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Clinical Trial Data Sharing Through Blockchain-AI Platforms

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ABSTRACT

Clinical trial data are essential public goods, yet sharing them remains constrained by fragmented infrastructure, inconsistent consent management, complex regulatory landscapes, and legitimate concerns about privacy, security, and scientific misuse. Traditional repositories and bilateral data-use agreements often struggle to provide verifiable provenance, enforceable permissions, and scalable mechanisms for cross-institutional analysis. This manuscript proposes and analyzes a reference architecture for a permissioned blockchain–AI platform that enables compliant, trustworthy, and efficient sharing and secondary use of clinical trial data. The platform couples a consortium ledger for tamper-evident consent, access control, and auditability with a privacy-preserving AI layer that supports federated learning, differential privacy, and secure aggregation across sites. Interoperability is addressed via HL7 FHIR-based schemas and metadata harmonization pipelines; off-chain encrypted stores (e.g., content-addressed storage) manage bulk data while on-chain smart contracts encode governance rules, data-use conditions, and revocation. We situate the approach within current policy frameworks (e.g., ICMJE data sharing, EU GDPR, NIH Data Management and Sharing Policy, EMA Policy 0070) and synthesize evidence from the healthcare blockchain and federated learning literatures regarding security, performance, and adoption barriers. A methodology section details system components, identity/consent models, threat assumptions, and evaluation metrics (governance, privacy, model utility, and operational performance). The results section presents a design-level analysis and an implementation blueprint derived from prior prototypes and standards, along with realistic operational scenarios—such as consent withdrawal mid-trial, cross-border data requests, and audit preparation for regulators. We conclude that blockchain–AI platforms can materially improve verifiability, accountability, and privacy-by-design for trial data sharing, provided that governance is robust, identity and key management are user-centric, and interoperability and change management are prioritized. The scope and limitations outline legal heterogeneity, organizational readiness, cost, and algorithmic fairness as persistent challenges and point to future translational work, including sandbox pilots with

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ethics boards and regulators and longitudinal measurement of scientific and societal impact.

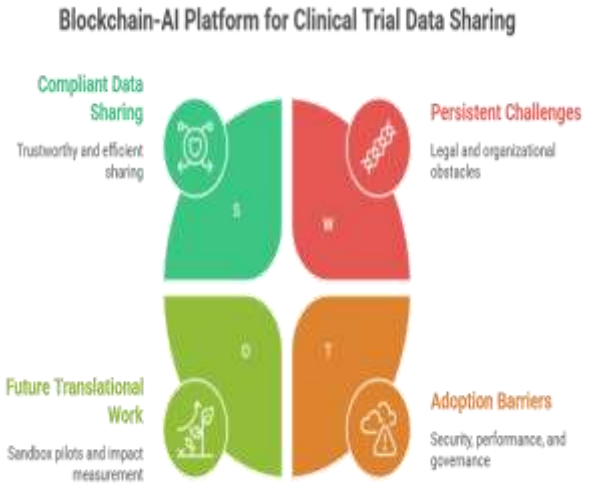

Figure-1.Blockchain-AI Platform for Clinical Trial Data Sharing

KEYWORDS

Clinical Trials, Data Sharing, Blockchain, Federated Learning, Privacy, Consent, HL7 FHIR, Auditability, Governance, Differential Privacy

INTRODUCTION

The social value of clinical trials depends not only on rigorous design and ethical conduct but also on effective dissemination and responsible reuse of the resulting data. Secondary analyses enable validation, meta-analyses, subgroup exploration, and discovery of adverse events that initial studies may be underpowered to detect. Over the last decade, global stakeholders—from journal editors and funders to regulators—have signaled strong expectations for greater transparency and data availability. Yet practical sharing remains sporadic. Many sponsors and investigators face difficulties in harmonizing heterogeneous datasets, managing consent at scale, proving compliance, and safeguarding participants' privacy in the presence of modern re-identification risks. Technical infrastructure is fragmented; governance is often bespoke and labor-intensive; provenance trails are incomplete; and incentives for timely sharing are uneven.

