

		Date://
		ENTRY PROCEDURES AND CRITERIA FOR ENROLLMENT
Yes No		Inclusion Criteria: The answers for Items 1-8 must be YES to qualify for study.
	1.	Males and postmenopausal females at least 50 years of age.
	2.	Diagnosis of probable AD as defined by National Institute of Neurological and Communicative Disorders and Stroke (NINCDS) and the Alzheimer's Disease and Related Disorders Association (ADRDA) guidelines (Protocol Attachment LZZT.7).
	3.	MMSE score of 10 to 23.
	4.	Modified Hachinski Ischemic Scale score of £4. (Protocol Attachment LZZT.8).
	5.	CNS imaging (CT scan or MRI of brain) compatible with AD within past 1 year.
		The following findings are incompatible with AD.

#### 1. Large vessel strokes

- a. Any definite area of encephalomalacia consistent with ischemic necrosis in any cerebral artery territory.
- b. Large, confluent areas of encephalomalacia in parieto-occipital or frontal regions consistent with watershed infarcts.

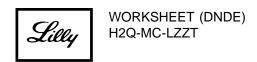
The above are exclusionary. Exceptions are made for small areas of cortical asymmetry which may represent a small cortical stroke or a focal area of atrophy provided there is no abnormal signal intensity in the immediately underlying parenchyma. Only one such questionable area allowed per scan, and size is restricted to £1 cm in frontal/parietal/temporal cortices and £2 cm in occipital cortex.

#### 2. Small vessel ischemia

- a. Lacunar infarct is defined as an area of abnormal intensity seen on CT scan or on both T1 and T2 weighted MRI images in the basal ganglia, thalamus or deep white matter which is £1 cm in maximal diameter. A maximum of one lacune is allowed per scan.
- b. Leukoariosis or leukoencephalopathy is regarded as an abnormality seen on T2 but not T1 weighted MRIs, or on CT. This is accepted if mild or moderate in extent, meaning involvement of less than 25% of cortical white matter.

#### 3. Miscellaneous

- a. Benign small extra-axial tumors (ie, meningiomas) are accepted if they do not contact or indent the brain parenchyma.
- b. Small extra-axial arachnoid cysts are accepted if they do not indent or deform the brain parenchyma.



## **ENTRY PROCEDURES AND CRITERIA FOR ENROLLMENT**

Yes	No		Inclusion Criteria: The answers for Items 1-8 must be YES to qualify for study.
		6.	Investigator has obtained informed consent signed by the patient (and/or legal representative) and by the caregiver.
		7.	Geographic proximity to investigator's site that allows adequate follow-up.
		8.	A reliable caregiver who is in frequent or daily contact with the patient and who will accompany the patient to the office and/or be available by telephone at designated times, will monitor administration of prescribed medications, and will be responsible for the overall care of the patient at home. The caregiver and the patient must be able to communicate in English and willing to comply with 26 weeks of transdermal therapy.
Yes	No		Exclusion Criteria: The answers for Items 9-31 must be NO to qualify for study.
		9.	Persons who have previously completed or withdrawn from this study or any other investigating xanomeline TTS or the oral formulation of xanomeline.
		10.	Use of any investigational agent or approved Alzheimer's therapeutic medication within 30 days prior to enrollment into the study.
		11.	Serious illness which required hospitalization within 3 months of screening.
		12.	Diagnosis of serious neurological conditions, including
			a) Stroke or vascular dementia documented by clinical history and/or radiographic findings interpretable by the investigator as indicative of these disorders
			b) Seizure disorder other than simple childhood febrile seizures
			c) Severe head trauma resulting in protracted loss of consciousness within the last 5 years, or multiple episodes of head trauma
			d) Parkinson's disease
			e) Multiple sclerosis
			f) Amyotrophic lateral sclerosis
			g) Myasthenia gravis.
		13.	Episode of depression meeting DSM-IV criteria within 3 months of screening.
		14.	A history within the last 5 years of the following:
			a) Schizophrenia
			b) Bipolar Disease
			c) Ethanol or psychoactive drug abuse or dependence.

Yes No	<b>Exclusion Criteria:</b> The answers for Items 9-31 must be NO to qualify for study.
<u> </u>	A history of syncope within the last 5 years.
☐ 16.	Evidence from ECG recording at screening of any of the following conditions:
	a) Left bundle branch block
	b) Bradycardia £50 beats per minute
	c) Sinus pauses >2 seconds
	d) Second or third degree heart block unless treated with a pacemaker
	e) Wolff-Parkinson-White syndrome
	f) Sustained supraventricular tachyarrhythmia
□ □ 17.	A history within the last 5 years of a serious cardiovascular disorder, including
	a) Clinically significant arrhythmia
	b) Symptomatic sick sinus syndrome not treated with a pacemaker
	c) Congestive heart failure refractory to treatment
	d) Angina except angina controlled with PRN nitroglycerin
	e) Resting heart rate <50 or >100 beats per minute, on physical exam
	f) Uncontrolled hypertension
□ □ 18.	A history within the last 5 years of a serious gastrointestinal disorder, including
	a) Chronic peptic/duodenal/gastric/esophageal ulcer that are untreated or refractory to treatment
	b) Symptomatic diverticular disease
	c) Inflammatory bowel disease
	d) Pancreatitis
	e) Hepatitis
	f) Cirrhosis of the liver

Yes No	<b>Exclusion Criteria:</b> The answers for Items 9-31 must be NO to qualify for study.
<u> </u>	A history within the last 5 years of a serious endocrine disorder, including
	a) Uncontrolled Insulin Dependent Diabetes Mellitus (IDDM)
	b) Diabetic ketoacidosis
	c) Untreated hyperthyroidism
	d) Untreated hypothyroidism
	e) Other untreated endocrinological disorder
<b>2</b> 0.	A history within the last 5 years of a serious respiratory disorder, including
	a) Asthma with bronchospasm refractory to treatment
	b) Decompensated chronic obstructive pulmonary disease.
□ □ 21.	A history within the last 5 years of a serious genitourinary disorder, including
	a) Renal failure
	b) Uncontrolled urinary retention
<b>22</b> .	A history within the last 5 years of a serious rheumatologic disorder, including
	a) Lupus
	b) Temporal arteritis
	c) Severe rheumatoid arthritis
☐ 23.	A known history of human immunodeficiency virus (HIV) within the last 5 years.
☐ 24.	A history within the last 5 years of a serious infectious disease including
	a) Neurosyphilis
	b) Meningitis
	c) Encephalitis
25.	A history within the last 5 years of a primary or recurrent malignant disease with the exception of resected cutaneous squamous cell carcinoma in situ, basal cell carcinoma, cervical carcinoma in situ, or in situ prostate cancer with a normal PSA postresection.
<b>2</b> 6.	Visual, hearing, or communication disabilities impairing the ability to participate in the study; (for example, inability to speak or understand English, illiteracy).

Yes No	<b>Exclusion Criteria</b> : The answers for Items 9-31 must be NO to qualify for study.
<b>27</b> .	Laboratory test values exceeding the Lilly Reference Range III for the patient's age in any of the following analytes: -creatinine, -total bilirubin, - SGOT, - SGPT, - alkaline phosphatase, - GGT, - hemoglobin, - white blood cell count, - platelet count, - serum sodium, potassium or calcium.
	If values exceed these laboratory reference ranges, clinical significance will be judged by the monitoring physicians.
28.	Central laboratory test values below reference range for folate, and vitamin $B_{12}$ , and outside reference range for thyroid function tests.
<b>2</b> 9.	Positive syphilis screening with confirmatory testing.
30.	Central laboratory test value above reference range for glycosylated hemoglobin $(A_{1C})$ (insulin dependent diabetes mellitus patients only)
☐ 31.	Treatment with the following medications within 1 month prior to enrollment
	a) Anticonvulsants including but not limited to - Tegretolâ (carbamazepine) - Depakoteâ (valproic acid)
	<ul><li>b) Alpha receptor blockers including but not limited to</li><li>Catapresâ (clonidine)</li><li>Aldometâ (methyldopa)</li></ul>
	c) Calcium channel blockers that are CNS active including but not limited to - Nimotopâ (nimodipine)
	d) Beta blockers including but not limited to - Inderalâ (propranolol) -Tenorminâ (atenolol)
	e) Beta sympathomimetics (unless inhaled) including but not limited to - Proventil Repetabsâ, Ventolinâ tablets (albuterol tablets) - Dopamineâ
	f) Parasympathomimetics (cholinergics) (unless ophthalmic) including but not limited to - Urecholineâ (bethanechol) -Reglanâ (metoclopramide)
	<ul> <li>g) Muscle relaxants-centrally active including but not limited to</li> <li>- Flexerilâ (cyclobenzaprine)</li> <li>- Somaâ (carisoprodol)</li> </ul>
	h) Monoamine oxidase inhibitors (MAOI) including but not limited to - Nardilâ (phenelzine) - Eldeprylâ (selegiline) - Parnateâ (tranylcypromine)

**Exclusion Criteria:** The answers for Items 9-31 must be NO to qualify for study.

- i) Parasympatholytics (anticholinergics) including but not limited to
  - Ditropanâ (oxybutynin)
  - Urispasa (flavoxate)
  - Antivertâ (meclizine)
- j) Antidepressants including but not limited to
  - Prozacâ (fluoxetine)
  - Elavilâ (amitriptyline)
- k) Systemic corticosteroids including but not limited to
  - Depo-medrolâ (methylprednisolone)
- I) Xanthine derivatives including but not limited to
  - Theo-Durâ (theophylline)
- m) Histamine (H<sub>2</sub>) antagonists including but not limited to
  - Tagametâ (cimetidine)
  - Axidâ (nizatidine)
- n) Narcotic Analgesics including but not limited to
  - Darvocet-N 100â, Propacetâ (propoxyphene + acetaminophen)

Percocet (oxycodone with acetaminophen) and Tylenolâ with codeine #2, #3, #4 (acetaminophen + codeine) ARE allowed in the month prior to enrollment, but are not permitted in the 4 days prior to enrollment.

- o) Neuroleptics (antipsychotics) including but not limited to
  - Haldolâ (haloperidol)
  - Mellarilâ (thioridazine)

The use of neuroleptics on an as needed basis is permitted during the month prior to enrollment, but are to be discontinued at least 7 days prior to enrollment.

- p) Antianxiety agents including but not limited to
  - BuSparâ (buspirone)
  - Libriumâ (chlordiazepoxide)

Ativana (lorazepam) is allowed on an as needed basis in the month prior to enrollment, but is not permitted in the 24 hours prior to enrollment.

- q) Hypnotics/Sedatives including but not limited to
  - Restorilâ (temazepam)

Chloral Hydrate is allowed on an as needed basis in the month prior to enrollment, but is not permitted in the 24 hours prior to enrollment.

- r) Histamine (H<sub>4</sub>) antagonists including but not limited to
  - Benadryla (diphenhydramine)
  - Seldaneâ (terfenadine)

Intermittent use of these antihistamines is permitted during the month prior to enrollment, but is not permitted in the 4 days prior to enrollment.





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## PATIENT AND VISIT IDENTIFICATION

## **INFORMED CONSENT**

Date patient and caregiver signed the consent document

Not Entered In Database

Not Entered In Database

/\_\_\_/\_\_
MM DD YY

## **DEMOGRAPHICS**

Date of birth  $\frac{\phantom{a}}{\phantom{a}}/\frac{\phantom{a}}{\phantom{a}}/\frac{\phantom{a}}{\phantom{a}}$  SEX Sex  $\Box_F$  Female  $\Box_M$  Male

RACE Origin  $\Box_{CA}$  Caucasian (European, Mediterranean, Middle Eastern)  $\Box_{AF}$  African Descent (Negro, Black)

□ East/Southeast Asian (Burmese, Chinese, Japanese, Korean, Mongolian, Vietnamese)
 □ Western Asian (Pakistani, Indian Sub-continent)
 □ Hispanic (Mexican-American, Mexico, Central and South America)
 □ Other (Mixed-racial parentage, American Indian, Eskimo)

#### REMINDER

Record the patient's pre-existing conditions on the Pre-existing Conditions and Study Adverse Events page.

Record all medications the patient is currently taking on the Concomitant Medication page.

A physical examination must be performed at this visit. Any clinically significant abnormalities must be listed on the Pre-existing Conditions and Study Adverse Events page.



Visit 1 Page 2 of 14

## **EDUCATION**

SCTESTCD

Number of years of education completed

SCORRES

years

SCORRESU

HABITS: SMOKING

INFORMATION NOT OBTAINED Not Entered In Database

Enter the average current daily use

**0** = None

L = Less than one (eg, cigar or pipe smoker who smokes only 1 or 2x a week)

1, 2, 3, etc = Whole numbers ONLY

Number of cigarettes Not Entered In Database

Number of cigars

Not Entered In Database

Number of pipesful Not Entered In Database

Enter the number of years (past or current) patient has smoked. If patient has never smoked, enter 0.

Not Entered In Database

years

(If the patient has NEVER smoked or is still smoking, leave the following question blank.)

Enter the month and year that the patient guit smoking.

Not Entered In Database

\_\_\_\_/\_ MM YY

HABITS: ALCOHOL

INFORMATION NOT OBTAINED Not Entered In Database

Enter the average current weekly consumption

0 = None

L = Less than one

1, 2, 3, etc = Whole numbers ONLY

Number of beers or wine coolers/spritzers

Not Entered In Database

Number of glasses of wine

Not Entered In Database

Number of drinks containing distilled spirits

Not Entered In Database

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QS407, HB31205, HB30902

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HABITS: CAFFEINE

INFORMATION NOT OBTAINED Not Entered In Database

Enter the average current daily consumption

0 = None

**L** = Less than one

1, 2, 3, etc = Whole numbers ONLY

Number of cups of coffee

Not Entered In Database

Not Entered In Database

Number of cups of tea \_\_\_\_\_

Number of colas Not Entered In Database

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H2Q-MC-LZZT

Visit 1

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#### **QSCAT MINI-MENTAL STATE** Not Entered In Database INFORMATION NOT OBTAINED Score Maximum QSSCAT Score Orientation **QSTESTCD QSORRES** What is the (year) (season) (date) (day) (month)? QSTESTCD **QSORRES** (5)Where are we: (state) (county) (town) (hospital) (floor)? QSSCAT Registration **QSTESTCD** (3)3. Name 3 objects: 1 second to say each. Then ask the patient all 3 after you have said them. Give 1 point for each correct answer. Then repeat them until he learns all 3. Count trials and record. **QSSCAT Attention and Calculation QSTESTCD QSORRES** (5)Serial 7's. 1 point for each correct. Stop after 5 answers. Alternatively, spell "world" backwards. **QSSCAT** Recall **QSTESTCD** 5. (3)Ask for the 3 objects repeated above. Give 1 point for each correct. **QSSCAT** Language **QSTESTCD** QSORRES (9)Name a pencil, and watch (2 points) 6. Repeat the following "No ifs, ands, or buts." (1 point) Follow a 3-stage command: 'Take a paper in your right hand, fold it in half, and put it on the floor" (3 points) Read and obey the following: Close your eyes (1 point) Write a sentence (1 point) Copy design (1 point) (DNDE) Not Entered In Datab

Total score NOTE: Patient must have a score of 10-23 on the MMSE at Visit 1 to be enrolled in this study.						
ASSESS level of consc	iousness along a continuum	Not Ent	ered In Datab	ase		
		Alert	Drowsy	Stupor	Coma	

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# MODIFIED HACHINSKI ISCHEMIC SCORE QSCAT

INFORMATION NOT OBTAINED Not Entered In Database

Circle the score that corresponds to the feature being present or absent.

	<u>Feature</u>	<u>Present</u> A	<u>bsent</u>
QSTESTCD	1. Abrupt onset	2 QSORRES	0
QSTESTCD	2. Gropwidd ddionorddion	1 QSORRES	0
QSTESTCD	3. Fluctuating course	2 QSORRES	0
QSTESTCD	4. Nocturnal confusion	1 QSORRES	0
QSTESTCD	5. Relative preservation of personality	1 QSORRES	0
-			
QSTESTCD	6. Depression	1 QSORRES	0
QSTESTCD	7. Somatic complaints	1 QSORRES	0
QSTESTCD	8. Emotional incontinence	1 QSORRES	0
QSTESTCD	9. History of hypertension	1 QSORRES	0
QSTESTCD .	10. History of strokes	2 QSORRES	0
-			
QSTESTCD	11. Evidence of associated atherosclerosis	1 QSORRES	0
QSTESTCD	12. Focal neurological symptoms	2 QSORRES	0
QSTESTCD	13. Focal neurological signs	2 QSORRES	0

Total Score NOTE: Patient must have a score of £4 on the Modified Hachinski Ischemic Scale at Visit 1 to be enrolled in this study.	(DNDE)	Not Entere	ed In Data	a <mark>base</mark>
	Total Score	e	NOTE:	

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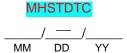
Visit 1

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#### **PATIENT HISTORY** : ALZHEIMER'S DISEASE ONSET DATE

MHTERM

Date of onset of the first definite symptoms of Alzheimer's Disease



# **CLINICAL FEATURES**: ALZHEIMER'S DISEASE

INFORMATION NOT OBTAINED Not Entered In Database

Do	oes the patient display or has the patient displayed the following clinical features:					
1.	Extrapyramidal features (masked facies, bradykinesia, slowed rapid alternating movements, flexed posture, gait difficulty) without a resting tremor	□ <sub>1</sub> Yes	☐ <sub>2</sub> No Not Entered In Database			
2.	Essential tremor (action or postural)	□ <sub>1</sub> Yes	Not Entered In Database			
3.	Sensitivity to neuroleptics	$\square_{1}$ Yes	Not Entered In Database			
4.	Marked deficit of attention and/or fluctuations in level of attention and alertness; confusional episodes	□ <sub>1</sub> Yes	☐ <sub>2</sub> No Not Entered In Database			
5.	Visual hallucinations and/or paranoid delusions	□ <sub>1</sub> Yes	☐ <sub>2</sub> No Not Entered In Database			



Visit 1 Page 7 of 14

# **EXTRAPYRAMIDAL FINDINGS**

INF	ORMATION NOT OBTAINED Not Entered In Database
1.	Masked facies Not Entered In Database
	□ <sub>0</sub> None
	□ <sub>3</sub> Severe
2.	Rigidity of upper extremity Not Entered In Database
	□ None
	☐ 1 Mild
	☐ <sub>2</sub> Moderate
	□ <sub>3</sub> Severe
3.	Essential tremor Not Entered In Database
	□ None
	□ 1 Mild
	□ <sub>3</sub> Severe
1	
4.	Ambulation  Not Entered In Database  How long did it take the patient to walk 25 yards?
	seconds



Visit 1

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## SIGNIFICANT HISTORICAL DIAGNOSIS

NO SIGNIFICANT HISTORICAL DIAGNOSIS		Not Entered In Database
-------------------------------------	--	-------------------------

List each clinically significant (at the discretion of the investigator) historical diagnosis that is **NO LONGER PRESENT.** If exact date is unknown, enter the month and year. A year MUST be entered.

	Historical Diagnosis	Date Recovered/Date Surgical Procedure		
MHSPID	COSTART Class Term	MM	DD	YY
0.	MHTERM			
	Not Entered In Database	N	MHSTDTC	
1.				
2.				
3.				
4.				
5.				
,				
6.				
7.				
8.				



Visit 1 Page 8 \_\_ of 14

# SIGNIFICANT HISTORICAL DIAGNOSIS

List each clinically significant (at the discretion of the investigator) historical diagnosis that is **NO LONGER PRESENT.** If exact date is unknown, enter the month and year. A year MUST be entered.

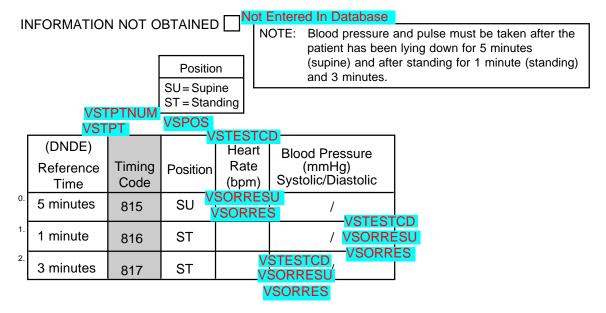
Historical Diagnosis	Date Recovered/Date of Surgical Procedure		
COSTART Class Term	MM DD YY		
MHTERM			
Not Entered In Database	N	HSTDTC	



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WEIGHT VSTESTCD
INFORMATION NOT OBTAINED Not Entered In Database
Measure with shoes off. Round up or down to the nearest tenth kilogram or tenth pound.
WeightVSORRES         Kilogram       Pound   VSORRESU
HEIGHT VSTESTCD
INFORMATION NOT OBTAINED   Not Entered In Database
Measure with shoes off. Round up or down to the nearest <u>tenth inch</u> or <u>tenth centimeter</u> .
Height VSORRESU cm Centimeter in Inch

# VITAL SIGNS: HEART RATE AND BLOOD PRESSURE



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VITAL SIGNS : TEMPERATUR	VSTEST	TCD		<u> </u>
INFORMATION NOT OBTAINED N	t Entered Ir	Database		
Temperature VSORRES				
Unit of measure ☐ F Fahrenheit ☐ C	Centigrade	VSORRESU		
Method VSLOC PO Oral R	Rectal	☐ <sub>A</sub> Axillary	□ <sub>E</sub> Ear	☐ <sub>O</sub> Other
ELECTROCARDIOGRAM				
NOT DONE Not Entered In Data	abase			
Electrocardiogram date  Not Entered  MM DD	In Databas / YY	е		
Electrocardiogram result	able 🔲 <sub>1</sub>	3 Not Acceptabl	e Not Entere	ed In Database
NOTE: If abnormality present and the Pre-existing Conditions abnormalities in the ECG C  COMMENTS: NON-RELEVAN	and Study Comments s	Adverse Events section below.	page. Note	
NO COMMENTS Not Entered In Da				
Print legibly and do not use abbreviations  Not Entered In Database	or symbols	S.		



Visit 1 Page 11 of 14

CHEST X-RA	Y
NOT DONE N	lot Entered In Database
Was the chest x-r	Not Entered In Database ay Taken for this visit Historical (within the previous 6 months)
Date of chest x-ra	Not Entered In Database  y// MM DD YY  Not Entered In Database
Chest x-ray result	☐ <sub>12</sub> Acceptable ☐ <sub>13</sub> Not Acceptable
Pre	bnormality present and clinically relevant, enter the diagnosis or symptom on the existing Conditions and Study Adverse Events page. Note non-relevant normalities in the Chest X-ray Comments section below.
COMMENTS	: NON-RELEVANT CHEST X-RAY ABNORMALITIES
NO COMMENTS	Not Entered In Database
Print legibly and o	lo not use abbreviations or symbols. atabase
	<del>-</del>



Visit 1

				Page 12 of 1
	OCEDU	Not Entered In Da	atabase com	her a CT scan OR MRI of the brain, which is mpatible with Alzheimer's Disease, is required enter this trial.  In Database
Was	the MRI	☐ <sub>1</sub> Taken f	for this visit	
Date	of MRI	Not Entere	ed In Database	e e
	NOTE:	Pre-existing Cond	litions and Stu	cally relevant, enter the diagnosis or symptom on the udy Adverse Events page. Note non-relevant nents section below.
CO	MMEN	TS: NON-RE	LEVANT M	IRI ABNORMALITIES
NO (	COMMEN	NTS Not Ente	red In Databa	ase
	• .	nd do not use abbi In Database	reviations or s	symbols.



Visit 1 Page 13 of 14

PR	OCEDURE	: CT SCAN		
	_	Entered In Databa	NOTE:	Either a CT scan OR MRI of the brain, which is compatible with Alzheimer's Disease, is required
1101	DONE MINOR			to enter this trial.
Was	the CT scan	Not Er  ☐ 1 Taken for th		Database     Database
Date	of CT scan	Not Entered In		e e
	Pre-e	xisting Conditions	and Stud	Illy relevant, enter the diagnosis or symptom on the y Adverse Events page. Note non-relevant mments section below.
NO 0	COMMENTS [	Not Entered In	Database	_
NOT	Entered In Data	adase		



Visit 1 Page 14 of 14

COMMENTS: VISIT
NO COMMENTS Not Entered In Database
Comments should address any clinical report form items that require further explanation. Repeating information from the clinical report form is discouraged.
Comment on all clinically significant lab values that are outside a clinically accepted reference range or clinically significant values that differ importantly from previous values.
If the patient is ending participation in the study at this visit, enter only comments that apply to this visit; then complete the Patient Summary and Study Summary Comments pages.
Print legibly and do not use abbreviations or symbols.  Not Entered In Database
The information reported for this visit is accurate and complete.
Not Entered In Database  Not Entered In Database
Signature MM DD YY

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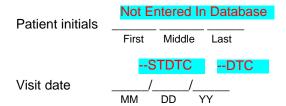
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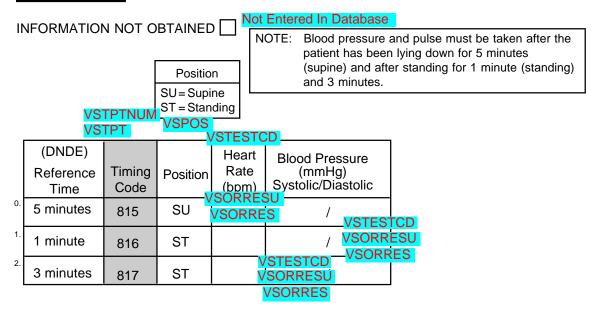




## PATIENT AND VISIT IDENTIFICATION



# VITAL SIGNS: HEART RATE AND BLOOD PRESSURE



#### REMINDER

On the Pre-existing Conditions and Study Adverse Events page, record new events that occurred since the previous visit and re-evaluate any on-going conditions or events.

On the Concomitant Medication page, record new medications the patient has taken since the previous visit and record a stop date for any medication the patient is no longer taking.

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VITAI	L SIGNS	: TEMPE	RATURE VSTE	STCD		
INFORI	1 NOITAN	NOT OBTAINE	Not Entere	d In Database		
Temper	rature	VSORRES	<u>.                                    </u>			
Unit of ı	measure	☐ <sub>F</sub> Fahrenh	neit	de VSORRESU		
Method	VSLOC	☐ <sub>PO</sub> Oral	☐ <sub>R</sub> Rectal	☐ <sub>A</sub> Axillary	□ <sub>E</sub> Ear	□ <sub>O</sub> Other
PROC	CEDURE	: AMBUL	ATORY ECG			
NOT D	ONE 🔲 🛚	Not Entered In	Database			
Date of	ambulato	ry ECG	Entered In Databa // MM DD YY	ise .		
N	the	Pre-existing (	esent and clinically Conditions and Stu the Ambulatory EC	dy Adverse Events	s page. Note	
			ELEVANT AMB	ULATORY EC	G ABNORI	MALITIES
	MMENTS		ered In Database			
7	gibly and o t <mark>ered In D</mark>		oreviations or symb	ols.		



Visit 2 Page 3 of 3

COMMENTS: VISIT
NO COMMENTS Not Entered In Database
Comments should address any clinical report form items that require further explanation. Repeating information from the clinical report form is discouraged.
Comment on all clinically significant lab values that are outside a clinically accepted reference range or clinically significant values that differ importantly from previous values.
If the patient is ending participation in the study at this visit, enter only comments that apply to this visit; then complete the Patient Summary and Study Summary Comments pages.
Print legibly and do not use abbreviations or symbols.  Not Entered In Database
The information reported for this visit is accurate and complete.
Not Entered In Database Not Entered In Database
Signature MM DD YY

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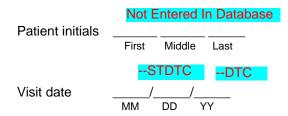
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Visit 3 Page 1 of 7

## PATIENT AND VISIT IDENTIFICATION



## **KIT NUMBER**

NONE DISPENSED Not Entered In Database

Not Entered In Database

Not Entered In Database

Kit number dispensed

# STUDY DRUG: DAILY PRESCRIBED DOSAGE

For this visit interval, record the number of patches (25-cm<sup>2</sup> and 50-cm<sup>2</sup> patches) that the patient is to wear per day.

Number of 25-cm<sup>2</sup> patches prescribed/day

Not Entered In Database

25-cm<sup>2</sup> patches

Number of 50-cm<sup>2</sup> patches prescribed/day

Not Entered In Database

50-cm<sup>2</sup> patches

#### **REMINDER**

On the Pre-existing Conditions and Study Adverse Events page, record new events that occurred since the previous visit and re-evaluate any on-going conditions or events.

On the Concomitant Medication page, record new medications the patient has taken since the previous visit and record a stop date for any medication the patient is no longer taking.



Visit 3 Page 2 of 7

#### **QSCAT**

# ALZHEIMER'S DISEASE ASSESSMENT SCALE: COGNITIVE with ATTENTION/CONCENTRATION TASKS

INFORMATION NOT OBTAINED Not Entered In Database

	Entere	d In Dat	abase
Clinician's initials	First	Middle	Last

QSTESTCD 1.	Word Recall Task	(max = 10)	QSORRES
QSTESTCD 2.	Naming Objects and Fingers (refer to 5 categories in manual)	(max = 5)	QSORRES
QSTESTCD 3.	Delayed Word Recall	(max = 10)	QSORRES
QSTESTCD 4.	Commands	(max = 5)	QSORRES
QSTESTCD 5.	Constructional Praxis	(max = 5)	QSORRES
QSTESTCD 6.	Ideational Praxis	(max = 5)	QSORRES
QSTESTCD 7.	Orientation	(max = 8)	QSORRES
QSTESTCD 8.	Word Recognition	(max = 12)	QSORRES
QSTESTCD 9.	Attention/Visual Search Task	(max = 40)	QSORRES
QSTESTCD 10.	Maze Solution	(max = 240)	QSORRES (seconds)
QSTESTCD 11.	Spoken Language Ability	(max = 5)	QSORRES
QSTESTCD 12.	Comprehension of Spoken Language	(max = 5)	QSORRES
QSTESTCD 13.	Word Finding Difficulty in Spontaneous Speech	(max = 5)	QSORRES
QSTESTCD 14.	Recall of Test Instructions	(max = 5)	QSORRES

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<u>American Journal of Psychiatry</u> 1984;141:1356-64.



H2Q-MC-LZZT

Visit 3 Page 3 of 7

# NEUROPSYCHIATRIC INVENTORY - REVISED (NPI-X) QSCAT

INFORMATION NOT OBTAINED Not Entered In Database

	Entered	d In Data	abase
Clinician's initials		- <del></del> -	
	First	Middle	Last

The screening question (from worksheet) is asked of the caregiver to determine if the behavioral change is present or absent in the patient. If the answer to the screening question is negative (NO) or if the question is not applicable to the patient, circle the appropriate response (Not Applicable [96] or Absent [0]) and proceed to the next screening question without asking the subquestions to determine frequency, severity, and distress.

