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ENHANCED POST-MARKETING SURVEILLANCE OF AI SOFTWARE AS A MEDICAL DEVICE: COMBINING RISK-BASED METHODS WITH ACTIVE CLINICAL FOLLOW-UP

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ABSTRACT

Artificial intelligence (AI) is revolutionizing healthcare and software as a medical device (SaMD). The implementation of AI-based SaMDs can increase diagnostic accuracy, individualize care pathways, and expedite the healthcare process. However, these technologies have their own safety, efficacy, and regulatory compliance challenges. Frequent post-marketing surveillance (PMS) is necessary due to the dynamic nature of AI SaMD, which evolves with the collection of new data in real-world clinical settings. Traditional risk-based strategies are inadequate for efficiently managing AI SaMDs. The proposed, enhanced PMS model combines real-time risk evaluation with active clinical follow-up to expedite the detection and rectification of emerging safety issues. This proposed approach includes real-time performance monitoring, compliance with regulations, and consistency checks of performances to ensure safety and effectiveness over time for AI SaMDs. The authors evaluated their method using ablation studies and comparative analyses, with accuracies exceeding 93% over prior works in terms of risk minimization, fusion capacity on the data level between models, and regulatory compliance. This addresses the myriads of AI challenges present in medical applications that are otherwise a threat to patient safety and regulatory credibility.

KEYWORDS: *Artificial Intelligence (AI), Software as a Medical Device (SaMD), Post-Marketing Surveillance (PMS), Risk Assessment, Active Clinical Follow-Up, Real-Time Data Monitoring.*