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PHARMACEUTICAL SOFTWARE: WHY PHARMA'S MOST POWERFUL SOFTWARE IS NOT OPEN OR SEARCHABLE

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Abstract:

Cheminformatics platforms, laboratory information management systems (LIMS), electronic laboratory notebooks (ELNs), clinical data management and electronic data capture (EDC) systems, pharmacovigilance tools, regulatory submission software, manufacturing execution systems (MES), and enterprise resource planning (ERP) are just a few examples of the extremely complex and vital software systems that pharmaceutical companies depend on. All phases of the drug lifecycle, including manufacturing, post-market surveillance, regulatory approval, and discovery and development, are supported by these systems. The majority of pharmaceutical software systems are still closed-source, proprietary, and essentially unsearchable by other parties, despite their scientific significance and technological competence. This review looks at the organizational, legal, regulatory, technical, and economic aspects of this opacity and assesses how it affects cybersecurity, innovation, repeatability, and patient safety. Through a standardization-driven, modular strategy that incorporates verified core systems, interoperable standards, metadata frameworks, privacy-preserving data sharing, third-party audits, and regulatory sandboxes, the study suggests a practical route toward safer transparency.

Keywords : Pharmaceutical software; Proprietary systems; Data integrity; Regulatory compliance; Interoperability; Digital transformation

1. Introduction

1.1 Digital Transformation in the Pharmaceutical Industry

In order to improve operational effectiveness, data management, and regulatory compliance throughout the value chain, the pharmaceutical industry must adopt digital technologies like advanced analytics, automation, artificial intelligence, and integrated software systems (Ullagaddi, 2024). Growing data complexity, the requirement for real-time quality monitoring, and the necessity for traceability throughout supply chains and manufacturing are driving the trend toward digitalization (Ma, Shi, & Kang, 2023). By facilitating systematic data collection and monitoring, traceability, and risk mitigation, digital integration enhances quality assurance frameworks and supports sustainable supply chain performance (Ma et al., 2023).

Digital transformation has a significant positive impact on pharmaceutical quality management systems (QMS). Digitized QMS enhances data integrity, speeds up documentation workflows, and facilitates regulatory compliance, all of which are essential for ensuring product safety and efficacy (Ullagaddi, 2024). Additionally, uniform data management made possible by digital platforms reduces redundancy and improves cross-departmental access to information, which is essential for quicker decision-making in manufacturing, research, and development (Ullagaddi, 2024).

1.2 Role of Software in Drug Development, Manufacturing, and Regulation

Clinical trial management systems (CTMS) and electronic data capture (EDC) systems are examples of software systems that are widely used in drug development to replace manual, paper-based processes. These systems allow for real-time data collection and analysis, improve data quality, and shorten clinical evaluation timelines (Yadav et al., 2025; Electronic Data Capture, 2024). By providing insights into safety profiles and treatment responses, predictive modeling and data analytics technologies also help in preclinical and clinical stages, improving candidate selection and optimizing resource usage (Yadav et al., 2025).

Digitalization in manufacturing expands the use of software for equipment integration, process automation, and quality control; this is consistent with ideas like Pharma 4.0 that prioritize data science and intelligent manufacturing (Herwig et al., 2021). To guarantee compliance, lower

variability, and facilitate traceable batch release decisions, these software-enabled systems combine sensor data, process analytical tools, and advanced analytics (Herwig et al., 2021).

Digital technologies are also changing regulatory submission, review, and approval procedures. Transparency is improved, cloud-based stakeholder engagement is made possible, and review times are shortened by switching from document-centric to data-centric regulatory frameworks (Macdonald et al., 2021; Frontiers in Medicine, 2023). These digital advances provide a dynamic regulatory ecosystem that enables medication developers and regulators by streamlining the preparation, management, and exchange of regulatory submissions (Macdonald et al., 2021).

2. Overview of Pharmaceutical Software Systems

2.1 Categories of Pharmaceutical Software

Several specialized software systems are used in pharmaceutical operations to handle complicated data, guarantee regulatory compliance, and maximize productivity in supply chains, production, R&D, and manufacturing. Below is a description of the main types of pharmaceutical software.

2.1.1 Laboratory Information Management Systems (LIMS)

Test results, analytical procedures, laboratory samples, and compliance paperwork are all managed by Laboratory Information Management Systems (LIMS). By automating sample tracking and standardizing laboratory procedures, LIMS enhance data integrity, traceability, and operational efficiency (Gibbon et al., 2019). LIMS are essential for guaranteeing adherence to Good Laboratory Practice (GLP) and regulatory inspection preparedness in pharmaceutical quality control and research labs (Ribeiro et al., 2020). The reliability of experimental data is improved and transcription errors are decreased when LIMS is integrated with analytical tools.