		Not														
QSSCAT QSTESTCD	<u>Item</u> <u>A</u> p	oplicable QSORI	Abse	ent <u>[</u> QSTES	requestions.	ueno QSC	C <u>y</u> ORRES	Se QSTES	veri	<u>ty</u> OSORI	RES n		Distr STC			EC
A. QSSCAT QSTESTCD	Delusions	96 QSOR	0 RES	1	2	3	4 DRRES	1	2	3	0	1	2 STCI	3	4	5
QSSCAT QSTESTCD	Hallucinations	96 QSOR	0 RES	1	2	3	4 ORRES	1	2	3	0	1	2	3	4	5
C. QSSCAT QSTESTCD	Agitation/Agression	96 QSOR	0	1	2	3	4 DRRES	1	2	3	0	1	STCI 2	3	4	5
D.	Depression/ Dysphoria	96	0	1	2	3	4	1	2	QSOR 3	O O	STE 1	STCI 2	<sup>2</sup> QS	ORR 4	<mark>≀ES</mark> 5
QSSCAT QSTESTCD	Буѕрпопа	QSORF	RES	QSTES	TCD	QSO	RRES	QSTES	TCD	QSORF	RES O	STE	STCE	) OS	ORR'	FS
QSSCAT QSTESTCD	Anxiety	96 QSORF	0 RES	1 QSTES	2	3	4	1	2	3	0	1	2 STCE	3	4	5
F. QSSCAT QSTESTCD	Euphoria/Elation	96 QSORI	0 RES	1 QSTES	2	3	4	1	2	3	0	1	2	3	4	5
G.	Apathy/ Indifference	96	0	1	2	3	4	1	2	3	0	51E 1	STCI 2	3	ORR 4	ES 5
QSSCAT QSTESTCD	mainerence	QSOR	RES	QSTES	STCD	QSC	RRES	QSTES	TCD	OSORI	RES n	STE	STCE	108	OPP	EQ
QSSCAT QSTESTCD	Disinhibition	96 QSORF	0 RES	1 QSTES	2	3	4	1	2	3	0	1	2	3	4	5
QSSCAT QSTESTCD	Irritability/Lability	96 QSORI	0 RES	1 QSTES	2	3	4	1	2	3	0	1	STCE 2	3	4	5
J.	Aberrant Motor Behavior	96	0	1	2	3	4	1	2	3	0	1	STCI 2	3	4	5
QSSCAT QSTESTCD	Deliavioi	QSOR	RES	QSTE	STCD	QSC	ORRES	QSTES	STCD	QSOR	RES Q	STE	STCI	Dos	ORR	RES
QSSCAT QSTESTCD	Night-Time Behavior	96 QSOR	0 RES	1	2	3	4 DRRES	1	2	3	0	1 STF	2 STCI	3	4 ORR	5
L.	Appetite/Eating Change	96	0	1	2	3	4	1	2	3	0	1	2	3	4	5

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Visit 3 Page 4 of 7

# DISABILITY ASSESSMENT FOR DEMENTIA (DAD)

	IN	FORMATION NOT OBTAINED Not Entered In Database				
		Not Entered In Database Clinician's initials First Middle Last				
	Dι	Iring the past two weeks, did the patient without help or reminder:	tion	Planning & Organization	Effective Performance	
		QSSCAT HYGIENE  SCORING: Yes = 1 No = 0 Not Applicable = 96	Initiation	Planr Orga	Effec	
QSTESTCD	1.	Undertake to wash himself/herself or to take a bath or a shower				QSORRES
QSTESTCD	2.	Undertake to brush his/her teeth or care for his/her dentures				QSORRES
QSTESTCD	3.	Decide to care for his/her hair (wash and comb)				QSORRES
QSTESTCD	4.	Prepare the water, towels, and soap for washing, taking a bath, or a shower				QSORRES
QSTESTCD	5.	Wash and dry completely all parts of his/her body safely				QSORRES
QSTESTCD	6.	Brush his/her teeth or care for his/her dentures appropriately				QSORRES
QSTESTCD	7.	Care for his/her hair (wash and comb)				QSORRES
		DRESSING QSSCAT	<u> </u>			
QSTESTCD	8.	Undertake to dress himself/herself				QSORRES
QSTESTCD	9.	Choose appropriate clothing (with regard to the occasion, neatness, the weather, and color combination)				QSORRES
QSTESTCD	10.	Dress himself/herself in the appropriate order (undergarments, pant/dress, shoes)				QSORRES
QSTESTCD	11.	Dress himself/herself completely				QSORRES
QSTESTCD	12.	Undress himself/herself completely				QSORRES
		CONTINENCE QSSCAT				
QSTESTCD		Decide to use the toilet at appropriate times				QSORRES
QSTESTCD	14.	Use the toilet without "accidents"				QSORRES
		EATING QSSCAT				l
QSTESTCD	15.	Decide that he/she needs to eat				QSORRES
QSTESTCD	16.	Choose appropriate utensils and seasonings when eating				QSORRES
QSTESTCD	17.	Eat his/her meals at a normal pace and with appropriate manners				QSORRES
		MEAL PREPARATION QSSCAT				I
QSTESTCD	18.	Undertake to prepare a light meal or snack for himself/herself				QSORRES
QSTESTCD	19.	Adequately plan a light meal or snack (ingredients, cookware)				QSORRES
QSTESTCD	20.	Prepare or cook a light meal or a snack safely				QSORRES

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Visit 3 Page 5 of 7

# DISABILITY ASSESSMENT FOR DEMENTIA (DAD)

		QSSCAT TELEPHONING	SCORING:	Yes = 1	No = 0	Not App	olicable = 96	Initiation	Planning & Organization	Effective Performance	
QSTESTCD	21.	Attempt to telephone	e someone at	a suitable t	time						QSORRES
QSTESTCD	22.	Find and dial a telephone number correctly									QSORRES
	23.										QSORRES
QSTESTCD	24.										QSORRES
		GOING ON AN OUT	ING QSSCA	T							•
QSTESTCD	25.	Undertake to go out	(walk, visit, sh	nop) at an	appropriate t	ime					QSORRES
QSTESTCD	26.	Adequately organi weather, necessal			t to transpor	tation, keys	s, destination,				QSORRES
QSTESTCD	27.	Go out and rea	ach a familiar o	destination	without getti	ng lost					QSORRES
<b>QSTESTCD</b>	28.	Safely take the adequate mode of transportation (car, bus, taxi)  QSORRE								QSORRES	
QSTESTCD	29.										QSORRES
	ı	FINANCE AND COR	RESPONDEN	CE QSSC	CAT						'
QSTESTCD	30.	Show an interest in correspondence	his/her person	al affairs s	uch as his/h	er finances	and written				QSORRES
QSTESTCD	31.	Organize his/her finances to pay his/her bills (cheques, bankbook, bills)								QSORRES	
QSTESTCD				1110/1101 011	iis (citeques,	bankbook,	, Dilis)				
		Adequately organize									QSORRES
	32. 33.	Adequately organize	e his/her corresp	oondence w	ith respect to						
	32. 33.	Handle adequate	e his/her corresp	oondence w	ith respect to						QSORRES
	32. 33.	Handle adequate	e his/her correspely his/her mone	oondence w	ith respect to						QSORRES
QSTESTCD QSTESTCD	32. 33.	Handle adequate	e his/her corresponded his/her mone assections.	condence we ey (make ch	ith respect to nange)	stationery, a	address, stamps				QSORRES QSORRES
QSTESTCD QSTESTCD	32. 33. 34. 35.	Handle adequate  MEDICATIONS  Decide to take his/h	e his/her corresponded his/her mone else his/her corresponded his/her mone else his/her mo	condence we ey (make ch	ith respect to nange)	stationery, a	address, stamps				QSORRES QSORRES QSORRES
QSTESTCD QSTESTCD QSTESTCD	32. 33. 34. 35.	Handle adequate  MEDICATIONS  Decide to take his/her make	e his/her corresponded his/her mone else his/her	ey (make characters at the corprescribed	ith respect to nange)	stationery, a	address, stamps				QSORRES QSORRES QSORRES
QSTESTCD QSTESTCD QSTESTCD QSTESTCD	32. 33. 34. 35.	Handle adequate  MEDICATIONS  Decide to take his/her m  LEISURE AND HOU	e his/her correspends his/her mone elle his/her	ey (make characters) at the corprescribed SSCAT	ith respect to nange) rect time (according t	stationery, a	dosage)				QSORRES QSORRES QSORRES
QSTESTCD QSTESTCD QSTESTCD QSTESTCD QSTESTCD	32. 33. 34. 35.	Handle adequate  MEDICATIONS  Decide to take his/her m  LEISURE AND HOU  Show an interest in	e his/her correspond his/her mone descriptions as descriptions	condence we were (make characters) at the corprescribed SSCAT (ies)	ith respect to nange) rect time (according to	stationery, a	dosage)				QSORRES QSORRES QSORRES QSORRES
QSTESTCD QSTESTCD QSTESTCD QSTESTCD QSTESTCD QSTESTCD	32. 33. 34. 35. 36.	Handle adequate  MEDICATIONS  Decide to take his/her m  LEISURE AND HOU  Show an interest in  Take an interest in here.	e his/her corresponder his/her mone descriptions as the discription of	ey (make che can the corprescribed SSCAT (ies) res that he ehold chore	ith respect to nange)  rect time (according to she used to she used to shat he/she	stationery, a	dosage)				QSORRES QSORRES QSORRES QSORRES QSORRES QSORRES

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Visit 3 Page 6 of 7

WEIGHT VSTESTCD								
INFORMATION NOT OBTAINED Not Entered In Database								
Measure with shoes off. Round up or down to the nearest tenth kilogram or tenth pound.								
Weight VSORRESU Solution Weight Solution Solutio								
INFORMATION NOT OBTAINED  Position SU = Supine ST = Standing  VSTPTNUM VSTPT  WOTE Entered In Database  NOTE: Blood pressure and pulse must be taken after the patient has been lying down for 5 minutes (supine) and after standing for 1 minute (standing) and 3 minutes.								
(DNDE) Reference Timing Time Code  1								
VITAL SIGNS: TEMPERATURE VSTESTCD  INFORMATION NOT OBTAINED Not Entered In Database  Temperature VSORRES  Unit of measure Fahrenheit C Centigrade VSORRESU  Method VSLOC Po Oral Rectal Axillary Ear O Other								
PO TIME IN THE TANK IN THE TAN								



Visit 3 Page 7 of 7

COMMENTS: VISIT
NO COMMENTS Not Entered In Database
Comments should address any clinical report form items that require further explanation. Repeating information from the clinical report form is discouraged.
Comment on all clinically significant lab values that are outside a clinically accepted reference range or clinically significant values that differ importantly from previous values.
If the patient is ending participation in the study at this visit, enter only comments that apply to this visit; then complete the Patient Summary and Study Summary Comments pages.
Print legibly and do not use abbreviations or symbols.  Not Entered In Database
The information reported for this visit is accurate and complete.
Not Entered In Database  Not Entered In Database // /
Signature MM DD YY

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VISIT

Visit 3e Page 1 of 4

## PATIENT AND VISIT IDENTIFICATION

Patient initials

--STDTC

Visit date

Not Entered In Database

--STDTC

--DTC

--DTC

Visit date

**STUDY DRUG**: COMPLIANCE

INFORMATION NOT OBTAINED Not Entered In Database

Since the previous visit, on how many days was the patient unable to complete the therapy?

Not Entered In Database days

# **STUDY DRUG**: DAILY PRESCRIBED DOSAGE

For this visit interval, record the number of patches (25-cm<sup>2</sup> and 50-cm<sup>2</sup> patches) that the patient is to wear per day.

Number of 25-cm<sup>2</sup> patches prescribed/day

Not Entered In Database

25-cm<sup>2</sup> patches

Number of 50-cm<sup>2</sup> patches prescribed/day

Not Entered In Database

50-cm<sup>2</sup> patches

#### REMINDER

On the Pre-existing Conditions and Study Adverse Events page, record new events that occurred since the previous visit and re-evaluate any on-going conditions or events.

On the Concomitant Medication page, record new medications the patient has taken since the previous visit and record a stop date for any medication the patient is no longer taking.



Visit 3e Page 2 of 4

#### **HEART RATE AND BLOOD PRESSURE** VITAL SIGNS : Not Entered In Database INFORMATION NOT OBTAINED NOTE: Blood pressure and pulse must be taken after the patient has been lying down for 5 minutes (supine) and after standing for 1 minute (standing) Position and 3 minutes. SU = Supine ST = Standing **VSTPTNUM** VSPOS **VSTPT** VSTESTCD (DNDE) Heart **Blood Pressure Timing** Rate Reference (mmHg) Position Systolic/Diastolic Code (bpm) Time **VSORRESU** 5 minutes SU 815 **VSORRES** VSTESTCD **VSORRÉSU** 1 minute ST 816 **VSORRES VSTESTCD** 3 minutes 817 ST **VSORRESU VSORRES** VITAL SIGNS: TEMPERATURE VSTESTCD Not Entered In Database INFORMATION NOT OBTAINED **VSORRES** Temperature Fahrenheit Centigrade VSORRESU Unit of measure Method VSLOC ☐ PO Oral Axillary Ear Other Rectal



Visit 3e Page 3 of 4

PROCEDURE: AMBULATORY ECG
NOT DONE Not Entered In Database
Date of ambulatory ECG  Not Entered In Database //  MM DD YY
NOTE: If abnormality present and clinically relevant, enter the diagnosis or symptom on the Pre-existing Conditions and Study Adverse Events page. Note non-relevant abnormalities in the Ambulatory ECG Comments section below.
<b>COMMENTS</b> : NON-RELEVANT AMBULATORY ECG ABNORMALITIES
NO COMMENTS Not Entered In Database
Print legibly and do not use abbreviations or symbols.  Not Entered In Database



Visit 3e Page 4 of 4

COMMENTS: VISIT
NO COMMENTS Not Entered In Database
Comments should address any clinical report form items that require further explanation. Repeating information from the clinical report form is discouraged.
Comment on all clinically significant lab values that are outside a clinically accepted reference range or clinically significant values that differ importantly from previous values.
If the patient is ending participation in the study at this visit, enter only comments that apply to this visit; then complete the Patient Summary and Study Summary Comments pages.
Print legibly and do not use abbreviations or symbols.  Not Entered In Database
The information reported for this visit is accurate and complete.
Not Entered In Database  Not Entered In Database
Signature MM DD YY

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## PATIENT AND VISIT IDENTIFICATION

Patient initials

---STDTC

Visit date

Not Entered In Database

---STDTC

---DTC

MM DD YY

## **STUDY DRUG: COMPLIANCE**

INFORMATION NOT OBTAINED Not Entered In Database

Since the previous visit, on how many days was the patient unable to complete the therapy?

Not Entered In Database

#### **REMINDER**

On the Pre-existing Conditions and Study Adverse Events page, record new events that occurred since the previous visit and re-evaluate any on-going conditions or events.

On the Concomitant Medication page, record new medications the patient has taken since the previous visit and record a stop date for any medication the patient is no longer taking.

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Visit 4 Page 2 of 6

#### **STUDY DRUG**: PATCH ADHERENCE - PREVIOUS THREE DOSES

INFORMATION NOT OBTAINED Not Entered In Database

For the previous three doses of study drug (patch administration), give the date and the number of hours that a patch was NOT applied (if applicable).

Number of hours Number of hours 25-cm<sup>2</sup> patch 50-cm<sup>2</sup> patch **NOT** applied **NOT** applied <u>Date</u> Not Entered In Database Not Entered In Database 1. Today's (visit) date DD hours hours Not Entered In Database Not Entered In Database 2. Yesterday's date hours hours Not Entered In Database Not Entered In Database 3. Day before yesterday's date DD hours hours

### **STUDY DRUG**: DAILY PRESCRIBED DOSAGE

For this visit interval, record the number of patches (25-cm<sup>2</sup> and 50-cm<sup>2</sup> patches) that the patient is to wear per day.

Number of 25-cm<sup>2</sup> patches prescribed/day

Not Entered In Database

25-cm<sup>2</sup> patches

Number of 50-cm<sup>2</sup> patches prescribed/day

Not Entered In Database

50-cm<sup>2</sup> patches



H2Q-MC-LZZT

Visit 4 Page 3 of 6

### NEUROPSYCHIATRIC INVENTORY - REVISED (NPI-X) QSCAT

INFORMATION NOT OBTAINED Not Entered In Database

Clinician's initials

Not Entered In Database
First Middle Last

Not

The screening question (from worksheet) is asked of the caregiver to determine if the behavioral change is present or absent in the patient. If the answer to the screening question is negative (NO) or if the question is not applicable to the patient, circle the appropriate response (Not Applicable [96] or Absent [0]) and proceed to the next screening question without asking the subquestions to determine frequency, severity, and distress.

000017	Item A	pplicable	Abse	nt F	requ	uenc	CV	Se	veri	ity			Disti	ess		
QSSCAT QSTESTCD		QSOR		QSTES	TCĎ	QSC	RRES	QSTES	TCD	QSORI	RES C	STE	STCI	os	ORR	RES
A.	Delusions	96	0	1	2	3	4	1	2	3	0	1	2	3	4	5
QSSCAT QSTESTCD		QSOR	RES	QSTES	TCD	QSC	DRRES	QSTES	STCD	QSORI	RES (	STE	STC	DQS	ORF	RES
QSSCAT OSTESTOD	Hallucinations	96	0	1	2	3	4	1	2	3	0	1	2	3	4	5
QUIEUTOB		QSOR		QSTES	TCD	QSC	DRRES	QSTES	STCD	QSORI	RES C	STE	STC	DQS	ORF	RES
C.	Agitation/Agression	96	0	1	2	3	4	1	2	3	0	1	2	3	4	5
QSSCAT QSTESTCD	D /	QSOR		QSTES	SICD	QSC	ORRES	QSTES	STCD	QSOR	RES	QSŢE	STC	DQS	ORF	RES
D.	Depression/	96	0	1	2	3	4	1	2	3	0	1	2	3	4	5
QSSCAT QSTESTCD	Dysphoria	QSORF	RES	OSTES	TCD	റടറ	RRES	OSTES	TCD.							
E.	Anxiety	96	0	QSTES	2	3	4	<b>QSTES</b> 1	2	QSORF 3	RES Q O	STE 1	STCI 2	QS 3	ORR 4	ES 5
QSSCAT QSTESTCD	Allxiety	QSOR	-	QSTES	_	_		ı OSTES	_	_	·	ا .	_	_	•	•
F.	Euphoria/Elation	96	0	1	2	3	4	1	2	3	(ES Q	51E 1	STCE 2	3 QS	ORR 4	<u>ES</u>
QSSCAT QSTESTCD	_ up	QSOR	RES	QSTES	TCD	QSC	RRES	OSTES	TCD		) 	· OTE	STC	-	OD D	)FO
G.	Apathy/	96	0	1	2	3	4	1	2	3	0	1	2	3	4	5
00004T	Indifference															
QSSCAT QSTESTCD		QSORI	RES	QSTES	TCD	QSC	RRES	QSTES	TCD	QSORF	RES Q	STE	STC	os	ORR	ES
H.	Disinhibition	96	0	1	2	3	4	1	2	3	0	1		3		5
QSSCAT QSTESTCD		QSORI	RES	QSTES	TCD	QSC	RRES	QSTES	TCD		RES Q	STE	STC	ogs	ORR	ES
OSSCAT COTTON	Irritability/Lability	96	0	1	2	3	4	1	2	3	0	1	2	3	4	5
QSSCAT QSTESTCD		QSOR		QSTES								SŢE	STCI			
J.	Aberrant Motor	96	0	1	2	3	4	1	2	3	0	1	2	3	4	5
QSSCAT QSTESTCD	Behavior	QSOR	DEC	OSTES	TCD	000		00750								
	Night Time Dehavior		0	QSTES 1	2	3	JKKES 4	QSTES	2	QSORI 3		STE 1	STC	D QS 3		
QSSCAT QSTESTCD	Night-Time Behavior	QSOR		QSTES				OSTE			0				4	5
1	Appetite/Eating	96	0	1	2	3	4	1	2	QSOR 3	RES (	JSTE 1	STC 2	Digs 3	ORF	RES 5
<u></u>	Change	50	J	'	_	J	7	'	_	J	J	•	_	J	7	J

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Visit 4 Page 4 of 6

WEIGHT VSTESTCD								
INFORMATION NOT OBTAINED Not Entered In Database								
Measure with shoes off. Round up or down to the nearest tenth kilogram or tenth pound.								
Weight VSORRES								
VITAL SIGNS: HEART RATE AND BLOOD PRESSURE								
INFORMATION NOT OBTAINED  Position SU = Supine ST = Standing  Not Entered In Database  NOTE: Blood pressure and pulse must be taken after the patient has been lying down for 5 minutes (supine) and after standing for 1 minute (standing) and 3 minutes.								
VSTPT VSPOS VSTESTCD								
(DNDE) Heart Blood Pressure Reference Timing Position (bpm) Systolic/Diastolic								
0. 5 minutes 815 SU VSORRES / VSTESTCD								
1 minute 816 ST / VSORRESU								
3 minutes 817 ST VSORRESU								
VITAL SIGNS : TEMPERATURE VSTESTCD								
INFORMATION NOT OBTAINED Not Entered In Database								
Temperature								
Unit of measure								
Method VSLOC ☐ PO Oral ☐ R Rectal ☐ A Axillary ☐ Ear ☐ O Other								



Visit 4 Page 5 of 6

ELECTROCARDIOGRAM
NOT DONE Not Entered In Database
Electrocardiogram date  Not Entered In Database  MM DD YY  Not Entered In Database  Electrocardiogram result  Acceptable 13 Not Acceptable
13 Not Acceptable
NOTE: Any clinically relevant change from Visit 1 (baseline) ECG must be recorded on the Pre-existing Conditions and Adverse Events page. Note non-relevant abnormalities in the ECG Comments section below.
COMMENTS: NON-RELEVANT ECG ABNORMALITIES
Not Entered in Detabase
NO COMMENTS   Not Entered in Database
Print legibly and do not use abbreviations or symbols.
Not Entered In Database



Visit 4 Page 6 of 6

COMMENTS: VISIT
NO COMMENTS Not Entered In Database
Comments should address any clinical report form items that require further explanation. Repeating information from the clinical report form is discouraged.
Comment on all clinically significant lab values that are outside a clinically accepted reference range or clinically significant values that differ importantly from previous values.
If the patient is ending participation in the study at this visit, enter only comments that apply to this visit; then complete the Patient Summary and Study Summary Comments pages.
Print legibly and do not use abbreviations or symbols.  Not Entered In Database
The information reported for this visit is accurate and complete.
Not Entered In Database Not Entered In Database
Signature MM DD YY

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VISIT
VISITNUM
Visit 5
Page 1 of 7

#### PATIENT AND VISIT IDENTIFICATION

Patient initials

First Middle Last

--STDTC --DTC

Visit date

MM DD YY

#### **STUDY DRUG**: COMPLIANCE

INFORMATION NOT OBTAINED Not Entered In Database

Since the previous visit, on how many days was the patient unable to complete the therapy? Not Entered In Database

#### **REMINDER**

On the Pre-existing Conditions and Study Adverse Events page, record new events that occurred since the previous visit and re-evaluate any on-going conditions or events.

On the Concomitant Medication page, record new medications the patient has taken since the previous visit and record a stop date for any medication the patient is no longer taking.



Visit 5 Page 2 of 7

#### **STUDY DRUG**: PATCH ADHERENCE - PREVIOUS THREE DOSES

INFORMATION NOT OBTAINED Not Entered In Database

For the previous three doses of study drug (patch administration), give the date and the number of hours that a patch was NOT applied (if applicable).

Number of hours

Number of hours

50-cm<sup>2</sup> patch 25-cm<sup>2</sup> patch **Date NOT** applied **NOT** applied Not Entered In Database Not Entered In Database 1. Today's (visit) date MM DD hours hours Not Entered In Database Not Entered In Database 2. Yesterday's date hours Not Entered In Database 3. Day before Not Entered In Database yesterday's date hours

#### **STUDY DRUG**: DAILY PRESCRIBED DOSAGE

For this visit interval, record the number of patches (25-cm<sup>2</sup> and 50-cm<sup>2</sup> patches) that the patient is to wear per day.

Number of 25-cm<sup>2</sup> patches prescribed/day

25-cm<sup>2</sup> patches

Number of 50-cm<sup>2</sup> patches prescribed/day

Not Entered In Database

Not Entered In Database

50-cm<sup>2</sup> patches

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Visit 5 Page 3 of 7

#### NEUROPSYCHIATRIC INVENTORY - REVISED (NPI-X) QSCAT

INFORMATION NOT OBTAINED Not Entered In Database

Clinician's initials

Not Entered In Database
First Middle Last

Not

The screening question (from worksheet) is asked of the caregiver to determine if the behavioral change is present or absent in the patient. If the answer to the screening question is negative (NO) or if the question is not applicable to the patient, circle the appropriate response (Not Applicable [96] or Absent [0]) and proceed to the next screening question without asking the subquestions to determine frequency, severity, and distress.

000017	Item A	pplicable	Abse	nt F	requ	uenc	CV	Se	veri	ity			Disti	ess		
QSSCAT QSTESTCD		QSOR		QSTES	TCĎ	QSC	RRES	QSTES	TCD	QSORI	RES C	STE	STCI	os	ORR	RES
A.	Delusions	96	0	1	2	3	4	1	2	3	0	1	2	3	4	5
QSSCAT QSTESTCD		QSOR	RES	QSTES	TCD	QSC	DRRES	QSTES	STCD	QSORI	RES (	STE	STC	DQS	ORF	RES
QSSCAT OSTESTOD	Hallucinations	96	0	1	2	3	4	1	2	3	0	1	2	3	4	5
QUIEUTOB		QSOR		QSTES	TCD	QSC	DRRES	QSTES	STCD	QSORI	RES C	STE	STC	DQS	ORF	RES
C.	Agitation/Agression	96	0	1	2	3	4	1	2	3	0	1	2	3	4	5
QSSCAT QSTESTCD	D /	QSOR		QSTES	SICD	QSC	ORRES	QSTES	STCD	QSOR	RES	QSŢE	STC	DQS	ORF	RES
D.	Depression/	96	0	1	2	3	4	1	2	3	0	1	2	3	4	5
QSSCAT QSTESTCD	Dysphoria	QSORF	RES	OSTES	TCD	റടറ	RRES	OSTES	TCD.							
E.	Anxiety	96	0	QSTES	2	3	4	<b>QSTES</b> 1	2	QSORF 3	RES Q O	STE 1	STCI 2	QS 3	ORR 4	ES 5
QSSCAT QSTESTCD	Allxiety	QSOR	-	QSTES	_	_		ı OSTES	_	_	·	ا .	_	_	•	•
F.	Euphoria/Elation	96	0	1	2	3	4	1	2	3	(ES Q	51E 1	STCE 2	3 QS	ORR 4	<u>ES</u>
QSSCAT QSTESTCD	_ up	QSOR	RES	QSTES	TCD	QSC	RRES	OSTES	TCD		פר כ	· OTE	STC	-	OD D	)FO
G.	Apathy/	96	0	1	2	3	4	1	2	3	0	1	2	3	4	5
00004T	Indifference															
QSSCAT QSTESTCD		QSORI	RES	QSTES	TCD	QSC	RRES	QSTES	TCD	QSORF	RES Q	STE	STC	os	ORR	ES
H.	Disinhibition	96	0	1	2	3	4	1	2	3	0	1		3		5
QSSCAT QSTESTCD		QSORI	RES	QSTES	TCD	QSC	RRES	QSTES	TCD		RES Q	STE	STC	ogs	ORR	ES
OSSCAT COTTON	Irritability/Lability	96	0	1	2	3	4	1	2	3	0	1	2	3	4	5
QSSCAT QSTESTCD		QSOR		QSTES								SŢE	STCI			
J.	Aberrant Motor	96	0	1	2	3	4	1	2	3	0	1	2	3	4	5
QSSCAT QSTESTCD	Behavior	QSOR	DEC	OSTES	TCD	000		00750								
	Night Time Dehavior		0	QSTES 1	2	3	JKKES 4	QSTES	2	QSORI 3		STE 1	STC	D QS 3		
QSSCAT QSTESTCD	Night-Time Behavior	QSOR		QSTES				OSTE			0				4	5
1	Appetite/Eating	96	0	1	2	3	4	1	2	QSOR 3	RES (	JSTE 1	STC 2	Digs 3	ORF	RES 5
<u></u>	Change	50	J	'	_	J	7	'	_	J	J	•	_	J	7	J

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Visit 5 Page 4 of 7

\	WEIGHT	/STEST(	CD CD							
۱N	IFORMATION			No No	t Entere	ed In Database	9			
M	leasure with s	shoes off.	Round u	up or dow	n to the	nearest tenth	kilogi	ram or tenth	ı pound.	
V	/eight <mark>VSC</mark>	RRES	— Dı	<sub>kg</sub> Kilogra <mark>VS</mark> 0	m [ ORRES	្ន <sub>lb</sub> Pound <mark>U</mark>				
	VITAL SIGN			— Not		LOOD PRE	SSUI	RE		
11.	NFORMATIO		Positio SU=Supi		p (:	Blood pressure a atient has been supine) and afte nd 3 minutes.	lying	down for 5 m		
	VST VST	PTNUM PT	ST = Stan	ding						
	(DNDE) Reference Time	Timing Code	Position	STESTC Heart Rate (bpm)	Blood (n Systol	l Pressure nmHg) ic/Diastolic				
0.	5 minutes	815		SORRES SORRES		/ VSTEST	CD			
1.	1 minute	816	ST			/ VSORRE	SU			
2.	3 minutes	817	ST	VS	STEST( SORRE	SU				
VITAL SIGNS : TEMPERATURE VSTESTCD										
IN	IFORMATION	NOT O	BTAINED	Not	t Entere	d In Database	•			
Т	emperature	VSC	ORRES							
U	nit of measur	e □ <sub>F</sub> I	ahrenhe	it □c	Centigra	de VSORRES	SU			
M	lethod VSLC	C PC	Oral	□ <sub>R</sub> F	Rectal	Axilla	ary	□ <sub>E</sub> Ear	□ o Other	



Visit 5 Page 5 of 7

ELECTROCARDIOGRAM
NOT DONE Not Entered In Database
Electrocardiogram date    Not Entered In Database
Electrocardiogram result
NOTE: Any clinically relevant change from Visit 1 (baseline) ECG must be recorded on the Pre-existing Conditions and Adverse Events page. Note non-relevant abnormalities in the ECG Comments section below.
COMMENTS: NON-RELEVANT ECG ABNORMALITIES
NO COMMENTS Not Entered In Database
Print legibly and do not use abbreviations or symbols.
Not Entered In Database



Visit 5 Page 6 of 7

Page 6
PROCEDURE: AMBULATORY ECG
NOT DONE Not Entered In Database
Not Entered In Database
Date of ambulatory ECG  MM DD YY
NOTE: If abnormality present and clinically relevant, enter the diagnosis or symptom on the Pre-existing Conditions and Study Adverse Events page. Note non-relevant abnormalities in the Ambulatory ECG Comments section below.
<b>COMMENTS</b> : NON-RELEVANT AMBULATORY ECG ABNORMALITIES
NO COMMENTS Not Entered In Database
Print legibly and do not use abbreviations or symbols.  Not Entered In Database



Visit 5 Page 7 of 7

COMMENTS: VISIT
NO COMMENTS Not Entered In Database
Comments should address any clinical report form items that require further explanation. Repeating information from the clinical report form is discouraged.
Comment on all clinically significant lab values that are outside a clinically accepted reference range or clinically significant values that differ importantly from previous values.
f the patient is ending participation in the study at this visit, enter only comments that apply to this visit; then complete the Patient Summary and Study Summary Comments pages.
Print legibly and do not use abbreviations or symbols.  Not Entered In Database
The information reported for this visit is accurate and complete.
Not Entered In Database  Not Entered In Database
Signature MM DD YY

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Visit 6 Page 1 of 3

#### PATIENT AND VISIT IDENTIFICATION

Patient initials

--STDTC

Visit date

Not Entered In Database

First Middle Last

--STDTC

--DTC

MM DD YY

STUDY DRUG : COMPLIANCE

INFORMATION NOT OBTAINED Not Entered In Database

Since the previous visit, on how many days was the patient unable to complete the therapy? Not Entered In Database

days

#### STUDY DRUG: DAILY PRESCRIBED DOSAGE

For this visit interval, record the number of patches (25-cm<sup>2</sup> and 50-cm<sup>2</sup> patches) that the patient is to wear per day.

