A guide for Authors submitting manuscripts incorporating AI, Deep Learning or Machine Learning methods to the *IEEE Journal of Translational Engineering in Health and Medicine.*

Artificial Intelligence and the subthemes of Deep and Machine Learning have emerged as powerful tools with profound and far-reaching positive implications for health, revolutionizing various aspects of medical practice and patient care. We have seen examples of improved diagnosis and treatment, enhanced patient monitoring and management, as well as improved drug discovery and development. However, there has been less progress in using AI tools in other areas, such as healthcare resource optimization, specifically in predicting patient admissions, optimizing the allocation of healthcare resources or staff schedules, and identifying inefficiencies in hospital operations.

As the *IEEE Journal of Translational Engineering in Health and Medicine*, we are keen to publish studies incorporating AI methods that have been translated into clinical environments.

The translation and implementation of AI methods into clinical environments have often struggled due to their difficulty in generalizing systems trained on small datasets to actual patient data. However, to publish in the *IEEE Journal of Translational Engineering in Health and Medicine* validating AI methods on real patient data is crucial to ensure their reliability, robustness, and applicability to healthcare and clinical scenarios. Such testing data is imperative for several critical reasons that stem from the potential impact of these technologies on patients and clinicians, the clinical environment and the healthcare system. As AI systems become increasingly integrated into healthcare environments, ensuring ethical and responsible use of these technologies becomes paramount.

The efficacy of healthcare AI systems is typically reported in submitted manuscripts using a combination of quantitative metrics, qualitative evaluation, and validation against established clinical standards or clinical guidelines. However, The Editorial Board of the *IEEE Journal of Translational Engineering in Health and Medicine* looks to ensure that a number of extra points are addressed in submitted manuscripts:

Clinical Validation: Manuscripts reporting healthcare AI systems must undergo rigorous clinical validation to ensure their safety, effectiveness, and accuracy in real-world clinical settings. This should involve testing the AI system's performance on diverse patient populations, including different demographic groups, disease severity levels, and comorbidities. Clinical validation studies should involve collaboration with national healthcare regulatory agencies to design robust study protocols and obtain necessary approvals.

Clinical Impact: Besides technical performance metrics, submitted manuscripts should report the efficacy of healthcare AI systems based on their clinical impact and utility. This includes assessing whether the AI system improves patient outcomes, clinical decision-making, workflow efficiency, resource utilization, and overall quality of care. Clinical impact studies should involve observational studies or real-world implementation studies conducted in clinical practice settings.

Interpretability and Explainability: manuscripts describing healthcare AI systems should be interpretable and explainable to clinicians and end-users. Assessing the interpretability and explainability of AI models involves evaluating the transparency of model predictions, identifying the factors influencing model decisions, and assessing the clinical relevance and trustworthiness of AI-generated recommendations. Transparency and accountability are essential for building the trust of patients and the clinical community in AI technologies and mitigating potential risks.

Robustness and Generalization: Healthcare AI systems should demonstrate robust performance across diverse and challenging scenarios, including variations in data quality, noise, missing data, and adversarial attacks. Robustness testing involves evaluating the AI system's performance under different conditions and assessing its ability to generalize to unseen data and real-world clinical settings.

Ethical and Regulatory Compliance: Lastly, the efficacy of healthcare AI systems is evaluated based on ethical considerations and regulatory compliance. This includes ensuring patient privacy, data security, fairness, bias mitigation, and compliance with relevant healthcare regulations and standards, such as the Health Insurance Portability and Accountability Act (HIPAA) in the United States or the General Data Protection Regulation (GDPR) in Europe.

The *IEEE Journal of Translational Engineering in Health and* Medicine is keen to publish manuscripts reporting the translation and efficacy of healthcare AI systems once they address the points above.

We look forward to hearing from you.