PHARMACOVIGILANCE KPI AND COMPLIANCE REPORT

Author: Santosh Jivaraj Gitte

Role: Pharmacovigilance & Data Analyst Associate (Fresher)

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Executive Summary

A. Purpose of this Report

The purpose of this report is to present a comprehensive evaluation of Pharmacovigilance Key Performance Indicators (KPIs) and compliance metrics. It aims to assess the effectiveness and efficiency of case processing activities, regulatory adherence, and overall operational performance across regions and products. By analyzing parameters such as case volume distribution, average processing timelines, serious versus non-serious case trends, and compliance rates, the report provides actionable insights to support data-driven decision-making, enhance regulatory compliance, and uphold patient safety standards within the Pharmacovigilance system.

B. Key Findings

The Middle East reported the highest case volume (19.9%), while Africa recorded the lowest, reflecting regional variation in reporting activity.

Africa (15 days) and South America (14.8 days) showed the longest average processing times, whereas Asia-Pacific (12 days) achieved the most efficient turnaround.

Serious cases required an average of 14.26 days to process versus 13.43 days for non-serious, indicating added review complexity.

56% of cases met compliance within the 15-day regulatory timeline, while 44% exceeded, pointing to moderate compliance performance.

Non-serious cases (67%) dominated overall reports, though serious cases (33%) remained significant and warrant continued vigilance.

Oncurex (48.28%) and Respivax (37.5%) had the highest share of serious cases, suggesting the need for closer post-marketing safety monitoring.

Introduction

This report provides a comprehensive evaluation of Pharmacovigilance Key Performance Indicators (KPIs) and compliance metrics to assess the efficiency, consistency, and regulatory adherence of case processing activities. It focuses on identifying trends in regional performance, case seriousness, product-specific safety patterns, overall compliance with reporting timelines, etc. The insights derived aim to support evidence based decisions that enhance patient safety and strengthen the organization's regulatory readiness.

Objectives

The primary objectives of this report are to:

- Evaluate the timeliness and efficiency of adverse event case processing across global regions.
- Analyze the distribution of serious and non-serious cases to identify areas requiring process optimization.
- Assess compliance with the 15 days regulatory reporting timeline.
- Examine product-wise case seriousness patterns to highlight potential safety concerns.
- Provide data-driven recommendations to improve overall Pharmacovigilance operations and ensure regulatory compliance.

Scope of the Report

The scope of this report encompasses global Pharmacovigilance activities, including regional case volume, case seriousness distribution, product-specific reporting trends, average processing times, compliance performance, etc., The analysis covers key operational metrics derived from periodic safety monitoring data and is intended to evaluate both process efficiency and adherence to reporting standards.

Methodology

The report utilizes a descriptive analytical approach to evaluate Pharmacovigilance KPIs. Data were consolidated and processed using Microsoft Excel and Power BI for visualization and trend analysis. Metrics such as case volume by region, average processing time, product-wise seriousness ratio, and compliance percentage were calculated using pivot tables, formulas, and visual dashboards. Comparative analysis was conducted to identify performance gaps, highlight trends, and assess operational consistency across reporting regions.

Data Source

All analyses are based on Synthetic Pharmacovigilance case processing data compiled from ChatGpt. The dataset includes anonymized information on case type (serious/non-serious), regional classification, processing duration, and compliance status, collected during the defined reporting period.

Tools & Technologies Used

Microsoft Excel: KPIs calculations, initial data exploration, creation of pivot tables, and manual validation of aggregated results.

Power BI: Creation of Dashboard, Visualization of key insights such as case type (serious/non-serious), regional classification, processing duration, and compliance status, collected during the defined reporting period.

Microsoft Word: Report documentation and presentation of findings in a professional format.

