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Target Trial Emulation Methods

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Observational data are increasingly used to investigate effects of a treatment on clinical outcomes in situations where evidence from randomized clinical trials is inadequate. However, unbiased estimation of the treatment effect using observational data is challenging, mainly because the treatment assignment is not random. Any observed differences in outcomes between treatment strategies could be due to different distribution in prognostic factors rather than a treatment itself. Also, study design can be complex when using observational data to quantify a treatment effect. For example, selecting the appropriate start of follow-up (time zero) is often not simple, in contrast to the clear time zero – time of randomization – in a randomized clinical trial.

Estimating treatment effects using observational data can be viewed as an effort to emulate a target trial (hypothetical randomized clinical trial). This approach mimics the ideal design components of randomized clinical trials in observational analyses. Better understanding of the methods used to emulate a target trial may facilitate translation of study findings into clinical practice to improve patient outcomes. This lecture will provide a summary of a target trial emulation methods and guidance on how to evaluate this type of study.