

Clinical Trials & Approval of Anti-Cancer Agents

In recent years, the participation in the global study has been recognized as an efficient process to deliver the promising drugs to the patients in Japan simultaneously with those in Western countries, and this has been applied to the oncology field very actively. As this global study with a reasonable number of patients enables us to prove the real clinical value of oncology products, and to accumulate the wide range and quantity of safety information, this methodology has been accepted as an appropriate tool for the new anti-cancer drug development. On the other hand, it is well known that the drug response has been influenced by regional factors, and consequently the optimal dose and safety profile may differ from one to another region. Thus taking into account these regional characteristics, the global total development strategy has to be well prepared prior to the conduction of the confirmatory clinical study. In Asian countries, the prevalence of several cancer types, such as gastric cancer and HCC, has been reported to be very high, and along with the progress of genetic research, examples showing the ethnic variations have been reported. Thinking about these observations, Asian countries may have different features from Western in the responses of anti-cancer agents, and thus this has to be well investigated at the early stage of drug development, by using the collaboration of Asian countries. We believe the development of anti-cancer agents based on this process will be an acceptable scenario for the agency in each region, and contribute to the smooth review, leading to the faster approval in each country.

It will be desirable for each Asian country to harmonize the regulations for the drug development and approval, which enables us to promote the collaboration of Asian countries, and realize the global simultaneous filing and approval of new anti-cancer agents. We hope this conference will contribute to the progress of Asian collaborative research and clinical work in the oncology field.