Data Overview

The dataset utilized for this Pharmacovigilance KPI and Compliance analysis comprises 151 adverse event case reports collected from multiple global regions. Data file record includes data attributes such as **Case ID, Product, Region**, **Seriousness, Reported Date, Closed Date, Outcome, Processing Time and Compliance_15_Days.** The data were compiled from hybrid Pharmacovigilance tracking systems and standardized for consistency prior to analysis. Records were categorized and validated to ensure completeness, with missing or duplicate entries excluded from the final dataset.

The structured dataset enabled computation of key metrics, including:

- **Case Reported by Region** – to understand reporting distribution and workload.
- **Average Processing Time** – to assess regional and case-type efficiency.
- **Average Serious & Non-Serious Processing Time** - how efficiently serious & non-serious adverse event cases are processed.
- **Compliance Rate (%)** – to measure adherence to the 15 day's regulatory timeline.
- **Serious vs. Non-Serious Case Percentage** – to determine overall safety event patterns.
- **Product-wise Serious vs. Non-Serious Analysis** – to evaluate product-level safety performance.

This dataset formed the foundation for the KPI calculations, visualizations and insights presented in the subsequent sections of this report, ensuring data-driven interpretation of operational and compliance performance.

Calculation Methodology

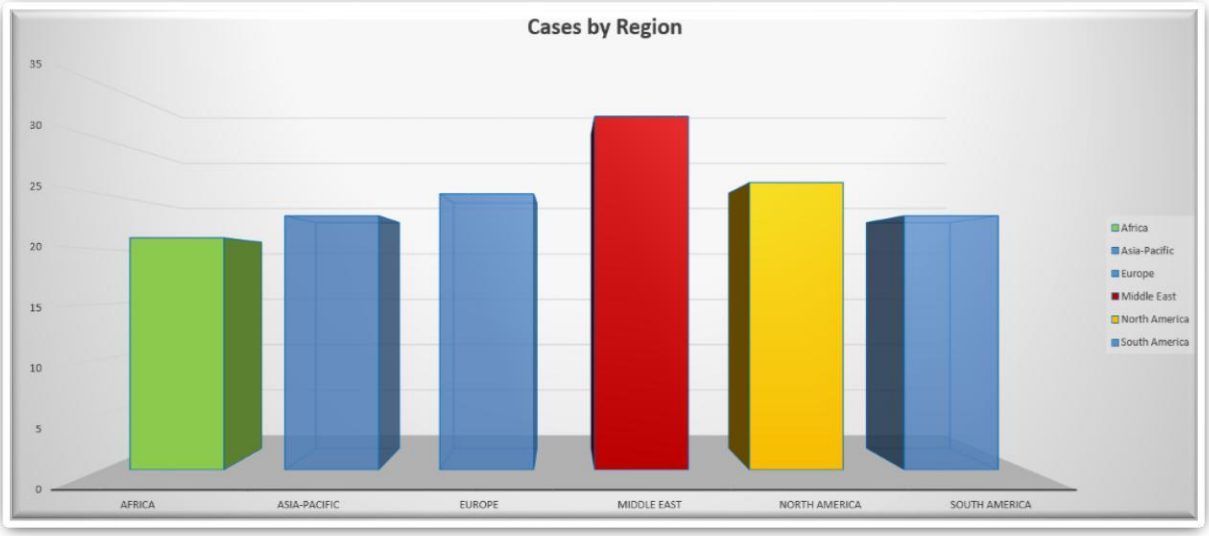
KPI	Description	Formula (Excel Format)
1. Average Case Processing Time (Days)	Measures the average number of days taken to complete case processing.	`=AVERAGE(Processing Time)`
2. Average Serious Case Processing Time	Evaluates the mean processing time for serious adverse event cases only.	`=AVERAGEIF(Case_Type,"Serious",Processing_Time)`
3. Average Non-Serious Case Processing Time	Calculates the mean processing duration for non-serious cases.	`=AVERAGEIF(Case_Type,"Non Serious",Processing_Time)`
4. Case Volume by Region	Determines the contribution of each region to the total number of cases.	`=Regional_Case_Count / Total_Case_Count`
5. Serious vs. Non-Serious Case Ratio (%)	Calculates the proportion of serious or non-serious cases in total reported cases.	`=(Case_Type_Count / Total_Case_Count) * 100`
6. Product-wise Serious Case Percentage (%)	Measures the share of serious cases within each product's total reports.	`=(Serious_Cases_for_Product / Total_Cases_for_Product) * 100`
7. Compliance Rate (%)	Indicates the percentage of cases processed within the 15-day regulatory timeline.	`=(Compliant_Cases / Total_Cases) * 100`