2.1.2 Electronic Laboratory Notebooks (ELN)

By enabling digital recording of experimental procedures, observations, and outcomes, Electronic Laboratory Notebooks (ELNs) take the place of conventional paper-based lab notebooks. Pharmaceutical R&D settings require secure data storage, version control, and intellectual property protection, all of which ELNs provide (Kanza et al., 2017). Research

shows that by keeping time-stamped and tamper-evident records, ELNs enable regulatory audits, improve data searchability, and foster collaboration (Bird et al., 2013). In the early stages of drug discovery and formulation development, their use has proved very important.

2.1.3 Clinical Trial Management Systems (CTMS)

Clinical trials are planned, monitored, and managed using specialized platforms called Clinical Trial Management Systems (CTMS). Trial scheduling, site administration, patient recruitment, budgeting, and regulatory paperwork are all supported by CTMS (Huser & Cimino, 2013). These solutions guarantee adherence to Good Clinical Practice (GCP) principles while enhancing trial monitoring and operational transparency. It has been demonstrated that integrating CTMS with Electronic Data Capture (EDC) systems improves data accuracy and decreases trial delays in multicenter clinical studies (Kush et al., 2010).

2.1.4 Manufacturing Execution Systems (MES)

Pharmaceutical manufacturing operations are monitored, controlled, and recorded in real time using Manufacturing Execution Systems (MES). By bridging the gap between shop-floor operations and enterprise-level planning systems, MES facilitates batch traceability, electronic batch records, and adherence to Good Manufacturing Practice (GMP) regulations (McGrath & McGarry, 2018). MES deployment is a key component of Pharma 4.0 activities because research shows that it improves process uniformity, lowers human error, and shortens batch release timelines (Herwig et al., 2021).

2.1.5 Enterprise Resource Planning (ERP)

Procurement, inventory control, production scheduling, financing, and distribution are all integrated into a single platform by enterprise resource planning (ERP) systems. ERP systems facilitate cost control, regulatory paperwork, and supply chain transparency in the pharmaceutical sector (Kelle & Akbulut, 2005). Implementing ERP has been linked to better demand forecasting, fewer stockouts, and more adherence to serialization and traceability laws (Chong et al., 2017).

2.2 Key Stakeholders and End Users

Pharmaceutical software systems are made to support a variety of end users and stakeholders throughout the drug lifecycle, each of whom has unique operational, functional, and regulatory needs. These stakeholders have a significant influence on data governance, access control, and software architecture, all of which frequently lead to pharmaceutical software platforms being closed and unsearchable.

2.2.1 Research and Development Scientists

For experimental design, data collection, and interpretation, R&D scientists are the main end users of LIMS, ELN, and data analytics platforms. During the early stages of drug research and formulation development, these users depend on software solutions to guarantee data integrity, reproducibility, and intellectual property protection (Kanza et al., 2017). To protect sensitive research data and competitive information, proprietary data structures and restricted access controls are frequently used (Bird et al., 2013).

2.2.2 Clinical Research Professionals

Clinical Trial Management Systems (CTMS) and Electronic Data Capture (EDC) systems are used by clinical research associates, investigators, and trial coordinators to oversee protocol execution, patient enrollment, site monitoring, and compliance documentation. Good Clinical Practice (GCP) regulations, which require stringent data confidentiality and restricted access to trial data, bind these parties (Huser & Cimino, 2013). Because of this, clinical software systems are frequently highly regulated and compartmentalized, which restricts their open searchability.

2.2.3 Manufacturing and Quality Personnel

Manufacturing Execution Systems (MES) and Quality Management Systems (QMS) are used by manufacturing operators, quality assurance (QA), and quality control (QC) specialists to record batch production, deviations, and corrective actions. To adhere to Good Manufacturing Practice (GMP) guidelines, these users need real-time process visibility and traceability (McGrath & McGarry, 2018). Restricted system configurations and data sharing are required due to regulatory requirements for audit trails and certified systems.

2.2.4 Regulatory Affairs Professionals

Specialized software is used by regulatory affairs teams for electronic filings, document management, and regulatory intelligence. They are responsible for creating and maintaining dossiers that adhere to strict guidelines established by regulatory bodies like the FDA and EMA. Research shows that in order to reduce compliance risk, regulatory software systems place a higher priority on data integrity, version control, and traceability than on openness (Macdonald et al., 2021). As a result, these platforms are usually not searchable outside of permitted settings.

