

SHIVA – A randomized phase II trial comparing therapy based on tumor molecular profiling versus conventional therapy in patients with refractory cancer - A statistical and clinical overview-

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場所：医学部三号館別棟 5F（E501）

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Abstract

Most molecularly targeted agents (MTAs) are expected to work in subgroups of cancer patients characterized by the presence of molecular alterations in the tumor cells. However, clinical development is generally carried out according to tumor type. The SHIVA randomized trial on the contrary has been set up to investigate which of tumor biology or tumor location and histology is the most important to select treatment in patients with cancer refractory to standard of care. Statistical principles, specificities, strengths and limitations of this trial that evaluates an omic-based algorithm to select the targeted agent are reviewed. In particular, the need for a randomized trial where the various steps to build the algorithm are explicitly described and standardized is emphasized. The impact of an algorithm that would be partly misspecified (i.e., that would lead to correct treatment selection for some tumor molecular profile but not for all) is quantified.