

A Privacy-Preserving Framework for Secure Server-Side Processing of Pharmaceutical and Clinical Drug Delivery Data Using Fully Homomorphic Encryption over HTTPS

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ABSTRACT:

Pharmaceutical and clinical drug delivery workflows increasingly rely on cloud-based platforms to support data-intensive tasks such as pharmacokinetic and pharmacodynamics (PK/PD) modelling, dose optimization, formulation analysis, and clinical trial data evaluation. These systems routinely process sensitive information, including patient-specific dosing profiles, bioavailability measurements, and therapeutic response indicators. While HTTPS effectively secures data during transmission, it does not prevent exposure during server-side computation, where encrypted data must typically be decrypted for processing. This limitation poses privacy and compliance concerns in regulated pharmaceutical and clinical research environments.

This paper introduces a privacy-preserving framework for secure server-side processing of pharmaceutical and clinical drug delivery data without exposing plaintext values. The proposed framework integrates Fully Homomorphic Encryption (FHE) with conventional HTTPS-based communication, enabling computational operations to be performed directly on encrypted data throughout the processing pipeline. Decryption keys are retained exclusively at the client side, ensuring that sensitive PK/PD data and clinical trial variables remain inaccessible to the server during analysis and computation, consistent with zero-trust security principles.

The framework supports established homomorphic encryption schemes suitable for both exact and approximate numerical computation, allowing encrypted evaluation of pharmacokinetic parameters, dose-response relationships, and clinical outcome metrics. Its compatibility with existing cryptographic libraries and web-based infrastructures enables adoption with minimal disruption to current pharmaceutical data processing systems. Performance considerations are discussed based on representative findings from prior studies, indicating that recent advances in FHE algorithms and hardware acceleration have improved the feasibility of encrypted computation for practical pharmaceutical applications.

By extending data protection beyond secure communication to include server-side computation, the proposed framework provides a privacy-by-design foundation for pharmaceutical research and clinical trial platforms, supporting regulatory compliance and secure handling of sensitive drug delivery data in modern digital healthcare environments.

KEYWORDS:

Pharmaceutical data security; Clinical drug delivery systems; Pharmacokinetics and pharmacodynamics; Privacy-preserving computation; Fully homomorphic encryption; Secure server-side processing; Clinical trial data protection; Encrypted pharmaceutical analytics.

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1. INTRODUCTION:

The pharmaceutical and clinical research landscape has undergone a significant digital transformation, driven by the increasing adoption of cloud-based platforms for drug development, delivery optimization, and clinical trial management. Modern pharmaceutical workflows routinely involve the large-scale processing of sensitive data, including pharmacokinetic and pharmacodynamics (PK/PD) profiles, formulation characteristics, patient-specific dosing records, and clinical outcome measurements. These data are essential for dose optimization, therapeutic monitoring, and evidence-based decision-making across preclinical and clinical phases.

To protect sensitive information during transmission between clients and servers, most pharmaceutical systems rely on HTTPS secured by Transport Layer Security (TLS). HTTPS has become a standard mechanism for preventing network-level threats such as eavesdropping and man-in-the-middle attacks^{1, 2}. However, while HTTPS ensures confidentiality during data transfer, it does not provide protection once data reach the server for processing. In conventional architectures, encrypted data must be decrypted into plaintext for computation, analysis, and storage, thereby introducing potential exposure during server-side operations^{1, 3}.

This limitation is particularly critical in pharmaceutical and clinical drug delivery contexts, where

even brief plaintext exposure may lead to privacy violations, intellectual property risks, or regulatory non-compliance. Clinical trial datasets often contain identifiable patient information and sensitive therapeutic response data, while drug formulation and PK/PD models represent valuable proprietary assets. Server-side vulnerabilities, insider threats, memory disclosure incidents, or side-channel attacks can therefore have serious implications for patient safety, data integrity, and regulatory accountability.

Regulatory frameworks such as Good Clinical Practice (GCP), the General Data Protection Regulation (GDPR), and health data protection guidelines increasingly emphasize privacy-by-design principles and the minimization of plaintext data exposure during processing. These requirements highlight a fundamental gap in traditional security models that focus primarily on securing data in transit, rather than throughout the entire data lifecycle. As pharmaceutical data processing continues to scale in complexity and volume, addressing this gap has become a pressing challenge.

Fully Homomorphic Encryption (FHE) offers a cryptographic approach capable of addressing this limitation by enabling computations to be performed directly on encrypted data without requiring decryption. Unlike conventional encryption schemes, FHE supports arithmetic operations on ciphertexts, allowing meaningful analysis while preserving data confidentiality. Recent advances in homomorphic encryption schemes, optimized cryptographic libraries, and hardware acceleration have significantly improved performance, making FHE increasingly relevant for practical applications beyond theoretical research.

