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Under representation of vulnerable population in clinical trials impacts negatively on drug development and safety evaluation of new medicine

Representation of vulnerable population in drug development clinical trials is inadequate. Age-adapted medicines are a recognized challenge in the overall process of drug development, due to the specific requirements of pediatric and geriatric patients that makes the one-fits-all approach not applicable with respect to the standard products for adults. Pharmacokinetics and pharmacodynamics are strongly influenced by co-morbidity, multiple-drug use or reduced organ functions in the elderly, while pharmacokinetics and pharmacodynamics are more influenced by enzyme immaturity in neonates and infants. Pregnant women are another population that is poorly represented in clinical trials and the major physiological changes accompanying pregnancy and its effect on pharmacokinetics and pharmacodynamics were not studied sufficiently. The regulatory system worldwide sharply divides the legal use of pharmaceuticals into licensed and unlicensed categories. In 2000, 65% of National Health Service (NHS) doctors reported that they had prescribed off-label within the last month, 12% for a patient outside the specified population, for example the elderly, pediatric or pregnant women. Safety and efficacy of a medicinal product should be demonstrated in the target population before they should have access to these medications. The adverse effects can be more severe, or less tolerated and has more profound consequences than in other population. Considering the mechanism of action of the investigational drug and the characteristics of the disease, certain specific adverse events and age-related efficacy endpoints should actively be pursued in that population, e.g., effects on cognitive function, balance and falls, urinary incontinence or retention, weight loss and sarcopenia. Risk assessment is another area of great interest and a crucial step in evaluating a protocol and conducting a drug development program. Potential harm (real or theoretical) or potential consequence of an action that might be physical, psychological, or social and could be immediate or delayed, varies massively according to patients age groups. Risk, therefore, should be assessed in terms of probability, magnitude and duration. Hence adequate representation of vulnerable population in clinical trials is essential to ensure appropriate and accurate analysis for potential risks, including those that may not usually be of concern in younger adults or non-pregnant women because medicines or procedures may cause adverse effects in older participants that have not been identified in young adults.

Biography

Assem S el Baghdady has graduated from Cairo, Egypt and trained in Ireland at Richmond Institute of Neurological Sciences in Dublin. He has joined the academic department of Clinical Neurology at University of Sheffield, UK, as a Clinical Research Fellow/Lecturer and continued his research and training in Clinical-Neuroscience and Cognitive-Psychology.

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