Number of 25-cm<sup>2</sup> patches prescribed/day

Number of 50-cm<sup>2</sup> patches prescribed/day

Not Entered In Database

25-cm<sup>2</sup> patches

Not Entered In Database

50-cm<sup>2</sup> patches

On the Pre-existing Conditions and Study Adverse Events page, record new events that occurred since the previous visit and re-evaluate any on-going conditions or events.

REMINDER

On the Concomitant Medication page, record new medications the patient has taken since the previous visit and record a stop date for any medication the patient is no longer taking.



Visit 6 Page 2 of 3

#### VITAL SIGNS: HEART RATE AND BLOOD PRESSURE Not Entered In Database INFORMATION NOT OBTAINED NOTE: Blood pressure and pulse must be taken after the patient has been lying down for 5 minutes (supine) and after standing for 1 minute (standing) Position and 3 minutes. SU = Supine ST = Standing **VSTPTNUM VSPOS VSTPT VSTESTCD** (DNDE) Heart **Blood Pressure** Timing Rate (mmHg) Reference Position Systolic/Diastolic Code (bpm) Time **VSORRESU** 5 minutes SU 815 **VSORRES VSTESTCD** / VSORRESU 1 minute ST 816 **VSORRES** VSTESTCD 3 minutes ST 817 **VSORRESU VSORRES**

VITAL SIGNS	: TEMPERA	TURE VSTESTO	CD		
INFORMATION N	OT OBTAINED	Not Entered In	n Database		
Temperature	VSORRES .	_			
Unit of measure	☐ <sub>F</sub> Fahrenheit	☐ <sub>C</sub> Centigrade	/SORRESU		
Method VSLOC	□ <sub>PO</sub> Oral	☐ <sub>R</sub> Rectal	Axillary	□ <sub>E</sub> Ear	□ o Other



Visit 6 Page 3 of 3

COMMENTS: VISIT
NO COMMENTS Not Entered In Database
Comments should address any clinical report form items that require further explanation. Repeating information from the clinical report form is discouraged.
Comment on all clinically significant lab values that are outside a clinically accepted reference range or clinically significant values that differ importantly from previous values.
If the patient is ending participation in the study at this visit, enter only comments that apply to this visit; then complete the Patient Summary and Study Summary Comments pages.
Print legibly and do not use abbreviations or symbols.  Not Entered In Database
The information reported for this visit is accurate and complete.
Not Entered In Database Not Entered In Database
Signature MM DD YY

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VISITNUM
Visit 7
Page 1 of 6

#### PATIENT AND VISIT IDENTIFICATION

Patient initials

--STDTC

Visit date

Not Entered In Database

--STDTC

--DTC

--DTC

#### STUDY DRUG: COMPLIANCE

INFORMATION NOT OBTAINED Not Entered In Database

Since the previous visit, on how many days was the patient unable to complete the therapy?

Not Entered In Database

#### **REMINDER**

On the Pre-existing Conditions and Study Adverse Events page, record new events that occurred since the previous visit and re-evaluate any on-going conditions or events.

On the Concomitant Medication page, record new medications the patient has taken since the previous visit and record a stop date for any medication the patient is no longer taking.



Visit 7 Page 2 of 6

#### **STUDY DRUG**: PATCH ADHERENCE - PREVIOUS THREE DOSES

INFORMATION NOT OBTAINED Not Entered In Database

For the previous three doses of study drug (patch administration), give the date and the number of hours that a patch was NOT applied (if applicable).

Number of hours Number of hours 25-cm<sup>2</sup> patch 50-cm<sup>2</sup> patch **Date NOT** applied **NOT** applied Not Entered In Database Not Entered In Database 1. Today's (visit) date MM DD ΥY hours hours Not Entered In Database Not Entered In Database 2. Yesterday's date hours 3. Day before Not Entered In Database Not Entered In Database yesterday's date hours

### **STUDY DRUG**: DAILY PRESCRIBED DOSAGE

For this visit interval, record the number of patches (25-cm<sup>2</sup> and 50-cm<sup>2</sup> patches) that the patient is to wear per day.

Number of 25-cm<sup>2</sup> patches prescribed/day

Not Entered In Database

25-cm<sup>2</sup> patches

Number of 50-cm<sup>2</sup> patches prescribed/day

Not Entered In Database

50-cm<sup>2</sup> patches

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H2Q-MC-LZZT Visit 7
Page 3 of 6

#### NEUROPSYCHIATRIC INVENTORY - REVISED (NPI-X) QSCAT

INFORMATION NOT OBTAINED Not Entered In Database

Entered In Database	Э
t Middle Last	
_	st Middle Last

The screening question (from worksheet) is asked of the caregiver to determine if the behavioral change is present or absent in the patient. If the answer to the screening question is negative (NO) or if the question is not applicable to the patient, circle the appropriate response (Not Applicable [96] or Absent [0]) and proceed to the next screening question without asking the subquestions to determine frequency, severity, and distress.

		Not														
QSSCAT QSTESTCD	<u>Item</u> A	p <u>plicable</u> QSORI	Abse	nt F	requ	uenc QSC	<u>X</u> XRES	Se QSTES	veri	<u>ty</u> QSOR	RES n		Distr		ORR	ES
QSSCAT QSTESTCD	Delusions	96 <mark>QSOR</mark> I	0 RES	1 QSTES	2	3	4	1	2	3	0	1	2 STCI	3	4	5
QSSCAT QSTESTCD	Hallucinations	96 <b>QSOR</b> I	0 RES	1 QSTES	2	3	4	1	2	3	0	1	2 STCI	3	4	5
C. QSSCAT QSTESTCD	Agitation/Agression	96 QSOR	0 RES	1 QSTES	2	3	4	1	2	3	0	1	2	3	4	5
D.	Depression/ Dysphoria	96	0	1	2	3	4	1	2	3	0	1	STCI 2	3	4	5
QSSCAT QSTESTCD	Бубриона	QSORF	RES	QSTES	TCD	QSO	RRES	QSTES	TCD	QSORI	RES Q	STE	STCD	OSO	ORRI	FS
QSSCAT QSTESTCD	Anxiety	96 <mark>QSORF</mark>	0 RES	1 QSTES	2 TCD	3 <b>2SO</b>	4 RRES	1 QSTES	2 TCD	3 DSORI	0	1	2 STCE	3	4	5
F. QSSCAT QSTESTCD	Euphoria/Elation	96 QSORI	0 RES	1 QSTES	2	3	4	1	2	3	0	1	2	3	4	5
G.	Apathy/ Indifference	96	0	1	2	3	4	1	2	3	0	SIE 1	2	3	ORR 4	ES 5
QSSCAT QSTESTCD	mamerence	QSORF	RES	QSTES	TCD	QSO	RRES	QSTES	TCD	OSOR	RES O	STE	STCE	108	ODD	EQ
QSSCAT QSTESTCD	Disinhibition	96 QSORF	0 RES	1 QSTES	2	3	4	1	2	3	0	1	2 STCE	3	4	5
QSSCAT QSTESTCD	Irritability/Lability	96 QSORI	0 RES	1 QSTES	2	3	4	1	2	3	0	1	2	3	4	5
J.	Aberrant Motor Behavior	96	0	1	2	3	4	1	2	3	0	1	STCI 2	3	4	5
QSSCAT QSTESTCD	Deliavior	QSORI	RES	QSTES	TCD	QSC	RRES	QSTES	STCD	QSOR	RES C	STE	STCI	os	ORR	FS
QSSCAT QSTESTCD	Night-Time Behavior	r 96 <mark>QSOR</mark>	0 RES	1 QSTES	2	3	4	1	2	3	0	1	2 STCI	3	4	5
L.	Appetite/Eating Change	96	0	1	2	3	4	1	2	3	0	1	2	3	4	5

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Visit 7 Page 4 of 6

WEIGHT	VSTEST(	חי						
INFORMATION NOT OBTAINED Not Entered In Database								
Measure with	Measure with shoes off. Round up or down to the nearest tenth kilogram or tenth pound.							
Weight	ORRES _	— Di	<sub>kg</sub> Kilogra <mark>VS</mark> 0	m [	] <sub>lb</sub> Pound J			
VITAL SIG			Not Not	Entered	In Database	oulse must be t		
	patient has been lying down for 5 minutes (supine) and after standing for 1 minute (standing) and 3 minutes.							
VST	PTNUM	SU=Supi ST=Stan						
VST		VSPOS	STECTOR	•				
(DNDE)		VS	STESTCE   Heart		Pressure			
Reference Time	Timing Code	Position	Rate (bpm)	(m Systoli	nmHg) c/Diastolic			
o. 5 minutes	815		SORRESI SORRES		/ VSTESTCD			
1 minute	816	ST			/ VSORRESU DVSORRES			
3 minutes	817	ST		TESTC ORRES	U ,			
			V	SORRE	S			
VITAL SIG	NS : T	EMPER	ATURE	VSTE	STCD			
INFORMATIO	N NOT C	BTAINED	) No	t Entere	ed In Database			
Temperature	VSC	DRRES						
Unit of measu	re 🔲 <sub>F</sub>	Fahrenhe	it □cC	Centigra	de VSORRESU			
Method VSL0	OC PO	<sub>o</sub> Oral	$\square_R$ F	Rectal	☐ <sub>A</sub> Axillary	□ <sub>E</sub> Ear	☐ o Other	



Visit 7 Page 5 of 6

ELECTROCARDIOGRAM
NOT DONE Not Entered In Database  Not Entered In Database  Electrocardiogram date//
MM DD YY  Not Entered In Database  Electrocardiogram result
NOTE: Any clinically relevant change from Visit 1 (baseline) ECG must be recorded on the Pre-existing Conditions and Adverse Events page. Note non-relevant abnormalities in the ECG Comments section below.
COMMENTS: NON-RELEVANT ECG ABNORMALITIES
NO COMMENTS Not Entered In Database
Print legibly and do not use abbreviations or symbols.  Not Entered In Database  Not Entered In Database



Visit 7 Page 6 of 6

COMMENTS: VISIT	
NO COMMENTS Not Entered In D	Database
Comments should address any clinical information from the clinical report form	report form items that require further explanation. Repeating is discouraged.
Comment on all clinically significant lab or clinically significant values that differ	values that are outside a clinically accepted reference range importantly from previous values.
	ne study at this visit, enter only comments that apply to this ry and Study Summary Comments pages.
Print legibly and do not use abbreviation  Not Entered In Database	ns or symbols.
The information reported for this visit is	accurate and complete.
Not Entered In Database	Not Entered In Database
Signature	MM DD YY

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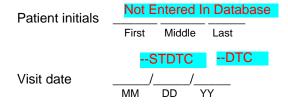
CM30501

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VISIT
VISITNUM
Visit 8
Page 1 of 9

#### PATIENT AND VISIT IDENTIFICATION



#### STUDY DRUG : COMPLIANCE

INFORMATION NOT OBTAINED Not Entered In Database

Since the previous visit, on how many days was the patient unable to complete the therapy?

Not Entered In Database

#### STUDY DRUG: DAILY PRESCRIBED DOSAGE

For this visit interval, record the number of patches (25-cm<sup>2</sup> and 50-cm<sup>2</sup> patches) that the patient is to wear per day.

Number of 25-cm<sup>2</sup> patches prescribed/day

Not Entered In Database

25-cm<sup>2</sup> patches

Number of 50-cm<sup>2</sup> patches prescribed/day

Not Entered In Database

50-cm<sup>2</sup> patches

#### REMINDER

On the Pre-existing Conditions and Study Adverse Events page, record new events that occurred since the previous visit and re-evaluate any on-going conditions or events.

On the Concomitant Medication page, record new medications the patient has taken since the previous visit and record a stop date for any medication the patient is no longer taking.



Visit 8 Page 2 of 9

#### **QSCAT**

# ALZHEIMER'S DISEASE ASSESSMENT SCALE: COGNITIVE with ATTENTION/CONCENTRATION TASKS

INFORMATION NOT OBTAINED Not Entered In Database

	Not Entered In Databas								
Clinician's initials	First	Middle	Last						

PRRES
RRES
RRES
DRRES
RRES
RRES
DRRES
PRRES
ORRES
RES (seconds)
ORRES
PRRES
DRRES
RRES

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<u>American Journal of Psychiatry</u> 1984;141:1356-64.

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QS572

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## CLINICIAN'S INTERVIEW-BASED IMPRESSION OF CHANGE (CIBIC+) INFORMATION NOT OBTAINED Not Entered In Database Not Entered In Database Clinician's initials First Middle Check one box to indicate the extent of change, if any, observed since the initial baseline interview. **QSTESTCD** ☐ ₁ Marked improvement QSORRES Moderate improvement ☐ 3 Minimal improvement ☐ ₄ No change ☐ 5 Minimal worsening ☐ 6 Moderate worsening Marked worsening The clinical interview-based impression of change scale in this study is from a pilot instrument, the Clinical Global Impression of Change, developed and currently undergoing validity studies by the National Institute

on Aging Alzheimer's Disease Study Units Program (1 U01 AG10483; Leon Thal, Principal Investigator), and is in the public domain.



Γ Visit 8 Page 4 of 9

#### NEUROPSYCHIATRIC INVENTORY - REVISED (NPI-X) QSCAT

INFORMATION NOT OBTAINED Not Entered In Database

	Not E	ntered l	n Datab	as	е
Clinician's initials	First	Middle	Last		

The screening question (from worksheet) is asked of the caregiver to determine if the behavioral change is present or absent in the patient. If the answer to the screening question is negative (NO) or if the question is not applicable to the patient, circle the appropriate response (Not Applicable [96] or Absent [0]) and proceed to the next screening question without asking the subquestions to determine frequency, severity, and distress.

		Not														
QSSCAT QSTESTCD	<u>Item</u> <u>A</u> p	oplicable QSORI	Abse	nt F	requ	ueno QSC	C <u>y</u> DRRES	Se QSTES	veri	<u>ty</u> OSORI	RES n		Distr			EC
A. QSSCAT QSTESTCD	Delusions	96 QSOR	0 RES	1	2	3	4 DRRES	1	2	3	0	1	2 STCI	3	4	5
QSSCAT QSTESTCD	Hallucinations	96 QSOR	0 RES	1	2	3	4 DRRES	1	2	3	0	1	2	3	4	5
C. QSSCAT QSTESTCD	Agitation/Agression	96 QSOR	0	1	2	3	4 DRRES	1	2	3	0	1	STCI 2	3	4	5
D.	Depression/ Dysphoria	96	0	1	2	3	4	1	2	3	RES 0	ISTE 1	STCI 2	ogs 3	ORR 4	<mark>≀ES</mark> 5
QSSCAT QSTESTCD	Буѕрпопа	QSORF	RES	QSTES	TCD	QSO	RRES	QSTES	TCD	SORF	RES O	STE	STCE	) OS	ORR'	FS
QSSCAT QSTESTCD	Anxiety	96 QSORF	0 RES	1 QSTES	2	3	4	1	2	3	0	1	2 STCE	3	4	5
F. QSSCAT QSTESTCD	Euphoria/Elation	96 QSORI	0 RES	1 QSTES	2	3	4	1	2	3	0	1	2	3	4	5
G.	Apathy/ Indifference	96	0	1	2	3	4	1	2	3	0	SIE 1	STCI 2	3	ORR 4	ES 5
QSSCAT QSTESTCD	mainerence	QSOR	RES	QSTES	TCD	QSC	RRES	QSTES	TCD	OSORI	RES n	STE	STCE	108	OPP	EQ
QSSCAT QSTESTCD	Disinhibition	96 <b>QSOR</b> F	0 RES	1 QSTES	2	3	4	1	2	3	0	1	2	3	4	5
QSSCAT QSTESTCD	Irritability/Lability	96 QSORI	0 RES	1 QSTES	2	3	4	1	2	3	0	1	STCE 2	3	4	5
J.	Aberrant Motor Behavior	96	0	1	2	3	4	1	2	3	0	1	STCI 2	3	4	5
QSSCAT QSTESTCD	Deliavioi	QSOR	RES	QSTES	STCD	QSC	ORRES	QSTES	TCD	QSOR	RES C	STE	STCI	DOS	ORR	PES .
QSSCAT QSTESTCD	Night-Time Behavior	96 QSOR	0 RES	1	2	3	4 DRRES	1	2	3	0	1	2 STC	3	4 ORR	5
L.	Appetite/Eating Change	96	0	1	2	3	4	1	2	3	0	1	2	3	4	5

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Visit 8 Page 5 of 9

### DISABILITY ASSESSMENT FOR DEMENTIA (DAD) QSCAT

	۲	ICABIETT ACCESSMENT FOR DEMERTIA (DAD)				
	IN	FORMATION NOT OBTAINED Not Entered In Database				
		Clinician's initials  Not Entered In Database First Middle Last				
	Dι	ring the past two weeks, did the patient without help or reminder:	Initiation	Planning & Organization	Effective Performance	
OCTECTOR		SCORING: Yes = 1 No = 0 Not Applicable = 96 HYGIENE	Initik	Plan	Effe	i
QSTESTCD	1.	Undertake to wash himself/herself or to take a bath or a shower				QSORRES
QSTESTCD	2.	Undertake to brush his/her teeth or care for his/her dentures				QSORRES
QSTESTCD	3.	Decide to care for his/her hair (wash and comb)				QSORRES
QSTESTCD	4.	Prepare the water, towels, and soap for washing, taking a bath, or a shower				QSORRES
QSTESTCD	5.	Wash and dry completely all parts of his/her body safely				QSORRES
QSTESTCD	6.	Brush his/her teeth or care for his/her dentures appropriately				QSORRES
QSTESTCD	7.	Care for his/her hair (wash and comb)				QSORRES
		DRESSING QSSCAT				
QSTESTCD	8.	Undertake to dress himself/herself				QSORRES
QSTESTCD	9.	Choose appropriate clothing (with regard to the occasion, neatness, the weather, and color combination)				QSORRES
QSTESTCD	10.	Dress himself/herself in the appropriate order (undergarments, pant/dress, shoes)				QSORRES
QSTESTCD	11.	Dress himself/herself completely				QSORRES
QSTESTCD	12.	Undress himself/herself completely				QSORRES
		CONTINENCE QSSCAT				
QSTESTCD		Decide to use the toilet at appropriate times				QSORRES
QSTESTCD	14.	Use the toilet without "accidents"				QSORRES
		EATING QSSCAT			<u> </u>	l
QSTESTCD	15.	Decide that he/she needs to eat	T			QSORRES
QSTESTCD		Choose appropriate utensils and seasonings when eating				QSORRES
QSTESTCD	17.	Eat his/her meals at a normal pace and with appropriate manners				QSORRES
		MEAL PREPARATION QSSCAT			1	I
QSTESTCD	18.	Undertake to prepare a light meal or snack for himself/herself				QSORRES
QSTESTCD	19.	Adequately plan a light meal or snack (ingredients, cookware)				QSORRES
QSTESTCD	20.	Prepare or cook a light meal or a snack safely				QSORRES

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Visit 8 Page 6 of 9

### DISABILITY ASSESSMENT FOR DEMENTIA (DAD)

		QSSCAT SCORING: Yes = 1 No = 0 Not Applicable = 96 TELEPHONING	Initiation	Planning & Organization	Effective Performance						
QSTESTCD	21.	Attempt to telephone someone at a suitable time				QSORRES					
QSTESTCD	22.	Find and dial a telephone number correctly									
QSTESTCD	23.	Carry out an appropriate telephone conversation									
QSTESTCD	24.	Write and convey a telephone message adequately									
0.075.07.05		GOING ON AN OUTING QSSCAT									
QSTESTCD	25.	Undertake to go out (walk, visit, shop) at an appropriate time				QSORRES					
QSTESTCD	26.	Adequately organize an outing with respect to transportation, keys, destination, weather, necessary money, shopping list				QSORRES					
QSTESTCD	27.	Go out and reach a familiar destination without getting lost									
QSTESTCD	28.	Safely take the adequate mode of transportation (car, bus, taxi)									
QSTESTCD	29.	Return from the store with the appropriate items									
		FINANCE AND CORRESPONDENCE QSSCAT				J					
		FINANCE AND CORRESPONDENCE SCOOM			_	_					
QSTESTCD	30.	Show an interest in his/her personal affairs such as his/her finances and written correspondence				QSORRES					
QSTESTCD	30.	Show an interest in his/her personal affairs such as his/her finances and written correspondence  Organize his/her finances to pay his/her bills (cheques, bankbook, bills)				QSORRES QSORRES					
QSTESTCD QSTESTCD	30. 31.	Show an interest in his/her personal affairs such as his/her finances and written correspondence  Organize his/her finances to pay his/her bills (cheques, bankbook, bills)									
QSTESTCD	30.	Show an interest in his/her personal affairs such as his/her finances and written correspondence  Organize his/her finances to pay his/her bills (cheques, bankbook, bills)				QSORRES					
QSTESTCD QSTESTCD	<ul><li>30.</li><li>31.</li><li>32.</li><li>33.</li></ul>	Show an interest in his/her personal affairs such as his/her finances and written correspondence  Organize his/her finances to pay his/her bills (cheques, bankbook, bills)  Adequately organize his/her correspondence with respect to stationery, address, stamps				QSORRES QSORRES					
QSTESTCD QSTESTCD	<ul><li>30.</li><li>31.</li><li>32.</li><li>33.</li></ul>	Show an interest in his/her personal affairs such as his/her finances and written correspondence  Organize his/her finances to pay his/her bills (cheques, bankbook, bills)  Adequately organize his/her correspondence with respect to stationery, address, stamps  Handle adequately his/her money (make change)				QSORRES QSORRES					
QSTESTCD QSTESTCD QSTESTCD	<ul><li>30.</li><li>31.</li><li>32.</li><li>33.</li></ul>	Show an interest in his/her personal affairs such as his/her finances and written correspondence  Organize his/her finances to pay his/her bills (cheques, bankbook, bills)  Adequately organize his/her correspondence with respect to stationery, address, stamps  Handle adequately his/her money (make change)  MEDICATIONS  QSSCAT				QSORRES QSORRES QSORRES					
QSTESTCD QSTESTCD QSTESTCD	<ul><li>30.</li><li>31.</li><li>32.</li><li>33.</li><li>34.</li><li>35.</li></ul>	Show an interest in his/her personal affairs such as his/her finances and written correspondence  Organize his/her finances to pay his/her bills (cheques, bankbook, bills)  Adequately organize his/her correspondence with respect to stationery, address, stamps  Handle adequately his/her money (make change)  MEDICATIONS  OSSCAT  Decide to take his/her medications at the correct time				QSORRES QSORRES QSORRES QSORRES					
QSTESTCD QSTESTCD QSTESTCD QSTESTCD QSTESTCD	<ul><li>30.</li><li>31.</li><li>32.</li><li>33.</li><li>34.</li><li>35.</li></ul>	Show an interest in his/her personal affairs such as his/her finances and written correspondence  Organize his/her finances to pay his/her bills (cheques, bankbook, bills)  Adequately organize his/her correspondence with respect to stationery, address, stamps  Handle adequately his/her money (make change)  MEDICATIONS QSSCAT  Decide to take his/her medications at the correct time  Take his/her medications as prescribed (according to the right dosage)				QSORRES QSORRES QSORRES QSORRES					
QSTESTCD QSTESTCD QSTESTCD QSTESTCD QSTESTCD QSTESTCD QSTESTCD	<ul><li>30.</li><li>31.</li><li>32.</li><li>33.</li><li>34.</li><li>35.</li></ul>	Show an interest in his/her personal affairs such as his/her finances and written correspondence  Organize his/her finances to pay his/her bills (cheques, bankbook, bills)  Adequately organize his/her correspondence with respect to stationery, address, stamps  Handle adequately his/her money (make change)  MEDICATIONS  QSSCAT  Decide to take his/her medications at the correct time  Take his/her medications as prescribed (according to the right dosage)  LEISURE AND HOUSEWORK  QSSCAT  Show an interest in leisure activity(ies)				QSORRES QSORRES QSORRES QSORRES					
QSTESTCD QSTESTCD QSTESTCD QSTESTCD QSTESTCD QSTESTCD QSTESTCD QSTESTCD	<ul><li>30.</li><li>31.</li><li>32.</li><li>33.</li><li>34.</li><li>35.</li><li>36.</li></ul>	Show an interest in his/her personal affairs such as his/her finances and written correspondence  Organize his/her finances to pay his/her bills (cheques, bankbook, bills)  Adequately organize his/her correspondence with respect to stationery, address, stamps  Handle adequately his/her money (make change)  MEDICATIONS  QSSCAT  Decide to take his/her medications at the correct time  Take his/her medications as prescribed (according to the right dosage)  LEISURE AND HOUSEWORK  QSSCAT  Show an interest in leisure activity(ies)				QSORRES QSORRES QSORRES QSORRES QSORRES					
QSTESTCD QSTESTCD QSTESTCD QSTESTCD QSTESTCD QSTESTCD QSTESTCD	<ul><li>30.</li><li>31.</li><li>32.</li><li>33.</li><li>34.</li><li>35.</li><li>36.</li><li>37.</li></ul>	Show an interest in his/her personal affairs such as his/her finances and written correspondence  Organize his/her finances to pay his/her bills (cheques, bankbook, bills)  Adequately organize his/her correspondence with respect to stationery, address, stamps  Handle adequately his/her money (make change)  MEDICATIONS QSSCAT  Decide to take his/her medications at the correct time  Take his/her medications as prescribed (according to the right dosage)  LEISURE AND HOUSEWORK QSSCAT  Show an interest in leisure activity(ies)  Take an interest in household chores that he/she used to perform in the past				QSORRES QSORRES QSORRES QSORRES QSORRES QSORRES					

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QS571



Visit 8 Page 7 of 9

									i age	, 0
\	WEIGHT	/STEST(	CD CD							
II.	NFORMATIO	NOT C	BTAINED	Not	Entered I	n Database				
M	leasure with s	shoes off.	Round u	ıp or dow	n to the n	earest <u>tenth</u>	kilogr	am or tenth	pound.	
V	Veight <mark>VSC</mark>	ORRES	— □,	<sub>kg</sub> Kilogra <mark>VS</mark> (	m □∥ ORRESU	Pound				
	<b>VITAL SIGI</b> NFORMATIOI			Not	Entered In	Database				7
••		PTNUM	Positio SU = Supi	n ne	pati (sup	ent has been	lying o	down for 5 m	aken after the inutes nute (standing)	
	VST	PT_	VSPOS	STESTC	<u> </u>					
	(DNDE) Reference Time	Timing Code	Position	Heart Rate (bpm)	Blood P (mm Systolic/	Hg)				
0.	5 minutes	815		SORRES SORRES		/ _VSTEST(	C.D			
1.	1 minute	816	ST			/ VSORRE	SU			
2.	3 minutes	817	ST	VS	STESTCD SORRESU					
_	<b>VITAL SIGI</b> NFORMATIOI			ATURE			•			
			ORRES		Littered ii	Database				
	emperature		·			VOODDEC				
U	nit of measur	e  F	Fahrenhei	it □c	Centigrade	VSORRES	U			
M	lethod <mark>VSLC</mark>	C PC	<sub>o</sub> Oral	□ <sub>R</sub> F	Rectal	A Axilla	ary	□ <sub>E</sub> Ear	☐ o Other	



Visit 8 Page 8 of 9

ELECTROCARDIOGRAM
NOT DONE Not Entered In Database
Electrocardiogram date    Not Entered In Database
NOTE: Any clinically relevant change from Visit 1 (baseline) ECG must be recorded on the Pre-existing Conditions and Adverse Events page. Note non-relevant abnormalities in the ECG Comments section below.
COMMENTS: NON-RELEVANT ECG ABNORMALITIES  NO COMMENTS Not Entered In Database
Print legibly and do not use abbreviations or symbols.  Not Entered In Database



Visit 8 Page 9 of 9

COMMENTS: VISIT
NO COMMENTS Not Entered In Database
Comments should address any clinical report form items that require further explanation. Repeating information from the clinical report form is discouraged.
Comment on all clinically significant lab values that are outside a clinically accepted reference range or clinically significant values that differ importantly from previous values.
If the patient is ending participation in the study at this visit, enter only comments that apply to this visit; then complete the Patient Summary and Study Summary Comments pages.
Print legibly and do not use abbreviations or symbols.  Not Entered In Database
The information reported for this visit is accurate and complete.
Not Entered In Database Not Entered In Database
Signature MM DD YY

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VISIT VISITNUM

Visit 9 Page 1 of 6

#### PATIENT AND VISIT IDENTIFICATION

Patient initials

First Middle Last

--STDTC --DTC

Visit date

MM DD YY

STUDY DRUG: COMPLIANCE

INFORMATION NOT OBTAINED Not Entered In Database

Since the previous visit, on how many days was the patient unable to complete the therapy?

Not Entered In Database

days

#### **REMINDER**

On the Pre-existing Conditions and Study Adverse Events page, record new events that occurred since the previous visit and re-evaluate any on-going conditions or events.

On the Concomitant Medication page, record new medications the patient has taken since the previous visit and record a stop date for any medication the patient is no longer taking.



