Chapter 11 - The Importance of Ethnicity Definitions: Pharmacogenomics in Ethnobridging and Pharmacovigilance

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Abstract

The International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH) document on Ethnic Factors in the Acceptability of Foreign Clinical Data, ICH E5(R1), provides guidelines for assessing ethnicity as a cause of differences in drug responses as well as bridging strategies. It aims to avoid unnecessary duplication of clinical trials without compromising the quality, safety, and efficacy of the drug, hence expediting the drug-approval process. This guideline have, however, not been fully adopted by all countries, and there are differences in the way the bridging concept is applied. One approach that may provide the resolution to this dilemma is the multiregional parallel-bridging method, or simultaneous drug development. However, the definition of ethnicity is, currently, too vague and imprecise for clinical trial data to be easily understood and extrapolated across borders. The integration of pharmacogenomics and biomarkers in drug development and the postmarket phase may provide greater clarity to the characterization of drug-response variability between populations.

Keywords

Data applicability, Ethnicity, Ethnobridging, Genetic gradients, Global drug development, Pharmacogenomics, Pharmacovigilance, Variability in drug response