

## 治験推進のためのインフラストラクチャー整備

—厚生労働省の治験推進施策—\*\*

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## New 5 Yearly Clinical Trial Action Plan

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## Summary

In 2003, MHLW drew up and published the “Nationwide 3-Yearly Clinical Trial Activation Plan”, under which it promoted various measures, including the creation of clinical trial networks and fostering of clinical research coordinators (CRCs). As a result, the number of trials in Japan has been increasing gradually.

However, difficulties remain; for example, clinical trials in Japan are said to be slower and more expensive than those elsewhere in Asia, and perhaps reflecting this situation, the number of international multi-centered trials in Japan has not increased as much as that in Korea, where the clinical research infrastructure has been consolidated rapidly in recent years.

To improve these problems, MHLW launched “The New 5-yearly Clinical Trial Activation Plan” in March, 2007. The major goals of the plan are to reinforce clinical research infrastructure to ensure patients’ safe and secure access to new drugs and devices. Specifically, the plan aims to promote (1) institutional infrastructure building with Core Clinical Research Centers’ network, and (2) human resource development for clinical research, etc. The Office of Clinical Trial Promotion, Research and Development Division, Health Policy Bureau, MHLW was created in April, 2007 to promote such measures and increase the number of clinical trials in Japan.

## Key words

Clinical trial, Activation plan, Infrastructure building, Human resource development, Public promotion