Visit 9 Page 2 of 6

#### **STUDY DRUG**: PATCH ADHERENCE - PREVIOUS THREE DOSES

INFORMATION NOT OBTAINED Not Entered In Database

For the previous three doses of study drug (patch administration), give the date and the number of hours that a patch was NOT applied (if applicable).

Number of hours Number of hours 50-cm<sup>2</sup> patch 25-cm<sup>2</sup> patch **NOT** applied **NOT** applied <u>Date</u> Not Entered In Database Not Entered In Database 1. Today's (visit) date MM DD hours hours Not Entered In Database Not Entered In Database 2. Yesterday's date hours 3. Day before Not Entered In Database Not Entered In Database yesterday's date hours

Not Entered In Database

### STUDY DRUG : DAILY PRESCRIBED DOSAGE

For this visit interval, record the number of patches (25-cm<sup>2</sup> and 50-cm<sup>2</sup> patches) that the patient is to wear per day.

Number of 25-cm<sup>2</sup> patches prescribed/day

Not Entered In Database

25-cm<sup>2</sup> patches

Number of 50-cm<sup>2</sup> patches prescribed/day

Not Entered In Database

50-cm<sup>2</sup> patches

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H2Q-MC-LZZT Visit 9
Page 3 of 6

#### NEUROPSYCHIATRIC INVENTORY - REVISED (NPI-X) QSCAT

INFORMATION NOT OBTAINED Not Entered In Database

	Not Entered In Databa							
Clinician's initials	First	Middle	Last					

Not

The screening question (from worksheet) is asked of the caregiver to determine if the behavioral change is present or absent in the patient. If the answer to the screening question is negative (NO) or if the question is not applicable to the patient, circle the appropriate response (Not Applicable [96] or Absent [0]) and proceed to the next screening question without asking the subquestions to determine frequency, severity, and distress.

	lt a ma	Annliaahla	۸۵۰۰					0-	:	4			<b>\:</b> -4-			
QSSCAT QSTESTCD	<u>ltem</u>	Applicable QSOR	Abse		requ			<u>56</u>	veri	ty		Ī	<u>Distr</u>	<u>ess</u>		
Q31L31CD			KES	QSTES			RRES	QSTES			ES Q	STE	STC	QS	ORR	ES
A.	Delusions	96	0	1	2	3	4	1	2	3	0	1	2	3	4	5
QSSCAT QSTESTCD		<b>QSOR</b>	RES	QSTES	TCD	QSC	DRRES	QSTES	TCD	QSORR	ES O	STF	STC	205	ORR	ES
В.	Hallucinations	96	0	1	2	3	4	1	2	3	0	1	2	3	4	5
QSSCAT QSTESTCD		QSOR	RES	QSTES	TCD	QSC	DRRES	OSTES	TCD		ES O	СТЕ	стсг	200	000	\FO
C.	Agitation/Agression	า 96	0	1	2	3	4	1	2	3	0	1	2	3	4	5
QSSCAT QSTESTCD	, igitatio: ,, igi occio.	QSOR		OSTES	STCD	) OSC	DDDES	OSTE	TCD					-	-	
D.	Depression/	96	0	1	2	3	ORRES 4	1	2	QSORR 3	LES Q	STE	STCI	ogs	ORF	≀ES
Б.	Dysphoria	30	U	'	_	3	7	'	_	3	U	•	_	5	-	5
QSSCAT QSTESTCD	Буѕрпопа	QSORI	DEC	OSTES	TCD	000	DDEC	00750								
QUILUIUD				QSTES				QSTES				STES	STCD			
QSSCAT OSTESTOD	Anxiety	96	0	1	2	3	4	1	2	3	0	1	2	3	4	5
QSSCAT QSTESTCD		QSOR	RES	QSTES	TCD	QSO	RRES	<b>QSTES</b>	TCD	SORRI	ES QS	STES	STCD	OS	ORR	FS
F.	Euphoria/Elation	96	0	1	2	3	4	1	2	3	0	1	2	3	4	5
QSSCAT QSTESTCD	•	<b>QSOR</b>	RES	QSTES	TCD	QSC	RRES	QSTES	TCD	OSORR	ES O	STE	STCE	100		EC
G.	Apathy/	96	0	1	2	3	4	1	2	3	0	1	2	3	4	5
	Indifference	00	Ŭ		_	Ū	•	•	_	Ŭ	Ū	•	_	Ŭ	•	Ü
QSSCAT QSTESTCD	mamoronoc	QSORI	RES	QSTES	TCD	080	DDEC	OCTEC	TCD							
	Distribution			1								STES	STCE			
QSSCAT QSTESTCD	Disinhibition	96	0		2	3	4	1	2	3	0	1	2	3	4	5
QSTESTED		QSORI	KES	QSTES			RRES	QSTES			ES QS	STES	STCE	QS	ORR	ES
I.	Irritability/Lability	96	0	1	2	3	4	1	2	3	0	1	2	3	4	5
QSSCAT QSTESTCD		QSOR	RES	QSTES	TCD	QSC	RRES	QSTES	TCD	QSORR	ES O	STE!	STCE	os	ORR	FS
J.	Aberrant Motor	96	0	1	2	3	4	1	2	3	0	1	2	3	4	5
	Behavior															
QSSCAT QSTESTCD		QSOR	RES	QSTES	TCD	OSC	ORRES	OSTES	TCD	OSOBB	FC 0	OTE:	отог	200	000	
K.	Night-Time Behavi	or 96	0	1	2	3	4	1	2	3		51E	STCI 2	208 3	ORR 4	5
QSSCAT QSTESTCD	Tagne Time Deliavi	QSOR		OSTES			ORRES	OSTE				•	_	_	-	-
	A							QOTES			_	STE	STCI			
L.	Appetite/Eating	96	0	1	2	3	4	7	2	3	0	7	2	3	4	5
	Change															

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H2Q-MC-LZZT Visit 9
Page 4 of 6

WEIGHT VSTESTCD
INFORMATION NOT OBTAINED Not Entered In Database
Measure with shoes off. Round up or down to the nearest tenth kilogram or tenth pound.
Weight VSORRES Note: Weight Source So
VITAL SIGNS : HEART RATE AND BLOOD PRESSURE  INFORMATION NOT OBTAINED Not Entered In Database
Position  SU = Supine  NOTE: Blood pressure and pulse must be taken after the patient has been lying down for 5 minutes (supine) and after standing for 1 minute (standing) and 3 minutes.
VSTPTNUM ST = Standing VSPOS
VSTESTCD
Reference Timing Position Rate (mmHg) Time Code (bpm) Systolic/Diastolic
5 minutes 815 SU VSORRESU / VSORRES / VSTESTCD
1 minute 816 ST / VSORRESU
3 minutes 817 ST VSORRESU
VSORRES
VITAL SIGNS : TEMPERATURE VSTESTCD
INFORMATION NOT OBTAINED Not Entered In Database
Temperature VSORRES
Unit of measure
Method VSLOC Po Oral Rectal Axillary Ear Other



Visit 9 Page 5 of 6

<b>ELECTROCARDIOG</b>	RAM
NOT DONE Not Entere	ed In Database
Electrocardiogram date	Not Entered In Database //
Electrocardiogram result	☐ <sub>12</sub> Acceptable ☐ <sub>13</sub> Not Acceptable
Pre-existing	y relevant change from Visit 1 (baseline) ECG must be recorded on the Conditions and Adverse Events page. Note non-relevant es in the ECG Comments section below.
COMMENTS : NO	N-RELEVANT ECG ABNORMALITIES
NO COMMENTS No	t Entered In Database
Print legibly and do not use  Not Entered In Database	e abbreviations or symbols.
Not Entered in Database	



Visit 9 Page 6 of 6

COMMENTS: VISIT
NO COMMENTS Not Entered In Database
Comments should address any clinical report form items that require further explanation. Repeating information from the clinical report form is discouraged.
Comment on all clinically significant lab values that are outside a clinically accepted reference range or clinically significant values that differ importantly from previous values.
If the patient is ending participation in the study at this visit, enter only comments that apply to this visit; then complete the Patient Summary and Study Summary Comments pages.
Print legibly and do not use abbreviations or symbols.  Not Entered In Database
The information reported for this visit is accurate and complete.
Not Entered In Database  Not Entered In Database
Signature MM DD YY

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VISIT

VISITNUM

Visit 10 Page 1 of 9

## PATIENT AND VISIT IDENTIFICATION

Patient initials

--STDTC

Visit date

Not Entered In Database

--STDTC

--DTC

MM DD YY

STUDY DRUG: COMPLIANCE

INFORMATION NOT OBTAINED Not Entered In Database

Since the previous visit, on how many days was the patient unable to complete the therapy? Not Entered In Database

days

## **STUDY DRUG**: DAILY PRESCRIBED DOSAGE

For this visit interval, record the number of patches (25-cm<sup>2</sup> and 50-cm<sup>2</sup> patches) that the patient is to wear per day.

Number of 25-cm<sup>2</sup> patches prescribed/day

Not Entered In Database

25-cm<sup>2</sup> patches

Number of 50-cm<sup>2</sup> patches prescribed/day

Not Entered In Database

50-cm<sup>2</sup> patches

#### REMINDER

On the Pre-existing Conditions and Study Adverse Events page, record new events that occurred since the previous visit and re-evaluate any on-going conditions or events.

On the Concomitant Medication page, record new medications the patient has taken since the previous visit and record a stop date for any medication the patient is no longer taking.



Visit 10 Page 2 of 9

#### QSCAT

# ALZHEIMER'S DISEASE ASSESSMENT SCALE : COGNITIVE with ATTENTION/ CONCENTRATION TASKS

				. =		NCENTRATION
INFC	RMATION NOT OBTA	AINED L	No	t Entered	In Database	
	Clinician's initials	Not En	tered Ir	n Databas	e	
		First	Middle	Last		
QSTESTCD 1.	Word Recall Task				(max = 10)	QSORRES
QSTESTCD 2.	Naming Objects and (refer to 5 categories	-	al)		(max = 5)	QSORRES
QSTESTCD 3.	Delayed Word Recall				(max = 10)	QSORRES
QSTESTCD 4.	Commands				(max = 5)	QSORRES
QSTESTCD 5.	Constructional Praxis				(max = 5)	QSORRES
QSTESTCD 6.	Ideational Praxis				(max = 5)	QSORRES
QSTESTCD 7.	Orientation				(max = 8)	QSORRES
QSTESTCD 8.	Word Recognition				(max = 12)	QSORRES
QSTESTCD 9.	Attention/Visual Sear	ch Task			(max = 40)	QSORRES
QSTESTCD 10.	Maze Solution				(max = 240)	SORRES (seconds)
QSTESTCD 11.	Spoken Language Ab	oility			(max = 5)	QSORRES
QSTESTCD 12.	Comprehension of Sp	oken La	ınguage	e	(max = 5)	QSORRES
QSTESTCD 13.	Word Finding Difficult	y in Spo	ntaneo	us Speec	h (max = 5)	QSORRES
QSTESTCD 14.	Recall of Test Instruc	tions			(max = 5)	QSORRES

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<u>American Journal of Psychiatry</u> 1984;141:1356-64.

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							i age o oi s
CLINIC	CIAN'S INTERVI	EW-BAS	ED IMPR	RESSION C	F CHANG	E (CIBIC+)	QSCAT
INFORM	MATION NOT OBTA	INED 🗌	Not Enter	ed In Databa	se		
	Clinician's initials	Not Entere	ed In Datak — ———— le Last	pase			
OSTESTCD Check o	ne box to indicate th	ne extent of	change, if	any, observe	d since the ir	nitial baseline ir	nterview.
QSORRES 1	Marked improveme	nt					
$\square_2$	Moderate improvem	nent					
$\square_3$	Minimal improveme	nt					
	No change						
	Minimal worsening						
	Moderate worsening	g					
$\square_7$	Marked worsening						
Global Imp	al interview-based impres	loped and cur	ently underg	oing validity stud	lies by the Natio	nal Institute	

on Aging Alzheimer's Disease Study Units Program (1 U01 AG10483; Leon Thal, Principal Investigator), and is in the public domain.



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## NEUROPSYCHIATRIC INVENTORY - REVISED (NPI-X) QSCAT

INFORMATION NOT OBTAINED Not Entered In Database

	Not En	tered In	Databas	e
Clinician's initials	First	Middle	Last	

The screening question (from worksheet) is asked of the caregiver to determine if the behavioral change is present or absent in the patient. If the answer to the screening question is negative (NO) or if the question is not applicable to the patient, circle the appropriate response (Not Applicable [96] or Absent [0]) and proceed to the next screening question without asking the subquestions to determine frequency, severity, and distress.

		Not														
QSSCAT QSTESTCD	<u>Item</u> A	p <u>plicable</u> QSORI	Abse	nt F	requ	uenc QSC	<u>X</u> XRES	Se QSTES	veri	<u>ty</u> QSOR	RES n		Distr		ORR	ES
QSSCAT QSTESTCD	Delusions	96 <mark>QSOR</mark> I	0 RES	1 QSTES	2	3	4	1	2	3	0	1	2 STCI	3	4	5
QSSCAT QSTESTCD	Hallucinations	96 <b>QSOR</b> I	0 RES	1 QSTES	2	3	4	1	2	3	0	1	2 STCI	3	4	5
C. QSSCAT QSTESTCD	Agitation/Agression	96 QSOR	0 RES	1 QSTES	2	3	4	1	2	3	0	1	2	3	4	5
D.	Depression/ Dysphoria	96	0	1	2	3	4	1	2	3	0	1	STCI 2	3	4	5
QSSCAT QSTESTCD	Бубриона	QSORF	RES	QSTES	TCD	QSO	RRES	QSTES	TCD	QSORI	RES Q	STE	STCD	OSO	ORRI	FS
QSSCAT QSTESTCD	Anxiety	96 <mark>QSORF</mark>	0 RES	1 QSTES	2 TCD	3 <b>2SO</b>	4 RRES	1 QSTES	2 TCD	3 DSORI	0	1	2 STCE	3	4	5
F. QSSCAT QSTESTCD	Euphoria/Elation	96 QSORI	0 RES	1 QSTES	2	3	4	1	2	3	0	1	2	3	4	5
G.	Apathy/ Indifference	96	0	1	2	3	4	1	2	3	0	SIE 1	2	3	ORR 4	ES 5
QSSCAT QSTESTCD	mamerence	QSORF	RES	QSTES	TCD	QSO	RRES	QSTES	TCD	OSOR	RES O	STE	STCE	108	ODD	EQ
QSSCAT QSTESTCD	Disinhibition	96 QSORF	0 RES	1 QSTES	2	3	4	1	2	3	0	1	2 STCE	3	4	5
QSSCAT QSTESTCD	Irritability/Lability	96 QSORI	0 RES	1 QSTES	2	3	4	1	2	3	0	1	2	3	4	5
J.	Aberrant Motor Behavior	96	0	1	2	3	4	1	2	3	0	1	STCI 2	3	4	5
QSSCAT QSTESTCD	Deliavior	QSORI	RES	QSTES	TCD	QSC	RRES	QSTES	STCD	QSOR	RES C	STE	STCI	os	ORR	FS
QSSCAT QSTESTCD	Night-Time Behavior	r 96 <mark>QSOR</mark>	0 RES	1 QSTES	2	3	4	1	2	3	0	1	2 STCI	3	4	5
L.	Appetite/Eating Change	96	0	1	2	3	4	1	2	3	0	1	2	3	4	5

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Visit 10 Page 5 of 9

# DISABILITY ASSESSMENT FOR DEMENTIA (DAD) QSCAT

	IN	FORMATION NOT OBTAINED Not Entered In Database				
		Clinician's initials  Not Entered In Database First Middle Last				
	Dι	uring the past two weeks, did the patient without help or reminder:	tion	Planning & Organization	Effective Performance	
		QSSCAT HYGIENE  SCORING: Yes = 1 No = 0 Not Applicable = 96	Initiation	Planning Organiza	Effec	
QSTESTCD	1.	Undertake to wash himself/herself or to take a bath or a shower				QSORRES
QSTESTCD	2.	Undertake to brush his/her teeth or care for his/her dentures				QSORRES
QSTESTCD	3.	Decide to care for his/her hair (wash and comb)				QSORRES
QSTESTCD	4.	Prepare the water, towels, and soap for washing, taking a bath, or a shower				QSORRES
QSTESTCD	5.	Wash and dry completely all parts of his/her body safely				QSORRES
QSTESTCD	6.	Brush his/her teeth or care for his/her dentures appropriately				QSORRES
QSTESTCD	7.	Care for his/her hair (wash and comb)				QSORRES
		DRESSING QSSCAT	•			•
QSTESTCD	8.	Undertake to dress himself/herself				QSORRES
QSTESTCD	9.	Choose appropriate clothing (with regard to the occasion, neatness, the weather, and color combination)				QSORRES
QSTESTCD	10.	Dress himself/herself in the appropriate order (undergarments, pant/dress, shoes)				QSORRES
QSTESTCD	11.	Dress himself/herself completely				QSORRES
QSTESTCD	12.	Undress himself/herself completely				QSORRES
		CONTINENCE QSSCAT				
QSTESTCD	13.	Decide to use the toilet at appropriate times				QSORRES
QSTESTCD	14.	Use the toilet without "accidents"				QSORRES
		EATING QSSCAT				1
QSTESTCD		Decide that he/she needs to eat				QSORRES
QSTESTCD		Choose appropriate utensils and seasonings when eating				QSORRES
QSTESTCD	17.	Eat his/her meals at a normal pace and with appropriate manners				QSORRES
		MEAL PREPARATION QSSCAT				•
	18.	Undertake to prepare a light meal or snack for himself/herself				QSORRES
QSTESTCD		Adequately plan a light meal or snack (ingredients, cookware)				QSORRES
QSTESTCD	20.	Prepare or cook a light meal or a snack safely				QSORRES

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# DISABILITY ASSESSMENT FOR DEMENTIA (DAD)

		QSSCAT SCORING: Yes = 1 No = 0 Not Applicable TELEPHONING	le = 96	Initiation	Planning & Organization	Effective Performance	
QSTESTCD	21.	Attempt to telephone someone at a suitable time					QSORRES
QSTESTCD	22.	Find and dial a telephone number correctly				QSORRES	
QSTESTCD	23.	Carry out an appropriate telephone conversation					QSORRES
QSTESTCD	24.	Write and convey a telephone message adequately					QSORRES
		GOING ON AN OUTING QSSCAT					
QSTESTCD	25.	Undertake to go out (walk, visit, shop) at an appropriate time					QSORRES
QSTESTCD	26.	Adequately organize an outing with respect to transportation, keys, dest weather, necessary money, shopping list	tination,				QSORRES
QSTESTCD	27.	Go out and reach a familiar destination without getting lost					QSORRES
QSTESTCD	28.	Safely take the adequate mode of transportation (car, bus, taxi)					QSORRES
QSTESTCD	29.	Return from the store with the appropriate items					QSORRES
		FINANCE AND CORRESPONDENCE QSSCAT				<u> </u>	
		FINANCE AND CORRESPONDENCE					
QSTESTCD	30.	Show an interest in his/her personal affairs such as his/her finances and w correspondence	vritten				QSORRES
QSTESTCD	30.	Show an interest in his/her personal affairs such as his/her finances and w	vritten				QSORRES QSORRES
QSTESTCD QSTESTCD	30. 31.	Show an interest in his/her personal affairs such as his/her finances and w correspondence					
QSTESTCD	30.	Show an interest in his/her personal affairs such as his/her finances and w correspondence  Organize his/her finances to pay his/her bills (cheques, bankbook, bills)					QSORRES
QSTESTCD QSTESTCD	<ul><li>30.</li><li>31.</li><li>32.</li><li>33.</li></ul>	Show an interest in his/her personal affairs such as his/her finances and we correspondence  Organize his/her finances to pay his/her bills (cheques, bankbook, bills)  Adequately organize his/her correspondence with respect to stationery, address Handle adequately his/her money (make change)					QSORRES QSORRES
QSTESTCD QSTESTCD	<ul><li>30.</li><li>31.</li><li>32.</li><li>33.</li></ul>	Show an interest in his/her personal affairs such as his/her finances and we correspondence  Organize his/her finances to pay his/her bills (cheques, bankbook, bills)  Adequately organize his/her correspondence with respect to stationery, address  Handle adequately his/her money (make change)					QSORRES QSORRES
QSTESTCD QSTESTCD QSTESTCD	<ul><li>30.</li><li>31.</li><li>32.</li><li>33.</li></ul>	Show an interest in his/her personal affairs such as his/her finances and we correspondence  Organize his/her finances to pay his/her bills (cheques, bankbook, bills)  Adequately organize his/her correspondence with respect to stationery, address Handle adequately his/her money (make change)  MEDICATIONS QSSCAT	s, stamps				QSORRES QSORRES QSORRES
QSTESTCD QSTESTCD QSTESTCD	<ul><li>30.</li><li>31.</li><li>32.</li><li>33.</li><li>34.</li><li>35.</li></ul>	Show an interest in his/her personal affairs such as his/her finances and we correspondence  Organize his/her finances to pay his/her bills (cheques, bankbook, bills)  Adequately organize his/her correspondence with respect to stationery, address Handle adequately his/her money (make change)  MEDICATIONS QSSCAT  Decide to take his/her medications at the correct time	s, stamps				QSORRES QSORRES QSORRES QSORRES
QSTESTCD QSTESTCD QSTESTCD QSTESTCD QSTESTCD	<ul><li>30.</li><li>31.</li><li>32.</li><li>33.</li><li>34.</li><li>35.</li></ul>	Show an interest in his/her personal affairs such as his/her finances and we correspondence  Organize his/her finances to pay his/her bills (cheques, bankbook, bills)  Adequately organize his/her correspondence with respect to stationery, address Handle adequately his/her money (make change)  MEDICATIONS QSSCAT  Decide to take his/her medications at the correct time  Take his/her medications as prescribed (according to the right dosage)	s, stamps				QSORRES QSORRES QSORRES QSORRES
QSTESTCD QSTESTCD QSTESTCD QSTESTCD QSTESTCD QSTESTCD QSTESTCD	<ul><li>30.</li><li>31.</li><li>32.</li><li>33.</li><li>34.</li><li>35.</li></ul>	Show an interest in his/her personal affairs such as his/her finances and we correspondence  Organize his/her finances to pay his/her bills (cheques, bankbook, bills)  Adequately organize his/her correspondence with respect to stationery, address Handle adequately his/her money (make change)  MEDICATIONS QSSCAT  Decide to take his/her medications at the correct time  Take his/her medications as prescribed (according to the right dosage)  LEISURE AND HOUSEWORK QSSCAT	s, stamps ge)				QSORRES QSORRES QSORRES QSORRES QSORRES
QSTESTCD QSTESTCD QSTESTCD QSTESTCD QSTESTCD QSTESTCD QSTESTCD QSTESTCD	<ul><li>30.</li><li>31.</li><li>32.</li><li>33.</li><li>34.</li><li>35.</li><li>36.</li></ul>	Show an interest in his/her personal affairs such as his/her finances and we correspondence  Organize his/her finances to pay his/her bills (cheques, bankbook, bills)  Adequately organize his/her correspondence with respect to stationery, address Handle adequately his/her money (make change)  MEDICATIONS QSSCAT  Decide to take his/her medications at the correct time  Take his/her medications as prescribed (according to the right dosage)  LEISURE AND HOUSEWORK QSSCAT  Show an interest in leisure activity(ies)	s, stamps ge)				QSORRES QSORRES QSORRES QSORRES QSORRES
QSTESTCD QSTESTCD QSTESTCD QSTESTCD QSTESTCD QSTESTCD QSTESTCD	<ul><li>30.</li><li>31.</li><li>32.</li><li>33.</li><li>34.</li><li>35.</li><li>36.</li><li>37.</li></ul>	Show an interest in his/her personal affairs such as his/her finances and we correspondence  Organize his/her finances to pay his/her bills (cheques, bankbook, bills)  Adequately organize his/her correspondence with respect to stationery, address:  Handle adequately his/her money (make change)  MEDICATIONS QSSCAT  Decide to take his/her medications at the correct time  Take his/her medications as prescribed (according to the right dosage)  LEISURE AND HOUSEWORK QSSCAT  Show an interest in leisure activity(ies)  Take an interest in household chores that he/she used to perform in the page of the performance of the	ge) ast the past				QSORRES QSORRES QSORRES QSORRES QSORRES QSORRES

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Visit 10 Page 7 of 9

									i age	, , ,	
١	WEIGHT	/STEST(	D CD								
IN	NFORMATION	O TON P	BTAINED	Not	Entered Ir	Database					
M	leasure with s	shoes off.	Round u	ıp or dow	n to the ne	earest tenth	kilog	ram or tenth	pound.		
V	/eight <mark>VSC</mark>	ORRES _	— D <sub>k</sub>	<sub>kg</sub> Kilogra <mark>VS0</mark>	m □ lb DRRESU	Pound					
	VITAL SIGI			Not	Entered Ir OTE: Bloc patie	Database d pressure a ent has been	and pu	Ilse must be t down for 5 m			
			Position	<del></del>		ine) and afte 3 minutes.	er stan	ding for 1 mi	nute (standing)		
	VST	PTNUM ,	ST = Stan							_	
ı	VSTF	PT	VSPOS	STESTCE	) <mark></mark>						
	(DNDE) Reference Time	Timing Code	Position	Heart Rate (bpm)	Blood Pi (mm Systolic/[	Hg)					
0.	5 minutes	815		ORRESU SORRES		/ _VSTESTO	חי				
1.	1 minute	816	ST			VSORRES  VSORRE	SU				
2.	3 minutes	817	ST		TESTCD ORRESU	,	U				
\	VITAL SIGNS : TEMPERATURE VSTESTCD										
IN	NFORMATION	O TON P	BTAINED	No No	t Entered I	n Database					
Т	emperature	VS	ORRES								
U	nit of measur	e □ <sub>F</sub> I	Fahrenhei	it □ <sub>c</sub> C	Centigrade	VSORRES	SU				
M	lethod VSL0	OC PC	Oral	□ <sub>R</sub> F	Rectal	Axilla	ary	☐ <sub>E</sub> Ear	☐ o Other		



Visit 10 Page 8 of 9

NOT DONE Not Entered In Database
Electrocardiogram date  Not Entered In Database  MM DD YY  Not Entered In Database
Electrocardiogram result
NOTE: Any clinically relevant change from Visit 1 (baseline) ECG must be recorded on the Pre-existing Conditions and Adverse Events page. Note non-relevant abnormalities in the ECG Comments section below.
COMMENTS: NON-RELEVANT ECG ABNORMALITIES
NO COMMENTS Not Entered In Database
Print legibly and do not use abbreviations or symbols.
Print legibly and do not use abbreviations or symbols.
Print legibly and do not use abbreviations or symbols.
Print legibly and do not use abbreviations or symbols.
Print legibly and do not use abbreviations or symbols.
Print legibly and do not use abbreviations or symbols.
Print legibly and do not use abbreviations or symbols.



Visit 10 Page 9 of 9

COMMENTS: VISIT
NO COMMENTS Not Entered In Database
Comments should address any clinical report form items that require further explanation. Repeating information from the clinical report form is discouraged.
Comment on all clinically significant lab values that are outside a clinically accepted reference range or clinically significant values that differ importantly from previous values.
If the patient is ending participation in the study at this visit, enter only comments that apply to this visit; then complete the Patient Summary and Study Summary Comments pages.
Print legibly and do not use abbreviations or symbols.  Not Entered In Database
The information reported for this visit is accurate and complete.
Not Entered In Database  Not Entered In Database
Signature MM DD YY

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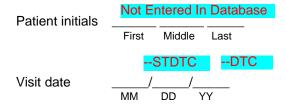
CM30501

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VISIT
VISITNUM
Visit 11
Page 1 of 6

## PATIENT AND VISIT IDENTIFICATION



## STUDY DRUG: COMPLIANCE

INFORMATION NOT OBTAINED Not Entered In Database

Since the previous visit, on how many days was the patient unable to complete the therapy? Not Entered In Database

days

#### **REMINDER**

On the Pre-existing Conditions and Study Adverse Events page, record new events that occurred since the previous visit and re-evaluate any on-going conditions or events.

On the Concomitant Medication page, record new medications the patient has taken since the previous visit and record a stop date for any medication the patient is no longer taking.

ID301, SD411

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Visit 11 Page 2 of 6

## **STUDY DRUG**: PATCH ADHERENCE - PREVIOUS THREE DOSES

INFORMATION NOT OBTAINED Not Entered In Database

For the previous three doses of study drug (patch administration), give the date and the number of hours that a patch was NOT applied (if applicable).

Number of hours Number of hours 50-cm<sup>2</sup> patch 25-cm<sup>2</sup> patch **Date NOT** applied **NOT** applied Not Entered In Database Not Entered In Database 1. Today's (visit) date MM DD ΥY hours hours Not Entered In Database Not Entered In Database 2. Yesterday's date hours 3. Day before Not Entered In Database Not Entered In Database yesterday's date hours

## **STUDY DRUG**: DAILY PRESCRIBED DOSAGE

For this visit interval, record the number of patches (25-cm<sup>2</sup> and 50-cm<sup>2</sup> patches) that the patient is to wear per day.

Number of 25-cm<sup>2</sup> patches prescribed/day

Not Entered In Database

25-cm<sup>2</sup> patches

Number of 50-cm<sup>2</sup> patches prescribed/day

Not Entered In Database

50-cm<sup>2</sup> patches

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SD412, SD413

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H2Q-MC-LZZT Visit 11
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## NEUROPSYCHIATRIC INVENTORY - REVISED (NPI-X) QSCAT

INFORMATION NOT OBTAINED Not Entered In Database

Not Entered In Detabase								
Not Entered in Database								
First	Middle	Last						
			Not Entered In Databa First Middle Last					

The screening question (from worksheet) is asked of the caregiver to determine if the behavioral change is present or absent in the patient. If the answer to the screening question is negative (NO) or if the question is not applicable to the patient, circle the appropriate response (Not Applicable [96] or Absent [0]) and proceed to the next screening question without asking the subquestions to determine frequency, severity, and distress.

