WORKSHEET (DNDE)
H2Q-MC-LZZT

Date: _____/_____/_____

ENTRY PROCEDURES AND CRITERIA FOR ENROLLMENT

Inclusion Criteria: The answers for Items 1-8 must be YES to qualify for study**.**

Yes No

☐ ☐ 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.

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ENTRY PROCEDURES AND CRITERIA FOR ENROLLMENT

Inclusion Criteria: The answers for Items 1-8 must be YES to qualify for study**.**

Yes No

☐ ☐ 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.

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

Yes No

☐ ☐ 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.

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

Yes	No	
☐	☐	15. 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

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

Yes	No		
☐	☐	19.	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
☐	☐	20.	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
☐	☐	22.	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.
☐	☐	26.	Visual, hearing, or communication disabilities impairing the ability to participate in the study; (for example, inability to speak or understand English, illiteracy).

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

Yes No

☐ ☐ 27. 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.

☐ ☐ 29. 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)

b) Alpha receptor blockers including but not limited to
- Catapresâ (clonidine)
- Aldometâ (methyldopa)

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)

g) Muscle relaxants-centrally active including but not limited to
- Flexerilâ (cyclobenzaprine)
- Somaâ (carisoprodol)

h) Monoamine oxidase inhibitors (MAOI) including but not limited to
- Nardilâ (phenelzine)
- Eldeprylâ (selegiline)
- Parnateâ (tranylcypromine)

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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)
- Urispasâ (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)

l) Xanthine derivatives including but not limited to
- Theo-Durâ (theophylline)

m) Histamine (H_2) 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)
- Librumâ (chlordiazepoxide)

Ativanâ (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_1) antagonists including but not limited to
- Benadrylâ (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

Patient initials _____ _____ _____
First Middle Last

Visit date _____/_____/_____
MM DD YY

INFORMED CONSENT

Date patient and caregiver signed the consent document _____/_____/_____
MM DD YY

DEMOGRAPHICS

Date of birth _____/_____/_____
MM DD YY

Sex ☐$_{F}$ Female ☐$_{M}$ Male

Origin ☐$_{CA}$ Caucasian (European**,** Mediterranean, Middle Eastern)

☐$_{AF}$ African Descent (Negro, Black)

☐$_{EA}$ East/Southeast Asian (Burmese, Chinese, Japanese, Korean, Mongolian, Vietnamese)

☐$_{AS}$ Western Asian (Pakistani, Indian Sub-continent)

☐$_{HP}$ Hispanic (Mexican-American, Mexico, Central and South America)

☐$_{O}$ 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.

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EDUCATION

Number of years of education completed _____ years

HABITS : SMOKING

INFORMATION NOT OBTAINED ☐

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 _____

Number of cigars _____

Number of pipesful _____

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

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

Enter the month and year that the patient quit smoking. _____/_____ MM YY

HABITS : ALCOHOL

INFORMATION NOT OBTAINED ☐

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 _____

Number of glasses of wine _____

Number of drinks containing distilled spirits _____

HABITS : CAFFEINE

INFORMATION NOT OBTAINED ☐

Enter the average current daily consumption	
0	= None
L	= Less than one
1, 2, 3, etc	= Whole numbers ONLY

Number of cups of coffee _____

Number of cups of tea _____

Number of colas _____

MINI-MENTAL STATE

INFORMATION NOT OBTAINED ☐

	Score	Maximum Score	
			Orientation
1.	___	(5)	What is the (year) (season) (date) (day) (month)?
2.	___	(5)	Where are we: (state) (county) (town) (hospital) (floor)?
			Registration
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.
			Attention and Calculation
4.	___	(5)	Serial 7's. 1 point for each correct. Stop after 5 answers. Alternatively, spell "world" backwards.
			Recall
5.	___	(3)	Ask for the 3 objects repeated above. Give 1 point for each correct.
			Language
6.	___	(9)	Name a pencil, and watch (2 points) 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)

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 consciousness along a continuum _____

Alert Drowsy Stupor Coma

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MODIFIED HACHINSKI ISCHEMIC SCORE

INFORMATION NOT OBTAINED ☐

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

Feature	Present	Absent
1. Abrupt onset	2	0
2. Stepwise deterioration	1	0
3. Fluctuating course	2	0
4. Nocturnal confusion	1	0
5. Relative preservation of personality	1	0
6. Depression	1	0
7. Somatic complaints	1	0
8. Emotional incontinence	1	0
9. History of hypertension	1	0
10. History of strokes	2	0
11. Evidence of associated atherosclerosis	1	0
12. Focal neurological symptoms	2	0
13. Focal neurological signs	2	0

(DNDE)

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.

Arch Neurol 1975;32:632-37.

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PATIENT HISTORY : ALZHEIMER'S DISEASE ONSET DATE

Date of onset of the first definite symptoms of Alzheimer's Disease _____/___/_____
MM DD YY

CLINICAL FEATURES : ALZHEIMER'S DISEASE

INFORMATION NOT OBTAINED ☐

Does 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 ☐1 Yes ☐2 No
2. Essential tremor (action or postural) ☐1 Yes ☐2 No
3. Sensitivity to neuroleptics ☐1 Yes ☐2 No
4. Marked deficit of attention and/or fluctuations in level of attention and alertness; confusional episodes ☐1 Yes ☐2 No
5. Visual hallucinations and/or paranoid delusions ☐1 Yes ☐2 No

EXTRAPYRAMIDAL FINDINGS

INFORMATION NOT OBTAINED ☐

1. Masked facies
   - ☐ 0 None
   - ☐ 1 Mild
   - ☐ 2 Moderate
   - ☐ 3 Severe

2. Rigidity of upper extremity
   - ☐ 0 None
   - ☐ 1 Mild
   - ☐ 2 Moderate
   - ☐ 3 Severe

3. Essential tremor
   - ☐ 0 None
   - ☐ 1 Mild
   - ☐ 2 Moderate
   - ☐ 3 Severe

4. Ambulation

   How long did it take the patient to walk 25 yards? _____ seconds

SIGNIFICANT HISTORICAL DIAGNOSIS

NO 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 COSTART Class Term	Date Recovered/Date of Surgical Procedure MM	DD	YY
0.				
1.				
2.				
3.				
4.				
5.				
6.				
7.				
8.				

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 COSTART Class Term	Date Recovered/Date of Surgical Procedure MM	DD	YY

WEIGHT

INFORMATION NOT OBTAINED ☐

Measure with shoes off. Round up or down to the nearest tenth kilogram or tenth pound.

Weight ___ ___ ___ . ___ ☐ kg Kilogram ☐ lb Pound

HEIGHT

INFORMATION NOT OBTAINED ☐

Measure with shoes off. Round up or down to the nearest tenth inch or tenth centimeter.

Height ___ ___ ___ . ___ ☐ cm Centimeter ☐ in Inch

VITAL SIGNS : HEART RATE AND BLOOD PRESSURE

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) and 3 minutes.

Position
SU = Supine
ST = Standing

	(DNDE) Reference Time	Timing Code	Position	Heart Rate (bpm)	Blood Pressure (mmHg) Systolic/Diastolic
0.	5 minutes	815	SU		/
1.	1 minute	816	ST		/
2.	3 minutes	817	ST		/

VITAL SIGNS : TEMPERATURE

INFORMATION NOT OBTAINED ☐

Temperature ___ ___ ___ . ___

Unit of measure ☐ F Fahrenheit ☐ C Centigrade

Method ☐ PO Oral ☐ R Rectal ☐ A Axillary ☐ E Ear ☐ O Other

ELECTROCARDIOGRAM

NOT DONE ☐

Electrocardiogram date _____/_____/_____
MM DD YY

Electrocardiogram result ☐ 12 Acceptable ☐ 13 Not Acceptable

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 ECG Comments section below.

COMMENTS : NON-RELEVANT ECG ABNORMALITIES

NO COMMENTS ☐

Print legibly and do not use abbreviations or symbols.

CHEST X-RAY

NOT DONE ☐

Was the chest x-ray ☐ 1 Taken for this visit ☐ 611 Historical (within the previous 6 months)

Date of chest x-ray _____/_____/_____
MM DD YY

Chest x-ray result ☐ 12 Acceptable ☐ 13 Not Acceptable

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 Chest X-ray Comments section below.

COMMENTS : NON-RELEVANT CHEST X-RAY ABNORMALITIES

NO COMMENTS ☐

Print legibly and do not use abbreviations or symbols.

PROCEDURE : MRI

NOTE: **Either** a CT scan **OR** MRI of the brain, which is compatible with Alzheimer's Disease, is required to enter this trial.

NOT DONE ☐

Was the MRI ☐ 1 Taken for this visit ☐ 2 Historical (within the previous 12 months)

Date of MRI _____/_____/_____
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 MRI Comments section below.

COMMENTS : NON-RELEVANT MRI ABNORMALITIES

NO COMMENTS ☐

Print legibly and do not use abbreviations or symbols.

PROCEDURE : CT SCAN

NOTE: **Either** a CT scan **OR** MRI of the brain, which is compatible with Alzheimer's Disease, is required to enter this trial.

NOT DONE ☐

Was the CT scan ☐ 1 Taken for this visit ☐ 2 Historical (within the previous 12 months)

Date of CT scan _____/_____/_____
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 CT Scan Comments section below.

COMMENTS : NON-RELEVANT CT SCAN ABNORMALITIES

NO COMMENTS ☐

Print legibly and do not use abbreviations or symbols.

