucial role in the global health cum safety of millions of Nigerians.

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Globally, food/drug safety and security has continued to be of critical importance – as over 12.2 millions persons in Nigeria get sick annually due to consumption of infected food as well as food poisoning [84]. Often, a value chains is advanced as a means to effectively and efficiently manage and trace its production processes of consumable livestock [85] – even with their high demand. The food value chain consists a set of activities linked together by raw materials (i.e. freshly harvested agricultural yields, products, and processed foods) and their corresponding flow to and from a demand-supply chain from the producers to their consumers across organizational boundaries [86]–[88].

Inherent benefits of traceability of the drug value chain includes [89]:

1. **Ownership ascertainment:** Once a drug is registered and tagged, its records are etched therein on to the blockchain so that it becomes easy for its manufacturer and vendor to prove ownership of the drug asset. This helps to control theft assertiveness, and reduce the inconveniences associated with getting clearance for the transportation of the drugs shipment on road from one place to another [90], [91].
2. **Regulatory Control(s):** If any disease-causing agent is detected as constituents of any drug during its quality control and quality assurance(s) testing(s), traceability features provided by the blockchain to help trace all such drug(s) and aid faster recall/callback of such drugs to its vendor/manufacturer. Thus, with drug source identified, controls are implemented and measures initiated to aid fake/counterfeit drugs destruction and other programs [92]–[94].
3. **Developmental schemes:** Schemes can be implemented via government agencies and regulatory policies to promote support to drug manufacturers and vendors as the lack cum shortage of knowledge/information regarding drug owners may lead to the arbitrary selection of beneficiaries. This in turn may impact on the effectiveness of such a scheme. A centralized bank of manufacturers/vendors will help in the effective formulation and efficient implementation of the government schemes for support and others [95].
4. **Quality assurance:** Traceability-based quality assurance programs can help record the physical, chemical & microbial quality of the drugs. This knowledge collected, will help all the stakeholders on the value-supply chain to implement the required quality control measures – as this also, will help evaluate efficacy of the drug control programs practiced and enforced within the nation’s borders especially as with National Agency for Food and Drugs Administration and Control (NAFDAC) in Nigeria [96].
5. **Increased Performance and Productivity:** The selection of drugs by manufacturers for use in Nigeria as regulated by NAFDAC – should be based solely on its authenticity to resolve the challenges (a function of performance) with a compilation made therein of a traceability database can provide for collection and update of such drugs. The performance analysis of drugs that have passed these rigorous tests as conducted by NAFDAC over a period of time (as released) can help as decision support systems by users pertaining to the drugs. This practice if sustained, can improve the overall quality of the germplasm.

6. **Increased Market Opportunities:** Many nations have established stringent drugs supply and traceability system with the requisite support via legislative framework and policies. Thus, nations wishing to export drugs to these countries must adapt to this traceability scheme on par with domestic, local regulations. Traceback capability enhances user-level trust and confidence for both local and international market(s). And in turn, help businesses to exploit and explore all export potential(s) via increased market access to yield more/increased monetization for all stakeholders [97].

### 1.2. On the Food/Drugs Assets Value Chain: Related Literatures

The adoption of the blockchain technology to drugs supply value chain can help ensure drugs quality assurance and safety. Tian [69] investigate its adoption also on the food value chain via RFID tech, which ensured the food-records were easily monitored and traced via the sensor-based tags and ubiquitous smart devices. These were activated on the chain to ensure immutability and integrity of records with increased user-trust that assured users of food quality and safety. It also helped the Chinese food market to efficiently enhance food quality, traceability, and safety. Caro et al. [71] fused sensor-based IoT with food records to yield a decentralized tracer support system to help it address issues with the centralized supply infrastructure. With such IoT support, they created the AgriBlockIoT as a more robust, transparent, resilient, immutable, and auditable records.

