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Designing a Blockchain-Based System for Tracking Rare and Specialty Drugs in Iran's Pharmaceutical Supply Chain

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Abstract

The management of treatment for rare diseases such as spinal muscular atrophy within Iran's pharmaceutical supply chain is accompanied by significant challenges, including extremely high costs, lack of transparency in distribution, and the occurrence of drug leakage into the black market. These issues have led to reduced access for genuine patients to vital medications. In this study, a blockchain-based system has been designed and implemented with the aim of improving traceability, transparency, and auditability within the supply chain of rare and special medicines. The system has been developed using the Ethereum network and the Solidity programming language, and implemented through the Remix environment for the development and testing of smart contracts. In the system design, multiple roles have been considered, including importers, distribution centers, pharmacies/clinics, certified physicians, and patients. Based on a review of scientific literature, theses, reported projects, and existing national systems, no platform with this level of blockchain integration, traceability of rare medicines, and recording of treatment processes has been reported in Iran to date. The results of the implementation and technical evaluation indicate that the proposed system is capable of enabling precise drug traceability, establishing a transparent and auditable infrastructure, and potentially reducing violations within the distribution chain. Evaluations conducted in a test environment demonstrate that the proposed design, in terms of architecture and data-recording logic, provides a higher level of structural transparency and accountability compared to traditional processes. Given the immutability of data, end-to-end traceability, and the elimination of informational blind spots, the proposed system can, from a design perspective, contribute to reducing misconduct in the pharmaceutical distribution chain. This approach represents a practical step toward preventing the diversion of pharmaceutical resources within the country.

Keywords: Blockchain, Drug traceability, Ethereum, Pharmaceutical supply chain, Smart contract, Rare and specialty drugs.

1 | Introduction

Rare-disease treatment pathways are especially vulnerable to coordination failures because they depend on repeated treatment cycles, strict eligibility criteria, and medicines whose financial and clinical value makes

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diversion particularly harmful. Spinal muscular atrophy is a relevant example because it is a progressive genetic disease, often diagnosed in infancy or childhood, and its treatment has major clinical and economic implications for patients, families, and health systems [1–4]. In settings where the public sector participates in procurement or subsidized access, the consequences of weak traceability extend beyond logistics and directly affect distributive justice, clinical continuity, and public trust.

The central problem addressed in this study is not limited to counterfeit detection. In the Iranian context, the deeper challenge is the absence of an end-to-end mechanism that can connect import approval, unique medicine identification, distribution logging, patient eligibility verification, and treatment reporting within one auditable workflow. When each actor stores only a fragment of the process in separate systems, visibility becomes incomplete, oversight becomes retrospective, and the probability of diversion or undocumented allocation rises. This study therefore frames rare-drug governance as an information-integration problem as much as a pharmaceutical one.

Blockchain has attracted sustained attention in supply chain management because it can provide a distributed, tamper-resistant ledger that supports shared records, event traceability, and programmable control logic through smart contracts [5–7]. In the pharmaceutical domain, these features are attractive for provenance tracking, anti-diversion controls, and stronger accountability across multiple actors. However, the literature remains uneven. Many published studies discuss transparency, provenance, or authenticity in general terms, while far fewer propose systems that connect logistics with patient-linked allocation and downstream treatment documentation in a rare-disease setting [6–10].

This study addresses that gap by presenting a structured article extraction from that designed and evaluated a blockchain-based architecture for tracking rare and specialty medicines in Iran’s pharmaceutical supply chain. The study asks two practical questions: how blockchain can improve the current supply chain for rare-disease medicines, and which operational challenges it can reduce or introduce in the Iranian context. The contribution is not a generic conceptual framework. It is a concrete, modular architecture with defined stakeholders, modeled workflows, implemented smart contracts, and a multi-dimensional evaluation that includes functional execution, cost, scalability, usability, and user-facing transparency outcomes.

2 | Literature Review

2.1 | Pharmaceutical Traceability and Supply Chain Transparency

Supply chain traceability depends on the ability to identify products, verify their movement, and connect dispersed events into a coherent chronological record. In healthcare, these requirements are particularly important because failures in transparency can expose patients to counterfeit, diverted, or inappropriately allocated medicines [5]. More broadly, supply chain research has shown that blockchain is attractive for transparency because it substitutes fragmented bilateral records with a shared ledger whose history is difficult to alter retrospectively [6], [7]. For high-value medicines, this matters not only for trust between institutions but also for regulatory auditability.