COMMENTS : VISIT

NO COMMENTS ☐

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.

The information reported for this visit is accurate and complete.

_____ _____/_____/_____
Signature MM DD YY

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PATIENT AND VISIT IDENTIFICATION

Patient initials _____ _____ _____
First Middle Last

Visit date _____/_____/_____
MM DD YY

VITAL SIGNS : HEART RATE AND BLOOD PRESSURE

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) and 3 minutes.

Position
SU = Supine
ST = Standing

	(DNDE) Reference Time	Timing Code	Position	Heart Rate (bpm)	Blood Pressure (mmHg) Systolic/Diastolic
0.	5 minutes	815	SU		/
1.	1 minute	816	ST		/
2.	3 minutes	817	ST		/

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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VITAL SIGNS : TEMPERATURE

INFORMATION NOT OBTAINED ☐

Temperature ___ ___ ___ . ___

Unit of measure ☐ F Fahrenheit ☐ C Centigrade

Method ☐ PO Oral ☐ R Rectal ☐ A Axillary ☐ E Ear ☐ O Other

PROCEDURE : AMBULATORY ECG

NOT DONE ☐

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.

COMMENTS : NON-RELEVANT AMBULATORY ECG ABNORMALITIES

NO COMMENTS ☐

Print legibly and do not use abbreviations or symbols.

COMMENTS : VISIT

NO COMMENTS ☐

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.

The information reported for this visit is accurate and complete.

_____ _____/_____/_____
Signature MM DD YY

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PATIENT AND VISIT IDENTIFICATION

Patient initials _____ _____ _____
First Middle Last

Visit date _____/_____/_____
MM DD YY

KIT NUMBER

NONE DISPENSED ☐

Kit number dispensed _____

STUDY DRUG : DAILY PRESCRIBED DOSAGE

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

Number of 25-cm^2 patches prescribed/day _____
25-cm^2 patches

Number of 50-cm^2 patches prescribed/day _____
50-cm^2 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.

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

INFORMATION NOT OBTAINED ☐

Clinician's initials _____ _____ _____
First Middle Last

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

American Journal of Psychiatry 1984;141:1356-64.

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NEUROPSYCHIATRIC INVENTORY - REVISED (NPI-X)

INFORMATION NOT OBTAINED ☐

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.

Item	Not Applicable	Absent	Frequency	Severity	Distress
A. Delusions	96	0	1 2 3 4	1 2 3	0 1 2 3 4 5
B. Hallucinations	96	0	1 2 3 4	1 2 3	0 1 2 3 4 5
C. Agitation/Agression	96	0	1 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 2 3 4 5
E. Anxiety	96	0	1 2 3 4	1 2 3	0 1 2 3 4 5
F. Euphoria/Elation	96	0	1 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 1 2 3 4 5
H. Disinhibition	96	0	1 2 3 4	1 2 3	0 1 2 3 4 5
I. Irritability/Lability	96	0	1 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 2 3 4 5
K. Night-Time Behavior	96	0	1 2 3 4	1 2 3	0 1 2 3 4 5
L. Appetite/Eating Change	96	0	1 2 3 4	1 2 3	0 1 2 3 4 5

DISABILITY ASSESSMENT FOR DEMENTIA (DAD)

INFORMATION NOT OBTAINED ☐

Clinician's initials _____ _____ _____
First Middle Last

During the past two weeks, did the patient without help or reminder:

SCORING: **Yes = 1** **No = 0** **Not Applicable = 96**

		Initiation	Planning & Organization	Effective Performance
	HYGIENE			
1.	Undertake to wash himself/herself or to take a bath or a shower			
2.	Undertake to brush his/her teeth or care for his/her dentures			
3.	Decide to care for his/her hair (wash and comb)			
4.	Prepare the water, towels, and soap for washing, taking a bath, or a shower			
5.	Wash and dry completely all parts of his/her body safely			
6.	Brush his/her teeth or care for his/her dentures appropriately			
7.	Care for his/her hair (wash and comb)			
	DRESSING			
8.	Undertake to dress himself/herself			
9.	Choose appropriate clothing (with regard to the occasion, neatness, the weather, and color combination)			
10.	Dress himself/herself in the appropriate order (undergarments, pant/dress, shoes)			
11.	Dress himself/herself completely			
12.	Undress himself/herself completely			
	CONTINENCE			
13.	Decide to use the toilet at appropriate times			
14.	Use the toilet without "accidents"			
	EATING			
15.	Decide that he/she needs to eat			
16.	Choose appropriate utensils and seasonings when eating			
17.	Eat his/her meals at a normal pace and with appropriate manners			
	MEAL PREPARATION			
18.	Undertake to prepare a light meal or snack for himself/herself			
19.	Adequately plan a light meal or snack (ingredients, cookware)			
20.	Prepare or cook a light meal or a snack safely			

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DISABILITY ASSESSMENT FOR DEMENTIA (DAD)

SCORING: **Yes = 1** **No = 0** **Not Applicable = 96**

		Initiation	Planning & Organization	Effective Performance
	TELEPHONING			
21.	Attempt to telephone someone at a suitable time			
22.	Find and dial a telephone number correctly			
23.	Carry out an appropriate telephone conversation			
24.	Write and convey a telephone message adequately			
	GOING ON AN OUTING			
25.	Undertake to go out (walk, visit, shop) at an appropriate time			
26.	Adequately organize an outing with respect to transportation, keys, destination, weather, necessary money, shopping list			
27.	Go out and reach a familiar destination without getting lost			
28.	Safely take the adequate mode of transportation (car, bus, taxi)			
29.	Return from the store with the appropriate items			
	FINANCE AND CORRESPONDENCE			
30.	Show an interest in his/her personal affairs such as his/her finances and written correspondence			
31.	Organize his/her finances to pay his/her bills (cheques, bankbook, bills)			
32.	Adequately organize his/her correspondence with respect to stationery, address, stamps			
33.	Handle adequately his/her money (make change)			
	MEDICATIONS			
34.	Decide to take his/her medications at the correct time			
35.	Take his/her medications as prescribed (according to the right dosage)			
	LEISURE AND HOUSEWORK			
36.	Show an interest in leisure activity(ies)			
37.	Take an interest in household chores that he/she used to perform in the past			
38.	Plan and organize adequately household chores that he/she used to perform in the past			
39.	Complete household chores adequately as he/she used to perform in the past			
40.	Stay safely at home by himself/herself when needed			

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WEIGHT

INFORMATION NOT OBTAINED ☐

Measure with shoes off. Round up or down to the nearest tenth kilogram or tenth pound.

Weight ___ ___ ___ . ___ ☐ kg Kilogram ☐ lb Pound

VITAL SIGNS : HEART RATE AND BLOOD PRESSURE

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) and 3 minutes.

Position
SU = Supine
ST = Standing

	(DNDE) Reference Time	Timing Code	Position	Heart Rate (bpm)	Blood Pressure (mmHg) Systolic/Diastolic
0.	5 minutes	815	SU		/
1.	1 minute	816	ST		/
2.	3 minutes	817	ST		/

VITAL SIGNS : TEMPERATURE

INFORMATION NOT OBTAINED ☐

Temperature ___ ___ ___ . ___

Unit of measure ☐ F Fahrenheit ☐ C Centigrade

Method ☐ PO Oral ☐ R Rectal ☐ A Axillary ☐ E Ear ☐ O Other

COMMENTS : VISIT

NO COMMENTS ☐

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.

The information reported for this visit is accurate and complete.

_____ _____/_____/_____
Signature MM DD YY

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PATIENT AND VISIT IDENTIFICATION

Patient initials _____ _____ _____
First Middle Last

Visit date _____/_____/_____
MM DD YY

STUDY DRUG : COMPLIANCE

INFORMATION NOT OBTAINED ☐

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

STUDY DRUG : DAILY PRESCRIBED DOSAGE

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

Number of 25-cm^2 patches prescribed/day _____
25-cm^2 patches

Number of 50-cm^2 patches prescribed/day _____
50-cm^2 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.

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VITAL SIGNS : HEART RATE AND BLOOD PRESSURE

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) and 3 minutes.

Position
SU = Supine
ST = Standing

	(DNDE) Reference Time	Timing Code	Position	Heart Rate (bpm)	Blood Pressure (mmHg) Systolic/Diastolic
0.	5 minutes	815	SU		/
1.	1 minute	816	ST		/
2.	3 minutes	817	ST		/

VITAL SIGNS : TEMPERATURE

INFORMATION NOT OBTAINED ☐

Temperature ___ ___ ___ . ___

Unit of measure ☐ F Fahrenheit ☐ C Centigrade

Method ☐ PO Oral ☐ R Rectal ☐ A Axillary ☐ E Ear ☐ O Other

PROCEDURE : AMBULATORY ECG

NOT DONE ☐

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.

COMMENTS : NON-RELEVANT AMBULATORY ECG ABNORMALITIES

NO COMMENTS ☐

Print legibly and do not use abbreviations or symbols.

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COMMENTS : VISIT

NO COMMENTS ☐

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.

The information reported for this visit is accurate and complete.

_____ _____/_____/_____
Signature MM DD YY

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PATIENT AND VISIT IDENTIFICATION

Patient initials _____ _____ _____
First Middle Last

Visit date _____/_____/_____
MM DD YY

STUDY DRUG : COMPLIANCE

INFORMATION NOT OBTAINED ☐

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

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STUDY DRUG : PATCH ADHERENCE - PREVIOUS THREE DOSES

INFORMATION NOT OBTAINED ☐

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).