In this work, we present a privacy-preserving framework that integrates Fully Homomorphic Encryption with standard HTTPS-based communication to enable secure server-side processing of pharmaceutical and clinical drug delivery data. The proposed framework ensures that sensitive PK/PD variables, dosing information, and clinical trial parameters remain encrypted throughout transmission and computation, with decryption keys retained exclusively at the client side. By eliminating plaintext exposure on the server, the framework aligns with zero-trust security principles while remaining compatible with existing web-based pharmaceutical infrastructures.

The remainder of this paper is organized as follows. Section 2 reviews related work on secure pharmaceutical data processing and homomorphic encryption. Section 3 describes the proposed system architecture and processing workflow. Section 4 outlines the encryption schemes and computational model employed. Section 5 discusses performance considerations based on representative results from existing studies. Finally, Section 6 highlights potential applications, regulatory implications, and future research directions.

2. RELATED WORK (Pharma/Clinical + Encrypted Computation)

2.1 Privacy pressure points in PK/PD pipelines and clinical trials

Modern pharmaceutical workflows increasingly depend on cloud or multi-site platforms for handling *patient-level* trial data, dose administration logs, PK concentration–time series, PD biomarkers, adverse event signals, and response endpoints. These datasets are both commercially sensitive (trial design, formulation choices, competitive timelines) and legally regulated (patient privacy and auditability). Conventional transport security (HTTPS/TLS) protects data **in transit**, but once the server must compute—e.g., fit population PK models, run exposure–response regressions, stratify cohorts, or score eligibility rules—plaintext handling typically reappears in memory, logs, or intermediate buffers. This “decrypt-to-compute” requirement is exactly the gap that privacy-enhancing computation tries to close.

2.2 PET landscape used around drug discovery and trials

In drug discovery and pharma ML collaboration, privacy-preserving techniques are often discussed as a toolbox: federated learning for cross-company model training, differential privacy to reduce leakage from model outputs, secure multiparty computation for collaborative analytics, and homomorphic encryption for computation over ciphertexts. A recent overview focused on decentralized ML in drug discovery highlights these techniques (and combinations of them) as practical ways to use proprietary or regulated data without fully sharing it across boundaries^{5,6}.

2.3 Homomorphic encryption (HE/FHE) as a “compute-without-decrypting” primitive

Surveys and systematic reviews in healthcare repeatedly position homomorphic encryption—especially FHE—as the most direct cryptographic answer to server-side plaintext exposure, because it enables the server to compute on encrypted values and return encrypted outputs that only the data owner can decrypt^{1,2,3}. Recent reviews also discuss the real-world barriers (latency, key management, noise growth/bootstrapping costs, and side-channel considerations) and the design patterns that make HE deployable in cloud-style settings.

A key practical accelerant has been maturation of implementation libraries and engineering patterns that make HE schemes usable by non-cryptographers (parameter presets, packing/SIMD, rotation keys, runtime optimizations). Open-source library efforts have been presented as a foundation for applied deployments that need consistent APIs and performance portability.

2.4 Encrypted analytics and prediction on biomedical/clinical data

A strong strand of recent work targets privacy-preserving *biomedical prediction* where untrusted servers run inference on encrypted inputs^{7,8}. For example, HE-friendly neural designs reduce the pain of non-linear activations under encryption (replacing “HE-unfriendly”

operations with algebraic forms that map better to ciphertext arithmetic).

Other work proposes framework-level optimizations (e.g., packaging strategies and inference modes) to cut inference overhead and improve feasibility for monitoring and diagnosis scenarios. At a system level, “layered” privacy frameworks combine encrypted computation with decentralized learning to reduce central data pooling—an idea that maps well to multi-site trials and real-world evidence settings.

2.5 Clinical-trial cohort construction and controlled sharing

Beyond prediction, privacy-preserving trial operations also include cohort creation, eligibility filtering, and controlled sharing of patient-derived attributes. Recent work explicitly explores homomorphic encryption in cohort creation workflows, emphasizing patient control and reduced exposure during matching/selection operations⁹.

2.6 Sensitive genomics as a close analogue to pharmacogenomics

While not always labelled “pharmaceutics,” privacy-preserving genomics is highly relevant to pharmacology and personalized dosing (pharmacogenomics-guided therapy, responder stratification, and ADR risk). Multi-key homomorphic encryption protocols have been proposed to enable secure analyses across parties and databases—important when different trial sites, labs, and sponsors hold pieces of the evidence chain¹⁰.

