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Review Article

Harmonizing Drug Safety and Data Integrity: A Review on the Integration of Pharmacovigillance and Clinical Data Management

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ABSTRACT

Pharmacovigilance (PV) and Clinical Data Management (CDM) are increasingly linked domains that are of enormous importance in ensuring the safety of drugs throughout the entire process. In the review, the evolving landscape of pharmacovigilance is reviewed with significant aspects such as Adverse Drug Reactions (ADRs), signal discovery, post-marketing surveillance, and the regulatory framework stipulated by the WHO, EMA, and USFDA. It demonstrates the value of standard codes such as MedDRA and the E2B (R3) format in normalizing the way that safety reports are submitted on a global scale. Data capture, data cleaning, or database locking CDM practices can be used to generate quality clinical datasets required in regulatory submissions. New technologies such as AI, machine learning, and blockchain are transforming not only PV and CDM by making the discovery of signals simpler, automating the process of reconciliation, and more easily tracing the data. The review shows it is paramount to share data and codes and establish interdepartmental cooperation to interface PV and CDM functions. Through identifying and resolving issues such as duplicated reporting, data inconsistency, and unified platforms, as well as real-time dashboards, the synergy between PV and CDM can be enhanced so as to make the patients safer, compliant with the regulations, and more efficient in operation.

Keywords: Pharmacovigilance, Clinical Data Management, Adverse Drug Reactions, Signal Detection, Regulatory Compliance.

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INTRODUCTION

The word "pharmacovigilance" comes from the greek word "pharmacon," which means "drug" or "medicinal substance," and the latin word "vigilare," which means "to keep watch." it's true that pharmacovigilance is a big part of making drugs. It means always looking for, figuring out, and understanding any problems or side effects that could happen with a drug. This kind of monitoring will help keep patients safe by looking at both the good and bad sides of some drugs (tripathi & shiv, 2017, p. 262).

The most important parts of pharmacovigilance are icsr, signal detection, and post-marketing surveillance. The World Health Organization (WHO) said in 2002 that a "signal" is the recording of a possible link between a drug and an adverse event that was not known or fully documented. To make a signal, there usually needs to be more than one report of the event, and the event and the information need to be serious enough (world health organization, 2002).

The CIOMS working group iv defines a signal as a report or reports of an event that is not clearly linked to treatment and requires further investigation and monitoring (CIOMS working group iv, 1999, p. 95). Another important part of pharmacovigilance is post-marketing surveillance. This is the process of looking for Adverse Drug Reactions (ADRS) in clinical trials of drugs that are already on the market (Vlahović-Palčevski & Mentzer, 2011). Phase iii clinical trials are the final step before a drug can be sold (Hartzema *et al*., 1987). PMS research is believed to be phase iv tests (Spelsberg *et al*., 2017). Determining the necessary components for an individual case safety report is a crucial aspect of reporting adverse events. During the triage phase of a possible adverse event report, it is important to make sure that there is a patient, a reporter, a drug that is suspected, and an adverse event. These are the four most important parts of a valid individual case safety report (council for international organizations of medical sciences working group v, 2001). Drug-related events are likely to occur that worsen life, hospitalize individuals, and even result in fatalities. Lazarou did a groundbreaking study in 1998 with 32,000 patients who had bad effects. ADRS were noted as the fourth to sixth most prevalent cause of mortality. Adverse

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drug reactions (ADRS) are thought to be responsible for 3-7% of all hospital admissions (lazarou, pomeranz, & corey, 1998). The purpose of this review is to look at all the different ways that pharmacovigilance and clinical data management can work together, as well as the problems that can happen. It will cover best practices, new technologies, and regulatory issues that will help make data more accurate, determine safety signals more quickly, and, in the end, keep patients safe throughout the drug lifecycle.

PHARMACOVIGILANCE: ENSURING DRUG SAFETY

Pharmacovigilance is necessary to identify safety signals and ensure that rules are followed. It does this by processing Individual Case Safety Reports (ICSRs) and making reports that group them together, like Periodic Safety Update Reports (PSURs) and Development Safety Update Reports (DSURs) (European Medicines Agency, 2017). Adverse Drug Reactions (ADRs) are harmful or unintended responses to medications that happen at doses that are usually used for prevention, diagnosis, or treatment (Coleman & Pontefract, 2016; Kommu, Carter, & Whitfield, 2025). ADRs are a major public health problem because they cause more sickness, death, hospital stays, and healthcare costs. For instance, in 2022, the U.S. FDA Adverse Event Reporting System reported more than 1.25 million serious adverse events and almost 175,000 deaths linked to ADRs (Kommu, Carter, & Whitfield, 2025). ADRs are a major reason why people go to the hospital without an appointment, and they can also hurt the relationship between the doctor and the patient (Coleman & Pontefract, 2016; Kommu, Carter). Table 1 provides a comprehensive classification of Adverse Drug Reactions (ADRs), highlighting their clinical characteristics and underlying mechanisms.

