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Request for Information on the National Digital Twins R&D Strategic Plan

Jason Hsu

Via FDMS

Jason Hsu, 7/27/2024

[redacted]

When Digital Twins techniques are applied to assess the efficacy of a new medical treatment relative to a control (a placebo or a Standard of Care), the FDA should be cautious in accepting claims of unbiasedness in the estimation, especially when such claims are based on Real-World Evidence (RWE) data instead of Randomized Controlled Trial (RCT) data. For example, using a Digital Twins technique to predict, for a patient given the new treatment, what the outcome would be had that patient been given the control requires deep statistical knowledge to overcome potential bias from a lack of randomization and/or noise in predictive covariates.