		Not														
QSSCAT QSTESTCD	<u>Item</u> A	p <u>plicable</u> QSORI	Abse	nt F	requ	uenc QSC	<u>X</u> XRES	Se QSTES	veri	<u>ty</u> QSOR	RES n		Distr		ORR	ES
QSSCAT QSTESTCD	Delusions	96 <mark>QSOR</mark> I	0 RES	1 QSTES	2	3	4	1	2	3	0	1	2 STCI	3	4	5
QSSCAT QSTESTCD	Hallucinations	96 <b>QSOR</b> I	0 RES	1 QSTES	2	3	4	1	2	3	0	1	2 STCI	3	4	5
C. QSSCAT QSTESTCD	Agitation/Agression	96 QSOR	0 RES	1 QSTES	2	3	4	1	2	3	0	1	2	3	4	5
D.	Depression/ Dysphoria	96	0	1	2	3	4	1	2	3	0	1	STCI 2	3	4	5
QSSCAT QSTESTCD	Бубриона	QSORF	RES	QSTES	TCD	QSO	RRES	QSTES	TCD	QSORI	RES Q	STE	STCD	OSO	ORRI	FS
QSSCAT QSTESTCD	Anxiety	96 <mark>QSORF</mark>	0 RES	1 QSTES	2 TCD	3 <b>2SO</b>	4 RRES	1 QSTES	2 TCD	3 DSORI	0	1	2 STCE	3	4	5
F. QSSCAT QSTESTCD	Euphoria/Elation	96 QSORI	0 RES	1 QSTES	2	3	4	1	2	3	0	1	2	3	4	5
G.	Apathy/ Indifference	96	0	1	2	3	4	1	2	3	0	SIE 1	2	3	ORR 4	ES 5
QSSCAT QSTESTCD	mamerence	QSORF	RES	QSTES	TCD	QSO	RRES	QSTES	TCD	OSOR	RES O	STE	STCE	108	ODD	EQ
QSSCAT QSTESTCD	Disinhibition	96 QSORF	0 RES	1 QSTES	2	3	4	1	2	3	0	1	2 STCE	3	4	5
QSSCAT QSTESTCD	Irritability/Lability	96 QSORI	0 RES	1 QSTES	2	3	4	1	2	3	0	1	2	3	4	5
J.	Aberrant Motor Behavior	96	0	1	2	3	4	1	2	3	0	1	STCI 2	3	4	5
QSSCAT QSTESTCD	Deliavior	QSORI	RES	QSTES	TCD	QSC	RRES	QSTES	STCD	QSOR	RES C	STE	STCI	os	ORR	FS
QSSCAT QSTESTCD	Night-Time Behavior	r 96 <mark>QSOR</mark>	0 RES	1 QSTES	2	3	4	1	2	3	0	1	2 STCI	3	4	5
L.	Appetite/Eating Change	96	0	1	2	3	4	1	2	3	0	1	2	3	4	5

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Visit 11 Page 4 of 6

WEIGHT	STCD											
INFORMATION NO		t Entered In Database										
Measure with shoes	off. Round up or dov	vn to the nearest <u>tenth kil</u>	ogram or tenth pound.									
Weight VSORRES												
VITAL SIGNS: HEART RATE AND BLOOD PRESSURE  INFORMATION NOT OBTAINED Not Entered In Database  NOTE: Blood pressure and pulse must be taken after the												
	Position SU=Supine	patient has been lyi	ng down for 5 minutes tanding for 1 minute (standin									
VSTPTNU VSTPT	VSPOS	_										
(DNDE) Reference Time Coo	de (bpm)	Blood Pressure (mmHg) Systolic/Diastolic										
5 minutes 815	VOORRE	VSTESTCD / VSORRESU										
1 minute 816 2. 3 minutes 817	V	STESTCD VSORRES SORRESU/	I									
VITAL SIGNS :		/SORRES										
INFORMATION NO	T OBTAINED 🔲 🚾	t Entered In Database										
Temperature _	VSORRES											
Unit of measure	Fahrenheit □ c	Centigrade VSORRESU										
Method VSLOC	] <sub>PO</sub> Oral □ <sub>R</sub>	Rectal	□ <sub>E</sub> Ear □ <sub>O</sub> Othe	er								



Visit 11 Page 5 of 6

ELECTROCARDIOGRAM
NOT DONE Not Entered In Database
Electrocardiogram date  Not Entered In Database /  MM DD YY  Not Entered In Database
Electrocardiogram result
NOTE: Any clinically relevant change from Visit 1 (baseline) ECG must be recorded on the Pre-existing Conditions and Adverse Events page. Note non-relevant abnormalities in the ECG Comments section below.
<b>COMMENTS</b> : NON-RELEVANT ECG ABNORMALITIES
NO COMMENTS Not Entered In Database
Print legibly and do not use abbreviations or symbols.  Not Entered In Database
<del></del>



Visit 11 Page 6 of 6

	<del>-</del>
COMMENTS: VISIT	
NO COMMENTS Not Entered In Data	abase
Comments should address any clinical repinformation from the clinical report form is	oort form items that require further explanation. Repeating discouraged.
Comment on all clinically significant lab va or clinically significant values that differ im	lues that are outside a clinically accepted reference range portantly from previous values.
If the patient is ending participation in the visit; then complete the Patient Summary	study at this visit, enter only comments that apply to this and Study Summary Comments pages.
Print legibly and do not use abbreviations  Not Entered In Database	or symbols.
The information reported for this visit is ac	curate and complete.
Not Entered In Database N	ot Entered In Database
Signature	// MM DD YY

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CM30501

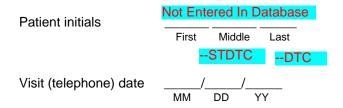
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Telephone Visit Visit 11t Page 1 of 2

# PATIENT AND VISIT IDENTIFICATION





Telephone Visit Visit 11t Page 2 of 2

## NEUROPSYCHIATRIC INVENTORY - REVISED (NPI-X) QSCAT

INFORMATION NOT OBTAINED Not Entered In Database

Oliniaia ala initiala	Not En	tered In	Databas	se
Clinician's initials	First	Middle	Last	

The screening question (from worksheet) is asked of the caregiver to determine if the behavioral change is present or absent in the patient. If the answer to the screening question is negative (NO) or if the question is not applicable to the patient, circle the appropriate response (Not Applicable [96] or Absent [0]) and proceed to the next screening question without asking the subquestions to determine frequency, severity, and distress.

		Not														
QSSCAT QSTESTCD	<u>Item</u> <u>A</u> p	oplicable QSORI	Abse	nt F	requ	ueno QSC	C <u>y</u> DRRES	Se QSTES	veri	<u>ty</u> OSORI	RES n		Distr			EC
A. QSSCAT QSTESTCD	Delusions	96 QSOR	0 RES	1	2	3	4 DRRES	1	2	3	0	1	2 STCI	3	4	5
QSSCAT QSTESTCD	Hallucinations	96 QSOR	0 RES	1	2	3	4 DRRES	1	2	3	0	1	2	3	4	5
C. QSSCAT QSTESTCD	Agitation/Agression	96 QSOR	0	1	2	3	4 DRRES	1	2	3	0	1	STCI 2	3	4	5
D.	Depression/ Dysphoria	96	0	1	2	3	4	1	2	3	RES 0	ISTE 1	STCI 2	<sup>2</sup> QS	ORR 4	<mark>≀ES</mark> 5
QSSCAT QSTESTCD	Буѕрпопа	QSORF	RES	QSTES	TCD	QSO	RRES	QSTES	TCD	SORF	RES O	STE	STCE	) OS	ORR'	FS
QSSCAT QSTESTCD	Anxiety	96 QSORF	0 RES	1 QSTES	2	3	4	1	2	3	0	1	2 STCE	3	4	5
F. QSSCAT QSTESTCD	Euphoria/Elation	96 QSORI	0 RES	1 QSTES	2	3	4	1	2	3	0	1	2	3	4	5
G.	Apathy/ Indifference	96	0	1	2	3	4	1	2	3	0	SIE 1	STCI 2	3	ORR 4	ES 5
QSSCAT QSTESTCD	mainerence	QSOR	RES	QSTES	TCD	QSC	RRES	QSTES	TCD	OSORI	RES n	STE	STCE	108	OPP	EQ
QSSCAT QSTESTCD	Disinhibition	96 <b>QSOR</b> F	0 RES	1 QSTES	2	3	4	1	2	3	0	1	2	3	4	5
QSSCAT QSTESTCD	Irritability/Lability	96 QSORI	0 RES	1 QSTES	2	3	4	1	2	3	0	1	STCE 2	3	4	5
J.	Aberrant Motor Behavior	96	0	1	2	3	4	1	2	3	0	1	STCI 2	3	4	5
QSSCAT QSTESTCD	Deliavioi	QSOR	RES	QSTES	STCD	QSC	ORRES	QSTES	TCD	QSOR	RES C	STE	STCI	DOS	ORR	PES .
QSSCAT QSTESTCD	Night-Time Behavior	96 QSOR	0 RES	1	2	3	4 DRRES	1	2	3	0	1	2 STC	3	4 ORR	5
L.	Appetite/Eating Change	96	0	1	2	3	4	1	2	3	0	1	2	3	4	5

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## PATIENT AND VISIT IDENTIFICATION

Patient initials

--STDTC
Visit date

Not Entered In Database

--STDTC
--DTC

--DTC

MM DD YY

STUDY DRUG: COMPLIANCE

INFORMATION NOT OBTAINED Not Entered In Database

Since the previous visit, on how many days was the patient unable to complete the therapy?

Not Entered In Database
days

## **STUDY DRUG**: DAILY PRESCRIBED DOSAGE

For this visit interval, record the number of patches (25-cm<sup>2</sup> and 50-cm<sup>2</sup> patches) that the patient is to wear per day.

Number of 25-cm<sup>2</sup> patches prescribed/day

Not Entered In Database

25-cm<sup>2</sup> patches

Number of 50-cm<sup>2</sup> patches prescribed/day

Not Entered In Database

50-cm<sup>2</sup> patches

#### REMINDER

On the Pre-existing Conditions and Study Adverse Events page, record new events that occurred since the previous visit and re-evaluate any on-going conditions or events.

On the Concomitant Medication page, record new medications the patient has taken since the previous visit and record a stop date for any medication the patient is no longer taking.



Visit 12 Page 2 of 9

#### QSCAT

# ALZHEIMER'S DISEASE ASSESSMENT SCALE: COGNITIVE with ATTENTION/CONCENTRATION TASKS

INFO	DRMATION NOT OBTAINED Not Entered In I	Database	to Eltrito trioit
	Clinician's initials  Not Entered In Database  First Middle Last		
QSTESTCD 1.	Word Recall Task	(max = 10)	QSORRES
QSTESTCD 2.	Naming Objects and Fingers (refer to 5 categories in manual)	(max = 5)	QSORRES
QSTESTCD 3.	Delayed Word Recall	(max = 10)	QSORRES
QSTESTCD 4.	Commands	(max = 5)	QSORRES
QSTESTCD 5.	Constructional Praxis	(max = 5)	QSORRES
QSTESTCD 6.	Ideational Praxis	(max = 5)	QSORRES
QSTESTCD 7.	Orientation	(max = 8)	QSORRES
QSTESTCD 8.	Word Recognition	(max = 12)	QSORRES
QSTESTCD 9.	Attention/Visual Search Task	(max = 40)	QSORRES
QSTESTCD 10.	Maze Solution	(max = 240)	SORRES (seconds)
QSTESTCD 11.	Spoken Language Ability	(max = 5)	QSORRES
QSTESTCD 12.	Comprehension of Spoken Language	(max = 5)	QSORRES
QSTESTCD 13.	Word Finding Difficulty in Spontaneous Speech	(max = 5)	QSORRES
QSTESTCD 14.	Recall of Test Instructions	(max = 5)	QSORRES

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<u>American Journal of Psychiatry</u> 1984;141:1356-64.

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QS572

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	ıα	ge 5 oi
C	CLINICIAN'S INTERVIEW-BASED IMPRESSION OF CHANGE (CIBIC+)	SCAT
IN	NFORMATION NOT OBTAINED Not Entered In Database	
	Clinician's initials  Not Entered In Database  First Middle Last	
OSTESTED C	Check one box to indicate the extent of change, if any, observed since the initial baseline inter	view.
QSORRES		
	Moderate improvement	
	☐ 3 Minimal improvement	
	☐ <sub>4</sub> No change	
	☐ <sub>5</sub> Minimal worsening	
	☐ 6 Moderate worsening	
	☐ <sub>7</sub> Marked worsening	
GI	he clinical interview-based impression of change scale in this study is from a pilot instrument, the Clinical slobal Impression of Change, developed and currently undergoing validity studies by the National Institute and Alzheimer's Disease Study Units Program (1 U01 AG10483: Leon Thal, Principal Investigator)	

and is in the public domain.



H2Q-MC-LZZT

Visit 12 Page 4 of 9

# NEUROPSYCHIATRIC INVENTORY - REVISED (NPI-X) QSCAT

INFORMATION NOT OBTAINED Not Entered In Database

Clinician's initials	Not E	Not Entered In Databa							
Omnoidir 5 miliais	First	Middle	Last						

The screening question (from worksheet) is asked of the caregiver to determine if the behavioral change is present or absent in the patient. If the answer to the screening question is negative (NO) or if the question is not applicable to the patient, circle the appropriate response (Not Applicable [96] or Absent [0]) and proceed to the next screening question without asking the subquestions to determine frequency, severity, and distress.

		Not														
QSSCAT QSTESTCD	<u>Item</u> A	p <u>plicable</u> QSORI	Abse	nt F	requ	uenc QSC	<u>X</u> XRES	Se QSTES	veri	<u>ty</u> QSOR	RES n		Distr		ORR	ES
QSSCAT QSTESTCD	Delusions	96 <mark>QSOR</mark> I	0 RES	1 QSTES	2	3	4	1	2	3	0	1	2 STCI	3	4	5
QSSCAT QSTESTCD	Hallucinations	96 <b>QSOR</b> I	0 RES	1 QSTES	2	3	4	1	2	3	0	1	2 STCI	3	4	5
C. QSSCAT QSTESTCD	Agitation/Agression	96 QSOR	0 RES	1 QSTES	2	3	4	1	2	3	0	1	2	3	4	5
D.	Depression/ Dysphoria	96	0	1	2	3	4	1	2	3	0	1	STCI 2	3	4	5
QSSCAT QSTESTCD	Бубриона	QSORF	RES	QSTES	TCD	QSO	RRES	QSTES	TCD	QSORI	RES Q	STE	STCD	OSO	ORRI	FS
QSSCAT QSTESTCD	Anxiety	96 <mark>QSORF</mark>	0 RES	1 QSTES	2 TCD	3 <b>2SO</b>	4 RRES	1 QSTES	2 TCD	3 DSORI	0	1	2 STCE	3	4	5
F. QSSCAT QSTESTCD	Euphoria/Elation	96 QSORI	0 RES	1 QSTES	2	3	4	1	2	3	0	1	2	3	4	5
G.	Apathy/ Indifference	96	0	1	2	3	4	1	2	3	0	SIE 1	2	3	ORR 4	ES 5
QSSCAT QSTESTCD	mamerence	QSORF	RES	QSTES	TCD	QSO	RRES	QSTES	TCD	OSOR	RES O	STE	STCE	108	ODD	EQ
QSSCAT QSTESTCD	Disinhibition	96 QSORF	0 RES	1 QSTES	2	3	4	1	2	3	0	1	2 STCE	3	4	5
QSSCAT QSTESTCD	Irritability/Lability	96 QSORI	0 RES	1 QSTES	2	3	4	1	2	3	0	1	2	3	4	5
J.	Aberrant Motor Behavior	96	0	1	2	3	4	1	2	3	0	1	STCI 2	3	4	5
QSSCAT QSTESTCD	Deliavior	QSORI	RES	QSTES	TCD	QSC	RRES	QSTES	STCD	QSOR	RES C	STE	STCI	os	ORR	FS
QSSCAT QSTESTCD	Night-Time Behavior	r 96 <mark>QSOR</mark>	0 RES	1 QSTES	2	3	4	1	2	3	0	1	2 STCI	3	4	5
L.	Appetite/Eating Change	96	0	1	2	3	4	1	2	3	0	1	2	3	4	5

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## DISABILITY ASSESSMENT FOR DEMENTIA (DAD) QSCAT

	IN	FORMATION NOT OBTAINED Not Entered In Database				
		Clinician's initials Not Entered In Database				
		Clinician's initials  First Middle Last				_
	_			٥ يد	JC e	
	Dι	iring the past two weeks, did the patient without help or reminder:	ا ا	ng 8 izati	ive	
		QSSCAT HYGIENE  SCORING: Yes = 1 No = 0 Not Applicable = 96	Initiation	Planning & Organization	Effective Performance	
QSTESTCD	1.	Undertake to wash himself/herself or to take a bath or a shower				QSORRES
QSTESTCD	2.	Undertake to brush his/her teeth or care for his/her dentures	+			QSORRES
QSTESTCD	3.	Decide to care for his/her hair (wash and comb)	1			QSORRES
QSTESTCD	4.	Prepare the water, towels, and soap for washing, taking a bath, or a shower				QSORRES
QSTESTCD	5.	Wash and dry completely all parts of his/her body safely				QSORRES
QSTESTCD		Brush his/her teeth or care for his/her dentures appropriately				QSORRES
	7.	Care for his/her hair (wash and comb)				QSORRES
						QOUNTE
QSTESTCD		DRESSING QSSCAT	Г			
QSTESTCD	8.	Undertake to dress himself/herself				QSORRES
QSTESTOD	9.	Choose appropriate clothing (with regard to the occasion, neatness, the weather, and color combination)				QSORRES
QSTESTCD	10.	Dress himself/herself in the appropriate order (undergarments, pant/dress, shoes)				QSORRES
QSTESTCD	11.	Dress himself/herself completely				QSORRES
QSTESTCD	12.	Undress himself/herself completely				QSORRES
		CONTINENCE QSSCAT				_
QSTESTCD	13.	Decide to use the toilet at appropriate times				QSORRES
QSTESTCD	14.	Use the toilet without "accidents"				QSORRES
		EATING QSSCAT				_
QSTESTCD	-	Decide that he/she needs to eat				QSORRES
QSTESTCD	16.	Choose appropriate utensils and seasonings when eating				QSORRES
QSTESTCD	17.	Eat his/her meals at a normal pace and with appropriate manners				QSORRES
		MEAL PREPARATION QSSCAT		_		
	18.	Undertake to prepare a light meal or snack for himself/herself				QSORRES
QSTESTCD		Adequately plan a light meal or snack (ingredients, cookware)				QSORRES
QSTESTCD	20.	Prepare or cook a light meal or a snack safely				QSORRES

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Visit 12 Page 6 of 9

# DISABILITY ASSESSMENT FOR DEMENTIA (DAD)

		QSSCAT SCORING: Yes = 1 No = 0 Not Applicable TELEPHONING	le = 96	Initiation	Planning & Organization	Effective Performance	
QSTESTCD	21.	Attempt to telephone someone at a suitable time					QSORRES
QSTESTCD	22.	Find and dial a telephone number correctly					QSORRES
QSTESTCD	23.	Carry out an appropriate telephone conversation					QSORRES
QSTESTCD	24.	Write and convey a telephone message adequately					QSORRES
		GOING ON AN OUTING QSSCAT					
QSTESTCD	25.	Undertake to go out (walk, visit, shop) at an appropriate time					QSORRES
QSTESTCD	26.	Adequately organize an outing with respect to transportation, keys, dest weather, necessary money, shopping list	tination,				QSORRES
QSTESTCD	27.	Go out and reach a familiar destination without getting lost					QSORRES
QSTESTCD	28.	Safely take the adequate mode of transportation (car, bus, taxi)					QSORRES
QSTESTCD	29.	Return from the store with the appropriate items					QSORRES
		FINANCE AND CORRESPONDENCE QSSCAT				<u> </u>	
		FINANCE AND CORRESPONDENCE					
QSTESTCD	30.	Show an interest in his/her personal affairs such as his/her finances and w correspondence	vritten				QSORRES
QSTESTCD	30.	Show an interest in his/her personal affairs such as his/her finances and w	vritten				QSORRES QSORRES
QSTESTCD QSTESTCD	30. 31.	Show an interest in his/her personal affairs such as his/her finances and w correspondence					
QSTESTCD	30.	Show an interest in his/her personal affairs such as his/her finances and w correspondence  Organize his/her finances to pay his/her bills (cheques, bankbook, bills)					QSORRES
QSTESTCD QSTESTCD	<ul><li>30.</li><li>31.</li><li>32.</li><li>33.</li></ul>	Show an interest in his/her personal affairs such as his/her finances and we correspondence  Organize his/her finances to pay his/her bills (cheques, bankbook, bills)  Adequately organize his/her correspondence with respect to stationery, address Handle adequately his/her money (make change)					QSORRES QSORRES
QSTESTCD QSTESTCD	<ul><li>30.</li><li>31.</li><li>32.</li><li>33.</li></ul>	Show an interest in his/her personal affairs such as his/her finances and we correspondence  Organize his/her finances to pay his/her bills (cheques, bankbook, bills)  Adequately organize his/her correspondence with respect to stationery, address  Handle adequately his/her money (make change)					QSORRES QSORRES
QSTESTCD QSTESTCD QSTESTCD	<ul><li>30.</li><li>31.</li><li>32.</li><li>33.</li></ul>	Show an interest in his/her personal affairs such as his/her finances and we correspondence  Organize his/her finances to pay his/her bills (cheques, bankbook, bills)  Adequately organize his/her correspondence with respect to stationery, address Handle adequately his/her money (make change)  MEDICATIONS QSSCAT	s, stamps				QSORRES QSORRES QSORRES
QSTESTCD QSTESTCD QSTESTCD	<ul><li>30.</li><li>31.</li><li>32.</li><li>33.</li><li>34.</li><li>35.</li></ul>	Show an interest in his/her personal affairs such as his/her finances and we correspondence  Organize his/her finances to pay his/her bills (cheques, bankbook, bills)  Adequately organize his/her correspondence with respect to stationery, address Handle adequately his/her money (make change)  MEDICATIONS QSSCAT  Decide to take his/her medications at the correct time	s, stamps				QSORRES QSORRES QSORRES QSORRES
QSTESTCD QSTESTCD QSTESTCD QSTESTCD QSTESTCD	<ul><li>30.</li><li>31.</li><li>32.</li><li>33.</li><li>34.</li><li>35.</li></ul>	Show an interest in his/her personal affairs such as his/her finances and we correspondence  Organize his/her finances to pay his/her bills (cheques, bankbook, bills)  Adequately organize his/her correspondence with respect to stationery, address Handle adequately his/her money (make change)  MEDICATIONS QSSCAT  Decide to take his/her medications at the correct time  Take his/her medications as prescribed (according to the right dosage)	s, stamps				QSORRES QSORRES QSORRES QSORRES
QSTESTCD QSTESTCD QSTESTCD QSTESTCD QSTESTCD QSTESTCD QSTESTCD	<ul><li>30.</li><li>31.</li><li>32.</li><li>33.</li><li>34.</li><li>35.</li></ul>	Show an interest in his/her personal affairs such as his/her finances and we correspondence  Organize his/her finances to pay his/her bills (cheques, bankbook, bills)  Adequately organize his/her correspondence with respect to stationery, address Handle adequately his/her money (make change)  MEDICATIONS QSSCAT  Decide to take his/her medications at the correct time  Take his/her medications as prescribed (according to the right dosage)  LEISURE AND HOUSEWORK QSSCAT	s, stamps ge)				QSORRES QSORRES QSORRES QSORRES QSORRES
QSTESTCD QSTESTCD QSTESTCD QSTESTCD QSTESTCD QSTESTCD QSTESTCD QSTESTCD	<ul><li>30.</li><li>31.</li><li>32.</li><li>33.</li><li>34.</li><li>35.</li><li>36.</li></ul>	Show an interest in his/her personal affairs such as his/her finances and we correspondence  Organize his/her finances to pay his/her bills (cheques, bankbook, bills)  Adequately organize his/her correspondence with respect to stationery, address Handle adequately his/her money (make change)  MEDICATIONS QSSCAT  Decide to take his/her medications at the correct time  Take his/her medications as prescribed (according to the right dosage)  LEISURE AND HOUSEWORK QSSCAT  Show an interest in leisure activity(ies)	s, stamps ge)				QSORRES QSORRES QSORRES QSORRES QSORRES
QSTESTCD QSTESTCD QSTESTCD QSTESTCD QSTESTCD QSTESTCD QSTESTCD	<ul><li>30.</li><li>31.</li><li>32.</li><li>33.</li><li>34.</li><li>35.</li><li>36.</li><li>37.</li></ul>	Show an interest in his/her personal affairs such as his/her finances and we correspondence  Organize his/her finances to pay his/her bills (cheques, bankbook, bills)  Adequately organize his/her correspondence with respect to stationery, address:  Handle adequately his/her money (make change)  MEDICATIONS QSSCAT  Decide to take his/her medications at the correct time  Take his/her medications as prescribed (according to the right dosage)  LEISURE AND HOUSEWORK QSSCAT  Show an interest in leisure activity(ies)  Take an interest in household chores that he/she used to perform in the page of the performance of the	ge) ast the past				QSORRES QSORRES QSORRES QSORRES QSORRES QSORRES

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١	WEIGHT	/STEST(	CD							
١N	NFORMATION	O TON N	BTAINED	Not	t Entered I	n Database	<del>)</del>			
M	leasure with s	shoes off.	Round u	ıp or dow	n to the ne	arest tenth	kilog	ram or tenth	<u>pound</u> .	
V	/eight <mark>VSC</mark>	DRRES	— □,	<sub>kg</sub> Kilograi <mark>VSC</mark>	m □ <sub>lb</sub> DRRESU	Pound				
	VITAL SIGN			— Not		OD PRES	SSUI	RE		
Iľ	NFORMATION		Positio SU = Supi ST = Stan	n ne	patie (sup	ent has been	lying	down for 5 m	taken after the ninutes nute (standing)	
_	VST VST	PTNUM   PT	VSPOS	STESTCE	)					
	(DNDE) Reference Time	Timing Code	Position	Heart Rate (bpm)	Blood Pr (mm Systolic/[	Hg)				
0.	5 minutes	815		SORRESU SORRES		/ _VSTESTO	חב			
1.	1 minute	816	ST			VSORRES VSORRE	SU			
2.	3 minutes	817	ST	VS	STESTCD ORRESU		.0			
\	/ITAL SIGN	NS : T	EMPER		SORRES	CD				
IN	NFORMATION			Not	t Entered I	n Database	<del>)</del>			
T	emperature	VS	ORRES							
U	nit of measur	e 🔲 <sub>F</sub>	Fahrenhe	it □ <sub>c</sub> C	Centigrade	VSORRES	SU			
M	lethod <mark>VSL0</mark>	OC PC	Oral	□ <sub>R</sub> R	Rectal	A Axilla	ary	□ <sub>E</sub> Ear	☐ <sub>O</sub> Other	



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ELECTROCARDIOGRAM
NOT DONE Not Entered In Database
Electrocardiogram date  Not Entered In Database  MND YY  Not Entered In Database
Electrocardiogram result
NOTE: Any clinically relevant change from Visit 1 (baseline) ECG must be recorded on the Pre-existing Conditions and Adverse Events page. Note non-relevant abnormalities in the ECG Comments section below.
COMMENTS: NON-RELEVANT ECG ABNORMALITIES
NO COMMENTS Not Entered In Database
Print legibly and do not use abbreviations or symbols.  Not Entered In Database



Visit 12 Page 9 of 9

COMMENTS: VISIT
NO COMMENTS Not Entered In Database
Comments should address any clinical report form items that require further explanation. Repeating information from the clinical report form is discouraged.
Comment on all clinically significant lab values that are outside a clinically accepted reference range or clinically significant values that differ importantly from previous values.
If the patient is ending participation in the study at this visit, enter only comments that apply to this visit; then complete the Patient Summary and Study Summary Comments pages.
Print legibly and do not use abbreviations or symbols.  Not Entered In Database
The information reported for this visit is accurate and complete.
Not Entered In Database  Not Entered In Database
Signature MM DD YY



VISIT
VISITNUM
Visit 13
Page 1 of 9

## PATIENT AND VISIT IDENTIFICATION

Patient initials

--STDTC

Visit date

Not Entered In Database

First Middle Last

--STDTC

--DTC

MM DD YY

## **STUDY DRUG**: COMPLIANCE

INFORMATION NOT OBTAINED Not Entered In Database

Since the previous visit, on how many days was the patient unable to complete the therapy?

Not Entered In Database

days

#### REMINDER

On the Pre-existing Conditions and Study Adverse Events page, record new events that occurred since the previous visit and re-evaluate any on-going conditions or events.

On the Concomitant Medication page, record new medications the patient has taken since the previous visit and record a stop date for any medication the patient is no longer taking.

A physical examination must be performed at this visit. Any clinically significant abnormalities must be listed on the Pre-existing Conditions and Study Adverse Events page.

