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Softwares In Pharmacovigilance and Clinical Trials Review

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ABSTRACT: The increasing complexity of clinical trials and post-marketing surveillance has made software systems indispensable tools in modern drug development. These digital platforms support regulatory-compliant data collection, management, and reporting while significantly reducing administrative workload for investigators, coordinators, and administrators. Clinical Trial Management Systems (CTMS), Electronic Data Capture (EDC) tools, and Clinical Data Management Systems (CDMS) streamline protocol setup, patient recruitment, visit tracking, data validation, financial management, and study documentation. In parallel, pharmacovigilance software such as Argus, ArisGlobal, PvNet, and VigiFlow enables efficient processing of adverse drug reactions, automated case assessment, global safety reporting, and early signal detection. The historical shift from paper-based processes to cloud-based and AI-supported systems has enhanced data accuracy, traceability, and integrity. International guidelines, including ICH-GCP, EMA-GVP, and 21 CFR Part 11, further ensure that these digital systems maintain high scientific and ethical standards. Collectively, software solutions strengthen operational efficiency, improve communication across research teams, support regulatory compliance, and ensure timely identification of safety concerns. This review highlights the evolution, regulatory framework, and key applications of software used in clinical trials and pharmacovigilance, emphasizing their central role in producing reliable and high-quality clinical evidence.

KEYWORDS: Clinical trials; Pharmacovigilance; CTMS; CDMS; Electronic data capture; Drug safety software; ADR reporting; Signal detection

INTRODUCTION

Digital software tools have become a core component of today's clinical research and pharmacovigilance activities. In clinical trials, these systems greatly reduce administrative burden by bringing all study information together in a single platform. This central workspace allows smooth coordination among investigators, coordinators, monitors, and administrative teams, while also minimizing manual work and lowering the chances of error.

For investigators, clinical trial software provides an easier way to design study protocols, build electronic case report forms, and maintain accurate participant records. During the course of the study, the software tracks participant recruitment, visit schedules, clinical outcomes, and overall study progress. Many systems also manage financial elements such as reimbursements, budgets, and site payments, which improves clarity and financial planning. Integrated communication tools further support teamwork by enabling quick information exchange and faster problem-solving.

From the administrator's perspective, these platforms allow centralized oversight of multiple ongoing studies across various departments or sites. They streamline document management, regulatory reporting, audits, monitoring activities, and staff coordination. Financial tracking features help institutions manage study budgets, grants, and expenses more accurately. Importantly, these tools promote compliance by enforcing standardized workflows, maintaining secure records, and supporting timely submission of required documents. Overall, software enhances operational efficiency, strengthens data quality, and ensures better organizational accountability.

In pharmacovigilance, specialized applications support the collection, assessment, and reporting of adverse drug reactions. Automated workflows help safety teams process a large number of cases, identify emerging safety concerns, and generate

regulatory reports efficiently. When clinical trial systems are integrated with pharmacovigilance software, safety information is shared quickly and accurately. This ultimately enhances patient protection and contributes to safer, higher-quality drug development.

HISTORY OF SOFTWARE IN PHARMACOVIGILANCE AND CLINICAL TRIALS

The development of software used in pharmacovigilance and clinical trials has progressed gradually over many decades, shaped by advances in technology, increasingly stringent regulatory requirements, and the growing complexity of drug development processes. Before the 1980s, clinical research relied almost entirely on paper-based methods. Investigators manually recorded patient information on case report forms, and adverse drug reactions were reported via handwritten notes, telephone calls, or mailed letters. Data managers used typewriters and calculators to create datasets, while large physical storage areas were required to archive study documents. Since most countries did not yet have centralized drug safety databases, pharmacovigilance activities were limited, leading to significant delays in the identification and reporting of adverse events. Although this period laid the groundwork for future research practices, the system was inefficient, slow, and vulnerable to human error.[9]

The arrival of personal computers in the 1980s marked the beginning of digital transformation in clinical research. Early software tools such as dBASE, Lotus 1-2-3, and the first Oracle systems enabled researchers to store data electronically and conduct simple analyses. Pharmaceutical companies began developing internal databases for clinical and safety data, and statistical programs like SAS became more widely used. While these early systems were far less advanced than modern technology, they represented an essential first step toward computer-based data management and improved operational efficiency.[10]

