

## Visits

### Screen

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- 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

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

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- Termination

### Running Records

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- 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

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Demography

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Enrollment Form

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Inclusion Criteria

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## ***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	<b>VISIT</b> Screening	
CDISC01	Assessment Date: <b>IEDTC</b>	
ELIGIBILITY CRITERIA		
<b>INCLUSION CRITERIA</b> <b>IECAT</b> Check the appropriate response <b>IETEST</b>	Yes	No
<b>IEORRES when IETESTCD = INCL01</b>		
1. Is age 18 - 85.	<input type="checkbox"/>	<input type="checkbox"/>
<b>IEORRES when IETESTCD = INCL02</b>		
2. Has Xyz disease of at least 10 weeks duration confirmed by biopsy	<input type="checkbox"/>	<input type="checkbox"/>
<b>IEORRES when IETESTCD = INCL03</b>		
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	<b>VISIT</b>	Screening
Study CDISC01	Assessment Date: <b>IEDTC</b> / /	
ELIGIBILITY CRITERIA		
<b>EXCLUSION CRITERIA</b> <b>IECAT</b> Check the appropriate response <b>IETEST</b>	Yes	No
	<b>IEORRES when IETESTCD = EXCL01</b>	
1. Is pregnant, nursing, or planning to become pregnant within 6 months of last study treatment.	<input type="checkbox"/>	<input type="checkbox"/>
	<b>IEORRES when IETESTCD = EXCL02</b>	
2. Is unable or unwilling to undergo multiple venipunctures.	<input type="checkbox"/>	<input type="checkbox"/>
	<b>IEORRES when IETESTCD = EXCL03</b>	
3. Is known to have had a substance abuse (drug or alcohol) problem within the previous 3 years.	<input type="checkbox"/>	<input type="checkbox"/>

*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: \_\_\_\_/\_\_\_\_/\_\_\_\_ BIRTHDTC

SEX

Gender: ☐ Male ☐ Female

ETHNIC

Ethnicity: ☐ Hispanic or Latino ☐ Not Hispanic or Latino

RACE

Race: Check all that apply

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

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

**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		
MHTERM		
MHPRESP=Y		
MHSTDTC		
MHOCCUR=Y		
1. Date of onset of probable Alzheimer's Disease?		
<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>		
2. Date of onset of depression of Alzheimer's Disease?		
<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>		

**MH=Medical History**

CDISC Study CDISC01	SCREENING
	Assessment Date: <b>MHDTC</b>

**MEDICAL AND SURGICAL HISTORY** **MHCAT**

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

# 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	
			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

VSPOS

Sitting Blood Pressure

Systolic

/

Diastolic

VSORRES / VSORRESU when  
VSTESTCD = SYSBP, DIABP

mmHg

Radial Pulse Rate

bpm

VSORRES / VSORRESU when  
VSTESTCD = PULSE

☐ Small

Body Fame Size

☐ Medium

☐ Large

VSORRES when VSTESTCD = FRMSIZE

## 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

1. ANXIETY  
Anxious expression, ruminations, worrying

QSTEST

QSORRES when QSTESTCD = CSDD01

0 1 2

2. SADNESS  
Sad expression, sad voice, tearfulness

QSORRES when QSTESTCD = CSDD02

0 1 2

3. LACK OF REACTIVITY TO PLEASANT EVENTS

QSORRES when QSTESTCD = CSDD03

0 1 2

4. IRRITABILITY  
Easily annoyed, short tempered

QSORRES when QSTESTCD = CSDD04

0 1 2

### B. BEHAVIORAL DISTURBANCE

5. AGITATION  
Restlessness, handwringing, hairpulling

QSORRES when QSTESTCD = CSDD05

0 1 2

6. RETARDATION  
Slow movements, slow speech, slow reactions

QSORRES when QSTESTCD = CSDD06

0 1 2

7. MULTIPLE PHYSICAL COMPLAINTS  
(score 0 if GI symptoms only)

QSORRES when 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)

QSORRES when QSTESTCD = CSDD08

0 1 2

# **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 INTERMITTENT	SEVERE

#### **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** **DSTERM**  
Protocol Violation (specify): \_\_\_\_\_

☐ 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"/>
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		/ /	<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.

**CM=Concomitant Medications**

CDISC

## Study CDIOSC01

**PRIOR / CONCOMITANT MEDICATIONS** **CMCAT**

**CMCAT**

[illegible]