Leng et al. [98] adopted a double chain architecture for the Chinese public service platform to yield a framework that enhanced its transaction service(s) credibility for users on its platform. The gains of their system included its ability to manage system resources without knowing or having access to the organization's private data or resources. Result shows it ensured record integrity and data privacy for users. Behnke and Janssen [99] sought to investigate blockchain boundaries to ascertain the conditions under which its traceability for the food value supply chain must meet in a bid to exist and be effectively implemented. Findings showed that their chain needed to fulfill government regulation boundary conditions.

Bako et al. [100] investigated similar conditions on the Nigerian Poultry value chain via a regulation framework that sought to understand the Nigerian food traceability value chain system. Findings noted the blockchain traceability model resolves the issues of food recall, and presented itself as a more realistic strategy to achieve visibility within the value chain as well as emphasize the significance of food safety, recall and quality assurance feats by vendors and/or farms. Akazue et al. [101] investigated adapting of IoTs with blockchain technology to extended [71]. They provided the roadmap for adoption of the blockchain to contribute to the Nigerian food industry by exposing it as a means of electronic management systems and virtualization of processes to achieve food traceability.

Other contributions so far made both on the Nigerian Front and globally, with the blockchain technology includes (but not limited to) thus:

**Table 1. Related Literatures Contributions**

Authors	Blockchain Schemes Adopted	Metrics Measured		
		Throughput	Response	Scalable
Akazue et al. [101]	Permissionless blockchain with the distributed Ethereum ledger technology	30-tps	Query 0.38secs https 0.32secs	Yes
Ibor et al. [102]	Adopted permissionless blockchain on the medical record with the distributed hyper-ledger fabric technology	68-tps	Query 0.68secs https 0.53secs	Yes
Oladele et al.. [103]	Permissioned blockchain on medical records with Hyperledger fabric smart-contracts	56-tps	Query 0.38secs https 0.32secs	Yes
Quamara and Singh [68]	Permissioned blockchain on medical records with the Corda ledger and smart-contracts	143-tps	Query 158secs https 143secs	Yes
Valenta and Sander [104]	Permissioned blockchain on medical records with Hyperledger fabric smart-contracts	45-tps	Query 0.54secs https 0.55secs	Yes
Ojugo et al. [105]	Permissioned blockchain on beef processing records with the distributed Corda ledger and smart-contracts	1101-tps	Query 188secs https 193secs	Yes

### 1.3. Study Motivation

Study is motivated as thus:

1. Counterfeit drugs have continued to pose significant obstacle to both health administration, pharmaceutical companies and patient's welfare. To address this, we adopt the study [106] that presents policies on counterfeit technique alongside regulatory protocols rendered by NAFDAC to yield a highly potent anti-counterfeit identification scheme, which is then coded on the blockchain smart-contracts as a unique keyset and state of the drug records. This is coded as `drugs_list` – which is further explained below [107].
2. ORcode – In Nigeria, drugs are easily identified with the barcode markings on their packaging to ensure authenticity of the drug product. Counterfeit products in turn, also try to replicate such markings of holograms and other distinctive elements attached to the blister foil, film or paper substrate for consumer eased identification. To the untrained eyes, both the genuine and fake/substandard drugs seem identical. Thus, we will adopt QR-Coding for the drug recordset as a feature to help classify between genuine and fake/substandard drugs [108], [109].

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Thus, we adopt the blockchain-based ensemble to render a decision support system that will ensure improved user-trust against counterfeit drugs vis-à-vis the regulatory policies. Our encrypted solution will explore the use of QRcode to scan barcode marking with Relational Database Management System (RDBMS) on the blockchain ensemble. This results in the chain's flexibility to yield optimal solution [110] that will address record immutability [111], enhanced drugs quality [112], assurance [113], safety [114], and recall capability [115] with faster system construction [116] and improved security that will ensure better throughput, improved response time to queries, page retrieval and web-server [117], and availability with scalability features [118].

