CDISC	Study	Site #	Patient ID#	Subject Initials	*VISITNUM* **VISIT 1** *VISIT* **SCREEN**
					Visit Date: Visit Date:
	CDISC01	___ ___ ___	— — —	— — —	*IEDTC*

ELIGIBILITY CRITERIA

INCLUSION CRITERIA *IECAT* Check the appropriate response	Yes	No	N/A
		IEORRES	
1. Is age 18 - 85. *IETEST where IETESTCD = INCL01*	☐	☐	
2. Has Xyz disease of at least 10 weeks duration confirmed by biopsy *IETEST where IETESTCD = INCL02*	☐	☐	
3. Did not respond to a standard course of medication ABC. *IETEST where IETESTCD = INCL03*	☐	☐	

*All **Inclusion Criteria** questions 1-3 must be answered **YES** or **N/A** to enter the study.*

CDISC	Study	Site #	Patient ID#	Subject Initials	*VISITNUM* **VISIT 1** *VISIT* **SCREEN**
	CDISC01	___ ___ ___	— — —	— — —	Visit Date: Visit Date: _____ *IEDTC* _____

ELIGIBILITY CRITERIA

EXCLUSION CRITERIA *IECAT* Check the appropriate response	**Yes**	**No**
	IEORRES	
1. Is pregnant, nursing, or planning to become pregnant within 6 months of last study treatment. *IETEST where IETESTCD = EXCL01*	☐	☐
2. Is unable or unwilling to undergo multiple venipunctures. *IETEST where IETESTCD = EXCL02*	☐	☐
3. Is known to have had a substance abuse (drug or alcohol) problem within the previous 3 years. *IETEST where IETESTCD = EXCL03*	☐	☐

*All **Exclusion Criteria** questions 1-3 must be answered **NO** to enter the study.*

CDISC	SDTM Example			*VISITNUM* VISIT 1 *VISIT* SCREEN	
	Study *STUDYID*	**Site #** *SITEID*	**Patient ID#** *SUBJID*	**Subject Initials** *SCORRES where SCTESTCD =INITIALS*	**Visit Date:** *SCDTC*

DEMOGRAPHY

Date of Birth: _____ *BRTHDTC* _____

Gender: *SEX*
☐ Male   ☐ Female

Ethnicity: *ETHNIC*
☐ Hispanic/Latino   ☐ Not Hispanic/Latino

Race: *RACE*
☐ White   ☐ American Indian or Alaska Native
☐ Black   ☐ Native Hawaiian or Pacific Islander
☐ Asian   ☐ Other: *SCORRES where SCTESTCD = RACEOTH*

FamilyStatus: ☐ Single   ☐ Living with Partner
☐ Married   ☐ Divorced   *SCORRES where SCTESTCD = FAMILY*
☐ Separated   ☐ Widowed

Education: ☐ Some High School   ☐ College Graduate   *SCORRES where SCTESTCD = EDUCATN*
☐ High School Graduate/GED   ☐ Graduate Degree & Beyond
☐ Some College   ☐ Other:: *SUPPSC.QVAL where QNAM =EDUOTH*

INFORMED CONSENT *DSDECOD*

Date consent form signed: _____ *DSSTDTC* _____

CDISC	Study CDISC01	Site # __ __ __	Patient ID# __ __ __	Patient ID# __ __ __	Subject Initials __ __ __	VISIT 1 SCREEN Visit Date: *MHDTC* __/__/__

PSYCHIATRIC HISTORY *MHCAT*

MHTERM

MHSTDTC

1. Date of onset of probable Alzheimer's Disease?   □□ □□ □□□□

2. Date of onset of depression of Alzheimer's Disease?   □□ □□ □□□□

CDISC	Study CDISC01	Site # ___ ___ ___	Patient ID# ___ ___ ___	Patient ID# ___ ___ ___	Subject Initials ___ ___ ___	Visit Date: *MHDTC* ___ ___ ___

MEDICAL AND SURGICAL HISTORY *MHCAT*

Does the subject have any significant medical or surgical history? *[Not Submitted]*	ONSET		"√" if RESOLVED	"√" if ONGOING
☐ Yes, list the condition(s) below ☐ No	*Month*	*Year*		
MHTERM	*MHSTDTC* ☐☐	☐☐☐☐	*MHENRF = BEFORE* ☐	*MHENRF = DURING/ AFTER*
	☐☐	☐☐☐☐	☐	
	☐☐	☐☐☐☐	☐	☐
	☐☐	☐☐☐☐	☐	☐
	☐☐	☐☐☐☐	☐	☐
	☐☐	☐☐☐☐	☐	☐
	☐☐	☐☐☐☐	☐	☐
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	☐☐	☐☐☐☐	☐	☐
	☐☐	☐☐☐☐	☐	☐
	☐☐	☐☐☐☐	☐	☐
	☐☐	☐☐☐☐	☐	☐
	☐☐	☐☐☐☐	☐	☐
	☐☐	☐☐☐☐	☐	☐