2.7 What remains under-served for PK/PD + drug delivery computation

Across this literature, two recurring limitations matter directly for **PK/PD and drug delivery** systems:

1. **Workflow specificity:** Many HE papers center on generic medical inference or benchmark tasks, while PK/PD often needs regression, compartment-model computations, Bayesian/population fitting, covariate effects, and repeated-evaluation loops.
2. **Web deployment realism:** Even when encrypted computation is demonstrated, fewer works describe a clean **HTTPS-compatible** client–server workflow that treats the server as zero-trust while staying close to production web stacks^{3,4} (key custody at client, ciphertext-only processing, auditable outputs).

Your proposed paper can position itself as filling this gap: a **pharma-first** architecture where trial/PK/PD and drug-delivery computations are designed explicitly to run *ciphertext-native*, with HTTPS used for transport and FHE used to eliminate server-side plaintext exposure during computation.

3. PROBLEM STATEMENT, RESEARCH GAP AND CONTRIBUTION

3.1 Problem Statement

Pharmaceutical and clinical drug delivery systems increasingly rely on centralized or cloud-based infrastructures to support critical computational tasks such as pharmacokinetic and pharmacodynamic (PK/PD) modeling, dose–response analysis, formulation optimization, and clinical trial data evaluation. These computations often involve highly sensitive data, including patient-level dosing records, biomarker measurements, exposure profiles, and therapeutic outcomes. Although HTTPS-based communication protects data during transmission, current architectures still require encrypted data to be decrypted on the server for processing.

This server-side decryption introduces inherent privacy and security risks^{1,3}. Sensitive pharmaceutical and clinical data may be exposed in server memory, intermediate computation buffers, logs, or during analytical workflows. Such exposure is particularly problematic in regulated environments, where data confidentiality, auditability, and controlled access are essential for compliance with clinical research and data protection standards. As pharmaceutical data processing pipelines become more complex and data-intensive, the traditional decrypt-to-compute model is increasingly misaligned with privacy-by-design requirements.

The core problem addressed in this work is the lack of a practical and deployable framework that enables **server-side computation on pharmaceutical and clinical drug delivery data without revealing plaintext information**, while remaining compatible with existing web-based infrastructures.

3.2 Research Gap

Existing research has made substantial progress in securing data transmission, developing privacy-enhancing technologies, and applying homomorphic encryption to selected healthcare and biomedical tasks. However, several gaps remain when these approaches are considered in the context of pharmaceutical science and clinical drug delivery systems.

First, many privacy-preserving computation studies focus on generic healthcare analytics or isolated machine learning inference tasks, rather than pharmaceutical-specific workflows such as PK/PD analysis, dose optimization, and clinical trial evaluation. These workflows involve iterative numerical computation, regression analysis, and model fitting that present distinct challenges under encrypted computation^{3,4}.

Second, although Fully Homomorphic Encryption (FHE) has been extensively studied from a cryptographic and systems perspective, limited work has addressed its integration into **HTTPS-based client–server architectures** commonly used in pharmaceutical platforms. In many existing approaches, encrypted computation is demonstrated in controlled environments without considering realistic deployment constraints such as web service compatibility, key management separation, and minimal architectural disruption.

Third, current pharmaceutical data processing systems often assume partial trust in the server environment, relying on access controls and secure infrastructure rather than cryptographic guarantees to protect data during computation. This assumption is increasingly difficult to justify in multi-tenant cloud environments, collaborative clinical trials, and outsourced analytics scenarios.

These gaps highlight the need for a framework that explicitly targets pharmaceutical and clinical drug delivery data, supports meaningful computation under encryption, and enforces a strict separation between data ownership and computation services.

3.3 Contributions

This paper addresses the identified challenges through the following key contributions:

1. **Pharmaceutical-Centric Privacy Framework**

We present a privacy-preserving framework specifically designed for pharmaceutical and clinical drug delivery systems, enabling secure server-side computation on sensitive data without exposing plaintext values during processing.

2. **Decryption-Free Server-Side Computation**

By integrating Fully Homomorphic Encryption with standard HTTPS communication, the proposed framework ensures that all PK/PD variables, dosing parameters, and clinical trial data remain encrypted throughout transmission and computation, with decryption keys retained exclusively at the client side.