	Date	Number of hours 25-cm^2 patch **NOT** applied	Number of hours 50-cm^2 patch **NOT** applied
1. Today's (visit) date	____/____/____ MM DD YY	_____ hours	_____ hours
2. Yesterday's date	____/____/____ MM DD YY	_____ hours	_____ hours
3. Day before yesterday's date	____/____/____ MM DD YY	_____ hours	_____ hours

STUDY DRUG : DAILY PRESCRIBED DOSAGE

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

Number of 25-cm^2 patches prescribed/day _____ 25-cm^2 patches

Number of 50-cm^2 patches prescribed/day _____ 50-cm^2 patches

NEUROPSYCHIATRIC INVENTORY - REVISED (NPI-X)

INFORMATION NOT OBTAINED ☐

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.

Item	Not Applicable	Absent	Frequency	Severity	Distress
A. Delusions	96	0	1 2 3 4	1 2 3	0 1 2 3 4 5
B. Hallucinations	96	0	1 2 3 4	1 2 3	0 1 2 3 4 5
C. Agitation/Agression	96	0	1 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 2 3 4 5
E. Anxiety	96	0	1 2 3 4	1 2 3	0 1 2 3 4 5
F. Euphoria/Elation	96	0	1 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 1 2 3 4 5
H. Disinhibition	96	0	1 2 3 4	1 2 3	0 1 2 3 4 5
I. Irritability/Lability	96	0	1 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 2 3 4 5
K. Night-Time Behavior	96	0	1 2 3 4	1 2 3	0 1 2 3 4 5
L. Appetite/Eating Change	96	0	1 2 3 4	1 2 3	0 1 2 3 4 5

WEIGHT

INFORMATION NOT OBTAINED ☐

Measure with shoes off. Round up or down to the nearest tenth kilogram or tenth pound.

Weight ___ ___ ___ . ___ ☐ kg Kilogram ☐ lb Pound

VITAL SIGNS : HEART RATE AND BLOOD PRESSURE

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) and 3 minutes.

Position
SU = Supine
ST = Standing

	(DNDE) Reference Time	Timing Code	Position	Heart Rate (bpm)	Blood Pressure (mmHg) Systolic/Diastolic
0.	5 minutes	815	SU		/
1.	1 minute	816	ST		/
2.	3 minutes	817	ST		/

VITAL SIGNS : TEMPERATURE

INFORMATION NOT OBTAINED ☐

Temperature ___ ___ ___ . ___

Unit of measure ☐ F Fahrenheit ☐ C Centigrade

Method ☐ PO Oral ☐ R Rectal ☐ A Axillary ☐ E Ear ☐ O Other

ELECTROCARDIOGRAM

NOT DONE ☐

Electrocardiogram date _____/_____/_____
MM DD YY

Electrocardiogram result ☐ 12 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

NO COMMENTS ☐

Print legibly and do not use abbreviations or symbols.

COMMENTS : VISIT

NO COMMENTS ☐

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.

The information reported for this visit is accurate and complete.

_____ _____/_____/_____
Signature MM DD YY

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PATIENT AND VISIT IDENTIFICATION

Patient initials _____ _____ _____
First Middle Last

Visit date _____/_____/_____
MM DD YY

STUDY DRUG : COMPLIANCE

INFORMATION NOT OBTAINED ☐

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

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STUDY DRUG : PATCH ADHERENCE - PREVIOUS THREE DOSES

INFORMATION NOT OBTAINED ☐

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).

	Date	Number of hours 25-cm^2 patch **NOT** applied	Number of hours 50-cm^2 patch **NOT** applied
1. Today's (visit) date	____/____/____ MM DD YY	_____ hours	_____ hours
2. Yesterday's date	____/____/____ MM DD YY	_____ hours	_____ hours
3. Day before yesterday's date	____/____/____ MM DD YY	_____ hours	_____ hours

STUDY DRUG : DAILY PRESCRIBED DOSAGE

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

Number of 25-cm^2 patches prescribed/day _____ 25-cm^2 patches

Number of 50-cm^2 patches prescribed/day _____ 50-cm^2 patches

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NEUROPSYCHIATRIC INVENTORY - REVISED (NPI-X)

INFORMATION NOT OBTAINED ☐

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.

Item	Not Applicable	Absent	Frequency	Severity	Distress
A. Delusions	96	0	1 2 3 4	1 2 3	0 1 2 3 4 5
B. Hallucinations	96	0	1 2 3 4	1 2 3	0 1 2 3 4 5
C. Agitation/Agression	96	0	1 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 2 3 4 5
E. Anxiety	96	0	1 2 3 4	1 2 3	0 1 2 3 4 5
F. Euphoria/Elation	96	0	1 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 1 2 3 4 5
H. Disinhibition	96	0	1 2 3 4	1 2 3	0 1 2 3 4 5
I. Irritability/Lability	96	0	1 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 2 3 4 5
K. Night-Time Behavior	96	0	1 2 3 4	1 2 3	0 1 2 3 4 5
L. Appetite/Eating Change	96	0	1 2 3 4	1 2 3	0 1 2 3 4 5

WEIGHT

INFORMATION NOT OBTAINED ☐

Measure with shoes off. Round up or down to the nearest tenth kilogram or tenth pound.

Weight ___ ___ ___ . ___ ☐ kg Kilogram ☐ lb Pound

VITAL SIGNS : HEART RATE AND BLOOD PRESSURE

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) and 3 minutes.

Position
SU = Supine ST = Standing

	(DNDE) Reference Time	Timing Code	Position	Heart Rate (bpm)	Blood Pressure (mmHg) Systolic/Diastolic
0.	5 minutes	815	SU		/
1.	1 minute	816	ST		/
2.	3 minutes	817	ST		/

VITAL SIGNS : TEMPERATURE

INFORMATION NOT OBTAINED ☐

Temperature ___ ___ ___ . ___

Unit of measure ☐ F Fahrenheit ☐ C Centigrade

Method ☐ PO Oral ☐ R Rectal ☐ A Axillary ☐ E Ear ☐ O Other

ELECTROCARDIOGRAM

NOT DONE ☐

Electrocardiogram date _____/_____/_____
MM DD YY

Electrocardiogram result ☐ 12 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

NO COMMENTS ☐

Print legibly and do not use abbreviations or symbols.

PROCEDURE : AMBULATORY ECG

NOT DONE ☐

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.

COMMENTS : NON-RELEVANT AMBULATORY ECG ABNORMALITIES

NO COMMENTS ☐

Print legibly and do not use abbreviations or symbols.

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COMMENTS : VISIT

NO COMMENTS ☐

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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.

The information reported for this visit is accurate and complete.

_____ _____/_____/_____
Signature MM DD YY

PATIENT AND VISIT IDENTIFICATION

Patient initials _____ _____ _____
First Middle Last

Visit date _____/_____/_____
MM DD YY

STUDY DRUG : COMPLIANCE

INFORMATION NOT OBTAINED ☐

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

STUDY DRUG : DAILY PRESCRIBED DOSAGE

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

Number of 25-cm^2 patches prescribed/day _____
25-cm^2 patches

Number of 50-cm^2 patches prescribed/day _____
50-cm^2 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.

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VITAL SIGNS : HEART RATE AND BLOOD PRESSURE

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) and 3 minutes.

Position
SU = Supine
ST = Standing

	(DNDE) Reference Time	Timing Code	Position	Heart Rate (bpm)	Blood Pressure (mmHg) Systolic/Diastolic
0.	5 minutes	815	SU		/
1.	1 minute	816	ST		/
2.	3 minutes	817	ST		/

VITAL SIGNS : TEMPERATURE

INFORMATION NOT OBTAINED ☐

Temperature ___ ___ ___ . ___

Unit of measure ☐ F Fahrenheit ☐ C Centigrade

Method ☐ PO Oral ☐ R Rectal ☐ A Axillary ☐ E Ear ☐ O Other

COMMENTS : VISIT

NO COMMENTS ☐

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Print legibly and do not use abbreviations or symbols.

The information reported for this visit is accurate and complete.

_____ _____/_____/_____
Signature MM DD YY

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PATIENT AND VISIT IDENTIFICATION

Patient initials _____ _____ _____
First Middle Last

Visit date _____/_____/_____
MM DD YY

STUDY DRUG : COMPLIANCE

INFORMATION NOT OBTAINED ☐

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

REMINDER

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STUDY DRUG : PATCH ADHERENCE - PREVIOUS THREE DOSES

INFORMATION NOT OBTAINED ☐

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).

	Date	Number of hours 25-cm^2 patch **NOT** applied	Number of hours 50-cm^2 patch **NOT** applied
1. Today's (visit) date	____/____/____ MM DD YY	_____ hours	_____ hours
2. Yesterday's date	____/____/____ MM DD YY	_____ hours	_____ hours
3. Day before yesterday's date	____/____/____ MM DD YY	_____ hours	_____ hours

STUDY DRUG : DAILY PRESCRIBED DOSAGE

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

Number of 25-cm^2 patches prescribed/day _____ 25-cm^2 patches

Number of 50-cm^2 patches prescribed/day _____ 50-cm^2 patches

NEUROPSYCHIATRIC INVENTORY - REVISED (NPI-X)

INFORMATION NOT OBTAINED ☐

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.