CDISC	Study	Site #	Patient ID#	Subject Initials	Visit Date:
	CDISC01	___ ___ ___	___ ___ ___	___ ___ ___	_____/_____/_____

PSYCHOTROPIC DRUG TREATMENT HISTORY *CMCAT*

List all the Psychotropic drugs the patient has taken within the past 5 years.
If NONE, CHECK BOX: ☐ *[Not Submitted]*

Generic Drug Name (Enter the trade name for combination drugs)	Response Code	Total Daily Dose	Units	Start Date (M/D/Y)	Stop Date (M/D/Y)	Indication	Reason for Discontinuation
CMTRT		*CMDOSTOT*		*CMSTDTC*	/ /	*CMINDC*	
	SUPPCM.QVAL where QNAM =PDRESP		*CMDOSU*	/ /	*CMENDTC*		*SUPPCM.QVAL where QNAM = PDDREAS*
				/ /	/ /		
				/ /	/ /		
				/ /	/ /		
				/ /	/ /		
				/ /	/ /		
				/ /	/ /		
				/ /	/ /		
				/ /	/ /		

	Study	Site #	Patient ID#	Subject Initials	**VISITNUM** **VISIT 1** **VISIT** **SCREEN**
	CDISC01	___ ___ ___	— — —	— — —	Visit Date: Visit Date: **PEDTC** ___

PHYSICAL EXAM			

PHYSICAL EXAM **PESPID** **PETEST**	**PEORRES** **Normal**	**Abnormal**	**PEORRES** **Comment only if abnormal**
1. Appearance/Skin	☐	☐	
2. Head/Neck (Including Thyroid)	☐	☐	
3. Eyes-Ears-Nose-Throat	☐	☐	
4. Cardiovascular	☐	☐	
5. Pulmonary	☐	☐	
6. Abdomen	☐	☐	
7. Neurological	☐	☐	
8. Musculoskeletal	☐	☐	
9. Other	☐	☐	

PETESTCD = PETEST

PE01 = Appearance/Skin
PE02 = Head/Neck (Including Thyroid)
PE03 = Eyes-Ears-Nose-Throat
PE04 = Cardiovascular
PE05 = Pulmonary
PE06 = Abdomen
PE07 = Neurological
PE08 = Musculoskeletal
PE09 = Other

					VISITNUM **VISIT 1**
CDISC	**Study**	**Site #**	**Patient ID#**	**Subject Initials**	*VISIT* **SCREEN**
	CDISC01	———	———	———	Visit Date: *VSDTC* ___

VITAL SIGNS

VSPOS where

Height

☐ cm
☐ in

VSORRES where VSTESTCD = HEIGHT

VSORRESU where VSTESTCD = HEIGHT

Sitting Blood Pressure

[   ] / [   ] mmHg

Systolic   Diastolic

VSORRES where   *VSORRES where*

VSORRESU where VSTESTCD = SYSBP or DIABP

Weight

☐ kgs
☐ lbs

VSORRES where VSTESTCD = WEIGHT

VSORRESU where VSTESTCD = WEIGHT

Radial Pulse Rate

[   ] bps

VSORRES where VSTESTCD = PULSE

VSORRESU where VSTESTCD = PULSE

LABORATORY

[Not Submitted]

Were laboratory tests performed at this visit?   ☐ Yes   ☐ No

CDISC	Study	Site #	Patient ID#	Subject Initials	*VISITNUM* VISIT 1 *VISIT* SCREEN
	CDISC01	__ __ __	__ __ __	__ __ __	Visit Date: ____/____/____

12- LEAD ECG

Date Performed: ☐☐ / ☐☐ / ☐☐☐☐

Month   **Day**   **Year**

EGDTC

EGTEST

ECG RESULTS

Ventricular Heart Rate	☐☐☐ bpm	*EGORRES where EGTESTCD = VRATE*	*EGORRESU where EGTESTCD = VRATE*
PR Interval	☐☐☐ msec	*EGORRES where EGTESTCD = PR*	*EGORRESU where EGTESTCD = PR*
QRS Interval	☐☐☐ msec	*EGORRES where EGTESTCD = QRS*	*EGORRESU where EGTESTCD = QRS*
QT Interval:	☐☐☐ msec	*EGORRES where EGTESTCD = QT*	*EGORRESU where EGTESTCD = QT*

OVERALL INTERPRETATION (Please check one): *EGORRES where EGTESTCD = INTP*

1 = ☐   **Normal (do not comment)**

2 = ☐   **Abnormal, not clinically significant (do not comment)**

3 = ☐   **Abnormal, clinically significant. Specify and comment:**
       Comments [char(200)]

EGORRES where EGTESTCD = INTP

_____

_____

_____

CDISC	Study	Site #	Patient ID#	Subject Initials	VISITNUM VISIT 1 VISIT SCREEN Visit Date
	CDISC01				QSDTC

QSCAT	MINI-MENTAL STATE EXAMINATION (MMSE SUMMARY PAGE)

Instructions: Please transcribe the appropriate scores from the MMSE workbook into the boxes below.

