International Journal of Science and Research (IJSR)
ISSN: 2319-7064
Impact Factor 2024: 7.101

Improvement Opportunities in Aggregate Reporting Process by Applying DataOps and AIOps Framework

Rajashekhar Jayasheela[1], Udit Mathur[2], Md Tauseef Raza[3]

Abstract: ***The world of pharmacovigilance is at a pivotal turning point, with aggregate reporting no longer being a back-office compliance task but an essential driver of patient safety and regulatory precision. This article provides a layered exploration of how modern pharmacovigilance is evolving through intelligent integration of AI, automation, and data science. It is evident that emerging technologies-particularly when anchored by robust DataOps and AIOps frameworks-are not just streamlining reporting processes but fundamentally reshaping them. Companies are moving beyond manual, time-intensive systems toward agile platforms that support real-time analytics, predictive modeling, and tailored reporting across diverse regulatory landscapes. That said, adopting these innovations is not without challenges: data silos, legacy system integration, and regulatory variability remain persistent hurdles. Still, the narrative here is optimistic-through scalable infrastructure, process standardization, and intelligent automation, pharmaceutical organizations can now drive meaningful reductions in manual workload, improve accuracy, and achieve audit-readiness with consistency. The detailed case examples suggest that when operational frameworks align with cutting-edge technologies, they unlock measurable gains in speed, transparency, and compliance. Ultimately, this signals a shift toward a more proactive, resilient, and insight-driven pharmacovigilance future-one where patient safety is not just preserved but elevated through digital precision.***

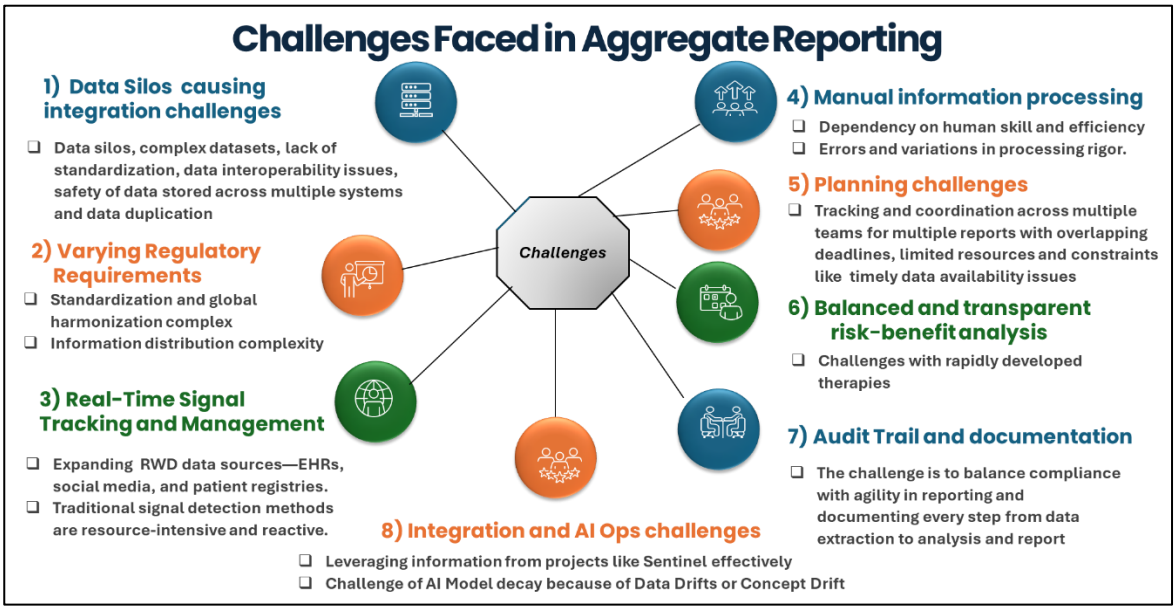
Keywords: pharmacovigilance automation, aggregate reporting, DataOps and AIOps, AI in safety monitoring, regulatory compliance

1. Overview

In today's fast-evolving pharmacovigilance landscape, aggregate reporting is undergoing a significant transformation, driven by advancements in technology and data science. Emerging trends like predictive analytics, real-world evidence integration, and cross-border data harmonization are reshaping how safety data is managed. Recent regulatory changes emphasize transparency, standardization, and global consistency, pushing companies to innovate while maintaining compliance.