## 2. MATERIAL AND METHOD

The dataset used to design the blockchain ensemble was obtained as updated drugs record-set from NAFDAC as of March 2024. It consists of about 292,364 records.

### 2.1. Proposed Counterfeit Drugs Blockchain Tracer Support System (DuBoTeSS)

The proposed pharmaceutical supply chain (PSC) ensemble is a tracer management support system with various dynamism, complexity, and functionality. It presents a management scenario as in figure 1 – which consist of 5-major stakeholder namely: manufacturers (with chemical input stakeholders, and packaging stakeholders), distribution (with wholesale stakeholders) and consumers (private stakeholders and public stakeholders).

Each stakeholder category consists of members that undertakes and plays the same role(s) in the tracer management support supply chain. Chain(s) represents smart-contracts on the blockchain framework. Each chain seeks to process the business and transaction logic of the support system, and uploads the drugs recordset traceability support data of the corresponding stakeholder to the chain. Target consumers are direct (patient) users who can query the blockchain network database for the complete traceability data of drugs.

## NIGERIA - PHARMACEUTICAL SUB-SECTOR

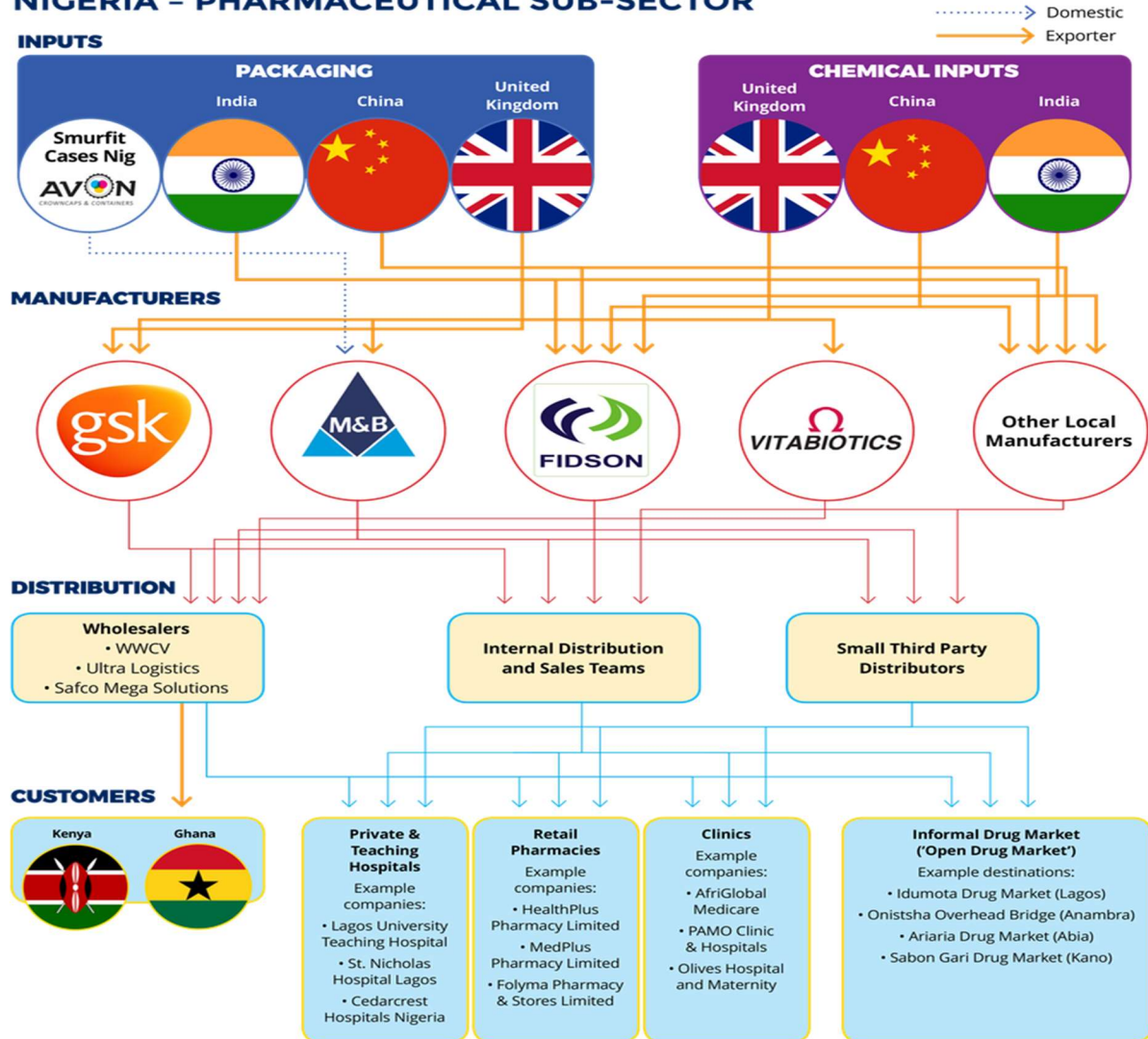


Figure 1. Nigeria's Pharmaceutical Tracer Value Supply Chain

The chaincode(s) represent stakeholders from manufacturers to target\_consumer as in Figure 2. It yields all various transition of drugs between the various states and amongst the various stakeholders – detailing how the drugs are distributed (changing its state as it moves from one stakeholder to another). It also shows how these transaction exchange, explores and employs the smart-contract logic to execute and regulate each transaction transitions to yields the desired traceability, transparency and efficiency as these drugs (genuine or counterfeited) transit/move between the unique states [119].



The CoDuBoTeSS model provides target consumers with a historic record of the materials that constitute a drug (chemical) make-up, its packaging details, whole distribution network, and how they were administered. With the requirement analysis, process inquiries, its data design, and major technical activities – we model the smart contracts as a gateway to *k-chains* with