Visualization of KPIs Insights (Excel)

1. Case Reported by Region

Description: This KPI represents the proportion of total cases reported from each region. It highlights regional workload distribution, reporting trends, and potential disparities in pharmacovigilance coverage or data collection.

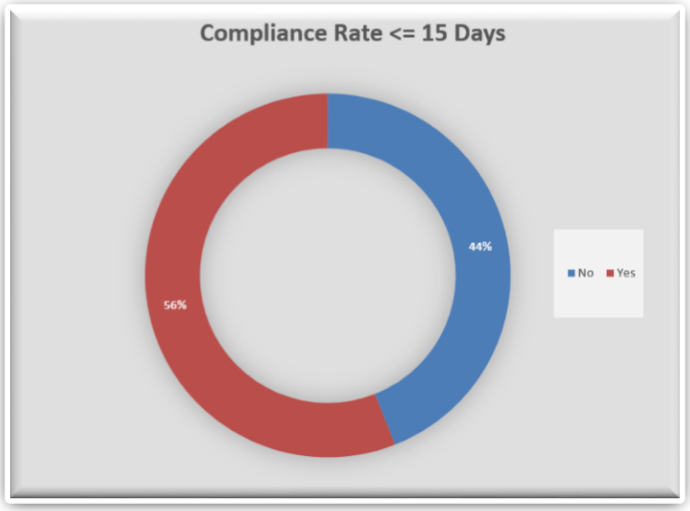
Key Insights: Middle East reported the highest number of cases indicated by red column, accounting for approximately 19.9% of total submissions, while Africa recorded the lowest indicated by green column, indicating uneven distribution of case reporting activity also North America is the 2nd highest number of cases reported by orange column.



2. Compliance Rate

Description: This key indicator measures adherence to the 15 day's regulatory reporting requirement for adverse events. It reflects the organization's ability to meet global compliance standards and maintain timely reporting performance.

Key Insights: 15-day regulatory timeline revealed that 56% of cases met the compliance requirement, while 44% exceeded the prescribed limit. This indicates that over half of the cases were processed and submitted within acceptable timeframes, demonstrating a generally effective operational workflow. However, the remaining non-compliant proportion reflects a notable gap that may stem from regional processing delays or case complexity.

