



# Review On Pharmacovigilance In Clinical Trials: Ensuring Participant Safety

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## **Abstract:**

Clinical trials play a crucial role in evaluating the safety and efficacy of new therapeutic interventions. Pharmacovigilance, the science and activities related to the detection, assessment, understanding, and prevention of adverse effects or any other drug-related problems, is of paramount importance during clinical trials. This review article explores the significance of pharmacovigilance in clinical trials, focusing on the measures taken to ensure participant safety. Key aspects include monitoring and reporting adverse events, maintaining data integrity, and assessing the balance between drug benefits and risks.

**Key words :-** Clinical trials ,Safety, efficacy ,Pharmacovigilance ,Adverse effects, Drug-related problems ,Participant safety ,Monitoring Reporting, adverse events Data ,integrity Benefits and risks.

## 1.Introduction:

Clinical trials are a cornerstone of the drug development process, serving as a crucial step in assessing the safety and efficacy of new therapeutic interventions. Within the realm of clinical trials, pharmacovigilance plays a paramount role in ensuring participant safety. Pharmacovigilance encompasses a range of activities focused on the detection, assessment, understanding, and prevention of adverse effects or any other drug-related problems.

The primary objective of pharmacovigilance in clinical trials is to monitor and evaluate the safety profile of investigational products. It involves systematic data collection, analysis, and reporting of adverse events, as well as the assessment of the overall benefit-risk balance. By employing rigorous pharmacovigilance practices, researchers and regulatory authorities can effectively identify and mitigate potential risks associated with the use of investigational drugs.

This review article aims to emphasize the importance of pharmacovigilance in clinical trials and delve into the various measures taken to ensure participant safety throughout the trial process. It will explore the key components of pharmacovigilance, such as adverse event monitoring and reporting, data integrity and quality assurance, benefit-risk assessment, and the responsibilities of different stakeholders involved in clinical trials.

Understanding the significance of pharmacovigilance in clinical trials is essential for researchers, healthcare professionals, regulators, and other stakeholders in the drug development ecosystem. By comprehensively examining the practices and processes employed to ensure participant safety, this review article aims to contribute to a better understanding of the critical role played by pharmacovigilance in clinical trials. Ultimately, this knowledge will help in enhancing the reliability, integrity, and ethical conduct of clinical research, leading to the development of safe and effective therapeutic interventions for patients in need.

## 2.pharmacovigilance Processes in Clinical Trials:

- **Pre-trial planning and safety assessment:**

Prior to the initiation of a clinical trial, thorough pre-trial planning takes place. This involves designing the study protocol, selecting appropriate study populations, and conducting comprehensive safety assessments. Safety assessments typically involve a review of preclinical data, previous clinical trial results, and available information on the investigational product to identify potential risks and determine safety monitoring requirements.

- **Adverse event monitoring and reporting:**

Adverse event monitoring is a critical component of pharmacovigilance in clinical trials. It involves the systematic collection, documentation, and analysis of adverse events or any other untoward medical occurrences experienced by trial participants. Adverse events can range from mild to severe and include both expected and unexpected reactions. Rigorous monitoring allows for the early detection of safety signals and the timely implementation of risk management strategies. Adverse events are reported according to regulatory requirements and guidelines, ensuring the timely and accurate submission of safety data.

- **Data collection and management:**

Proper data collection and management are crucial to pharmacovigilance in clinical trials. Robust systems and procedures are established to ensure the accurate and consistent collection of safety data. This may involve the use of standardized case report forms (CRFs) or electronic data capture (EDC) systems. Data management includes processes such as data entry, coding of adverse events, and quality control measures to maintain the integrity and reliability of the collected data.

- **Safety evaluation and risk assessment:**

Pharmacovigilance in clinical trials involves the ongoing evaluation of safety data to assess the potential risks associated with the investigational product. This includes the analysis of individual adverse events as well as the overall safety profile of the drug. Safety evaluations may involve statistical analysis, signal detection techniques, and comparison with relevant control groups. Risk assessment considers factors such as the severity, frequency, and predictability of adverse events to determine the overall benefit-risk balance of the investigational product.