Additional expanded classifications include

Type C (Chronic): Linked to prolonged usage, encompassing corticosteroid-induced adrenal suppression. • Type D (Delayed): Happens slowly over time (like when cancer cells grow). • Type E (End-of-use/Withdrawal): This happens after you stop using drugs, like when you stop taking opioids. • Type F (Failure): When something doesn't work as expected, usually because of drug interactions (Chenchula, Atal, & Uppugunduri, 2024). ADRs are checked and watched for • Causality is assessed using tools like the Naranjo Algorithm, which categorizes reactions into groups such as certain, likely, or possible. • Severity: Hartwig's scale divides ADRs into three groups: mild, moderate, and severe. Severe adverse drug reactions can lead to mortality, lasting injury, or the necessity for intensive medical care. Preventability: The Schumock and Thornton scale shows which Adverse Drug Reactions (ADRs) can be stopped, which ones are not likely to be stopped, and which ones can't be stopped. Research says that more than half of Adverse Drug Reactions (ADRs) could be avoided (Jiang *et al*., 2022).

A lot of signal monitoring is part of pharmacovigilance. It means finding, looking at, sorting, and judging signals. A "signal" is a piece of information that shows a new link between a drug and a bad event or a new part of an old one. It is very important to handle signals correctly so that the decision about the drug's safety profile is always up to date. How to Answer Signals (Valdiserra *et al*., 2023).

Signal Detection and Signal Management in Pharmacovigilance

A key component of pharmacovigilance is signal detection, which is the methodical discovery of novel, possibly causal relationships between a pharmaceutical product and an adverse event that were either not previously known or not fully documented. Early detection of safety issues is made possible by effective signal detection, which minimizes patient harm and allows for prompt regulatory interventions. Signal detection is a multifaceted process in contemporary pharmacovigilance systems that combines regulatory supervision, qualitative medical evaluation, and quantitative statistical screening (Hauben & Zhou, 2003).

Quantitative Approaches to Signal Detection

Disproportionality analysis applied to large spontaneous reporting databases like VigiBase, EudraVigilance, and FAERS is the main method used in quantitative signal detection. These techniques find disproportionate reporting patterns that may indicate a safety signal by comparing the observed and expected frequencies of a particular drug-event combination. The Reporting Odds Ratio (ROR), Proportional Reporting Ratio (PRR), and Bayesian-based techniques like the Information Component (IC) are frequently used metrics.

While Bayesian approaches, like the IC, offer greater robustness in handling sparse data and variability across reporting systems, the ROR and PRR are commonly used because of their simplicity and interpretability. These statistical techniques have inherent drawbacks, such as underreporting, reporting bias, and confounding by indication, despite their usefulness. As a result, qualitative assessment must be added to statistical correlations in order to verify causality (Hauben & Zhou, 2003; van Puijenbroek *et al*., 2002; Bate *et al*., 1998).

Qualitative and Clinical Assessment of Signals

A thorough medical review of Individual Case Safety Reports (ICSRs), evaluation of temporal relationships, dose-response patterns, dechallenge and rechallenge data, and biological plausibility are all part of qualitative signal detection. Contextualizing statistical signals requires the use of clinical trial data, literature monitoring, and expert clinical judgment. By using a medical review process, signals are guaranteed to represent clinically significant risks rather than artifacts resulting from inconsistent data or reporting patterns. (European Medicines Agency, 2017).

Signal Management Lifecycle and Regulatory Oversight

According to EMA Good Pharmacovigilance Practices (GVP Module IX), signal detection is integrated into a structured signal management lifecycle. Signal detection, validation, confirmation, prioritization, assessment, and regulatory action are all included in this lifecycle. A signal is thoroughly examined after validation to ascertain its clinical significance and possible impact on public health. To identify the best risk-reduction strategies, regulatory bodies like the US FDA, the WHO Programme for International Drug Monitoring, and the EMA's Pharmacovigilance Risk Assessment Committee (PRAC) evaluate signals.

Regulatory actions can include changing the labels on products, sending Direct Healthcare Professional Communications (DHPCs), putting Risk Management Plans (RMPs) into place, or, in very rare cases, taking the medicine off the market. An important part of good signal management is making sure that healthcare professionals and patients get clear and timely information about safety findings.

Role of Clinical Data Management in Enhancing Signal Detection

High-quality clinical data management helps pharmacovigilance find safety problems early. It keeps safety data accurate, complete, and consistent. First, standardized case report forms ensure that adverse events are recorded correctly. Next, careful data cleaning removes errors. Then, timely database lock prevents missing or late information.

In addition, using consistent MedDRA terms allows everyone to speak the same safety language. As a result, clinical trial data can be easily combined with drug safety databases. This improves understanding of medicine risks.

Moreover, matching adverse event records between clinical and safety systems reduces mistakes and duplicate reports. Therefore, real safety signals are easier to detect. However, poor data quality or delayed checks can hide true risks or create false alarms. For this reason, strong coordination between clinical data management and pharmacovigilance is essential to protect patients.

Integration of Real-World Data in Signal Detection

Beyond spontaneous reports, real-world data help improve drug safety monitoring. For example, electronic health records, insurance claims, and patient registries provide useful safety information. Systems like the FDA Sentinel program actively track medicine risks.

As a result, real-world data allow safety evaluation in larger and more diverse patient groups. They also help detect rare and long-term side effects. However, these data come from many different sources. Therefore, strong clinical data management is needed to organize and standardize the information. This process turns real-world data into reliable evidence that supports safe use of medicines (Beninger, P, 2020).

Emerging Role of Artificial Intelligence in Signal Detection

Artificial intelligence helps improve drug safety monitoring. It finds hidden patterns in large amounts of data. For example, machine learning tools can sort important safety cases faster. They can also read free-text reports using language analysis.

As a result, safety teams can detect risks earlier. However, these tools must be tested carefully. Therefore, regulators require clear methods, proper validation, and strong oversight. This ensures reliable results and protects patient safety (Malikova, M. A., 2020).