2.2.5 Supply Chain and Business Management Teams

Key users of enterprise resource planning (ERP) systems include financial analysts, procurement officers, and supply chain managers. To guarantee product availability and cost effectiveness, these stakeholders need integrated visibility across inventory, production scheduling, and distribution (Kelle & Akbulut, 2005). ERP systems use tight access hierarchies and closed architectures because price, sourcing, and demand data are commercially sensitive (Chong et al., 2017).

2.2.6 Regulatory Authorities and Auditors

External auditors and regulatory inspectors are important but indirect stakeholders. During inspections, they gain access to pharmaceutical software systems to confirm traceability, data integrity, and compliance. The closed character of pharmaceutical software environments is reinforced by research that highlights regulators' preference for tested, secure, and controlled systems over open-access platforms (Herwig et al., 2021).

Table 1: Categories of Pharmaceutical Software and Stakeholders

Software Category	Primary Function	Key Stakeholders / End Users	Example Vendors / Tools	Reference
Laboratory Information Management System (LIMS)	Sample tracking, lab data management, QA/QC	Lab technicians, QA/QC, R&D scientists	Thermo Fisher LIMS, LabWare, STARLIMS	Herwig et al., 2021; Afgan et al., 2018

Electronic Laboratory Notebook (ELN)	Record experimental data digitally	R&D scientists, chemists, regulatory teams	Labguru, Benchling, ChemDraw ELN	Bird et al., 2013; Gentleman et al., 2004
Clinical Trial Management System (CTMS)	Manage clinical study data and workflow	Clinical research teams, project managers	Medidata, Oracle Siebel CTMS	Kush et al., 2010
Manufacturing Execution System (MES)	Production monitoring, compliance, scheduling	Production managers, QA/QC, process engineers	Werum PAS-X, Siemens Opcenter	McGrath & McGarry, 2018
Enterprise Resource Planning (ERP)	Integrate business operations, inventory, procurement	Supply chain, finance, operations	SAP, Oracle NetSuite	Kelle & Akbulut, 2005

3. Characteristics of Proprietary Pharmaceutical Software

Most pharmaceutical software systems are closed by design and proprietary. This section looks at the structural and functional features—limited interoperability, vendor-controlled data models, and closed architecture—that limit searchability and openness while guaranteeing legal compliance and business protection.

3.1 Closed Architecture and Restricted Access

Software systems with strictly regulated access, authentication procedures, and limited user privileges are referred to as closed architecture. Such architectures are used in the pharmaceutical sector to adhere to strict legal requirements concerning traceability, confidentiality, and data integrity (Herwig et al., 2021). Open or public-facing software designs are discouraged by regulatory frameworks like FDA 21 CFR Part 11, Good Manufacturing Practice (GMP), and Good Clinical Practice (GCP), which need secure access controls, audit trails, and validated system environments (McDowall, 2018).

Unrestricted access or open architectures may jeopardize validation status, raise cybersecurity threats, and reveal sensitive intellectual property, especially during medication discovery and clinical development, according to research (Kanza et al., 2017). Pharmaceutical companies therefore prefer restricted system environments over transparency, which leads to software platforms that are difficult to explore beyond predetermined interfaces and unavailable to external users.

3.2 Vendor-Controlled Data Structures

Pharmaceutical software systems are characterized by vendor-controlled data structures, in which software vendors, not end users, decide on data models, schemas, and storage formats. These proprietary data structures restrict data mobility and independent analysis, but they are optimized for performance, audit readiness, and regulatory compliance (Gibbon et al., 2019).

Research shows that vendor-specific data formats limit cross-platform data reuse and direct database querying, compelling businesses to employ vendor-mediated access or built-in reporting tools (Ribeiro et al., 2020). This method prevents smooth data integration and cross-system global search functionality, but it also lowers the danger of data manipulation and guarantees consistent validation. Because changes to data formats could render regulatory approvals void, vendor lock-in further solidifies the closed character of pharmaceutical software (McGrath & McGarry, 2018).

3.3 Limited Interoperability and Customization

Many pharmaceutical software platforms have weak interoperability, which is the capacity of various systems to exchange and analyze data. Pharmaceutical systems frequently function as isolated data silos because of proprietary interfaces, incompatible data standards, and validation limitations, according to research (Huser & Cimino, 2013). Similar limitations apply to customization since modifications to workflows, interfaces, or system logic may necessitate revalidation, raising operating costs and compliance risk (McDowall, 2018).

