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Global Clinical Trials for Alzheimer's Disease: Chapter 21. Application of Pharmacogenomics in Global Alzheimer's Disease Clinical Trials and Ethical Implications

Sidney A. Spector

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Decades ago, pharmacogenetic research established that one’s genetic profile might predict efficacy and safety of medicines. Polymorphic expression of isoenzymes of the cytochrome P-450 enzyme system explains a significant amount of the variability of inter-individual responses to medicines. In Alzheimer’s disease, the highly variable clinical response to cholinesterase inhibitors metabolized by the liver is explained on this basis. More recently, translation of basic pharmacogenomic research through the drug development process has led to the approval of ”personalized“ medicines, for example, in the field of oncology, cardiology and psychiatry, based on an individual’s underlying genotypic variance of phenotypically expressed pathogenic targets and pathways. Translational pharmacogenomic research in Alzheimer’s disease has emerged as a viable alternative to the study of large populations with similar phenotypic expression of symptoms through stratification of sub-groups based on ApoE carrier status in clinical trials. When initiating a global research protocol, it is incumbent upon sponsors to actively engage stakeholders in developing and underdeveloped countries, including local government authorities, regulatory bodies, ethics review boards, community representatives and participants, to address all aspects of the clinical trial, especially informed consent, which may be more challenging in countries where local customs and practices dictate the need for innovative approaches. Implementation of pharmacogenomics in the clinical trial requires further attention to ethical detail related to what kind of informed consent is needed for use of stored DNA samples for future, unforeseen related or unrelated research, whether and to whom to disclose current and future study results, and ways by which the benefits of current and future discoveries are shared by stakeholders in developed and underdeveloped or developing countries.

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