Pharmaceutical blockchain studies have already demonstrated the promise of distributed ledgers for governance and traceability. Tseng et al. [8] proposed blockchain-enabled governance logic for the drug supply chain, and Musamih et al. [9] presented a traceability approach with attention to cost in healthcare logistics. More recent work continues to emphasize blockchain for stronger traceability and drug-authenticity verification in pharmaceutical settings [10], [11]. Yet the dominant focus of this literature remains either general anti-counterfeit control or product-level traceability rather than integrated governance of publicly important rare medicines.

2.2 | Blockchain, Smart Contracts, and Healthcare-Specific Design Issues

At the technical level, the appeal of Ethereum and comparable platforms lies in the combination of distributed consensus, programmable smart contracts, and immutable event logging [12–14]. These

characteristics allow operational rules to be embedded directly into the digital infrastructure. For medicine governance, such rules may include who can register a product, who can log a transfer, who can validate eligibility, and what type of information should remain private.

At the same time, the literature is clear that blockchain adoption in operational settings is not without cost. Ethereum smart contracts are vulnerable to well-documented implementation pitfalls if they are poorly designed, and secure development requires structured analysis rather than simple deployment enthusiasm [15], [16]. In addition, although blockchain-based provenance has been discussed extensively in adjacent supply chains such as agri-food, those systems do not automatically solve the distinctive challenges of rare-drug allocation, patient-linked verification, and clinical follow-up in healthcare [17]. Accordingly, a healthcare system must balance transparency with confidentiality and must separate public audit trails from protected patient-level data.

The literature also highlights a broader implementation issue. The most compelling theoretical arguments for blockchain often appear before large-scale real-world deployment. Reviews of blockchain and supply chain integration show strong conceptual momentum but comparatively limited operational evidence, especially in highly regulated environments [7], [11]. This gap is even more visible in developing-country health systems, where interoperability, regulation, and infrastructure constraints shape what can actually be deployed.

The cumulative implication of the literature is that a publishable healthcare systems engineering study should not only argue that blockchain is useful in principle. It should specify the artifact, define the roles, explain the logic of public versus private data, and report how the system performs when implemented and evaluated. That requirement shaped the present study.

Table 1. Representative prior studies.

S/N	Study	Primary Contributions
1	Kshetri [6]	Shows how blockchain can support core supply chain objectives such as transparency and provenance
2	Francisco and Swanson [7]	Explains blockchain-enabled transparency in supply chains and adoption implications
3	Tseng et al. [8]	Applies blockchain governance logic to the drug supply chain
4	Musamih et al. [9]	Proposes blockchain-based drug traceability in healthcare supply chains.
5	Tian [17]	Demonstrates blockchain traceability in another supply-chain domain

3 | Research Gap

Against this background, the key research gap is the lack of a decentralized, auditable architecture that links five things at once: medicine registration, unique identifier control, distribution history, patient eligibility verification, and treatment-process documentation. Previous work explains why traceability matters and how blockchain can support it, but much less work shows how those elements can be joined in a single workflow for rare and specialty medicines under real institutional constraints [6–11], [17]. This study directly to that gap by designing a modular system for the Iranian setting and evaluating it beyond a purely conceptual level.

4 | Materials and Methods

The study followed a design-oriented systems-engineering methodology. Rather than testing an already deployed platform, it moved from problem analysis and workflow reconstruction to artifact design, implementation, and evaluation. The approach can be summarized in four stages: identifying the current supply-chain problem and its communication bottlenecks, modeling the intended end-to-end process,

implementing the blockchain-based solution, and evaluating the resulting system from technical, structural, economic, and user-centered perspectives.

Process discovery relied on a combination of literature review, informal consultations, and contextual inquiry into the current Iranian rare-drug pathway. Access to formal process blueprints from national authorities was limited because of data sensitivity and institutional restrictions. The practical workflow was therefore reconstructed from field-informed accounts and reviewed with domain specialists. This produced a stepwise representation of medicine registration, identifier assignment, distribution, clinic validation, patient allocation, physician oversight, and reporting. The reconstructed process was then modeled in BPMN to make actor roles, event sequences, and control points explicit.