Signal Evaluation and Verification

To determine the existence and clinical relevance of a cause, a more thorough evaluation by specialists is necessary. The PRAC at EMA and other regulatory bodies may be able to help with this. Because of this, the authorities may do more, like changing the labels on products or lowering the risk. • Signal Prioritization: This ongoing process decides which signals need to be dealt with right away based on how serious they are, how they affect public health, and who they are meant for (Gauffin *et al*., 2023).

Artificial Intelligence (AI) and Machine Learning (ML) help identify signals more easily. Some AI tools are gradient boosting machines, K-means clustering, and random forests. These methods are often better than old disproportionality statistics because they make it easier to find safety problems. Natural language processing, or NLP, makes it easier to look at case studies and other types of unstructured data. You can also use it to verify and rate signals. There are still no public benchmark datasets for testing AI models, reproducing results, and being open about methods (Warner, Prada Jardim, & Albera, 2025). People who work in pharmacovigilance are cautiously hopeful that generative AI and Artificial Intelligence (AI) will be able to automate some parts of signal management, like looking at cases and deciding which ones are most important based on causality. Surveys of pharmacovigilance leaders indicate that it is very important to use these technologies safely, follow the rules, and keep data safe. Ensuring that all the data is present and that the new system integrates effectively with the existing systems is crucial.

Signals are sorted by how important they are and watched

The Pharmacovigilance Risk Assessment Committee (PRAC) of the European Medicines Agency and other regulatory agencies must sort signals based on how they could affect public health. The product may be taken off the market, have its label changed, or have its risk lowered, if needed, after a thorough review process. Another important part of signal management is being able to

talk to doctors and patients in a way that is clear and helpful (European Medicines Agency, 2025).

Using real-world data (RWD)

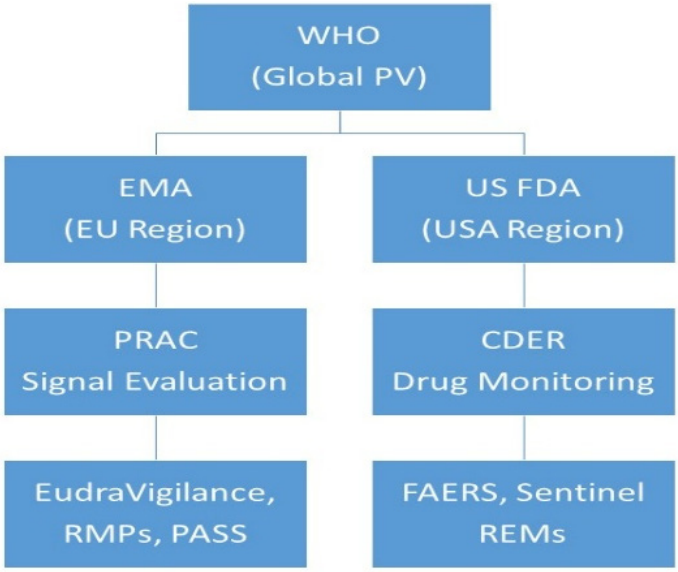
More and more, RWD is being used to rank and confirm signals from electronic health records and other sources. RWD can put things in context and help with signal evaluation, but more work needs to be done to make sure that data governance and analytical methods are the same (Indegene, 2025). Recent studies reveal that calls are evolving due to the existence of more rigid regulations, ethical issues, and utilization of AI and sophisticated analytics or actual information. These new concepts will eventually enhance the efficiency, precision, and helpfulness of pharmacovigilance, thereby preventing patient harm.

Regulatory Frameworks for Pharmacovigilance: WHO, EMA, and USFDA

One crucial component of regulating drug safety is pharmacovigilance, or PV. Finding, assessing, comprehending, and averting adverse drug reactions (ADRs) are all part of it. The World Health Organization (WHO), the European Medicines Agency (EMA), and the United States Food and Drug Administration (USFDA) all set up rules to ensure that medicines are safe at all stages of their lives (Hans & Gupta, 2018).

World Health Organization (WHO)

The World Health Organization (WHO) defines pharmacovigilance as the study of finding, evaluating, understanding, and stopping bad drug effects. It helps with global harmonization, especially by helping low- and middle-income countries set up their national PV systems. WHO's International Drug Monitoring Programme makes it easier for people all over the world to share data through VigiBase, which is run by the Uppsala Monitoring Centre. This lets people identify signals and assess risks on a global scale. WHO also gives member states advice and technical help to help them set up regulatory frameworks, reporting systems, and PV capacity (World Health Organization, 2025). The European Medicines Agency (EMA) PRAC is responsible for finding signals and assessing risks. Under EU law, the European Medicines Agency (EMA) is responsible for monitoring drug safety. EudraVigilance is used for reporting ADRs in the EU. Resources: Updates on public safety, PASS, RMPs, and stakeholder involvementThe Food and Drug Administration (FDA) in the US The US FDA's Center for Drug Evaluation and Research (CDER) is responsible for pharmacovigilance under the Federal Food, Drug, and Cosmetic Act. For real-world data monitoring, the Sentinel Initiative is used; for managing high-risk drugs, the REMS is used; and for reporting ADRs, the FAERS is used. The FDA also keeps doing safety checks on drugs after they are on the market and gives advice on how to protect people's health. Table 2 provides a comparative overview of pharmacovigilance signal detection and management frameworks adopted by the WHO, EMA, and US FDA, highlighting key regulatory similarities and differences (European Medicines Agency, 2025).