- **Pharmacovigilance responsibilities of different stakeholders:**

Various stakeholders play critical roles in ensuring pharmacovigilance in clinical trials. Sponsors are responsible for overseeing the trial and implementing pharmacovigilance systems. Investigators are responsible for the accurate and timely reporting of adverse events, while ethics committees ensure the protection of trial participants. Regulatory authorities provide guidelines and oversight to ensure compliance with safety reporting requirements and may conduct inspections to monitor pharmacovigilance practices.

### **3. Adverse Event Monitoring and Reporting:**

Adverse event monitoring and reporting are critical components of pharmacovigilance in clinical trials. The systematic collection, documentation, analysis, and reporting of adverse events are essential for assessing the safety profile of investigational products. Here are the key aspects of adverse event monitoring and reporting:

- **Definitions and classifications of adverse events:**

Clear definitions and classifications of adverse events are established to ensure consistency in their identification and reporting. Adverse events are generally defined as any untoward medical occurrence experienced by a participant during the course of a clinical trial, whether or not it is considered to be related to the investigational product. Common classifications, such as the Medical Dictionary for Regulatory Activities (MedDRA) terminology, help standardize adverse event reporting.

- **Methods of capturing and documenting adverse events:**

Various methods are employed to capture and document adverse events effectively. These may include participant interviews, physical examinations, laboratory tests, diagnostic procedures, and patient diaries. Structured reporting forms are used to ensure standardized data collection and capture relevant information, such as the nature, severity, onset, duration, and outcome of adverse events.

- **Importance of timely and accurate reporting:**

Timely and accurate reporting of adverse events is crucial to ensure participant safety and enable prompt risk management. Investigators and study personnel are responsible for promptly documenting and reporting adverse events as per regulatory requirements and trial protocols. Adverse events are typically reported to the sponsor or designated safety personnel within specified timelines to facilitate appropriate actions and minimize potential risks to participants.

- **Regulatory requirements and guidelines for adverse event reporting:**

Regulatory authorities provide specific requirements and guidelines for adverse event reporting in clinical trials. These guidelines outline the reporting timelines, data elements, and formats to be followed. Adherence to these requirements ensures compliance with regulatory standards and facilitates the consistent collection and reporting of adverse event data across different trials.

- **Adverse event assessment and causality determination:**

Adverse events reported during clinical trials are carefully assessed and evaluated to determine their relationship to the investigational product. Causality assessment methods, such as the World Health Organization (WHO) causality assessment criteria or the Naranjo algorithm, are utilized to determine the likelihood of the adverse event being related to the study drug. This helps differentiate between adverse events and other factors unrelated to the investigational product.

- **Signal detection and management:**

Adverse event reporting plays a crucial role in signal detection, which involves identifying potential safety concerns or patterns from the reported data. The data is analyzed for any emerging safety signals or unexpected adverse event patterns. Detected signals may trigger additional investigations, safety evaluations, or modifications to the trial design or risk management strategies.

- **Reporting to regulatory authorities and ethics committees:**

In addition to reporting adverse events to the sponsor or designated safety personnel, there is a requirement to report certain adverse events to regulatory authorities and ethics committees. These reports, known as expedited or serious adverse event reports, provide a comprehensive overview of severe adverse events, unexpected events, or events that lead to serious harm or death. Reporting to regulatory authorities and ethics committees ensures transparency, regulatory compliance, and protection of trial participants.

