

Visits

Screen

- Enrollment Form
- Inclusion Criteria
- Exclusion Criteria
- Demography
- Informed Consent
- Psychiatric History
- Medical and Surgical History
- Psychotropic Drug Treatment History
- Physical Exam
- Vital Signs
- Laboratory
- 12-Lead ECG
- Mini-Mental State Examination
- Cornell Scale For Depression in Dementia

Baseline

- Randomization
- Vital Signs
- Mini-Mental State Examination
- Cornell Scale For Depression in Dementia

Week 2

- Vital Signs
- Laboratory
- Cornell Scale for Depression in Dementia
- Clinical Global Impression

Week 24

- Physical Examination
- Vital Signs
- Laboratory
- 12-Lead ECG
- Mini-Mental State Examination
- Cornell Scale For Drepression in Dementia
- Clinical Global Impression

End of Study / Termination

- Termination

Running Records

- Study Medication Inventory
- Medication Record
- Adverse Events
- Prior/Concomitant Medications

Domains

12-Lead ECG

- Screen
- Week 24

Adverse Events

- Running Records

Clinical Global Impression

- Week 2
- Week 24

Cornell Scale for Depression in Dementia

[Screen](#)

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Demography

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Enrollment Form

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Inclusion Criteria

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Informed Consent

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Exclusion Criteria

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Laboratory

[Screen](#)

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Medication Records

[Running Records](#)

Medical and Surgical History

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Mini-Mental State Examination

[Screen](#)

[Baseline](#)

[Week 24](#)

Physical Examination

[Screen](#)

[Week 24](#)

Prior/Concomitant Medications

[Running Records](#)

Psychiatric History

[Screen](#)

Psychotropic Drug Treatment History

[Screen](#)

Randomization

[Baseline](#)

Study Medication Inventory

[Running records](#)

Termination

[End of Study / Termination](#)

Vital Signs

[Screen](#)

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[Week 2](#)

[Week 24](#)

DM=Demographics

CDISC
Study
CDISC01

Enrollment Form

Enroll the subject by entering the 3-digit Site # and the 5-digit Subject ID#

Site #

___ _ _

SITEID

Subject ID#

___ _ _ _ _

SUBJID

SC=Subject Characteristics

Subject
Initials

___ _ _

***SCORRES when SCTESTCD
= SUBJINIT***

Form Design Note:

Subject ID is mapped forward to the Subject Demographic Data eCRF.

IE=Inclusion/Exclusion

CDISC Study	VISIT Screening	
CDISC01	Assessment Date: IEDTC	
ELIGIBILITY CRITERIA		
INCLUSION CRITERIA IECAT Check the appropriate response IETEST	Yes	No
IEORRES when IETESTCD = INCL01		
1. Is age 18 - 85.	<input type="checkbox"/>	<input type="checkbox"/>
IEORRES when IETESTCD = INCL02		
2. Has Xyz disease of at least 10 weeks duration confirmed by biopsy	<input type="checkbox"/>	<input type="checkbox"/>
IEORRES when IETESTCD = INCL03		
3. Did not respond to a standard course of medication ABC.	<input type="checkbox"/>	<input type="checkbox"/>

All Inclusion Criteria questions 1-3 must be answered YES to enter the study.

IE=Inclusion/Exclusion

CDISC Study CDISC01	VISIT Screening
	Assessment Date: IEDTC / /
ELIGIBILITY CRITERIA	
EXCLUSION CRITERIA IECAT Check the appropriate response IETEST	Yes No
	IEORRES when IETESTCD = EXCL01
1. Is pregnant, nursing, or planning to become pregnant within 6 months of last study treatment.	<input type="checkbox"/> <input type="checkbox"/>
	IEORRES when IETESTCD = EXCL02
2. Is unable or unwilling to undergo multiple venipunctures.	<input type="checkbox"/> <input type="checkbox"/>
3. Is known to have had a substance abuse (drug or alcohol) problem within the previous 3 years.	<input type="checkbox"/> <input type="checkbox"/>
	IEORRES when IETESTCD = EXCL03

