Self-Reflection on the Literature Review: *Machine Learning Approaches for Medication Safety Analysis*

Writing this literature review enabled me to draw on my dual background as a data scientist in the pharmaceutical industry and as a medical doctor experienced in clinical research. The task provided a structured opportunity to bridge quantitative analytics with clinical reasoning, critically examining how machine learning (ML) can enhance medication safety across the drug-development and post-marketing continuum. It deepened my appreciation of how methodological innovation, clinical insight, and regulatory oversight must converge to deliver trustworthy, real-world impact. I have structured my reflection below in line with the instructions and grading criteria.

Knowledge and understanding

I began by framing medication safety as a public health priority, supported by WHO data and large-scale observational studies. My medical background helped me interpret the clinical consequences of adverse drug events (ADEs) and adverse drug reactions (ADRs), while my data-science perspective clarified how digital infrastructures and algorithmic models can improve surveillance sensitivity and timeliness. Reviewing the shift from spontaneous reporting systems to real-world data (RWD) sources allowed me to connect clinical pharmacovigilance concepts with modern informatics approaches. Understanding how ML handles complex, high-dimensional datasets reinforced my grasp of its potential to complement, rather than replace, traditional evidence-generation processes.

Use of relevant sources

I deliberately combined seminal AI references (Jordan and Mitchell, 2015; Russell and Norvig, 2021) with current regulatory and empirical works (Ball et al., 2024; EMA, 2024a,b). This integration reflected my awareness of the translational pipeline from academic innovation to regulatory acceptance and clinical application. Reading recent case studies and reviews expanded my perspective on ML's role not only in pharmacovigilance but also in clinical trial monitoring, error prevention, and signal detection. However, I recognised a lack of representation from low-resource settings and early-phase clinical environments, a gap that future research should address.

Criticality

My clinical experience made me attentive to patient safety implications, while my data-science training prompted scrutiny of model assumptions, validation, and bias. I evaluated supervised and unsupervised ML paradigms, considering their trade-offs between accuracy, interpretability, and scalability. Drawing parallels with clinical-trial methodology, I reflected on the importance of external validation and reproducibility as equivalents to multicentre study replication. Recognising that opaque models can undermine clinical trust, I emphasised explainability as a prerequisite for regulatory and ethical acceptability. Future work could benefit from a more systematic comparison of evaluation metrics across datasets.

Structure, presentation, and academic integrity

I structured the review to progress from conceptual background to technical methods, applications, limitations, and future directions. Using Harvard Cite Them Right referencing reinforced transparency and traceability. Translating technical concepts into concise, academically rigorous prose was challenging but strengthened my communication skills, which

are essential for interdisciplinary collaboration between clinicians, data scientists, and regulators.

Personal development and learning

This assignment consolidated my ability to synthesise interdisciplinary knowledge and critically evaluate emerging evidence. It reaffirmed that improving medication safety requires not only algorithmic precision but also clinical validity, interpretability, and ethical governance. The process enhanced my confidence in bridging scientific, technical, and regulatory perspectives. vital skills for advancing safe and evidence-based integration of ML into pharmaceutical research and patient care.