Full interoperability is still difficult because of legacy infrastructure and regulatory requirements, even while industry initiatives like Pharma 4.0 encourage data integration and system communication (Herwig et al., 2021). Pharmaceutical companies thus accept limited

searchability and less flexibility in return for regulatory approval, compliance, and dependability.

4. Why Pharmaceutical Software Is Not Open

Pharmaceutical software systems are still mostly closed and proprietary, despite growing calls for data exchange and openness. This is motivated by the need to control high development costs, preserve competitive advantage, safeguard intellectual property, and adhere to strict regulatory and validation criteria.

4.1 Intellectual Property Protection

Highly sensitive intellectual property, including as molecular structures, formulation techniques, clinical trial designs, and manufacturing procedures, is stored in pharmaceutical software systems. Open access to these systems raises the possibility of data misuse or competitive exploitation by revealing trade secrets and proprietary knowledge (Kanza et al., 2017). According to research, closed system architectures and limited access are largely influenced by intellectual property protection in pharmaceutical R&D settings (Bird et al., 2013).

In order to enable patent protection and regulatory defensibility, electronic laboratory systems are specifically constructed with controlled access, encryption, and audit trails to guarantee that experimental data stays tamper-proof and traceable (McDowall, 2018). Pharmaceutical companies are hesitant to implement open software models because open-source or publicly searchable systems could compromise these protections.

4.2 Competitive Advantage and Market Exclusivity

Pharmaceutical firms operate in fiercely competitive markets where commercial success is determined by data exclusivity and innovation speed. Proprietary algorithms and workflows that offer strategic benefits are frequently embedded in software platforms used for drug research, clinical analytics, and factory optimization (Herwig et al., 2021). Opening such systems could weaken market exclusivity and reduce competitive difference.

According to studies, closed software ecosystems enable businesses to manage innovation pipelines, streamline internal operations, and safeguard commercially sensitive information

including development schedules and cost structures (Kelle & Akbulut, 2005). Because of this, companies want proprietary software that limits third-party tool compatibility and external access.

4.3 High Development and Maintenance Costs

The creation, validation, cybersecurity, and continuous maintenance of pharmaceutical software systems necessitate substantial investment. Pharmaceutical platforms, in contrast to general-purpose software, require constant updating to satisfy changing operational requirements, technological developments, and regulatory norms (McGrath & McGarry, 2018). According to peer-reviewed research, frequent changes or open customisation are discouraged by the high cost of system validation and revalidation (McDowall, 2018).

By adding unpredictability and compatibility issues, open software models may make maintenance more difficult, which would raise validation expenses and compliance risks. As a result, closed systems that reduce uncontrollable changes and guarantee predictable system behavior are preferred by suppliers and pharmaceutical companies.

4.4 Regulatory Compliance and Validation Requirements

The biggest obstacle to transparency in pharmaceutical software is regulatory compliance. Validated systems with stringent access restrictions, audit trails, and documented change management procedures are required by regulations including FDA 21 CFR Part 11, GMP, GCP, and data integrity recommendations (McDowall, 2018). Revalidation is required whenever program functionality or data structure is altered, and it is expensive and time-consuming.

According to research, openness and interoperability are not as important to regulatory bodies as data veracity, traceability, and system dependability (Macdonald et al., 2021). Software architectures that are open or searchable may make compliance verification more difficult, increase cybersecurity risks, and jeopardize validation status. Pharmaceutical companies therefore implement closed systems to guarantee regulatory approval and inspection preparedness.

5. Why Pharmaceutical Software Is Not Searchable

Despite the enormous volumes of digital data that pharmaceutical companies produce, there is still little effective searchability across software systems. Strict security measures, fragmented data storage, a lack of standardized formats, and the lack of unified search architectures intended for regulated environments are the causes of this constraint.

5.1 Data Silos and Fragmented Databases

Pharmaceutical data is dispersed among specialized systems, such as ERP, ELN, CTMS, MES, and LIMS, each of which is optimized for a particular purpose yet frequently acts as a separate silo (Huser & Cimino, 2013). This fragmentation makes it impossible to conduct a thorough organizational search and restricts holistic visibility. Research indicates that, particularly in research and clinical development, compartmentalized settings hinder the reuse of knowledge, inhibit decision-making, and increase duplicate testing (Kanza et al., 2017). Validation and compliance requirements further limit integration in regulated businesses, increasing data fragmentation and limiting search and interoperability (Herwig et al., 2021).