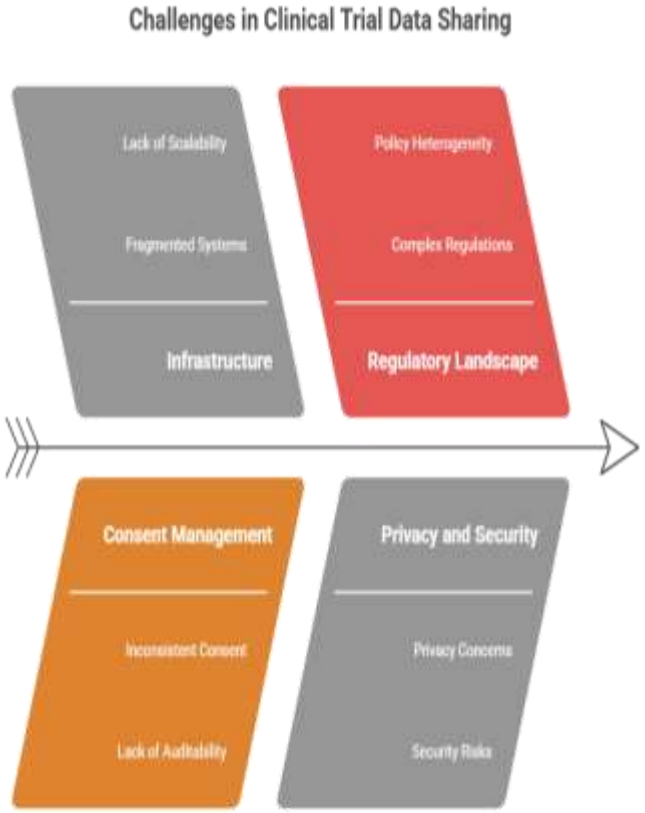

Figure-2.Challenges in Clinical Trial Data Sharing

Two technological trajectories have matured sufficiently to alter this landscape. First, permissioned blockchains provide replicated, tamper-evident ledgers with fine-grained, programmable governance (via smart contracts) and consistent, timestamped audit trails. When applied to clinical research, such ledgers can capture consent transactions, data-use approvals, data-set fingerprints, protocol amendments, and attribution events, enabling verifiable compliance and reducing disputes over scope and timing of use. Second, advances in privacy-preserving machine learning—particularly federated learning (FL), secure aggregation, and differential privacy—allow multi-institutional model training without centralizing raw participant-level data. Combined with standards-based

interoperability (e.g., HL7 FHIR), these capabilities suggest a platform model where trial data remain where they are collected, access conditions are enforced with cryptographic proofs, and analytics occur either at the edge or on encrypted derivatives.

This paper presents a comprehensive, practical blueprint for clinical trial data sharing through a blockchain–AI platform. We synthesize relevant policy requirements and research lines, specify a modular architecture, articulate a defensible threat model, and propose evaluation metrics that balance privacy, utility, and operational feasibility. We aim to support investigators, sponsors, institutional review boards (IRBs)/ethics committees, regulators, and patient communities in assessing whether, when, and how such platforms can be responsibly deployed.

LITERATURE REVIEW

Policy and Normative Foundations

Journal and funder policies have pushed for structured data sharing. The ICMJE encourages data sharing statements and transparency around availability and conditions; public health agencies and funders (e.g., NIH) require data management and sharing plans; European regulators (e.g., EMA Policy 0070) set expectations for public access to clinical data packages, with redaction for confidentiality and personal data protection. GDPR establishes foundational principles (lawfulness, purpose limitation, data minimization, storage limitation, integrity, and accountability) and introduces heightened obligations (e.g., data protection impact assessments, rights to access/erasure, and restrictions on cross-border transfer without adequate safeguards). These obligations intensify the need for traceable consent and auditable data-use pathways. In parallel, reporting (CONSORT) and protocol (SPIRIT) standards underscore documentation quality and reproducibility.

Blockchain for Health Data and Clinical Research

Early prototypes (e.g., MedRec) demonstrated the use of blockchain for permission management and provenance in medical data exchange. The healthcare blockchain literature has since expanded to include frameworks for fine-grained access control, patient-mediated consent, and immutable audit logs. Permissioned platforms (e.g., Hyperledger Fabric) support membership management and channelized data flows that align with consortium governance typical of multi-site trials. Research has explored tokenization of data-use rights, hashed fingerprints of datasets (“content addresses”) for integrity verification, and hybrid designs where sensitive payloads are stored off-chain with on-chain pointers and policies. For clinical trials specifically, authors have argued that blockchain can support pre-registration integrity (e.g., anchoring protocols and amendments), randomization transparency, supply chain tracking for investigational products, and adjudication of endpoint events—each dependent on reliable timestamps and tamper evidence.

