**Journal of Computer Science and Technology Studies**
ISSN: 2709-104X
DOI: 10.32996/jcsts
Journal Homepage: www.al-kindipublisher.com/index.php/jcsts

JCSTS
AL-KINDI CENTER FOR RESEARCH AND DEVELOPMENT

**| RESEARCH ARTICLE**

# Blockchain-Enabled Traceability in Pharmaceutical Supply Chains: An Integrated Engineering and It Management Framework for Regulatory Compliance and Pandemic Resilience

**Md Ruhul Amin[1], Nahin Akhtar[2], Md Ekramul Hoque[3], Ashrafur Rahman Nabil[4] ✉ and Kazi Md Shahadat Hossain[5]**

*[12]MSA in Engineering Management, Central Michigan University, Mount Pleasant, Michigan USA*
*[3]Department, Ketner School of Business, Master's of Science in Business Analytics, Trine University*
*[4]MS in Information Technology Management, St. Francis College, Brooklyn, New York, USA*
*[5]MBA in Logistics Management, Central Michigan University, Mount pleasant, Michigan, USA*
**Corresponding Author:** Ashrafur Rahman Nabil, **E-mail**: anabil@sfc.edu

**| ABSTRACT**

Due to the growing risk of counterfeit medicines, the highly disjointed international regulatory landscape, and the strong desire to learn more about where the medicines are supplied in health emergencies like the COVID-19 pandemic, pharmaceutical supply chains are experiencing mounting pressure to guarantee transparency, authenticity, and compliance. These complexities were used to show the necessity to have robust, secure, and interoperable systems that can facilitate real-time traceability at all levels of the pharmaceutical value chain. Blockchain technology has emerged as a revolutionary remedy that can integrate such problems since it provides unalterable records, decentralized data management, and automated smart contracts. Nevertheless, knowing how to introduce it into the spheres of the pharmaceutical world demands a multi-disciplinary approach to planning that closes the gap between engineering processes and IT management procedures. This paper suggests a new combined engineering and IT governance system that uses blockchain powered traceability to achieve regulatory compliance and be resilient to the pandemic. The framework involves end-to-end coverage of manufacturing all the way to point-of-care, including the physical traceability through IoT-based tracking and blockchain design, compliance-oriented data layers, and the capability of smart contracts. The framework also allows agile incident response to supply chain interruptions, increased recall speed, and proactive measures when dealing with counterfeits, since the digital infrastructure will be aligned with major regulatory requirements, such as the U.S. Drug Supply Chain Security Act (DSCSA) and the EU Falsified Medicines Directive (FMD). Besides conceptualized design, there are well-organized tables explaining regulatory mappings, framework components, and performance measures in this article. The framework presents a crossdisciplinary and scalable concept of modernization of the pharmaceutical supply chain, which is expected to facilitate the process of digitalization to align with the goals of Pharma 4.0 and the security of public health in the post-pandemic world.

**| KEYWORDS**

Blockchain Traceability, Pharmaceutical Supply Chain**,** Regulatory Compliance**,** ITEngineering Integration, Pandemic Resilience**,** Supply Chain Transparency**,** Pharma 4.0.

**| ARTICLE INFORMATION**

**ACCEPTED:** 03 October 2025 **PUBLISHED:** 17 October 2025 **DOI:** 10.32996/jcsts.2025.7.10.37

## 1. Introduction

The pharmaceutical supply chain is a sensitive and multifaceted framework that moves across the globe in manufacturing, distribution, and delivery systems. It is also important in that the existence of medicine, vaccines, and life-saving therapeutics reaches patients efficiently, correctly, and consistently. Nevertheless, the sphere is being more and more confronted by the

concerns connected with traceability, genuineness of the products, openness of data, and nonconformity with regulations. The global scope of the pharmaceutical business, along with the list of intermediaries, including contract manufacturers and logistics providers, has led to a lack of visibility and low confidence in the integrity of medical products.

Among the numerous issues, there is the spread of counterfeit medicines, as the World Health Organization (WHO) estimates that they occupy about 10 percent of the medicine market globally, and even more in low-income and middle-income nations. These counterfeit or substandard drugs endanger general health as well as slur and damage the economic well-being of genuine pharmaceutical enterprises. National and international regulatory agencies, such as the U.S. Food and Drug Administration (FDA), European Medicines Agency (EMA), and the health ministries in many countries, have listened to the prescription of serialization, product tracking, and auditability, but actual implementation has been sporadic and expensive.

The COVID-19 pandemic exposed even more weaknesses of pharmaceutical supply chains, especially the issuance of vaccines, personal protective equipment (PPE) logistics, and real-time inventory tracking. The pandemic demonstrated flaws in a traditional centralized system, which was not flexible, secure, and transparent enough to act quickly in times of changing demand in the global world. This crisis instanced the need for strong and nimble infrastructure that has to support occasional shocks without punishing any compliance with regard to full regulation.

It is on this background that blockchain technology has been seen as a potential traceability and trust provider in the pharmaceutical industry. Blockchain is an immutable data record, transparent audit trail, and decentralized consensus idea using a distributed ledger system. Such characteristics can substantially lessen the threat of information manipulation, facilitate the regulatory reporting, and automate the compliance tasks via smart contracts. Nevertheless, technological implementation alone is not the only factor that contributes to the successful adoption of blockchain in pharmaceutical logistics because it also demands a comprehensive framework that reflects a combination of the technical innovative solution, organizational, regulatory, and operational needs.

The present article presents an engineering and IT management concept integrating traceability in the pharmaceutical supply chain that is enabled by blockchains. The framework is meant not only to support the current problem of traceability and regulatory compliance but, at the same time, improve pandemic resilience through responsiveness and data integrity of the supply chain. It integrates systems engineering, IT governance, and regulatory harmonization to make sure that blockchain is simultaneously technically sound and strategically feasible.

The most notable attributes of the framework are the integration of physical products tracking with IoT, with bookkeeping digital ledgers powered by blockchain, a layered architecture of regulatory compliance, as well as an articulated and elaborated set of respective roles and responsibilities of the stakeholders. With this setup, pharmaceutical firms will be able to realise real-time availability throughout the supply chain, minimise risks in their operations, and anticipate future interruptions in public health. The framework is also scalable, which allows it to be presented to various regulatory settings and organizational capabilities.