Role of MedDRA coding and E2B standard

An example of such common medical terminology is MedDRA (Medical Dictionary for Regulatory Activities): standardized, clinically validated medical terminology that is used in pharmacovigilance to uniformly code adverse events, medical conditions, and interventions used in clinical trials, post-marketing surveillance, and regulatory reporting.

Standardization and Communication

MedDRA has five hierarchical levels reflecting the level of specificity, with the System Organ Classes (SOC) being very broad to the Lowest Level Terms (LLT) being very specific. It allows discussing the medical events in a consistent and understandable manner. Such a level of standardization facilitates communications between pharmaceutical companies, medical practitioners, and regulating organizations worldwide (Nagarajan & Mahapatro, 2024). **Adherence to rules**: Regulatory bodies require coded data of the MedDRA type to report undesirable occurrences. Such uniformity forms a significant aspect of abiding in the global rules of pharmacovigilance (Dutta, 2021).

Difficulties

Studies indicate that the terminology is excessively complex and should be upgraded constantly, and the possible vague or erroneous coding is likely to happen. As an illustration, an analysis of safety data on the COVID-19 vaccine reveals that numerous entries were coded improperly or too generally, which may have contributed to a decreased level of data reliability

and the inaccuracy of the assessments of the vaccine's safety. Resolving these problems is rather important in terms of training and quality control.

How to Do Things Best: This can be done by having effective quality control systems, providing coders with intensive training, and using automated coding tools (with caution) (Khushal, 2022).

Role of E2B standard in pharmacovigilance

E2B The E2B specification is an internationally agreed technical standard created by the International Council for Harmonisation (ICH) to describe the electronic exchange of Individual Case Safety Reports (ICSRs) in macovigilance. It identifies the data items and structure necessary for consistently and efficiently reporting Adverse Drug Reactions (ADRs) across pharmaceutical industry companies, national regulatory authorities, and other stakeholders.

E2B has undergone several evolutions and versions

First built in 1997, E2B replaced paper-based reporting with electronic reporting. The latest incarnation (completed in 2013) is E2B(R3), which adds data granularity (in the form of attachments (e.g., PDFs), 333 data items compared to 271 in R2) and more definition of case-level structure to assist with clarity (IQVIA, n.d.).

International adoption of regulations

The FDA, the European Medicines Agency, and the PMDA of Japan are some of the key regulatory agencies that have adopted or are in the process of adopting E2B(R3) as a standard for filing Individual Case Safety Reports (ICSRs). As an example, EMA started sending ICSRs in E2B(R3) in November of 2017. The E2B(R3) format and the R2 format can coexist during the transition period. The release of E2B(R3) regional implementation specifications by the FDA was in 2016, and it is expected that in 2017-2018 mandatable adoption will be put into effect (U.S. Food and Drug Administration, 2022).

Business and Technical Impact

The change to E2B (R3) demands considerable modifications to pharmacovigilance systems and processes. Business enterprises need to re-engineer their ICSR generation, validation, and transmission processes to support the greater nuance of data and new message formats. This process involves compatibility with regulatory files (such as EudraVigilance and FAERS12). The standardization leads to more accurate and cross-compatible sharing of safety data, resulting in improved signal and risk assessment capacities (IQVIA, n.d.).

Correspondence with other standards

E2B(R3) makes the data systems in healthcare more uniform, since they all use ISO language regarding pharmaceutical dose forms and modes of administration, and they may be compatible with other international standards, such as ISO IDMP (Identification of Medicinal Products) to identify products (IQVIA, n.d.).

The implementation of E2B (R3) necessitates substantial financial resources, technical expertise, and employee training. It does, however, offer the opportunity to improve the data, automate safety reporting, and facilitate adherence to regulations. The use of automation, artificial intelligence, and machine learning to handle the larger and more intricate datasets that E2B(R3) enables is growing (IQVIA, n.d.).

CLINICAL DATA MANAGEMENT

The basis for data integrity

The gathering, purification, and administration of data produced in clinical trials are the main objectives of clinical data management, or CDM. For regulatory submissions and the legitimacy of clinical research findings, it guarantees that the data is correct, trustworthy, and prepared for analysis (Pharma IQ, n.d.).

Table 1: Provides a comprehensive classification of adverse drug reactions (ADRs), highlighting their clinical characteristics and underlying mechanisms.

Sl. No.	Description	Predictability	Dose dependence	Frequency	Example
a	Augmented reactions: Linked to the established pharmacology of the drug; foreseeable.	Yes	Yes	Common	Hypotension with antihypertensives, hypoglycemia from insulin, NSAID-induced gastric ulcers (Coleman & Pontefract, 2016).
b	Strange-reactions: unique,not related to known pharmacology, and hard to predict.	No	No	Rare	Anaphylaxis with penicillin, Stevens-Johnson syndrome, halothane-induced hepatitis (Coleman & Pontefract, 2016).

Table 2: Table 3 outlines the typical workflow for adverse event (AE) reconciliation between clinical data management and pharmacovigilance systems (European Medicines Agency, 2025).