AI for Multi-Site Analytics and Privacy Preservation

Federated learning enables decentralized model training by sending model updates—not raw data—from each site to an aggregator; secure aggregation protocols and differential privacy reduce leakage from updates. In healthcare, FL has been applied across imaging, EHR phenotyping, and pharmacovigilance, with studies showing comparable performance to centralized baselines under certain conditions. Research surveys identify open problems (heterogeneity of data distributions, communication efficiency, fairness across sites, and robustness to poisoning). For clinical trials, FL can enable cross-sponsor or cross-site subgroup analyses, predictive modeling for recruitment/retention, and safety signal detection while aligning with policies that restrict broad data exports. Privacy-enhancing technologies (PETs) such as homomorphic encryption, secure multiparty computation, and zero-

knowledge proofs (ZKPs) extend the space of verifiable yet privacy-preserving workflows—for example, proving that a model used only permitted data or that de-identification thresholds were applied without revealing the raw data.

Interoperability and Data Quality

Interoperability challenges undermine reuse. HL7 FHIR provides a resource-oriented, extensible schema suitable for harmonizing core trial data elements (participants, interventions, outcomes, adverse events) and linking to study metadata (protocol identifiers, arms, visit schedules). Practical deployments require robust extract–transform–load (ETL) pipelines, data quality checks (completeness, consistency, plausibility), and transparent data dictionaries. Metadata richness and standard terminologies (e.g., SNOMED CT, RxNorm, LOINC) are essential for cross-trial comparability.

METHODOLOGY

Overview and Design Goals

We describe a **permissioned blockchain–AI platform** for clinical trial data sharing centered on five goals:

1. **Compliance by design:** encode consent and data-use conditions and maintain an immutable audit trail;
2. **Privacy by design:** avoid centralization of raw data; apply PETs to updates and queries;
3. **Interoperability:** adopt HL7 FHIR and controlled vocabularies;
4. **Verifiability and provenance:** content-addressed data with cryptographic fingerprints;
5. **Operational feasibility:** align with existing site workflows and regulatory inspections.

System Architecture

- **Consortium Layer (Governance & Membership):** Trial sponsors, lead sites, participating sites, data monitoring committees, and registries (e.g., ClinicalTrials.gov nodes or national registries) become members of a permissioned network. A governance charter defines roles (endorsers, orderers, auditors), quorum thresholds, and change control.
- **Ledger Layer (Smart Contracts):** Smart contracts manage:
  - **Consent**: registration of initial consent, amendments, and withdrawals; linkage to protocol versions; consent scope tags (e.g., primary analysis, IPD meta-analysis, specific secondary research).
  - **Data-use permissions**: conditions, expiry, geographic restrictions, embargo periods, and attribution requirements.
  - **Access requests and approvals**: standardized templates and decision logs.
  - **Provenance**: hashes of datasets, models, and ETL pipelines; versioning of study artifacts.
- **Data Layer (Off-chain Encrypted Storage):** Trial data (IPD, CRFs, imaging) reside at sites in encrypted stores. Large objects may use content-addressed systems (e.g., IPFS-style storage or cloud object stores) with on-chain pointers (URIs + hashes). Key management is local; access is mediated by policy smart contracts and audited on-chain.
- **Identity & Trust:** Role-based identities (X.509 in Fabric-style MSPs) integrate with research identities (ORCID), institutional credentials, and optional self-sovereign identifiers for patient-mediated features. Hardware-backed key storage (HSM/TPM) is recommended at sites.
- **Interoperability & Harmonization:** ETL pipelines map source EHR/EDC fields to FHIR resources. A

metadata registry maintains data dictionaries, code mappings, and data quality metrics.

- **AI/Analytics Layer:**
  - **Federated Learning Coordinator:** Orchestrates training across sites, handles client selection and secure aggregation.
  - **PETs:** Differential privacy for update noise; secure aggregation to prevent visibility of individual updates; optional homomorphic encryption for simple encrypted analytics; optional ZKPs to attest to policy compliance (e.g., "this model only trained on consented cohorts").
  - **Model Registry:** Hash-addressed models with lineage to data, parameters, and protocol versions.
- **Audit & Reporting:** Real-time dashboards for consent counts, access logs, and model lineage; exportable audit bundles for inspectors (EMA/FDA/IRBs).

Consent and Data-Use Modeling

Consent is modeled as a state machine with explicit transitions: Granted → (Amendment) → Active / Withdrawn / Expired*. Each consent record contains subject pseudonym, scope (primary/secondary uses), data categories, retention, and jurisdictional constraints. Data-use contracts reference consent scopes and include ODRL-like policy expressions (permitted purposes, obligations, prohibitions). Revocation triggers event-driven workflows: access keys are rotated; model registries flag dependent models for review; scheduled retraining excludes withdrawn data; analyses in progress receive a policy signal to drop affected cohorts if feasible.