The design of this paper is such that it covers an in-depth analysis of regulatory and operational pressures governing the pharmaceutical supply chain currently, the potential that the blockchain technology has to offer, a discussion of the suggested integrated strategy, and how it could enhance pandemic resilience. Strategic implications, challenges, and future directions towards blockchain-enabled pharmaceutical logistics are addressed, followed by the outlook of blockchain-enabled pharmaceutical logistics in a larger context of the Pharma 4.0.

## 2. Regulatory and Operational Pressures in Pharmaceutical Supply Chains

Pharmaceutical supply chains are in an ultra-regulated environment requiring no-compromise on product quality, safety, and transparency. These regulatory demands are based not only on health agencies, but also on international trade and international agreements on trade, drug surveillance, and newer issues related to health. The more pharmaceutical products flow on apparently globalized production and distribution chains, the greater is the necessity of harmonized regulatory control, especially when it comes to the aspects of traceability, authenticity, and control of risk.

### *2.1 Global and Regional Compliance Demands*

Countries and regulatory establishments across the globe have proposed laws that increase drug tracking and eradicate counterfeit drugs. As an example, the United States Drug Supply Chain Security Act (DSCSA) requires full-unit-level product serialization and interoperable, electronic product tracing system requirements by 2024. On the same note, the FMD in the European Union mandates serial numbering and tamper-proof packaging of prescription medicine that is distributed within the

EU region. Asia is a regulatory mix with some countries adopting serialization requirements, like India and China, with other countries developing trace systems.

Although the schedules of implementation and technical specifications are not identical, these frameworks have fundamental purposes, which are the guarantee of product authenticity, monitoring of drug circulation throughout the distribution chain, and the speedy recall in case of necessity. Nevertheless, heterogeneity of regulatory systems creates operational challenges to multinational pharmaceutical companies who have to go through various compliance regimes at the same time, ensuring that the costs and data integrity are upheld.

Table 1: Comparative Summary of Regulatory Frameworks in Pharmaceutical Supply Chains

| Region | Regulatory Authority | Legislation/Directive | Key Requirements | Implementation Timeline |
|---|---|---|---|---|
| United States | FDA | DSCSA | Serialization, aggregation, interoperable tracing | 2013–2024 (phased rollout) |
| European Union | EMA / National Health Agencies | FMD | Serialization, tamper-evidence, EMVS integration | Fully enforced since 2019 |
| China | NMPA (formerly CFDA) | Drug Traceability Code System | Electronic drug supervision codes | Enforced since 2018 |
| India | CDSCO | DAVA Portal (for exports) | Barcode-based traceability for exports | Mandatory for exports (since 2015) |
| Japan | MHLW | GS1-based traceability | Voluntary serialization and tracking | Encouraged, not mandated |

### *2.2. Counterfeit Drug Risks and Past Incidents*

The increasing challenge of counterfeited medicine highlights the need for traceability of products even more. The WHO reckons that one in every ten medical products used in the low- and middle-income countries may be of substandard or false quality. Such events as the 2008 mini-crisis involving the counterfeit heparin bought in the U.S., which involved at least several deaths based on the tainted foreign-sourced ingredients of the drug, have created the need to identify a systemic weakness in the drug system. Later on in 2012, counterfeited versions of the cancer drug Avastin were sold in the U.S., but did not contain any active ingredient.

Fake drugs not only cause damage to the patients, but they also reduce the trustworthiness of healthcare systems and cause immense economic costs. The traditional supply chain management processes, which are based on piecemeal databases and manual records, have been seen to be very ineffective in confronting this menace. In turn, regulators and industry players have been promoting technologies of digital traceability, where end-to-end visibility and data security are provided.

### *2.3 Pressure for Serialization and Digital Traceability*

Modern pharmaceutical traceability revolves around serialization, that is, the process of assigning a oneof-a-kind number to each unit that can be sold of a drug product. This mark, normally represented in a 2D DataMatrix barcode, can be used to verify products at different checkpoints by the stakeholders. Nevertheless, serialization is not enough, and efficient traceability presupposes aggregation (assignment of a single piece of goods to cases and pallets), data exchange interoperability, and real-time visibility through the multi-tiered ecosystem.

The long and expensive process of adopting digital traceability in the industry has been affected by the absence of any data format standard as well as differences in IT systems, along with uneven application of regulations. In addition, several firms are not prepared to integrate serialization data with the operating system to have control of inventory, logistics, and compliance

reporting. They end up with a hodgepodge of digital and old-fashioned, much of which comes up short of their complete traceability objectives.

### *2.4 Pandemic-Induced Stressors and Legacy System Failures*

During the COVID-19 pandemic, pharmaceutical supply chains were burdened to an exceptional extent. Big surges in demand for vaccines, anti-viral therapies, diagnostic kits, and PPE illuminated the vulnerabilities of legacy systems ill-equipped to do real-time tracking and dynamically assess risk.

Transparency between actors in the supply chain and regulators led to bottlenecks, stockouts, and distribution errors.
In a few cases, the inability to track the origin or the delivery path of the products postponed the withdrawal of the damaged batches or obstructed the delivery of the vaccines into the regions of need. In response, governments and international organizations have demanded that health supply chains be digitized and decentralized, and blockchain is one of the most commonly quoted technologies that can make the vision become a reality.

Now, pandemics come with a greater need than physical inventories or emergency deals; they need datadriven infrastructure so that transparency, agility, and accountability are made possible. These demands can be fulfilled utilizing blockchain in combination with engineering systems and IT governance frameworks, as it offers a way to achieve these demands by enabling a shared and tamper-resistant ledger to ensure compliance, authentication, and logistical planning across borders.

## 3. Blockchain Technology for End-to-End Traceability

Blockchain technology has in recent years become a game-changer in supply chain management as a new solution to data integrity, transparency, and decentralisation. In essence, blockchain is a decentralised record-keeping system where information in the system is duplicated on an array of nodes and consequently obstructed in consensus-based upgrades, and, hence, any tampering or falsification in the regime is inherently defective. This feature is particularly useful in the pharmaceutical business where the authenticity of the data matters most, and fraud or mistakes may result in grave consequences in terms of population health.