#### **4.Data Integrity and Quality Assurance :**

Data integrity and quality assurance are essential aspects of pharmacovigilance in clinical trials. Maintaining the accuracy, completeness, and reliability of the collected data is crucial for generating valid and meaningful safety assessments. Here are the key components of data integrity and quality assurance in clinical trial pharmacovigilance:

- **Ensuring data accuracy, completeness, and reliability:**

Data accuracy refers to the correctness and precision of the collected information. It involves minimizing errors, ensuring consistency, and avoiding data entry mistakes or transcription errors. Data completeness ensures that all relevant data points are collected and recorded. Data reliability pertains to the consistency and reproducibility of the collected data, ensuring that it can be trusted and relied upon for analysis and decision-making.

- **Data collection, coding, and analysis:**

Proper methods of data collection are employed to ensure consistency and standardization. This may involve the use of standardized case report forms (CRFs) or electronic data capture (EDC) systems. Adverse events are coded using standardized medical dictionaries, such as MedDRA, to facilitate uniformity and comparability across trials. Data analysis techniques are applied to identify patterns, trends, and potential safety signals, using appropriate statistical methods and data visualization tools.

- **Quality control and quality assurance processes:**

Quality control and quality assurance procedures are implemented throughout the data collection and management process. Quality control involves checks and validation to identify and correct errors or inconsistencies in the data. It includes procedures such as double data entry, source document

verification, and data validation checks. Quality assurance ensures that the overall process adheres to standard operating procedures, regulatory requirements, and guidelines. It may involve audits, inspections, and independent reviews to assess the compliance and reliability of the data.

- **Good Clinical Practice (GCP) guidelines and their role in maintaining data integrity:**

Good Clinical Practice (GCP) guidelines provide a framework for the conduct of clinical trials and play a vital role in maintaining data integrity. Adherence to GCP guidelines ensures that the trial is conducted ethically, with the highest level of data integrity and participant protection. GCP guidelines provide standards for trial design, data collection, documentation, reporting, and overall trial management, contributing to the reliability and validity of the collected data.

- **Data privacy and confidentiality:**

Data privacy and confidentiality are critical considerations in pharmacovigilance. Personal identifying information and individual participant data should be protected to ensure participant privacy. Adequate measures, such as data encryption, restricted access, and secure storage, are implemented to safeguard the confidentiality of participant information and comply with applicable data protection regulations.

- **Training and qualifications of personnel:**

Ensuring that personnel involved in data collection and management are adequately trained and qualified is essential for maintaining data integrity. Training programs educate staff on data collection procedures, adverse event reporting, coding, and quality control processes. Regular updates and refresher training help keep personnel informed about new developments, regulatory changes, and best practices in data integrity and quality assurance.

## **5. Benefit-Risk Assessment in Clinical Trials :**

Benefit-risk assessment is a crucial step in the evaluation of investigational drugs during clinical trials. It involves a systematic evaluation of the potential benefits and risks associated with the use of the investigational product. Here are the key aspects of benefit-risk assessment in clinical trials:

- **Balancing potential benefits and risks:**

Benefit-risk assessment aims to strike a balance between the potential benefits of the investigational

drug and the risks it may pose to trial participants. The potential benefits include therapeutic efficacy, improved health outcomes, disease management, or enhanced quality of life. Risks encompass any potential adverse effects, complications, or safety concerns that may arise from the use of the drug. Evaluating the balance between benefits and risks is essential for determining whether the potential benefits outweigh the potential risks.

- **Evaluation of safety endpoints and efficacy outcomes:**

Benefit-risk assessment involves the evaluation of safety endpoints and efficacy outcomes measured during the clinical trial. Safety endpoints focus on monitoring and assessing the occurrence and severity of adverse events, while efficacy outcomes measure the drug's intended therapeutic effects and its ability to achieve desired clinical outcomes.

Both safety and efficacy data are analyzed and compared to determine the overall benefit-risk profile of the investigational product.

- **Role of pharmacovigilance in identifying safety signals:**

Pharmacovigilance plays a significant role in benefit-risk assessment by actively monitoring and identifying safety signals during clinical trials. Safety signals are indications of potential risks or new safety concerns associated with the investigational drug. Through systematic adverse event monitoring, analysis, and signal detection techniques, pharmacovigilance helps identify emerging safety issues, enabling timely risk assessment and management.