ID301, SD411

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## **EXTRAPYRAMIDAL FINDINGS**

INF	ORMATION NOT OBTAINED Not Entered In Database
1.	Masked facies Not Entered In Database
	□ <sub>0</sub> None
	□ <sub>1</sub> Mild
	□ <sub>3</sub> Severe
2.	Rigidity of upper extremity Not Entered In Database
	□ <sub>0</sub> None
	□ <sub>1</sub> Mild
	□ <sub>3</sub> Severe
3.	Essential tremor Not Entered In Database
	□ <sub>0</sub> None
	□ <sub>1</sub> Mild
	□ <sub>3</sub> Severe
4.	Ambulation Not Entered In Database
	How long did it take the patient to walk 25 yards?  seconds
	Seconds



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## NEUROPSYCHIATRIC INVENTORY - REVISED (NPI-X) QSCAT

INFORMATION NOT OBTAINED Not Entered In Database

Clinician's initials

Not Entered In Database
First Middle Last

Not

The screening question (from worksheet) is asked of the caregiver to determine if the behavioral change is present or absent in the patient. If the answer to the screening question is negative (NO) or if the question is not applicable to the patient, circle the appropriate response (Not Applicable [96] or Absent [0]) and proceed to the next screening question without asking the subquestions to determine frequency, severity, and distress.

	la on	Annliaghla	۸۵۰۰					0.	:	4			<b>\:</b> -4-			
QSSCAT QSTESTCD	<u>ltem</u>	Applicable QSOR	Abse		requ			<u>56</u>	veri	ty		Ī	<u>Distr</u>	ess		
Q31L31CD			KES	QSTES			RRES	QSTES			ES Q	STE	STC	QS	ORR	RES
A.	Delusions	96	0	1	2	3	4	1	2	3	0	1	2	3	4	5
QSSCAT QSTESTCD		<b>QSOR</b>	RES	QSTES	TCD	QSC	DRRES	QSTES	TCD	QSORR	ES O	STF	STC	005	ORR	?ES
В.	Hallucinations	96	0	1	2	3	4	1	2	3	0	1	2	3	4	5
QSSCAT QSTESTCD		QSOR	RES	QSTES	TCD	QSC	DRRES	OSTES	TCD		ES O	СТЕ	стсг		000	) F O
C.	Agitation/Agression	n 96	0	1	2	3	4	1	2	3	0	1	2	3 3	4	5
QSSCAT QSTESTCD	7 .gggg.	QSOR		OSTES	STCD	) OSC	DDDES	OSTE	TCD					-	•	
D.	Depression/	96	0	1	2	3	ORRES 4	1	2	QSORR 3	LES Q	STE	STCI	Dgs		₹ĘŞ
Б.	Dysphoria	30	U	'	_	3	7	'	_	3	U		_	5	7	3
QSSCAT QSTESTCD	Буѕрпопа	QSORI	DEC	OSTES	TCD	000	DDEC	00750								
QUILUIUD				QSTES				QSTES				STES	STCD			
QSSCAT OSTESTOD	Anxiety	96	0	1	2	3	4	1	2	3	0	1	2	3	4	5
QSSCAT QSTESTCD		QSOR	RES	QSTESTCD QSORRES QSTESTCD QSORRES QSTESTCD QSO								ORR	FS			
F.	Euphoria/Elation	96	0	1	2	3	4	1	2	3	0	1	2	3	4	5
QSSCAT QSTESTCD	•	QSOR	RES	QSTES	TCD	QSC	RRES	QSTES	TCD	OSORR	ES O	STE	STCE	200		) E C
G.	Apathy/	96	0	1	2	3	4	1	2	3	0	1	2	3	4	5
	Indifference	00	Ŭ		_	Ū	•	•	_	Ŭ	Ū	•	_	Ŭ	•	Ū
QSSCAT QSTESTCD	mamerenee	QSORI	RES	QSTES	TCD	080	DDEC	OCTEC	TCD							
	Distribution			1								STES	STCE			
QSSCAT QSTESTCD	Disinhibition	96	0		2	3	4	1	2	3	0	1	2	3	4	5
QSTESTED		QSORI	KES	QSTES			RRES	QSTES			ES QS	STES	STCE	QS	ORR	ES
I.	Irritability/Lability	96	0	1	2	3	4	1	2	3	0	1	2	3	4	5
QSSCAT QSTESTCD		QSOR	RES	QSTES	TCD	QSC	RRES	QSTES	TCD	QSORR	ES O	STE!	STCE	os	ORR	PES
J.	Aberrant Motor	96	0	1	2	3	4	1	2	3	0	1	2	3	4	5
	Behavior															
QSSCAT QSTESTCD		QSOR	RES	QSTES	TCD	OSC	ORRES	OSTES	TCD	OSOBB	FC 0	OTE:	отог	200	000	
K.	Night-Time Behavi	or 96	0	1	2	3	4	1	2	3		51E	STCI 2	<del>اون</del> 3	ORK 4	(ES)
QSSCAT QSTESTCD	Tagin Time Deliavi	QSOR		OSTES			ORRES	OSTE				•	_	-	-	-
						QOTES			_	STE				RES		
L.	Appetite/Eating	96	0	1	2	3	4	1	2	3	0	7	2	3	4	5
	Change															

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									Page	4 of 9
WEIGHT  VSTESTCD  INFORMATION NOT OBTAINED Not Entered In Database										
M	leasure with s	shoes off.	Round u	ıp or dow	n to the n	earest <u>tenth</u>	kilog	g <u>ram</u> or <u>tenth</u>	pound.	
V	Measure with shoes off. Round up or down to the nearest tenth kilogram or tenth pound.  Weight									
	VITAL SIGNS: HEART RATE AND BLOOD PRESSURE  INFORMATION NOT OBTAINED Not Entered In Database  NOTE: Blood pressure and pulse must be taken after the									
			Positio	<del>'</del>	(su			down for 5 m nding for 1 min	nute (standing)	
	VST VSTI	PTNUM PT	SU = Supir ST = Stand		7					
	(DNDE) Reference Time	Timing Code	Position	Heart Rate (bpm)	Blood F (mn Systolic/	ressure hHg) Diastolic				
0.	5 minutes	815		ORRESI SORRES		/ VSTEST	ח			
1.	1 minute	816	ST			/ VSORRE 	SU			
2.	3 minutes	817	ST		STESTCD SORRESU		5			
VSORRES  VITAL SIGNS: TEMPERATURE VSTESTED										
	VITAL SIGNS : IEWIPERATURE VSIESIOD									
II.	INFORMATION NOT OBTAINED Not Entered In Database									
Т	TemperatureVSORRES									
U	Unit of measure									
M	lethod VSL0	OC PC	Oral	□ <sub>R</sub> F	Rectal	☐ <sub>A</sub> Axilla	ary	□ <sub>E</sub> Ear	☐ o Other	



Visit 13 Page 5 of 9

ELECTROCARDIOGRAM
NOT DONE Not Entered In Database
Not Entered In Database  Electrocardiogram date  MM DD YY
Not Entered In Database  Electrocardiogram result    Not Entered In Database   Not Acceptable   Not Acceptab
NOTE: Any clinically relevant change from Visit 1 (baseline) ECG must be recorded on the Pre-existing Conditions and Adverse Events page. Note non-relevant abnormalities in the ECG Comments section below.
COMMENTS: NON-RELEVANT ECG ABNORMALITIES
NO COMMENTS Not Entered In Database
Print legibly and do not use abbreviations or symbols.  Not Entered In Database



Visit 13 Page 6 of 9

ACCEPTABILITY : CAREGIVER'S RESPONSE ABOUT THE PATCH
INFORMATION NOT OBTAINED Not Entered In Database
The following question is to be answered by the caregiver.
Based on the experience of applying and wearing this patch, if the patient were prescribed a drug for Alzheimer's disease and was given the choice of this patch or an oral pill given twice daily (assume that both formulations are equally effective), would you (the caregiver):  Not Entered In Database
$\square_1$ Insist that the patient receive an <u>oral pill</u>
$\square_{2}$ Prefer that the patient receive an oral pill
$\square_{3}$ Have no preference (neutral) for an oral or patch formulation
$\square_{4}$ Prefer that the patient receive a patch
$\square_{5}$ Insist that the patient receive a <u>patch</u>



Visit 13 Page 7 of 9

#### H2Q-MC-LZZT ACCEPTABILITY: CAREGIVER'S RESPONSE ABOUT THE PATCH Not Entered In Database INFORMATION NOT OBTAINED The following questions are intended to be answered by the caregiver and address the patch's design and wearability. Focus only on the act of wearing and removing the transdermal patch. On each scale below, circle one number (do not circle on the scale between numbers) that best describes your feelings about the patch: 1. The <u>appearance</u> of the patch while being worn is acceptable: Not Entered In Database 1 2 3 5 6 7 Strongly Neutral Strongly Disagree Agree 2. The size of the patch is acceptable: Not Entered In Database 1 2 3 5 6 7 Strongly Neutral Strongly Disagree Agree

3. The patches were durable (eg, did not discolor, tear) while being worn:

Not Entered In Database 2 5 7 3 6 Strongly Neutral Strongly Disagree Agree

STUDY DRUG THERAPY: DATE OF FINAL DOSE

EXENDTC Date of final dose of study drug MM YY DD

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SD410, SD30701

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## PATIENT SUMMARY

	Patient Initials  Not Entered In Database  First Middle Last								
	CHECK ONE PRIMARY REASON FOR ENDING PART	ICIPATION IN THE STUDY							
DSTERM	☐₁ Protocol completed								
DSTERM	AESPID  Adverse event E	If # 4 is checked, enter date of death.							
DSTERM	Death* E AESPID  E_Code	DSSTDTC  Date of Death //  MM DD YY							
DSTERM DSTERM	<ul><li>□<sub>8</sub> Lack of efficacy, patient/caregiver perception</li><li>□<sub>9</sub> Lack of efficacy, physician perception</li></ul>								
DSTERM	☐ <sub>11</sub> Unable to contact patient (lost to follow-up)								
SDECOD	$\square_{_{13}}$ Personal conflict or other patient/caregiver decision								
OSDECOD	☐ 22 Physician decisionDSTERM	Specify							
DSTERM DSTERM	Specify  SUPPDS.QVAL  14 Protocol entry criteria not met Specify nu Specify  Specify	mber from entry criteria checklist)							
DSTERM	☐ <sub>18</sub> Sponsor decision (study or patient discontinued by	the Sponsor)							
	* Contact the Quintiles Drug Safety Unit immediately in event of death. Obtain a copy of the autopsy report (if autopsy performed) or hospital discharge summary. Forward to Quintiles Drug Safety Unit as soon as possible. Explain circumstances of the death on the Study Summary Comments page.								



Visit 13 Page 9 of 9

		9000.0
COMMENTS: STUDY SUMMAR	ARY	
NO COMMENTS Not Entered In Data	atabase	
	eport form is discouraged. If the patient is ending pa an protocol complete (Reason 1 on Patient Summary nces.	
Enter comments below. Print legibly and	d do not use abbreviations or symbols.	
Not Entered In Database		
All information reported for this patient is a  Not Entered In Database	s accurate and complete.  Not Entered In Database	
	MM DD YY	

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CM30502

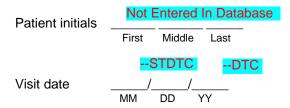
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Visit 201 Page 1 of 8

# PATIENT AND VISIT IDENTIFICATION



#### **REMINDER**

On the Pre-existing Conditions and Study Adverse Events page, record new events that occurred since the previous visit and re-evaluate any on-going conditions or events.

On the Concomitant Medication page, record new medications the patient has taken since the previous visit and record a stop date for any medication the patient is no longer taking.



INFORMATION NOT OBTAINED

Visit 201 Page 2 of 8

#### **QSCAT**

### ALZHEIMER'S DISEASE ASSESSMENT SCALE : COGNITIVE with ATTENTION/ CONCENTRATION TASKS

Not Entered In Database

Not Entered In Database Clinician's initials First Middle Last **QSTESTCD** QSORRES Word Recall Task (max = 10)QSTESTCD 2. Naming Objects and Fingers QSORRES (refer to 5 categories in manual) (max = 5)QSTESTCD 3. QSORRES **Delayed Word Recall** (max = 10)**QSTESTCD** QSORRES Commands (max = 5)**QSTESTCD** QSORRES **Constructional Praxis** (max = 5)QSTESTCD QSORRES **Ideational Praxis** (max = 5)**QSTESTCD** QSORRES Orientation (max = 8)QSTESTCD QSORRES Word Recognition (max = 12)**QSTESTCD** 

QSTESTCD

11. Spoken Language Ability (max = 5)

QSORRES

QSTESTCD 12. Comprehension of Spoken Language (max = 5)

QSTESTCD 13. Word Finding Difficulty in Spontaneous Speech (max = 5)

QSTESTCD 14. Recall of Test Instructions (max = 5)

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<u>American Journal of Psychiatry</u> 1984;141:1356-64.

**QSTESTCD** 

10.

QSORRES

(max = 240) QSORRES (seconds)

(max = 40)

Attention/Visual Search Task

Maze Solution



Visit 201 Page 3 of 8

_	- age 5 of C
	CLINICIAN'S INTERVIEW-BASED IMPRESSION OF CHANGE (CIBIC+)
I	NFORMATION NOT OBTAINED Not Entered In Database
	Clinician's initials  Not Entered In Database
	First Middle Last
QSTESTCD (	Check one box to indicate the extent of change, if any, observed since the initial baseline interview.
QSORRES	Marked improvement
	☐ 2 Moderate improvement
	☐ 3 Minimal improvement
	☐ 4 No change
	☐ 5 Minimal worsening
	☐ 6 Moderate worsening
	☐ <sub>7</sub> Marked worsening
	The clinical interview-based impression of change scale in this study is from a pilot instrument, the Clinical Global Impression of Change, developed and currently undergoing validity studies by the National Institute

The clinical interview-based impression of change scale in this study is from a pilot instrument, the Clinical Global Impression of Change, developed and currently undergoing validity studies by the National Institute on Aging Alzheimer's Disease Study Units Program (1 U01 AG10483; Leon Thal, Principal Investigator), and is in the public domain.



-MC-LZZT Visit 201
Page 4 of 8

### NEUROPSYCHIATRIC INVENTORY - REVISED (NPI-X) QSCAT

INFORMATION NOT OBTAINED Not Entered In Database

Clinician's initials	Not Entered In Database						
	First	Middle	Last				

Not

The screening question (from worksheet) is asked of the caregiver to determine if the behavioral change is present or absent in the patient. If the answer to the screening question is negative (NO) or if the question is not applicable to the patient, circle the appropriate response (Not Applicable [96] or Absent [0]) and proceed to the next screening question without asking the subquestions to determine frequency, severity, and distress.

	11	INOL	A I	–				0.					D:- (			
QSSCAT QSTESTCD	<u>Item</u> <u>A</u> p	plicable	Abse	ent E	requ	ueno	су	<u>Se</u>	veri	ty			Dist	ess		
QSIESICD		QSOR	KE5	QSTES	ICD	QSC	DRRES	QSTES	TCD	QSOR	RES	STE	STC	QS	ORR	ES
Α.	Delusions	96	0	1	2	3	4	1	2	3	0	1	2	3	4	5
QSSCAT QSTESTCD		<b>QSOR</b>	RES	QSTES	TCD	QSC	DRRES	QSTES	TCD	QSORI	RES (	OSTE	STC	000	OPP	PES
В.	Hallucinations	96	0	1	2	3	4	1	2	3	0	1	2	3	4	5
QSSCAT QSTESTCD		QSOR	RES	QSTES	TCD	QSC	ORRES	OSTES	TCD		DEC 7	OCTE	CTC		000	VEO.
C.	Agitation/Agression	96	0	1	2	3	4	1	2	3	0	1 1	2	3	4	5
QSSCAT QSTESTCD	· ·g·······	QSOR	RES	QSTES	TCD	OSC	ORRES	OSTES	TCD	OCOD	DEC 2	·	-			
D.	Depression/	96	0	QSTES 1	2	3	4	1	2	3	0	18L 1	2	3	4	SES 5
	Dysphoria		_	-	_	_	-	-		-	•	-		_	-	•
QSSCAT QSTESTCD	Буорнона	QSORI	RES	QSTES	TCD	OSC	RRES	OSTES	TCD	) CODE	DEC C	OTE	0.		000	=0
E.	Anxiety	96	0	1	2	3	4	1	2	3	(ES (	101E	STCI 2	3 3	ORR 4	5 5
QSSCAT QSTESTCD	Allalety	QSORI		QSTES	_	_		OCTEC	_	_	·	'	_	_	•	•
	Europania /Elatian			QUILU 4				QSTES				STE	STCE		ORR	
QSSCAT QSTESTCD	Euphoria/Elation	96	0	7	2	3	4	1	2	3	0	1	2	3	4	5
		QSOR		QSTES				QSTES			RES (	STE	STC		ORR	ES
G.	Apathy/	96	0	1	2	3	4	1	2	3	0	1	2	3	4	5
000047	Indifference															
QSSCAT QSTESTCD		QSOR	RES	<b>QSTES</b>	TCD	QSC	RRES	QSTES	TCD	QSORF	RES C	STE	STC	005	ORR	FS
H.	Disinhibition	96	0	1	2	3	4	1	2	3	0	1	2	3	4	5
QSSCAT QSTESTCD		<b>QSOR</b>	RES	<b>QSTES</b>	TCD	QSC	RRES	OSTES	TCD	asapr	DEG C	OTE	STC	100	0 D D	F0
	Irritability/Lability	96	0	1	2	3	4	1	2	3	0	1	2	3	<u>4</u>	5
QSSCAT QSTESTCD		QSOR	RES	QSTES	TCD	OSC	RRFS	OSTES	TCD	OCODI	250		_ 	200		
	Aberrant Motor	96	0	1	2	3	4	1	2	3	0	JSTE 1	STCI 2	3 3	ORR 4	
0.	Behavior	50	U	'	_	U	7	•	_	O	U	•	_	U	7	U
QSSCAT QSTESTCD	Denavioi	QSOR	RFS	OSTES	TCD	000	DDEC	COTEC	TOD							
	Mind Time Date in			QSTES				QSIES					STC			
QSSCAT QSTESTCD	Night-Time Behavior		0	1 00TE	2	3	4	1	2	3	0	1	2	3	4	5
QSTESTED		QSOR					ORRES	QSTES				QSTE	STC		ORF	
L.	Appetite/Eating	96	0	1	2	3	4	1	2	3	0	1	2	3	4	5
	Change															



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## DISABILITY ASSESSMENT FOR DEMENTIA (DAD) QSCAT

		ICABIETT ACCESSMENT FOR DEMERTIA (DAD)				
	IN	FORMATION NOT OBTAINED Not Entered In Database				
		Clinician's initials  Not Entered In Database  First Middle Last				
	Dι	ring the past two weeks, did the patient without help or reminder:	Initiation	Planning & Organization	Effective Performance	
OCTECTOR		QSSCAT SCORING: Yes = 1 No = 0 Not Applicable = 96 HYGIENE	Initis	Plan	Perf	i
QSTESTCD	1.	Undertake to wash himself/herself or to take a bath or a shower				QSORRES
QSTESTCD	2.	Undertake to brush his/her teeth or care for his/her dentures				QSORRES
QSTESTCD	3.	Decide to care for his/her hair (wash and comb)				QSORRES
QSTESTCD	4.	Prepare the water, towels, and soap for washing, taking a bath, or a shower				QSORRES
QSTESTCD	5.	Wash and dry completely all parts of his/her body safely				QSORRES
QSTESTCD	6.	Brush his/her teeth or care for his/her dentures appropriately				QSORRES
QSTESTCD	7.	Care for his/her hair (wash and comb)				QSORRES
		DRESSING QSSCAT				
QSTESTCD	8.	Undertake to dress himself/herself				QSORRES
QSTESTCD	9.	Choose appropriate clothing (with regard to the occasion, neatness, the weather, and color combination)				QSORRES
QSTESTCD	10.	Dress himself/herself in the appropriate order (undergarments, pant/dress, shoes)				QSORRES
QSTESTCD	11.	Dress himself/herself completely				QSORRES
QSTESTCD	12.	Undress himself/herself completely				QSORRES
		CONTINENCE QSSCAT			1	_
QSTESTCD	13.	Decide to use the toilet at appropriate times				QSORRES
QSTESTCD	14.	Use the toilet without "accidents"				QSORRES
		EATING QSSCAT				
QSTESTCD	15.	Decide that he/she needs to eat				QSORRES
QSTESTCD		Choose appropriate utensils and seasonings when eating				QSORRES
QSTESTCD	17.	Eat his/her meals at a normal pace and with appropriate manners				QSORRES
		MEAL PREPARATION QSSCAT				
QSTESTCD	18.	Undertake to prepare a light meal or snack for himself/herself				QSORRES
QSTESTCD	19.	Adequately plan a light meal or snack (ingredients, cookware)				QSORRES
QSTESTCD	20.	Prepare or cook a light meal or a snack safely				QSORRES

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Visit 201 Page 6 of 8

# DISABILITY ASSESSMENT FOR DEMENTIA (DAD)

		QSSCAT SCORING: Yes = 1 No = 0 Not Applicable TELEPHONING	le = 96	Initiation	Planning & Organization	Effective Performance	
QSTESTCD	21.	Attempt to telephone someone at a suitable time					QSORRES
QSTESTCD	22.	Find and dial a telephone number correctly					QSORRES
QSTESTCD	23.	Carry out an appropriate telephone conversation					QSORRES
QSTESTCD	24.	Write and convey a telephone message adequately					QSORRES
		GOING ON AN OUTING QSSCAT					
QSTESTCD	25.	Undertake to go out (walk, visit, shop) at an appropriate time					QSORRES
QSTESTCD	26.	Adequately organize an outing with respect to transportation, keys, dest weather, necessary money, shopping list	tination,				QSORRES
QSTESTCD	27.	Go out and reach a familiar destination without getting lost					QSORRES
QSTESTCD	28.	Safely take the adequate mode of transportation (car, bus, taxi)					QSORRES
QSTESTCD	29.						
		FINANCE AND CORRESPONDENCE QSSCAT				<u> </u>	
		FINANCE AND CORRESPONDENCE					
QSTESTCD	30.	Show an interest in his/her personal affairs such as his/her finances and w correspondence	vritten				QSORRES
QSTESTCD	30.	Show an interest in his/her personal affairs such as his/her finances and w	vritten				QSORRES QSORRES
QSTESTCD QSTESTCD	30. 31.	Show an interest in his/her personal affairs such as his/her finances and w correspondence					
QSTESTCD	30.	Show an interest in his/her personal affairs such as his/her finances and w correspondence  Organize his/her finances to pay his/her bills (cheques, bankbook, bills)					QSORRES
QSTESTCD QSTESTCD	<ul><li>30.</li><li>31.</li><li>32.</li><li>33.</li></ul>	Show an interest in his/her personal affairs such as his/her finances and we correspondence  Organize his/her finances to pay his/her bills (cheques, bankbook, bills)  Adequately organize his/her correspondence with respect to stationery, address Handle adequately his/her money (make change)					QSORRES QSORRES
QSTESTCD QSTESTCD	<ul><li>30.</li><li>31.</li><li>32.</li><li>33.</li></ul>	Show an interest in his/her personal affairs such as his/her finances and we correspondence  Organize his/her finances to pay his/her bills (cheques, bankbook, bills)  Adequately organize his/her correspondence with respect to stationery, address Handle adequately his/her money (make change)					QSORRES QSORRES
QSTESTCD QSTESTCD QSTESTCD	<ul><li>30.</li><li>31.</li><li>32.</li><li>33.</li></ul>	Show an interest in his/her personal affairs such as his/her finances and we correspondence  Organize his/her finances to pay his/her bills (cheques, bankbook, bills)  Adequately organize his/her correspondence with respect to stationery, address Handle adequately his/her money (make change)  MEDICATIONS QSSCAT	s, stamps				QSORRES QSORRES QSORRES
QSTESTCD QSTESTCD QSTESTCD	<ul><li>30.</li><li>31.</li><li>32.</li><li>33.</li><li>34.</li><li>35.</li></ul>	Show an interest in his/her personal affairs such as his/her finances and we correspondence  Organize his/her finances to pay his/her bills (cheques, bankbook, bills)  Adequately organize his/her correspondence with respect to stationery, address Handle adequately his/her money (make change)  MEDICATIONS QSSCAT  Decide to take his/her medications at the correct time	s, stamps				QSORRES QSORRES QSORRES QSORRES
QSTESTCD QSTESTCD QSTESTCD QSTESTCD QSTESTCD	<ul><li>30.</li><li>31.</li><li>32.</li><li>33.</li><li>34.</li><li>35.</li></ul>	Show an interest in his/her personal affairs such as his/her finances and we correspondence  Organize his/her finances to pay his/her bills (cheques, bankbook, bills)  Adequately organize his/her correspondence with respect to stationery, address Handle adequately his/her money (make change)  MEDICATIONS QSSCAT  Decide to take his/her medications at the correct time  Take his/her medications as prescribed (according to the right dosage)	s, stamps				QSORRES QSORRES QSORRES QSORRES
QSTESTCD QSTESTCD QSTESTCD QSTESTCD QSTESTCD QSTESTCD QSTESTCD	<ul><li>30.</li><li>31.</li><li>32.</li><li>33.</li><li>34.</li><li>35.</li></ul>	Show an interest in his/her personal affairs such as his/her finances and we correspondence  Organize his/her finances to pay his/her bills (cheques, bankbook, bills)  Adequately organize his/her correspondence with respect to stationery, address Handle adequately his/her money (make change)  MEDICATIONS QSSCAT  Decide to take his/her medications at the correct time  Take his/her medications as prescribed (according to the right dosage)  LEISURE AND HOUSEWORK QSSCAT	s, stamps ge)				QSORRES QSORRES QSORRES QSORRES QSORRES
QSTESTCD QSTESTCD QSTESTCD QSTESTCD QSTESTCD QSTESTCD QSTESTCD QSTESTCD	<ul><li>30.</li><li>31.</li><li>32.</li><li>33.</li><li>34.</li><li>35.</li><li>36.</li></ul>	Show an interest in his/her personal affairs such as his/her finances and we correspondence  Organize his/her finances to pay his/her bills (cheques, bankbook, bills)  Adequately organize his/her correspondence with respect to stationery, address Handle adequately his/her money (make change)  MEDICATIONS QSSCAT  Decide to take his/her medications at the correct time  Take his/her medications as prescribed (according to the right dosage)  LEISURE AND HOUSEWORK QSSCAT  Show an interest in leisure activity(ies)	s, stamps ge)				QSORRES QSORRES QSORRES QSORRES QSORRES
QSTESTCD QSTESTCD QSTESTCD QSTESTCD QSTESTCD QSTESTCD QSTESTCD	<ul><li>30.</li><li>31.</li><li>32.</li><li>33.</li><li>34.</li><li>35.</li><li>36.</li><li>37.</li></ul>	Show an interest in his/her personal affairs such as his/her finances and we correspondence  Organize his/her finances to pay his/her bills (cheques, bankbook, bills)  Adequately organize his/her correspondence with respect to stationery, address:  Handle adequately his/her money (make change)  MEDICATIONS QSSCAT  Decide to take his/her medications at the correct time  Take his/her medications as prescribed (according to the right dosage)  LEISURE AND HOUSEWORK QSSCAT  Show an interest in leisure activity(ies)  Take an interest in household chores that he/she used to perform in the page of the performance of the	ge) ast the past				QSORRES QSORRES QSORRES QSORRES QSORRES QSORRES

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QS571



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#### VITAL SIGNS: **HEART RATE AND BLOOD PRESSURE** Not Entered In Database INFORMATION NOT OBTAINED NOTE: Blood pressure and pulse must be taken after the patient has been lying down for 5 minutes (supine) and after standing for 1 minute (standing) Position and 3 minutes. SU = Supine ST = Standing **VSTPTNUM VSPOS** VSTPT STESTCD (DNDE) Heart **Blood Pressure** Timing Rate (mmHg) Reference Position Systolic/Diastolic Code (bpm) Time **VSORRESU** 0 5 minutes 815 **VSORRES VSTESTCD** 1 minute ST / VSORRESU 816 **VSORRES** 2 **VSTESTCD** 3 minutes ST 817 **VSORRESU VSORRES**

VITAL SIGNS	: TEMPERA	TURE VSTES	TCD				
INFORMATION NOT OBTAINED Not Entered In Database							
Temperature	VSORRES	_					
Unit of measure	☐ <sub>F</sub> Fahrenheit	☐ <sub>C</sub> Centigrade	VSORRESU				
Method VSLOC	□ <sub>PO</sub> Oral	☐ <sub>R</sub> Rectal	Axillary	□ <sub>E</sub> Ear	□ o Other		



Visit 201 Page 8 of 8

COMMENTS: STUDY SUMMARY
NO COMMENTS Not Entered In Database
Repeating information from the clinical report form is discouraged. If the patient is ending participation in the study for any reason other than protocol complete (Reason 1 on Patient Summary page) give a brief description of the circumstances.
Enter comments below. Print legibly and do not use abbreviations or symbols.
Not Entered In Database
All information reported for this patient is accurate and complete.
Not Entered In Database  Not Entered In Database
Investigator Signature MM DD YY

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Adverse Event Follow-up

Visit 501 Page 1 of 3

### PATIENT AND VISIT IDENTIFICATION

Patient initials

First Middle Last

Visit date

Not Entered In Database

First Middle Last

--STDTC --DTC

MM DD YY

### **REMINDER**

On the Pre-existing Conditions and Study Adverse Events page, record new events that occurred since the previous visit and re-evaluate any on-going conditions or events.

On the Concomitant Medication page, record new medications the patient has taken since the previous visit and record a stop date for any medication the patient is no longer taking.

