Postgraduate Certificate in Pharmacovigilance

Pharmacovigilance in Clinical Trials

Pharmacovigilance is the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problem (WHO, 2021). In clinical trials, pharmacovigilance plays a crucial role in ensuring the safety and well-being of trial participants, as well as in providing reliable information about the benefits and risks of investigational products. This explanation will focus on key terms and vocabulary related to pharmacovigilance in clinical trials within the context of the Postgraduate Certificate in Pharmacovigilance.

1. Adverse Drug Reaction (ADR): An ADR is a harmful and unintended response to an investigational product related to any dose used for prophylaxis, diagnosis, or therapy (ICH E2A, 1995). ADRs can be mild, moderate, or severe and may require hospitalization, medical intervention, or result in disability or death.
2. Adverse Event (AE): An AE is any untoward medical occurrence in a patient or clinical trial participant administered a pharmaceutical product and which does not necessarily have a causal relationship with this treatment (ICH E2A, 1995). AEs can be any unfavorable and unintended sign, symptom, or disease, whether or not related to the investigational product.
3. Serious Adverse Event (SAE): An SAE is any AE that results in death, is life-threatening, requires inpatient hospitalization or prolongation of existing hospitalization, results in persistent or significant disability or incapacity, or is a congenital anomaly or birth defect (ICH E2A, 1995). SAEs should be reported promptly to regulatory authorities and ethics committees, as required by local regulations.
4. Unexpected Adverse Reaction (UAR): A UAR is any ADR that is not consistent with the summary of product characteristics or product information previously known for the investigational product (EMA, 2017). UARs should be reported promptly to regulatory authorities, as they may indicate new safety information.
5. Pharmacovigilance System: A pharmacovigilance system is a set of organized activities intended to detect, assess, understand, and prevent adverse drug reactions or any other drug-related problem (WHO, 2021). Pharmacovigilance systems should be in place during clinical trials to ensure the safety and well-being of trial participants.
6. Pharmacovigilance Plan: A pharmacovigilance plan is a document outlining the strategies and procedures for monitoring, assessing, and reporting safety information during a clinical trial (EMA, 2017). The plan should include the identification of potential risks, the reporting and escalation procedures for SAEs and UARs, and the methods for collecting, analyzing, and reporting safety data.
7. Risk Management Plan (RMP): An RMP is a document that outlines the measures to be taken to minimize the risks associated with an investigational product (EMA, 2017). The RMP should include the identification of potential risks, the mitigation strategies, and the monitoring and evaluation plan.
8. Signal Detection: Signal detection is the process of identifying new or changing safety issues related to an investigational product (EMA, 2017). Signal detection involves the analysis of safety data from various

sources, including clinical trials, spontaneous reports, and literature reviews.
9. Signal Management: Signal management is the process of evaluating, prioritizing, and acting on safety signals (EMA, 2017). Signal management includes the assessment of the significance and impact of the signal, the implementation of risk mitigation measures, and the communication of the signal to relevant stakeholders.
10. Safety Database: A safety database is a system for collecting, storing, and analyzing safety data from clinical trials (EMA, 2017). The safety database should be designed to capture all relevant safety information, including AEs, SAEs, and UARs, and should be able to generate reports and analyses to support safety evaluations.

Examples and practical applications:

Pharmacovigilance plays a critical role in ensuring the safety and well-being of trial participants and in providing reliable information about the benefits and risks of investigational products. Sponsors and investigators should be familiar with key terms and concepts related to pharmacovigilance in clinical trials and should establish robust pharmacovigilance systems and plans to monitor and manage safety data.

For example, a clinical trial investigator may observe a previously unknown ADR in a trial participant and report it as a SAE to the sponsor. The sponsor would then assess the SAE and determine if it is a UAR, which would require prompt reporting to regulatory authorities. The sponsor would also update the safety database and the pharmacovigilance plan to reflect the new safety information.

Additionally, the sponsor may conduct signal detection analysis to identify any new or changing safety signals related to the investigational product. If a safety signal is identified, the sponsor would then evaluate and prioritize the signal and implement risk mitigation measures as needed.

Challenges in pharmacovigilance in clinical trials may include the need for timely and accurate reporting of safety data, the complexity of safety data analysis, and the need to balance the benefits and risks of investigational products. Sponsors and investigators should be prepared to address these challenges and to work collaboratively to ensure the safety and well-being of trial participants.

Conclusion:

Pharmacovigilance is a critical aspect of clinical trials and plays a crucial role in ensuring the safety and well-being of trial participants. Sponsors and investigators should be familiar with key terms and concepts related to pharmacovigilance and should establish robust pharmacovigilance systems and plans to monitor and manage safety data. By working collaboratively and proactively, sponsors and investigators can ensure the successful conduct of clinical trials and the safe and effective use of investigational products.