- **Making risk management decisions:**

Benefit-risk assessment informs the decision-making process regarding risk management strategies. If potential risks are identified, various risk mitigation measures can be implemented to minimize the occurrence or impact of adverse events. These may include dose adjustments, patient monitoring, safety monitoring committees, or modifications to the trial design or inclusion/exclusion criteria. By assessing the potential benefits and risks, appropriate risk management decisions can be made to ensure participant safety and maximize the benefit-risk balance.

- **Communicating benefit-risk information:**

Clear and transparent communication of benefit-risk information is crucial in clinical trials.

Participants, healthcare professionals, and other stakeholders need to be informed about the potential benefits and risks associated with the investigational drug. This enables informed decision-making, promotes participant understanding and autonomy, and ensures that participants can provide informed consent. Effective communication of benefit-risk information also contributes to building trust and confidence in the clinical trial process.

Benefit-risk assessment is an ongoing process throughout the clinical trial, starting from the design stage and continuing throughout the trial duration. It requires careful evaluation of safety and efficacy data, continuous monitoring of safety signals, and informed decision-making regarding risk management strategies. By systematically assessing the benefit-risk balance, researchers and regulatory authorities can make informed judgments about the safety and efficacy of investigational drugs, ultimately contributing to the development of safe and effective therapeutic interventions.

## 6. Emerging Trends and Technologies in Pharmacovigilance in Clinical Trials:

Pharmacovigilance in clinical trials is continuously evolving, and new trends and technologies are being adopted to enhance safety monitoring, signal detection, and risk assessment. Here are some of the emerging trends and technologies in pharmacovigilance in clinical trials:

- **Utilization of electronic data capture systems and e-health technologies:**

Electronic data capture (EDC) systems are increasingly being used to collect, manage, and analyze data in clinical trials. EDC systems streamline data collection processes, reduce errors, and facilitate real-time data access and analysis. In addition, e-health technologies, such as mobile apps, wearable devices, and remote monitoring tools, are being integrated into clinical trials to capture real-time patient-reported outcomes, adherence data, and physiological measurements. These technologies enable more efficient and comprehensive data collection, enhancing pharmacovigilance practices.

- **Integration of real-world evidence and patient-centered outcomes:**

The integration of real-world evidence (RWE) and patient-centered outcomes is gaining prominence in pharmacovigilance. RWE utilizes data from real-world clinical practice, electronic health records, claims databases, and patient registries to provide additional insights into the safety profile of investigational products. Patient-centered outcomes

focus on the perspectives and experiences of patients, allowing for a more comprehensive assessment of drug safety and efficacy. Incorporating RWE and patient-centered outcomes into pharmacovigilance



practices adds real-world context and patient perspectives to safety evaluations.

- **Application of data analytics, artificial intelligence, and machine learning:**

Data analytics, artificial intelligence (AI), and machine learning (ML) techniques are being leveraged to improve signal detection and risk assessment in pharmacovigilance. These technologies enable the analysis of large volumes of data, identification of patterns, and detection of safety signals that may go unnoticed with traditional methods. AI and ML algorithms can automate the detection of adverse events, classify and code safety data, and predict potential risks. They also facilitate data mining of various data sources, such as social media and electronic health records, for early identification of safety concerns.

- **Enhanced data visualization and interactive dashboards:**

Advanced data visualization techniques and interactive dashboards are being employed to present safety data in a more user-friendly and actionable manner. These tools allow for the visual exploration of adverse events, safety trends, and risk patterns. Interactive dashboards enable users to customize data views, drill down into specific subsets of data, and generate real-time reports. Enhanced data visualization facilitates better understanding and interpretation of safety data, aiding in timely decision-making and risk management.