Rater's Initials: ☐☐☐ QSEVAL

QSORRES

A. ORIENTATION

1. **TIME: The range of scores is 0 to 5.**

   QSTEST where QSTESTCD = MMSEA1

   Score (total number of correct responses ☐

2. **PLACE: The range of scores is 0 to 5.**

   QSTEST where QSTESTCD = MMSEA2

   Score (total number of correct responses ☐

B. REGISTRATION: The range of scores is 0 to 3.

QSTEST where QSTESTCD = MMSEB

Score (total number of correct responses ☐

C. ATTENTION AND CALCULATION: The range of scores is 0 to 5.

QSTEST where QSTESTCD = MMSEC

Score (total number of correct responses ☐

D. RECALL: The range of scores is 0 to 3.

QSTEST where QSTESTCD = MMSED

Score (total number of correct responses ☐

E. LANGUAGE: The range of scores is 0 to 9.

QSTEST where QSTESTCD = MMSEE

Score (total number of correct responses ☐

Sum of Scores for Sections A through E ☐☐
QSTEST where QSTESTCD = MMSETOT

CDISC	Study **CDISC01**	Site # ___ ___ ___	Patient ID# ___ ___ ___	Subject Initials ___ ___ ___	Visit Date: QSDTC ___ ___ ___

CORNELL SCALE FOR DEPRESSION IN DEMENTIA (CSDD) (PAGE 1 OF 2)
QSCAT

:
Instructions: For each item, select the "cue" which best characterizes the symptoms and signs occurring during the past week, and circle the appropriate number.

Rater's Initials: ☐ ☐ ☐
QSEVAL

| | QSORRES | | |
| | CUE | | |
A. MOOD - RELATED SIGNS	**ABSENT**	**MILD OR INTERMITTENT**	**SEVERE**
1. ANXIETY Anxious expression, ruminations, worrying QSTEST where QSTESTCD =CSDD01	0	1	2
2. SADNESS Sad expression, sad voice, tearfulness QSTEST where QSTESTCD = CSDD02	0	1	2
3. LACK OF REACTIVITY TO PLEASANT EVENTS QSTEST where QSTESTCD = CSDD03	0	1	2
4. IRRITABILITY Easily annoyed, short tempered QSTEST where QSTESTCD = CSDD04	0	1	2
B. BEHAVIORAL DISTURBANCE			
5. AGITATION Restlessness, handwringing, hairpulling QSTEST where QSTESTCD = CSDD05	0	1	2
6. RETARDATION Slow movements, slow speech, slow reactions QSTEST where QSTESTCD = CSDD06	0	1	2
7. MULTIPLE PHYSICAL COMPLAINTS (score 0 if GI symptoms only) QSTEST where QSTESTCD = CSDD07	0	1	2
8. LOSS OF INTEREST Less involved in usual activities (score only if change occurred acutely, i.e. in less than 1 month) QSTEST where QSTESTCD = CSDD08	0	1	2

CORNELL SCALE FOR DEPRESSION IN DEMENTIA (CSDD) (PAGE 2 OF 2)

	QSORRES		
		CUE	
C. PHYSICAL SIGNS	**ABSENT**	**MILD OR INTERMITTENT**	**SEVERE**
9. APPETITE LOSS Eating less than usual *QSTEST where QSTESTCD = CSDD09*	0	1	2
10. WEIGHT LOSS (score 2 if greater than 5 lbs. in 1 month) *QSTEST where QSTESTCD = CSDD10*	0	1	2
11. LACK OF ENERGY Fatigues easily, unable to sustain activities (score only if change occurred acutely, i.e., in less than 1 month) *QSTEST where QSTESTCD = CSDD11*	0	1	2
D. CYCLIC FUNCTIONS			
12. DIURNAL VARIATION OF MOOD Symptoms worse in the morning *QSTEST where QSTESTCD = CSDD12*	0	1	2
13. DIFFICULTY FALLING ASLEEP Later than usual for this individual *QSTEST where QSTESTCD = CSDD13*	0	1	2
14. MULTIPLE AWAKENINGS DURING SLEEP *QSTEST where QSTESTCD = CSDD14*	0	1	2
15. EARLY MORNING AWAKENING Earlier than usual for this individual *QSTEST where QSTESTCD = CSDD15*	0	1	2
E. IDEATIONAL DISTURBANCE			
16. SUICIDE Feels life is not worth living, has suicidal wishes, or makes suicide attempt *QSTEST where QSTESTCD = CSDD16*	0	1	2
17. POOR SELF-ESTEEM Self-blame, self-depreciation, feelings of failure *QSTEST where QSTESTCD = CSDD17*	0	1	2
18. PESSIMISM Anticipation of the worst *QSTEST where QSTESTCD = CSDD18*	0	1	2
19. MOOD-CONGRUENT DELUSIONS Delusions of poverty, illness, or loss *QSTEST where QSTESTCD = CSDD19*	0	1	2