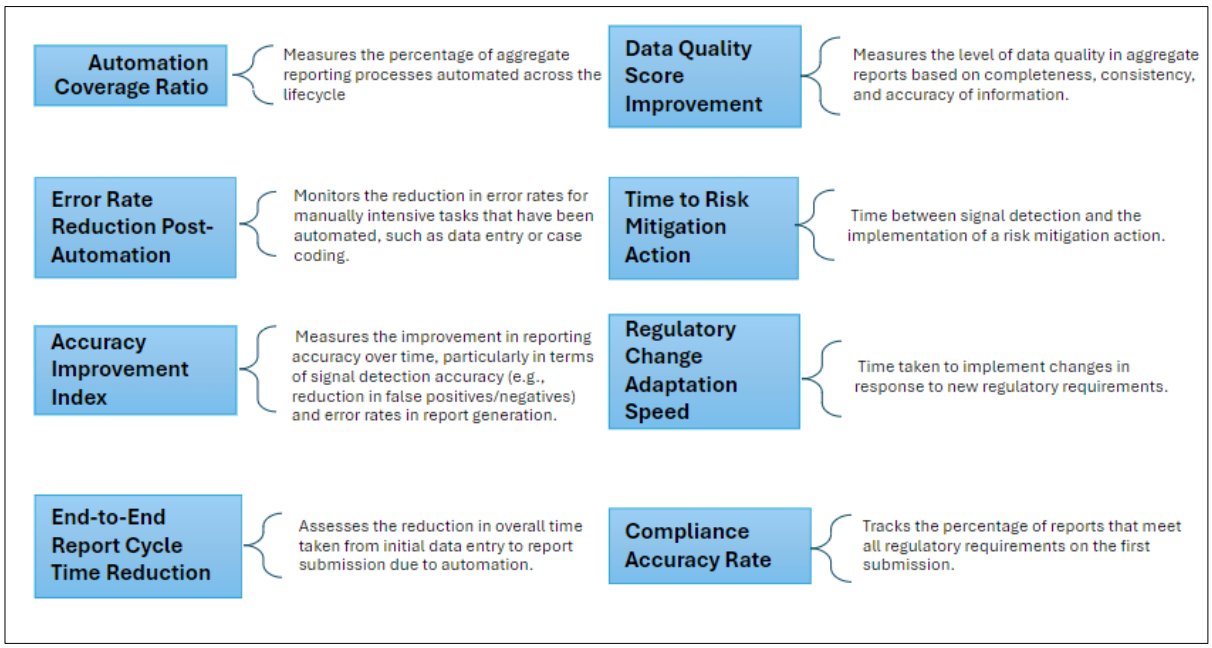
This white paper explores how existing practices can be enhanced using technology innovations and enhancements for redefining aggregate reporting, enabling timely and comprehensive safety assessments that align with the latest regulatory and industry expectations.

As regulatory expectations rise and patient safety remains paramount, organizations are increasingly turning to automation, AI, and real-time data analytics to enhance efficiency, accuracy, and transparency (TransPerfect Life Sciences). However, challenges persist, including data silos, evolving regulations, and a demand for skilled talent to interpret complex datasets. While advanced analytics and AI can enhance signal detection and data interpretation, integrating these technologies into legacy systems remains a challenge. Many companies face difficulties with standardization, data interoperability, and ensuring that AI outputs align with regulatory requirements. Some key challenges are depicted in below infographic.



Industry players use several strategies to overcome challenges, some key ones being 1) standardizing processes, templates, workflows and procedures, 2) using tools for automation and data integration, 3) leveraging tools for data validation, 4) using report structuring and automation tools, 5) mechanisms to get regulatory intelligence, 6) using process and tools for centralized planning and coordination, 7) leveraging tools for cross functional collaboration 8) CoE for knowledge retention, training/upskilling and outsourcing and etc.

To gauge the impact of transformation in aggregate reporting, transformational KPI can be used to measure improvement like degree of automation, analytics adoption, time for risk mitigation, data quality improvement, reduction in end-to-end cycle time for report preparation, measuring improvements in compliance accuracy:



In its engagement with leading pharma companies, TCS helped achieve 100% regulatory compliance with zero critical findings while reducing delays. TCS ADD platform enhanced consistency and operational excellence while delivering an unmatched user experience improving productivity by up to 60%, and reduction of workload by 30% while manual error rate ~4%, and ensuring 100% regulatory compliance.