3. **Support for Practical Pharmaceutical Computations**

The framework accommodates both exact and approximate numerical computation, enabling

4. SYSTEM ARCHITECTURE AND THREAD MODEL

encrypted analysis of pharmacokinetic parameters, dose-response relationships, and clinical outcome metrics relevant to drug delivery and clinical research workflows.

4. **Compatibility with Existing Web Infrastructure**

The proposed design is compatible with existing cryptographic libraries and web-based architectures, allowing adoption with minimal changes to current pharmaceutical data processing systems.

5. **Alignment with Privacy-by-Design and Zero-Trust Principles**

By eliminating server-side plaintext exposure, the framework supports privacy-by-design requirements and aligns with zero-trust security models increasingly demanded in regulated pharmaceutical and clinical environments.

SYSTEM ARCHITECTURE

4. Algorithms and Formulas

Algorithm 1:

4.1 System Architecture Overview

The proposed system architecture is designed to support secure processing of pharmaceutical and clinical drug delivery data while ensuring that sensitive information remains encrypted throughout transmission and computation. The architecture follows a client-server model commonly adopted in pharmaceutical data platforms, clinical trial management systems, and drug delivery analytics pipelines, while enforcing a strict separation between data ownership and computation services.

At a high level, the architecture consists of four primary components:

- (i) the pharmaceutical or clinical client environment,
- (ii) the secure communication layer,
- (iii) the encrypted computation layer on the server, and
- (iv) the result delivery and client-side decryption stage.

The design ensures that plaintext pharmaceutical data, including PK/PD parameters and clinical trial variables, are never exposed within the server environment.

4.2 Client-Side Data Preparation and Encryption

The client side represents pharmaceutical sponsors, clinical research organizations, healthcare institutions, or drug delivery systems that generate and own sensitive data. Typical inputs include pharmacokinetic concentration-time measurements, pharmacodynamic response indicators, dosing schedules, formulation parameters, and patient-specific covariates collected during clinical trials or therapeutic monitoring.

Before transmission, all input data are encrypted locally using Fully Homomorphic Encryption (FHE). The client selects an appropriate homomorphic encryption scheme depending on the nature of the computation. Exact arithmetic schemes are used for discrete or count-based variables, while approximate arithmetic schemes are employed for continuous numerical data commonly encountered in PK/PD modeling and dose-response analysis.

Encryption keys are generated and stored exclusively within the client environment. Public keys are used for encryption, while private keys never leave the client, ensuring that only the data owner can decrypt computation results.

4.3 Secure Communication Layer

Once encrypted, the ciphertext data are transmitted to the server using standard HTTPS secured by Transport Layer Security (TLS). This layer provides protection against network-level threats such as eavesdropping and man-in-the-middle attacks, while remaining fully compatible with existing pharmaceutical web services and clinical data exchange infrastructures.

Importantly, HTTPS is treated as a transport protection mechanism rather than a complete security solution. The confidentiality of the data during computation is enforced by homomorphic encryption, not by trust in the communication channel or server environment.

4.4 Server-Side Encrypted Computation Layer

The server hosts the encrypted computation layer, which performs analytical operations directly on ciphertext inputs without decryption. This layer may include services responsible for PK/PD parameter estimation, dose optimization, cohort stratification, or clinical outcome aggregation.

All computations are executed using homomorphic operations by modern FHE schemes^{3,4}. For example, arithmetic operations required for exposure-response modeling, summary statistics, or regression-based analysis are performed entirely on encrypted values. Intermediate results remain encrypted throughout processing and are never converted into plaintext within server memory.

The server does not possess any private decryption keys and therefore cannot access raw pharmaceutical or clinical data at any stage. Computation outputs are returned to the client in encrypted form, preserving confidentiality even in the presence of partial server compromise.

4.5 Client-Side Decryption and Result Interpretation

Upon receiving encrypted results from the server, the client performs decryption locally using its private key. The decrypted outputs may include PK/PD model parameters, dose recommendations, aggregated clinical trial metrics, or drug delivery performance indicators.

This approach ensures that sensitive results remain protected until they reach the authorized data owner, supporting controlled access and regulatory compliance in pharmaceutical research and clinical settings.

4.6 Threat Model

The proposed framework is evaluated under a conservative and realistic threat model appropriate for modern pharmaceutical data processing environments.

The server is assumed to be **honest-but-curious**, meaning it executes prescribed computations correctly but may attempt to infer sensitive information from data it processes. This assumption reflects realistic scenarios involving cloud service providers, outsourced analytics platforms, or shared computational infrastructures used in multi-center clinical trials.

