

<シンポジウム 01—3> 神経内科における大規模臨床治験

Clinical Trials in AD

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There are numerous potential therapies for the treatment of Alzheimer's disease in pre-clinical and clinical stages of development, so many that no one country or region of the world could test them all. Further, in the United States and, to some extent, in Western Europe, AD patients are not as motivated to participate in clinical trials as they were prior to the availability of approved treatments. Drug development for AD must be a global effort in order to effectively evaluate successful and non-successful approaches and to advance the treatment of AD patients everywhere. There are some recurrent challenges in AD trials that influence how these studies are performed. These include: 1) overlapping populations of AD patients from presymptomatic; to Mild Cognitive Impairment; to mild, moderate, severe and pro-

found stages of disease. Selection of the population determines the choice of outcome measures (which must be optimized for the population) as well as study design. 2) The availability of approved AD therapies (and the lack of uniformity in this variable worldwide) influences these studies by affecting rate of recruitment, effect size estimates, and the need to evaluate potential drug interactions. 3) The need for large trials, which often necessitates inclusion of subjects with cultural and language differences that can contribute to variability in outcomes and reduce the ability to detect drug placebo differences. These challenges can be met through collaborative efforts, the use of new technologies, and application of care in cross-cultural implementation.