

全例調査をどう考えるか**

—承認審査の立場から—

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PMDA's Perspectives on Observational Study of All Cases

—From the Viewpoint of New Drug Evaluation—

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Summary

An observational study of all patients who receive a newly approved drug is important in order to collect safety information as quickly as possible, as a part of the post-marketing surveillance (PMS). Such an observational study is especially needed for new drugs when the number of cases in clinical trials in Japan has been small, or when serious or noteworthy adverse effects have been reported.

Recently, the number of NDAs for which observational study of all cases has been an approval requirement has increased in Japan. In particular, observational study of all cases after approval is required for almost all NDAs for antineoplastic drugs.

Key words

Post-marketing surveillance, Observational study of all cases, PMDA, New drug evaluation