

新たな開発の展開

エスニックディファレンスを乗り越えて\*\*

—薬物代謝酵素活性と遺伝子型の関係に基づいた抗癌剤開発戦略の考察—

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**Overcoming the Influence of Ethnic Difference  
in the Development of Anticancer Drugs\*\*  
—Pharmacokinetic/Genotype Associations—**

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**Summary**

Utilization of foreign data is considered to be a viable measure to reduce the delay in approval of new anticancer drugs (drug lag) in Japan. A clinical pharmacological study on pharmacokinetic (PK)/genotype associations for major cytochrome P450 (CYP450) enzymes suggested that PK data obtained for Japanese and East Asian subjects are comparable, and even data obtained in Japanese and Caucasian subjects are comparable if subjects with the same genotype are used. When there is an existing drug which has a similar mechanism of action (MOA) to an investigational drug, the efficacy and safety of the investigational drug in Japanese could be predicted from available foreign PK data on the investigational drug, together with comparative data between Japanese and other ethnic groups on the pharmacokinetic/pharmacodynamic (PK/PD) relationship of the existing drug. In addition, when there is a reliable biomarker to predict the efficacy and/or safety of the investigational drug, and there is a similarity between Japanese and other ethnic groups in the PK/biomarker relationship, efficacy and safety of the investigational drug in Japanese could be predicted from these data. Ultimately, when there is some Japanese data on a primary endpoint of the efficacy of the investigational drug and the data shows a similarity to that from other ethnic groups, data from other ethnic groups may be used as a substitute for Japanese data in a Japan NDA filing. In conclusion, a flexible drug development strategy could be adopted by utilizing PK data on an investigational drug and on an existing drug with a similar MOA, and data on efficacy and safety including data on biomarkers. This may overcome the influence of ethnic difference, and may be an effective measure to reduce the drug lag.