Threat Model and Controls

- **Adversaries:** External attackers; malicious insiders; colluding sites; model inversion/membership inference adversaries; censorship or selective disclosure attempts.
- **Controls:**
  - **Ledger consensus and endorsement policies** for tamper evidence and multi-party validation.
  - **Least-privilege access** with short-lived tokens and mutual TLS.
  - **Privacy-preserving ML** (secure aggregation, DP) to mitigate leakage from updates.
  - **Monitoring & anomaly detection** for poisoning (e.g., outlier detection of updates, robust aggregation).
  - **Key management & HSMs**; periodic key rotation; backup and recovery procedures.
  - **Compliance mappings** to GDPR/HIPAA requirements (data minimization, accountability, DPIAs).
  - **Selective disclosure & ZKPs** for proving policy checks without exposing raw logs where necessary.

Interoperability and Data Quality Workflows

Data providers run a **Harmonization Agent** that:

1. validates incoming CRF/EHR extracts against FHIR profiles;
2. computes completeness and plausibility scores;
3. emits a data quality fingerprint (hashed report) stored on-chain;
4. supports remediations with versioned corrections linked to specific ETL pipelines.

Terminology servers standardize codes; mapping decisions are versioned for reproducibility.

Evaluation Plan and Metrics

- **Governance & Compliance:** proportion of access requests with complete, machine-verifiable decision trails; time-to-decision; audit coverage (share of events with on-chain evidence).
- **Privacy & Security:** empirical epsilon accounting for DP; success rate of red team membership-inference simulations (target reduction); poisoning robustness metrics (e.g., accuracy drop under bounded Byzantine clients).
- **Model Utility:** AUROC/F1 for target tasks versus centralized baselines; fairness metrics across sites and demographic subgroups; calibration.
- **Operational Performance:** synchronization latency; ledger throughput for typical consent/update volumes; overhead of PETs on training time.
- **Interoperability & Data Quality:** share of records meeting FHIR profile conformance; rate of harmonization errors detected/resolved.

RESULTS

Reference Implementation Blueprint

A pragmatic starting point is a three-tier pilot:

1. **Governance Network:** Deploy a Fabric-like permissioned network with an orderer service run jointly by the sponsor and an independent academic partner; endorsing peers at each participating site; an auditor peer operated by the data monitoring committee. The governance charter encodes endorsement policies (e.g., at least two organizations must endorse consent events and access approvals).
2. **Consent & Access Contracts:**
    - **ConsentContract**: records hashed consent forms, subject pseudonyms, protocol and version IDs, and scope tags.
    - **AccessContract**: implements a workflow for requests, including structured justifications, risk assessments, and IRB references; approvals are multisigned and time-bound.
    - **RevocationContract**: handles withdrawal events and notifies dependent services.
3. **Off-chain Data & Pointers:** Each site stores encrypted IPD and artifacts (e.g., DICOM, CSV, Parquet) in local or cloud object stores. Pointers (URI + SHA-256 hash) sit on-chain to ensure integrity. Bulk transfer is discouraged; cross-site analytics proceed via FL jobs.
4. **Federated Learning Stack:**
    - **Coordinator** triggers training rounds, tracks model versions, and manages secure aggregation keys.
    - **Client Agents** at sites preprocess local data, apply DP mechanisms to gradients, and return encrypted updates.
    - **Model Registry** records hashes, training policy attestations (e.g., DP noise parameters), and lineage links to consent and data-quality fingerprints.
5. **Dashboards & Audit Bundles:** Role-based dashboards show real-time consent distributions, active access requests, and model performance summaries; auditors can export signed bundles (ledger snapshots + provenance) for inspections.

Operational Scenarios

Scenario A: Mid-trial Consent Withdrawal

A participant withdraws consent for secondary analyses while remaining in the primary efficacy evaluation. The withdrawal event is posted to the ledger, scoped to “secondary analyses.”

The AccessContract marks any open data-use approvals referencing that participant and scope as "restricted"; the FL coordinator receives a revocation signal, refreshes client sampling lists, and issues a retroactive influence check: models trained after the withdrawal must exclude the participant; existing models are flagged for impact assessment. This orchestrated response is machine-verifiable via on-chain events.

