CitAD

Eligibility and Enrollment Checklist (EC-1)

Purpose: Record the confirmation of eligibility criteria and the completion of enrollment procedures.
When: At EN.
Completed by: CitAD certified coordinator.
Instructions: The checklist is to be used as a reference during the enrollment process. Section B lists procedures that are to be completed prior to randomization. The items in section C are procedures that are to be completed after randomization. For section D, check each eligibility criterion upon confirmation. Check each item when completed or confirmed.

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: 2 7 - o c t - 1 1
day month year

B. Enrollment procedures: *Complete all of the below enrollment procedures prior to randomization. In order to randomize, all items below are to be checked.*

Conduct consent procedures:

		Completed
7.	Patient	( )
8.	Caregiver	( )

Complete the following checklist and forms:

		Completed
9.	Eligibility checklist (see section D of this form)	( )
10.	PL form (Patient and Caregiver Location form use to collect patient and caregiver contact information)	( )
11.	EH form (Enrollment Medical History form used to record medical history, current medications, vital signs, etc.)	( )
12.	CA form (Caregiver Information form used to record caregiver demographics)	( )

Collect assessments (by CitAD certified clinician):

Completed

13. CW form (Clinical Global Impression Worksheet) . . . . . ( )

14. NR form (NeuroBehavioral Rating Scale) . . . . . ( )

15. Perform ECG and document on QT form (QT Prolongation Monitoring) . . . . . ( )

Collect assessments (by CitAD certified personnel):

Completed

16. MS form (Mini-Mental State Exam) . . . . . ( )

17. NP form (Neuropsychiatric Inventory) . . . . . ( )

18. CS form (Cornell Scale for Depression in Dementia) . . . . . ( )

19. CM form (Cohen-Mansfield Agitation Inventory) . . . . . ( )

20. AD form (Activities of Daily Living Scale) . . . . . ( )

21. GU form (Get up and Go) . . . . . ( )

Randomization procedures:

Completed

22. Review eligibility checks and complete ES form (Eligibility Summary form used to document eligibility) . . . . ( )

23. Enter ES form into the database . . . . . ( )

24. Obtain the treatment assignment . . . . . ( )

C. Procedures after randomization: *Complete the following procedures after randomization*

Administer treatment:

Completed

25. Dispense study drug . . . . . ( )

26. Complete SD form (Study Drug Issue form) . . . . . ( )

27. Document treatment assignment on DK form (Drug Kit Accountability Log) . . . . . ( )

28. Review instructions for medication use . . . . . ( )

29. Administer psychosocial intervention and provide educational materials to caregiver . . . . . ( )

Collect blood samples:

Completed

30. DNA . . . . . ( )

31. Electrolyte panels . . . . . ( )

32. Complete BC form (Blood Collection form) . . . . . ( )

Review with patient and caregiver:

Completed

33. Visit schedule, compliance monitoring, and adverse event reporting . . . . . ( )

D. Eligibility checklist: *Below is a summary of the eligibility criteria to be confirmed. For a detailed description on the eligibility criteria, refer to the corresponding numbered criteria on page 4 of this packet. In order to randomize, all items below are to be checked "Confirmed".*

Patient meets the following inclusion criteria:

Confirmed

34. Alzheimer's disease, with MMSE score of 5-26 inclusive (or 5-28, see page 4) . . . . . ( )

35. Significant agitation, as scored on NPI . . . . . ( )

36. Informed consent . . . . . ( )

37. Availability of primary caregiver . . . . . ( )

38. No change to AD treatment . . . . . ( )

Patient does <u>not</u> meet the following exclusion criteria:

