

# 我が国の臨床研究・治験に関する基盤整備状況調査

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## Investigation of clinical research activity in major general hospitals in Japan

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### Abstract

The Japanese Ministry of Health, Labor and Welfare issued the plan called the “Five-year plan 2012 on facilitation of clinical research/trials”. In order to evaluate the effect of this plan, we investigated the clinical research activity in approximately 60 Japanese major general hospitals in the most recent three years. Survey items were as follows: 1) the status of clinical research, 2) clinical research network, 3) human resources, 4) utilization of a site management organization, 5) handling of subjects/patients, 6) role of pharmaceutical industry and hospital in industry-initiated clinical trials, and 7) digitizing and/or computerization of clinical research data. Roughly speaking, most hospitals have achieved the goal of the “Five-year plan 2012”; however, they have three notable problems to be resolved. First, the correspondence in English, especially communication in English, was not yet sufficient in most hospitals. Second, digitizing and/or computerization of clinical research data were not established yet. Although every hospital had an electronic health record and an electronic data capture system, no hospital had an automatic electronic data transfer system but used manual input. Remote source data verification (SDV) and sampling SDV were not yet ready to use, and no hospital used risk-based monitoring. An electronic documentation system was not sufficient to be used. Third, a status of implementation of investigator-initiated clinical research was insufficient. Every hospital had a clinical research supporting department; however, it had a lack of registration to a clinical trial database. No monitoring was done in most hospitals. However, due to the effect of a new guideline issued in 2014, monitoring of clinical research had been done in most hospitals in 2015. Further investigation is needed to improve the performance of clinical research in Japan.

### Key words

Five-year plan 2012, clinical research, clinical trial

*Rinsho Hyoka (Clinical Evaluation)*. 2017 ; 45 : 571-608.