



# A General Framework for Sequential and Adaptive Methods in Survival Studies

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Adaptive treatment allocation schemes based on interim responses have generated a great deal of recent interest in clinical trials and other follow-up studies. An important application of such schemes is in survival studies, where the response variable of interest is time to the occurrence of a certain event. Due to possible dependency structures inherited from the enrollment and allocation schemes, existing approaches to survival models, including those that handle staggered entry, cannot be applied directly. This paper develops a new general framework with its theoretical foundation for handling such adaptive designs. The new approach is based on marked point processes and differs from existing approaches in that it considers entry and calendar times rather than survival and calendar times. Large sample properties, which are essential for statistical inference, are established. Special attention is given to the Cox model and related score processes. Applications to adaptive and sequential designs are discussed.

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