Reminder: The patient must have a minimum total score of 13 on the CSDD at both Screening and Baseline visits to be eligible for study participation.

Total Score: [ ][ ]

[Not Submitted]

CDISC	Study CDISC01	Site # — — —	Patient ID# — — —	Subject Initials — — —	**VISIT 2** **BASELINE** Visit Date: *DSSTDTC*

RANDOMIZATION

DSDECOD = RANDOMIZED

Will the patient be randomized?　　☐ Yes　　Enter Randomization Number　☐☐☐☐　*SUPPDM.QVAL where QNAM = RANDNO*

SUPPDM.QVAL where QNAM = RAND

　　☐ No　　Complete Termination

CDISC					VISIT 2 BASELINE
	Study	**Site #**	**Patient ID#**	**Subject Initials**	**Visit Date:**
	CDISC01	— — —	— — —	___ ___ ___	____/____/____

VITAL SIGNS

Weight

☐☐☐ . ☐   ☐ kgs
☐ lbs

Sitting Blood Pressure

☐☐☐ / ☐☐☐ mmHg
Systolic   Diastolic

Radial Pulse Rate

☐☐☐ bpm

					VISIT 2 BASELINE
CDISC	**Study** **CDISC01**	**Site #**	**Patient ID#**	**Subject Initials**	**Visit Date** _____/_____/_____

MINI-MENTAL STATE EXAMINATION (MMSE SUMMARY PAGE)

A. ORIENTATION

For Annotations see CRF page 10

1. TIME: The range of scores is 0 to 5.

<div align="right">

Score (total number of correct responses ☐

</div>

2. PLACE: The range of scores is 0 to 5.

<div align="right">

Score (total number of correct responses ☐

</div>

B. REGISTRATION: The range of scores is 0 to 3.

<div align="right">

Score (total number of correct responses ☐

</div>

C. ATTENTION AND CALCULATION: The range of scores is 0 to 5.

<div align="right">

Score (total number of correct responses ☐

</div>

D. RECALL: The range of scores is 0 to 3.

<div align="right">

Score (total number of correct responses ☐

</div>

E. LANGUAGE: The range of scores is 0 to 9.

<div align="right">

Score (total number of correct responses ☐

</div>

<div align="right">

Sum of Scores for Sections A through E ☐☐

</div>

Please Note: Total Score must be at least 15 and not greater than 24 at both Screening and Baseline for patient to be randomized.

CDISC	Study CDISC01	Site # — — —	Patient ID# — — —	Subject Initials ___ ___ ___	Visit Date: ____/____/____

CORNELL SCALE FOR DEPRESSION IN DEMENTIA (CSDD) (PAGE 1 OF 2)

For Annotations see CRF page 11

:
Instructions: For each item, select the "cue" which best characterizes the symptoms and signs occurring during the past week, and circle the appropriate number.

Rater's Initials: ☐ ☐ ☐

A. MOOD - RELATED SIGNS	CUE		
	ABSENT	MILD OR INTERMITTENT	SEVERE
1. ANXIETY Anxious expression, ruminations, worrying	0	1	2
2. SADNESS Sad expression, sad voice, tearfulness	0	1	2
3. LACK OF REACTIVITY TO PLEASANT EVENTS	0	1	2
4. IRRITABILITY Easily annoyed, short tempered	0	1	2
B. BEHAVIORAL DISTURBANCE			
5. AGITATION Restlessness, handwringing, hairpulling	0	1	2
6. RETARDATION Slow movements, slow speech, slow reactions	0	1	2
7. MULTIPLE PHYSICAL COMPLAINTS (score 0 if GI symptoms only)	0	1	2
8. LOSS OF INTEREST Less involved in usual activities (score only if change occurred acutely, i.e. in less than 1 month)	0	1	2

CDISC	Study **CDISC01**	Site # __ __ __	Patient ID# __ __ __	Subject Initials __ __ __	Visit Date: ____/____/____