- **Use of natural language processing (NLP) for adverse event detection:**

Natural language processing (NLP) techniques are utilized to automate the extraction of relevant information from unstructured text, such as electronic medical records, clinical notes, and scientific literature. NLP algorithms can identify and extract adverse event information, facilitating efficient adverse event detection and analysis. By automating the process of adverse event identification from text sources, NLP contributes to the timely identification and reporting of safety signals.

- **Pharmacogenomics and personalized medicine approaches:**

Pharmacogenomics, the study of how an individual's genetic makeup influences their response to drugs, is increasingly integrated into pharmacovigilance practices. By considering genetic variations and individual susceptibility to adverse drug reactions, personalized medicine approaches can help identify individuals at higher risk of developing adverse events. This allows for tailored monitoring and risk management strategies, optimizing participant safety in clinical trials.

These emerging trends and technologies in pharmacovigilance aim to enhance the efficiency, effectiveness, and comprehensiveness of safety monitoring and risk assessment in clinical trials. By adopting these advancements, researchers can improve participant safety, detect safety signals more accurately, and make informed decisions regarding the

## 7.Challenges and Future Directions in Pharmacovigilance in Clinical Trials:

Despite advancements in pharmacovigilance practices, there are several challenges that need to be addressed. Additionally, there are several potential future directions that can further enhance the effectiveness of pharmacovigilance in clinical trials. Here are some of the key challenges and future directions:

### Challenges:

**Global harmonization and standardization:** Achieving global harmonization and standardization in pharmacovigilance practices remains a challenge. Differences in regulations, reporting requirements, and data collection methods across countries can create inconsistencies and hinder efficient data sharing and analysis.

**Ethical considerations and participant rights:** Ensuring ethical conduct and protecting participant rights are ongoing challenges. It is important to maintain participant confidentiality, informed consent, and privacy while collecting, analyzing, and reporting safety data. Balancing the need for data transparency with participant confidentiality can be challenging.

**Transparency and communication:** Effective communication and transparency between stakeholders, including researchers, sponsors, regulatory authorities, and participants, are vital. Ensuring timely and accurate communication of safety information, adverse event reporting, and risk management decisions is essential to maintain trust and confidence in the clinical trial process.

**Digital innovations and data management:** The integration of digital innovations, such as electronic health records, mobile health applications, and wearable devices, presents challenges in terms of data management, data privacy, and interoperability. Developing robust systems to handle and analyze large volumes of diverse data while maintaining data integrity and privacy is critical.

**Adverse event detection and signal management:** The timely detection and management of adverse events and safety signals pose challenges, particularly when dealing with rare or long-term effects. Enhancing signal detection methods, improving data collection and analysis, and utilizing advanced analytics can aid in identifying potential safety concerns.

## **Future Directions:**

**Real-time monitoring and proactive pharmacovigilance:** Advancements in technology can enable real-time monitoring of safety data, allowing for proactive identification and management of safety signals. Continuous monitoring of patient data, integrating wearable devices, and utilizing real-world evidence can enhance safety surveillance during clinical trials.

**Integration of artificial intelligence and machine learning:** Further integration of artificial intelligence (AI) and machine learning (ML) techniques can support automated adverse event detection, signal identification, and risk prediction. AI algorithms can analyze large datasets, identify patterns, and generate real-time safety alerts, improving the efficiency and accuracy of pharmacovigilance processes.

**Patient engagement and participatory pharmacovigilance:** Involving patients as active participants in pharmacovigilance can enhance safety reporting and adverse event monitoring. Empowering patients to report adverse events directly, providing patient education and support, and leveraging patient-centered platforms can improve data collection and contribute to a more comprehensive understanding of drug safety.

**Use of real-world data and evidence:** The integration of real-world data (RWD) and real-world evidence (RWE) can provide a broader perspective on drug safety and effectiveness. Leveraging RWD from electronic health records, claims databases, and patient registries can complement clinical trial data and provide valuable insights into the long-term safety profile of investigational drugs.

