

抗がん剤第 III 相試験のグローバルスタディに関する

企業（担当者）の考え方について*7

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**View of the Companies (Development Staff)
on Global Phase-III Trials of Antineoplastic Drugs**

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Summary

With the changes to the “Guideline on Clinical Evaluation Methods of Antineoplastic Drugs”, clinical evaluation methods have been diversified and the evaluation is conducted in two stages, i.e., clinical trials and post-marketing clinical trials, and further, post-marketing trials can now also be conducted abroad. In July 2006, COTEC (Clinical Oncology Trial Topics Exchange Circle) sent a questionnaire to its members on global trials of antineoplastic drugs, including in Japan. The results can be summarized as follows:

1. Japanese companies replied that global trials are necessary, but have not conducted them yet, while 33% of Japanese subsidiaries of foreign companies answered that they had already conducted them.

2. With regard to the expected sites for phase-III trials, the percentages of Japanese companies who hope to conduct the trials in Japan were as follows: 11% for gastric cancer, 22% for colorectal cancer, 11% for breast cancer, and 56% for non-small cell lung cancer. The percentages among Japanese subsidiaries of foreign companies were as follows: 17% for gastric cancer, and 8% for colorectal cancer, 8% for breast cancer, and 8% for non-small cell lung cancer.

3. Both Japanese companies and Japanese subsidiaries of foreign companies answered that their largest and second largest concerns in conducting global trials in Japan are “protocol” and “regulatory matters” (100% and 100% for Japanese companies and 83% and 75% for Japanese subsidiaries of foreign companies, respectively), followed by “medical sites” (89%) for Japanese companies and “company’s structure” (58%) for Japanese subsidiaries of foreign companies.

These results suggest that many phase-III clinical trials of antineoplastic drugs in Japan will be conducted on a global basis. The problem of “drug lag” in our country may be overcome by participating in such global phase-III clinical trials. It is desirable to promote and encourage such trials.

Key words

Global trials, Phase III trials, Guideline on clinical evaluation methods of antineoplastic drugs, COTEC