Aspect	WHO	EMA	USFDA
Scope	Help and advice from around the world	Centralised and national systems across the EU	The US's main regulatory body
Safety Data Systems	VigiBase (a database of global ADRs)	The EU ADR database, EudraVigilance	FAERS (the US ADR database) and the Sentinel system
Risk Management Tools	Guidelines and capacity building	Risk Management Plans (RMPs), PASS	Risk Evaluation and Mitigation Strategies (REMS)
Regulatory Committees	Advisory and technical support	Pharmacovigilance Risk Assessment Committee (PRAC)	Advisory committees and CDER
Transparency & Stakeholder Engagement	Encouraged globally	High transparency, public PRAC documents, and patient involvement	Public advisory meetings; published safety communications
Post-Marketing Surveillance	Encourages national programs and data sharing	Coordinated EU-wide surveillance and inspections	Active surveillance via Sentinel and mandatory reporting

Key Phases of CDM Data

Data Capture

Definition: The act of gathering information from people who are in clinical trials. **Methods:** Electronic Data Capture (EDC) systems, paper Case Report Forms (CRFs), or direct import from medical devices. **Goal:** Make sure that all of the study data that needs to be collected is done so correctly and completely**.**

Data Cleaning

Definition: Finding and fixing mistakes or inconsistencies in the data that has been collected. **Activities- Managing queries:** Making sure that site staff understand mistakes or missing information. Logic and range checks: Finding values that are too high or too low. **Ongoing review:** Making sure that the data is always correct at all times. Goal: Improve the quality of the data as much as possible before the database lock (Pharma IQ, n.d.; Allucent, n.d.).

Database Lock- Definition

The last step in managing data, when no more changes can be made to it. **Process:** Last check of quality and confirmation. Make sure that all questions have been answered and that the data is as complete as it can be. **What it means**: After a database lock, the dataset is final and can be used for study reporting and statistical analysis. Changes made after lockdown need to be done in a formal way and with a written reason (iProcess Global Research, n.d.; Quanticate, 2024).

CDM Workflow in Clinical Trial

Clinical Data Management (CDM) is a crucial process in clinical trials, aimed at generating high-quality, reliable, and statistically robust data for regulatory submission and medical decision-making. The CDM workflow encompasses several interconnected phases, starting from the development of the study protocol, through the design and annotation of Case Report Forms (CRFs), and the creation of a database structure that mirrors the CRF. Data is collected—often electronically-entered, and then rigorously cleaned and validated to identify and resolve errors, inconsistencies, or missing values. The process also includes medical coding to standardize terms, ongoing discrepancy management, and quality reviews. Each step is routinely evaluated to ensure compliance with regulatory standards and to maintain data integrity. The workflow concludes with database locking, after which no further changes are permitted, allowing clean data to be analyzed and reported. As electronic data management becomes a regulatory requirement, the role of CDM has expanded to ensure rapid, compliant, and accurate data handling throughout the clinical trial lifecycle (Krishnankutty *et al.*, 2012; Aher *et al.*, 2024).

Tools and Tech of CDM

The Clinical Data Management (CDM) tools and technologies have been fast evolving to meet the increased complexity of the clinical research as well as the size. To raise the reliability of data, speed up the process, and follow the regulations, contemporary DCM utilizes multiple specialized software programs and other digital solutions. Electronic Data Capture (EDC) platforms and Clinical Data Management Systems (CDMS) are at the nerve center of the process. They automate the management of query, validation, storage, and collection. Some of the best are Veeva CDMS, Medidata Rave, and Oracle Clinical. All of them are characterized by such features as rule-compliant audit trails, automatic edit checks, and real-time data access. It has also become easy to collect and assemble the data about the patient that was previously found in different sources due to the new technologies, the wearable and data integration tools, electronic Patient-Reported Outcomes (ePRO), and Clinical

Trial Management Systems (CTMS). Machine Learning (ML) and Artificial Intelligence (AI) to detect abnormal patterns, clean dirty data, and forecast are on the rise. Moreover, blockchain technology is also under exploration as the method of increasing data traceability and integrity. A small number of the safety functions built into numerous platforms to ensure both patient privacy and compliance with regulations include role-based access control, encryption, and audit logs, among others (element_admin, 2023; Vipparthi, 2024; Rao, 2023).

Role in Supporting Regulatory Submissions

Clinical Data Management (CDM) is also vital in regulatory submissions such as Clinical Study Report (CSR) and New Drug Application (NDA) since it ensures the data assembled through the clinical trials is accurate, complete, and reliable. CDM ensures that data is well collected, validated, cleaned, and securely stored to adhere to the resourceful regulation requirements of authoritative organizations such as the FDA and EMA (Quanticate, 2024; Pharma Connections, 2024; SpinoS Life Science, 2024). This is done by planned data management that incorporates phases right up to the locking of a database that includes testing its consistency, accuracy, and completeness throughout the process. The completed data become the foundation of the CSR, which provides the conclusions of clinical trials, and the NDA, which is the complete document sent to the regulators to obtain an allowance to sell the drug. It is highly necessary that CDM retains audits, institutes quality controls, and adheres to Good Clinical Practice (GCP) and other regulatory policies. This will facilitate the establishment of confidence in the results of the trial and ease the process of receiving regulatory approval (Rush, 2024; QAData, n.d.; Krishnankutty *et al.*, 2012). In the event that CDM is not done in a good way, data integrity failures or errors that may arise here may drag down the approval process or, worse still, commit new medical products to rejection.