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B. Hallucinations	96	0	1 2 3 4	1 2 3	0 1 2 3 4 5
C. Agitation/Agression	96	0	1 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 2 3 4 5
E. Anxiety	96	0	1 2 3 4	1 2 3	0 1 2 3 4 5
F. Euphoria/Elation	96	0	1 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 1 2 3 4 5
H. Disinhibition	96	0	1 2 3 4	1 2 3	0 1 2 3 4 5
I. Irritability/Lability	96	0	1 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 2 3 4 5
K. Night-Time Behavior	96	0	1 2 3 4	1 2 3	0 1 2 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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WEIGHT

INFORMATION NOT OBTAINED ☐

Measure with shoes off. Round up or down to the nearest tenth kilogram or tenth pound.

Weight ___ ___ ___ . ___ ☐ kg Kilogram ☐ lb Pound

VITAL SIGNS : HEART RATE AND BLOOD PRESSURE

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) and 3 minutes.

Position
SU = Supine
ST = Standing

	(DNDE) Reference Time	Timing Code	Position	Heart Rate (bpm)	Blood Pressure (mmHg) Systolic/Diastolic
0.	5 minutes	815	SU		/
1.	1 minute	816	ST		/
2.	3 minutes	817	ST		/

VITAL SIGNS : TEMPERATURE

INFORMATION NOT OBTAINED ☐

Temperature ___ ___ ___ . ___

Unit of measure ☐ F Fahrenheit ☐ C Centigrade

Method ☐ PO Oral ☐ R Rectal ☐ A Axillary ☐ E Ear ☐ O Other

ELECTROCARDIOGRAM

NOT DONE ☐

Electrocardiogram date _____/_____/_____
MM DD YY

Electrocardiogram result ☐ 12 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

NO COMMENTS ☐

Print legibly and do not use abbreviations or symbols.

COMMENTS : VISIT

NO COMMENTS ☐

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.

The information reported for this visit is accurate and complete.

_____ _____/_____/_____
Signature MM DD YY

PATIENT AND VISIT IDENTIFICATION

Patient initials _____ _____ _____
First Middle Last

Visit date _____/_____/_____
MM DD YY

STUDY DRUG : COMPLIANCE

INFORMATION NOT OBTAINED ☐

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

STUDY DRUG : DAILY PRESCRIBED DOSAGE

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

Number of 25-cm^2 patches prescribed/day _____
25-cm^2 patches

Number of 50-cm^2 patches prescribed/day _____
50-cm^2 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.

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

INFORMATION NOT OBTAINED ☐

Clinician's initials _____ _____ _____
First Middle Last

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

American Journal of Psychiatry 1984;141:1356-64.

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

INFORMATION NOT OBTAINED ☐

Clinician's initials _____ _____ _____
First Middle Last

Check one box to indicate the extent of change, if any, observed since the initial baseline interview.

☐ 1 Marked improvement

☐ 2 Moderate improvement

☐ 3 Minimal improvement

☐ 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.

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NEUROPSYCHIATRIC INVENTORY - REVISED (NPI-X)

INFORMATION NOT OBTAINED ☐

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.

Item	Not Applicable	Absent	Frequency	Severity	Distress
A. Delusions	96	0	1 2 3 4	1 2 3	0 1 2 3 4 5
B. Hallucinations	96	0	1 2 3 4	1 2 3	0 1 2 3 4 5
C. Agitation/Agression	96	0	1 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 2 3 4 5
E. Anxiety	96	0	1 2 3 4	1 2 3	0 1 2 3 4 5
F. Euphoria/Elation	96	0	1 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 1 2 3 4 5
H. Disinhibition	96	0	1 2 3 4	1 2 3	0 1 2 3 4 5
I. Irritability/Lability	96	0	1 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 2 3 4 5
K. Night-Time Behavior	96	0	1 2 3 4	1 2 3	0 1 2 3 4 5
L. Appetite/Eating Change	96	0	1 2 3 4	1 2 3	0 1 2 3 4 5

DISABILITY ASSESSMENT FOR DEMENTIA (DAD)

INFORMATION NOT OBTAINED ☐

Clinician's initials _____ _____ _____
First Middle Last

During the past two weeks, did the patient without help or reminder:

SCORING: **Yes = 1** **No = 0** **Not Applicable = 96**

		Initiation	Planning & Organization	Effective Performance
	HYGIENE			
1.	Undertake to wash himself/herself or to take a bath or a shower			
2.	Undertake to brush his/her teeth or care for his/her dentures			
3.	Decide to care for his/her hair (wash and comb)			
4.	Prepare the water, towels, and soap for washing, taking a bath, or a shower			
5.	Wash and dry completely all parts of his/her body safely			
6.	Brush his/her teeth or care for his/her dentures appropriately			
7.	Care for his/her hair (wash and comb)			
	DRESSING			
8.	Undertake to dress himself/herself			
9.	Choose appropriate clothing (with regard to the occasion, neatness, the weather, and color combination)			
10.	Dress himself/herself in the appropriate order (undergarments, pant/dress, shoes)			
11.	Dress himself/herself completely			
12.	Undress himself/herself completely			
	CONTINENCE			
13.	Decide to use the toilet at appropriate times			
14.	Use the toilet without "accidents"			
	EATING			
15.	Decide that he/she needs to eat			
16.	Choose appropriate utensils and seasonings when eating			
17.	Eat his/her meals at a normal pace and with appropriate manners			
	MEAL PREPARATION			
18.	Undertake to prepare a light meal or snack for himself/herself			
19.	Adequately plan a light meal or snack (ingredients, cookware)			
20.	Prepare or cook a light meal or a snack safely			

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DISABILITY ASSESSMENT FOR DEMENTIA (DAD)

SCORING: **Yes = 1** **No = 0** **Not Applicable = 96**

		Initiation	Planning & Organization	Effective Performance
	TELEPHONING			
21.	Attempt to telephone someone at a suitable time			
22.	Find and dial a telephone number correctly			
23.	Carry out an appropriate telephone conversation			
24.	Write and convey a telephone message adequately			
	GOING ON AN OUTING			
25.	Undertake to go out (walk, visit, shop) at an appropriate time			
26.	Adequately organize an outing with respect to transportation, keys, destination, weather, necessary money, shopping list			
27.	Go out and reach a familiar destination without getting lost			
28.	Safely take the adequate mode of transportation (car, bus, taxi)			
29.	Return from the store with the appropriate items			
	FINANCE AND CORRESPONDENCE			
30.	Show an interest in his/her personal affairs such as his/her finances and written correspondence			
31.	Organize his/her finances to pay his/her bills (cheques, bankbook, bills)			
32.	Adequately organize his/her correspondence with respect to stationery, address, stamps			
33.	Handle adequately his/her money (make change)			
	MEDICATIONS			
34.	Decide to take his/her medications at the correct time			
35.	Take his/her medications as prescribed (according to the right dosage)			
	LEISURE AND HOUSEWORK			
36.	Show an interest in leisure activity(ies)			
37.	Take an interest in household chores that he/she used to perform in the past			
38.	Plan and organize adequately household chores that he/she used to perform in the past			
39.	Complete household chores adequately as he/she used to perform in the past			
40.	Stay safely at home by himself/herself when needed			

WEIGHT

INFORMATION NOT OBTAINED ☐

Measure with shoes off. Round up or down to the nearest tenth kilogram or tenth pound.

Weight ___ ___ ___ . ___ ☐ kg Kilogram ☐ lb Pound

VITAL SIGNS : HEART RATE AND BLOOD PRESSURE

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) and 3 minutes.

Position
SU = Supine ST = Standing

	(DNDE) Reference Time	Timing Code	Position	Heart Rate (bpm)	Blood Pressure (mmHg) Systolic/Diastolic
0.	5 minutes	815	SU		/
1.	1 minute	816	ST		/
2.	3 minutes	817	ST		/

VITAL SIGNS : TEMPERATURE

INFORMATION NOT OBTAINED ☐

Temperature ___ ___ ___ . ___

Unit of measure ☐ F Fahrenheit ☐ C Centigrade

Method ☐ PO Oral ☐ R Rectal ☐ A Axillary ☐ E Ear ☐ O Other

ELECTROCARDIOGRAM

NOT DONE ☐

Electrocardiogram date _____/_____/_____
MM DD YY

Electrocardiogram result ☐ 12 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

NO COMMENTS ☐

Print legibly and do not use abbreviations or symbols.

COMMENTS : VISIT

NO COMMENTS ☐

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.

The information reported for this visit is accurate and complete.

_____ _____/_____/_____
Signature MM DD YY

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PATIENT AND VISIT IDENTIFICATION

Patient initials _____ _____ _____
First Middle Last

Visit date _____/_____/_____
MM DD YY

STUDY DRUG : COMPLIANCE

INFORMATION NOT OBTAINED ☐

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

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STUDY DRUG : PATCH ADHERENCE - PREVIOUS THREE DOSES

INFORMATION NOT OBTAINED ☐

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).

	Date	Number of hours 25-cm^2 patch **NOT** applied	Number of hours 50-cm^2 patch **NOT** applied
1. Today's (visit) date	____/____/____ MM DD YY	_____ hours	_____ hours
2. Yesterday's date	____/____/____ MM DD YY	_____ hours	_____ hours
3. Day before yesterday's date	____/____/____ MM DD YY	_____ hours	_____ hours

STUDY DRUG : DAILY PRESCRIBED DOSAGE

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

Number of 25-cm^2 patches prescribed/day _____ 25-cm^2 patches

Number of 50-cm^2 patches prescribed/day _____ 50-cm^2 patches

NEUROPSYCHIATRIC INVENTORY - REVISED (NPI-X)

INFORMATION NOT OBTAINED ☐

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.

