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Non-monotonic power in Bayesian dynamic borrowing: insights and practical remedies

Gianmarco Caruso, Pavel Mozgunov
MRC Biostatistics Unit, University of Cambridge, Cambridge, United Kingdom

Gianmarco Caruso
Please provide a brief biography for the Presenting author(s)
Gianmarco Caruso is a post-doctoral researcher at MRC Biostatistics Unit (University of Cambridge, UK) working on efficient design of clinical trials. His research focuses on the development of novel statistical methodology for Phase I-II clinical trials, with particular emphasis on multi-arm response-adaptive designs, group sequential trials and Bayesian methods to incorporate historical information into study designs. He has also contributed to various ongoing real-world trials in the UK, with a primary focus on oncology studies. He obtained his PhD in Methodological Statistics at Sapienza University of Rome in May 2023 with a thesis on topics related to MCMC methods, Bayesian prior elicitation and finite mixture models.

Pavel Mozgunov
Please provide a brief biography for the Presenting author(s)
Pavel is an MRC Investigator (Programme Leader Track) working on the development and implementation of adaptive designs in clinical trials. Pavel provides statistical support in a number of trials, both publicly and privately funded.

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Bayesian borrowing of historical data refers to a class of methods that efficiently incorporate knowledge from previous trials into the prior distribution, effectively reducing sample size requirements when the current trial data align with historical data. However, conflicts between these sources can result in power loss or inflation of type I error. Dynamic borrowing methods, such as Self-Adapting Mixture (SAM) priors, address this challenge by adjusting the degree of borrowing based on the extent of prior-data conflict: the larger the conflict, the less the borrowing. In this work, we review this emerging class of empirical Bayes methods and highlight a practical issue that can arise: as treatment effect or sample size increases, the statistical power may not increase as expected and, in some cases, may even decrease. This counterintuitive behaviour can result in underpowered trials, particularly when additional patients are recruited beyond the original plan. Focusing on real-world scenarios, we illustrate how and why this issue can occur and provide practical guidance to mitigate the risk of underpowered trials.