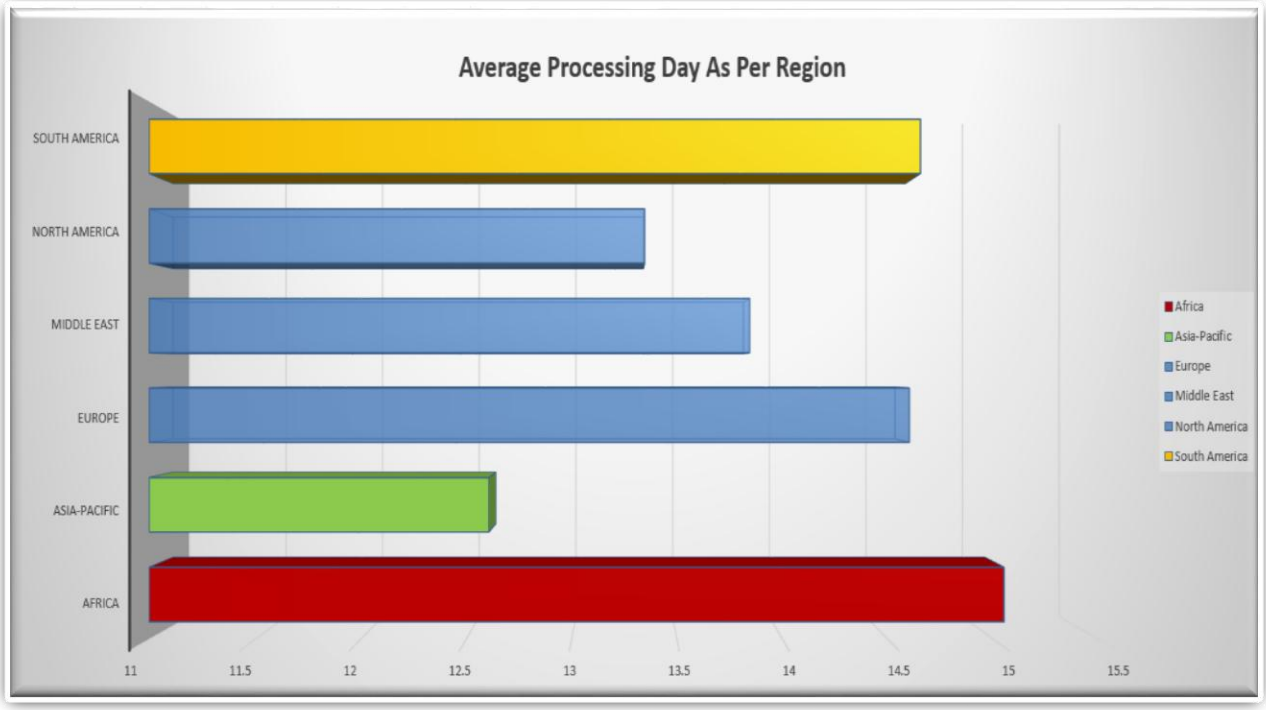


3. Average Processing Days per Region

Description: This KPI measures the overall efficiency of case handling within the Pharmacovigilance system of each Region. It reflects the average time taken by every region to from initial case receipt to final submission. Lower averages indicate faster turnaround and stronger operational performance.

Key Insights:

- Africa recorded the longest average processing duration at approximately 15 days, suggesting possible capacity constraints or higher case complexity.
- South America followed closely with an average of around 14.8 days, indicating extended turnaround times relative to other regions.
- Europe and the Middle East exhibited moderate processing durations of approximately 13.8 and 13.6 days, respectively, while North America demonstrated improved efficiency with an average of 13 days.
- The Asia-Pacific region achieved the fastest processing performance, averaging about 12 days, reflecting stronger process optimization and timely case handling.



