



## Sample Size Re-Estimation as an Adaptive Design

### **Using the promising-zone approach can salvage an underpowered trial.**

Sample size Re-estimation (SSRE) is a relatively new concept, but, thanks to its simplicity, SSRE using the promising zone is one that has grown in popularity in recent years. It comes with a host of benefits: it can increase study power, reduce upfront investment, and has the potential to shorten trial duration, for example. But it is important to note that it is not suited to all situations.

Despite its appeal, the promising-zone method, like other SSRE methods, comes with additional logistical and regulatory hurdles, and organizations must consider how each of these relate to their own individual development program. Ultimately, organizations should choose the design that best suits the needs of their study, because there is no panacea in the world of adaptive clinical trials.

The writer assesses the promising-zone SSRE method as an approach and explains it in practice. The article also poses SSRE's operational challenges so that sponsors and CROs make sure they consider and respond.

**Written by Laurence Collette, MSc, PhD., Principal Statistician, Consulting Services, IDDI. *Published in Applied Clinical Trials, September 1, 2021, Volume 30, Issue 9.***

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