POINTS OF INTERSECTION BETWEEN PV AND CDM

The combination of Pharmacovigilance (PV) and Clinical Data Management (CDM) is becoming more important as a strategic goal in clinical research and drug safety after the drug is on the market. PV and CDM come together when they have to report adverse events, reconcile data, code MedDRA, and obey the rules to keep patients safe and the data accurate. Recent studies and review articles emphasize how this intersection propels progress in patient safety, data integrity, regulatory compliance, and operational efficiency (Kashyap, 2024).

Shared Datasets

An Adverse Event (AE) is any negative medical event that happens to a patient or clinical trial participant after they take a drug. It doesn't have to be directly related to the treatment. An adverse event is classified as a Serious Adverse Event (SAE) if it results in death, endangers life, requires hospitalization, induces permanent disability, or constitutes a congenital anomaly (Yazdani *et al.*, 2025). The use of shared datasets for finding, studying, and predicting Adverse Events (AEs) and Serious Adverse Events (SAEs) is speeding up the progress of pharmacovigilance and clinical safety research.

CT-ADE and FAERS Datasets Overview

CT-ADE 28 is a fully loaded set of adverse drug events from clinical trials; its source is ClinicalTrials.gov. It contains events

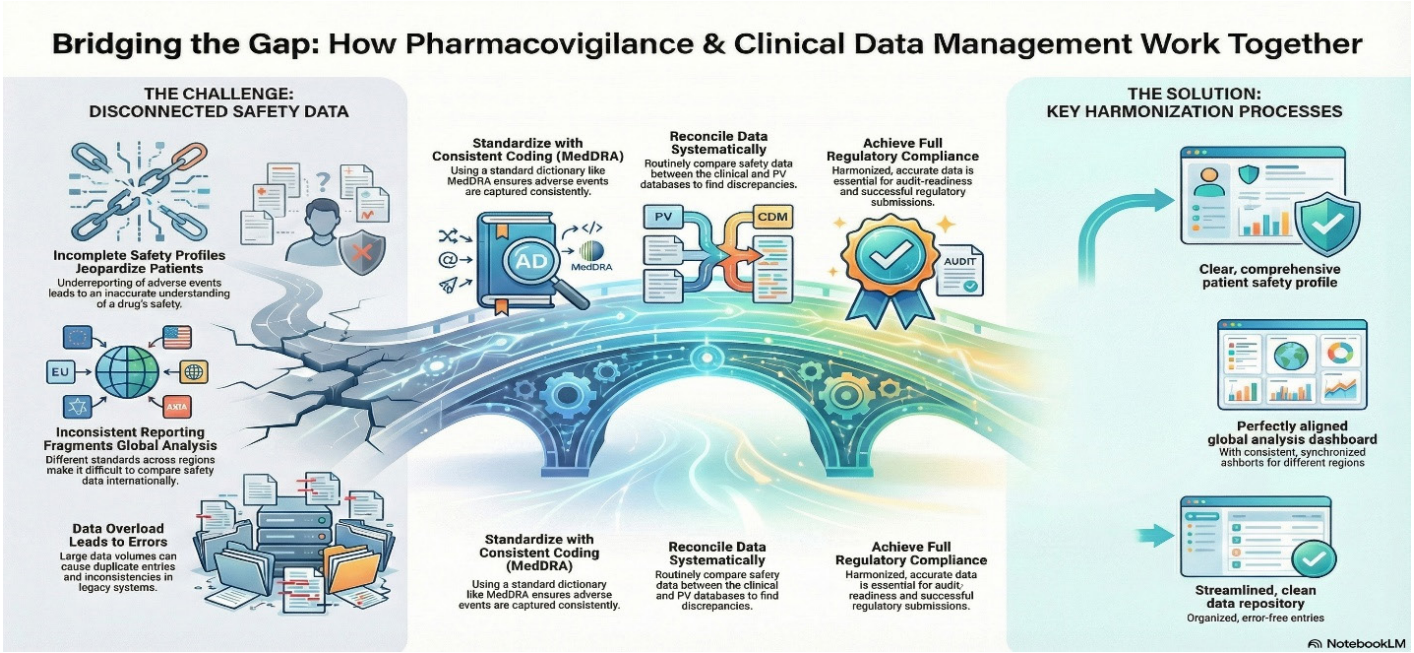


Figure 1: Collaboration Between Pharmacovigilance and Clinical Data Management in Safety Data Reconciliation.

regarding the patients, management plans (dose, period of administration, frequency, and route of administration), and an entire list of beneficial and negative ADE results. It has 2,497 drugs and 168,984 drug-ADE pairs with standardization done on MedDRA codes at SOC and PT. This enables researchers to evaluate drug-event relationships by getting the accurate judgments that are absent in the issues of polypharmacy (Yazdani *et al*., 2025). FAERS is a large database of spontaneous reports of adverse events maintained by the FDA. Recently it has been enhanced through the conversion of messy data, removal of duplicates, and rationalizing it (for drugs using RxNorm). It provides calculated metrics of disproportionality between drugs and events that are pre-calculated and aids in discovering safety signals on a mass scale. Data can easily be located by use of the FDA public dashboard. Sophisticated models such as GCAP are based on FAERS data, which determine the severity of adverse drug reactions, hence the improvement of safety assessment. Multi ADE and other examples of multimodal datasets integrate multiple sources, e.g., through natural language processing, to identify ADEs, including electronic health records, literature, and social media. One attempt at achieving uniformity in the form and language of the exchange of AE data internationally is the IMDRF Common Data Set (CDS). It also expands on existing models, such as ICH E2B (Khaleel *et al*., 2022).