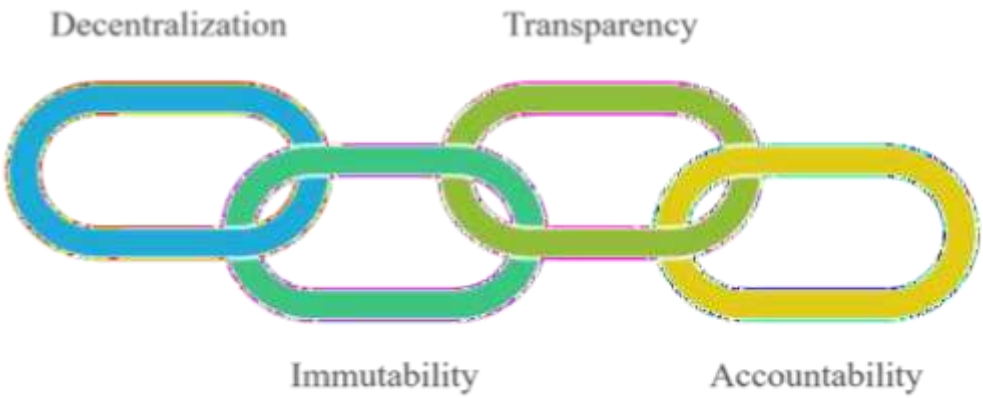


Figure 1: Blockchain Technology for End-to-End Traceability

### *3.1 Basics of Blockchain as Relevant to Supply Chains*

Blockchain functions in a network of nodes that confirm transactions and add chains of blocks that store time-stamped records. The blocks are cryptographically linked with each other, making a tamper-proof ledger. Within the supply chain context, blockchain technology can enable secure and transparent recording of transactions that take place in the line of product origin, manufacturing, packaging, warehousing, transportation, and delivery. Each transaction, whether it is the handoff of a product or a checkpoint, is represented by a new code and placed permanently into the blockchain.

It also implies that parcel-level control of drug packages would be possible throughout the pharmaceutical supply chain, and that every transaction between all stakeholders would be verifiable and transparent. It can be used to remove blind spots, prevent fraud, and speed up audits or recalls using this end-to-end visibility. In addition, blockchain can promote interoperability, acting as a source of truth, with accessibility by the different actors under different levels of permission.

### *3.2 Public vs. Private vs. Consortium Blockchains*

There are three main types of blockchain architectures: public blockchain, private blockchain, and consortium blockchain. Each has its specific trade-offs in terms of accessibility, scalability, performance, and governance.

Others like Ethereum or Bitcoin are public and anybody can use them, and are run by a distributed system of users. Although they provide the highest level of transparency, they are also constrained by lower transaction rates and increased energy intake to the extent that they do not have applications in enterprise supply chains.

Unlike the Bitcoin blockchain, participation is limited to a single organization or a community of trusted individuals using a private blockchain. They are more performative and privacy-promoting, but have the risk of centralization, which tends to interfere with the decentralized trust system.

Consortium blockchains form an intermediate option, where a consortium of organizations (e.g., manufacturers, regulators, logistics providers) collectively control the ledger. The model applies well to the pharmaceutical supply chain that requires sharing information among numerous stakeholders without losing privacy and security.

Consortium blockchains allow customized forms of governance and regulatory compliance procedures, which are necessary in highly confidential and liability-sensitive industries such as pharmaceuticals.

### *3.3 Smart Contracts for Compliance Automation*

The application of blockchain in pharma supply chains has huge potential. One of the areas that can be regarded as rather promising is that of using smart contracts, i.e., self-executing programs where preagreed rules and regulations are enforced automatically. A smart contract can, e.g., be programmed to: · Refuse to record shipment in case the temperature data of a product exceeds the limits set in the case of transportation.

· Send alerts to authorities in case of a failure of serialization or authentication processes. · Auto-reconcile products recall using the batch numbers.

The automation not only lowers the administrative loads but also minimizes the threat of human error and fraud. Smart contracts may be combined with Internet of Things (IoT) sensors to observe the state of the environment, hence viability in terms of Good Distribution Practices (GDP) and Good Manufacturing Practices (GMP) in real-time.

Smart contracts allow one to incorporate regulatory rules into the system logic, making it possible to continuously monitor compliance with the rules: regulatory audits stop being a reactive inspection procedure but become a proactive real-time audit process.

Table 2: Blockchain Features Mapped to Supply Chain Traceability Requirements

| **Traceability Requirement** | **Blockchain Feature** | **Value Proposition** |
|---|---|---|
| Product Serialization and Aggregation | Immutable Ledger | Prevents record tampering and supports unique product identities |
| Chain-of-Custody Tracking | Decentralized Transactions | Enables multi-party visibility and accountability |
| Real-Time Environmental Monitoring | Smart Contract + IoT Integration | Automates validation of storage/transport conditions |
| Regulatory Reporting and Audit Trails | Time-stamped, Transparent Records | Simplifies compliance and reduces audit time |
| Recall Management and Source Authentication | Verifiable Provenance | Speeds up recalls and identifies affected batches |
| Data Security and Access Control | Role-Based Permissioning in Private/Consortium Chains | Ensures privacy while maintaining transparency |

### *3.4 Case Examples or Theoretical Applications in Pharma*

Blockchain has been denoted as potentially valuable in the pharmaceutical setting in a variety of pilot project operations and theoretical models. By way of example, a consortium-based blockchain in the United States, the MediLedger Project, was launched with the aim of facilitating DSCSA compliance through secure and interoperable data transfer between manufacturers

and distributors. Using zeroknowledge proof, the system checks transactions without disclosing proprietary business data, a strategy between transparency and proprietary protection.

In Europe, PharmaLedger, funded through the Innovative Medicines Initiative (IMI), is identifying how blockchain can be used to support product verification, clinical trial transparency, and dissemination of electronic product information. Such projects demonstrate that blockchain may develop even beyond pilot stages to serve as a constituent part of the pharmaceutical digital infrastructure.

In theory, there could also be some support for blockchain in the vaccines issued with emergency use authorizations, including those used in such a pandemic, in a track-and-trace feature. Geotagging via smart devices with tamper-evident seals, the movement and the exchange of the products of the cold chain ensures quality and access without diversion or theft.

## 4. Integrated Engineering and IT Management Framework

Blockchain use in pharmaceutical supply chains cannot be described as a technology optimization; it necessitates a paradigm shift in how engineering systems and IT governance interface in organizing data, compliance, and operation. Modern pharmaceutical logistics has grown to be complex, and due to the high scrutiny in the pharmaceutical supply chain by regulatory agencies, a more coherent approach is required where physical tracking mechanisms, digital infrastructure, and regulatory automation elements are amalgamated into a single traceability model. In order to be able to implement it successfully, the two fields of systems engineering, which design, observe, and regulate the flow of physical processes, and IT management, which regulates the operation of digital systems, data integrity, and cybersecurity, must converge.