**Collaboration and data sharing:** Strengthening collaboration and data sharing among stakeholders, including researchers, regulatory authorities, and industry sponsors, can improve the efficiency and effectiveness of pharmacovigilance. Sharing safety data, adverse event reports, and safety analysis findings can facilitate a more comprehensive understanding of drug safety and enable early detection of potential risks.

Addressing these challenges and embracing future directions in pharmacovigilance can lead to improved participant safety, more efficient detection of safety signals, and better-informed risk management decisions during clinical trials. By adopting innovative technologies, promoting collaboration, and prioritizing participant-centered approaches, pharmacovigilance

## 8. Conclusion:

Pharmacovigilance plays a crucial role in ensuring participant safety during clinical trials. This article has discussed the importance of pharmacovigilance in clinical trials and highlighted key processes involved in monitoring and reporting adverse events, maintaining data integrity, and assessing the balance between drug benefits and risks.

Adverse event monitoring and reporting are essential components of pharmacovigilance, involving the identification, classification, and timely reporting of adverse events. Data integrity and quality assurance processes are critical to ensure accurate and reliable data collection, coding, and analysis. Benefit-risk assessment allows for the evaluation of potential benefits and risks associated with investigational drugs, considering safety endpoints, efficacy outcomes, and the role of pharmacovigilance in identifying safety signals.

The article has also discussed emerging trends and technologies in pharmacovigilance in clinical trials. These include the utilization of electronic data capture systems, integration of real-world evidence and patient-centered outcomes, application of data analytics, artificial intelligence, and machine learning, and the use of natural language processing

for adverse event detection. These advancements aim to enhance safety monitoring, signal detection, and risk assessment.

However, several challenges need to be addressed, such as global harmonization and standardization, ethical considerations, transparency, and communication. Overcoming these challenges requires collaborative efforts and the adoption of digital innovations and robust data management systems.

The future directions of pharmacovigilance in clinical trials include real-time monitoring, proactive pharmacovigilance, integration of artificial intelligence and machine learning, patient engagement, utilization of real-world data and evidence, and enhanced collaboration and data sharing. These future directions aim to improve participant safety, enhance signal detection, and promote a more comprehensive understanding of drug safety.

In conclusion, pharmacovigilance is essential for participant safety during clinical trials. By implementing effective pharmacovigilance processes, addressing challenges, and embracing future directions, researchers, regulatory authorities, and stakeholders can enhance the safety and effectiveness of investigational drugs, ultimately contributing to improved healthcare outcomes.

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2. International Conference on Harmonisation (ICH): The ICH provides guidelines on various aspects of pharmaceutical development, including pharmacovigilance. The ICH E2A guideline, titled "Clinical Safety Data Management: Definitions and Standards for Expedited Reporting," provides recommendations for safety reporting in clinical trials.
3. Journal Articles: Scientific and medical journals often publish articles on pharmacovigilance in clinical trials. You can search databases like PubMed or other online resources to find relevant articles on the topic.
4. Pharmacovigilance Organizations: Organizations dedicated to pharmacovigilance, such as the International Society of Pharmacovigilance (ISoP) or the Drug Information Association (DIA), may provide resources and publications related to pharmacovigilance practice.
5. World Health Organization (WHO): The WHO provides guidelines and resources on pharmacovigilance, including those specific to clinical trials. Their website offers access to publications, reports, and guidelines related to drug safety and pharmacovigilance.
6. Clinical Trial Registries: Clinical trial registries, such as ClinicalTrials.gov, may include information about pharmacovigilance procedures and safety monitoring in specific trials. While they may not provide comprehensive guidelines, they can give insights into how pharmacovigilance is implemented in different studies.
7. Pharmacovigilance Textbooks: Textbooks on pharmacovigilance may cover topics related to participant safety in clinical trials. Examples include "Pharmacovigilance: Principles and Database Systems" by Patrick Waller and "Pharmacovigilance: A Practical Approach" by Ronald D. Mann.

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