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治験推進のためのインフラストラクチャー整備
—国際共同治験における日本法人の取組み—***

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Drastic Changes in CPO Japan for Global Clinical Trials

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Summary

The number of global clinical trials being conducted has been increasing not only in the US and European countries but also in Latin America and Asian countries. At the sametime, though the figures differ among each pharmaceutical company, the number of pharmaceutical companies participating in global clinical trials is steadily rising. About half of them are involved in global trials related to oncology. In order to conduct global clinical trials more actively, in 2004 Novartis Pharma K. K. systematically changed itself into a similar organization as the global headquarters, and in September 2004 abolished the Japan-specific standard operating procedures (SOPs) to become in-line with the Global SOP's.

In June 2007, twelve member companies of the European Federation of Pharmaceutical Industries Association (EFPIA) conducted a survey on the speed of clinical trial progress in the field of oncology in each country. The survey showed that patient enrollment in Japan is much slower than in other countries, though it is comparable in non-oncology areas. To catch up with the speed of clinical trial progress of other countries, Novartis Pharma K. K. has introduced Global Lead CRA's who can lead monitors who participate in global clinical trials. The roles and expected advantages of Global Lead CRA's are discussed in this report.

Key words

Global study, Lead CRA, Patient enrollment, Efficient clinical trial