### *4.1 The Need for Convergence Between Systems Engineering and IT Governance*

In the past, systems engineering and IT governance have been practiced in silos in pharmaceutical organizations. The engineering workforces are dedicated more towards optimization, quality assurance, and GMP compliance, whereas the IT departments implement ERP systems, digital computing infrastructure, and data protection. Nevertheless, synchronization of operations between these areas must exist in order to enable blockchain-enabling traceability. To cite an instance, the data recorded in the sensors of the environment should be smoothly moved to blockchain records, and the reports created through smart contracts should be within the regulatory requirements of IT security.

Sealing this divide entails the development of an interoperable architecture that enables the realization of real-time information exchange, multi-party cooperation, and autonomous execution of compliance requirements devoid of any compromise to data confidentiality and operational performance.

### *4.2 A Layered Model for Blockchain-Enabled Traceability*

The suggested architecture presents a four-layered design that combines physical, digital, and regulatory elements of a secure, scalable, and compliant pharmaceutical traceability:

**Layer 1: Physical Tracking (IoT Sensors and Serialization)**

The physical monitoring gadgets like the RFID tags, QR codes, the GPS modules, and the temperature sensors constitute this foundation level. At the point of manufacture, each unit of product will be given a unique identifier which will be connected to a digital token. IoT devices constantly control environmental parameters (temperature, humidity, etc.), and data is submitted to the blockchain layer.

**Layer 2: Blockchain for Traceability**

A permissioned blockchain network documents all the critical supply chain events such as the production, inspection, shipment, and receipt. Every transaction is verified, impervious, and encrypted. A consortium blockchain architecture guarantees that all the pharmaceutical manufacturers, regulators, logistic providers, and health agencies will have a synchronized product lifecycle vision.

**Layer 3: Compliance Automation via Smart Contracts**

The example of validation of shipping conditions, verification of serialization data, and issuance of certificates of analysis are the basic elements of compliance, facilitated in the case of smart contracts. It is a logic-regulation layer, because only the transactions with pre-set legal requirements are performed or logged.

**Layer 4: Data Governance and Cybersecurity**

This tier consists of access control, encryption, GDPR/HIPAA compliance tools, and overall audit tracing throughout the system. Permission authorization is role-based and makes sure that every stakeholder will see only the information corresponding to their role, and personal data is secured by high-level encryption algorithms when it is stored or transmitted.

Table 3: Proposed Integrated Framework: Components, Tools, and Roles

| Layer | Key Components | Tools & Technologies | Primary Stakeholders | Key Roles/Responsibilities |
|---|---|---|---|---|
| **Layer 1**: Physical Tracking | RFID tags, QR codes, IoT sensors, serialization IDs | Arduino, LoRa, NFC, barcode readers | Manufacturers, Distributors | Assign unique IDs, monitor storage & transit conditions |
| **Layer 2**: Blockchain Traceability | Distributed ledger, node validation, consensus models | Hyperledger Fabric, Ethereum (private), IPFS | Pharma firms, Logistics Providers | Record transactions, enable tamper-proof provenance |
| **Layer 3**: Smart Contracts & Compliance | Regulatory logic, conditioncheckers, digital triggers | Solidity, Chaincode, AI rule engines | Regulators, QA/RA Teams | Automate verification, flag violations |
| **Layer 4**: Data Governance & Cybersecurity | Access control, audit trails, encryption modules | PKI, Role-Based Access Control (RBAC), TLS/SSL | IT Departments, Legal, Data Officers | Ensure data protection, regulatory data retention |

### *4.3 Stakeholder Roles and Responsibilities*

The multi-actor environment requires well-defined stakeholder responsibilities to avoid data silo and to ensure that the operations and regulations are fully integrated:

- Pharmaceutical Manufacturers are to start serialization, IoT device attachment, and record all production-related events in the blockchain.
- Regulatory Agencies (e.g., FDA, EMA) are involved in the validation of the authenticity of data, enforcement of compliance through automated smart contracts, and audit dashboards.
- Technology Vendors create the blockchain infrastructure, the integration systems of the sensor, and the smart contract logics, which are scalable and interoperable.
- To make transport compliant, the Logistics Providers can transmit real-time data about the location and the environmental conditions to the blockchain.
- The final product check is also done by the Hospitals and Pharmacies, and the adverse events are reported and permanently recorded to be traced and used in the future in the regulatory process.

This model encompasses decentralized collaboration without loss of control, allowing each of the parties to confirm drug integrity, act on the alerts, and selectively share information.

### *4.4 Implementation Phases*

To make the framework operational, a staged implementation mode is suggested:

- Assessment Phase - Find legacy systems, compliance gaps, and technical readiness.
- Pilot Phase - Implement the integration of blockchain and IoT within a small section of the supply chain (e.g., high-value biologics).
- Scale-Up Phase- Reinforce implementation to all categories of drugs and geographies, as well as gather feedback and improve smart contracts.

- Governance Phase- Build long-term stakeholder roles, including data dependencies, data sharing agreements, security procedures, and regulatory auditing interfaces.

This process is incremental; thus, it mitigates risks and aligns stakeholders, reduces ROI timelines, but does so without compromising compliance integrity.

**5. Enhancing Pandemic Resilience through Blockchain Traceability**

The COVID-19 pandemic was the stress test of the global pharmaceutical supply chains, which revealed weaknesses in the supply chain inventory control, international logistics, traceability probes, and realtime supply information. Supplies of the essential medicines, fake vaccines, and malfunctioning of cold chains exemplified the necessity of a digitally resilient infrastructure able to ensure continuity of operation and regulatory actions in a state of duress. Traceability using blockchain is an effective method to overcome these issues as it facilitates a quick recall, integrity of vaccines, and trusted multi-party collaboration between decentralized stakeholders.

***5.1 Traceability for Rapid Recall, Safe Distribution, and Vaccine Chain Integrity***

In the case of a pandemic, having a timely possibility to trace defective or hazardous pharmaceutical products may save the lives of people. The process to track a faulty product in traditional systems, which use batch-level tracking and siloed databases, usually takes days and, sometimes, even weeks to track a product that is not distributed to the market properly, causing a great deal of delays and exposure risks. In comparison, systems with blockchain technology offer unit-level traceability in real-time, so compromised lots can be identified instantly and promptly removed through the supply chain.