TCS has a proven track record in delivering transformative medical writing solutions that enhance efficiency, accuracy, and compliance for pharmaceutical companies. For a Europe-based pharma company, TCS helped the client developed 800 high-quality, scientifically accurate narratives for a Phase 3 trial in just one month, achieving a 70% effort reduction, 100% data accuracy, and enabling timely regulatory submission with minimal oversight. For a global Swiss-based pharma leader, TCS digitized scientific content creation using AI-ML and NLP technologies, reducing document finalization time by 40%, improving accuracy, and unlocking historical product knowledge, enabling seamless regulatory compliance and data-driven decision-making.

Our PV Pharmacovigilance and Generative AI (GenAI) and AI solution teams are working to realize potential to automate aggregate reporting in pharmacovigilance by processing large datasets, identifying patterns, and generating insights with unparalleled speed and accuracy using models for automating repetitive tasks such as drafting narrative summaries, creating structured outputs, and cross-referencing regulatory requirements, significantly reducing manual effort and error rates. AI-powered tools enhance consistency and compliance by ensuring adherence to global regulatory standards while offering real-time insights for proactive risk management, streamline workflows, personalize outputs based on specific regulatory or organizational needs, and continuously learn from historical data.

While technology applications like AI, ML, NLP, and automation are crucial for improving PV aggregate reporting, their success and sustainability depend on strong operational frameworks provided by DataOps and AIOps. DataOps (www.sprinkle.com, 2024) (AIOps: A holistic approach to operationalizing AI, 2024) and AIOps (AIOps: A holistic approach to operationalizing AI, 2024) are enterprise-wide operational frameworks that extend beyond specific domains like pharmacovigilance (PV) and aggregate reporting, forming the backbone for technology-driven improvements across all areas of an organization. When applied to PV and aggregate reporting, these concepts ensure seamless integration, automation, and optimization while aligning with the organization's broader data and AI strategies. These concepts ensure data quality, process efficiency, and system reliability, making aggregate reporting more accurate, scalable, and compliant in the long term. Technology applications for improving PV aggregate reporting, such as AI, ML, and automation, can only succeed on a sustainable basis if they are supported by robust DataOps and AIOps frameworks. These operational concepts ensure that technology implementations are scalable, efficient, and aligned with regulatory and organizational goals.

DataOps and AIOps enable sustainable technology application by providing following advantages

1) Foundation for AI/ML Tools:
- DataOps creates the infrastructure for clean, harmonized data, which is essential for training and deploying AI/ML models effectively.
- AIOps ensures these models are monitored, optimized, and updated for changing requirements.

2) Continuous Data Integration and Quality:
PV aggregate reporting relies on harmonized data from diverse sources like safety databases, EHRs, and clinical trials. DataOps ensures:
- **Seamless Integration**: Automates data pipelines for ingestion and transformation.
- **Data Quality**: Implements governance frameworks for cleaning and validating data.
- **Collaboration**: Enables cross-functional teams to work with synchronized, real-time data.

3) Reliability and Compliance:
- DataOps ensures that data flows are resilient, reducing downtime or errors during aggregate report preparation.
- AIOps continuously monitors system performance, ensuring reliability and compliance with minimal manual intervention.

4) Proactive Monitoring and Automation:
AIOps uses AI and ML to monitor systems and detect anomalies, ensuring that data pipelines and reporting processes run smoothly. This includes:
- **Anomaly Detection:** Identifying inconsistencies or errors in safety data.
- **Predictive Analytics:** Forecasting potential risks or bottlenecks in reporting workflows.