Confirmed

39. Major Depressive Episode (see page 5 of packet) . . . . . ( )

40. Brain disease explaining dementia . . . . . ( )

41. Psychosis requiring antipsychotics . . . . . ( )

42. Prolonged QT interval . . . . . ( )

43. Contraindicated treatment with citalopram . . . . . ( )

44. Past treatment failure with citalopram . . . . . ( )

45. Contraindicated medication with citalopram . . . . . ( )

46. Psychiatric hospitalization or suicidal . . . . . ( )

47. Other clinical trial/study participation . . . . . ( )

48. Prohibited psychotropic use . . . . . ( )

49. Other medical condition . . . . . ( )

CitAD eligibility criteria

Inclusion criteria

34 Probable Alzheimer's disease (NINCDS-ADRDA criteria), with MMSE score of 5-26 inclusive (MMSE score of 27 or 28 also allowed with approval of protocol version 2.2 or a more recent version and written approval from the study chairman)

35 Medication is appropriate in the opinion of the study physician; clinically significant agitation for which either 1) the frequency agitation as assessed by the NPI is "very frequently" or 2) 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".

36 Provision of informed consent for participation in the study by patient or surrogate (if necessary), and caregiver

37 Availability of 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

38 No change to AD medications within the month preceding randomization, including starting, stopping, or dosage modifications

Exclusion criteria

39 Meets criteria for Major Depressive Episode by DSM-IV (TR) criteria

40 Presence of 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

41 Psychosis (delusions or hallucinations) requiring antipsychotic treatment in the opinion of the study physician

42 Prolonged QT interval

43 Treatment with citalopram is contraindicated in the opinion of the study physician

44 Failure of past treatment with citalopram for agitation after adequate trial at a minimally accepted dose (greater than or equal to 20mg/day)

45 Treatment with a medication that would prohibit the safe concurrent use of citalopram, such as MAO inhibitors

46 Need for psychiatric hospitalization, or suicidal

47 Current participation in a clinical trial or in any study that may add a significant burden or affect neuropsychological or other study outcomes

48 Current treatment with antipsychotics, anticonvulsants (other than dilantin), other antidepressants (other than trazodone, less than or equal to 50 mg per day at bedtime), benzodiazepines (other than lorazepam), or psychostimulants

49 Any condition that, in the opinion of the study physician, makes it medically inappropriate or risky for the patient to enroll in the trial

Major Depressive Episode (DSM-IV (TR) criteria)

A. Five (or more) of the following symptoms have been present during the same 2-week period and represent a change from the previous functioning; at least one of the symptoms is either (1) depressed mood or (2) loss of interest or pleasure.

Note: Do not include symptoms that are clearly due to a general medical condition, or mood-incongruent delusions or hallucinations.

(1) depressed mood most of the day, nearly every day, as indicated by either subjective report (e.g., feel sad or empty) or observation made by others (e.g., appears tearful)
(2) markedly diminished interest or pleasure in all, or almost all, activities most of the day, nearly every day (as indicated by either subjective account or observation made by others)
(3) significant weight loss when not dieting or weight gain (e.g., a change of more than 5% of body weight in a month), or decrease or increase in appetite nearly every day
(4) insomnia or hypersomnia nearly every day
(5) psychomotor agitation or retardation nearly every day (observable by others, not merely subjective feelings of restlessness or being slowed down)
(6) fatigue or loss of energy nearly every day
(7) feelings of worthlessness or excessive or inappropriate guilt (which may be delusional) nearly every day (not merely self-reproach or guilt about being sick)
(8) diminished ability to think or concentrate, or indecisiveness, nearly every day (either by subjective account or as observed by others)
(9) recurrent thoughts of death (not just fear of dying), recurrent suicidal ideation without a specific plan, or a suicide attempt or a specific plan for committing suicide

B. The symptoms do not meet criteria for a Mixed Episode.

C. The symptoms cause clinically significant distress or impairment in social, occupational, or other important areas of functioning.

D. The symptoms are not due to the direct physiological effects of a substance (e.g., a drug of abuse, a medication) or a general medical condition (e.g., hypothyroidism).

E. The symptoms are not better accounted for by bereavement, i.e., after the loss of a loved one, the symptoms persist for longer than 2 months or are characterized by marked functional impairment, morbid preoccupation with worthlessness, suicidal ideation, psychotic symptoms, or psychomotor retardation.