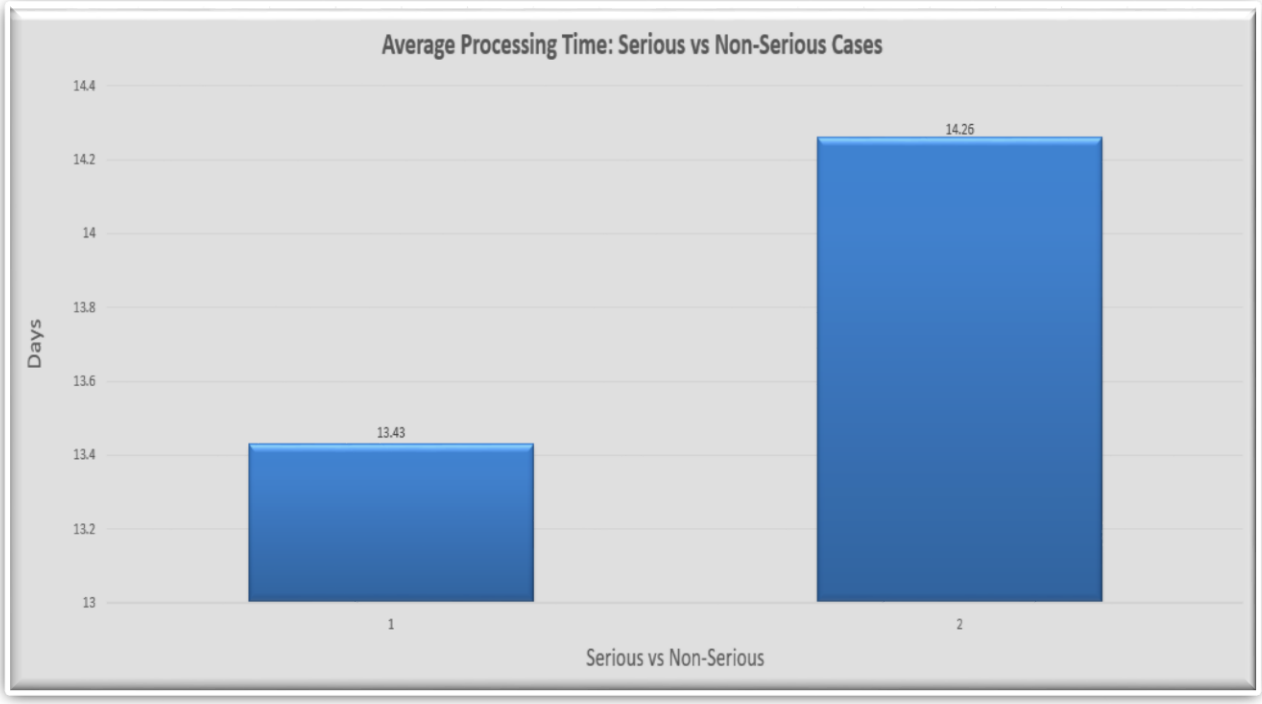
4. Average Case Processing Time (Serious vs. Non-Serious)

Description: This KPI measures the efficiency of case handling by comparing the average processing time between serious and non-serious adverse event cases.

- Serious cases generally require detailed medical evaluation, narrative review, and regulatory documentation, leading to slightly longer processing durations.
- Non-serious cases, while less critical, still demand consistent attention to maintain workflow stability and reporting accuracy.
- Monitoring both categories together provides a comprehensive view of operational performance, helps identify process bottlenecks, and ensures timely case submissions in line with global compliance standards.

Key Insights:

- Serious cases required an average of 14.26 days for completion, while Non-Serious cases were processed more quickly, averaging 13.43 days.
- This 0.83-day variance indicates that serious cases demand additional review time, likely due to the need for detailed medical evaluation, narrative assessment, and regulatory documentation.