CORNELL SCALE FOR DEPRESSION IN DEMENTIA (CSDD) (PAGE 2 OF 2)

For Annotations see CRF page 12

C. PHYSICAL SIGNS	CUE		
	ABSENT	**MILD OR INTERMITTENT**	**SEVERE**
9. APPETITE LOSS Eating less than usual	0	1	2
10. WEIGHT LOSS (score 2 if greater than 5 lbs. in 1 month)	0	1	2
11. LACK OF ENERGY Fatigues easily, unable to sustain activities (score only if change occurred acutely, i.e., in less than 1 month)	0	1	2
D. CYCLIC FUNCTIONS			
12. DIURNAL VARIATION OF MOOD Symptoms worse in the morning	0	1	2
13. DIFFICULTY FALLING ASLEEP Later than usual for this individual	0	1	2
14. MULTIPLE AWAKENINGS DURING SLEEP	0	1	2
15. EARLY MORNING AWAKENING Earlier than usual for this individual	0	1	2
E. IDEATIONAL DISTURBANCE			
16. SUICIDE Feels life is not worth living, has suicidal wishes, or makes suicide attempt	0	1	2
17. POOR SELF-ESTEEM Self-blame, self-depreciation, feelings of failure	0	1	2
18. PESSIMISM Anticipation of the worst	0	1	2
19. MOOD-CONGRUENT DELUSIONS Delusions of poverty, illness, or loss	0	1	2

Reminder: The patient must have a minimum total score of 13 on the CSDD at both Screening and Baseline visits to be eligible for study participation.

Total Score: [ ][ ]

CDISC	Study	Site #	Patient ID#	Subject Initials	*VISITNUM* VISIT 2 *VISIT* BASELINE
	CDISC01				Visit Date ____/____/____

| **VISIT 2 TO VISIT 3 - STUDY MEDICATION INVENTORY** ||||

Date Tablets Dispensed	*DATEST* Number of Tablets Dispensed	Date Tablets Returned	*DATEST* Number of Tablets Returned
DADTC where DATESTCD = DADISNO ☐☐ ☐☐	*DAORRES where DATESTCD = DADISNO*	*DADTC where DATESTCD = DARETNO* ☐☐ ☐☐	*DAORRES where DATESTCD = DARETNO* ☐
Month Day Year		Month Day Year	
☐☐ ☐☐ ☐☐☐☐	☐☐	☐☐ ☐☐ ☐☐☐☐	☐☐
Month Day Year		Month Day Year	
☐☐ ☐☐ ☐☐☐☐	☐☐	☐☐ ☐☐ ☐☐☐☐	☐☐
Month Day Year		Month Day Year	
☐☐ ☐☐ ☐☐☐☐	☐☐	☐☐ ☐☐ ☐☐☐☐	☐☐
Month Day Year		Month Day Year	
☐☐ ☐☐ ☐☐☐☐	☐☐	☐☐ ☐☐ ☐☐☐☐	☐☐
Month Day Year		Month Day Year	

	Study	Site #	Patient ID#	Subject Initials	Visit Date:
	CDISC01	___ ___ ___	___ ___ ___	___ ___ ___	____/____/____

Medication Record Visit 2 to Visit 3 *VISIT*

Please record the total number of tablets taken for the consecutive days that the patient received that dose.

From			To			Number of Tablets per Day	Provide the reason for any dose change or missed dose
Month	Day	Year	Month	Day	Year	*SUPPEX.QVAL where QNAM = SMNO*	*COVAL where IDVAR = EXSEQ*
	EXSTDTC			*EXENDTC*			

CDISC	Study	Site #	Patient ID#	Subject Initials	Visit Date:
	CDISC01	— — —	— — —	__ __ __	____/____/____

VITAL SIGNS

For Annotations see CRF page 8

Weight

☐ kgs
☐ lbs

Sitting Blood Pressure

/ mmHg

Systolic Diastolic

Radial Pulse Rate

bpm

CDISC	Study	Site #	Patient ID#	Subject Initials	VISITNUM VISIT 3 VISIT WEEK 2
	CDISC01	— — —	— — —	— — —	Visit Date: _ QSDTC _

CLINICAL GLOBAL IMPRESSION (CGI-I) QSCAT

QSEVAL

Rater's Initials: ☐ ☐ ☐

GLOBAL IMPROVEMENT

Rate total improvement or worsening relative to baseline with respect to the patient's Disease. Compared to his/her condition at baseline, how much has the patient changed?