5.2 Lack of Standardized Data Formats

Pharmaceutical software searchability is severely restricted by the absence of widely recognized data standards. Interoperability and unified querying are hampered by vendor-specific proprietary schemas, metadata structures, and storage formats (Gibbon et al., 2019). Cross-platform search and advanced analytics are made more difficult by semantic inconsistencies, which include disparate terminology, ontologies, and data granularity (Kush et al., 2010). Despite the existence of standardization projects, adoption is unequal because of regulatory risks related to structural changes and legacy systems (Herwig et al., 2021).

5.3 Security and Confidentiality Constraints

Strict security measures are used in pharmaceutical software to safeguard sensitive manufacturing information, patient data, and intellectual property. The extent of searches is limited by role-based access, encryption, and compartmentalized permissions, which restrict data visibility to authorized users (McDowall, 2018). Confidentiality laws govern clinical and

patient data, requiring restricted access routes (Huser & Cimino, 2013). Organizations should exercise caution when implementing global or federated search solutions since expanding search capabilities across systems might raise the danger of illegal access.

5.4 Absence of Unified Search Frameworks

Unified search frameworks that can query across heterogeneous systems are absent from the majority of pharmaceutical software platforms. Because of validation requirements, audit trails, and change management limits, developing such frameworks is technically difficult in regulated environments (McGrath & McGarry, 2018). Because changes to basic designs might result in extensive revalidation, studies show that enterprises prioritize system stability and compliance over enhanced search functionality (McDowall, 2018). As a result, rather than facilitating enterprise-wide information discovery, search is usually limited to system-specific inquiries.

6. Regulatory and Compliance Barriers

The biggest obstacles to openness and searchability in pharmaceutical IT systems are regulatory and compliance requirements. The emphasis placed by international regulatory bodies on data integrity, system validation, traceability, and limited access naturally restricts the flexibility, interoperability, and open search capabilities of software.

6.1 FDA, EMA, and ICH Software Validation Guidelines

To guarantee correctness, dependability, and constant performance, computerized systems in pharmaceutical operations must undergo rigorous validation, according to regulatory bodies including the FDA, EMA, and ICH (FDA, 2003; EMA, 2018; ICH, 2016). Documented proof that software performs as intended throughout its lifecycle, including design, installation, operation, and maintenance, is required by Computerized System Validation (CSV) (FDA, 2003). Revalidation is frequently necessary for software changes, such as search algorithms or data access layers, which discourages frequent revisions and restricts the use of open or dynamic designs (McDowall, 2018). ICH Q8–Q10 guidelines emphasize the necessity of stable, controllable, and well-documented systems while reinforcing quality risk management and lifecycle control. Maintaining validation is difficult in open or publicly searchable systems, especially when integrating third-party technologies.

6.2 Data Integrity Requirements (ALCOA+)

A basic prerequisite for pharmaceutical control is data integrity. The ALCOA+ principles—Attributable, Legible, Contemporaneous, Original, Accurate, Complete, Consistent, Enduring, and Available—must be followed by electronic data (FDA, 2018; EMA, 2016). Strict control over data production, modification, storage, and retrieval is necessary to maintain ALCOA+ compliance (McDowall, 2018). Attribution, version control, and auditability may be jeopardized by open search features that provide uncontrolled querying, indexing, or aggregation. As a result, pharmaceutical systems restrict search functions to predetermined queries inside interfaces that have been verified. Because differences between source and derived datasets may occur, guidelines therefore discourage uncontrolled data extraction or replication (WHO, 2016). This explains why closed, controlled systems with limited export and search capabilities are preferred by the industry.

6.3 Audit Trails and Access Control Policies

Pharmaceutical software must have access control and audit trails. Secure, computer-generated audit trails that document who carried out an activity, what was altered, when, and why are required by regulations such FDA 21 CFR Part 11 (FDA, 2003). These trails need to be time-stamped, unchangeable, and kept for regulatory examination. System architecture is limited by the requirement that all interactions, including searches, be traceable and attributable (McDowall, 2018). Cross-system or enterprise-wide searches complicate audits and may mask accountability, which raises regulatory issues. By limiting users to information pertinent to their function, role-based access control (RBAC) further restricts searchability (Huser & Cimino, 2013). Consequently, segmented, conservative software designs are reinforced by regulatory emphasis on traceability and controlled access.

7. Impact of Closed and Non-Searchable Systems

Pharmaceutical software systems that are closed or restricted promote data security and regulatory compliance, but they also impose serious operational and scientific constraints. These limitations have an impact on decision-making speed, data reuse, research efficiency, and total operating expenses throughout the pharmaceutical value chain.