A significant shift occurred during the 1990s with the introduction of uniform global regulations. The International Conference on Harmonisation (ICH) issued the Good Clinical Practice (GCP) guidelines in 1996, focusing on maintaining high standards of ethics, accuracy, and data quality in clinical studies.[11] The U.S. FDA followed in 1997 with 21 CFR Part 11, which legally recognized electronic signatures and electronic records. This encouraged broader digital adoption across the pharmaceutical industry.[12] As a result, some of the earliest structured electronic data capture (EDC) and pharmacovigilance systems—such as Oracle Clinical, ClinTrial, and the initial versions of ArisG—were created. These tools enabled systematic data entry, query resolution, and standardized case processing.[13]

Between 2000 and 2010, digital platforms quickly became the norm in clinical research. Electronic Data Capture (EDC) solutions such as Medidata Rave, Macro, and OpenClinica were widely adopted, replacing traditional paper CRFs and allowing real-time data checks and remote data entry.[14] Pharmacovigilance systems also advanced during this period, with platforms like Oracle Argus, ArisGlobal, and the FDA's AERS offering faster case processing and improved regulatory reporting. At the same time, the WHO Uppsala Monitoring Centre strengthened global drug safety efforts through the expansion of VigiBase, which enabled international sharing and evaluation of safety data.[15] Clinical Trial Management Systems (CTMS) gained popularity as well, helping organizations manage sites, monitor patient visits, track study progress, and oversee financial activities more efficiently.[16]

From 2010 to 2020, cloud-based technologies and automation significantly reshaped the research environment. Organizations increasingly adopted cloud platforms that offered greater flexibility, real-time global accessibility, and enhanced data security. EDC, CTMS, and pharmacovigilance systems became more deeply integrated, allowing the smooth exchange of safety and clinical data across different departments. Artificial intelligence began to play a growing role in pharmacovigilance, supporting automated case triage, natural language processing for narrative generation, and machine learning–based signal detection.[17] During this period, regulatory authorities worldwide transitioned to mandatory electronic safety reporting formats, including ICH E2B(R3), further driving digital transformation.[18]

After 2020, the COVID-19 pandemic accelerated the move toward digital and decentralized clinical trials. Remote monitoring tools, telemedicine, wearable health devices, and electronic consent platforms became essential for conducting research during global lockdowns. Pharmacovigilance also expanded to incorporate real-world data sources such as electronic health records, mobile health applications, and social media platforms, necessitating advanced big data analytics and AI-driven tools.[19] Cloud-native solutions, blockchain-based security mechanisms, and integrated systems connecting clinical and safety operations have since become industry standards. Today, software used in clinical trials and pharmacovigilance is highly automated, technologically sophisticated, and globally aligned, contributing significantly to improved data integrity, enhanced patient safety, and more efficient drug development.[20]

GLOBAL REGULATORY GUIDELINES AFFECTING SOFTWARE USE

The adoption and functioning of software in clinical trials and pharmacovigilance are largely governed by multiple international regulatory frameworks that aim to ensure ethical conduct, participant protection, and the reliability of research data. Among these, the International Conference on Harmonisation's Good Clinical Practice (ICH-GCP) guideline is one of the most influential, as it outlines the essential requirements for planning, executing, monitoring, and documenting clinical studies using both electronic and paper-based methods. According to ICH-GCP, any software used in research must be properly validated, include complete audit trails, and generate accurate and reproducible records that can withstand regulatory review.[21] Another critical regulation is the U.S. FDA's 21 CFR Part 11, which defines how electronic records and electronic signatures should be managed. It mandates that all digital systems used in clinical research and pharmacovigilance incorporate controlled user access, secure audit logs, validated procedures, and robust long-term data preservation to ensure that electronic records are equivalent to their paper counterparts.[22] The European Medicines Agency (EMA) also contributes significantly through its EudraLex Volume 10 and Good Pharmacovigilance Practice (GVP) guidelines, which require the use of standardized electronic reporting formats such as E2B(R3) for safety submissions and specify the technical requirements for safety databases operated by both sponsors and regulatory bodies.[23] For global post-marketing surveillance, the World Health Organization (WHO) and the Uppsala Monitoring Centre (UMC) offer detailed recommendations on the electronic collection of safety data, transmission of reports to VigiBase, and the consistent use of MedDRA terminology across various pharmacovigilance platforms.[24] In addition, regulatory authorities across different regions—such as the European Union, Japan's PMDA, Health Canada, and India's CDSCO—have established their own guidelines governing electronic submissions, software validation, cybersecurity, and data governance.[25] Together, these international and national regulations dictate how digital systems must be designed and implemented, ensuring that software used in clinical research and pharmacovigilance supports high-quality evidence generation and safeguards the well-being of study participants.

