

EDITORIAL

OUTCOMES FOR ALZHEIMER'S TRIALS

B. VELLAS

IAGG President Elect, Department of Internal Medicine and Geriatrics, Toulouse, Univeristy Hospital, INSERM U 558, Toulouse, 31300, France

One of the most difficult domains in Alzheimer's Therapeutic Trials is the definition of a good and clinically relevant end-point. We are please to present in this issue of the Journal the proceeding of the II International Task Force on Therapeutics Trials in Alzheimers disease devoted to outcomes. The meeting was held in Lisbon, (Portugal). April 12, 13, 2007 and attracted participants at the top level from academic, pharmaceutical research and regulatory agencies. C Sampaio underlines [1], the minimum clinically relevant parameters; Minimal Clinical Important Change (MCIC) and Minimal Clinical Important Difference (MCID). G Wilcok [2] summarises outcome for disease modifying trials. Delaying the transition from one stage of the disease to another could be included in a "time to event" protocol. We learnt from J Durga [3] interesting data from the Facit Trial, one example of a preventive trial looking at cognitive outcomes. The measurment of cognitive change in Alzheimer's disease clinical trials has been challenged by E Salmon [4] and JE Harrison [5] with some new data on the NTB (neuropsychological test battery). Changes on the ADAS-Cog has been reported by F Cortes [6] and B Vellas [7] at 6 and 18 months in mild to moderate Alzheimer's patients treated with acetylcholinesterases inhibitors. The papers by F Verhey [8], P Robert [9] and G Frisoni [10] are focused respectively on caregivers, neuropsychiatric and neuroimaging outcomes. The costs of care for a patient with dementia is known to depend on a wide range of factors including the care setting, presence of informal caregivers, cognitive function, ADL and instrumental ADL abilities, behavioural disturbances and co-morbidities and this topic is elaborated by

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L. Jonhson, [11]. Finally, even if new disease-modifying drugs do become available in the (near) future, they benefit may be outweighed by the benefits delivered by currently available symptomatic drugs. Therefore, a combination of potentially disease-modifying drugs with symptomatic drugs appears very likely. Questions of reimbursement will be connected to differential benefit assessments between these classes of drugs. Thus careful assessment of outcomes of symptomatic drugs remains an issue of importance [12, 13].

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