



DATA SHEET

Safety & PV

Cloudbyz Safety & Pharmacovigilance Solution is a cloud-based software solution designed to streamline the drug safety and pharmacovigilance operations for pharmaceutical and life science companies. The solution helps to automate the process of collecting, processing, analyzing and reporting adverse event data in compliance with global regulatory requirements. Cloudbyz Safety & Pharmacovigilance Solution enables companies to reduce risk, improve compliance, and enhance patient safety while accelerating drug development.



Key Features

Automated Case Intake

Cloudbyz Safety and Pharmacovigilance solution automates the intake of cases received from various sources and formats (ICH E2B R3/R2) by utilizing cutting-edge technologies. This entire process leads to significant increase in case management efficiency, scalability and enhanced accuracy.

Case Processing

Cloudbyz Safety and Pharmacovigilance solution enables resilient processes and ensures scalability along with end-to-end, individual or bulk case processing capabilities. This comprises multi-source case intake, validation, automated triage, user friendly data entry, medical reviews and submissions etc.

Single Source of Truth

The case management solution, which acts as a single source of truth for comprehensive and adaptable case management capabilities for future aggregate analytics and signal detection, is the foundational element of the Cloudbyz multivigilance system. It serves as the single repository for all information pertaining to adverse events, including source documents, follow-up details, coding, evaluations, and regulatory reports.

WHO DD/ MedDRA Medical Coding

Leveraging MedDRA or WHODrug drug dictionaries, Cloudbyz Safety and PV solution enables coding of adverse events, medical histories, laboratory tests, medications, and more.

Dynamic Auto Labeling

Dynamic auto labeling/ expectedness assessment provides detailed information for recording product and adverse event pair analysis to the case processing team.

Monitoring and Notifications

Cloudbyz Safety and PV solution offers faster monitoring and notification of adverse events through automated processes and risk-profile driven assessments. Also provide access to integrated safety technology solutions that allow for real-time data reviews and give complete control of adverse event data.

Auto Narratives & Medical Review

The Event Analysis functionality enables generation and review of narrative case descriptions. It supports additional data entry for generating the MedWatch 3500A and BfArM pharmacovigilance reports.

Configurable Workflow Automation

Cloudbyz PV solutions include workflow automation that is adaptable and agile, which makes case processing easier and faster. Improves the efficiency and scalability of the processing team to accommodate a variety of work instructions.

Regulatory Reports & e-Submissions

Submission of regulatory reports (ICH E2B R2/R3 XMLs, CIOMS, MedWatch, eMDR etc.) to regulatory bodies through manual and automatic regulatory report generation and submission. It enables comprehensive regulatory reporting which helps customers to attain compliance from start through completion.

Interactive Reports & Dashboard

Facilitates creation of striking, vibrant reports for C-suite executives and end-users to understand insights regarding daily pharmacovigilance operations with bundled reports.

AI/ML & NLP

Cloudbyz Safety and PV solution uses AI/ ML and automation to improve efficiency and user experience in multiple scenarios, including Case Management, Aggregate Reporting, and Signal Detection. This leading-edge, safety solution technology enables all stakeholders to access the same content, data and workflow within a single platform.

ICSR in E2B R2 & R3

Real-time import, export, and gateway submissions of ICSRs in E2B R2 & R3 XMLs that are easy to customize based on global reporting standards along with regional implementation conformance.

Benefits

Cloudbyz provides end-to-end management of the pharmacovigilance lifecycle, including adverse event processing, case management, regulatory reporting, signal detection, and risk management. With Cloudbyz, you can optimize your pharmacovigilance processes, accelerate case processing, and increase the accuracy of your safety data, while minimizing risk and ensuring compliance. The benefits of our solution are listed below-

- Improved Efficiency with Automation
- Increased data accuracy
- Real-time visibility
- Improved Collaboration
- Enhanced regulatory compliance

Cloudbyz solution is designed and built to be highly scalable, secure, and reliable, providing a robust and comprehensive solution for managing Safety & Pharmacovigilance processes. Our platform is built on cutting-edge cloud technology and is fully compliant with global regulatory standards. The benefits of the cloud platform are listed below-

- Real-time analytics using reports & dashboards
- Robust data security through fine-grained access control
- Deliver seamless processes through workflow orchestration
- Scalable Data processing & storage with audit trail
- Ease of integration through open APIs

System Requirements

- **Internet Connection:** The solution requires a stable internet connection to access the cloud-based platform.
- **Browser:** The solution supports the latest versions of Google Chrome, Mozilla Firefox, Microsoft Edge, and Apple Safari.
- **Device:** The solution is compatible with desktops, laptops, tablets, and smartphones running on Windows, MacOS, iOS, or Android.

Pricing

Cloudbyz Safety and PV solution offers a subscription-based pricing model, which is based on the module and per user per year.

Compliance

All Cloudbyz products and solutions are regulatory compliant. Security, privacy, compliance, and transparency are foundational pillars of our software development process and we ensure rigorous implementation of the same through several international standards, regulations and guidelines.

Our products and services meet below listed Standards, Frameworks and Guidelines. It includes national, regional, and industry-specific requirements governing the collection and use of data.

- ISO/ IEC 27001:2013
- ISO 9001
- Good Pharmacovigilance Practices (GPV)
- Good Clinical Practice (GCP)
- Good Automated Manufacturing Practice (GAMP 5)
- Health Insurance Portability and Accountability Act (HIPAA)
- 21 CFR Part 11
- General Data Protection Regulation (GDPR)
- California Consumer Privacy Act (CCPA)

Support

Cloudbyz Safety and PV solution provides 24/7 customer support through phone, email, and online chat. The solution also offers training and implementation services to ensure seamless deployment and adoption.