Table 3: Outlines the typical workflow for Adverse Event (AE) reconciliation between clinical data management and pharmacovigilance systems (Contu *et al*., 2025).

Step	Description
Data Extraction	Get AE/SAE information from the PV and CDM databases.
Preparation	Put datasets in a similar order.
Initial comparison	AE details and subject-specific match records.
Discrepancy flag	Emphasize any discrepancies or cases that were overlooked or mismatched.
review and query	Inconsistencies with websites or accountable parties.
Correction and update	Address disparities and make the necessary updates to both systems.
Audit and documentation	Keep records and records to ensure compliance.

Importance of coding consistency

When using coded data at the clinical level, e.g., using standardized terms, e.g., MedDRA (Medical Dictionary of Regulatory Activities), data relating to the adverse events, medical conditions, and the treatments are always captured consistently under the same standards in any study, site, and across the drug development phases. This will help in the interpretation of the rules, comparison, and compliance. In contrast to the low level of ambiguity and variability, standardized coding enhances the consistency in the datasets. This makes it possible to promptly synthesize safety and efficacy data across geographies or sources, and this is important in the internationalization of pharmacovigilance activities and in conducting multinational clinical trials (MediPharm Solutions, 2023; Clival Database, 2025; Clinical Data Management Team, 2024). Application of consistent MedDRA coding makes it easy to communicate among sponsors, regulatory bodies, safety teams, and clinical researchers. It also aids in identifying safety indicators promptly and reporting to the government in a timely manner (ProRelix Research, n.d.). The issue of error, which may be misclassification or vague description, may hide safety issues or make analysis awkward, according to studies. It enables, theoretically, the pharmacovigilance databases and clinical datasets and contributes to the reconciliation and the audit-readiness of data (QAData, n.d.).

Data Reconciliation: matching AE data in PV and CDM

Data reconciliation is a process critical throughout the development of a clinical trial in ensuring precise and reliable comparison of Adverse Event (AE) and Serious Adverse Event (SAE) data in the Clinical Data Management (CDM) to the Pharmacovigilance (PV) systems. This process involves systematically comparing key data elements that are derived out of clinical and safety databases; these data elements include the subject identifiers, MedDRA-coded event terms, and onset and resolution dates (Caulfield, 2024). Inconsistent coding practices, verbatim terms reported by each site, or variations in data entry time can cause these differences (Soterius, 2025). On discovering such differences, they will be officially recorded and handled through Data Clarification Forms (DCFs), site-based inquiries, or medical revisions. This reconciliation is typically conducted at preselected time points during the trial and again before the database lock to ensure no differences and create a complete alignment before regulatory submissions (Medidata, 2022). Automated tools and platforms can make this process more efficient, especially when the research is significant in scale. Besides ensuring improvements in the quality of data, the process will ensure regulatory compliance, eliminate missing or duplicate reports, and allow the accurate detection of safety signals. Nonetheless, unless proactively addressed, problems such as inaccurate forms of MedDRA, slow responsiveness on the part of sites, or even a disconnect between PV and CDM functions may

hinder the reconciliation process (Ethical, 2020). Table 3 outlines the typical workflow for Adverse Event (AE) reconciliation between clinical data management and pharmacovigilance systems (Contu *et al*., 2025).

Duplicate Reporting and Data Inconsistency Challenge

Data reporting and data inconsistency pose significant challenges in Pharmacovigilance (PV) and clinical data management. Underreporting of Adverse Events (AEs) is common due to lack of awareness, time constraints, or the perceived insignificance of events, leading to incomplete safety profiles that may jeopardize patient safety and regulatory evaluation (Drug-Card, 2024). Variability in reporting standards across regions and healthcare systems further fragments data collection, complicating global safety analyses and compliance. Additionally, the influx of large volumes of data from clinical trials, Electronic Health Records (EHRs), and real-world sources often overwhelms legacy PV systems, causing data overload and interoperability issues (Oracle, n.d.). These factors delay the detection of safety signals and risk overlooking critical safety concerns, hindering timely regulatory submissions. Outdated manual processes contribute to problems such as duplicate or inconsistent entries, further undermining data integrity and effective pharmacovigilance operations (PQE Group, n.d.) (Figure 1). Collaboration Between Pharmacovigilance and Clinical Data Management in Safety Data Reconciliation

INTEGRATION STRATEGIES

Oracle Unified Platforms Oracle Argus + Clinical / SAS-based CDM Pairing Oracle Argus Safety with Oracle Clinical or SAS-based CDM makes it easy to send in, analyze, and report adverse events:

Automated data flows

Solutions like the Oracle InForm-Argus Safety integration allow real-time secure transfer of SAE data whereby less manual data input and better reconciliation are achieved. The process is consistent with applicable international standards such as E2B of pharmacovigilance and also consistency between the safety database and clinical database (Oracle Corporation, 2025). SAS Integration-SAS is frequently applied in the processing, normalizing, and analyzing of clinical information prior to the transfer of such data into safety systems, which facilitates automation and audit trail needs (ScienceSoft, n.d.; Handson System, n.d.).

Real-Time AE Reconciliation Dashboards Automation & Accuracy

Real-time dashboards compare adverse event reporting between clinical and safety data sets, eliminating much manual effort to reconcile reports. Newer platforms such as Reconciliaid or custom dashboards can match and validate incidents with a high degree of both efficiency and accuracy, bolstering compliance and being audit-ready (Contu *et al*., 2025; National Center for Biotechnology Information, n.d.). Regulatory Perspective As per NCBI, AE reporting between clinical data systems and safety systems must be synchronized according to regulatory requirements in order to have effective safety oversight (Badary, 2025).

