

Informative method to identify biomarkers for guiding therapy decisions

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A randomized biomarker-stratified design, which uses the biomarker to guide analysis but not treatment assignment, provides a rigorous assessment of the utility of a potential biomarker for guiding therapy, according to a commentary published online January 14 in the *Journal of the National Cancer Institute*.

In the commentary, Boris Freidlin, Ph.D., of the Biometric Research Branch at the National Cancer Institute in Bethesda, Md., and colleagues discuss both advantages and disadvantages of commonly used randomized trial designs, including biomarker-stratified, enrichment, and biomarker-strategy designs.

According to the authors, clinical biomarker tests will play an important role in achieving personalized medicine for [cancer](#) patients.

Based on a comprehensive review of the three designs, the researchers concluded that biomarker-stratified designs were usually best, when feasible, because they show complete information on the relationship between treatment effect and the biomarker. In this design, patients are randomly assigned regardless of biomarker status, but the analysis is centered on the relationship between the biomarker and the effect of the treatment.

"The biomarker-stratified design maximizes the advantage of randomization by providing unbiased estimates of benefit to risk ratios across different biomarker-defined subgroups and for the entire

randomly assigned population," the authors write.

Provided by Journal of the National Cancer Institute

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