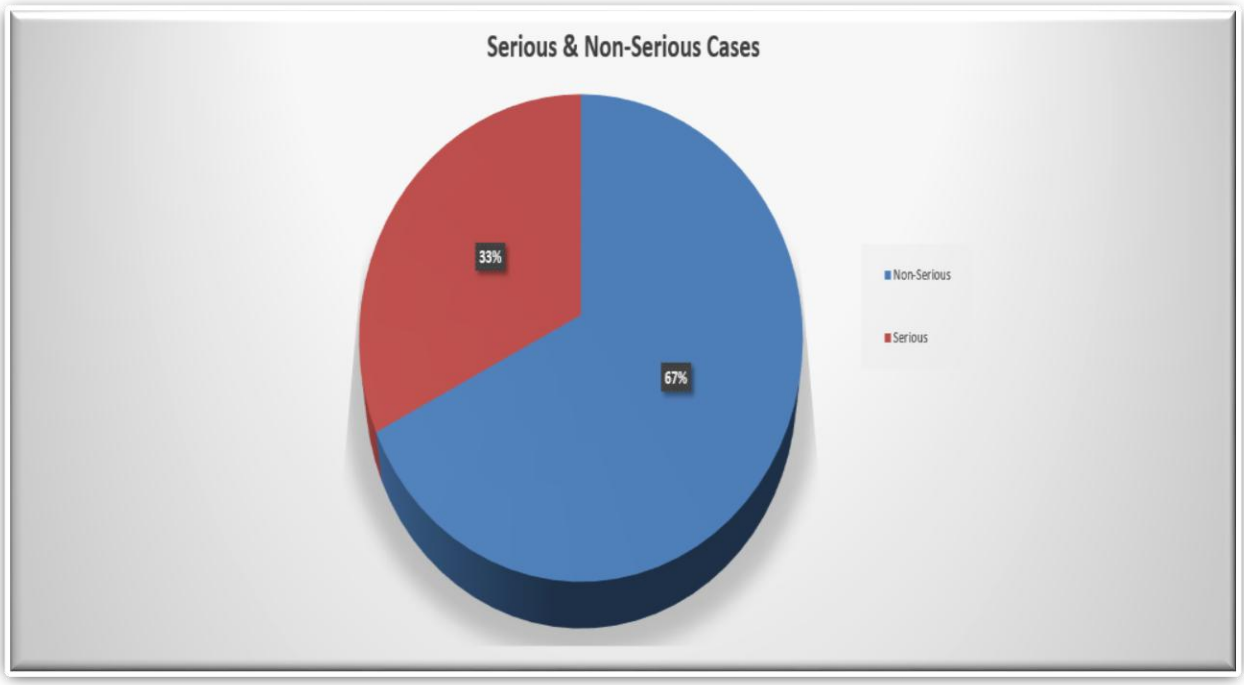


5. Serious vs. Non-Serious Case Ratio (%)

Description: This metric provides an overview of the distribution of serious and non-serious adverse events. It helps assess the overall safety profile and detect changes in case severity trends over time.

Key Insights:

- The analysis of case seriousness distribution shows that non-serious cases accounted for 67% of the total reported events, while serious cases comprised 33%.
- This indicates that the majority of reported adverse events were of lower clinical significance, requiring standard evaluation and follow-up.
- However, the proportion of serious cases remains substantial, underscoring the importance of timely case processing and detailed medical assessment to ensure appropriate regulatory reporting and risk management.