QSORRES where
QSTESTCD = CGIGLOB

1 ☐ Very much improved

2 ☐ Much improved

3 ☐ Minimally improved

4 ☐ No change

5 ☐ Minimally worse

6 ☐ Much worse

7 ☐ Very much worse

CDISC	Study **CDISC01**	Site # — — —	Patient ID# — — —	Subject Initials ___ ___ ___	Visit Date: ____/____/____

CORNELL SCALE FOR DEPRESSION IN DEMENTIA (CSDD) (PAGE 1 OF 2)

:

For Annotations see CRF page 11

Instructions: For each item, select the "cue" which best characterizes
the symptoms and signs occurring during the past week,
and circle the appropriate number.

Rater's Initials: ☐ ☐ ☐

A. MOOD - RELATED SIGNS	CUE		
	ABSENT	**MILD OR INTERMITTENT**	**SEVERE**
1. ANXIETY Anxious expression, ruminations, worrying	0	1	2
2. SADNESS Sad expression, sad voice, tearfulness	0	1	2
3. LACK OF REACTIVITY TO PLEASANT EVENTS	0	1	2
4. IRRITABILITY Easily annoyed, short tempered	0	1	2
B. BEHAVIORAL DISTURBANCE			
5. AGITATION Restlessness, handwringing, hairpulling	0	1	2
6. RETARDATION Slow movements, slow speech, slow reactions	0	1	2
7. MULTIPLE PHYSICAL COMPLAINTS (score 0 if GI symptoms only)	0	1	2
8. LOSS OF INTEREST Less involved in usual activities (score only if change occurred acutely, i.e. in less than 1 month)	0	1	2

CDISC	Study **CDISC01**	Site # ___ ___ ___	Patient ID# ___ ___ ___	Subject Initials ___ ___ ___	Visit Date: ____/____/____

CORNELL SCALE FOR DEPRESSION IN DEMENTIA (CSDD) (PAGE 2 OF 2)

For Annotations see CRF page 12

C. PHYSICAL SIGNS	CUE		
	ABSENT	MILD OR INTERMITTENT	SEVERE
9. APPETITE LOSS Eating less than usual	0	1	2
10. WEIGHT LOSS (score 2 if greater than 5 lbs. in 1 month)	0	1	2
11. LACK OF ENERGY Fatigues easily, unable to sustain activities (score only if change occurred acutely, i.e., in less than 1 month)	0	1	2
D. CYCLIC FUNCTIONS			
12. DIURNAL VARIATION OF MOOD Symptoms worse in the morning	0	1	2
13. DIFFICULTY FALLING ASLEEP Later than usual for this individual	0	1	2
14. MULTIPLE AWAKENINGS DURING SLEEP	0	1	2
15. EARLY MORNING AWAKENING Earlier than usual for this individual	0	1	2
E. IDEATIONAL DISTURBANCE			
16. SUICIDE Feels life is not worth living, has suicidal wishes, or makes suicide attempt	0	1	2
17. POOR SELF-ESTEEM Self-blame, self-depreciation, feelings of failure	0	1	2
18. PESSIMISM Anticipation of the worst	0	1	2
19. MOOD-CONGRUENT DELUSIONS Delusions of poverty, illness, or loss	0	1	2

Used with permission from Alexpoulos, GS. Biol Psychiatry, 1988a. Volume 23: 271-284

Study	Site #	Patient ID#	Subject Initials	Visit Date
CDISC01				_____/_____/_____

VISIT 3 TO VISIT 6 - STUDY MEDICATION INVENTORY

For Annotations see CRF page 18

Date Tablets Dispensed	Number of Tablets Dispensed	Date Tablets Returned	Number of Tablets Returned
☐☐ ☐☐ ☐☐☐☐ **Month Day Year**	☐☐	☐☐ ☐☐ ☐☐☐☐ **Month Day Year**	☐☐
☐☐ ☐☐ ☐☐☐☐ **Month Day Year**	☐☐	☐☐ ☐☐ ☐☐☐☐ **Month Day Year**	☐☐
☐☐ ☐☐ ☐☐☐☐ **Month Day Year**	☐☐	☐☐ ☐☐ ☐☐☐☐ **Month Day Year**	☐☐
☐☐ ☐☐ ☐☐☐☐ **Month Day Year**	☐☐	☐☐ ☐☐ ☐☐☐☐ **Month Day Year**	☐☐
☐☐ ☐☐ ☐☐☐☐ **Month Day Year**	☐☐	☐☐ ☐☐ ☐☐☐☐ **Month Day Year**	☐☐

ISC	Study CDISC01	Site # ___ ___ ___	Patient ID# ___ ___ ___	Subject Initials ___ ___ ___	Visit Date: ___/___/___

Medication Record Visit 3 to Visit 6

Please record the total number of tablets taken for the consecutive days that the patient received that dose.

