

From the difference to the similarity

Kazuhiko Nakajima

(Drug Evaluation Committee, Japan Pharmaceutical Manufacturers Associations)

The role that ICH-E5 guideline has served to offer useful medicines to Japan fast may not be small at all. However, the development technique to examine whether extrapolation is possible of overseas data by bridging study cannot solve so-called drug-lag in our country, and it is necessary for our country to participate from early period of the global development. The guidance "Basic way of thinking about the international joint clinical trial" to push forward the development that rose in this stance was delivered by MHLW in September, 2007. How should we think about "Japanese" expressed by this guidance? Though development areas are considerably various by the clinical evaluation in the global development by the western companies, there is the actual situation that is not almost considered about the race difference though, in addition, the races in some areas are various. For the recent study, the similarity among each races in the East Asia is pointed out by comparison with Europe or other regions in various factors such as genome, disease structure, frame or life style. The simultaneous development in each East Asia country and the mutual utilization of clinical evaluation data are useful, but a careful action is expected from a point of view to secure the effectiveness and the safety of medicines. The scientific research of MHLW about the possibility of mutual practical use based on clinical trial results of Japan / China / Korea 3 countries is being pushed forward and the result of this research is expected.