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

DM=Demographics

Screening

CDISC
Study: CDISC01

Assessment Date

STUDYID

SCDTC

___/___/___

DEMOGRAPHY

Date of Birth: ___/___/___ **BRTHDTC**

SEX

Gender: ☐ Male ☐ Female

ETHNIC

Ethnicity: ☐ Hispanic or Latino ☐ Not Hispanic or Latino

RACE

Race: Check all that apply

**RACE, when more than one selected,
RACE=MULTIPLE and individual responses are
RACE1, RACE2, etc. in SUPPDM**

- ☐ White
☐ American Indian or Alaska Native
☐ Black or African American
☐ Native Hawaiian or Other Pacific Islander
☐ Asian
☐ Other::___

RACEOTH in SUPPDM

SC=Subject Characteristics

FamilyStatus: ☐ Never Married ☐ Domestic Partner
☐ Married ☐ Divorced
☐ Legally Separated ☐ Widowed

**SCORRES when SCTESTCD
= MARISTAT**

Education: ☐ Some High School ☐ College Graduate
☐ High School Graduate/GED ☐ Graduate Degree & Beyond
☐ Some College ☐ Other::___

**SCORRES when
SCTESTCD = EDLEVEL**

EDUOTH in SUPPSC

DS=Disposition

INFORMED CONSENT

DSDECOD

DSTERM

DSSTDTC

Date consent form signed: ___/___/___
MM DD YYYY

MH=Medical History

CDISC Study CDISC01		
	Screening MHDTC	
		Assessment Date: ____/____/____
PSYCHIATRIC HISTORY MHCAT		
<div><div>MHTERM</div><div>MHPRESP=Y</div><div>MHSTDTC</div><div>MHOCCUR=Y</div></div> <div><div>1. Date of onset of probable Alzheimer's Disease?</div><div><div><div></div><div></div></div><div><div></div><div></div></div><div><div></div><div></div><div></div><div></div></div></div><div><div>2. Date of onset of depression of Alzheimer's Disease?</div><div><div><div></div><div></div></div><div><div></div><div></div></div><div><div></div><div></div><div></div><div></div></div></div></div></div>		

MH=Medical History

CDISC Study CDISC01	SCREENING
	Assessment Date: MHDTC

MEDICAL AND SURGICAL HISTORY **MHCAT**

Does the subject have any significant medical or surgical history? [NOT SUBMITTED]	Year	“√” if RESOLVED	“√” if ONGOING
<input type="checkbox"/> Yes, list the condition(s) below <input type="checkbox"/> No	MHSTDTC	MHENRF = BEFORE	MHENRF = DURING/AFTER
MHTERM	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/>	<input type="text"/>
	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/>	<input type="text"/>
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	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/>	<input type="text"/>
	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/>	<input type="text"/>
	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/>	<input type="text"/>

CM=Concomitant Medications

CDISC	SCREENING						
	Assessment Date: ____/____/____						
PSYCHOTROPIC DRUG TREATMENT HISTORY							CMCAT
[NOT SUBMITTED]							
List all the Psychotropic drugs the patient has taken within the past 5 years. If NONE, CHECK BOX: <input type="checkbox"/> [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		CMDOSTXT		CMSTDTC		CMINDC	
				/ /	/ /		
	PDRESP in SUPPCM		CMDOSU		CMENDTC		PDDREAS in SUPPCM
				/ /	/ /		
				/ /	/ /		
				/ /	/ /		
				/ /	/ /		
				/ /	/ /		
				/ /	/ /		
				/ /	/ /		
				/ /	/ /		

Response Code

- 1 No Change
- 2 Poor
- 3 Good

Reason for Discontinuation

- 0 Ongoing
- 1 Adverse Event
- 2 Insufficient Response
- 3 Satisfactory Response
- 99 Other

PE=Physical Examination

CDISC Study CDISC01		<div>PEDTC</div> Assessment Date: ____/____/____		
PHYSICAL EXAM				
<div>PESTAT</div>				
<div>PETEST</div>				
PHYSICAL EXAM	Normal	Abnormal	Not Done	Comment only if abnormal
	<div>PEORRES when PETESTCD=PE01</div>			
1. Appearance/Skin	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	<div>PEORRES when PETESTCD=PE02</div>			
2. Head/Neck (Including Thyroid)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	<div>PEORRES when PETESTCD=PE03</div>			
3. Eyes-Ears-Nose-Throat	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	<div>PEORRES when PETESTCD=PE04</div>			
4. Cardiovascular	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	<div>PEORRES when PETESTCD=PE05</div>			
5. Pulmonary	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
6. Abdomen	<div>PEORRES when PETESTCD=PE06</div>			
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
7. Neurological	<div>PEORRES when PETESTCD=PE07</div>			
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
8. Musculoskeletal	<div>PEORRES when PETESTCD=PE08</div>			
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
9. Other	<div>PEORRES when PETESTCD=PE09</div>			
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