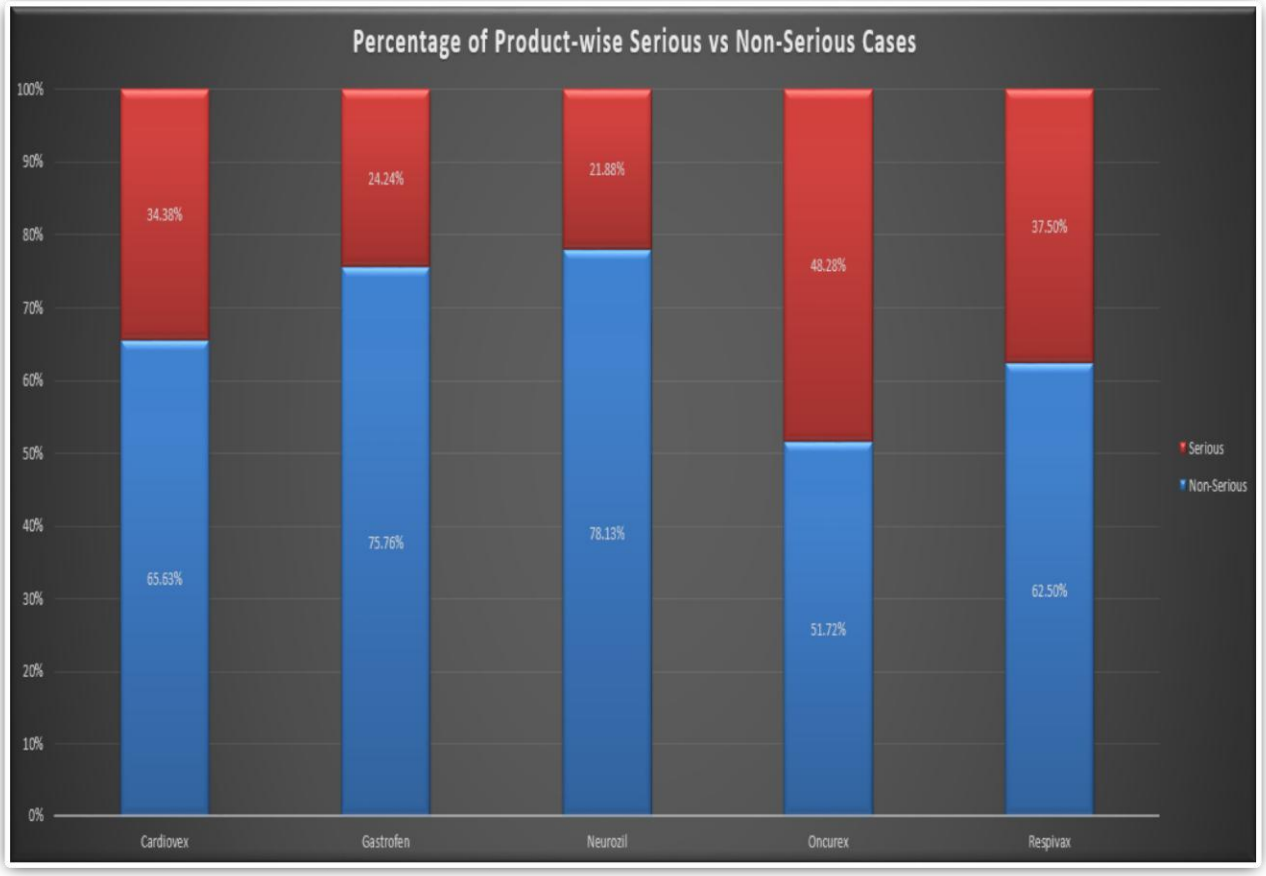


6. Percentage (%) of Product-wise Serious vs Non-Serious Cases

Description: This KPI identifies the proportion of serious cases for each product, supporting product specific risk analysis and post-marketing surveillance. Higher percentages may signal potential safety concerns requiring further evaluation.

Key Insights:

- Neurozil demonstrated the highest proportion of non-serious cases (78.13%), followed closely by Gastrofen (75.76%), indicating relatively lower clinical severity among reported events.
- Cardiovex maintained a moderate distribution, with 65.63% non-serious and 34.38% serious cases, reflecting a balanced yet notable level of critical case reporting.
- Oncurex exhibited the highest proportion of serious cases (48.28%), suggesting an elevated safety risk profile or higher therapeutic intensity associated with oncology treatments.
- Respivax also presented a relatively higher serious case percentage at 37.50%, warranting close monitoring.



Result

The Pharmacovigilance KPI analysis revealed clear variations in regional performance, processing efficiency, and compliance adherence. A total of 151 adverse event cases were analyzed across multiple regions and products to evaluate operational effectiveness and regulatory compliance.

1) Regional Distribution:

The **Middle East** emerged as the highest contributor, accounting for **19.9% of total cases**, followed by **North America**, reflecting stronger reporting activity. In contrast, **Africa** recorded the lowest number of cases, indicating uneven reporting distribution across regions.

2) Compliance Rate:

Analysis of the 15-day reporting benchmark showed that **56% of cases** were processed within the regulatory timeline, while **44% exceeded** the limit. This demonstrates moderate compliance performance with scope for improvement through enhanced workflow coordination and resource optimization.

