The utility of biomarkers in CNS drug development

A biomarker can be defined as a biological variable that has a statistically significant relationship with parameters of disease states or the activity of a drug or drug candidate. Biomarkers are fast becoming an essential part of clinical development, largely because they: (i) offer the prospect of more homogenous patient populations in clinical trials through patient selection and stratification; (ii) permit assessment of target engagement; (iii) allow the consequences of target engagement to be measured; and (iv) provide markers of disease modification... Because biomarkers can increase the power of clinical trials and predict drug efficacy more quickly than conventional clinical endpoints, they hold the potential to substantially accelerate product development and increase confidence of demonstrating therapeutic efficacy in Phase III trials. This presentation will review the utility of biomarkers in CNS drug development, with particular emphasis on their use in clinical trials for anti-amyloid drug candidates that aim to slow the progression of Alzheimer's disease.

Biography

Alan M Palmer has formed or co-founded seven biotech start-up companies. He is presently a board director of Cerebroscience Ltd., MS Therapeutics Ltd, One Nucleus Ltd, Cerestim Ltd, Health e-games Ltd and the British Neuroscience Association. His career has focussed on CNS disorders and their treatment and, with over 100 peer-reviewed papers to his name, his scientific research has had a high impact in the areas of dementia and traumatic brain injury. He is visiting Professor at University College London and the University of Reading and Life Science Entrepreneur in Residence at the University of Bristol. He was voted London Biotechnology Network Entrepreneur of the Year in 2005.

alan.palmer@cerebroscience.com