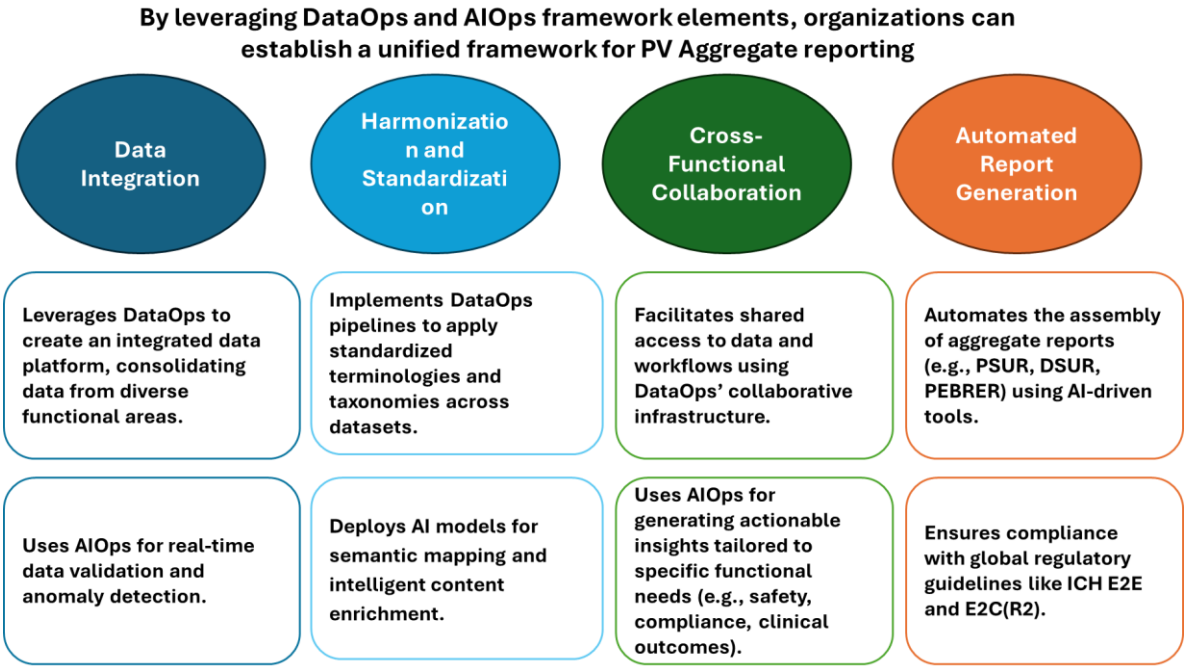
5) Compliance and Audit Readiness:
- DataOps and AIOps maintain audit trails, versioning, and real-time monitoring to support regulatory audits and reduce compliance risks.
- DataOps ensures that all data is aligned with global regulatory frameworks such as ICH E2E and E2C (R2), reducing compliance risks and enabling consistent reporting.

6) Continuous Improvement:
- Feedback loops enabled by DataOps and AIOps allow organizations to refine processes, improve efficiency, and adapt to new challenges in PV reporting.

7) Scalability and Adaptability:
- With the growing volume and complexity of PV data, DataOps facilitates scalability by automating workflows and enabling rapid adaptation to new data sources or regulatory requirements.

8) Enhanced Efficiency and Accuracy:
- By automating repetitive tasks like data extraction, signal detection, and narrative drafting, AIOps reduces human effort while improving accuracy and consistency.

9) Enhanced customizability in Aggregate Reporting:
- DataOps and AIOps frameworks enable flexibility and scalability to tailor aggregate reports, such as PSURs, DSURs, and PBRERs, to meet the specific needs of regulatory authorities, organizational goals, and diverse stakeholder requirements.
- For region-specific reports, DataOps can automatically extract and format country-specific data (e. g., EU-specific PSUR vs. US FDA submissions) and enable selective inclusion of patient demographics, sub-population analyses, or geographic trends based on the report's requirements.
- DataOps creates modular data pipelines that aggregate and harmonize data from diverse sources (e. g., safety databases, EHRs, claims, registries) and allows customization of data extraction rules to tailor the datasets included in reports for specific regulatory or organizational needs.
- AIOps provides real-time dashboards and alerts for reporting progress, safety signals, and compliance status, enabling faster decision-making.



Expected improvement to Aggregate Reporting

- Efficiency: 40–60% reduction in manual effort through automated data pipelines and report generation.
- Accuracy: 100% compliance with regulatory requirements by harmonizing data and detecting errors early.
- Scalability: Seamless handling of increasing data volumes and complexity as pharmaceutical portfolios expand.
- Timeliness: Faster report submissions by reducing delays in data preparation and analysis.

