Seminar on

Artificial Intelligence and Machine Learning — The perspective from a FDA project

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JABSOM MEB, Grid room 202

Artificial intelligence (AI) has made a significant mark in the past decade and demonstrated its utility in the broad area of predictive medicine. The rapid advancement in AI also poses several challenges and opportunities for regulatory agencies such as FDA: what is the regulatory structure to approve ever evolving nature of AI-based devices and application and how we implement the AI-based framework to improve regulatory process. Reproducibility is a key element to realize the potential of AI in biomedical application and regulatory implementation. The FDA has led a large consortium, called MicroArray and Sequencing Quality Control (MAQC/SEQC), which has interrogated various machine learning approaches in developing gene-expression based biomarkers for both clinical and preclinical applications. Specifically, the questions relating to reproducibility have been extensively investigated such as whether a reproducible result is (1) dataset-dependent, (2) AI methodology dependent, (3) experience-dependent, and (4) technology-dependent. The presentation will conclude with some lessons learned about what is needed to close the gap in reproducibility of AI in predictive medicine.

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