From			To			Number of Tablets per Day	Provide the reason for any dose change or missed dose
Month	Day	Year	Month	Day	Year		
							For Annotations see CRF page 19

CDISC	Study	Site #	Patient ID#	Subject Initials	Visit Date:
	CDISC01	— — —	— — —	___ ___ ___	____/____/____

VITAL SIGNS

For annotation see CRF page 8

Weight

☐☐☐ . ☐ ☐ kgs
☐ lbs

Sitting Blood Pressure

☐☐☐ / ☐☐☐ mmHg
Systolic   Diastolic

Radial Pulse Rate

☐☐☐ bpm

CDISC	Study	Site #	Patient ID#	Subject Initials	Visit Date:
	CDISC01	— — —	— — —	— — —	___/___/____

12- LEAD ECG

Date Performed: ☐☐ / ☐☐ / ☐☐☐☐

Month   **Day**   **Year**

For Annotations see CRF page 9

ECG RESULTS

Ventricular Heart Rate	☐☐☐ **bpm**		
PR Interval	☐☐☐ **msec**		
QRS Interval	☐☐☐ **msec**		
QT Interval:	☐☐☐ **msec**		

OVERALL INTERPRETATION (Please check one):

1 = ☐   **Normal (do not comment)**

2 = ☐   **Abnormal, not clinically significant (do not comment)**

3 = ☐   **Abnormal, clinically significant. Specify and comment:**
      Comments [char(200)]

_____

_____

_____

CDISC	Study	Site #	Patient ID#	Subject Initials	Visit Date
	CDISC01				____/____/____

MINI-MENTAL STATE EXAMINATION (MMSE SUMMARY PAGE)

A. ORIENTATION *For Annotations see CRF page 10*

   1. PLACE: The range of scores is 0 to 5.

                                    Score (total number of correct responses ☐

   2. PLACE: The range of scores is 0 to 5.

                                    Score (total number of correct responses ☐

B. REGISTRATION: The range of scores is 0 to 3.

                                    Score (total number of correct responses ☐

C. ATTENTION AND CALCULATION: The range of scores is 0 to 5.

                                    Score (total number of correct responses ☐

D. RECALL: The range of scores is 0 to 3.

                                    Score (total number of correct responses ☐

E. LANGUAGE: The range of scores is 0 to 9.

                                    Score (total number of correct responses ☐

                              Sum of Scores for Sections A through E ☐☐

CDISC	Study **CDISC01**	Site # — — —	Patient ID# — — —	Subject Initials — — —	Visit Date: ____/____/____

CORNELL SCALE FOR DEPRESSION IN DEMENTIA (CSDD) (PAGE 1 OF 2)

For Annotations see CRF page 11

:
Instructions: For each item, select the "cue" which best characterizes
the symptoms and signs occurring during the past week,
and circle the appropriate number.

Rater's Initials: ☐☐☐

	CUE		
A. MOOD - RELATED SIGNS	**ABSENT**	**MILD OR INTERMITTENT**	**SEVERE**
1. ANXIETY Anxious expression, ruminations, worrying	0	1	2
2. SADNESS Sad expression, sad voice, tearfulness	0	1	2
3. LACK OF REACTIVITY TO PLEASANT EVENTS	0	1	2
4. IRRITABILITY Easily annoyed, short tempered	0	1	2
B. BEHAVIORAL DISTURBANCE			
5. AGITATION Restlessness, handwringing, hairpulling	0	1	2
6. RETARDATION Slow movements, slow speech, slow reactions	0	1	2
7. MULTIPLE PHYSICAL COMPLAINTS (score 0 if GI symptoms only)	0	1	2
8. LOSS OF INTEREST Less involved in usual activities (score only if change occurred acutely, i.e. in less than 1 month)	0	1	2

CORNELL SCALE FOR DEPRESSION IN DEMENTIA (CSDD) (PAGE 2 OF 2)

For Annotations see CRF page 12

C. PHYSICAL SIGNS	CUE		
	ABSENT	**MILD OR INTERMITTENT**	**SEVERE**
9. APPETITE LOSS Eating less than usual	0	1	2
10. WEIGHT LOSS (score 2 if greater than 5 lbs. in 1 month)	0	1	2
11. LACK OF ENERGY Fatigues easily, unable to sustain activities (score only if change occurred acutely, i.e., in less than 1 month)	0	1	2
D. CYCLIC FUNCTIONS			
12. DIURNAL VARIATION OF MOOD Symptoms worse in the morning	0	1	2
13. DIFFICULTY FALLING ASLEEP Later than usual for this individual	0	1	2
14. MULTIPLE AWAKENINGS DURING SLEEP	0	1	2
15. EARLY MORNING AWAKENING Earlier than usual for this individual	0	1	2
E. IDEATIONAL DISTURBANCE			
16. SUICIDE Feels life is not worth living, has suicidal wishes, or makes suicide attempt	0	1	2
17. POOR SELF-ESTEEM Self-blame, self-depreciation, feelings of failure	0	1	2
18. PESSIMISM Anticipation of the worst	0	1	2
19. MOOD-CONGRUENT DELUSIONS Delusions of poverty, illness, or loss	0	1	2

