

ICH E5 ガイドライン (外国臨床データを受け入れる  
際に考慮すべき民族的要因) Q & A 11 について

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**Q & A 11 of ICH E5; Ethnic Factors in the Acceptability  
of Foreign Clinical Data; Guideline**

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**Summary**

International trials, which have been conducted mainly outside of Japan, could be a reminiscent of multi-site trials without consideration of interactions between treatment and investigational site, since the country factor could have similar function to the site factor. In this regard, ethnic factors have not been taken into account in data evaluation. The Q & A 11 of ICH E5 Guideline proposes multi-regional trials with consideration of ethnic factors. This Q&A provides points to consider in the planning, analysis and evaluation of a multi-regional trial serving as a bridging study. As mentioned above, a demonstration of insensitivity of a drug to ethnic factors by a multi-regional trial for the purpose of bridging would enable mutual utilization of data among regions. This may enhance the value of multi-regional trials in terms of not only earlier approval of a drug, but also scientific relevance. Joining a multi-regional trial at an early stage of a clinical development program would foster recognition of regions as equal partners in the world.

**Key words**

Multi-regional trial, Bridging study, Global drug development program, Hierarchy of persuasiveness, ICH E5