In addition, blockchain traceability is essential in ensuring the stability of the cold chain regarding vaccines, a prerequisite for the success of biologics, such as the mRNA-based vaccines. It uses IoT sensors combined with blockchain networks to keep a temperature, humidity, and location record of goods during the distribution process. The introduction of smart contracts can automate the ability to flag anomalies (e.g., in case of a vaccine, a vial has been subject to suboptimal temperatures) and send alerts to stop the further distribution of this product--this will ensure that ineffective products or unsafe products do not reach patients.

Blockchain makes stakeholders and the general population trust the end-to-end visibility, thus increasing uptake and compliance with the use of vaccines in an emergency response campaign.

***5.2 Scalability of the Framework under Public Health Crises***

One of the characteristics of pandemic situations is the volatility of their magnitude, the territory, and the urgency. The suggestive layered architecture, anchored on blockchain and IoT, is going to be scalable and modular, and thus capable of performing due to a sharp drive in production, extra distribution points, or new regulatory jurisdictions. Blockchain stores are characterized by consortiumbased architectures, which enable new organizations (e.g., provisional vaccine points or NGOs) to be added fairly quickly with role-based access, resulting in minimal intrusion and the best possible coordination.

Smart contracts are easy to update and could be modified to incorporate new guidelines of physical health regulations, procedures, etc. Moreover, access to decentralized ledgers allows international organizations, regulatory agencies, and manufacturers to collaborate in real-time without the utilization of costly middleware and manual data exchange protocols.

This dynamic scalability means that the framework will not only shut down of the framework only when there is a pandemic but also when there is another global health crisis related to new pathogens or emergent diseases.


Figure 2: Scalability of the Framework under Public Health Crises

### *5.3 Simulation or Modeling Perspectives*

Digital simulations and chain models should also be used to stress pandemic resilience frameworks before they are implemented on a wide scale. It is possible to use agent-based models (ABM), discrete event simulations (DES), and system dynamics models (SDM) to determine how blockchain traceability systems react to disruption or delays, cyberattacks, or the shortage of raw materials.

Simulated situations could be:

- Recall of contaminated vaccine: Countermeasure is time-to-trace and time-to-isolate within a multi-country network.
- Cold chain violation: Model automated and intelligent smart contract interventions.
- Black market penetration: Monitor the unauthorized intrusion that gets identified and isolated.
- Spikes in global demand: Study the issues of scalability and efficiency in terms of node synchronization.

These simulations offer quantitative evidence on how blockchain can improve the operational resilience, lower the risk of contagion, and assist adaptive behavior of the supply chain under stress.

### *5.4 Resilience Indicators: Measuring Performance*

In order to test the performance of the traceability potential of blockchain in crisis circumstances, a list of resilience indicators must be determined and tracked. Such metrics enable the decision-makers to measure robustness, responsiveness, and integrity of the systems:

- Time-to-Trace (TtT): It is the time spent on tracing those units affected by a quality incident.
- Source Authentication Accuracy (SAA): The probability of a genuine verification of the source of the product.
- Data Latency: Delay between an event occurring in a supply chain and the time it appears in the blockchain.
- Tamper Detection Rate: How often are integrity breaches properly raised?
- Cold Chain Compliance Rate (CCCR): Fraction of shipments of vaccines that have satisfied the necessary environmental conditions.

Table 4: Blockchain Contributions to Pandemic Resilience Metrics

| Resilience Indicator | Blockchain Contribution | Impact on Crisis Response |
|---|---|---|
| **Time-to-Trace (TtT)** | Immutable audit trail with unit-level serialization | Enables rapid identification and recall of products |
| **Source Authentication Accuracy (SAA)** | Verifiable digital signatures on transactions | Prevents counterfeiting, ensures source legitimacy |
| **Data Latency** | Real-time IoT integration and automated updates | Improves responsiveness and coordination |
| **Tamper Detection Rate** | Smart contracts with anomaly triggers | Flags compromised packages for quarantine |
| **Cold Chain Compliance Rate** | Continuous temperature logging on-chain | Maintains vaccine efficacy and public trust |

Traceability enabled by blockchain solutions can not only protect supply chain integrity in the context of a public health emergency but also develop sustainable resilience by means of real-time tracking, automation, and data transparency. Such digital infrastructures will be an inevitable solution to the response of the healthcare systems with speed, safety, and efficacy as pandemics are increasingly becoming common as a result of globalization and climate-related factors.

**6. Challenges, Risks, and Strategic Considerations**

Although blockchain-based traceability seems to be a good solution to inefficiencies and uncertainties in the pharmaceutical supply chain, this notion is bedeviled with technical, legal, organizational, and socio-economic issues. These barriers are what must be clearly understood to come up with a successful deployment strategy that seemingly cuts along the requirement in balancing innovation against compliance, cost-effectiveness, and cooperation among the stakeholders.

***6.1 Data Privacy and Regulatory Constraints (e.g., HIPAA, GDPR)***

When it comes to a healthcare setting in general and the pharmaceutical industry in specific, one issue that is at the top of the agenda during blockchain implementation is the process of working with sensitive data, especially in cases when personal health information (PHI) or any manufacturing money-making secrets are brought up. Such regulations as the Health Insurance Portability and Accountability Act (HIPAA) in the U.S. and the General Data Protection Regulation (GDPR) in the European Union dictate the severe requirements regarding data privacy, consent, and the right to be forgotten.

These demands seem to be against the fundamental trait of blockchain immutability. When data is stored in a blockchain, it is impossible to edit or remove it; this becomes a concern when users demand to have their data removed in the face of GDPR. One countermeasure against this is to use a hybrid system, in which sensitive data is not stored on-chain, but is stored in off-chain secure, encrypted databases, and only hashed references or access points are stored on-chain. The architecture of the blockchain should also incorporate role-based access controls and cryptographic protocols so as to maintain the aspect of data minimization, accountability, and auditability without contravening the privacy laws.

