

治験推進のためのインフラストラクチャー整備

—治験相談を通じて感じ、考えている事—**

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Outcome of PMDA's Clinical Trials Consultation

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Summary

PMDA has been consulting about ways to further anti-cancer drug development in Japan. One difficulty has been the clinical trial environment in Japan. It is difficult to carry out the randomized controlled trial using the hard end point currently carried out one after another in Europe and America in Japan. For this reason, NDA review of the anticancer drug in Japan is greatly dependent on the results of overseas large-scale comparative clinical trials.

At present, only a few institutions and specialists (clinical oncologists) can carry out clinical trials at an international level from the viewpoints of speed, quality, and cost. It is therefore important for PMDA to decide how limited clinical development resources are to be utilized and how to promote the clinical trials of new anti-cancer drugs. One approach would be to take part in global clinical trials. Therefore, PMDA released "Basic Principles on Global Clinical Trials" in March this year, and this document was approved by MHLW in September. This guidance includes Q&A dealing with common questions relating to global clinical trials of anti-cancer drugs.

Key words

PMDA, Clinical trials consultation, Anti-cancer drug development, Global clinical trial