



Understanding PSUR and DSUR in Pharmacovigilance

Pharmacovigilance, the science of detecting, assessing, understanding, and preventing adverse effects or any other drug-related problems, plays a crucial role in ensuring drug safety. Among the many regulatory requirements, Periodic Safety Update Reports (PSUR) and Development Safety Update Reports (DSUR) stand out as key documents in the pharmacovigilance landscape. These reports are essential for maintaining an ongoing assessment of the risk-benefit balance of medicinal products. Here, we delve into the purpose, structure, and importance of PSUR and DSUR in pharmacovigilance.

What is a PSUR?

A PSUR is a pharmacovigilance document intended to provide an update on the worldwide safety experience of a medicinal product at defined time points post-authorization. Its primary purpose is to ensure that regulators are consistently informed about the product's safety profile and any new risks that may emerge.

Key Elements of a PSUR:

1. Executive Summary: A brief overview of the report, including main conclusions and actions taken.
2. Introduction: Background information about the product, including its indications, dosage, and administration.
3. Worldwide Marketing Authorization Status: An update on the product's approval status across different regions.
4. Summary of Significant Findings: Data on adverse reactions, significant findings from post-marketing studies, and regulatory actions taken.
5. Signal and Risk Evaluation: Analysis of new safety signals and an updated benefit-risk assessment.
6. Effectiveness of Risk Minimization: Evaluation of how well the risk minimization measures are working.
7. Changes to Reference Safety Information: Updates on any changes made to the safety information provided with the product.

What is a DSUR?

A DSUR is required for drugs under clinical development. Its purpose is to provide a comprehensive annual review of the safety information gathered during the drug's clinical trial phase. The DSUR is designed to be in harmony with the International Conference on Harmonisation (ICH) guidelines and aligns closely with the US FDA's Investigational New Drug (IND) Annual Report.

Key Elements of a DSUR:

1. Introduction: Overview of the investigational product and its clinical development plan.
2. Worldwide Developmental Status: Information about the clinical trials being conducted globally, including phase and status.
3. Summary of Significant Findings: Highlights from clinical trials, including new safety data and significant findings from non-clinical studies.
4. Safety Information: Detailed data on adverse events, serious adverse events, and deaths, categorized by clinical trial phase.

5. Analysis of Patient Exposure: Data on the number of patients exposed to the drug, categorized by dosage and duration.
6. Cumulative Safety Information: An integrated analysis of all available safety data, including a benefit-risk assessment.
7. Summary of Important Risks: Discussion of new and emerging risks and how they are being managed.

Importance of PSUR and DSUR in Pharmacovigilance

Continuous Monitoring

Both PSURs and DSURs ensure continuous monitoring of a drug's safety profile. PSURs focus on the post-authorization phase, helping to identify any new risks that arise once the drug is on the market. DSURs, on the other hand, are crucial during the clinical development phase, ensuring that any safety concerns are identified and addressed before the drug reaches the market.

Regulatory Compliance

Regulatory authorities worldwide mandate the submission of these reports. Non-compliance can result in severe consequences, including withdrawal of the drug from the market or halting of clinical trials. Thus, timely and accurate submission of PSUR and DSUR is essential for maintaining regulatory approval.

Benefit-Risk Assessment

A thorough benefit-risk assessment is central to both PSURs and DSURs. These reports help in understanding whether the benefits of a drug continue to outweigh the risks, ensuring that only safe and effective drugs remain available to patients.

Enhancing Drug Safety

By compiling comprehensive safety data, these reports contribute to enhancing the overall safety of medicinal products. They provide valuable insights into the drug's performance in the real world (PSUR) and under clinical trial conditions (DSUR), allowing for informed decision-making by healthcare professionals and regulatory bodies.

Conclusion

PSURs and DSURs are indispensable tools in the pharmacovigilance arsenal. They ensure that drug safety is continuously monitored from the clinical trial phase through to post-marketing. By maintaining a robust framework for safety reporting, these documents help protect public health and maintain trust in pharmaceutical products. For companies, adhering to PSUR and DSUR requirements is not just about regulatory compliance—it's about demonstrating a commitment to patient safety and the responsible development of new therapies.



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