

新たな開発の展開
エスニックディファレンスを乗り越えて**
—規制側から—
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**PMDA's View on Evaluation of Ethnic Differences
of Drug Safety and Efficacy****

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Summary

We already have the results of ICHE5 on utilizing foreign clinical data. In PMDA's consultation for anticancer drug development in Japan, discussions about utilizing data from multinational clinical trials or foreign clinical data have increased. In applications for new anticancer drug approval in Japan, many of the clinical data packages have included foreign clinical data. In evaluating the foreign data, an important consideration is that ethnic differences may affect the safety and efficacy of drugs.

Regarding the consideration of ethnic differences in the review of clinical data, many applicants emphasize the similarity of drug safety and efficacy between Japanese patients and patients from other countries. However, the analysis of potential differences is more important than that of the similarities. In applications that include only a few data for Japanese patients in the clinical data package, therefore, we have difficulty in evaluating potential ethnic differences. It is important to enroll more Japanese patients in multinational clinical trials to help us overcome this problem.

Key words

PMDA, Anti-cancer drug, Clinical trial, Ethnic difference, Safety