

改訂抗悪性腫瘍薬の臨床評価方法に関する

ガイドラインの背景と趣旨**

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**Background to Revision of The Guideline for Clinical Evaluation of
Anticancer Drugs and Introduction of Revised Version**

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Summary

In Japan, the revised Guideline for Clinical Evaluation of New Anticancer Drugs was published in November 2005. In the revised guideline, companies are required to submit the results of Phase III trial with the application for approval of any anticancer drug that is expected to be used in the treatment of a large number of patients. Although foreign clinical data are important for starting Japanese development, it is the intention of the revised guideline that Japanese clinical data will be used for drug approval applications not only in Japan, but also in foreign countries, in the future. Therefore, multinational clinical Phase III trials, including Japan, should become an important strategy for clinical development of anticancer drugs. It is hoped that such trials will speed up the clinical development of new drugs in Japan.

Key words

Anticancer drugs, Multinational clinical trial