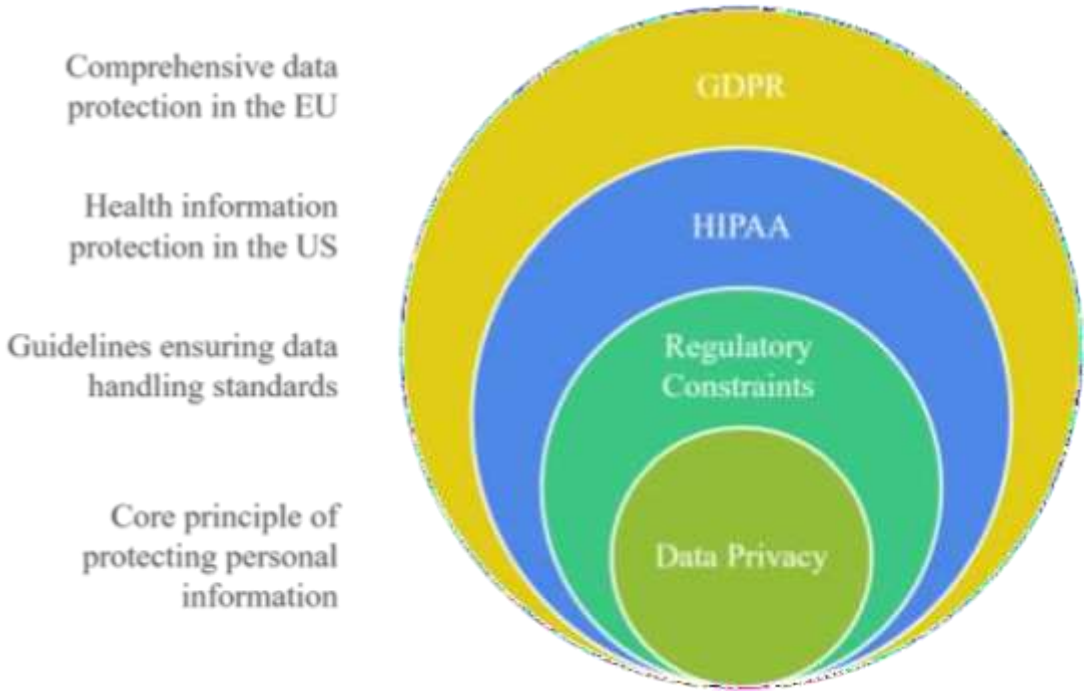


Figure 3: Data Privacy and Regulatory Constraints

***6.2 Interoperability Issues***

Enterprise Resource Planning (ERP) tools, Warehouse Management System (WMS), Laboratory Information Management systems (LIMS), and electronic health records (EHRs) are also a huge array of systems used within a pharmaceutical supply chain, and they are highly fragmented, proprietary, and non-standardized. Putting blockchain in such an environment needs cross-platform compatibility.

Insufficient cross-modelability of data models and agreed industry standards of integration may generate information silos, howls, and duplication of work. Moreover, the stakeholders might apply various blockchain protocols (e.g., Hyperledger Fabric, Corda, Ethereum) featuring their peculiarities, which results in increased complexity of data exchangeability. In a bid to address this challenge, there is a need to adopt global standards to appropriately serialise using ones like GS1 and to track the events chronologically using EPCIS, among others. The intersection between legacy systems and blockchain networks can be implemented with a middleware solution or an Application Programming Interface (APIs), which will ensure a continuous data flow between dissimilar systems.

***6.3 Resistance from Legacy Stakeholders***

Although there are obvious advantages, a lack of organizational flexibility and change resistance continue to pose major challenges. The existing systems have been heavily invested in by a majority of pharmaceutical firms, and their desire to upgrade them to work with disruptive technologies is likely to lure them into avoiding the floor due to the necessity to undergo a restructuring of their operations, retraining of their workforce, or reengagement with the regulatory domain. Moreover, certain members of the supply chain, especially the intermediaries, might view blockchain as a threat to their control or takeover because the lack of information asymmetry would render the information asymmetry supposedly enjoyed by intermediaries.

In an endeavour to overcome this opposition, stakeholders need to be involved at an early stage through collaborative forms of governance, demonstration of proof-of-concept, and demonstration projects, translating the ROI and risk reduction. By focusing on how blockchain can be used to meet regulatory requirements, to protect brands and limit counterfeits, it should be possible to generate buy-in and strategic alignment.

***6.4 Infrastructure Costs and the Global Digital Divide***

Implementation of a blockchain-based traceability system would require a huge capital outlay, which will entail the costs associated with the deployment of blockchain nodes, sensor hardware (IoT), implementations of cybersecurity infrastructure, and integration of the system. These are prohibitive costs, especially to the likes of small and medium-sized enterprises (SMEs), generic drugs producers, or where the entity is working in a low-resource environment.

In addition, disparity in the modernization of the supply chain may increase with the digital divide between the developed world and the developing world. Elements of infrastructural inadequacies like poor internet connectivity, failure to have cloud setups, or even lack of skilled manpower can impede the application of blockchain in chunks of Africa, South Asia, and Latin America, which are key hubs in global pharma supply roads.

To deal with it, the funding of the blockchain infrastructure in critical regions should be a priority of the public-private partnership and development aid programs. The entry barriers can also be minimized by developing scalable, low-cost blocks hosted on safe platforms known as cloud-based Blockchain-as-aService (BaaS) platforms.

### *6.5 Strategic Recommendations for Pharmaceutical Enterprises and Regulators*

To maximize the potential of blockchain but to control its risks with strategic thinking, the following considerations ought to be applied:

- Take a hybrid data approach: Store sensitive data off-chain, and store events, hashes, and smart contracts on-chain in order to stay compliant with regulatory issues.
- Standardization of mandate: Even promote or mandate the use of GS1, HL7 FHIR, and EPCIS standards to maintain interoperability across systems and geographies.
- Design multi-stakeholder governance consortia: Design regulatory-technology-business unions to co-parallel the governance policies, framework, and shared infrastructure.
- Start with pilot programs: Start with pilot programs on high-risk, high-value product categories like vaccines, biologics, and oncology drugs.
- Regulatory preparedness: During early design, work with regulators to ensure practice and conform to data protection, audit, and validation requirements.
- An incentive to act: Provide tax credits, grants, or regulatory bypass to early implementers of blockchain-based traceability systems.

By being aware of these challenges and implementing mitigating efforts, the pharmaceutical stakeholders will be able to counter the obstacles on the way to the adoption of blockchain and develop secure, transparent, and resistant to various crises supply chains.

## 7. Conclusion and Future Outlook

The rising sophistication of international pharmaceutical supply chains combined with the risk of counterfeited medicine, disjointed regulatory systems, and exploited vulnerabilities observed in the context of pandemics has revealed the urgency of transparent, high-performance supply chains that are able to resist adversities and offer increased stability in the goods flow. This paper has given a proposal of a Blockchain-enabled traceability framework, which brings together systems engineering, IT governance, compliance automation, and use of real-time physical tracking to assist regulatory compliance and pandemic resilience in the pharmaceutical sector.