The implementation stage focused on Ethereum smart contracts written in Solidity and deployed in the Remix development environment. The smart-contract layer was complemented by an application layer built with Node.js and Express.js, blockchain interaction via Ethers.js, and off-chain storage in MongoDB. The design intentionally separated public and private records. Sensitive patient and clinical information remained off-chain, while hashes and operational events were stored on-chain to preserve immutability and verifiability without exposing protected data.

Evaluation was multi-dimensional. Functional testing examined whether the contracts could execute core events correctly in a test environment [15], [16], [18]. Architectural evaluation examined maintainability and scalability under a modular contract design. Economic assessment estimated gas consumption and projected execution cost under stated public-network assumptions. User-centered assessment combined moderated usability testing, thematic analysis, quantitative task-performance review, and error analysis, drawing on well-established usability and qualitative-analysis methods [19–22]. In addition, the study also included a controlled comparative user study that contrasted the current display condition with the proposed interface for medicine availability.

5 | System Architecture and Implementation

The proposed system is built around six stakeholder groups: the regulator, the importer, the distributor, the clinic, the certified physician, and the patient. Each role is functionally distinct. The regulator approves medicines and oversees the chain; the importer initializes formal medicine entries and obtains unique identifiers; the distributor records movement and destination; the clinic validates identifiers and allocates medicines to eligible patients; the certified physician records post-allocation treatment evidence; and the patient accesses permitted status information. This role separation is essential because the system is not simply a logistics registry. It is a governance framework that coordinates distribution, allocation, and downstream clinical confirmation.

Table 2. Stakeholders and principal responsibilities in the proposed system.

Stakeholder	Principal Responsibility	Main Interaction with the System
Regular	Approves medicines and supervises the chain	Confirms registrations and monitors traceability records
Importer	Initiates medicine records and registers unique identifiers	Requests registration and creates product identity anchors
Distributor	Logs movement and distribution events	Records transfers, destinations, clinic allocations, and quantities
Clinic	Verifies identifier validity and patient eligibility	Confirms UID authenticity, checks receipt interval, and records dispensing
Certified Physician	Documents treatment-related outcomes	Registers clinical-report hashes after medicine use
Patient	Accesses permitted transparency information	Reviews authorized status and public drug-journey records

The workflow reconstructed in the study contains nine operational steps. First, medicine information is registered with the regulator before import. Second, a unique identifier is assigned to each unit or package. Third, medicines are transferred to distribution centers. Fourth, receiving centers verify UID validity. Fifth, receipt confirmation is logged. Sixth, eligible patients are notified. Seventh, the patient's eligibility is checked at the clinic. Eighth, the patient is referred to a certified physician for treatment authorization. Ninth, treatment use is documented and linked back into the system. This sequence is significant because it connects the administrative and clinical phases of medicine use rather than treating traceability as a warehouse-only function.

At the smart-contract level, the architecture is modular. The DrugRegistration contract acts as the official on-chain registry for approved medicines and enforces non-reusable unique identifiers. UIDTracker records per-UID transfer records and aggregated distribution events. ClinicVerification serves as the allocation-control layer: it validates the UID against the registration registry, checks whether the patient is eligible based on the interval since the last receipt, and updates the receipt status. PublicDrugJourney makes non-sensitive distribution history available for public-facing transparency by medicine type rather than individual patient-linked identifiers. DoctorReport stores hashes of physician reports so that treatment documentation can be connected to the traceability chain without disclosing protected content.

Table 3. Smart contract modules and their functions.

Stakeholder	Principal Responsibility	Main Interaction with the System
DrugRegistration	Registers approved medicines and creates official UID anchors	Rejects duplicate UIDs and constrains write access to the authorized authority
UIDTracker	Logs transfers and distribution events	Preserves immutable product movement history across the chain
ClinicVerification	Verifies UID authenticity and patient eligibility	Prevents premature or unauthorized re-dispensing and updates receipt interval
PublicDrugJourney	Exposes non-sensitive distribution visibility	Supports public traceability without exposing protected clinical information
DoctorReport	Stores hashes of treatment-related reports	Preserves tamper-evident proof of clinical documentation while keeping content off-chain

The application layer extends the contracts into a usable system. The backend follows a modular pattern in which routes direct requests to controllers, controllers call service logic, and services interact with the database and the blockchain interface. Three off-chain data domains are emphasized in this study: patient records, medicine-related records, and regional quota information. This design choice reflects a principled privacy trade-off. Hot-path governance events remain auditable on-chain, while more sensitive and mutable healthcare data stay in controlled off-chain storage. The resulting architecture is therefore hybrid rather than purely on-chain.

