Reference #: _____

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 STOP 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: C ____ ____ ____ ____

3. Patient four-letter code: ____ ____ ____ ____

4. Date form completed:

____ ____ – ____ ____ ____ – ____ ____
day month year

5. Visit ID: E N

6. Form revision date:

0 1 – d 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:

( ) Yes (1) ( ) No (2)
STOP

a. Specify score: ____ ____
score

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

( ) Yes (1) ( ) No (2)
8.

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

( ) Yes (1) ( ) No (2)
STOP

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

( ) Yes (1) ( ) No (2)
STOP

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 (1) ( ) No (2) → STOP

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

( ) Yes (1) ( ) No (2) → 9.

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":

( ) Yes (1) ( ) No (2) → STOP

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:

( ) Yes (1) ( ) No (2) → STOP

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

( ) Yes (1) ( ) No (2) → STOP

11. Has the caregiver signed the consent form:

( ) Yes (1) ( ) No (2) → STOP

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

( ) Yes (1) ( ) No (2) → STOP

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 (1) → STOP ( ) No (2)

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:

( ) Yes (1) → STOP ( ) No (2)

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

( ) Yes (1) → STOP ( ) No (2)

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

( ) Yes (1) → STOP ( ) No (2)

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:

( ) Yes (1) → STOP ( ) No (2)

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

Yes (1) No (2) STOP

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

Yes (1) No (2) STOP

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

Yes (1) No (2) STOP

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:

Yes (1) No (2) STOP

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:

Yes (1) No (2) STOP

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:

Yes (1) No (2) STOP

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

Yes (1) No (2) STOP

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:

Yes (1) No (2) STOP

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

D. Administrative information

25. Date form reviewed by study coordinator:

____ ____–____ ____ ____–____ ____
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:

____ ____–____ ____ ____–____ ____
day month year

29. Study physician ID: ____ ____ ____

30. Study physician signature:

_____

E. Treatment assignment *(issued by data system)*

31. Drug Kit ID: C ____ ____ ____ ____