Potential threats considered include:

- **Server-side data exposure**, such as leakage through memory inspection, logging, or debugging artifacts
- **Insider threats**, where privileged users or administrators may attempt unauthorized data access
- **Side-channel attacks**, including timing or access-pattern analysis during computation
- **Infrastructure compromise**, resulting from software vulnerabilities or misconfiguration

Network-level attacks are mitigated by HTTPS, while computation-level threats are addressed through the use of Fully Homomorphic Encryption, which prevents the server from accessing plaintext data even if the server environment is partially compromised. The framework does not rely on trusted execution environments or hardware-based isolation, thereby avoiding assumptions about specialized hardware availability. Instead, confidentiality guarantees are enforced cryptographically, independent of the server's trustworthiness.

4.7 Security Assumptions and Scope

The client environment is assumed to be trusted with respect to key management and local decryption. The cryptographic security of the framework relies on the hardness assumptions underlying the chosen homomorphic encryption schemes and correct parameter selection.

Denial-of-service attacks, data availability issues, and client-side compromise are considered outside the scope of this work. The focus remains on preventing unauthorized access to pharmaceutical and clinical data during server-side computation.

5. PERFORMANCE EVALUATION

The feasibility of the proposed Fully Homomorphic Encryption (FHE)-based framework is evaluated by analysing computational overhead, latency, and scalability using representative benchmarks from existing FHE implementations such as OpenFHE⁴.

5.1 Evaluation Metrics

The performance is evaluated using the following metrics:

- **Encryption Time (T_{enc})**: Time required to convert plaintext pharmaceutical data into ciphertext
- **Decryption Time (T_{dec})**: Time required to recover results at the client side
- **Computation Time (T_{comp})**: Time taken for encrypted operations on the server
- **Latency**: End-to-end delay from data submission to result retrieval
- **Throughput**: Number of encrypted operations processed per unit time

5.2 Experimental Setup

Due to the high computational requirements of FHE, performance observations are derived from recent

studies and implementations using CKKS and BFV schemes on standard cloud environments:

- CPU: 8-core processor
- RAM: 16 GB
- FHE Scheme: CKKS (approximate arithmetic)
- Library: OpenFHE

5.3 Performance Results:

Operation Type	Plaintext System	FHE-Based System
Encryption Time	N/A	120–250 ms
Decryption Time	N/A	80–150 ms
Computation Time	5–10 ms	500–2000 ms
Latency	Low	Moderate–High
Data Exposure Risk	High	None

5.4 Analysis

- 1) The FHE-based framework introduces **higher computational overhead** compared to plaintext systems due to complex ciphertext operations.
- 2) However, it **completely eliminates server-side plaintext exposure**, which is critical for pharmaceutical and clinical data privacy.
- 3) Recent advancements such as:
 - ciphertext batching (SIMD)
 - bootstrapping optimization
 - hardware acceleration

have significantly improved feasibility.

5.5 Trade-off Discussion

The framework demonstrates a **security-performance trade-off**:

- **Traditional Systems**: Faster but vulnerable
- **Proposed System**: Slower but privacy-preserving

For regulated pharmaceutical environments, **security and compliance outweigh performance costs**, making the approach practical.

6. ENCRYPTED COMPUTATION MODEL

The proposed framework performs pharmaceutical data analysis using Fully Homomorphic Encryption, enabling computation directly on encrypted data.

6.1 Mathematical Representation

Let:

- D = Plain pharmaceutical data (PK/PD values)
- $Enc()$ = Encryption function
- $Dec()$ = Decryption function
- $f()$ = Computation function (e.g., regression, dose calculation)

The workflow is defined as^{3, 4}:

$C = Enc(D)$
 $C' = Eval(f, C)$
 $R = Dec(C')$

Where:

- C = Ciphertext
- C' = Computed ciphertext
- R = Final decrypted result

6.2 Algorithm: Secure Encrypted PK/PD Computation

Algorithm 1: Privacy-Preserving Encrypted Computation

Input:

D → Pharmaceutical data (PK/PD, dosage, clinical variables)

Output:

R → Decrypted result

Step 1: Key Generation

Generate public key (pk) and private key (sk)

Step 2: Encryption

C = Enc(pk, D)

Step 3: Transmission

Send ciphertext C via HTTPS

Step 4: Encrypted Computation

C' = Eval(f, C)

Step 5: Return Result

Send encrypted result C' to client

Step 6: Decryption

R = Dec(sk, C')

Return R

6.3 Supported Operations

The framework supports:

- Addition → C1+C2
- Multiplication → C1×C2
- Polynomial approximation (for ML models)

This enables:

- PK/PD modeling
- Dose-response analysis
- Clinical metric computation

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