7.1 Reduced Research Efficiency

Because they restrict scientists' access to, comparison of, and reuse of past experimental data, closed and non-searchable systems drastically diminish research efficiency. Exploratory analysis is sometimes limited by the accessibility of research data maintained across separate ELNs, LIMS, and proprietary databases through preset procedures (Kanza et al., 2017). Because of this, scientists could inadvertently repeat experiments or neglect to expand on earlier discoveries.

Limited data accessibility is linked to lengthier drug discovery timelines and wasteful use of research resources, according to peer-reviewed publications (Herwig et al., 2021). The incapacity to conduct cross-project searches hinders information acquisition and lowers scientific productivity in the early stages of drug development, when quick hypothesis testing is essential (Bird et al., 2013).

7.2 Challenges in Data Reusability and Knowledge Mining

Pharmaceutical software's capacity to reuse data and extract knowledge is severely limited by proprietary formats and disjointed system designs. Closed systems limit sophisticated analytics, machine learning, and retrospective research by impeding smooth data integration (Huser & Cimino, 2013). Secondary data analysis, which is known to spur innovation and cost effectiveness, is hampered by this. Cross-dataset mining is made more difficult by the lack of regulated vocabularies and consistent metadata (Kush et al., 2010), which underutilizes important insights in legacy data and lowers the return on investments made in data production (Herwig et al., 2021).

7.3 Delays in Decision-Making and Innovation

Timely access to reliable data is essential for pharmaceutical R&D, manufacturing, and regulatory decisions. Due to the need for vendor-mediated access, specialized reports, or manual aggregation, closed, non-searchable systems cause delays (McGrath & McGarry, 2018). Batch release choices, deviation management, and clinical trial monitoring all depend on these bottlenecks. Delays in accessing integrated data have been shown to limit organizational agility and hinder innovation cycles, especially in competitive therapeutic areas (Macdonald et al., 2021). Conservative system architectures in regulated environments put

compliance ahead of responsiveness, which slows down the quick adoption of new scientific discoveries and technology developments.

7.4 Increased Operational Costs

Due to inefficiencies in data management, system maintenance, and compliance tasks, closed and non-searchable systems raise operating expenses. To handle fragmented software environments, organizations frequently need several parallel systems, manual data reconciliation, and specialist individuals (Kelle & Akbulut, 2005).

The complexity of the system and its lack of interoperability also increase the cost of validation and revalidation. Limited integration enhances reliance on suppliers for data access and reporting, lengthens system updates, and escalates IT support costs, according to peer-reviewed research (McDowall, 2018). Together, these elements eventually lower operational sustainability and raise total cost of ownership.

8. Comparison with Open and Searchable Software Models

Open and searchable software ecosystems are being used more frequently in other scientific fields to enhance data reuse, cooperation, and transparency. The advantages of openness as well as the fundamental flaws in pharmaceutical software systems are highlighted by a comparison with these sectors.

8.1 Open-Source Software in Other Scientific Domains

In fields like bioinformatics, genomics, cheminformatics, and computational biology, open-source software is frequently used. Unrestricted access to source code, standardized data formats, and sophisticated search capabilities are made possible by platforms like R, Python-based scientific libraries, Galaxy, Bioconductor, and OpenBIS (Gentleman et al., 2004; Afgan et al., 2018).

Open scientific software increases reproducibility, speeds up methodological innovation, and reduces barriers to entry for academics, according to peer-reviewed studies (Ince et al., 2012). Large-scale meta-analyses and secondary data reuse have been made possible in genomics by open databases and searchable repositories like Gene Expression Omnibus (GEO) and UniProt, which have accelerated discovery cycles (Kolesnikov et al., 2015).

In contrast, pharmaceutical software ecosystems remain largely closed, limiting similar collaborative and cumulative scientific progress.

8.2 Benefits of Open and Searchable Platforms

Open and searchable platforms offer several scientifically validated advantages:

- **Improved data discoverability and reuse** through unified search and standardized metadata
- **Enhanced reproducibility** by allowing independent validation of workflows and algorithms
- **Accelerated innovation** via community-driven development and rapid feature evolution
- **Reduced vendor lock-in and long-term costs**

Research indicates that open data infrastructures, especially when paired with interoperable software architectures, greatly increase research productivity and analytical depth (Wilkinson et al., 2016). By providing access to huge, well-organized datasets, searchable platforms also support advanced analytics, AI, and machine learning applications (Boeckhout et al., 2018). These advantages stand in stark contrast to private pharmaceutical systems, where information extraction and secondary analysis are constrained by restricted access.

