BIOMAPAS

Whitepaper

Breaking the silos across Medical Information & Pharmacovigilance

Leveraging technology to gain operational efficiency for fully integrated Pharmacovigilance/ Medical Information processes

Introduction

Integrated Pharmacovigilance (PV) and Medical Information (MI) processes – following the Single Source of Truth (SSOT) framework – are indispensable for (Bio)pharmaceutical companies in ensuring patient safety, regulatory compliance, and operational efficiency. These processes enable proactive identification and management of Adverse Events (AEs) and Product Quality Complaints (PQCs), fostering trust and prioritising patient well-being.

Regulatory agencies impose strict requirements on (Bio)pharmaceutical organisations to monitor the safety profile of marketed drugs and assess their risk-benefit balance continuously. Compliance with these regulations necessitates robust PV/MI systems capable of capturing, analysing data, and reporting AEs and PQCs in a timely manner.

Integrated PV/MI systems facilitate seamless data aggregation and analysis, enabling companies to identify trends timely and respond promptly to inquiries from healthcare professionals and patients regarding product safety and efficacy, thereby enhancing transparency and accountability.

By automating routine tasks and providing real-time insights, organisations can increase operational efficiency and enhance responsiveness to safety queries. Ultimately, embracing technological innovations in PV/MI management is essential for maintaining competitiveness and fulfilling the mission of delivering safe and effective therapies to patients worldwide.

Background

Identifying Errors and Needs:

In the context of PV, MI, AEs, and PQCs within (Bio)pharmaceutical organisations, a comprehensive analysis was undertaken to evaluate potential solutions aimed at enhancing efficiency in cost, time spent on intake and processing, reducing compliance errors, and improving oversight and process streamlining. This analysis identified significant challenges associated with handling diverse data streams across organisations of varying sizes, portfolios, and capacities.

Establishing Objectives and Partnership:

Existing approaches showed limitations in consistency and integrity among local and global teams. Therefore, a solution that can centralise MI and PV activities was sought, while at the same time providing relevant tasks to local level in a user-friendly and efficient manner.

To address these challenges, a partnership with a technology provider was established to design and develop a cloud-based, omnichannel database for the intake and end-to-end management of MI, AE, and PQC data, using an SSOT framework. This innovative solution was intended to meet daily operational needs and provide a sustainable framework for future operations.

Solution Implementation:

The primary objective was to manage all types of intakes from various sources through a single interface. This system would automatically document incoming data, actions, decisions, and evidence in a common repository, eliminating the need for external tools such as call centres, content management systems, paper forms, mailboxes, and SharePoint.

Additionally, a task manager was integrated to facilitate the identification and tracking of relevant tasks, documentation of follow-up attempts, quality checks of AE/PQC translations, and accuracy of data entry, all within the database. The system's workflow automations, alerts, and notifications provided comprehensive oversight of pending actions.

Validating Usability and Effectiveness:

The usability and effectiveness of the system were validated through User Acceptance Testing and processing of mock cases, leading to system adaptations based on user feedback. Transition activities were meticulously planned, including the harmonisation of PV/MI/QA standard operating procedures (SOPs), communication protocols, change management strategies, and testing of integrations with safety databases. Extensive training was provided to end users to ensure a smooth transition and correct implementation of the new working practices.

Learning Objectives

- Understand the significance of consolidating Medical Information (MI), Adverse Event (AE), and Product Quality Complaints (PQC) intake & handling within a unified database system to secure the quality and safe use of medicinal products and medical devices as well as their consistent, compliant, and efficient handling.

- Prospect the benefits of automation and validation rules in day-to-day activities.

- Comprehend the value of using standardised AE/PQC forms for data capture to achieve integration and direct intake of outputs into Safety/Quality Databases.

- Acknowledge that MI is not only a legal requirement but also a valuable investment that can provide a competitive advantage to pharmaceutical companies through generation of insights and analysis of big data originating from AEs/MIs/PQCs.

- Explore the potential benefits of streamlining data management processes for patient safety, regulatory compliance, and product quality assurance.

- Recognise the value of having the ability to provide medical insights from MI/AE/PQC data, resulting in better awareness and comprehension of product use. In addition to the development of insight-driven decision-making, and its use as a tracking and repository tool.

- Evaluate the impact of integrated database solutions and processes on healthcare workflows and stakeholder collaboration, from Medical Affairs to Pharmacovigilance and Quality Assurance (QA).

- Recognise the importance of the collaborative endeavours between operational teams and technology providers in the development of databases tailored for effective healthcare data management. Additionally, emphasize the importance of establishing clear expectations and fostering successful collaboration to mitigate business disruption during system launches.

- Acknowledge the efficiency and reduced non-conformities of an integrated PV/MI operation and infrastructure.

Benefits of Implementing a Centralised Intake & Management System

The implementation of a single interface system for the omnichannel intake, triage, tracking, and handling of adverse events, product quality complaints, and medical information inquiries, significantly amplified internal and external efficiencies, providing a seamless integration of PV, QA, MI, and Medical Affairs departments. From initial user feedback and process, quality and efficiency parameters observed, significant enhancements in healthcare data management were noticed. Below are detailed observations and outcomes from the deployment of this system.