Note: If the result is Abnormal then PEORRES=Comment

VS=Vital Signs

CDISC

Study: CDISC01

Assessment Date:

VSDTC

____/____/____

VITAL SIGNS

VSTEST

Height

. ☐ cm
☐ in

VSORRES / VSORRESU when
VSTESTCD = HEIGHT

Weight

. ☐ kgs
☐ lbs

VSORRES / VSORRESU when
VSTESTCD = WEIGHT

☐ Small

Body Fame Size

☐ Medium

☐ Large

VSORRES when VSTESTCD = FRMSIZE

VSPOS

Sitting Blood Pressure

/ mmHg
Systolic Diastolic

VSORRES / VSORRESU when
VSTESTCD = SYSBP, DIABP

Radial Pulse Rate

bpm

VSORRES / VSORRESU when
VSTESTCD = PULSE

LABORATORY

[NOT SUBMITTED]

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

EG=ECG

CDISC
Study CDISC01

EGDTC

Assessment Date: ____/____/____

12- LEAD ECG

ECG RESULTS

EGTEST

Ventricular Heart
Rate

bpm

EGORRES / EGORRESU when EGTESTCD = VRMEAN

PR Interval

msec

EGORRES / EGORRESU when EGTESTCD = PRMEAN

QRS Interval

msec

EGORRES / EGORRESU when EGTESTCD = QRSDUR

QT Interval:

msec

EGORRES / EGORRESU when EGTESTCD = QTMEAN

EGTESTCD = INTP

OVERALL INTERPRETATION (Please check one):

1 = ☐ Normal (do not comment) **EGORRES = NORMAL**

2 = ☐ Abnormal, not clinically significant (do not comment) **EGORRES = ABNORMAL**
EGCLSIG=N in SUPPEG

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

EGCLSIG=Y in SUPPEG

EGCLSP in SUPPEG

QS=Questionnaires

CDISC

Study CDISC01

Assessment Date: 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:

RTRINIT in SUPPQS

QSTEST

A. ORIENTATION

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

QSORRES when QSTESTCD = MMSEA1

Score (total number of correct responses)

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

QSORRES when QSTESTCD = MMSEA2

Score (total number of correct responses)

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

QSORRES when QSTESTCD = MMSEB

Score (total number of correct responses)

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

QSORRES when
QSTESTCD = MMSEC

Score (total number of correct responses)

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

QSORRES when QSTESTCD = MMSED

Score (total number of correct responses)

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

QSORRES when QSTESTCD = MMSEET

Score (total number of correct responses)

QSORRES when QSTESTCD = MMSETOT

Sum of Scores for Sections A through E

QS=Questionnaires

CDISC

Study CDISC01

QSDTC

Assessment Date ____/____/____

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

QSCAT

RTRINIT in SUPPQS

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:

QSEVLINT

QSSCAT 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

QSORRES when QSTESTCD = CSDD01

QSORRES when QSTESTCD = CSDD02

QSORRES when QSTESTCD = CSDD03

QSORRES when QSTESTCD = CSDD04

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

QSORRES when QSTESTCD = CSDD05

QSORRES when QSTESTCD = CSDD06

QSORRES when QSTESTCD = CSDD07

QSORRES when QSTESTCD = CSDD08

QS=Questionnaires

CDISC

Study CDISC01

QSDTC

Assessment Date: ____ / ____ / ____

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

QSCAT

QSSCAT C. PHYSICAL SIGNS

CUE
ABSENT MILD OR SEVERE
INTERMITTENT

9. APPETITE LOSS

Eating less than usual

QSTEST

QSORRES when QSTESTCD = CSDD09

0 1 2

10. WEIGHT LOSS

(score 2 if greater than 5 lbs. in 1 month)

QSORRES when 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)

