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The First-ever Report on Multi-Company Survey of the Cost of Medical Device Clinical Trials in Japan —Results of a Collaborative Study—

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Summary

The Clinical Trial Cost Survey Working Group of The Japan Federation of Medical Devices Association GCP Committee and Harmonization By Doing Working Group3 Japan collaboratively conducted the first-ever multi-company survey on the cost of medical device clinical trials in Japan. Twenty-three out of 52 companies surveyed had conducted 27 clinical trials in total during the past 8 years. The patient enrollment period from contract executed to last patient-in was, on average, 11.9 months. The enrollment speed was, on average, 1.86 patients per month per investigation site. One monitor covered as few as 1.8 sites and 22.3 patients on average. The total costs including those for sponsors and investigation sites, were, on average, about 233 million Yen per trial and 4.58 million Yen per patient. Only 13 sites (7%) employed a performance-based payment system for the contract fee, while 46 % of the sites employed an advanced payment system with no pay settlement. Adopted payment systems varied depending on the types of investigation sites. Although the present first-ever study of clinical trial costs is insufficient to establish a clear benchmark trial cost in Japan, because of limitations of the available cost data and the great variation among the devices tested, nevertheless the trial cost structure appears to be broadly similar from that for pharmaceutical products. Further study of trial costs in Japan in comparison with those in other countries seems desirable.

Key words

Cost survey, Medical device, Clinical trial cost, JFMDA, HBD, Enrollment speed, Monitor performance