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Adverse Event Follow-up

Visit 501 Page 2 of 3

### **ADVERSE EVENT FOLLOW-UP**

	1.	Patient initials	Not E	ntered In	Database					
	•	_	First	Middle	Last					
	2.	Primary event caus	sing dis	continua	tion (E Cod Patient Summ					
Not Er		Check one PRIMA red In Database		son for e	nding the AD		ntered		eriod tabase YY	
		☐ <sub>102</sub> Laboratory t	est res	ult return	ed to accepta	able range				
		☐ <sub>11</sub> Patient is los	st to fol	low-up						
		$\square_{103}$ Event or cor	dition	is stable	and not expe	ected to change				
		$\square_{99}$ Other		Specif						
	4.	Check one patient	outcon	ne						
Not Ente		d In Database								
		$\square_{_{104}}$ No residual	effect							
		□ <sub>105</sub> Impairment	or disa	bility						
		$\square_{_4}$ Death*								
		$\square_{99}$ Other								
				Specif	у					
	*	Contact the Quir of the autopsy rep as soon as possib Comments page.	ort (if a	autopsy p	erformed) or	hospital dischar	rge sur	nmary	. Forwar	d to Lilly



Adverse Event Follow-up

Visit 501 Page 3 of 3

COMMENTS: STUDY SUMMARY
NO COMMENTS Not Entered In Database
Repeating information from the clinical report form is discouraged. If the patient is ending participation in the study for any reason other than protocol complete (Reason 1 on Patient Summary page) give a brief description of the circumstances.
Enter comments below. Print legibly and do not use abbreviations or symbols.
Not Entered In Database
All information reported for this patient is accurate and complete.  Not Entered In Database  Not Entered In Database
Investigator Signature MM DD YY

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Addendum Study - Early Termination Visit \_\_\_\_\_ Page 1 of 1

PROCEDURE : MRSI

NOT DONE Not Entered In Database

Not Entered In Database

Date of MRSI

\_\_\_/\_\_/ MM DD YY



Addendum Study Visit 3
Page 1 of 1

PROCEDURE : MRSI				
NOT DONE	Not Entered In Database			
Date of MRSI	Not Entered In Database  /// MM DD YY			





### PRE-EXISTING CONDITIONS AND STUDY ADVERSE EVENTS

NO CONDITIONS OR EVENTS  Not Entered In Database	*Serious Codes	* If Event is se	•
' ' AECDICAD	2 = Life-threatening AESLI	notify the Qu FESafety Unit ir	nmediately.
List all clinically relevant abnormalities found on the physical exam, ECG, chest x-ray, or Holter monitor.  AESOD  AESMIE	44 = Hospitalization 55 = Congenital anomaly 6 = Cancer AESCAN	Severity Codes  1 = Mild 2 = Moderate 3 = Severe	Evaluate when event stops or at end of patient's participation in study
<ul> <li>List all events that occur during study.</li> </ul>			

Severity of Condition/Event Onset Date Description of Condition/Event Record the onset visit number MM DD Serious\* Relationship ΥY and maximum severity at that visit during to Code Then record the maximum severity in Stop Date Study Drug trial? **COSTART Class Term** each subsequent visit ONLY if there MM DD YY AEREL is a change in severity 1 = None □ <sub>N</sub> No SPID Number 2 = Remote If Yes, --TERM (Unlikely) E01 enter Serious 3 = Possible Code(s) AESER Severity Not Entered In Database 4 = Probable Visit □ No --STDTC Number 2 = Remote If Yes, E02 (Unlikely) enter Serious 3 = Possible --ENDTC Code(s) Severity 4 = Probable 1 = None ☐<sub>N</sub> No Visit 2 = Remote If Yes, Number (Unlikely) enter Serious E03 3 = Possible Code(s) Severity 4 = Probable 1 = None Visit ∐ <sub>N</sub> No Number 2 = Remote If Yes, E04 enter Serious Code(s) (Unlikely) 3 = Possible Severity = Probable Visit 1 = None□ <sub>N</sub> No If Yes, Number 2 = Remote enter Serious E05 (Unlikely) 3 = Possible Code(s) Severity = Probable 1 = None Visit □ <sub>N</sub> No Number If Yes, 2 = Remote E06 enter (Unlikely) Serious 3 = Possible Code(s) Severity 4 = Probable 1 = None Visit No No Number 2 = Remote If Yes, (Unlikely) enter E07 Serious 3 = Possible Code(s) Severity

4 = Probable



VISITNUM						
Visit						
Page 1 a of	1					

### PRE-EXISTING CONDITIONS AND STUDY ADVERSE EVENTS

Continue listing all pre-existing \* If Event is serious, \*Serious Codes conditions and events that occur notify the Quintiles Drug during the study. AESDTH 1 = Fatal 2 = Life-threatening AESLIFE Safety Unit immediately. AESDISAB 3 = Permanently disabling AESHOSP 4 = Hospitalization Evaluate when Severity Codes event stops or at AESCONG5 = Congenital anomaly 6 = Cancer AESCAN 1 = Mildend of patient's 7 = Overdose participation in 2 = Moderate **AESOD** AESMIE 8 = Other reason study 3 = Severe

	Code	Description of Condition/Event  COSTART Class Term	du			Serious* during trial?	Severity of Condition/Event Record the onset visit number and maximum severity at that visit. Then record the maximum severity in each subsequent visit ONLY if there is a change in severity.  Relationship to Study Drug AEREL
5	E08	TERM	    +			If Yes, enter Serious Code(s) AESER	Visit 1 = None 2 = Remote (Unlikely)
	E09		+	STDT 	C —	If <b>Yes</b> , enter Serious	4 = Probable
	E10		   		 	If Yes, enter Serious Code(s)	Visit
	E11		 			If Yes, enter Serious Code(s)	Visit Number  1 = None 2 = Remote (Unlikely) 3 = Possible 4 = Probable
	E12		    			If <b>Yes</b> , enter Serious Code(s)	Visit
•	E13		    			☐ No If <b>Yes</b> , enter Serious Code(s)	Visit
	E14		      			If Yes, enter Serious Code(s)	Visit Number  1 = None 2 = Remote (Unlikely) 3 = Possible 4 = Probable



Continue listing all pre-existing

V	VISITNUM						
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Page 1		of 1					

### PRE-EXISTING CONDITIONS AND STUDY ADVERSE EVENTS

			*Serious Codes  1 = Fatal 2 = Life-threatening AESLIF 3 = Permanently disabling				* If Event is serious, notify the Quintiles Drug  FE Safety Unit immediately.				
	AESH	OSP ONG OD	4 = Ho 5 = Co	spital ngen ncer erdos	ization ital anom AESC se	naly	1 = 2 =	erity Co Mild Modera Severe	ate	ever end	uate when nt stops or a of patient's cipation in y
Code	Description of Condition/Event		Onset I	Date YY	Serious*	Record and ma	d the or aximum	of Condit nset visit n severit	t num	ber nat visit.	
Code	COSTART Class Term		Stop Da	ate YY	trial?	each su	ubseque	e <i>maxin</i> ent visit <u>(</u> severit	ONLY		Study Drug
SPID E	TERM	_	   	   <del> -</del>	If Yes, enter Serious Code(s)	Visit Numbe — — Severit	+ -	ESEV	-	<del>-</del>	1 = None 2 = Remote (Unlikely) 3 = Possible 4 = Probable
E		<u>ا</u> ــــا	+ -STDT + — - ENDT		If <b>Yes</b> , enter Serious	Visit Numbe — — Severit	r _		+	+-	1 = None 2 = Remote (Unlikely) 3 = Possible
E			<del> </del>   	 	No If <b>Yes</b> , enter Serious Code(s)	Visit Numbe	+-		<del> </del>  -	+-	4 = Probable 1 = None 2 = Remote (Unlikely) 3 = Possible
E			<del> </del>   	 	No If Yes, enter Serious Code(s)	Visit Numbe — — Severit	er		<del> </del>  -	<u> </u>	4 = Probable 1 = None 2 = Remote (Unlikely) 3 = Possible
E			<del>                                     </del>	   	If Yes, enter Serious Code(s)	Visit Numbe — — Severit	r		+	+-	4 = Probable 1 = None 2 = Remote (Unlikely) 3 = Possible 4 = Probable
E			<del>                                     </del>	     	If Yes, enter Serious Code(s)	Visit Numbe — — Severit	+-		+	+-	1 = None 2 = Remote (Unlikely) 3 = Possible
			<u> </u>	ļ 	No No	Visit	, <u> </u>				4 = Probable 1 = None

Number

Severity

If Yes,

enter

Serious Code(s)

E\_

= Remote

(Unlikely)

3 = Possible

4 = Probable





Visit \_\_\_ Page 1 of 1

### **CONCOMITANT MEDICATION**

NO CONCOMITANT MEDICATIONS

Not Entered In Database

Enter all medications, other than study drug, the patient is taking at **entry** and **during the study**.

#### Indication for Use (IFU)

Enter code from patient's Pre-existing Conditions and Study Adverse Events page.

E\_\_ = Pre-Existing Condition or Event (eg, E01)

or

X1 = Primary study condition

X2 = Prophylaxis or non-therapeutic

use

#### **CMTRT**

	<u> </u>											
	Brand or Trade Name (Use generic if brand or trade name unknown)	CMDOS Dose	E Unit	Fre- quency	Route	Sta MM	art Da	te YY	Sto MM	op Dat	e YY	IFU
0.	trade name unknown,	CI	<b>MDOS</b>	U MDOSFI		141141						CMINE
			U	C	MROUT			 				
1.						CN	MSTD	TC	CN	IEND	ГС	
2.							 	 		 		
3.								 				
4.							<u> </u>	<u> </u> 				
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11.								 				





Visit \_\_\_\_ Page 1 a of 1

### **CONCOMITANT MEDICATION**

Continue entering all medications, other than study drug, the patient is taking at **entry** and **during the study**.

#### Indication for Use (IFU)

Enter code from patient's Pre-existing Conditions and Study Adverse Events page.

E\_\_ = Pre-Existing Condition or Event (eg, E01)

or

X1 = Primary study condition

X2 = Prophylaxis or non-therapeutic

use

#### **CMTRT**

	CIVITICI											
	Brand or Trade Name (Use generic if brand or trade name unknown)		Unit	Fre- quency	Route	Sta MM	art Da	te YY	Sto MM	op Dat	e YY	IFU
12.		CN	MDOS C	MDOSFI	RQ MROUT	ΓE		   				CMINE
13.						CN	MSTD	TC	CM	IEND	С	
14.												
15.								   				
16								<u>                                       </u>			   	
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Page 1		of	1

### **CONCOMITANT MEDICATION**

Continue entering all medications, other than study drug, the patient is taking at **entry** and **during the study**.

Indication for Use (IFU)

Enter code from patient's Pre-existing Conditions and Study Adverse Events page.

E\_\_ = Pre-Existing Condition or Event (eg, E01)

٥r

X1 = Primary study condition

X2 = Prophylaxis or non-therapeutic

use

**CMTRT** 

CMTRT											
Brand or Trade Name (Use generic if brand or	CMDOS Dose	E Unit	Fre- quency	Route		art Da			op Dat		IFU
trade name unknown)					MM	DD	YY	MM	DD	YY	
	CI	MDOS	U								CMIN
		C	MDOSF	RQ	<u> </u>						Civili
			C	MROU		L					
					CIV	ISTD	I C	0.			
						ĺ	l	CIV	IEND	IC	
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DOSING CHANGE	Visit	
	Page	1 of 1

# **STUDY DRUG DOSE CHANGE**: START DATE (12-14 hour patch)

	Vot E	Entered	In Da	atabase
Start date of the new study drug dosing regimen (12-14 hour patch	n) _	/_	/	
		MM	DD	YY





Early Termination Visit \_\_\_\_\_ Page 1 of 13

### PATIENT AND VISIT IDENTIFICATION

Patient initials

--STDTC --DTC

Visit date

Not Entered In Database

--STDTC --DTC

--DTC

MM DD YY

### STUDY DRUG : COMPLIANCE

INFORMATION NOT OBTAINED Not Entered In Database

Since the previous visit, on how many days was the patient unable to complete the therapy?

Not Entered In Database

#### **REMINDER**

On the Pre-existing Conditions and Study Adverse Events page, record new events that occurred since the previous visit and re-evaluate any on-going conditions or events.

On the Concomitant Medication page, record new medications the patient has taken since the previous visit and record a stop date for any medication the patient is no longer taking.

A physical examination must be performed at this visit. Any clinically significant abnormalities must be listed on the Pre-existing Conditions and Study Adverse Events page.

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# EXTRAPYRAMIDAL FINDINGS

NF	ORMATION NOT OBTAINED Not Entered In Database
1.	Masked facies  Not Entered In Database  Not Entered In Database  Not Entered In Database  Not Entered In Database  Not Entered In Database  Severe
2.	Rigidity of upper extremity  Not Entered In Database  Not Entered In Database  Not Entered In Database  Mild  Moderate  Severe
3.	Essential tremor Not Entered In Database  One None  Mild  Moderate  Severe
4.	Ambulation  Not Entered In Database  How long did it take the patient to walk 25 yards?  seconds



Early Termination Visit	
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#### ALZHEIMER'S DISEASE ASSESSMENT SCALE: COGNITIVE with ATTENTION/ **QSCAT**

**CONCENTRATION TASKS** 

	Not En	tered In	Database	9
Clinician's initials	First	Middle	Last	

INFORMATION NOT OBTAINED Not Entered In Database

QSTESTCD 1.	Word Recall Task	(max = 10)	QSORRES
QSTESTCD 2.	Naming Objects and Fingers (refer to 5 categories in manual)	(max = 5)	QSORRES
QSTESTCD 3.	Delayed Word Recall	(max = 10)	QSORRES
QSTESTCD 4.	Commands	(max = 5)	QSORRES
QSTESTCD 5.	Constructional Praxis	(max = 5)	QSORRES
QSTESTCD 6.	Ideational Praxis	(max = 5)	QSORRES
QSTESTCD 7.	Orientation	(max = 8)	QSORRES
QSTESTCD 8.	Word Recognition	(max = 12)	QSORRES
QSTESTCD 9.	Attention/Visual Search Task	(max = 40)	QSORRES
QSTESTCD 10.	Maze Solution	(max = 240)	QSORRES (seconds)
QSTESTCD 11.	Spoken Language Ability	(max = 5)	QSORRES
QSTESTCD 12.	Comprehension of Spoken Language	(max = 5)	QSORRES
QSTESTCD 13.	Word Finding Difficulty in Spontaneous Speech	(max = 5)	QSORRES
QSTESTCD 14.	Recall of Test Instructions	(max = 5)	QSORRES
— <del>——</del> 14.	Recail Of Test Instructions	(IIIax = 5)	

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# CLINICIAN'S INTERVIEW-BASED IMPRESSION OF CHANGE (CIBIC+)

INFORMATION NOT OBTAINED Not Entered In Database

Clinician's initials

Not Entered In Database

First Middle Last

□ 4 No change
 □ 5 Minimal worsening
 □ 6 Moderate worsening
 □ 7 Marked worsening

The clinical interview-based impression of change scale in this study is from a pilot instrument, the Clinical Global Impression of Change, developed and currently undergoing validity studies by the National Institute on Aging Alzheimer's Disease Study Units Program (1 U01 AG10483; Leon Thal, Principal Investigator), and is in the public domain.

EM31501

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Early Termination Visit	
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### NEUROPSYCHIATRIC INVENTORY - REVISED (NPI-X)

INFORMATION NOT OBTAINED Not Entered In Database

	Not En	itered In	Databa	se
Clinician's initials	First	Middle	Last	

The screening question (from worksheet) is asked of the caregiver to determine if the behavioral change is present or absent in the patient. If the answer to the screening question is negative (NO) or if the question is not applicable to the patient, circle the appropriate response (Not Applicable [96] or Absent [0]) and proceed to the next screening question without asking the subquestions to determine frequency, severity, and distress.

		Not														
QSSCAT QSTESTCD	<u>Item</u> A	p <u>plicable</u> QSORI	Abse	nt F	requ	uenc QSC	<u>X</u> RRES	Se QSTES	veri	<u>ty</u> QSOR	RES n		Distr		ORR	ES
QSSCAT QSTESTCD	Delusions	96 <mark>QSOR</mark> I	0 RES	1 QSTES	2	3	4	1	2	3	0	1	2 STCI	3	4	5
QSSCAT QSTESTCD	Hallucinations	96 <b>QSOR</b> I	0 RES	1 QSTES	2	3	4	1	2	3	0	1	2 STCI	3	4	5
C. QSSCAT QSTESTCD	Agitation/Agression	96 QSOR	0 RES	1 QSTES	2	3	4	1	2	3	0	1	2	3	4	5
D.	Depression/ Dysphoria	96	0	1	2	3	4	1	2	3	0	1	STCI 2	3	4	5
QSSCAT QSTESTCD	Бубриона	QSORF	RES	QSTES	TCD	QSO	RRES	QSTES	TCD	QSORI	RES Q	STE	STCD	OSO	ORRI	FS
QSSCAT QSTESTCD	Anxiety	96 <mark>QSORF</mark>	0 RES	1 QSTES	2 TCD	3 <b>2SO</b>	4 RRES	1 QSTES	2 TCD	3 DSORI	0	1	2 STCE	3	4	5
F. QSSCAT QSTESTCD	Euphoria/Elation	96 QSORI	0 RES	1 QSTES	2	3	4	1	2	3	0	1	2	3	4	5
G.	Apathy/ Indifference	96	0	1	2	3	4	1	2	3	0	SIE 1	2	3	ORR 4	ES 5
QSSCAT QSTESTCD	mamerence	QSORF	RES	QSTES	TCD	QSO	RRES	QSTES	TCD	OSOR	RES O	STE	STCE	108	ODD	EQ
QSSCAT QSTESTCD	Disinhibition	96 QSORF	0 RES	1 QSTES	2	3	4	1	2	3	0	1	2 STCE	3	4	5
QSSCAT QSTESTCD	Irritability/Lability	96 QSORI	0 RES	1 QSTES	2	3	4	1	2	3	0	1	2	3	4	5
J.	Aberrant Motor Behavior	96	0	1	2	3	4	1	2	3	0	1	STCI 2	3	4	5
QSSCAT QSTESTCD	Deliavior	QSORI	RES	QSTES	TCD	QSC	RRES	QSTES	STCD	QSOR	RES C	STE	STCI	os	ORR	FS
QSSCAT QSTESTCD	Night-Time Behavior	r 96 <mark>QSOR</mark>	0 RES	1 QSTES	2	3	4	1	2	3	0	1	2 STCI	3	4	5
L.	Appetite/Eating Change	96	0	1	2	3	4	1	2	3	0	1	2	3	4	5

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#### **DISABILITY ASSESSMENT FOR DEMENTIA (DAD) QSCAT** INFORMATION NOT OBTAINED Not Entered In Database Not Entered In Database Clinician's initials First Middle Last Effective Performance Organization During the past two weeks, did the patient without help or reminder: Planning 8 nitiation QSSCAT SCORING: Yes = 1Not Applicable = 96 No = 0**HYGIENE QSTESTCD** OSORRES Undertake to wash himself/herself or to take a bath or a shower **QSTESTCD QSORRES** Undertake to brush his/her teeth or care for his/her dentures QSTESTCD **QSORRES** Decide to care for his/her hair (wash and comb) **QSTESTCD QSORRES** Prepare the water, towels, and soap for washing, taking a bath, or a shower **QSTESTCD** Wash and dry completely all parts of his/her body safely QSORRES QSTESTCD Brush his/her teeth or care for his/her dentures appropriately **QSORRES** QSTESTCD 7. Care for his/her hair (wash and comb) **QSORRES** DRESSING QSSCAT **QSTESTCD** Undertake to dress himself/herself **QSORRES QSTESTCD** Choose appropriate clothing (with regard to the occasion, neatness, **QSORRES** the weather, and color combination) QSTESTCD 10. **QSORRES** Dress himself/herself in the appropriate order (undergarments, pant/dress, shoes) QSTESTCD 11. Dress himself/herself completely **QSORRES** QSTESTCD 12. Undress himself/herself completely **QSORRES** CONTINENCE QSSCAT QSTESTCD 13. OSORRES Decide to use the toilet at appropriate times QSTESTCD 14. Use the toilet without "accidents" **QSORRES** EATING QSSCAT QSTESTCD 15. Decide that he/she needs to eat **QSORRES QSTESTCD QSORRES** Choose appropriate utensils and seasonings when eating QSTESTCD **QSORRES** Eat his/her meals at a normal pace and with appropriate manners MEAL PREPARATION QSSCAT QSTESTCD **QSORRES** Undertake to prepare a light meal or snack for himself/herself QSTESTCD 19 **QSORRES** Adequately plan a light meal or snack (ingredients, cookware) QSTESTCD 20. **QSORRES** Prepare or cook a light meal or a snack safely

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# DISABILITY ASSESSMENT FOR DEMENTIA (DAD)

		QSSCAT SCORING: Yes = 1 No = 0 Not Applicable TELEPHONING	le = 96	Initiation	Planning & Organization	Effective Performance	
QSTESTCD	21.	Attempt to telephone someone at a suitable time					QSORRES
QSTESTCD	22.	Find and dial a telephone number correctly					QSORRES
QSTESTCD	23.	Carry out an appropriate telephone conversation					QSORRES
QSTESTCD	24.	Write and convey a telephone message adequately					QSORRES
		GOING ON AN OUTING QSSCAT					
QSTESTCD	25.	Undertake to go out (walk, visit, shop) at an appropriate time					QSORRES
QSTESTCD	26.	Adequately organize an outing with respect to transportation, keys, dest weather, necessary money, shopping list	tination,				QSORRES
QSTESTCD	27.	Go out and reach a familiar destination without getting lost					QSORRES
QSTESTCD	28.	Safely take the adequate mode of transportation (car, bus, taxi)					QSORRES
QSTESTCD	29.	Return from the store with the appropriate items					QSORRES
		FINANCE AND CORRESPONDENCE QSSCAT				<u> </u>	
		FINANCE AND CORRESPONDENCE					
QSTESTCD	30.	Show an interest in his/her personal affairs such as his/her finances and w correspondence	vritten				QSORRES
QSTESTCD	30.	Show an interest in his/her personal affairs such as his/her finances and w	vritten				QSORRES QSORRES
QSTESTCD QSTESTCD	30. 31.	Show an interest in his/her personal affairs such as his/her finances and w correspondence					
QSTESTCD	30.	Show an interest in his/her personal affairs such as his/her finances and w correspondence  Organize his/her finances to pay his/her bills (cheques, bankbook, bills)					QSORRES
QSTESTCD QSTESTCD	<ul><li>30.</li><li>31.</li><li>32.</li><li>33.</li></ul>	Show an interest in his/her personal affairs such as his/her finances and we correspondence  Organize his/her finances to pay his/her bills (cheques, bankbook, bills)  Adequately organize his/her correspondence with respect to stationery, address Handle adequately his/her money (make change)					QSORRES QSORRES
QSTESTCD QSTESTCD	<ul><li>30.</li><li>31.</li><li>32.</li><li>33.</li></ul>	Show an interest in his/her personal affairs such as his/her finances and we correspondence  Organize his/her finances to pay his/her bills (cheques, bankbook, bills)  Adequately organize his/her correspondence with respect to stationery, address Handle adequately his/her money (make change)					QSORRES QSORRES
QSTESTCD QSTESTCD QSTESTCD	<ul><li>30.</li><li>31.</li><li>32.</li><li>33.</li></ul>	Show an interest in his/her personal affairs such as his/her finances and we correspondence  Organize his/her finances to pay his/her bills (cheques, bankbook, bills)  Adequately organize his/her correspondence with respect to stationery, address Handle adequately his/her money (make change)  MEDICATIONS QSSCAT	s, stamps				QSORRES QSORRES QSORRES
QSTESTCD QSTESTCD QSTESTCD	<ul><li>30.</li><li>31.</li><li>32.</li><li>33.</li><li>34.</li><li>35.</li></ul>	Show an interest in his/her personal affairs such as his/her finances and we correspondence  Organize his/her finances to pay his/her bills (cheques, bankbook, bills)  Adequately organize his/her correspondence with respect to stationery, address Handle adequately his/her money (make change)  MEDICATIONS QSSCAT  Decide to take his/her medications at the correct time	s, stamps				QSORRES QSORRES QSORRES QSORRES
QSTESTCD QSTESTCD QSTESTCD QSTESTCD QSTESTCD	<ul><li>30.</li><li>31.</li><li>32.</li><li>33.</li><li>34.</li><li>35.</li></ul>	Show an interest in his/her personal affairs such as his/her finances and we correspondence  Organize his/her finances to pay his/her bills (cheques, bankbook, bills)  Adequately organize his/her correspondence with respect to stationery, address Handle adequately his/her money (make change)  MEDICATIONS QSSCAT  Decide to take his/her medications at the correct time  Take his/her medications as prescribed (according to the right dosage)	s, stamps				QSORRES QSORRES QSORRES QSORRES
QSTESTCD QSTESTCD QSTESTCD QSTESTCD QSTESTCD QSTESTCD QSTESTCD	<ul><li>30.</li><li>31.</li><li>32.</li><li>33.</li><li>34.</li><li>35.</li></ul>	Show an interest in his/her personal affairs such as his/her finances and we correspondence  Organize his/her finances to pay his/her bills (cheques, bankbook, bills)  Adequately organize his/her correspondence with respect to stationery, address Handle adequately his/her money (make change)  MEDICATIONS QSSCAT  Decide to take his/her medications at the correct time  Take his/her medications as prescribed (according to the right dosage)  LEISURE AND HOUSEWORK QSSCAT	s, stamps ge)				QSORRES QSORRES QSORRES QSORRES QSORRES
QSTESTCD QSTESTCD QSTESTCD QSTESTCD QSTESTCD QSTESTCD QSTESTCD QSTESTCD	<ul><li>30.</li><li>31.</li><li>32.</li><li>33.</li><li>34.</li><li>35.</li><li>36.</li></ul>	Show an interest in his/her personal affairs such as his/her finances and we correspondence  Organize his/her finances to pay his/her bills (cheques, bankbook, bills)  Adequately organize his/her correspondence with respect to stationery, address Handle adequately his/her money (make change)  MEDICATIONS QSSCAT  Decide to take his/her medications at the correct time  Take his/her medications as prescribed (according to the right dosage)  LEISURE AND HOUSEWORK QSSCAT  Show an interest in leisure activity(ies)	s, stamps ge)				QSORRES QSORRES QSORRES QSORRES QSORRES
QSTESTCD QSTESTCD QSTESTCD QSTESTCD QSTESTCD QSTESTCD QSTESTCD	<ul><li>30.</li><li>31.</li><li>32.</li><li>33.</li><li>34.</li><li>35.</li><li>36.</li><li>37.</li></ul>	Show an interest in his/her personal affairs such as his/her finances and we correspondence  Organize his/her finances to pay his/her bills (cheques, bankbook, bills)  Adequately organize his/her correspondence with respect to stationery, address:  Handle adequately his/her money (make change)  MEDICATIONS QSSCAT  Decide to take his/her medications at the correct time  Take his/her medications as prescribed (according to the right dosage)  LEISURE AND HOUSEWORK QSSCAT  Show an interest in leisure activity(ies)  Take an interest in household chores that he/she used to perform in the page of the performance of the	ge) ast the past				QSORRES QSORRES QSORRES QSORRES QSORRES QSORRES

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Early Termination Visit \_\_\_\_

									Page 8 of 1
	•	/STEST(		□ Not	Entered	n Database			
١N	NFORMATIO	N NOT C	BTAINED	) [] NOT	Entered	n Database	<b>3</b>		
M	leasure with s	shoes off	. Round	up or dow	n to the n	earest <u>tent</u>	h kilog	g <u>ram</u> or <u>tent</u>	<u>th pound</u> .
V	/eight <mark>VSC</mark>	ORRES <sub>.</sub>	_ □	<sub>kg</sub> Kilogra <mark>VS0</mark>	m □ ORRESU	<sub>b</sub> Pound			
	<b>VITAL SIGI</b> NFORMATIOI			O Not	Entered II OTE: Blo pat (su	ent has bee pine) and af	and po	ulse must be down for 5	e taken after the minutes ninute (standing)
			SU=Supi	ine	and	3 minutes.			
	VST	PTNUM	ST = Star	nding					
ı	<mark>VST</mark> (DNDE)	PT I		STESTC	<u> </u>		٦		
	Reference Time	Timing Code	Position	(bpm)	(mn Systolic	ressure nHg) Diastolic			
0.	5 minutes	815		SORRES SORRES		/			
1.	1 minute	816	ST			-VSTEST	SU		
2.	3 minutes	817	ST		STESTCE		ES		
		-			SORRES	_	_		
\	/ITAL SIGI	NS : T	EMPER	ATURE	VSTES	TCD			
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Т	emperature	VS	ORRES						
U	nit of measur	e 🔲 <sub>F</sub>	Fahrenhe	eit □ <sub>c</sub> C	Centigrade	VSORRE	SU		
M	lethod <mark>VSL</mark>	OC	Oral	□ <sub>R</sub> F	Rectal	☐ <sub>A</sub> Axil	lary	□ <sub>E</sub> Ear	□ o Other

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	i age 3 oi
ELECTROCARDIOGRAM	
NOT DONE Not Entered In Database	
Electrocardiogram date  Not Entered In Database  MM DD YY  Not Entered In Database	
Electrocardiogram result	
NOTE: Any clinically relevant change from Visit 1 (baseline) ECG m Pre-existing Conditions and Adverse Events page. Note nor abnormalities in the ECG Comments section below.	
<b>COMMENTS</b> : NON-RELEVANT ECG ABNORMALITIES	
NO COMMENTS Not Entered In Database	
Print legibly and do not use abbreviations or symbols.  Not Entered In Database	



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ACCEPTABILITY: CAREGIVER'S RESPONSE ABOUT THE PATCH
INFORMATION NOT OBTAINED Not Entered In Database
The following question is to be <u>answered by the caregiver</u> .
Based on the experience of applying and wearing this patch, if the patient were prescribed a drug for Alzheimer's disease and was given the choice of this patch or an oral pill given twice daily (assume that both formulations are equally effective), would you (the caregiver):  Not Entered In Database
$\Box_1$ Insist that the patient receive an <u>oral pill</u>
$\square_2$ Prefer that the patient receive an <u>oral pill</u>
$\square_{3}^{}$ Have no preference (neutral) for an oral or patch formulation
$\square_{_{4}}$ Prefer that the patient receive a patch
$\square_{5}$ Insist that the patient receive a <u>patch</u>



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### **ACCEPTABILITY**: CAREGIVER'S RESPONSE ABOUT THE PATCH

INFORMATION NOT OBTAINED Not Entered In Database

The following questions are intended to be answered by the caregiver and address the patch's design and wearability. Focus only on the act of wearing and removing the transdermal patch. On each scale below, <u>circle one number</u> (do not circle on the scale between numbers) that best describes your feelings about the patch:

1. The <u>appearance</u> of the patch while being worn is acceptable:

NOLENTERED IN Database	1	2	3	4	5	6	7
	Strongly Disagree		Ν	leutral			Strongly Agree
2.	The <u>size</u> of the	e patch is a	acceptable	e:			
Not Entered In Database	9 1	2	3	4	5	6	7
	Strongly Disagree		Ν	leutral			Strongly Agree
3. The patches were durable (eg, did not discolor, tear) while I							
Not Entered In Databas	<mark>e</mark> 1	2	3	4	5	6	7
	Strongly Disagree		٨	leutral			Strongly Agree

### **STUDY DRUG THERAPY**: DATE OF FINAL DOSE

Date of final dose of study drug

| \_\_\_\_/\_\_\_/
| MM | DD | YY |

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### PATIENT SUMMARY

	Patient Initials  Not Entered In Database				
	CHECK ONE PRIMARY REASON FOR ENDING PARTICIPATION IN THE STUDY				
DSTERM	<u> </u>				
DSTERM	Adverse event E AESPID  L Code  If # 4 is checked, enter date of death.  DSSTDTC				
DSTERM	Date of Death  Date of Death  Date of Death				
DSTERM DSTERM	Lack of efficacy, patient/caregiver perception  Lack of efficacy, physician perception				
DSTERM	☐ <sub>11</sub> Unable to contact patient (lost to follow-up)				
SDECOD	Personal conflict or other patient/caregiver decision				
OSDECOD	Physician decisionSpecify  Specify  Specify				
DSTERM DSTERM	SUPPDS.QVAL  Protocol entry criteria not met (Specify number from entry criteria checklist)  Specify  Protocol violation				
DSTERM	□ Sponsor decision (study or patient discontinued by the Sponsor)				
	* Contact the Quintiles Drug Safety Unit immediately in event of death. Obtain a copy of the autopsy report (if autopsy performed) or hospital discharge summary. Forward to Quintiles Drug Safety Unit as soon as possible. Explain circumstances of the death on the Study Summary Comments page.				



Early Termination V	isit	
Page <sup>2</sup>	13 c	f 13

COMMENTS: STUDY SUMMARY
NO COMMENTS Not Entered In Database
Repeating information from the clinical report form is discouraged. If the patient is ending participation in the study for any reason other than protocol complete (Reason 1 on Patient Summary page) give a brief description of the circumstances.
Enter comments below. Print legibly and do not use abbreviations or symbols.
Not Entered In Database
All information reported for this patient is accurate and complete.  Not Entered In Database  Not Entered In Database
Investigator Signature MM DD YY

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#### Instructions for Administration of the NPI

The purpose of the Neuropsychiatric Inventory (NPI) is to obtain information on the presence of psychopathology in patients with brain disorders. The NPI was developed for application to patients with Alzheimer's disease and other dementias, but it may be useful in the assessment of behavioral changes in other conditions. Twelve behavioral areas are included in the NPI:

Delusions Apathy
Hallucinations Disinhibition
Agitation Irritability

Depression Aberrant motor behavior Anxiety Night-time behaviors

Euphoria Appetite and eating changes

The NPI is based on responses from an informed caregiver, preferably one living with the patient. If an informed observer is not available, this instrument cannot be used or must be modified. The interview is best conducted with the caregiver in the absence of the patient to facilitate an open discussion of behaviors that may be difficult to describe with the patient present. Several points should be made when you introduce the NPI interview to the caregiver:

- Purpose of the interview
- Ratings frequency, severity, distress (described below)
- Answers apply to behaviors that are new since the onset of the disease and have been present for the past two weeks or other defined period
- Questions can usually be answered with "yes" or "no" and responses should be brief

When beginning the inventory, say to the caregiver "These questions are designed to evaluate your [husband's/wife's/etc] behavior. They can usually be answered 'yes' or 'no' so please try to be brief in your responses." If the caregiver lapses into elaborate responses that provide little useful information, they may be reminded of the need to be brief. Some of the issues raised with this are very emotionally disturbing to caregivers and the interviewer should reassure the caregiver that they will discuss the problems in more detail after completion of the inventory.

