University Hospital Clinical Trial Alliance (UHCT Alliance): Towards the Implementation of Multinational Studies in Cooperation with Sponsors

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There are many pharmaceutical companies in Japan that can explore and develop new chemical entities into medicines. However, the clinical development process is a bottleneck in Japan and even Japanese companies initiate clinical development, not in Japan, but in US or Europe in most new chemical entities. These situations cause significant delay in approval of new drugs in Japan by four years in average in recent data and about 40% of the world top hundred drugs are unapproved in Japan. To make things worse, recent international trends of introducing multinational studies for clinical development may exacerbate these situations because Japan tends to be excluded in multinational studies.

In general, speed and cost are said to be key issues in clinical development in Japan. There are three major critical paths in Japan. One is the consultation process with PMDA, a Japanese regulatory authority, before starting clinical trials. The second is the application and contract process with clinical institutions. Involvement of so many clinical institutions with relatively small number of subjects per site is time-consuming and leading to the relatively high cost. It is also problematic that application forms and procedures are not fully standardized among hospitals. The last is that patient enrollment process. Patients enrollment rate is the key issue to meet with global timeline. Much improvement has been recently achieved in clinics, where clinical trials for drugs for lifestyle-related diseases are conducted, at the cost of SMO, site-managing organizations.

This atmosphere of crisis drove us to establish UHCT Alliance consisting of major six national university hospitals in Kanto area, all of which have high performance in implementing clinical trials. The alliance is a model and not limited to six universities. We welcome new members if they have high performance in clinical trials and agree with our principles. Our goal is the immediate supply of world new drugs to Japanese patients by conducting multinational and domestic clinical studies in safe and more efficient way with the integration of processes and patients among the universities. The number of beds comes up to 5,000 and the number of outpatients is 2,900,000 patient-days (12,000 patients per day). The possible cooperation of the alliance with sponsors in the stage of protocol

development by providing relevant patient numbers and feasibility information is also important for the secure and smooth implementation of clinical trials.

The alliance was established in February 2006, officially acknowledged by each university hospital head in April. At present, six working groups are becoming to finalize their activities for public relations, prescreening of patients, application forms, assistance in review processes, safety reporting and education.

The UHCT alliance is featured by the higher order integration of well-established university hospitals with homogeneous clinical trial environments, patients with all fields of diseases, highly educated investigators and staff, emergency rooms and intensive care units and contracts in reasonable cost, all of which fit global studies in simultaneous development of new drugs. The alliance does not confine its activities to regulatory clinical trials but also will extend to the collaboration in non-regulatory clinical trials.

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