capable transaction rules. With registration, each target user/consumer is ceded a public and private key pair to digitally sign each operation on the distributed ledger. The framework uses weights via the chain – for internal validation and checks so that on detecting anomalies in the record (e.g stakeholder\_address, drug\_transaction\_batch, transport ID, etc) – the blockchain system can easily flag it.

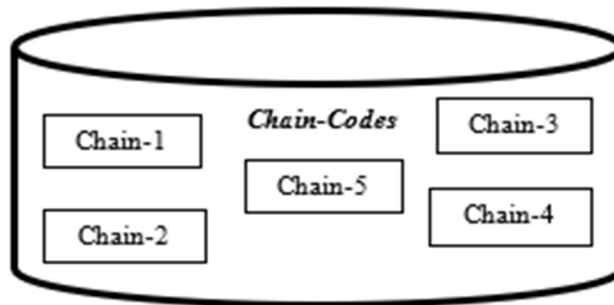


Figure 2. The Drug Blockchain Tracer Support System (source: [105])

The smart-contract is explained as thus:

1. **Stage 1: Ledger State** – ‘Drug’ is represented as a set of properties with assigned values – which creates a unique keyset as well as the state of the palliative. The drugs\_list is the complete keyset and the state of the drug(s) is initialized as a record in the world state on the hyper-fabric ledger. It supports several states with various attributes that allows the same ledger in its world-state to hold various forms of the same drug, and different types of drugs for use in patient treatments and administration – on the drug supply chain. This – ultimately makes possible the capability of the system to evolve and update its state(s) and structure [120]–[122].
2. **Stage 2: Proof-of-Trust** – With a variety of roles (i.e. manufacturer, stakeholders, target consumers, and users) alongside the varying transaction(s), transition of the drugs among the various stakeholders, how different business interests ascertains who must approve a transaction, and also how individuals state keys work – are enshrined within the smart contract. This means that in CoDuBoTeSS, we set a rule in the namespace to define a business that processes a specific drug, and later, set another rule to update all processed drug assets to portray trust relations of the trade transactions. These concepts can be combined to implement the smart contract [123].
3. **Stage 3: Smart Contract** codes initialize all drugs valid states with a logic that transitions a drug-asset from one state to another. These contracts essentially help us set-up all key-business processes and knowledge/records to be shared across the various organs or components that interact(s) on the network. It in turn, defines the various states of the business and how its many processes are managed to move a