Item	Not Applicable	Absent	Frequency	Severity	Distress
A. Delusions	96	0	1 2 3 4	1 2 3	0 1 2 3 4 5
B. Hallucinations	96	0	1 2 3 4	1 2 3	0 1 2 3 4 5
C. Agitation/Agression	96	0	1 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 2 3 4 5
E. Anxiety	96	0	1 2 3 4	1 2 3	0 1 2 3 4 5
F. Euphoria/Elation	96	0	1 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 1 2 3 4 5
H. Disinhibition	96	0	1 2 3 4	1 2 3	0 1 2 3 4 5
I. Irritability/Lability	96	0	1 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 2 3 4 5
K. Night-Time Behavior	96	0	1 2 3 4	1 2 3	0 1 2 3 4 5
L. Appetite/Eating Change	96	0	1 2 3 4	1 2 3	0 1 2 3 4 5

WEIGHT

INFORMATION NOT OBTAINED ☐

Measure with shoes off. Round up or down to the nearest tenth kilogram or tenth pound.

Weight ___ ___ ___ . ___ ☐ kg Kilogram ☐ lb Pound

VITAL SIGNS : HEART RATE AND BLOOD PRESSURE

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) and 3 minutes.

Position
SU = Supine
ST = Standing

	(DNDE) Reference Time	Timing Code	Position	Heart Rate (bpm)	Blood Pressure (mmHg) Systolic/Diastolic
0.	5 minutes	815	SU		/
1.	1 minute	816	ST		/
2.	3 minutes	817	ST		/

VITAL SIGNS : TEMPERATURE

INFORMATION NOT OBTAINED ☐

Temperature ___ ___ ___ . ___

Unit of measure ☐ F Fahrenheit ☐ C Centigrade

Method ☐ PO Oral ☐ R Rectal ☐ A Axillary ☐ E Ear ☐ O Other

ELECTROCARDIOGRAM

NOT DONE ☐

Electrocardiogram date _____/_____/_____
MM DD YY

Electrocardiogram result ☐ 12 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

NO COMMENTS ☐

Print legibly and do not use abbreviations or symbols.

COMMENTS : VISIT

NO COMMENTS ☐

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.

The information reported for this visit is accurate and complete.

_____ _____/_____/_____
Signature MM DD YY

PATIENT AND VISIT IDENTIFICATION

Patient initials _____ _____ _____
First Middle Last

Visit date _____/_____/_____
MM DD YY

STUDY DRUG : COMPLIANCE

INFORMATION NOT OBTAINED ☐

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

STUDY DRUG : DAILY PRESCRIBED DOSAGE

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

Number of 25-cm^2 patches prescribed/day _____
25-cm^2 patches

Number of 50-cm^2 patches prescribed/day _____
50-cm^2 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.

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

INFORMATION NOT OBTAINED ☐

Clinician's initials _____ _____ _____
First Middle Last

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

American Journal of Psychiatry 1984;141:1356-64.

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

INFORMATION NOT OBTAINED ☐

Clinician's initials _____ _____ _____
First Middle Last

Check one box to indicate the extent of change, if any, observed since the initial baseline interview.

☐ 1 Marked improvement

☐ 2 Moderate improvement

☐ 3 Minimal improvement

☐ 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.

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NEUROPSYCHIATRIC INVENTORY - REVISED (NPI-X)

INFORMATION NOT OBTAINED ☐

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.

Item	Not Applicable	Absent	Frequency	Severity	Distress
A. Delusions	96	0	1 2 3 4	1 2 3	0 1 2 3 4 5
B. Hallucinations	96	0	1 2 3 4	1 2 3	0 1 2 3 4 5
C. Agitation/Agression	96	0	1 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 2 3 4 5
E. Anxiety	96	0	1 2 3 4	1 2 3	0 1 2 3 4 5
F. Euphoria/Elation	96	0	1 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 1 2 3 4 5
H. Disinhibition	96	0	1 2 3 4	1 2 3	0 1 2 3 4 5
I. Irritability/Lability	96	0	1 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 2 3 4 5
K. Night-Time Behavior	96	0	1 2 3 4	1 2 3	0 1 2 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)

INFORMATION NOT OBTAINED ☐

Clinician's initials _____ _____ _____
First Middle Last

During the past two weeks, did the patient without help or reminder:

SCORING: **Yes = 1** **No = 0** **Not Applicable = 96**

		Initiation	Planning & Organization	Effective Performance
	HYGIENE			
1.	Undertake to wash himself/herself or to take a bath or a shower			
2.	Undertake to brush his/her teeth or care for his/her dentures			
3.	Decide to care for his/her hair (wash and comb)			
4.	Prepare the water, towels, and soap for washing, taking a bath, or a shower			
5.	Wash and dry completely all parts of his/her body safely			
6.	Brush his/her teeth or care for his/her dentures appropriately			
7.	Care for his/her hair (wash and comb)			
	DRESSING			
8.	Undertake to dress himself/herself			
9.	Choose appropriate clothing (with regard to the occasion, neatness, the weather, and color combination)			
10.	Dress himself/herself in the appropriate order (undergarments, pant/dress, shoes)			
11.	Dress himself/herself completely			
12.	Undress himself/herself completely			
	CONTINENCE			
13.	Decide to use the toilet at appropriate times			
14.	Use the toilet without "accidents"			
	EATING			
15.	Decide that he/she needs to eat			
16.	Choose appropriate utensils and seasonings when eating			
17.	Eat his/her meals at a normal pace and with appropriate manners			
	MEAL PREPARATION			
18.	Undertake to prepare a light meal or snack for himself/herself			
19.	Adequately plan a light meal or snack (ingredients, cookware)			
20.	Prepare or cook a light meal or a snack safely			

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DISABILITY ASSESSMENT FOR DEMENTIA (DAD)

SCORING: **Yes = 1** **No = 0** **Not Applicable = 96**

		Initiation	Planning & Organization	Effective Performance
	TELEPHONING			
21.	Attempt to telephone someone at a suitable time			
22.	Find and dial a telephone number correctly			
23.	Carry out an appropriate telephone conversation			
24.	Write and convey a telephone message adequately			
	GOING ON AN OUTING			
25.	Undertake to go out (walk, visit, shop) at an appropriate time			
26.	Adequately organize an outing with respect to transportation, keys, destination, weather, necessary money, shopping list			
27.	Go out and reach a familiar destination without getting lost			
28.	Safely take the adequate mode of transportation (car, bus, taxi)			
29.	Return from the store with the appropriate items			
	FINANCE AND CORRESPONDENCE			
30.	Show an interest in his/her personal affairs such as his/her finances and written correspondence			
31.	Organize his/her finances to pay his/her bills (cheques, bankbook, bills)			
32.	Adequately organize his/her correspondence with respect to stationery, address, stamps			
33.	Handle adequately his/her money (make change)			
	MEDICATIONS			
34.	Decide to take his/her medications at the correct time			
35.	Take his/her medications as prescribed (according to the right dosage)			
	LEISURE AND HOUSEWORK			
36.	Show an interest in leisure activity(ies)			
37.	Take an interest in household chores that he/she used to perform in the past			
38.	Plan and organize adequately household chores that he/she used to perform in the past			
39.	Complete household chores adequately as he/she used to perform in the past			
40.	Stay safely at home by himself/herself when needed			

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WEIGHT

INFORMATION NOT OBTAINED ☐

Measure with shoes off. Round up or down to the nearest tenth kilogram or tenth pound.

Weight ___ ___ ___ . ___ ☐ kg Kilogram ☐ lb Pound

VITAL SIGNS : HEART RATE AND BLOOD PRESSURE

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) and 3 minutes.

Position
SU = Supine
ST = Standing

	(DNDE) Reference Time	Timing Code	Position	Heart Rate (bpm)	Blood Pressure (mmHg) Systolic/Diastolic
0.	5 minutes	815	SU		/
1.	1 minute	816	ST		/
2.	3 minutes	817	ST		/

VITAL SIGNS : TEMPERATURE

INFORMATION NOT OBTAINED ☐

Temperature ___ ___ ___ . ___

Unit of measure ☐ F Fahrenheit ☐ C Centigrade

Method ☐ PO Oral ☐ R Rectal ☐ A Axillary ☐ E Ear ☐ O Other

ELECTROCARDIOGRAM

NOT DONE ☐

Electrocardiogram date _____/_____/_____
MM DD YY

Electrocardiogram result ☐ 12 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

NO COMMENTS ☐

Print legibly and do not use abbreviations or symbols.

COMMENTS : VISIT

NO COMMENTS ☐

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.

The information reported for this visit is accurate and complete.

_____ _____/_____/_____
Signature MM DD YY

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August 22, 1996

PATIENT AND VISIT IDENTIFICATION

Patient initials _____ _____ _____
First Middle Last

Visit date _____/_____/_____
MM DD YY

STUDY DRUG : COMPLIANCE

INFORMATION NOT OBTAINED ☐

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

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STUDY DRUG : PATCH ADHERENCE - PREVIOUS THREE DOSES

INFORMATION NOT OBTAINED ☐

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).

