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フォーラムの成果***
―規制側から―

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Results of the Forum for Anticancer Drug Development: Two Years Performance of the Review Team***

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Summary

Two years have passed since the first Forum for Anticancer Drug Development was held, and it is now necessary to evaluate the achievements to date, and look towards the future. Because the development of oncology drugs would be promoted by proper cooperation of industry, academia and the regulatory authorities, it seems natural for PMDA to encourage this. In the past two years, the review team for oncology has examined and approved no less than 20 new drug applications (NDAs). Moreover, NDAs have increased from 18 to 24 during this period. These facts indicate that the actions taken in relation to all the issues that were under examination two years ago have already started to bear fruit. Furthermore, the review team also supports around 50 clinical trial consultations per year in parallel with NDA review. The numbers of clinical trial consultations and clinical trial notifications (IND) of oncology drugs are increasing, including the planning and conduct of international joint clinical trials. It seems that clinical development in the oncology drug area is more active as a whole, and the forum has therefore been successful. To extend these achievements, strengthening of the review team of PMDA will be important. We need more clinical oncologists and biostatisticians to join the oncology area review team.

Key words

Oncology drug, NDA review, Clinical trials consultation, IND, Performance