6 | Evaluation and Results

The evaluation was organized around functional correctness, technical robustness, economic feasibility, architectural suitability, and user experience. This separation is important because the study's contribution lies not only in designing the artifact but also in demonstrating which parts performed well, which constraints emerged, and which trade-offs remain open.

Functional validation showed that the contract set can reproduce the principal events required for rare-drug traceability. In the first scenario, the DrugRegistration contract successfully registered a medicine identifier, and duplicate registration attempts were rejected with an "already approved" logic path. This made the UID the central anchor for all subsequent supply-chain events. In the next stage, UIDTracker recorded transfer and clinic-distribution events. ClinicVerification then confirmed whether a UID was valid and whether the patient was eligible to receive the medicine at the current time. If the patient presented earlier than

permitted, the logic returned a negative result; otherwise, allocation could proceed and the receipt interval was updated. At the clinical end of the chain, DoctorReport retrieved prior report hashes and recorded new ones using keccak256, so the proof of reporting was on-chain even though the source clinical document remained off-chain.

Economic testing revealed the main barrier to direct public-network deployment. For a full traceability path comprising six principal operations, the prototype consumed 635,186 gas. Under the assumptions —15 Gwei gas price and an Ether price of USD 3,000—this corresponds to approximately 0.00955 ETH, or USD 28.64 per medicine. UID registration alone consumed 185,963 gas, or roughly USD 8.36 per item under the same assumptions. Extrapolated to 2,000 rare and specialty medicines, the estimated cost is about USD 16,720 for UID registration alone and about USD 57,280 for end-to-end on-chain tracking. These numbers do not invalidate the architecture, but they strongly suggest that public Ethereum mainnet is not the economically optimal deployment target for a national health-governance use case.

Architectural analysis favored the modular design over a monolithic contract structure. For a system with multiple actors, multiple data domains, and evolving regulatory requirements, a single large contract would be difficult to test, document, debug, and upgrade. The modular pattern adopted here allows one contract domain—such as clinic verification or physician reporting—to evolve without forcing redesign of the full system. This decision improves maintainability and is especially important in healthcare infrastructures where policy and workflow requirements often change incrementally rather than all at once.

User-centered evaluation produced encouraging early evidence. Because of operational constraints during the study period, the moderated usability test was conducted with two pharmacists rather than a broader target group. Even so, both participants completed the tasks successfully. The mean task-completion times were 20 seconds and 32.5 seconds, respectively. Trust scores were high, and overall user-interface satisfaction was rated 4 out of 5 by both participants. Qualitative analysis revealed three recurring needs: clearer system messages, stronger institutional trust cues such as official visual markers, and more explicit explanations when a patient is deemed ineligible to receive the medicine.

The comparative user study reinforced the claim that the proposed design improves interpretability of medicine-availability information. The study reports that the proportion of users who believed the target medicine was available rose from 47% in the current condition to 81% in the proposed model. For quantity interpretation, 82% of users in the current condition selected “cannot be determined,” whereas that figure fell to 15% in the proposed model. In the improved interface, 61% selected the correct visible quantity. Confidence also increased markedly: 72% of users in the proposed condition reported high confidence in their answer, compared with 33% in the current condition. The study summarizes these shifts as gains of 34 percentage points in perceived availability, 58 percentage points in correct quantity interpretation, and 39 percentage points in high-confidence responses.

Table 4. Summary of the evaluation results.

