

EDITORIAL

OUTCOMES FOR ALZHEIMER'S TRIALS

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One of the most difficult domains in Alzheimer's Therapeutic Trials is the definition of a good and clinically relevant end-point. We are pleased to present in this issue of the Journal the proceeding of the II International Task Force on Therapeutics Trials in Alzheimer's 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 Clinically Important Change (MCIC) and Minimal Clinically Important Difference (MCID). G Wilcock (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 measurement 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 acetylcholinesterase 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 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)

References

1. C. Sampaio, Clinical Relevance on Alzheimer's Disease Endpoints, *J Nutr Health Aging* 2007, 11, 4: 316-317.
2. G. Wilcock, Outcomes for Disease Modifying Trials, *J Nutr Health Aging* 2007, 11, 4: 318-319.
3. J. Durga et al., What Can We Learn from the Facit Trial: A Randomized, Double Blind, Controlled Trial, *J Nutr Health Aging* 2007, 11, 4: 320-324.
4. E. Salmon, Outcome for secondary preventive trials (in Mild Cognitive Impairment), *J Nutr Health Aging* 2007, 11, 4: 325-326.
5. J.E. Harrison, Measuring Cognitive Change in Alzheimer's Disease Clinical Drug Trials, *J Nutr Health Aging* 2007, 11, 4: 327-329.
6. F. Cortes et al. Six and 18-month Changes in Mild to Moderate Alzheimer's Patients Treated with Acetylcholinesterase Inhibitors: What Can we Learn for Clinical Outcomes of Therapeutic trials? *J Nutr Health Aging* 2007, 11, 4: 330-337.
7. B. Vellas et al., Long-Term Changes in ADAS-cog: What Is Clinically Relevant for Disease Modifying Trials in Alzheimer? *J Nutr Health Aging* 2007, 11, 4: 338-341.
8. F.R.J. Verhey et al., Caregiver outcomes in disease modifying trials, *J Nutr Health Aging* 2007, 11, 4: 342-344.
9. P. Robert et al., Neuropsychiatric outcome for clinical trials, *J Nutr Health Aging* 2007, 11, 4: 345-347.
10. G.B. Frisoni et al., Neuroimaging Outcomes for Clinical Trials, *J Nutr Health Aging* 2007, 11, 4: 348-352.
11. L. Jönsson, Assessing health economic outcome in Alzheimer's disease clinical trials, *J Nutr Health Aging* 2007, 11, 4: 353-356.
12. L. Frölich, Outcomes for Clinical Trials in Mild-to-Moderate Dementia to Evaluate Drugs with Presumably Symptomatic Effects, *J Nutr Health Aging* 2007, 11, 4: 357-358.
13. S. Lovestone et al., Biomarkers for disease modification trials- the Innovative Medicines Initiative and AddNeuroMed, *J Nutr Health Aging* 2007, 11, 4: 359-361.