2. Conclusion

The Aggregate reporting process in pharmacovigilance plays a critical role in ensuring patient safety and regulatory compliance. However, the increasing complexity of global regulations, the growing volume of real-world data, and the need for timely and transparent risk-benefit analyses present significant challenges. Addressing these challenges requires a strategic and innovative approach involving leveraging elements from enterprise-wide operational framework like DataOps and AI Ops that drive efficiency, accuracy, and compliance across all functions. By applying these concepts to PV, organizations can leverage a unified, scalable infrastructure to transform aggregate reporting, ensuring regulatory readiness and operational excellence while aligning with broader enterprise goals.

By adopting these elements organizations can eliminate data silos and discrepancies, ensuring a single source of accurate and reliable data. Leveraging artificial intelligence and advanced analytics transforms traditional processes, allowing for proactive signal detection, enhanced insights, and improved decision-making. AI-powered risk-benefit analysis further ensures that safety and efficacy evaluations are accurate, transparent, and aligned with regulatory expectations. Empowering users with customizable reporting tools enables faster adaptation to dynamic regulatory requirements without depending on IT support.
Implementing these solutions not only improves the efficiency and quality of aggregate reporting but also future-proofs pharmacovigilance systems to handle the growing complexities of modern healthcare. Companies that invest in these technologies and methodologies will not only achieve compliance but also position themselves as leaders in patient safety and regulatory excellence.

In conclusion, transforming aggregate reporting through harmonization, AI, and analytics is no longer an option but a necessity for organizations striving to meet evolving pharmacovigilance demands. A proactive, technology-driven approach will ensure better regulatory outcomes, faster time-to-market for therapies, and, most importantly, enhanced patient care.

References

[1] *AIOps: A holistic approach to operationalizing AI*. (2024, Oct 31). Retrieved April 17, 2025, from www.slalom. com: https: //www.slalom. com/us/en/insights/aiops-holistic-approach-to-operationalizing-ai#: ~: text=AIOps%20is%20the%20critical%20practice, %2C%20monitoring%2C%20and%20continuous%20optimization.
[2] *DataOps and AI: Unleashing the Power of Data for Machine Learning*. (2023, October 19). Retrieved April 17, 2025, from www.linkedin. com: https: //www.linkedin. com/pulse/dataops-ai-unleashing-power-data-machine-learning-paly-paul-varghese-z3rnf/
[3] TransPerfect Life Sciences. (n. d.). *The Ultimate Guide to AI in Pharmacovigilance and Safety Reporting.* Retrieved April 17, 2025, from https: //lifesciences. transperfect. com/: https: //lifesciences. transperfect. com/resource/white-paper/clinical-research/transforming-pharmacovigilance-ai-and-automation
[4] www.sprinkle. com. (2024, Sept 9). *DataOps Best Practices: Enhancing Data Quality, Management, and Operations*. Retrieved April 17, 2025, from www.sprinkle. com: https: //www.sprinkledata.

com/blogs/dataops-best-practices-enhancing-data-quality-management-and-operations

Author Profile

Dr Rajashekhar Jayasheela
External designation: **Domain consultant**
Role: **Offering lead**
Domain/area of expertise (relevant to the asset): **Pharmacovigilance**
Years of experience (optional): **19 years**
E mail**: jayasheela.rajashekhar[at]tcs.com**
Dr Jay is a pharmacovigilance leader with over 22 years of work experience in core pharmaceutical organizations with consulting, innovative portfolios, outsourcing partners, CROs, and academia. With more than 19 years of experience in pharmacovigilance operations and consulting, he brings vast knowledge and exposure to expanding the PV footprint globally.

Udit Mathur
External designation: **Consulting Partner**
Role: **Business Process Consulting lead – Life Science and Health Care**
Domain/area of expertise (relevant to the asset): **Lean Business Process Consulting, Business Value Engineering and Pharmacovigilance**
Years of experience (optional): **31 years**
E mail**: udit.mathur[at]tcs.com**
Udit Mathur is a seasoned business process consulting leader, domain expert, and architect with over 30 years of experience, specializing in driving process improvement, innovation and operational excellence in life sciences and healthcare. Udit leads a lean process improvement team that works on transforming complex workflows to enhance efficiency and compliance in pharmacovigilance and patient safety, through innovative solutions and value management.

Md Tauseef Raza
Author name: **Tauseef Raza**
External designation: **Business process analyst**
Role: **Business process analyst-Life Science and Health Care**
Domain/area of expertise (relevant to the asset): **Lean Business Process Consulting and Pharmacovigilance**
Years of experience (optional): **2 years**
Email: **mt.raza[at]tcs.com**