

New Five Yearly Clinical Trial Activation Plan and its implementation

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As the clinical trial environment in Japan has been recognized lengthy and costly, compared to other Asian countries, we observe growing number of clinical trials conducted in US/EU and Asia prior to the development in Japan for Japanese regulatory submission for approval. Ministry of Health, Labour & Welfare (MHLW) and Ministry of Education, Culture, Sports, Science & Technology (MEXT) jointly launched “New Five Yearly Clinical Trial Activation Plan” in March 2007 to secure timely patient access to new medicine as well as to keep the uptake level of new medical technologies through improving clinical trial infrastructure in Japan. In the five-yearly plan an international multi-centered clinical trial is also strongly invited in Japan.

The five-yearly plan lays down the five essential challenges; 1) establishment of Core Centers of Excellence (CCE) and Clinical Trial Centers (CTC), 2) human resource development, 3) education and encouragement to volunteers, 4) trial efficiency improvement and reduction of sponsor’s burden, 5) appropriate regulation and human subject protection.

Based on the plan, MHLW started governmental subsidies (16M\$/year) to 10 CCEs & 30 CTCs in 2007. In collaboration with 8 Translational Research Centers (designated by MEXT), MHLW formed the Conference of National Clinical Research Centers Network, participated by stakeholders. MHLW and the conference has been working actively on clinical trial environment in Japan such as; 1) to set clear metrics of the centers’ performance improvement, 2) to harmonize clinical trial documentation format, 3) to introduce information technology. Also, MHLW has been taking measures, with medical communities, to develop human resources for clinical research, not limited to providing CRC training, but including carrier ladder scheme and appraisal process of medical staff to motivate them.