Chapter 10 – The Importance of Ethnicity Definitions and Pharmacogenomics in Ethnobridging

Elsa Haniffah Mejia Mohamed,† Lou Huei-xin‡, Jalene Poh‡‡, Dorothy Toh¶, Edmund Jon Deoon Lee‡

Abstract

Concerns about ethnicity-related differences have resulted in a significant “drug lag” in regulatory approvals. The International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) document on Ethnic Factors in the Acceptability of Foreign Clinical Data, ICH E5, provides guidelines for assessing ethnicity as a cause of differences in drug treatment and using bridging strategies to avoid unnecessary duplication of clinical trials without compromising the quality, safety, and efficacy of the drug, with the goal of expediting the drug approval process. However, these guidelines have not been fully adopted by all countries, and there are differences in the way the bridging concept is applied. An approach that may provide the resolution to this dilemma is the multi-regional 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 may provide greater clarity to the characterization of drug response variability between populations.

Key words

ethnicity; pharmacogenomics; ethnobridging; variability in drug response; global drug development

Objectives

1. Emphasize the complexity of defining ethnicity and the need for a standardized definition of scientific research.
2. Outline the ethnic intrinsic and extrinsic factors in determining outcome of treatment.
3. Identify the factors considered in acceptability of foreign clinical data for drug approval.
4. Highlight the role of pharmacogenomics in global drug development.