

国際共同治験に参加するための条件**第 I 相試験の工夫について****

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**Prerequisites for Participation in Global Clinical Trials:
How to Exercise Ingenuity in Phase I Trials**

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Summary

Many important new drugs are unavailable in Japan, despite their widespread availability throughout the rest of the world. This is called “drug lag,” and is an important issue in Japanese medical care. One of the options to solve this problem is to start clinical development of new drugs earlier in Japan, ideally at the same time as in western countries. However, the high cost and limited capacity for conducting Phase I oncology studies may prevent us from initiating so many Phase I studies in Japan. A bridging strategy is another option to catch up with Western development programs, but repetition of similar studies in Japan is often less attractive to investigators. Participation in global Phase III studies is another option, and would be the best way to eliminate the “drug lag.” In order for Japan to have enough time to enroll patients in global studies, the time necessary for Phase I and Phase II studies needs to be shortened. The “ICH E5 Guidelines” and the “Japan Guidelines for Clinical Evaluation of Anti-Cancer Drugs” encourage us to exercise ingenuity when we conduct Phase I studies. In this article, the authors present some ideas for Phase I studies that might enable us to take part in global Phase III studies simultaneously with Western countries. These ideas may be of some help in eliminating the “drug lag” in Japan.

Key words

Drug lag, Phase I, Clinical trial, Global study, Oncology