"21 CFR PART 11 COMPLIANCE"

The U.S. Food and Drug Administration's 21 CFR Part 11 regulation is one of the most important guidelines governing the use of electronic systems in clinical trials and pharmacovigilance. Introduced in 1997, this regulation establishes the criteria under which electronic records and electronic signatures are considered trustworthy, reliable, and equivalent to paper records with handwritten signatures.[26] According to Part 11, any software used in research—such as Electronic Data Capture (EDC) systems, Clinical Trial Management Systems (CTMS), and pharmacovigilance databases—must be fully validated to demonstrate accuracy, consistency, and reproducibility of results.[27] The regulation requires secure and controlled system access, ensuring that only authorized personnel can enter, modify, or view data. It also mandates the presence of time-stamped audit trails that automatically capture every change made to electronic records, including what was changed, who made the change, and when it occurred.[28] Additionally, Part 11 emphasizes data integrity through backup procedures, long-term data retention, and system safeguards that prevent unauthorized alterations or data loss. Electronic signatures must be unique to each user, verified, and linked to their electronic records to ensure accountability.[29] To maintain compliance, organizations must implement policies related to password protection, staff training, system documentation, and periodic system checks.[30] Overall, 21 CFR Part 11 ensures that digital systems used in clinical research

uphold the same ethical, legal, and scientific standards as traditional paper-based methods, thereby supporting regulatory confidence in electronically generated data.

Fig 1." 21 CFR Part 11"

SOFTWARE USED IN CLINICAL RESEARCH

1.Clinical Trial management.
2. CDM (Clinical Data management)
3. Pharmacovigilance.

1. CLINICAL TRIAL MANAGEMENT SYSTEM (CTMS)

This is a software system which maintains and administers planning, performing and reporting functions. It is employed in the venues where clinical research is conducted such as research hospitals, physician offices, academic medical centres and cancer centres and pharmaceutical and biotechnology industries. It is involved in Patient management and recruitment, investigator management at the research site and CRO site.

Software for CTMS

(a) **Open clinical:** it is a free, open source web based program for electronic data capture built by Akaza research, assists in management of multiple clinical trials through a single interface also in clinical data entry and validation, data extraction.
(b) **Realtime CTMS:** Developed by realtime CTMS. It is a CTMS developed to streamline activities within a clinical research site. It manages important activities of research such as patient recruiting, study tracking, financial accounting, scheduling, reporting.
(c) **Allergo CTMS:** Developed by Forte research systems. This program is created exclusively for investigator sites and research groups. It gives immediate access to information about the complete clinical trial in one location and immediate visibility into activities and statuses for each study and retains control over the financial health.
(d) **Clinical conductor CTMS:** Developed by Bio optronics, leading CTMS for research sites, site networks, hospitals, AMC's (ADR Monitoring Centres), CRO (contract Research Organisations) and health system.
(e) **Bioclinica CTMS:** Developed by Bioclinica, this program is adaptable and accommodates research of various types, sizes and complexity.
(f) **Ag clinical**: Developed by Aris global. It is a cloud based system with clinical trial activities clinical trial activities like planning, tracking and control for life science enterprises.
(g) **Clinical Trials Management**: Developed by Clin plus. It is aimed to help speed clinical trials specially sponsors and CRO's, enhances user accessibility and communications.
(h) **Open Text Clinica:** produced by open Text. Improves case report forms (CRF) tracking process. It scans the reports and stores each image making them easier to find and retrieve.
(i) **Ques Gen platform**: Web-based system created specifically for configuring and managing clinical databases. [2]
(j) **Clinplus CTMS:** this program includes quick study setup with fully integrated monitoring features and good system integration. [3]

