Eligibility Summary (ES-1)

Purpose: Document eligibility.

When: Just prior to randomization, at EN. Completed by: CitAD certified personnel.

Information obtained from: Patient and caregiver.

Instructions: This must be the last form completed at EN after eligibility and enrollment checklist (EC) form is completed. If a significance is checked, the person is currently ineligible for the trial. If entry criteria are met, the patient is to be randomized.

A. Clinic, patient, and visit identification

- **1.** Clinic ID: ____ ___ ___
- **2.** Patient ID: ____ ___ ___ ___
- **3.** Patient four-letter code:
- **4.** Date form completed:

_		_
day	month	year

5. Visit ID:

- E N
- **6.** Form revision date:

_0	1	<u> </u>	e	c	- 1	_1
day			month			year

B. Inclusion criteria

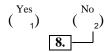
7. Does the patient have probable Alzheimer's disease (NINCDS-ADRDA criteria), with MMSE score of 5-28 inclusive:



a. Specify score:



b. Is the MMSE score (item 7a) greater than 26:



c. Has protocol version 2.2 or a more recent version been approved by the IRB at your site:



d. Is there written documentation from the study chairman confirming that the patient has probable Alzheimer's disease:



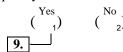
Attach the documentation from the study chairman confirming that the patient has probable Alzheimer's disease to this form.

- **8.** Does the patient have clinically significant agitation for which:
 - **a.** A medication is appropriate, in the opinion of the study physician:

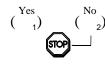
 Yes



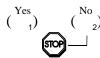
b. The frequency of agitation as assessed by the NPI is "Very frequently":



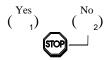
c. The frequency of agitation as assessed by the NPI is "Frequently" AND the severity of the agitation as assessed by the NPI is "Moderate", or "Marked":



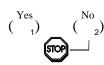
9. Does the patient have an available primary caregiver, who spends several hours a week with the patient and supervises his/her care, to accompany the patient to study visits and to participate in the study:



10. Has the patient (or legal surrogate) signed the consent form:



11. Has the caregiver signed the consent form:



12. Have there been no changes in the patient's AD medications within the month preceding randomization, including starting, stopping, or dose modification:

Yes

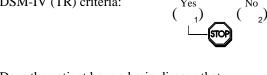


See PPM 18 for details on the changes to the wording of the eligibility criterion regarding AD medications.

C. Exclusion criteria

13. Does the patient currently meet criteria for Major Depressive Episode by DSM-IV (TR) criteria:

Yes



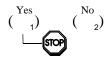
14. Does the patient have a brain disease that might otherwise explain the presence of dementia, such as extensive brain vascular disease, Parkinson's disease, dementia with Lewy bodies, traumatic brain injury, or multiple sclerosis:



15. Does the patient have psychosis (delusions or hallucinations) requiring antipsychotic treatment in the opinion of the study physician:



15a. Does the patient have a prolonged QT interval:



Note: Patients with QTc intervals greater than 450 ms for men and greater than 470 ms for women are ineligible.

16. Is treatment with citalopram contraindicated in the opinion of the study physician:



17. Has the patient failed treatment with citalopram for agitation after adequate trial at minimally accepted dose (≥20mg/day):



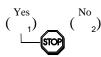
18. Is the patient on a medication that would prohibit the safe concurrent use of citalopram, such as MAO inhibitors:



19. Does the patient currently require psychiatric hospitalization or is suicidal:



20. Is the patient currently participating in a clinical trial or in any study that may add a significant burden or affect neuropsychological or other study outcomes:



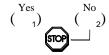
21. Is the patient currently on treatment with antipsychotics, anticonvulsants (other than dilantin), other antidepressants (other than trazodone, ≤50mg per day at bedtime), benzodiazepines (other than lorazepam), or psychostimulants:



22. Does the patient have any condition that, in the opinion of the study physician, makes it medically inappropriate or risky for the participant to enroll in the trial:



23. Have all pre-randomization procedures been completed as specified in the handbook:



If no, complete procedures prior to randomization.

24. In connection to this visit, has the study physician examined the patient and determined that the patient meets all eligibility criteria specified in the eligibility and enrollment checklist:



If no, the study physician must confirm eligibility prior to randomization.

- D. Administrative information
 - **25.** Date form reviewed by study coordinator:

<u></u> _		
day	month	year

- **26.** Study coordinator ID: ____ ___
- **27.** Study coordinator signature:

By affixing your signature below, you affirm that you have seen the patient, reviewed this form and that all the information is correct.

28. Date form reviewed by study physician:



- **29.** Study physician ID: ____ ___
- **30.** Study physician signature:
- E. Treatment assignment (issued by data system)