Used with permission from Alexpoulos, GS. Biol Psychiatry, 1988a. Volume 23: 271-284

CDISC	Study	Site #	Patient ID#	Subject Initials	Visit Date:
	CDISC01	— — —	— — —	— — —	___/___/___

CLINICAL GLOBAL IMPRESSION (CGI-I)

For Annotations see CRF page 21

Rater's Initials: ☐☐☐

GLOBAL IMPROVEMENT

Rate total improvement or worsening relative to baseline with respect to the patient's Disease. Compared to his/her condition at baseline, how much has the patient changed?

1 ☐ Very much improved

2 ☐ Much improved

3 ☐ Minimally improved

4 ☐ No change

5 ☐ Minimally worse

6 ☐ Much worse

7 ☐ Very much worse

Study	Site #	Patient ID#	Subject Initials	Visit Date
CDISC01				____/____/____

VISIT 6 - STUDY MEDICATION INVENTORY

For Annotations see CRF page 18

Date Tablets Dispensed	Number of Tablets Dispensed	Date Tablets Returned	Number of Tablets Returned
□□ □□ □□□□ Month Day Year	□□	□□ □□ □□□□ Month Day Year	□□
□□ □□ □□□□ Month Day Year	□□	□□ □□ □□□□ Month Day Year	□□
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CDISC	Study CDISC01	Site # __ __ __	Patient ID# __ __ __	Subject Initials ___ ___ ___	Visit Date: ___/___/___

TERMINATION

Did patient complete the study?   ☐ Yes   ☐ No   *DSDECOD= where COMPLETE = YES*

If patient did not complete the study, indicate the date of termination and check one primary reason to indicate why:

Date of Termination: ☐ ☐ / ☐ ☐ / ☐ ☐ ☐ ☐   *DSSTDTC*

DSDECOD

☐   Patient did not meet Inclusion/Exclusion Criteria at Screening or baseline (specify): : _*DSTERM*___
_____

☐   Discontinued due to lack of Therapeutic Response

☐   Discontinued due to Adverse Event (Complete the ADVERSE EVENTS Form)

☐   Protocol Violation (specify) : _*DSTERM*_____

☐   Discontinued due to Consent Withdrawn

☐   Discontinued due to Lost to Follow Up

☐   Discontinued due to Sponsor/Investigator Decision, specify: _*DSTERM*_____

[Not Submitted]

I have reviewed the data associated with the case report forms for this subject and have determined that the data are accurate and are consistent with supporting source documentation.

Investigator's Signature: _____   Date: _____/_____/_____

Investigator's Name: _____

CDISC	Study	Site #	Patient ID#	Subject Initials	
	CDISC01	__ __ __		__ __ __	

ADVERSE EVENTS

Adverse Event	Onset Date (MM/DD/YY)	Relation to Study Drug			Maximum Intensity			Action Taken				Serious Adverse Event?		Resolution (Complete One)	Ongoing
		Not Related	Possibly Related	Related	Mild	Moderate	Severe	None	Stud Drug Dose Reduced	Study Drug Stopped Temporarily	Study Drug Discontinued	Yes	No	Resolution Date (M/M/DD/YY)	
AETERM	**AESTDTC**	☐	**AEREL** ☐	☐	☐	**AESEV** ☐	☐	☐	☐	**AEACN** ☐	☐	☐	**AESER** ☐	**AEENDTC**	**AEENRF = AFTER**
	/ /	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	/ /	☐
	/ /	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	/ /	☐
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	/ /	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	/ /	☐

If one or more serious outcomes are reported, notify a sponsor IMMEDIATELY.

CDISC	Study CDISC01	Site # ___ ___ ___	Patient ID# ___ ___ ___	Subject Initials ___ ___ ___	

PRIOR/CONCOMITANT MEDICATIONS *CMCAT*

Has the patient taken any concomitant medications? ☐ Yes ☐ No *[Not Submitted]*

Medication	Start Date (M/D/Y)	Stop Date (M/D/Y)	Continuing	Dose	Unit	Route	Frequency	Indication
CMTRT	*CMSTDTC*	*CMENDTC*	☐	*CMDOSTXT*		*CMROUTE*		*CMINDC*
	/ /	/ /	*CMENRF = AFTER*		*CMDOSU*		*CMDOSFRQ*	
	/ /	/ /	☐					
	/ /	/ /	☐					
	/ /	/ /	☐					
	/ /	/ /	☐					
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