**Factors which potentially impact on investigational sites initiation time of oncology clinical trials**

**Background:** In recent years, responsibilities and roles of Clinical Research Organizations (CROs) have been considered more important as the number of oncology clinical trials increases. In association with intensifying development competition among pharmaceutical companies, requirements demanded for CROs include service quality, expertise and promptness in conducting clinical trials. Because reduction/prolongation of duration to initiate a clinical trial (hereinafter, duration) significantly contributed to duration of conduct of the whole study, factors which potentially impact on it were investigated.

**Method:** In this investigation, duration is defined as a period from the Site Selection Visit (SSV) to the Site Initiation Visit (SIV). In order to extract factors which may contribute to reduction/prolongation of duration, clinical trials which were conducted at 10 or more sites in the recent 10 years (32 studies) were extracted from our Clinical Trial Management System (CTMS), and 5 sites each with the shortest and longest mean time among sites which conducted 10 or more clinical trials (17 sites) in these participating sites were extracted based on the mean at each site. Then, possible factors were internally investigated in approximately 140 Clinical Research Associates (CRAs) who were in charge of these sites, and based on the results of this investigation, actual conditions of study administrative structures were investigated by using a questionnaire format in approximately 110 sites which conducted oncology clinical trials. Results including those from the investigation based on questionnaire are reported.

**Results:** The duration at the 5 sites each with the shortest duration and longest duration were 180 ± 6 days and 250 ± 34 days, respectively. The factor to reduce duration is considered to be various efforts to improve efficiency of clinical trial activities.