

# 橋渡し研究の背景を考慮したバイオマーカーの 重要性と臨床研究倫理の展望

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## Significance of biomarkers with future prospects for ethical guidelines for clinical studies from the history of translational research

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### Abstract

Translational research is considered to be one of the most effective means for solving many issues including the “drug lag” problem facing regulatory authorities and pharmaceutical companies in Japan. However, only a few reports on translational research are available. Considering the background of translational research, this article provides information concerning biomarkers for clinical trials with future prospects for ethical guidelines for clinical studies. In the present drug development environment, we do need to have precise clinical trial data coming from the best protocols with monitoring and others under ALCOA (Attributable, Legible, Contemporaneous, Original and Accurate). As a result of this process, it will be found that translational research has been conducted with a wide variation in involvement of clinical studies. We therefore conclude that clinical trial development strategies including the selection of biomarkers and ethical guidelines for clinical studies need to reflect the individual positions of studies in the clinical context as well as the performance of researchers. Also, in the drastically changing climate of clinical trials, by using translational research, it is crucial to keep updating the latest trend of clinical trials in order to create good development strategies through translational research under ethical guidelines for clinical studies without having conflicts of interest.

### Key words

translational research, biomarker, ALCOA, conflict of interest

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