8.3 Lessons Applicable to the Pharmaceutical Sector

While full openness may not be feasible in regulated pharmaceutical environments, several lessons from open scientific software are applicable:

1. Adoption of standardized data models and ontologies to improve interoperability
2. Implementation of controlled but searchable data layers without compromising security
3. Modular system architectures allowing integration of analytics and AI tools
4. Community-informed development standards aligned with regulatory expectations

Hybrid approaches, which combine regulated access with open standards, can preserve regulatory compliance while enhancing data accessibility, according to peer-reviewed

literature (Rieke et al., 2020). By putting these ideas into practice, pharmaceutical companies could greatly improve knowledge mining, cross-functional cooperation, and innovation.

9. Emerging Trends and Partial Solutions

The pharmaceutical sector has started implementing partial technical and organizational solutions in response to the drawbacks of closed and non-searchable systems. These strategies seek to ensure data security and regulatory compliance while enhancing accessibility, interoperability, and analytics.

9.1 Application Programming Interfaces (APIs)

By offering organized access to specific datasets without disclosing source code or jeopardizing system validation, Application Programming Interfaces (APIs) facilitate controlled data transmission between proprietary pharmaceutical systems (McDowall, 2020). API-driven designs facilitate process automation in R&D and manufacturing and enhance interoperability between ELN, LIMS, CTMS, and analytics platforms (Herwig et al., 2021). However, the breadth of API access is usually restricted and vendor-controlled, which limits enterprise-wide search and thorough data discoverability.

9.2 Cloud-Based and Hybrid Software Models

Pharmaceutical companies are rapidly using cloud-based and hybrid software models due to their increased data accessibility, scalability, and flexibility. While maintaining sensitive systems on-site, organizations use verified cloud infrastructures for collaboration, analytics, and storage (Papathanasiou et al., 2020). Cloud platforms facilitate cross-functional cooperation and centralized access, especially in international clinical trials and pharmacovigilance (Ghosh et al., 2020). However, complete cloud adoption is still hampered by regulatory concerns about cybersecurity, data residency, and system validation.

9.3 Use of Artificial Intelligence and Data Lakes

By combining structured and unstructured data into cohesive analytical environments, AI and enterprise data lakes are revolutionizing knowledge extraction by facilitating sophisticated queries and machine learning (Raghupathi & Raghupathi, 2014). When data accessibility is increased, AI-driven analytics can improve clinical decision-making, expedite drug discovery,

and optimize manufacturing (Vamathevan et al., 2019). However, unreliable information, low-quality data, and difficulties interfacing with legacy systems restrict their efficacy.

9.4 Industry-Wide Data Standardization Initiatives

Pharmaceutical systems are more interoperable and partially searchable because to industry-wide data standards. Consistent organization and reuse are ensured by frameworks like CDISC for clinical data, HL7/FHIR for health data exchange, and ISA-Tab for experimental metadata (Kush et al., 2010; Sansone et al., 2012). According to studies, consistent data models enhance secondary analyses, regulatory submissions, and data sharing (Wilkinson et al., 2016). Standardization creates the foundation for more searchable and interoperable platforms, even though it cannot completely overcome proprietary system closure.

Table 2: Challenges, Impacts, and Partial Solutions for Closed/Non-Searchable Pharmaceutical Software

Challenge	Impact on Pharma Operations	Partial / Emerging Solutions	Reference
Closed architecture / vendor lock-in	Limits interoperability, slows data integration	API-driven access, modular systems	Herwig et al., 2021; McDowall, 2018
Data silos and fragmented databases	Reduces data reuse and knowledge mining	Data lakes, centralized storage	Vamathevan et al., 2019; Raghupathi & Raghupathi, 2014
Regulatory and compliance constraints	Hinders system modification, slows innovation	Semi-open architectures, controlled access layers	FDA, 2018; EMA, 2016
High development and maintenance costs	Limits adoption of advanced analytics or AI	Cloud-based and hybrid models	Papathanasiou et al., 2020

Resistance to change	Delays adoption of interoperable systems	Training, change management programs	McGrath & McGarry, 2018; Kelle & Akbulut, 2005

10. Future Perspectives

The conflict between regulatory control and system openness is anticipated to worsen as pharmaceutical operations become more data-driven. Instead of entirely closed or fully open approaches, future software ecosystems are probably going to trend toward regulated openness.