QSORRES when QSTESTCD = CSDD11

0 1 2

D. CYCLIC FUNCTIONS

QSORRES when QSTESTCD = CSDD12

12. DIURNAL VARIATION OF MOOD

Symptoms worse in the morning

0 1 2

13. DIFFICULTY FALLING ASLEEP

Later than usual for this individual

QSORRES when QSTESTCD = CSDD13

0 1 2

14. MULTIPLE AWAKENINGS DURING SLEEP

QSORRES when QSTESTCD = CSDD14

0 1 2

15. EARLY MORNING AWAKENING

Earlier than usual for this individual

**QSORRES when
QSTESTCD =
CSDD15**

0 1 2

E. IDEATIONAL DISTURBANCE

16. SUICIDE

Feels life is not worth living, has suicidal wishes,
or makes suicide attempt

QSORRES when QSTESTCD = CSDD16

0 1 2

QSORRES when QSTESTCD = CSDD17

17. POOR SELF-ESTEEM

Self-blame, self-depreciation, feelings of failure

0 1 2

QSORRES when QSTESTCD = CSDD18

18. PESSIMISM

Anticipation of the worst

0 1 2

QSORRES when QSTESTCD = CSDD19

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.

QSORRES when QSTESTCD = CSDDTOT

Total Score:

DS=Disposition

CDISC

Study CDISC01

RANDOMIZATION

DSTERM / DSDECOD = RANDOMIZED

DM=Demographics

RANDNO in SUPPDM

Will the patient be randomized?

☐

Yes

Enter Randomization Number

RAND in SUPPDM

Randomization Date

MM

DD

YYYY

DSSTDTC

☐

No

Complete Termination

QS=Questionnaires

CDISC
Study CDISC01

Assessment Date / /

QSDTC

QSCAT CLINICAL GLOBAL IMPRESSION (CGI-I)

RTRINIT in SUPPQS

Rater's Initials:

--	--	--

QSTEST

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 when QSTESTCD = CGIGLOB

- | | | |
|---|--------------------------|--------------------|
| 1 | <input type="checkbox"/> | Very much improved |
| 2 | <input type="checkbox"/> | Much improved |
| 3 | <input type="checkbox"/> | Minimally improved |
| 4 | <input type="checkbox"/> | No change |
| 5 | <input type="checkbox"/> | Minimally worse |
| 6 | <input type="checkbox"/> | Much worse |
| 7 | <input type="checkbox"/> | Very much worse |

DS=Disposition

CDISC

Study CDISC01

Assessment Date: ____/____/____

[NOT SUBMITTED]

TERMINATION

Did patient complete the study? ☐ Yes ☐ No

DSDECOD / DSTERM = COMPLETED when 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 **DSDECOD**

☐ Discontinued due to Adverse Event
Adverse Event No. _____ (Enter the number from the ADVERSE EVENTS Form)

☐ **Linked to related AE record via RELREC**
Protocol Violation (specify): **DSTERM**

☐ Discontinued due to Consent Withdrawn

☐ Discontinued due to Lost to Follow Up

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

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: _____

DA=Drug Accountability

CDISC		STUDY MEDICATION INVENTORY					
Study CDISC01							
Date Tablets Dispensed		DATEST Number of Tablets Dispensed DAORRESU		DATEST Date Tablets Returned Number of Tablets Returned DAORRESU			
DADTC when DATESTCD=DISPAMT		DAORRES when DATESTCD=DISPAMT		DADTC when DATESTCD=RETAMT DAORRES when DATESTCD=RETAMT			
<div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div></div> <div>MonthDayYear</div>		<div><div></div><div></div></div>		<div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div></div> <div>MonthDayYear</div>		<div><div></div><div></div></div>	
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EX=Exposure

[illegible]

AE=Adverse Events

CDISC Study CDISC01		ADVERSE EVENTS														
AE No.	Adverse Event	Onset Date (MM/DD/ YY)	Relation to Study Drug			Maximum Intensity			Action Taken				Serious Adverse Event?		Resolution (Complete One)	
			AEREL			AESEV			AEACN				AESER		AEENDTC	
			Not Related	Possibly Related	Related	Mild	Moderate	Severe	Dose Not Changed	Dose Reduced	Drug Interrupted	Drug Withdrawn	Yes	No	Resolution Date (M/M/DD/YY)	
AESPID	AETERM	/ /	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	/ /	<input type="checkbox"/>
		/ /	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	/ /	<input type="checkbox"/>
		/ /	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	/ /	<input type="checkbox"/>
		/ /	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	/ /	<input type="checkbox"/>
		/ /	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	/ /	<input type="checkbox"/>
		/ /	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	/ /	<input type="checkbox"/>
		/ /	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	/ /	<input type="checkbox"/>

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

CDISC	PRIOR / CONCOMITANT MEDICATIONS CMCAT
Study CDIOSC01	

[illegible]