Breaking down regulatory requirements in different jurisdictions around the globe, this piece highlighted the benefits of end-to-end serialization, traceability, and data integrity. The outlined layered framework, with its three distinct layers (IoT-based physical monitoring, blockchain infrastructure, smart contracts, and cybersecurity governance can be considered a modular and scalable solution. It acts not only by the international regulatory guidelines such as the DSCSA and FMD but also promotes decentralized cooperation among the actors, including manufacturers, distributors, regulators, and healthcare providers.

This framework is expected to bring multidimensional benefits. Blockchain traceability can balance operational and public health needs: Beyond helping to recall products faster (and more securely) and safeguarding the cold-chain of vaccines, blockchain traceability helps ensure that falsified medicines do not spread as well. It also develops regulatory harmonisation through a common digital infrastructure that is capable of interoperating across borders and jurisdictions in mutually recognised situations, avoiding unnecessary duplication of audits or compliance bottlenecks.

Nevertheless, the implementation will require addressing the essential obstacles such as data privacy issues, infrastructural challenges, and legacy stakeholder resistance alongside the requirement for interoperability. In that line of thought, this article has offered strategic guidelines starting with the hybrid architecture design and up to the stakeholder incentivization and policy innovation.

In the future, opportunities need to be pursued in a number of ways. First, the framework's resilience could be measured quantitatively in crisis scenario studies based on simulation, so that the study would predict response time and risk mitigation. Second, smart contracts with AI may be created that allow them to be adaptive and detect anomalies in real-time. Third, since blockchain maturity is developing, cross-chain protocols can facilitate a smooth integration between diffuse pharmaceutical ecosystems.

To sum up, the proposed framework is not only a technological intervention but a paradigm shift to digitally smart, resilient, and ethically responsible pharmaceutical supply chains. Its adoption will not only protect the health of the world but also make the industry future-proof in an evolving regulatory, technological, and epidemiological environment.

**Funding:** This research received no external funding
**Conflicts of Interest:** The authors declare no conflict of interest
**Publisher's Note:** All claims expressed in this article are solely those of the authors and do not necessarily represent those of their affiliated organizations, or those of the publisher, the editors and the reviewers.

**References**

[1] Agrawal, T. K., Kumar, V., Pal, R., Wang, L., & Chen, Y. (2021). Blockchain-based framework for supply chain traceability: A case example of textile and clothing industry. *Computers and Industrial Engineering*, *154*. https://doi.org/10.1016/j.cie.2021.107130
[2] Alamsyah, A., Widiyanesti, S., Wulansari, P., Nurhazizah, E., Dewi, A. S., Rahadian, D., … Tyasamesi, P. (2023). Blockchain traceability model in the coffee industry. *Journal of Open Innovation: Technology, Market, and Complexity*, *9*(1). https://doi.org/10.1016/j.joitmc.2023.100008 the Pharmaceutical Supply Chain. *IBIMA Business Review*, *2020*. https://doi.org/10.5171/2020.562376
[3] Assadi, A., Laussen, P. C., Goodwin, A. J., Goodfellow, S., Dixon, W., Greer, R. W., … Mazwi, M. L. (2022). An integration engineering framework for machine learning in healthcare. *Frontiers in Digital Health*, *4*. https://doi.org/10.3389/fdgth.2022.932411
[4] Beach, T. H., Hippolyte, J. L., & Rezgui, Y. (2020). Towards the adoption of automated regulatory compliance checking in the built environment. *Automation in Construction*, *118*. https://doi.org/10.1016/j.autcon.2020.103285
[5] Behnke, K., & Janssen, M. F. W. H. A. (2020). Boundary conditions for traceability in food supply chains using blockchain technology. *International Journal of Information Management*, *52*. https://doi.org/10.1016/j.ijinfomgt.2019.05.025
[6] Bø, E., Hovi, I. B., & Pinchasik, D. R. (2023). COVID-19 disruptions and Norwegian food and pharmaceutical supply chains: Insights into supply chain risk management, resilience, and reliability. *Sustainable Futures*, *5*. https://doi.org/10.1016/j.sftr.2022.100102
[7] Brun, A., Karaosman, H., & Barresi, T. (2020). Supply chain collaboration for transparency. *Sustainability (Switzerland)*, *12*(11). https://doi.org/10.3390/su12114429
[8] Dasaklis, T. K., Voutsinas, T. G., Tsoulfas, G. T., & Casino, F. (2022, February 1). A Systematic Literature Review of Blockchain-Enabled Supply Chain Traceability Implementations. *Sustainability (Switzerland)*. MDPI. https://doi.org/10.3390/su14042439
[9] Demestichas, K., Peppes, N., Alexakis, T., & Adamopoulou, E. (2020). Blockchain in agriculture traceability systems: A review. *Applied Sciences (Switzerland)*, *10*(12), 1–22. https://doi.org/10.3390/APP10124113
[10] Donkor, F., Papadopoulos, T., & Spiegler, V. (2024). Supply chain integration and supply chain sustainability relationship: a qualitative analysis of the UK and Ghana pharmaceutical industry. *Production Planning and Control*, *35*(6), 535–558. https://doi.org/10.1080/09537287.2022.2105762
[11] Eriksson, P. E. (2015). Partnering in engineering projects: Four dimensions of supply chain integration. *Journal of Purchasing and Supply Management*, *21*(1), 38–50. https://doi.org/10.1016/j.pursup.2014.08.003
[12] Fan, Z. P., Wu, X. Y., & Cao, B. B. (2022). Considering the traceability awareness of consumers: should the supply chain adopt the blockchain technology? *Annals of Operations Research*, *309*(2), 837–860. https://doi.org/10.1007/s10479-020-03729-y
[13] Feng, H., Wang, X., Duan, Y., Zhang, J., & Zhang, X. (2020, July 1). Applying blockchain technology to improve agri-food traceability: A review of development methods, benefits and challenges. *Journal of Cleaner Production*. Elsevier Ltd. https://doi.org/10.1016/j.jclepro.2020.121031
[14] Fetter, B., & Zilahy, G. (2022). Challenges of the green supply chain management in the pharmaceutical industry. *Vestnik Sankt-Peterburgskogo Universiteta. Ekonomika*, *38*(2), 235–258. https://doi.org/10.21638/spbu05.2022.204
[15] Ghadge, A., Bourlakis, M., Kamble, S., & Seuring, S. (2023). Blockchain implementation in pharmaceutical supply chains: A review and conceptual framework. *International Journal of Production Research*. Taylor and Francis Ltd. https://doi.org/10.1080/00207543.2022.2125595
[16] Guzey, S. S., Moore, T. J., & Harwell, M. (2016). Building up stem: An analysis of teacherdeveloped engineering design-based stem integration curricular materials. *Journal of PreCollege Engineering Education Research*, *6*(1). https://doi.org/10.7771/21579288.1129
[17] Hadjielias, E., Christofi, M., & Tarba, S. (2022). Contextualizing small business resilience during the COVID-19 pandemic: evidence from small business owner-managers. *Small Business Economics*, *59*(4), 1351–1380. https://doi.org/10.1007/s11187021-00588-0
[18] Hariry, R. E., Barenji, R. V., & Paradkar, A. (2022, January 1). Towards Pharma 4.0 in clinical trials: A future-orientated perspective. *Drug Discovery Today*. Elsevier Ltd. https://doi.org/10.1016/j.drudis.2021.09.002
[19] Hemanth Kumar, S., Talasila, D., Gowrav, M. P., & Gangadharappa, H. V. (2020, March 1). Adaptations of pharma 4.0 from industry 4.0. *Drug Invention Today*. JPR Solutions.
[20] Alharthi, S., Cerotti, P. R., & Far, S. M. (2020). An Exploration of the Role of Blockchain in the Sustainability and Effectiveness of
[21] Hwang, S. (2022). Effects of Engineering Students' Soft Skills and Empathy on Their Attitudes toward Curricula Integration. *Education Sciences*, *12*(7). https://doi.org/10.3390/educsci12070452
[22] Jaberidoost, M., Nikfar, S., Abdollahiasl, A., & Dinarvand, R. (2013, December 19). Pharmaceutical supply chain risks: A systematic review. *DARU, Journal of Pharmaceutical Sciences*. https://doi.org/10.1186/2008-2231-21-69