	Date	Number of hours 25-cm^2 patch **NOT** applied	Number of hours 50-cm^2 patch **NOT** applied
1. Today's (visit) date	____/____/____ MM DD YY	_____ hours	_____ hours
2. Yesterday's date	____/____/____ MM DD YY	_____ hours	_____ hours
3. Day before yesterday's date	____/____/____ MM DD YY	_____ hours	_____ hours

STUDY DRUG : DAILY PRESCRIBED DOSAGE

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

Number of 25-cm^2 patches prescribed/day _____ 25-cm^2 patches

Number of 50-cm^2 patches prescribed/day _____ 50-cm^2 patches

NEUROPSYCHIATRIC INVENTORY - REVISED (NPI-X)

INFORMATION NOT OBTAINED ☐

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.

Item	Not Applicable	Absent	Frequency	Severity	Distress
A. Delusions	96	0	1 2 3 4	1 2 3	0 1 2 3 4 5
B. Hallucinations	96	0	1 2 3 4	1 2 3	0 1 2 3 4 5
C. Agitation/Agression	96	0	1 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 2 3 4 5
E. Anxiety	96	0	1 2 3 4	1 2 3	0 1 2 3 4 5
F. Euphoria/Elation	96	0	1 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 1 2 3 4 5
H. Disinhibition	96	0	1 2 3 4	1 2 3	0 1 2 3 4 5
I. Irritability/Lability	96	0	1 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 2 3 4 5
K. Night-Time Behavior	96	0	1 2 3 4	1 2 3	0 1 2 3 4 5
L. Appetite/Eating Change	96	0	1 2 3 4	1 2 3	0 1 2 3 4 5

WEIGHT

INFORMATION NOT OBTAINED ☐

Measure with shoes off. Round up or down to the nearest tenth kilogram or tenth pound.

Weight ___ ___ ___ . ___ ☐ kg Kilogram ☐ lb Pound

VITAL SIGNS : HEART RATE AND BLOOD PRESSURE

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) and 3 minutes.

Position
SU = Supine
ST = Standing

	(DNDE) Reference Time	Timing Code	Position	Heart Rate (bpm)	Blood Pressure (mmHg) Systolic/Diastolic
0.	5 minutes	815	SU		/
1.	1 minute	816	ST		/
2.	3 minutes	817	ST		/

VITAL SIGNS : TEMPERATURE

INFORMATION NOT OBTAINED ☐

Temperature ___ ___ ___ . ___

Unit of measure ☐ F Fahrenheit ☐ C Centigrade

Method ☐ PO Oral ☐ R Rectal ☐ A Axillary ☐ E Ear ☐ O Other

ELECTROCARDIOGRAM

NOT DONE ☐

Electrocardiogram date _____/_____/_____
MM DD YY

Electrocardiogram result ☐ 12 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

NO COMMENTS ☐

Print legibly and do not use abbreviations or symbols.

COMMENTS : VISIT

NO COMMENTS ☐

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.

The information reported for this visit is accurate and complete.

_____ _____/_____/_____
Signature MM DD YY

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PATIENT AND VISIT IDENTIFICATION

Patient initials _____ _____ _____
First Middle Last

Visit (telephone) date _____/_____/_____
MM DD YY

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August 22, 1996

NEUROPSYCHIATRIC INVENTORY - REVISED (NPI-X)

INFORMATION NOT OBTAINED ☐

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.

Item	Not Applicable	Absent	Frequency	Severity	Distress
A. Delusions	96	0	1 2 3 4	1 2 3	0 1 2 3 4 5
B. Hallucinations	96	0	1 2 3 4	1 2 3	0 1 2 3 4 5
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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 _____ _____ _____
First Middle Last

Visit date _____/_____/_____
MM DD YY

STUDY DRUG : COMPLIANCE

INFORMATION NOT OBTAINED ☐

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

STUDY DRUG : DAILY PRESCRIBED DOSAGE

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

Number of 25-cm^2 patches prescribed/day _____
25-cm^2 patches

Number of 50-cm^2 patches prescribed/day _____
50-cm^2 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.

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

INFORMATION NOT OBTAINED ☐

Clinician's initials _____ _____ _____
First Middle Last

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

American Journal of Psychiatry 1984;141:1356-64.

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

INFORMATION NOT OBTAINED ☐

Clinician's initials _____ _____ _____
First Middle Last

Check one box to indicate the extent of change, if any, observed since the initial baseline interview.

☐ 1 Marked improvement

☐ 2 Moderate improvement

☐ 3 Minimal improvement

☐ 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.

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NEUROPSYCHIATRIC INVENTORY - REVISED (NPI-X)

INFORMATION NOT OBTAINED ☐

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.

Item	Not Applicable	Absent	Frequency	Severity	Distress
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D. Depression/ Dysphoria	96	0	1 2 3 4	1 2 3	0 1 2 3 4 5
E. Anxiety	96	0	1 2 3 4	1 2 3	0 1 2 3 4 5
F. Euphoria/Elation	96	0	1 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 1 2 3 4 5
H. Disinhibition	96	0	1 2 3 4	1 2 3	0 1 2 3 4 5
I. Irritability/Lability	96	0	1 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 2 3 4 5
K. Night-Time Behavior	96	0	1 2 3 4	1 2 3	0 1 2 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)

INFORMATION NOT OBTAINED ☐

Clinician's initials _____ _____ _____
First Middle Last

During the past two weeks, did the patient without help or reminder:

SCORING: **Yes = 1** **No = 0** **Not Applicable = 96**

		Initiation	Planning & Organization	Effective Performance
	HYGIENE			
1.	Undertake to wash himself/herself or to take a bath or a shower			
2.	Undertake to brush his/her teeth or care for his/her dentures			
3.	Decide to care for his/her hair (wash and comb)			
4.	Prepare the water, towels, and soap for washing, taking a bath, or a shower			
5.	Wash and dry completely all parts of his/her body safely			
6.	Brush his/her teeth or care for his/her dentures appropriately			
7.	Care for his/her hair (wash and comb)			
	DRESSING			
8.	Undertake to dress himself/herself			
9.	Choose appropriate clothing (with regard to the occasion, neatness, the weather, and color combination)			
10.	Dress himself/herself in the appropriate order (undergarments, pant/dress, shoes)			
11.	Dress himself/herself completely			
12.	Undress himself/herself completely			
	CONTINENCE			
13.	Decide to use the toilet at appropriate times			
14.	Use the toilet without "accidents"			
	EATING			
15.	Decide that he/she needs to eat			
16.	Choose appropriate utensils and seasonings when eating			
17.	Eat his/her meals at a normal pace and with appropriate manners			
	MEAL PREPARATION			
18.	Undertake to prepare a light meal or snack for himself/herself			
19.	Adequately plan a light meal or snack (ingredients, cookware)			
20.	Prepare or cook a light meal or a snack safely			

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DISABILITY ASSESSMENT FOR DEMENTIA (DAD)

SCORING: **Yes = 1** **No = 0** **Not Applicable = 96**

		Initiation	Planning & Organization	Effective Performance
	TELEPHONING			
21.	Attempt to telephone someone at a suitable time			
22.	Find and dial a telephone number correctly			
23.	Carry out an appropriate telephone conversation			
24.	Write and convey a telephone message adequately			
	GOING ON AN OUTING			
25.	Undertake to go out (walk, visit, shop) at an appropriate time			
26.	Adequately organize an outing with respect to transportation, keys, destination, weather, necessary money, shopping list			
27.	Go out and reach a familiar destination without getting lost			
28.	Safely take the adequate mode of transportation (car, bus, taxi)			
29.	Return from the store with the appropriate items			
	FINANCE AND CORRESPONDENCE			
30.	Show an interest in his/her personal affairs such as his/her finances and written correspondence			
31.	Organize his/her finances to pay his/her bills (cheques, bankbook, bills)			
32.	Adequately organize his/her correspondence with respect to stationery, address, stamps			
33.	Handle adequately his/her money (make change)			
	MEDICATIONS			
34.	Decide to take his/her medications at the correct time			
35.	Take his/her medications as prescribed (according to the right dosage)			
	LEISURE AND HOUSEWORK			
36.	Show an interest in leisure activity(ies)			
37.	Take an interest in household chores that he/she used to perform in the past			
38.	Plan and organize adequately household chores that he/she used to perform in the past			
39.	Complete household chores adequately as he/she used to perform in the past			
40.	Stay safely at home by himself/herself when needed			

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WEIGHT

INFORMATION NOT OBTAINED ☐

Measure with shoes off. Round up or down to the nearest tenth kilogram or tenth pound.

Weight ___ ___ ___ . ___ ☐ kg Kilogram ☐ lb Pound

VITAL SIGNS : HEART RATE AND BLOOD PRESSURE

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) and 3 minutes.

Position
SU = Supine
ST = Standing

	(DNDE) Reference Time	Timing Code	Position	Heart Rate (bpm)	Blood Pressure (mmHg) Systolic/Diastolic
0.	5 minutes	815	SU		/
1.	1 minute	816	ST		/
2.	3 minutes	817	ST		/

VITAL SIGNS : TEMPERATURE

INFORMATION NOT OBTAINED ☐

Temperature ___ ___ ___ . ___

Unit of measure ☐ F Fahrenheit ☐ C Centigrade

Method ☐ PO Oral ☐ R Rectal ☐ A Axillary ☐ E Ear ☐ O Other

ELECTROCARDIOGRAM

NOT DONE ☐

Electrocardiogram date _____/_____/_____
MM DD YY

Electrocardiogram result ☐ 12 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

NO COMMENTS ☐

Print legibly and do not use abbreviations or symbols.