drug-asset between the states and amongst the various interacting nodes. Thus, for the CoDuBoTeSS chain, the same smart contract is shared and used by the different nodes and by the different applications connected therein. Thus, it jointly executes a shared business data and process. All members of the network must agree a specific version of smart contract to be used.

### 3. RESULTS AND DISCUSSION

#### 3.1. The CoDuBoTeSS Performance for Scalability and Response Time

This performance metric seeks to determine the time interval between a user's request and apps response time to provision feedback to the user [124]. We achieve this by measuring the response time from a query on the https page as in Table 1 – which presents two (2) scenarios namely [125]: (a) a population size of 2500-stakeholders, and (b) tripling the size to 7500-stakeholders from the varying categories.

**Table 3. Performance metrics with CoDuBoTeSS models**

Transactions	Case-1		Case-2	
	Time	Population	Time	Population
Queries	128secs	2500	278secs	7500
Httpps	88secs	2500	187secs	7500

For scenario 1 as in Table 1 with a population size of 2500-users, the response time of 128secs was achieved for queries and 88secs for https pages retrieval [126]. Conversely, with the sample size increased to 7500-users so as to check for scalability and reachability of the proposed system – there was naturally a longer response time of about 278secs and 187secs respectively for both queries and https pages retrieval feedbacks [127]–[129].

It was observed that querying data tracebacks implies reading data from the blockchain distributed (hyper fabric) ledger that is stored as a world-state database, which records only the key-value pairs to ease records retrieval directly the current key-value(s) of record(s) sought for, without it traversing the whole ledger. This will improve the effectiveness as well as the inherent efficiency in the CoDuBoTeSS network [130].

#### 3.2. Discussion of Findings

It provides insights into which characteristics have a bigger influence on overall performance and aids in identifying the most important aspects influencing the model's performance [131]. The proposed traceability support system uses chaincodes to control query permission(s) and other transactions on nodes; Thus, effectively protecting targeted user data privacy [132]. Stakeholders' roles were encrypted via SHA256 protocol to secure sensitive data [133], upload to the chain, and prevent data leakage [134]. The ensemble divides the roles into five (5) as represented via the 5-chaincodes on the distributed hyper fabric ledger [135] technology to effectively handle the business transaction logic on the blockchain [136]. The model control was deployed via chaincode permissions and encryption mechanisms to enhance data security and privacy control for the support system traceability model [137].

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The resulting model showed a low response time to the query request, alongside stable time convergence for the system throughput as supported by [138]–[140].

#### 4. CONCLUSIONS

With the surge in technological advances and the widespread adoption of new tech-driven business strategies, businesses can now operate more efficiently, productively, and profitably. Despite the enormous amount of data generated daily, we have observed that the healthcare industry has always kept up-to-date with technology; However, the adoption of data analytics and data science will bolster the field of medicine. So, for the future of this industry, this study as a positive step – can be improved upon. Furthermore, this research work signifies a paradigm shift in the application of artificial intelligence to mental health diagnostics as supported by [141]–[143].

We present a pharmaceutical support system based on a permissioned blockchain framework. Our contributions include: (a) used the hyper fabric ledger for permissioned blockchain ledger to record world-state key values of generated blocks, (b) used a QRcode data identification mode to identify all drug-records on the framework, and (c) optimized CoDuBoTeSS system for eased manageability, traceability and administration in Nigeria. Model sought to tackle the counterfeit drugs distribution crisis inherent in the pharmaceutical sector in Nigeria – through a high-performance, open-sourced, and user-friendly permissioned chain support model with transaction privacy and confidentiality.

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