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Predictive enrichment in trial design (why and how common data model can further support advanced analytics in life science)

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Abstract

In the age of precision medicine, drugs are increasingly developed to target subgroups of patients with certain common characteristics. In large all-comer trials using a risk stratified design, treating and following patients for clinical outcomes may be cost prohibitive. With a fixed number of randomized patients, the efficiency of testing certain treatments parameters, including the treatment effect among biomarker positive patients and the interaction between treatment and biomarker, can be improved by increasing the proportion of patients with predictively positive response to intervention on study. Such predictive enrichment strategy supported by advanced analytics leveraging clinical trial and real world data sources could lead to more targeted and cost efficient clinical development process. But the challenge of managing various data sources and heavy lifting machine modeling effort could hinder the use of such data driven approach.

In this session, we will describe recent developments in specification of the intended use population and estimating the treatment effect for clinical trials using a machine learning approach. We will also cover the benefits of common data model to support such effort with transparency and reproducibility.