

"A man is
great by
deeds, not by
birth"

-Chanakya

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Working Paper

IIMK/WPS/558/ITS/2023/04

March 2023

**PARIVAR-CT: Patients-at-Risk integrated with
Variance reduction for Clinical Trials**

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PARIVAR-CT: Patients-at-Risk integrated with Variance reduction for Clinical Trials

Abstract:

Allocation of incoming subjects into a clinical trial has the potential of causing high-variance outcomes as opposed to an expected allocation calculated apriori using estimators and trial design guidelines. This presents an ethical risk since a larger-than-expected fraction of subjects may be randomized to the drug (or placebo) with poor outcomes. Earlier, a framework known as Patients-at-Risk (PaR) was proposed to choose one clinical trial design decisively over another based on simple statistical metrics obtained via simulation. In this work, we first propose a new allocation function termed cascaded allocation using ρ (CAR) for an incoming subject to reduce the final variance of the allocation. Next, we modify CAR to further reduce the possibility of an ethically poor outcome, i.e. allocating a subject to the trial arm that is currently unfavourable - thus reducing PaR. We show analytical and empirical results for both the reducedvariance allocation algorithm as well as the low-PaR variant, i.e. PARIVAR-CT.

Keywords: hypothesis testing, clinical trials, randomized controlled trials.

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