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COMMENTS : VISIT

NO COMMENTS ☐

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.

The information reported for this visit is accurate and complete.

_____ _____/_____/_____
Signature MM DD YY

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August 22, 1996

PATIENT AND VISIT IDENTIFICATION

Patient initials _____ _____ _____
First Middle Last

Visit date _____/_____/_____
MM DD YY

STUDY DRUG : COMPLIANCE

INFORMATION NOT OBTAINED ☐

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

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EXTRAPYRAMIDAL FINDINGS

INFORMATION NOT OBTAINED ☐

1. Masked facies
   - ☐ 0 None
   - ☐ 1 Mild
   - ☐ 2 Moderate
   - ☐ 3 Severe

2. Rigidity of upper extremity
   - ☐ 0 None
   - ☐ 1 Mild
   - ☐ 2 Moderate
   - ☐ 3 Severe

3. Essential tremor
   - ☐ 0 None
   - ☐ 1 Mild
   - ☐ 2 Moderate
   - ☐ 3 Severe

4. Ambulation

   How long did it take the patient to walk 25 yards? _____ seconds

NEUROPSYCHIATRIC INVENTORY - REVISED (NPI-X)

INFORMATION NOT OBTAINED ☐

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.

Item	Not Applicable	Absent	Frequency	Severity	Distress
A. Delusions	96	0	1 2 3 4	1 2 3	0 1 2 3 4 5
B. Hallucinations	96	0	1 2 3 4	1 2 3	0 1 2 3 4 5
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G. Apathy/ Indifference	96	0	1 2 3 4	1 2 3	0 1 2 3 4 5
H. Disinhibition	96	0	1 2 3 4	1 2 3	0 1 2 3 4 5
I. Irritability/Lability	96	0	1 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 2 3 4 5
K. Night-Time Behavior	96	0	1 2 3 4	1 2 3	0 1 2 3 4 5
L. Appetite/Eating Change	96	0	1 2 3 4	1 2 3	0 1 2 3 4 5

WEIGHT

INFORMATION NOT OBTAINED ☐

Measure with shoes off. Round up or down to the nearest tenth kilogram or tenth pound.

Weight ___ ___ ___ . ___ ☐ kg Kilogram ☐ lb Pound

VITAL SIGNS : HEART RATE AND BLOOD PRESSURE

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) and 3 minutes.

Position
SU = Supine ST = Standing

	(DNDE) Reference Time	Timing Code	Position	Heart Rate (bpm)	Blood Pressure (mmHg) Systolic/Diastolic
0.	5 minutes	815	SU		/
1.	1 minute	816	ST		/
2.	3 minutes	817	ST		/

VITAL SIGNS : TEMPERATURE

INFORMATION NOT OBTAINED ☐

Temperature ___ ___ ___ . ___

Unit of measure ☐ F Fahrenheit ☐ C Centigrade

Method ☐ PO Oral ☐ R Rectal ☐ A Axillary ☐ E Ear ☐ O Other

ELECTROCARDIOGRAM

NOT DONE ☐

Electrocardiogram date _____/_____/_____
MM DD YY

Electrocardiogram result ☐ 12 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

NO COMMENTS ☐

Print legibly and do not use abbreviations or symbols.

ACCEPTABILITY : CAREGIVER'S RESPONSE ABOUT THE PATCH

INFORMATION NOT OBTAINED ☐

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):

☐ 1 Insist that the patient receive an oral pill

☐ 2 Prefer that the patient receive an oral pill

☐ 3 Have no preference (neutral) for an oral or patch formulation

☐ 4 Prefer that the patient receive a patch

☐ 5 Insist that the patient receive a patch

ACCEPTABILITY : CAREGIVER'S RESPONSE ABOUT THE PATCH

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 appearance of the patch while being worn is acceptable:

1	2	3	4	5	6	7
Strongly Disagree			Neutral			Strongly Agree

2. The size of the patch is acceptable:

1	2	3	4	5	6	7
Strongly Disagree			Neutral			Strongly Agree

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

1	2	3	4	5	6	7
Strongly Disagree			Neutral			Strongly Agree

STUDY DRUG THERAPY : DATE OF FINAL DOSE

Date of final dose of study drug _____/_____/_____
MM DD YY

PATIENT SUMMARY

Patient Initials _____ _____ _____
First Middle Last

CHECK ONE PRIMARY REASON FOR ENDING PARTICIPATION IN THE STUDY

☐ 1 Protocol completed

☐ 3 Adverse event E __ __
E__ Code

☐ 4 Death* E __ __
E__ Code

If # **4** is checked, enter date of death.

Date of Death ____/____/____
MM DD YY

☐ 8 Lack of efficacy, patient/caregiver perception

☐ 9 Lack of efficacy, physician perception

☐ 11 Unable to contact patient (lost to follow-up)

☐ 13 Personal conflict or other patient/caregiver decision _____
Specify

☐ 22 Physician decision _____
Specify

☐ 14 Protocol entry criteria not met _____ (Specify number from entry criteria checklist)
Specify

☐ 243 Protocol violation

☐ 18 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.

COMMENTS : STUDY SUMMARY

NO COMMENTS ☐

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.

All information reported for this patient is accurate and complete.

_____ _____/_____/_____
Investigator Signature MM DD YY

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PATIENT AND VISIT IDENTIFICATION

Patient initials _____ _____ _____
First Middle Last

Visit date _____/_____/_____
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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ALZHEIMER'S DISEASE ASSESSMENT SCALE : COGNITIVE with ATTENTION/ CONCENTRATION TASKS

INFORMATION NOT OBTAINED ☐

Clinician's initials _____ _____ _____
First Middle Last

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

American Journal of Psychiatry 1984;141:1356-64.

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

INFORMATION NOT OBTAINED ☐

Clinician's initials _____ _____ _____
First Middle Last

Check one box to indicate the extent of change, if any, observed since the initial baseline interview.

☐ 1 Marked improvement

☐ 2 Moderate improvement

☐ 3 Minimal improvement

☐ 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.

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NEUROPSYCHIATRIC INVENTORY - REVISED (NPI-X)

INFORMATION NOT OBTAINED ☐

Clinician's initials _____ _____ _____
First Middle Last

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H. Disinhibition	96	0	1 2 3 4	1 2 3	0 1 2 3 4 5
I. Irritability/Lability	96	0	1 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 2 3 4 5
K. Night-Time Behavior	96	0	1 2 3 4	1 2 3	0 1 2 3 4 5
L. Appetite/Eating Change	96	0	1 2 3 4	1 2 3	0 1 2 3 4 5

DISABILITY ASSESSMENT FOR DEMENTIA (DAD)

INFORMATION NOT OBTAINED ☐

Clinician's initials _____ _____ _____
First Middle Last

During the past two weeks, did the patient without help or reminder:

SCORING: **Yes = 1** **No = 0** **Not Applicable = 96**

		Initiation	Planning & Organization	Effective Performance
	HYGIENE			
1.	Undertake to wash himself/herself or to take a bath or a shower			
2.	Undertake to brush his/her teeth or care for his/her dentures			
3.	Decide to care for his/her hair (wash and comb)			
4.	Prepare the water, towels, and soap for washing, taking a bath, or a shower			
5.	Wash and dry completely all parts of his/her body safely			
6.	Brush his/her teeth or care for his/her dentures appropriately			
7.	Care for his/her hair (wash and comb)			
	DRESSING			
8.	Undertake to dress himself/herself			
9.	Choose appropriate clothing (with regard to the occasion, neatness, the weather, and color combination)			
10.	Dress himself/herself in the appropriate order (undergarments, pant/dress, shoes)			
11.	Dress himself/herself completely			
12.	Undress himself/herself completely			
	CONTINENCE			
13.	Decide to use the toilet at appropriate times			
14.	Use the toilet without "accidents"			
	EATING			
15.	Decide that he/she needs to eat			
16.	Choose appropriate utensils and seasonings when eating			
17.	Eat his/her meals at a normal pace and with appropriate manners			
	MEAL PREPARATION			
18.	Undertake to prepare a light meal or snack for himself/herself			
19.	Adequately plan a light meal or snack (ingredients, cookware)			
20.	Prepare or cook a light meal or a snack safely			

DISABILITY ASSESSMENT FOR DEMENTIA (DAD)

SCORING: **Yes = 1** **No = 0** **Not Applicable = 96**

		Initiation	Planning & Organization	Effective Performance
	TELEPHONING			
21.	Attempt to telephone someone at a suitable time			
22.	Find and dial a telephone number correctly			
23.	Carry out an appropriate telephone conversation			
24.	Write and convey a telephone message adequately			
	GOING ON AN OUTING			
25.	Undertake to go out (walk, visit, shop) at an appropriate time			
26.	Adequately organize an outing with respect to transportation, keys, destination, weather, necessary money, shopping list			
27.	Go out and reach a familiar destination without getting lost			
28.	Safely take the adequate mode of transportation (car, bus, taxi)			
29.	Return from the store with the appropriate items			
	FINANCE AND CORRESPONDENCE			
30.	Show an interest in his/her personal affairs such as his/her finances and written correspondence			
31.	Organize his/her finances to pay his/her bills (cheques, bankbook, bills)			
32.	Adequately organize his/her correspondence with respect to stationery, address, stamps			
33.	Handle adequately his/her money (make change)			
	MEDICATIONS			
34.	Decide to take his/her medications at the correct time			
35.	Take his/her medications as prescribed (according to the right dosage)			
	LEISURE AND HOUSEWORK			
36.	Show an interest in leisure activity(ies)			
37.	Take an interest in household chores that he/she used to perform in the past			
38.	Plan and organize adequately household chores that he/she used to perform in the past			
39.	Complete household chores adequately as he/she used to perform in the past			
40.	Stay safely at home by himself/herself when needed			

VITAL SIGNS : HEART RATE AND BLOOD PRESSURE

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) and 3 minutes.