Stakeholder	Principal Responsibility	Main Interaction with the System
Functional execution	Ethereum test-environment scenarios	Duplicate UIDs were rejected; transfers, clinic verification, and physician-report hashing executed as intended
Cost	Gas-consumption estimation	Full six-operation traceability path cost was estimated at about USD 28.64 per medicine under stated public Ethereum assumptions
Architectural scalability	Comparative architectural reasoning	Modular contracts were more maintainable and adaptable than a monolithic alternative
Moderated usability	Two pharmacist sessions with qualitative and quantitative analysis [19–22]	Both users completed tasks; trust and satisfaction were favorable, but messages and guidance required improvement
Comparative transparency study	Controlled comparison of current and proposed display condition	Proposed design improved perceived availability, correct quantity interpretation, and user confidence

7 | Discussion and Conclusion

7.1 | Implications for Healthcare Systems Engineering

The study suggests that the main value of blockchain in this context is not technological novelty for its own sake. Its real contribution is architectural. The proposed system turns a fragmented distribution process into a shared event chain that begins with medicine approval and ends with patient-linked treatment reporting. That full-chain logic is important because rare and specialty medicines are vulnerable to governance failures at the handoff points between institutions. By creating immutable checkpoints at those handoffs, the system reduces invisibility in the chain.

A second contribution is the explicit balance between transparency and confidentiality. Public blockchain implementations are often criticized for overexposing operational information, yet fully closed systems sacrifice traceability benefits. The architecture in this study avoids both extremes. Distribution events and identity anchors are recorded on-chain for auditability, while patient details and full clinical content remain off-chain, with hashes serving as verifiable references. In healthcare systems engineering terms, this is a privacy-preserving information-partitioning strategy rather than a maximalist transparency model.

The moderated usability and comparative display findings are also more important than they may first appear. In medicine-allocation systems, users do not merely need accurate data somewhere in the backend. They need interpretable data at the point of action. The study shows that a blockchain-informed design can improve not only backend auditability but also the clarity with which medicine-availability information is understood by human users. That point strengthens the system's relevance for healthcare operations, because poor interpretability can undermine even technically sound infrastructures.

8 | Limitations and Future Work

The study has several limitations that should be stated clearly. First, the system was evaluated at prototype level rather than in a live national deployment. Second, we did not have access to real regulatory datasets from the Ministry of Health or the national drug authority, so the workflow was reconstructed from field information and expert-informed process understanding rather than from full operational data exports. Third, some components necessarily remained off-chain because of privacy considerations. Fourth, the usability evaluation involved only two pharmacists, which limits the generalizability of behavioral conclusions even though the findings remain useful for design refinement. Finally, the public Ethereum cost analysis shows that direct mainnet deployment would likely be impractical at scale.

These limitations also define the future-research agenda. The next step is migration from a public test environment toward permissioned or hybrid blockchain infrastructures that offer lower transaction cost, stronger access control, and better institutional fit. Subsequent work should also explore interoperability with electronic health-record systems and hospital information systems so that treatment documentation can be hashed automatically rather than entered manually.

9 | Conclusion

This study demonstrates that a blockchain-enabled architecture can provide a coherent and technically grounded foundation for the traceability of rare and specialty medicines in Iran's pharmaceutical supply chain. Its main contribution lies in integrating medicine registration, UID control, distribution logging, patient eligibility verification, public traceability, and physician reporting within one modular framework. The evaluation indicates that the artifact is functionally credible and structurally valuable, while also making clear that privacy, institutional adoption, and public-network cost remain the major constraints on real-world deployment. For healthcare systems engineering, the most defensible conclusion is therefore that blockchain is not a complete solution by itself, but it can serve as a strong backbone for a more transparent, auditable, and patient-centered rare-medicine supply chain.

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Authors' Contributions

Conceptualization, M.D.; formal analysis, A.A.; Methodology, A.A.; Software, A.A.; Validation, S.C, A.A.; investigation, A.A.; resources, M.D, A.A.; data maintenance, A.A.; writing – original draft, A.A.; writing-review and editing, M.D, S.C, A.A.; visualization, A.A.; Supervision, S.C.; project administration, A.A.

The authors has read and agreed to the published version of the manuscript.

Data Availability

No public patient-level dataset accompanies this manuscript. The study is based on a prototype system and process reconstruction. Access to real operational data from national health authorities was restricted, and sensitive patient-related content was intentionally designed to remain off-chain because of privacy considerations. Accordingly, no new public dataset was generated for open release.

Conflicts of Interest

The author declares no conflict of interest. Funders played no role in the design of the study, in the collection, analysis, or interpretation of the data, in the writing of the manuscript, or in the decision to publish the results.

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