

グローバル開発における国内製造販売後臨床試験と臨床導入

—基調講演—**

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**New Trends for Post-approval Clinical Trials involving
Collaboration of Patients, Investigators, Industry and MHLW****

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Summary

Drug-lag, i.e., the delay of domestic approval of new anticancer drugs, seems to have improved recently. Revised guidelines for clinical evaluation of new anticancer drugs have made some impact on domestic drug development strategy as regards clinical trials for new anticancer drugs. Since publication of the revised guidelines, many new drugs have been approved faster than they previously would have been, based on foreign clinical data. The lack of domestic clinical data remains a problem after approval. So, many post-approval examinations or clinical trials have been directed by the authorities to support post-approval safety and efficacy in practical use. Two other types of post-approval clinical trials are also conducted independently. One is post-approval industry-initiated clinical trials for evaluating new combination therapy or safety in impaired patients. The other is investigator-initiated clinical trials to establish new standard treatments.

The first type of post-approval examination is of little interest to clinical oncologists. Workload, time requirements and costs for such surveillance are high. The quality and clinical significance of the results are not necessarily great.

In this forum, we would like to propose a new approach to post-approval clinical trials though collaboration of patients, investigators, industry and MHLW. Our current cancer treatments are still inadequate. We need to develop a better system for ensuring early access to new, effective treatments.

Key words

Drug-lag, Anti-cancer drug, Guideline, Post-approval examination, Clinical trial