Fig 2. "CTMS System Workflow and Capabilities"

CLINICAL DATA MANAGEMENT (CDM)

CDM is the process of collection, cleansing and management of subject data in compliance with regulatory criteria. The fundamental purpose of this is to provide high-quality, reliable, and statistically sound data from clinical trials for accurate drug evaluation and limit the number of errors and missing data. To reach this purpose best practices are implemented to make sure that the data is accurate, reliable and process thoroughly and this has been facilitated by the usage of software application. Some of the activities involved in CDM include: Case report form (CRF) designing, CRF annotation, Data base designing, Data entry, Data validation, Discrepancy management, Medical coding, Data extraction and Data base locking. [4]

Software for CDM

Many software programs are available for data management and these are named CDMS (clinical data management software). Most of the CDMS utilized in pharmaceutical companies are commercial, these software tools are expensive and need sophisticated information technology infrastructure to work. Commonly used CDM tools are: (a) Oracle clinical: Developed by Oracle, it has the provision of integrated clinical data management and remote data capture. (b) Clintrial: Developed by Phase Forward. This program automates the paper based clinical data entry and enables real time data access and increased data quality. (c) Macro: Developed by Infer Med, electronic data capturing for all trials from phase1 to phase 4, scaling from a single site to big multinational locations. (d) RAVE: Rave flexibility accommodate your workflow requirements, scalability from one research to hundreds and from phase 1-4 and quickly configure CRF's workflows.

[5] (e) e-Clinical suite: it's easy, fast affordable instrument for gathering of data in clinical trials.

Open source tools: these are the CDM software which are offered free of cost. This open source software can be downloaded from their respective websites. Among them the prominent ones are: Open Clinica: A web based solution for electronic data collecting and forms the framework for clinical research. Open CDMS: it enables clinical researchers to manage whole life cycle of their clinical research project from design to archiving without any specialist knowledge. Trial DB and Phosco-EDC for Electronic data capture.

Fig 3." Clinical Data Management (CDM)"

2.1 Medical Coding

Medical coding classifies the medical terms on the CRF to standard dictionary terms so as to avoid unnecessary redundancy and to maintain the uniformity in the process. It aids in proper coding of medical terms connected to the study. Several medical dictionaries are used which are available online, Commonly, Medical Dictionary for Regulatory Activities (MedDRA) is used for the coding of adverse events as well as other disorders. WHODDE (World health organisation Drug Dictionary Enhanced) – coding the drugs.

WHO-ART -adverse responses nomenclature. WHO HD - herbal concurrent medicines.

[6]

3. PHARMACOVIGILANCE

It is a safety database, Used for Adverse Event Reporting, Adverse Drug Reaction Data Management, Regulatory reporting of ICSR (Individual Case Safety Reporting), Signal detection in Adverse Drug Reactions.

SOFTWARE FOR PHARMACOVIGILANCE

a) Aris G : It's the world's leading pharmacovigilance and clinical safety system, about more than 300 firms are maintaining their clinical drug safety data in Aris G. [7] it manages adverse event reporting and adverse reaction requirements not just for drugs but also for vaccines, biologics and devices, it is flexible and fully scalable that is it can be used by both small companies in the early stages of clinical Trials for reporting severe adverse events and large organisations with worldwide pharmacovigilance operations.

b) PvNet: This program supports to segregate data entering, scientific assessment, assists in Extensive data validation and cross validation checks, it has MedRA version management and Covers full spectrum of creating good safety report.[8]

c) ARGUS : provides comprehensive foundation for case management and reporting, also helps to handle the data from multiple sources, fulfil tough worldwide compliance criteria and have access to adaptable drug safety databases.

d) Oracle AERS: Provides single global solution in handling worldwide safety information, it encompasses reporting and analysis of significant adverse events for all medicinal products including pharmaceuticals, medical devices, vaccines, biologics, gene therapies.

e) PV Works: provides complete data entry and reporting, it gathers and report safety data to fulfil all common worldwide Pcv management regulations including ICH, FDA.