Enhanced Efficiency and Integration

The omnichannel inbox management system significantly enhances efficiency and accuracy in triaging and handling all the types of queries, ensuring consistency, integrity, and compliance throughout the case 'journey'. Operational teams manage intake and triage of different types of queries via various channels such as email, calls, CRM, and webforms, while overseeing and securing adherence to regulatory standards. Key benefits include:

- **Increased Efficiency:** The omnichannel inbox management system enhances the efficiency and accuracy of triaging and handling all types of queries, ensuring consistency, integrity, and compliance throughout the case journey. Operational teams manage intake and triage via various channels while adhering to regulatory standards.

- **Security & Data Integrity:** From integrated call centre operations and email receipt to the centralised content management system, task manager, and safety database integration, everything is housed securely in the same environment. This reduces fragmentation and prevents information dispersion across disparate systems.

- **Improved Data Management:** PV/MI tasks – such as auto-assignment of AE/MI/PQC unique number and link subcases, tracking and documentation of follow-up attempts, data entry quality check and translation review, structured forms for AE/PQC intake and reporting, and medical inquiries fulfilment – are all managed within the same platform. This consolidation enhances business continuity, reduces short- and long-term costs, and boosts productivity and compliance by providing a SSOT for all stakeholders involved in medical information, AE, and PQC handling.

Quality and Performance Improvements

The centralised system has demonstrated significant qualitative and quantitative improvements in managing PV and MI. The increased oversight of performance and actions taken resulted in less corrective actions and non-conformities in tracking and triaging data, responding to inquiries, and reporting safety data worldwide:

- **Reduced Non-Conformities:** Automation and validation rules do not allow inconsistencies in data entry, reporting and fulfilment, having diminished the non-conformities (CAPAs) by 80% since the implementation of the system.

- **Enhanced Quality KPIs:** The auto- or manually assigned tasks and the validation rules significantly contributed to the remarkable improvement of all quality KPIs. Quality checks revealed the need for 1% of cases' re-opening compared to previous 14%. We noticed a reduction to almost zero in terms of missing reports, tasks, and lost timelines. This is likely to be attributed to the clear workflow tasks with alerts and notifications.

- **Efficient Metrics and Analytics:** Metrics and analytics are now easier to access, and less time is spent on report generation due to streamlined processes and more user-friendly tools. The system's configurable nature allows for customisation to facilitate medical communication and interactive management of responses from global to local levels, avoiding duplication of efforts and risks associated with data transfer.

Productivity and Strategic Focus

An additional productivity increase could be attributed to the system's configurable and integrable nature. Based on the specific needs of ourselves and our clients, it could be tailored to facilitate medical communication and interactive management of responses from global to local levels. This avoids duplication of efforts and risks associated with data transfer, and it's achieved through integration with other systems such as safety databases, CRMs, and quality systems.

- **AI-Agent Assist:** The introduction of an AI-agent assist has enhanced productivity by suggesting real-time responses through approved content.

- **Reduced Administrative Tasks:** Increased productivity allows for more focus on strategic business, given that fewer resources are required for administrative tasks. Working on different systems and processes was discouraging in the past due to the extended manual efforts and complexity. Duplication of efforts and manual development of compliance reports and metrics was unavoidable without the support of advanced technology.

- **Team Motivation:** An unexpected benefit of implementing an end-to-end solution was team motivation. Retraining used to be done 3.5 times more frequently to get consistency in entries, responses, and achieve timelines. The demotivating retrainings, are now a thing of the past.

The past practical difficulties in regard to manual efforts and unnecessary complexity, prevented resources from focusing on what really matters: the continuous learning of operational teams for daily growth and development to offer a highly scientific service; and the increasing awareness of (bio)pharma products and their use to ensure quality and safety aspects.

Additional Features and Benefits

The system's configurable nature has addressed specific business needs, providing advanced features such as:

- **Content Management System:** An integrated content management system with full approval workflow capability has created a global repository of content where multiple teams can interact for the development and maintenance of FAQs, standard and customer responses. Its use elevated the quality, consistency, and relevance of responses with only the need of localisation at affiliate level, guaranteeing that external and internal stakeholders receive accurate and timely information.

- **Interactive Dashboards:** The creation of interactive and personalised dashboards showing critical compliance and other metrics – such as categories and topics for medical inquiries and PQCs – helped us with the timely identification of trends and generation of insightful analytics, empowering stakeholders to make informed decisions based on data-driven strategies.

- **Operational Oversight:** It is important to note that the interactive approach and operational oversight by the PV, MI, QA team leaders – among the others – was observed to enhance the transparency across the different functions and bring them working closer to prevent silos, misalignment, and communication issues.

Conclusion

With the rise of complex therapies and personalised medicines, the complexity in providing medical information and safety data analysis about the safety and efficiency of the innovative products has risen equally fast. The collaborative effort between operational teams and the technological service provider yielded a robust database solution for Medical Information (MI), Adverse Event (AE) and Product Quality Complaint (PQC) end-to-end management.

Using collaborative techniques and agile development concepts, a unified omnichannel platform was established, resulting in improved Medical Information management, Adverse Event (AE) and Product Quality Complaint (PQC) reporting service and data management capabilities.

Continued collaboration is critical for maintaining up to date skills and capabilities and the agility required to effectively address changing healthcare concerns and challenges within the Medical Information world. Ongoing collaboration fosters a culture of continuous improvement, enabling the adaptation of database solutions to evolve healthcare and business needs.

Overall, the end-to-end management - Single Source of Truth (SSOT) - platform, simplified data management operations, decreased duplication of efforts and increased operational efficiency. This strategy improves compliance, consistency and accuracy while also facilitates informed decision-making, ultimately resulting in better care for our patients.

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