[23] Jamil, A. H., Mohd Sanusi, Z., Yaacob, N. M., Mat Isa, Y., & Tarjo, T. (2022). The Covid-19 impact on financial crime and regulatory compliance in Malaysia. *Journal of Financial Crime*, *29*(2), 491–505. https://doi.org/10.1108/JFC-05-2021-0107

[24] Johnson, W. G. (2023). Caught in quicksand? Compliance and legitimacy challenges in using regulatory sandboxes to manage emerging technologies. *Regulation and Governance*, *17*(3), 709–725. https://doi.org/10.1111/rego.12487

[25] Khan, F., & Ali, Y. (2022). Implementation of the circular supply chain management in the pharmaceutical industry. *Environment, Development and Sustainability*, *24*(12), 13705–13731. https://doi.org/10.1007/s10668-021-02007-6

[26] Labrague, L. J. (2021). Pandemic fatigue and clinical nurses' mental health, sleep quality and job contentment during the covid-19 pandemic: The mediating role of resilience. *Journal of Nursing Management*, *29*(7), 1992–2001. https://doi.org/10.1111/jonm.13383

[27] Lallas, E. N., Santouridis, I., Mountzouris, G., Gerogiannis, V. C., & Karageorgos, A. (2022). An SQWRL-Based Method for Assessing Regulatory Compliance in the Pharmaceutical Industry. *Applied Sciences (Switzerland)*, *12*(21). https://doi.org/10.3390/app122110923

[28] Njinyah, S., Asongu, S., & Adeleye, N. (2022). The interaction effect of government nonfinancial support and firm's regulatory compliance on firm innovativeness in Sub-Saharan Africa. *European Journal of Innovation Management*, *26*(7), 45–64. https://doi.org/10.1108/EJIM-07-2022-0352

[29] Ozdemir, D., Sharma, M., Dhir, A., & Daim, T. (2022). Supply chain resilience during the COVID-19 pandemic. *Technology in Society*, *68*. https://doi.org/10.1016/j.techsoc.2021.101847

[30] Papalexi, M., Bamford, D., Nikitas, A., Breen, L., & Tipi, N. (2022). Pharmaceutical supply chains and management innovation? *Supply Chain Management*, *27*(4), 485–508. https://doi.org/10.1108/SCM-12-2019-0456

[31] Sarawa, D. I., & Mas'ud, A. (2020). Strategic public procurement regulatory compliance model with mediating effect of ethical behavior. *Heliyon*, *6*(1). https://doi.org/10.1016/j.heliyon.2019.e03132

[32] Schäfer, N. (2023). Making transparency transparent: a systematic literature review to define and frame supply chain transparency in the context of sustainability. *Management Review Quarterly*, *73*(2), 579–604. https://doi.org/10.1007/s11301-021-00252-7

[33] Shashi, M. (2023). Sustainable Digitalization in Pharmaceutical Supply Chains Using Theory of Constraints: A Qualitative Study. *Sustainability (Switzerland)*, *15*(11). https://doi.org/10.3390/su15118752

[34] Soliman-Junior, J., Tzortzopoulos, P., & Kagioglou, M. (2022). Designers' perspective on the use of automation to support regulatory compliance in healthcare building projects. *Construction Management and Economics*, *40*(2), 123–141. https://doi.org/10.1080/01446193.2021.2022176

[35] Tan, A., Gligor, D., & Ngah, A. (2022). Applying Blockchain for Halal food traceability. *International Journal of Logistics Research and Applications*, *25*(6), 947–964. https://doi.org/10.1080/13675567.2020.1825653

[36] Tsolakis, N., Goldsmith, A. T., Aivazidou, E., & Kumar, M. (2023). Microalgae-based circular supply chain configurations using Industry 4.0 technologies for pharmaceuticals. *Journal of Cleaner Production*, *395*. https://doi.org/10.1016/j.jclepro.2023.136397

[37] Uddin, M., Salah, K., Jayaraman, R., Pesic, S., & Ellahham, S. (2021). Blockchain for drug traceability: Architectures and open challenges. *Health Informatics Journal*, *27*(2). https://doi.org/10.1177/14604582211011228

[38] Vinkers, C. H., van Amelsvoort, T., Bisson, J. I., Branchi, I., Cryan, J. F., Domschke, K., … van der Wee, N. J. A. (2020). Stress resilience during the coronavirus pandemic. *European Neuropsychopharmacology*, *35*, 12–16. https://doi.org/10.1016/j.euroneuro.2020.05.003

[39] Zaman, M. H. M., Mokhtar, M. H. H., Ibrahim, M. F., Huddin, A. B., & Beng, G. K. (2020). Integration of 3d printing in computer-aided design and engineering course. *International Journal of Evaluation and Research in Education*, *9*(4), 934–938. https://doi.org/10.11591/ijere.v9i4.20652