Questions should be asked exactly as written. Clarification should be provided if the caregiver does not understand the question. Acceptable clarifications are restatements of the questions in alternate terms.

The questions pertain to <u>changes</u> in the patient's behavior that have appeared since the onset of the illness. Behaviors that have been present throughout the patient's life and have not changed in the course of the illness are not scored even if they are abnormal (e.g., anxiety, depression). Behaviors that have been present throughout life but have <u>changed</u> since the illness are scored (e.g., the patient has always been apathetic but there has been a notable increase in apathy during the period of inquiry).

The NPI is typically used to assess changes in the patient's behavior that have appeared in a defined period of time (e.g., in the past four weeks or other defined interval). In some studies, the NPI may be used to address changes occurring in response to treatment or that have changed since the last clinic visit. The time frame of the question would then be revised to reflect this interest in recent changes. Emphasize to the caregiver that the questions pertain to behaviors that have appeared or changed since the onset of the illness. For example, the questions might be phrased "Since he/she began treatment with the new medications . . ." or "Since our last interview . . ."

The screening question is asked to determine if the behavioral change is present or absent. If the answer to the screening question is negative, mark NO and proceed to the next screening question without asking the subquestions. If the answer to the screening question is positive or if there are any

uncertainties in the caregiver's response or any inconsistencies between the response and other information known by the clinician (e.g., the caregiver responds negatively to the euphoria screening question but the patient appears euphoric to the clinician), the category is marked YES and is explored in more depth with the subquestions. If the subquestions confirm the screening question, the severity and frequency of the behavior are determined according to the criteria provided with each behavior. When determining frequency and severity, use the behaviors identified by the subquestions as most aberrant. For example, if the caregiver indicates that resistive behavior is particularly problematic when you are asking the subquestions of the agitation section, then use resistive behavior to prompt judgments regarding the frequency and severity of agitation. If two behaviors are very problematic, use the frequency and severity of both behaviors to score the item. For example, if the patient has two or more types of delusions, then use the severity and frequency of all delusional behaviors to phrase the questions regarding severity and frequency.

In some cases, the caregiver will provide a positive response to the screening question and a negative reply to all subquestions. If this happens, ask the caregiver to expand on why they responded affirmatively to the screen. If they provide information relevant to the behavioral domain but in different terms, the behavior should be scored for severity and frequency as usual. If the original affirmative response was erroneous, leading to a failure to endorse any subquestions, then the behavior is changed to "NO" on the screen.

Some sections such as the questions pertaining to appetite are framed so as to capture whether there is an increase or decrease in the behavior (increased or decreased appetite or weight). If the caregiver answer "yes" to the first member of the paired question (such as has the patient's weight decreased?), do not ask the second question (has the patient's weight increased?) since the answer to the second question is contained in the answer to the first. If the caregiver answers "no" to the first member of the pair of questions, then the second question must be asked.

When determining frequency, say to the person being interviewed "Now I want to find out how often these things [define using description of the behaviors they noted as most problematic on the subquestions] occur. Would you say that they occur less than once per week, about once per week, several times per week but not every day, or essentially every day?" Some behaviors, such as apathy eventually become continuously present, and then "are constantly present" can be substituted for "every day." When determining severity, tell the person being interviewed "Now I would like to find out how severe these behaviors are. By severity, I mean how disturbing or disabling they are for the patient. Would you say that [the behaviors] are mild, moderate, or marked?" Additional descriptors are provided in each section that may be used to help the interviewer clarify each grade of severity. In each case, be sure that the caregiver provides you with a definite answer as to the frequency and severity of the behaviors. Do not guess what you think the caregiver would say based on your discussion. We have found it helpful to provide the caregiver with a piece of paper on which is written the frequency and severity descriptions (less than once per week, about once per week, several times per week and daily or continuously for frequency and mild, moderate, and severe for severity) to allow them to visually see the response alternatives. This also saves the examiner from reiterating the alternatives with each question.

In very impaired patients or patients with special medical circumstances, a set of questions may not be applicable. For example, bed-bound patients may exhibit hallucinations or agitation but could not exhibit aberrant motor behavior. If the clinician or the caregiver believes that the questions are inappropriate, then the section should be marked NA (upper right corner of each section), and no further data are not recorded for the section. Likewise, if the clinician feels that the responses are invalid (e.g., the caregiver did not seem to understand the particular set of questions asked), NA should also be marked.

When each domain is completed and the caregiver has completed the frequency and severity rating, you may want to ask the associated <u>caregiver distress</u> question if your protocol includes the distress assessment. To do this, ask the caregiver how much, if any, "emotional or psychological" distress the behavior he or she just discussed causes him or her (the caregiver). The caregiver must rate their own distress on a five point scale from 0 - no distress, 1 - minimal, 2 - mild,

3 - moderate, 4 - moderately severe, 5 - very severe or extreme. The distress scale of this instrument was developed by Daniel Kaufer, M.D.

#### Scoring the NPI

#### Frequency is rated as:

- 1 Occasionally less than once per week
- 2 Often about once per week
- 3 Frequently several times per week but less than every day
- 4 Very frequently daily or essentially continuously present

#### Severity is rated as:

- 1 Mild produce little distress in the patient
- 2 Moderate more disturbing to the patient but can be redirected by the caregiver
- 3 Marked very disturbing to the patient and difficult to redirect

The score for each domain is: domain score = frequency x severity

#### Distress is scored as:

- 0 no distress
- 1 minimal
- 2 mild
- 3 moderate
- 4 moderately severe
- 5 very severe to extreme

Thus, for each behavioral domain there are four scores:

- Frequency
- Severity
- Total (frequency x severity)
- Caregiver distress

A <u>total NPI score</u> can be calculated by adding all domain scores together. The distress score is not included in the total NPI score.

#### Instructional Videotape

An instructional videotape demonstrating the use of the NPI is available through the UCLA Alzheimer's Disease Center, Neuropsychiatric Institute, 740 Westwood Plaza, Los Angeles, California, 90024. The cost of the videotape is \$25.00 (subject to change).

#### Reference

Cummings JL, Mega M, Gray K, Rosenberg-Thompson S, Carusi DA, Gornbein J. The Neuropsychiatric Inventory: comprehensive assessment of psychopathology in dementia. Neurology 1994; 44: 2308-2314.

<u>Acknowledgments</u>: UCLA Alzheimer's Disease Center, Academic Geriatric Resource Program, UCLA Center on Aging and the Irving and Helga Cooper Geriatric Research Award.



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### A. <u>Delusions</u>

Does the patient have beliefs that you know are not true? For example, insisting that people are try to harm him/her or steal from him/her. Has he/she said that family members are not who they say they are or that the house is not their home? I'm not asking about mere suspiciousness; I am interested if the patient is <u>convinced</u> that these things are happening to him/her.

NC	(If no, procee	d to th	ne next screening question)	YES (If yes, proceed to subque	stions).	
1.	Does the patient him/her?	ent be	elieve that he/she is in danger -	that others are planning to hurt		
2.	Does the patie	ent be	elieve that others are stealing fro	om him/her?		
3.	Does patient believe that his/her spouse is having an affair?					
4.	Does patient l	believ	re that unwelcome guests are liv	ring in his/her house?		
5.	Does the patie	ent be	elieve that his/her spouse or oth	ers are not who they claim to be?		
6.	Does the patie	ent be	elieve that his/her house is not h	nis/her home?		
7.	. Does the patient believe that family members plan to abandon him/her?					
8.			elieve that television or magazin Does he/she try to talk or intera	e figures are actually present in ct with them?]		
9.	Does the he/s	she be	elieve any other unusual things	that I haven't asked about?		
If ti	ne screening q	uestic	on is confirmed, determine the f	requency and severity of the delu	sions.	
	Frequency:	1. 2. 3. 4.	Occasionally - less than once Often - about once per week. Frequently - several times per Very frequently - once or more	week but less than every day.		
	Severity:	1. 2. 3.	patient.  Moderate - delusions are distre  Marked - delusions are very di	sruptive and are a major source o ations are prescribed, their use si	of behavioral	
	Distress:	Но	w emotionally distressing do yo	u find this behavior:		

Not at all
 Minimally
 Mildly
 Moderately
 Severely

5. Very severely or extremely



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## B. <u>Hallucinations</u>

Does the patient have hallucinations such as false visions or voices? Does he/she seem to see, hear or experience things that are not present? By this question we do not mean just mistaken beliefs such as stating that someone who has died is still alive; rather we are asking if the patient actually has abnormal experiences of sound, or visions.

NO	(If no, proceed	d to th	e next screening question)	YES (If yes, proceed to subque	estions).				
1.	Does the patie	ent de	scribe hearing voices or act as	if he/she hears voices?					
2.	Does the patient talk to people who are not there?								
3.	Does the patient describe seeing things not seen by others or behave as if he/she is seeing things not seen by others (people, animals, lights, etc)?								
4.	Does the patie	ent re	port smelling odors not smelled	by others?					
5.			scribe feeling things on his/herawling or toughing him/her?	skin or otherwise appear to be					
6.	Does the patie	ent de	scribe tastes that are without a	any known cause?					
7.	Does the patie	ent de	scribe any other unusual sense	ory experiences?					
If th	ne screening qu	uestio 1. 2. 3.	Occasionally - less than once Often - about once per week.	requency and severity of the halloper week.  week but less than every day.	ucinations.				
		4.	Very frequently - once or more						
	<ol> <li>Mild - hallucinations present but seem harmless and produce line in the patient.</li> <li>Moderate - hallucinations are distressing and disruptive to the patient.</li> <li>Marked - hallucinations are very disruptive and are a major soul behavioral disturbance. PRN medications may be required them.</li> </ol>								
	<u>Distress</u> :	Hov	w emotionally distressing do yo 0. Not at all 1. Minimally	ou find this behavior:					

Mildly
 Moderately
 Severely



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## C. Agitation/Aggression

Does the patient have periods when he/she refuses to cooperate or won't let people help him/her? Is he/she hard to handle?

NO	(If no, proceed to the next screening question)	YES (If yes, proceed to subquestions).						
1.	Does the patient get upset with those trying to care for him/her or resist activities such as bathing or changing clothes?							
2.	Is the patient stubborn, having to have things his/he	er way?						
3.	. Is the patient uncooperative, resistive to help from others?							
4.	. Does the patient have any other behaviors that make him hard to handle?							
5.	Does the patient shout or curse angrily?							
6.	Does the patient slam doors, kick furniture, throw the	nings?						
7.	Does the patient attempt to hurt or hit others?							
8.	Does the patient have any other aggressive or agita	ated behaviors?						

If the screening question is confirmed, determine the frequency and severity of the agitation.

### Frequency:

- 1. Occasionally less than once per week.
- 2. Often about once per week.
- 3. Frequently several times per week but less than every day.
- 4. Very frequently once or more per day.

#### Severity:

- 1. Mild behavior is disruptive but can be managed with redirection or reassurance.
- 2. Moderate behaviors disruptive and difficult to redirect or control.
- Marked agitation is very disruptive and a major source of difficulty; there may be a threat of personal harm. Medications are often required.

#### Distress:

How emotionally distressing do you find this behavior:

- 0. Not at all
- 1. Minimally
- 2. Mildly
- 3. Moderately
- 4. Severely
- 5. Very severely or extremely



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## D. <u>Depression/Dysphoria</u>

Does the patient seem sad or depressed? Does he/she say that he/she feels sad or

dep	pressed?								
NC	(If no, proceed to the next screening question) YES (If yes, proceed to subquestions)								
1.	Does the patient have periods of tearfulness or sobbing that seem to indicate sadness?								
2.	Does the patient say or act as if he/she is sad or in low spirits?								
3.	Does the patient put him/herself down or say the he/she feels like a failure?								
4.	Does the patient say that he/she is a bad person or deserves to be punished?								
5.	Does the patient seem very discouraged or say that he/she has no future?								
6.	Does the patient say he/she is a burden to the family or that the family would be better off without him/her?								
7.	Does the patient express a wish for death or talk about killing him/herself?								
8.	Does the patient show any other signs of depression or sadness?								
lf tl	ne screening question is confirmed, determine the frequency and severity of the depression								
	Frequency: 1 Occasionally - less than once per week								

- 2. Often - about once per week.
- 3. Frequently - several times per week but less than every day.
- Very frequently once or more per day.

#### Severity:

- Mild depression is distressing but usually responds to redirection or reassurance.
- 2. Moderate - depression is distressing, depressive symptoms are spontaneously voiced by the patient and difficult to alleviate.
- Marked depression is very distressing and a major source of suffering for the patient.

#### **Distress**:

How emotionally distressing do you find this behavior:

- 0. Not at all
- 1. Minimally
- 2. Mildly
- 3. Moderately
- 4. Severely
- 5. Very severely or extremely



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# E. Anxiety

Is the patient very nervous, worried, or frightened for no apparent reason? Does he/she seem very tense or fidgety? Is the patient afraid to be apart from you?

see	em very tense	or na	gety? Is the patient arraid to be apart from you?					
NC	(If no, procee	d to t	he next screening question) YES (If yes, proceed to subquest	ions)				
1.	Does the pati	ent sa	ay that he/she is worried about planned events?					
2.	Does the patient have periods of feeling shaky, unable to relax, or feeling excessively tense?							
3.	Does the patient have periods of [or complain of] shortness of breath, gasping, or sighing for no apparent reason other than nervousness?							
4.	Does the patient complain of butterflies in his/her stomach, or of racing or pounding of the heart in association with nervousness? [Symptoms not explained by ill health]							
5.			void certain places or situations that make him/her more nervous n the car, meeting with friends, or being in crowds?					
6.	•		ecome nervous and upset when separated from you [or his/her bes he/she cling to you to keep from being separated?]					
7.	Does the pati	ent sl	how any other signs of anxiety?					
lf tl	he screening q	uestic	on is confirmed, determine the frequency and severity of the anxiety	<b>/</b> .				
	Frequency:	1. 2. 3. 4.	Occasionally - less than once per week. Often - about once per week. Frequently - several times per week but less than every day. Very frequently - once or more per day.					
	Severity:	<ol> <li>1.</li> <li>2.</li> <li>3.</li> </ol>	<ul> <li>Mild - anxiety is distressing but usually responds to redirection or reassurance.</li> <li>Moderate - anxiety is distressing, anxiety symptoms are spontaneously voiced by the patient and difficult to alleviate.</li> <li>Marked - anxiety is very distressing and a major source of suffering for the patient.</li> </ul>					
	<u>Distress</u> :	Но	ow emotionally distressing do you find this behavior:  0. Not at all  1. Minimally  2. Mildly  3. Moderately					

4. Severely



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# F. Elation/Euphoria

Does the patient seem too cheerful or too happy for no reason? I don't mean the normal happiness that comes from seeing friends, receiving presents, or spending time with family members. I am asking if the patient has a persistent and <u>abnormally</u> good mood or finds humor where others do not.

NC	(If no, procee	d to t	ne next screening question) YES (If yes, proceed to subquestions).					
1.	Does the pati- usual self?		opear to feel too good or to be too happy, different from his/her					
2.	Does the pati	ent fi	nd humor and laugh at things that others do not find funny?					
3.	Does the patient seem to have a childish sense of humor with a tendency to giggle or laugh inappropriately (such as when something unfortunate happens to others)?							
4.	Does the patient tell jokes or make remarks that have little humor for others but seem funny to him/her?							
5.	Does he/she play childish pranks such as pinching or playing "keep away" for the fun of it?							
6.	Does the pati	ent "t	alk big" or claim to have more abilities or wealth than is true?					
7.	Does the patie	ent sl	now any other signs of feeling too good or being too happy?					
	ne screening q ohoria.	uesti	on is confirmed, determine the frequency and severity of the elation/					
	Frequency:	1. 2. 3. 4.	Occasionally - less than once per week.  Often - about once per week.  Frequently - several times per week but less than every day.  Very frequently - once or more per day.					
	Severity:	1. 2. 3.	Mild - elation is notable to friends and family but is not disruptive.  Moderate - elation is notably abnormal.  Marked - elation is very pronounced; patient is euphoric and finds nearly everything to be humorous.					
	<u>Distress</u> :	Ho	w emotionally distressing do you find this behavior:  0. Not at all  1. Minimally  2. Mildly  3. Moderately  4. Severely  5. Very severely or extremely					



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YES (If yes, proceed to subquestions).

## G. Apathy/Indifference

NO (If no, proceed to the next screening question)

Has the patient lost interest in the world around him/her? Has he/she lost interest in doing things or lack motivation for starting new activities? Is he/she more difficult to engage in conversation or in doing chores? Is the patient apathetic or indifferent?

Does the patient seem less spontaneous and less active than usual?
 Is the patient less likely to initiate a conversation?
 Is the patient less affectionate or lacking in emotions when compared to his/her usual self?
 Does the patient contribute less to household chores?
 Does the patient seem less interested in the activities and plans of others?
 Has the patient lost interest in friends and family members?
 Is the patient less enthusiastic about his/her usual interests?
 Does the patient show any other signs that he/she doesn't care about doing new things?

If the screening question is confirmed, determine the frequency and severity of the apathy/indifference.

Frequency:

- 1. Occasionally less than once per week.
- 2. Often about once per week.
- 3. Frequently several times per week but less than every day.
- 4. Very frequently once or more per day.

Severity:

- 1. Mild apathy is notable but produces little interference with daily routines; only mildly different from patient's usual behavior; patient responds to suggestions to engage in activities.
- 2. Moderate apathy is very evident; may be overcome by the caregiver with coaxing and encouragement; responds spontaneously only to powerful events such as visits from close relatives or family members.
- 3. Marked apathy is very evident and usually fails to respond to any encouragement or external events.

Distress:

How emotionally distressing do you find this behavior:

- 0. Not at all
- 1. Minimally
- 2. Mildly
- 3. Moderately
- 4. Severely
- 5. Very severely or extremely



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# H. Disinhibition

Does the patient seem to act impulsively without thinking? Does he/she do or say things that are not usually done or said in public? Does he/she do things that are embarrassing to you or others?

NO	(If no, proceed	d to th	e next screening question)	YES (If yes, proceed to subquestions).					
1.	Does the patie	ent ac	t impulsively without appearing	to consider the consequences?					
2.	Does the patie	ent tal	k to total strangers as if he/she	knew them?					
3.	Does the patient say things to people that are insensitive or hurt their feelings?								
4.	Does the patient say crude things or make sexual remarks that they would not usually have said?								
5.	Does the patient talk openly about very personal or private matters not usually discussed in public?								
6.	Does the patie for him/her		ce liberties or touch or hug other	ers in way that is out of character					
7.	Does the patie	ent sh	ow any other signs of loss of c	ontrol of his/her impulses?					
lf th	ne screening qu	uestio	n is confirmed, determine the f	requency and severity of the disinhibition.					
	Frequency:	1. 2. 3. 4.	Occasionally - less than once Often - about once per week. Frequently - several times per Very frequently - once or more	week but less than every day.					
	<u>Severity</u> :	<ol> <li>1.</li> <li>2.</li> <li>3.</li> </ol>	guidance.  Moderate - disinhibition is very caregiver.  Marked - disinhibition usually	ut usually responds to redirection and vevident and difficult to overcome by the fails to respond to any intervention by urce of embarrassment or social distress.					
	<u>Distress</u> :	Hov	v emotionally distressing do you 0. Not at all 1. Minimally 2. Mildly 3. Moderately 4. Severely 5. Very severely or extremely						



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# I. Irritability/Lability

Does the patient get irritated and easily disturbed? Are his/her moods very changeable? Is he/she abnormally impatient? We do not mean frustration over memory loss or inability to perform usual tasks; we are interested to know if the patient has <u>abnormal</u> irritability, impatience, or rapid emotional changes different from his/her usual self.

NO	(If no, procee	d to th	ne next screening question)	YES (If yes, proceed to subquestions)	) .				
1.	Does the patient have a bad temper, flying "off the handle" easily over little things?								
2.	Does the patient rapidly change moods from one to another, being fine one minute and angry the next?								
3.	Does the patient have sudden flashes of anger?								
4.	Is the patient impatient, having trouble coping with delays or waiting for planned activities?								
5.	Is the patient	crank	y and irritable?		_				
6.	Is the patient	argun	nentative and difficult to get alo	ng with?					
7.	Does the patie	ent sh	ow any other signs of irritability	?	_				
If th		uestic	n is confirmed, determine the f	requency and severity of the irritability/					
	Frequency:	1. 2. 3. 4.	Occasionally - less than once Often - about once per week. Frequently - several times per Very frequently - once or more	week but less than every day.					
	Severity:	<ol> <li>1.</li> <li>2.</li> <li>3.</li> </ol>	overcome by the caregive Marked - irritability and lability	ce. ty are very evident and difficult to	•				
	<u>Distress</u> :	Ho	w emotionally distressing do yo	u find this behavior:					

Minimally
 Mildly
 Moderately
 Severely



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# J. Aberrant Motor Behavior

Does the patient pace, do things over and over such as opening closets or drawers, or repeatedly pick at things or wind string or threads?

NC	(If no, procee	d to th	e next scre	ening question)	YES (If yes, proceed to subq	uestions).				
1.	Does the pati	ent pa	ce around t	he house withou	t apparent purpose?					
2.	Does the pati	Does the patient rummage around opening and unpacking drawers or closets?								
3.	Does the pati	ent re <sub>l</sub>	peatedly put	t on and take off	clothing?					
4.	Does the patient have repetitive activities or "habits" that he/she performs over and over?									
5.	Does the patient engage in repetitive activities such as handling buttons, picking wrapping string, etc?									
6.	Does the patient fidget excessively, seem unable to sit still, or bounce his/her feet or tap his/her fingers a lot?									
7.	Does the pati	ent do	any other a	activities over and	d over?					
	ne screening q ivity:	uestio	n is confirm	ed, determine the	e frequency and severity of the ab	errant motor				
	Frequency:	1. 2. 3. 4.	Often - abo Frequently	lly - less than one out once per wee - several times p ently - once or m	k. oer week but less than every day.					
	Severity:	<ol> <li>2.</li> <li>3.</li> </ol>	with da Moderate - the car Marked - a	nily routines. abnormal motor regiver. bnormal motor a intervention by the	ity is notable but produce little interactivity is very evident; can be overtivity is very evident, it usually faine caregiver and is are a major so	ercome by Is to respond				
	<u>Distress</u> :	Hov	w emotional 0. Not at a 1. Minima 2. Mildly 3. Modera 4. Severe	all ally ately	you find this behavior:					



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# K. Sleep

Does the patient have difficulty sleeping (do not count as present if the patient simply gets up once or twice per night only to go to the bathroom and falls back asleep immediately)? Is he/she up at night? Does he/she wander at night, get dressed, or disturb your sleep?

NC	) (If no. procee	d to th	e next screening question)	YES (If yes, proceed to subque	stions).				
1.									
•									
2.	Does the patient get up during the night (do not count if the patient gets up once or twice per night only to go to the bathroom and falls back asleep immediately)?								
3.	Does the patient wander, pace, or get involved in inappropriate activities at night?								
4.	Does the patient awaken you during the night?								
5.	Does the patient awaken at night, dress, and plan to go out thinking that it is morning and time to start the day?								
6.	Does the patie	ent av	vaken too early in the morning	(earlier that was his/her habit)?					
7.	Does the patie	ent sle	eep excessively during the day	?					
8.	Does the pation		ve any other night-time behav	ors that bother you that we					
	ne screening q navior disturba		n is confirmed, determine the f	requency and severity of the night	-time				
	Frequency:	1. 2. 3. 4.	Occasionally - less than once Often - about once per week. Frequently - several times per Very frequently - once or more	week but less than every day.					
	Severity:	1. 2.	Moderate - night-time behavio	cur but they are not particularly dis ors occur and disturb the patient and n one type of night-time behavior	nd the sleep				
		3.	Marked - night-time behaviors	occur; several types of night-time nt is very distressed during the nigedly disturbed.					
	<u>Distress</u> :	Hov	w emotionally distressing do yo 0. Not at all 1. Minimally	ou find this behavior:					

Mildly
 Moderately
 Severely



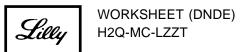
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# L. Appetite and eating disorders

Has he/she had any change in appetite, weight, or eating habits (count as NA if the patient is incapacitated and has to be fed)? Has there been any change in type of food he/she prefers?

NC	(if no, procee	a to the	e next screening question)	YES (If yes, proceed to subque	stions).					
1.	Has he/she ha	ad a lo	ss of appetite?							
2.	Has he/she had an increase in appetite?									
3.	Has he/she had a loss of weight?									
4.	Has he/she ga	ained w	veight?							
5.	Has he/she had a change in eating behavior such as putting too much food in his/her mouth at once?									
6.	Has he/she had a change in the kind of food he/she likes such as eating too many sweets or other specific types of food?									
7.			ed eating behaviors such as $\epsilon$ g the food in exactly the sam	eating exactly the same types of for early early early the same types of for early e	od 					
8.	Have there be	en any	other changes in appetite or	eating that I haven't asked about?	·					
	he screening q ting habits or a			frequency and severity of the chan	ges in					
	Frequency:	2. 3.	Occasionally - less than once Often - about once per week. Frequently - several times pe Very frequently - once or mor	r week but less than every day.						
	Severity:	2.	in weight and are not dist Moderate - changes in appeti fluctuations in weight. Marked - obvious changes in	eating are present but have not led urbing te or eating are present and cause appetite or eating are present and embarrassing, or otherwise distur	minor					
	<u>Distress</u> :	(	emotionally distressing do yo D. Not at all 1. Minimally	ou find this behavior:						

Mildly
 Moderately
 Severely



Tilly	H2	Q-MC-LZZ1 Investigate	r No.			_
		Patient No				_
		Visit		_		
	Ī	SABILITY ASSESSMENT FOR DEMENTIA (DAD)				
	IN	FORMATION NOT OBTAINED Not Entered In Database				
		Clinician's initials  Not Entered In Database				
		First Middle Last				1
	Di	uring the past two weeks, did the patient without help or reminder:	tion	Planning & Organization	Effective Performance	
		QSSCAT HYGIENE  SCORING: Yes = 1 No = 0 Not Applicable = 96	Initiation	Planr Orga	Effec	
QSTESTCD	1.	Undertake to wash himself/herself or to take a bath or a shower				QSORRES
QSTESTCD	2.	Undertake to brush his/her teeth or care for his/her dentures				QSORRES
QSTESTCD	3.	Decide to care for his/her hair (wash and comb)				QSORRES
QSTESTCD	4.	Prepare the water, towels, and soap for washing, taking a bath, or a shower				QSORRES
QSTESTCD	5.	Wash and dry completely all parts of his/her body safely				QSORRES
QSTESTCD	6.	Brush his/her teeth or care for his/her dentures appropriately				QSORRES
QSTESTCD	7.	Care for his/her hair (wash and comb)				QSORRES
		DRESSING QSSCAT			_	
QSTESTCD	8.	Undertake to dress himself/herself				QSORRES
QSTESTCD	9.	Choose appropriate clothing (with regard to the occasion, neatness, the weather, and color combination)				QSORRES
QSTESTCC	10.	Dress himself/herself in the appropriate order (undergarments, pant/dress, shoes)				QSORRES
QSTESTCD	11.	Dress himself/herself completely				QSORRES
QSTESTCD	12.	Undress himself/herself completely				QSORRES
		CONTINENCE QSSCAT				ı
QSTESTCD	13.	Decide to use the toilet at appropriate times				QSORRES
QSTESTCD	14.	Use the toilet without "accidents"				QSORRES
		EATING QSSCAT			-	•
QSTESTCD	15.	Decide that he/she needs to eat				QSORRES

Choose appropriate utensils and seasonings when eating

Undertake to prepare a light meal or snack for himself/herself

Prepare or cook a light meal or a snack safely

Adequately plan a light meal or snack (ingredients, cookware)

MEAL PREPARATION QSSCAT

Eat his/her meals at a normal pace and with appropriate manners

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**QSTESTCD** 

QSTESTCD <sub>17.</sub>

QSTESTCD 18.

QSTESTCD 19.

QSTESTCD <sub>20.</sub>

**QSORRES** 

**QSORRES** 

**QSORRES** 

# DISABILITY ASSESSMENT FOR DEMENTIA (DAD)

		QSSCAT TELEPHONING	SCORING:	Yes = 1	No = 0	Not Appli	cable = 96	Initiation	Planning & Organization	Effective Performance	
	21.	Attempt to telephone	e someone at	a suitable	time						QSORRES
	22.	Find and dial a tel	lephone numb	er correctly	/						QSORRES
	23.	Carry out an a	ppropriate tele	ephone con	versation						QSORRES
QSTESTCD	24.	Write and conv	vey a telephon	ne message	e adequately						QSORRES
		GOING ON AN OUT	ING QSSCA	\T							·
QSTESTCD	25.	Undertake to go out	(walk, visit, sl	hop) at an	appropriate	ime					QSORRES
QSTESTCD	26.	Adequately organi weather, necessar	•	•	t to transpor	tation, keys,	destination,				QSORRES
QSTESTCD	27.	Go out and rea	ach a familiar	destination	without gett	ing lost					QSORRES
<b>QSTESTCD</b>	28.	Safely take the	adequate mo	ode of trans	sportation (c	ar, bus, taxi)					QSORRES
COTFOTOR	29.	Return from the	e store with th	ne appropri	ate items						QSORRES
		FINANCE AND COR								<u> </u>	
QSTESTCD		Show an interest in correspondence				er finances a	nd written				QSORRES
QSTESTCD	31.	Organize his/her f	inances to pay	y his/her bi	lls (cheques	bankbook, b	ills)				QSORRES
QSTESTCD	32.	Adequately organize	e his/her corres	pondence w	ith respect to	stationery, add	dress, stamps				QSORRES
QSTESTCD	33.	Handle adequate	ely his/her mon	ey (make ch	nange)						QSORRES
		MEDICATIONS Q	SSCAT	_							•
QSTESTCD	34.	Decide to take his/h	er medications	s at the cor	rect time						QSORRES
QSTESTCD	35.	Take his/her m	nedications as	prescribed	(according	to the right do	osage)				QSORRES
		LEISURE AND HOU	SEWORK Q	SSCAT							•
	36.	Show an interest in	leisure activity	(ies)							QSORRES
	37.	Take an interest in h	nousehold cho	res that he	/she used to	perform in the	ne past				QSORRES
	38.	Plan and organize a	adequately hous	sehold chore	s that he/she	used to perfor	m in the past				QSORRES
	39.	Complete hous	sehold chores	adequately	/ as he/she i	used to perfo	rm in the past				QSORRES
QSTESTCD	40.	Stay safely at l	home by hims	elf/herself	when neede	d					QSORRES