Scenario B: Cross-border Secondary Use Request

An external research group requests IPD for a meta-analysis. Their request includes lawful basis, jurisdiction, and safeguards (e.g., standard contractual clauses). The network processes the request; if consent scopes and jurisdictional rules align, a data-use approval is granted with a **federated analysis mode** requirement instead of a raw data export. The group submits an FL task that runs at participating sites; aggregate results and model weights are shared, but raw IPD never leaves local stores.

Scenario C: Audit Preparation

Before a regulatory inspection, the sponsor compiles an audit bundle: protocol versions, randomization seeds hashed to the ledger (optional), consent event logs, and access decision trails. Inspectors verify checksums and timestamps, reducing manual collation and the risk of missing documentation.

Anticipated Performance and Trade-offs

- **Governance benefits:** Programmatic decision trails reduce ambiguity and speed reviews.
- **Privacy benefits:** FL with secure aggregation and DP reduces centralization risk and measurable leakage; ZKPs can prove adherence to consent scopes for a given model.
- **Utility considerations:** Under moderate heterogeneity, FL models approach centralized baselines; domain shift and small-site effects can be mitigated with personalization layers or reweighted aggregation.
- **Operational costs:** PETs add compute and communication overhead; ledger operations add minimal latency to human approval cycles but must be engineered to avoid bottlenecks for high-frequency events (e.g., IoT device ingestion in adaptive trials).
- **Interoperability lift:** Up-front harmonization is nontrivial but amortizes over subsequent studies and increases reusability.

CONCLUSION

Clinical trial data sharing is both an ethical imperative and a practical necessity for accelerating biomedical progress. Yet the prevailing model—a patchwork of repositories, emailed agreements, and ad hoc governance—struggles to deliver verifiable compliance, scalable privacy protection, and efficient analytics. A permissioned blockchain–AI platform offers a cohesive alternative: encode consent and data-use policies as smart contracts; maintain tamper-evident provenance for datasets, models, and decisions; keep bulk data off-chain but cryptographically linked; and enable federated, privacy-preserving analytics that respect legal constraints and participant choices. The architecture presented here emphasizes standards (HL7 FHIR), accountability (auditable workflows), and privacy-by-design (secure aggregation, differential privacy, and optional ZKPs). Our design-level results and scenarios show how such a system can handle consent withdrawals, cross-border requests, and audits with less friction and greater assurance than current practices.

However, technology is only part of the answer. Real-world success requires thoughtful consortium governance, patient engagement, rigorous key and identity management, and alignment with regulatory expectations. Interoperability and data quality investments are prerequisites; fairness and robustness in distributed modeling must be monitored

continuously; and economic sustainability (who pays, who benefits) needs transparent solutions. With these conditions in place, blockchain–AI platforms can make clinical trial data more findable, accessible, interoperable, and reusable, while honoring the dignity and rights of research participants. The next step is translational: multi-site pilots with IRBs and regulators in the loop, accompanied by rigorous evaluation of privacy, utility, and operational outcomes over time.

SCOPE AND LIMITATIONS

Scope

This manuscript targets interventional clinical trials that generate participant-level data across multiple sites. It addresses sharing for predefined secondary analyses, IPD meta-analyses, safety signal detection, and reproducibility assessments. The architecture focuses on permissioned networks operated by identifiable institutions (sponsors, sites, oversight bodies) and assumes willingness to adopt HL7 FHIR profiles and shared governance. Privacy-preserving analytics cover federated training and aggregate queries; raw data export is minimized but not eliminated in exceptional, policy-compliant cases.

Limitations

1. **Legal heterogeneity:** Divergent national rules (data localization, cross-border transfer, secondary-use constraints) complicate global deployments; even with policy encoding, legal interpretation may vary.
2. **Identity and key management:** Security depends on robust credential issuance, rotation, and recovery; patient-mediated features increase usability demands.
3. **Performance overhead:** PETs (DP, secure aggregation, HE) and ledger operations introduce compute and latency costs; careful engineering is required for large-scale trials and frequent interim analyses.
4. **Data quality and harmonization:** Interoperability work is substantial; mapping errors can propagate and bias models despite strong governance.
5. **Adoption and incentives:** Stakeholders may resist new workflows or fear competitive disadvantages; token-based incentives risk misalignment if not carefully designed and governed.
6. **Algorithmic risks:** FL can exacerbate site-level inequities; robustness to poisoning and fairness across subgroups must be monitored and mitigated.
7. **Generalizability:** Designs optimized for EHR/EDC tabular data may not fully capture imaging, omics, or device telemetry without additional adaptation.

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