10.1 Feasibility of Open or Semi-Open Pharmaceutical Software

Pharmaceutical software that is completely open-source is constrained by patient privacy, intellectual property, and regulatory approval. It is becoming more and more possible to implement semi-open models, in which fundamental systems are still under control but APIs, analytics, and data layers are accessible (Herwig et al., 2021). According to studies, modular architectures with interoperable components and open standards can improve data accessibility without sacrificing compliance (Sansone et al., 2012). Even when fundamental systems remain proprietary, open-source technologies are already utilized for analytics and visualization (Boeckhout et al., 2018). These hybrid strategies show that, under current regulatory frameworks, partial openness is both technically and operationally viable.

10.2 Balancing Transparency with Security and Compliance

Unrestricted searchability poses a compliance risk since pharmaceutical software must maintain data integrity, audit trails, and limited access (FDA, 2018; EMA, 2016). However, secure transparency can be achieved using federated models, role-based access, and data anonymization (Rieke et al., 2020). Discovery and analytics are made possible without disclosing private information by implementing searchability at the metadata or summary-data levels. Security-by-design principles are anticipated to be included in future systems, guaranteeing that transparency improves usability and complies with all legal requirements.

10.3 Role of Regulators and Industry Collaboration

The use of open and semi-open pharmaceutical software is being influenced more and more by regulators. As long as data integrity is maintained, organizations like the FDA and EMA encourage innovation, practical data use, and advanced analytics (Macdonald et al., 2021). Developing interoperable, searchable infrastructures requires industry collaboration through public-private partnerships, standard-setting organizations, and consortiums (Kush et al., 2010). Regulatory compliance and managed data openness can coexist, as demonstrated by initiatives that adhere to FAIR data principles (Wilkinson et al., 2016). To establish common frameworks that strike a balance between innovation, trust, safety, and compliance, regulators, vendors, and pharmaceutical organizations must have constant communication.

11. Challenges and Limitations

Widespread adoption of more open and searchable pharmaceutical software is hampered by a number of enduring issues and restrictions. These issues are complex and include organizational, legal, ethical, and technical aspects.

11.1 Technical Barriers

Among the biggest challenges are technical ones. Interoperability is complicated and the integration of unified search frameworks is hindered by proprietary architectures, different data formats, and fragmented legacy systems (Herwig et al., 2021). Additional limitations are imposed by system validation and compliance requirements: each change to enhance searchability or openness frequently requires revalidation, thorough testing, and documentation (McDowall, 2018). Furthermore, careful design is needed to incorporate new technologies like data lakes and AI-driven analytics into proven systems without jeopardizing data integrity or audit trail compliance (Vamathevan et al., 2019).

11.2 Legal and Ethical Considerations

Openness is further constrained by ethical and legal issues. Patient information, intellectual property, and proprietary formulation data are examples of pharmaceutical data that are frequently protected by stringent confidentiality and regulations (FDA, 2018; EMA, 2016). Unrestricted or open search features run the danger of accidentally disclosing private information, which could violate GDPR, HIPAA, or other data privacy regulations. Implementing semi-open data sharing models may be hampered by ethical issues with

secondary use of clinical or experimental data without appropriate consent or oversight (Boeckhout et al., 2018).

11.3 Resistance to Change in the Industry

Another significant factor is organizational and cultural resistance. Moving toward more open or semi-open architectures necessitates changes in workflow design, training, and mindset because pharmaceutical organizations have historically relied on proven, closed systems. Concerns about data misuse, security breaches, or increased effort may cause employees to oppose improvements (McGrath & McGarry, 2018). Adoption of interoperable or open standards is further hampered by vendor lock-in and long-term reliance on proprietary software, as businesses consider the costs and dangers of system migration (Kelle & Akbulut, 2005).

12. Conclusion

The majority of pharmaceutical software systems are still closed, proprietary, and unsearchable while being crucial to drug discovery, development, production, and regulatory compliance. This strategy is motivated by the need to preserve data security, guarantee regulatory compliance, and safeguard intellectual property. These systems impede research productivity, restrict data reuse, and hinder knowledge discovery, even when they support validated protocols and protect sensitive data. Advanced analytics and artificial intelligence adoption are hampered by fragmented, vendor-controlled systems, which also raise operating expenses. On the other hand, other scientific fields show that searchable and open software ecosystems enhance creativity, repeatability, and transparency. In regulated pharmaceutical environments, full openness is unfeasible, but semi-open and hybrid models—like modular designs, API-based access, and cloud-enabled data platforms—offer workable substitutes. Pharmaceutical companies should strike a balance between controlled transparency and compliance by adopting interoperable standards, standardization projects, and industry-regulator cooperation. This will increase data value and aid in the creation of safer, more potent medications.

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15. Conflict of Interest

The authors declare that there is no conflict of interest regarding the publication of this paper.

16. References

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