19 September 2013
EMA/471475/2013
Committee for Medicinal Products for Human Use (CHMP)

Submission of comments on 'Qualification opinion of a novel data driven model of disease progression and trial evaluation in mild and moderate Alzheimer's disease' (EMA/CHMP/SAWP/420174/2013)

Comments from:

Name of organisation or individual	
1	EUGMS
2	Swissmedic

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1. General comments

Stakeholder number *(see cover page)*	General comment (if any)	Outcome (if applicable)
1	I have three general comments on this document: 1. The only acceptable and world-wide accepted method to evaluate and follow-up “complex” patients is the use of the RAI (MDS) system. I propose to introduce this for these trials. 2. As in oncology, we see in the clinic two groups of patients: “responders” and “non-responders”. Mixing all the patients together was the mistake of most of clinical trials till today. We need the inclusion of real “complex” patients (very old and frail) in these trials.	We can only accept comments that are relevant to the current particular model in question.
2	Swissmedic, after revising the document, is of the opinion that the proposed disease progression and trial evaluation model, as defined in this document, is suitable for qualification for use in drug development as a longitudinal model for describing changes in cognition in patients with mild and moderate AD, and for use in assisting in trial designs in mild and moderate AD. As acknowledged by the applicant, it has no validity outside the range of mild to moderate AD. As also stated in the document, this simulation tool should not be intended to replace prospective randomized controlled clinical trials nor to replace scientific interpretation of clinical data and drug development guidance. It should be offered publically as an option to	Agreed, in line with the opinion.

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	use for a valuable tool. This model should also be continually developed and validated as further trials become available and integrate novel information such as disease progression according to profiling with biomarkers.	