f) Clintrace: It is a drug safety software solution that helps clients comply with complicated worldwide safety regulations and reporting connected with clinical research, post approval marketing, drug surveillance by accelerating the clinical evaluation and tracking of adverse events.

g) Pcv Manager: A drug safety management program based on E2B and MeDRA industry data standards that lets to classify, create, review, submit and preserve pharmacovigilance data and adverse event reports. [9]

3.1 Post marketing surveillance Tools:

a) VigiFlow - assists in the Collection and analysis of individual case safety reports. VigiLyze -this helps the study of vigibase data. It is a comprehensive search and analysis tool that allows access to Global, regional or National view of an ADR and Monitor international patient safety data.

b) VigiBase- Gives the information regarding safety profile of drugs and competitive items & optimise the queries.

c) PaniFlow- Helps to Monitor ADR following administration of medicines and vaccinations against influenza virus during the pandemic.

[10]

Softwares in Pharmacovigilance and Clinical Trials (With Explanation)

Domain	Software Name	Explanation (2–3 Lines)
Pharmacovigilance (Drug Safety)	Oracle Argus Safety	Argus is used to record, track, and manage adverse drug reactions (ADRs). It helps pharmacovigilance teams process cases, evaluate seriousness, and send regulatory safety reports like CIOMS and E2B.
Pharmacovigilance (Cloud PV System)	ArisGlobal LifeSphere Safety	A cloud-based platform that automates ADR collection and case processing. It speeds up regulatory reporting and

		improves accuracy in global safety submissions.
Pharmacovigilance Database	Veeva Vault Safety	Stores all safety-related data and documents in one place. Helps in efficient preparation of PSURs, DSURs, and other compliance documents.
Signal Detection in PV	Empirica Signal	Used to detect 'signals'—early warnings of possible drug safety problems. It analyzes large ADR databases to find unexpected patterns or increasing trends.
Global ADR Monitoring	WHO VigiBase	A worldwide ADR data repository managed by WHO. Used for comparing national ADR trends and identifying rare or serious global safety concerns.
Clinical Data Capture (EDC)	Medidata Rave	An electronic data capture system used during clinical trials. It replaces paper CRFs with eCRFs, reducing errors and improving data quality.
Academic/Investigator EDC	REDCap	A simple tool for clinical and academic researchers to collect and manage study data. Useful for small to medium-scale trials due to ease of use and quick setup.
Clinical Trial Management System (CTMS)	Veeva Vault CTMS	Manages trial activities such as site tracking, monitoring visits, documents, and study progress. Helps keep clinical trials organized and compliant.
Randomization & Trial Supply (RTSM/IRT)	ClinPhone	Automates patient randomization and supply allocation of investigational products. Ensures correct drug kit assignment and maintains blinding.
ePRO / eCOA	Signant Health	Captures patient-reported outcomes electronically using mobile devices or tablets.

CONCLUSION

The integration of advanced software platforms into clinical trials and pharmacovigilance has fundamentally reshaped the operational and scientific landscape of drug development. These technologies have evolved from basic electronic record-keeping tools into comprehensive digital ecosystems that support real-time data capture, automated validation, centralized monitoring, and seamless global reporting. Their adoption not only reduces administrative burden but also significantly enhances data accuracy, regulatory compliance, and process standardization across diverse research environments.

Within clinical trials, modern CTMS, CDMS, and EDC systems facilitate end-to-end study management—from protocol design and participant tracking to data cleaning and statistical analysis—thereby improving the overall efficiency and integrity of clinical evidence generation. In pharmacovigilance, specialized safety databases and AI-enabled surveillance tools strengthen the detection, evaluation, and reporting of adverse drug reactions, contributing to more robust risk–benefit assessments and enhanced patient safety.

Collectively, these digital solutions have become indispensable to contemporary research practice. They ensure that clinical and safety data are reliable, traceable, and globally compliant, enabling sponsors, investigators, and regulators to make informed, time-sensitive decisions. As drug research continues to grow in complexity and scale, the future of clinical development will increasingly depend on the continued innovation, integration, and intelligent automation of these software systems.

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