Interdepartmental SOPs and communication Clear SOPs

Clear SOPs describe the roles, schedules, and procedures of AE data sharing and reconciliation duties of the groups. The reduction of errors through SOPs dedicated to ensuring coherent communication between the teams of clinical operations, data management, and pharmacovigilance avoids any mistakes and ensures consistency (Albright *et al*., 2022; Joyce, 2025).

Best Practices

Some of the strategies that are being used are regular meetings with people from different departments, making sure everyone understands why SOPs are changing, two-way communication, and training that works for all stakeholders. It has been shown that these kinds of communication practices help the achievement of implementation fidelity and process improvement within the clinical development processes (Albright *et al*., 2022; Joyce, 2025).

Predictive role of AI/ML in safety signals with the use of CDM data AI/ML Apps

The use of artificial intelligence and machine learning is transforming pharmacovigilance because adverse event signals can now be detected automatically. Patterns in real-world and clinical data, in particular in structured data, can be revealed using ML algorithms to detect safety signals earlier than conventional methods (Badary, 2025; Chavhan & Uplenchwar, 2024; Dimitsaki *et al*., 2024).

Recent Studies

PubMed research demonstrates AI's effectiveness in prioritizing cases, identifying potential adverse events, and supporting a risk-based approach to safety surveillance. Such methods support proactive safety management and regulatory reporting (Dimitsaki *et al*., 2024).

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ABBREVIATIONS

AE: Adverse Event; **ADR:** Adverse Drug Reaction; **AI:** Artificial Intelligence; **CDER:** Centre for Drug Evaluation and Research; **CDM:** Clinical Data Management; **CDS:** Common Data Set; **CIOMS:** Council for International Organizations of Medical Sciences; **CRF:** Case Report Form; **CSR:** Clinical Study Report; **CTMS:** Clinical Trial Management Systems; **DCF:** Data Clarification Form; **DSURs:** Development Safety Update Reports; **EDC:** Electronic Data Capture; **EMA:** European Medicines Agency; **ePRO:** Electronic Patient-Reported Outcomes; **FAERS:** FDA Adverse Event Reporting System; **FDA:** Food and Drug Administration; **GCP:** Good Clinical Practice; **ICSR:** Individual Case Safety Reports; **ICH:** International Council for Harmonisation; **LLT:** Lowest Level Terms; **MedDRA:** Medical Dictionary for Regulatory Activities; **ML:** Machine Learning; **NDA:** New Drug Application; **NLP:** Natural Language Processing; **PMDA:** Pharmaceuticals and Medical Devices Agency; **PMS:** Post-Marketing Surveillance; **PRAC:** Pharmacovigilance Risk Assessment Committee; **PSURs:** Periodic Safety Update Reports; **PV:** Pharmacovigilance; **REMS:** Risk Evaluation and Mitigation Strategy; **RMPs:** Risk Management Plans; **ROR:** Reporting Odds Ratio; **RWD:** Real-World Data; **SAE:** Serious Adverse Event; **SAS:** Statistical Analysis System; **SOC:** System Organ Classes; **SOPs:** Standard Operating Procedures; **USFDA:** United States Food and Drug Administration; **WHO:** World Health Organization.

CONFLICT OF INTEREST

The authors declare no conflict of interest.

SUMMARY

The given document represents a systematic review paper, which covers the issue of combining Pharmacovigilance (PV) and Clinical Data Management (CDM). It begins by defining PV to be the science of observing, comprehending, and preventing Adverse Drug Reactions (ADRs) and mentions post-marketing surveillance as a significant component of the same. The ADRs fall into two broad categories, namely Augmented: the reactions that are predictable and linked to the known pharmacology of the drug, and Strange: the reactions whose prediction and linkage to the known pharmacology are not predicted. Another classification of ADRs developed and discussed in the paper is an expanded list of classifications containing Type C (Chronic), Type D (Delayed), Type E (End-of-use/Withdrawal), and Type F (Failure), in addition to A to F classifications. The review draws attention to international regulatory organizations such as the World Health Organization (WHO), the European Medicines Agency (EMA), and the U.S. Food and Drug Administration (USFDA), which establish regulations to maintain drug safety. It also reiterates the value of standardization in PV and specifically highlights the use of MedDRA to code adverse events and the use of the E2B standard to electronically exchange Individual Case Safety Reports (ICSRs). The paper thereafter dwells on Clinical Data Management (CDM), which refers to the activity of collecting, cleansing, and managing data from clinical trials to guarantee quality and trustworthiness for use in regulatory filings. The paper describes important stages of CDM, including data capture, data cleaning, and database lock. The interface between PV and CDM takes up a major part of the presentation and observes that PV and CDM converge in the reporting of adverse events, data reconciliation, and MedDRA coding. The paper outlines the critical process of data reconciliation, compares AE and SAE data between the two systems, and ensures their consistency before regulatory submissions. The interface between PV and CDM takes up a major part of the presentation and observes that PV and CDM converge in the reporting of adverse events, data reconciliation, and MedDRA coding. The paper outlines the critical process of data reconciliation, compares AE and SAE data in the two systems, and ensures their harmony before regulatory submissions.

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