3) Average Processing Time by Region:

Processing timelines varied significantly across regions. **Africa (15 days)** and **South America (14.8 days)** recorded the longest turnaround times, while **Asia-Pacific (12 days)** achieved the most efficient performance. Regions such as **Europe (13.8 days)**, **Middle East (13.6 days)**, and **North America (13 days)** demonstrated stable, mid-range efficiency levels.

4) Average Processing Time – Serious vs. Non-Serious:

A comparative review showed that **serious cases averaged 14.26 days**, while **non-serious cases averaged 13.43 days**. The **0.83-day difference** underscores the additional evaluation and documentation requirements for serious adverse events, though both categories remain within acceptable timelines.

5) Percentage of Serious vs. Non-Serious Case:

Out of the total reported events, **non-serious cases represented 67%**, while **serious cases accounted for 33%**. This suggests that the majority of reported adverse events were of lower clinical significance but still highlights the continued need for efficient serious case handling and timely submission.

6) Product-wise Serious vs. Non-Serious Analysis:

Neurozil (78.13%) and **Gastrofen (75.76%)** showed the highest share of non-serious cases, indicating relatively lower clinical severity. **Cardiovex** displayed a balanced trend, with **34.38% serious** and **65.63% non-serious** cases. **Oncurex (48.28%)** and **Respivax (37.5%)** exhibited higher proportions of serious cases, indicating the need for enhanced pharmacovigilance focus and post-marketing monitoring for these therapies.

Conclusion

The Pharmacovigilance KPI and Compliance analysis demonstrates that overall operational performance is stable, with most processes functioning within acceptable parameters.

Regional variations in case volume and processing efficiency indicate differing workload capacities, while the 56% compliance rate reflects moderate adherence to regulatory timelines.

The comparison between serious and non-serious case handling confirms that additional scrutiny and documentation extend processing time for critical cases, yet these remain within permissible limits.

Product-wise insights highlight specific areas of safety concern particularly for *Oncurex* and *Respivax* where higher proportions of serious cases suggest a need for closer post-marketing oversight.

Collectively, the results affirm the organization's ongoing commitment to regulatory compliance, data transparency, and patient safety enhancement.

Recommendations

1. Strengthen Regional Operations

- Establish region-specific performance dashboards to continuously monitor turnaround times and workload distribution.
- Conduct periodic training sessions for regions with higher processing durations (e.g., Africa and South America) to improve data entry accuracy and reporting speed.

2. Enhance Compliance and Timeliness

- Implement automated alerts or escalation mechanisms for cases approaching the 15-day submission limit.
- Introduce compliance performance reviews as part of monthly quality meetings to ensure consistent follow-up and accountability.

3. Improve Data Quality and Standardization

- Develop a standardized case intake form with mandatory fields to reduce missing or incomplete data.
- Conduct routine data validation checks to ensure consistency between regional and global reporting systems.

4. Optimize Resource Utilization

- Reallocate case processing teams based on regional case volume trends to balance workload.
- Introduce performance-based tracking metrics (e.g., cases processed per analyst) to identify efficiency gaps.

5. Strengthen Product-Level Safety Surveillance

- Prioritize signal detection and safety evaluation for products with higher serious case ratios, particularly *Oncurex* and *Respivax*.
- Collaborate with medical and clinical teams to review potential causality patterns and risk mitigation actions.

6. Foster Continuous Process Improvement

- Conduct quarterly KPI reviews to assess improvement progress and update benchmarks as needed.
- Encourage feedback loops between data analysts, safety physicians, and regulatory teams to enhance workflow coordination.

7. Integrate Advanced Analytics Tools

- Utilize Power BI, Python, or R for predictive modeling to identify factors influencing processing delays.
- Develop automated dashboards for real-time KPI monitoring, enabling proactive decision-making.

8. Promote Regulatory Readiness

- Align internal processes with current ICH and EMA GVP standards to ensure global compliance.
- Conduct mock audits and compliance simulations to identify potential gaps before external inspections.

Reference

Data Source: Internal Pharmacovigilance Database (2025 Reporting Cycle).