Position
SU = Supine ST = Standing

	(DNDE) Reference Time	Timing Code	Position	Heart Rate (bpm)	Blood Pressure (mmHg) Systolic/Diastolic
0.	5 minutes	815	SU		/
1.	1 minute	816	ST		/
2.	3 minutes	817	ST		/

VITAL SIGNS : TEMPERATURE

INFORMATION NOT OBTAINED ☐

Temperature ___ ___ ___ . ___

Unit of measure ☐ F Fahrenheit ☐ C Centigrade

Method ☐ PO Oral ☐ R Rectal ☐ A Axillary ☐ E Ear ☐ O Other

COMMENTS : STUDY SUMMARY

NO COMMENTS ☐

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.

All information reported for this patient is accurate and complete.

_____ _____/_____/_____
Investigator Signature MM DD YY

PATIENT AND VISIT IDENTIFICATION

Patient initials _____ _____ _____
First Middle Last

Visit date _____/_____/_____
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

1. Patient initials _____ _____ _____
   First Middle Last

2. Primary event causing discontinuation _____
   (E _ _ Code from Patient Summary page)

3. Check one PRIMARY reason for ending the ADVERSE EVENT follow-up period

   ☐ 101 Event resolved — Date resolved ____/_____/____ MM DD YY

   ☐ 102 Laboratory test result returned to acceptable range

   ☐ 11 Patient is lost to follow-up

   ☐ 103 Event or condition is stable and not expected to change

   ☐ 99 Other _____
   Specify

4. Check one patient outcome

   ☐ 104 No residual effect

   ☐ 105 Impairment or disability

   ☐ 4 Death*

   ☐ 99 Other _____
   Specify

* **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 Lilly as soon as possible. Explain circumstances of the death on the Adverse Event Follow-Up Comments page.

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COMMENTS : STUDY SUMMARY

NO COMMENTS ☐

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.

All information reported for this patient is accurate and complete.

_____ _____/_____/_____
Investigator Signature MM DD YY

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PROCEDURE : MRSI

NOT DONE ☐

Date of MRSI _____/_____/_____
MM DD YY

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PROCEDURE : MRSI

NOT DONE ☐

Date of MRSI _____/_____/_____
MM DD YY

Clinical Report Form
Safety and Efficacy of the Xanomeline
Transdermal Therapeutic System (TTS) in
Patients with Mild to Moderate Alzheimer's Disease
H2Q-MC-LZZT

PRE-EXISTING CONDITIONS AND STUDY ADVERSE EVENTS

NO CONDITIONS OR EVENTS ☐

- List all pre-existing conditions or symptoms present at entry to study.
- List all clinically relevant abnormalities found on the physical exam, ECG, chest x-ray, or Holter monitor.
- List all events that occur during study.

*Serious Codes
1 = Fatal
2 = Life-threatening
3 = Permanently disabling
4 = Hospitalization
5 = Congenital anomaly
6 = Cancer
7 = Overdose
8 = Other reason

*** If Event is serious, notify the Quintiles Drug Safety Unit immediately.**

Severity Codes
1 = Mild
2 = Moderate
3 = Severe

Evaluate when event stops or at end of patient's participation in study

Code	Description of Condition/Event COSTART Class Term	Onset Date MM DD YY Stop Date MM DD YY	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
E01			☐ N No If **Yes**, enter Serious Code(s) _____	Visit Number Severity	1 = None 2 = Remote (Unlikely) 3 = Possible 4 = Probable
E02			☐ N No If **Yes**, enter Serious Code(s) _____	Visit Number Severity	1 = None 2 = Remote (Unlikely) 3 = Possible 4 = Probable
E03			☐ N No If **Yes**, enter Serious Code(s) _____	Visit Number Severity	1 = None 2 = Remote (Unlikely) 3 = Possible 4 = Probable
E04			☐ N No If **Yes**, enter Serious Code(s) _____	Visit Number Severity	1 = None 2 = Remote (Unlikely) 3 = Possible 4 = Probable
E05			☐ N No If **Yes**, enter Serious Code(s) _____	Visit Number Severity	1 = None 2 = Remote (Unlikely) 3 = Possible 4 = Probable
E06			☐ N No If **Yes**, enter Serious Code(s) _____	Visit Number Severity	1 = None 2 = Remote (Unlikely) 3 = Possible 4 = Probable
E07			☐ N No If **Yes**, enter Serious Code(s) _____	Visit Number Severity	1 = None 2 = Remote (Unlikely) 3 = Possible 4 = Probable

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PRE-EXISTING CONDITIONS AND STUDY ADVERSE EVENTS

Continue listing all pre-existing conditions and events that occur during the study.

*Serious Codes
1 = Fatal
2 = Life-threatening
3 = Permanently disabling
4 = Hospitalization
5 = Congenital anomaly
6 = Cancer
7 = Overdose
8 = Other reason

*** If Event is serious, notify the Quintiles Drug Safety Unit immediately.**

Severity Codes
1 = Mild
2 = Moderate
3 = Severe

Evaluate when event stops or at end of patient's participation in study

Code	Description of Condition/Event COSTART Class Term	Onset Date MM DD YY Stop Date MM DD YY	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
E08			☐ N No If **Yes**, enter Serious Code(s) _____	Visit Number Severity	1 = None 2 = Remote (Unlikely) 3 = Possible 4 = Probable
E09			☐ N No If **Yes**, enter Serious Code(s) _____	Visit Number Severity	1 = None 2 = Remote (Unlikely) 3 = Possible 4 = Probable
E10			☐ N No If **Yes**, enter Serious Code(s) _____	Visit Number Severity	1 = None 2 = Remote (Unlikely) 3 = Possible 4 = Probable
E11			☐ N No If **Yes**, enter Serious Code(s) _____	Visit Number Severity	1 = None 2 = Remote (Unlikely) 3 = Possible 4 = Probable
E12			☐ N No If **Yes**, enter Serious Code(s) _____	Visit Number Severity	1 = None 2 = Remote (Unlikely) 3 = Possible 4 = Probable
E13			☐ N No If **Yes**, enter Serious Code(s) _____	Visit Number Severity	1 = None 2 = Remote (Unlikely) 3 = Possible 4 = Probable
E14			☐ N No If **Yes**, enter Serious Code(s) _____	Visit Number Severity	1 = None 2 = Remote (Unlikely) 3 = Possible 4 = Probable

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Clinical Report Form
Safety and Efficacy of the Xanomeline
Transdermal Therapeutic System (TTS) in
Patients with Mild to Moderate Alzheimer's Disease
H2Q-MC-LZZT

PRE-EXISTING CONDITIONS AND STUDY ADVERSE EVENTS

Continue listing all pre-existing conditions and events that occur during the study.

*Serious Codes
1 = Fatal
2 = Life-threatening
3 = Permanently disabling
4 = Hospitalization
5 = Congenital anomaly
6 = Cancer
7 = Overdose
8 = Other reason

*** If Event is serious, notify the Quintiles Drug Safety Unit immediately.**

Severity Codes
1 = Mild
2 = Moderate
3 = Severe

Evaluate when event stops or at end of patient's participation in study

Code	Description of Condition/Event / COSTART Class Term	Onset Date MM DD YY / Stop Date MM DD YY	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
E__			☐ N No / If **Yes**, enter Serious Code(s) ____	Visit Number / Severity						1 = None 2 = Remote (Unlikely) 3 = Possible 4 = Probable
E__			☐ N No / If **Yes**, enter Serious Code(s) ____	Visit Number / Severity						1 = None 2 = Remote (Unlikely) 3 = Possible 4 = Probable
E__			☐ N No / If **Yes**, enter Serious Code(s) ____	Visit Number / Severity						1 = None 2 = Remote (Unlikely) 3 = Possible 4 = Probable
E__			☐ N No / If **Yes**, enter Serious Code(s) ____	Visit Number / Severity						1 = None 2 = Remote (Unlikely) 3 = Possible 4 = Probable
E__			☐ N No / If **Yes**, enter Serious Code(s) ____	Visit Number / Severity						1 = None 2 = Remote (Unlikely) 3 = Possible 4 = Probable
E__			☐ N No / If **Yes**, enter Serious Code(s) ____	Visit Number / Severity						1 = None 2 = Remote (Unlikely) 3 = Possible 4 = Probable
E__			☐ N No / If **Yes**, enter Serious Code(s) ____	Visit Number / Severity						1 = None 2 = Remote (Unlikely) 3 = Possible 4 = Probable

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CONCOMITANT MEDICATION

NO CONCOMITANT MEDICATIONS ☐

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

	Brand or Trade Name (Use generic if brand or trade name unknown)	Dose	Unit	Fre-quency	Route	Start Date MM	Start Date DD	Start Date YY	Stop Date MM	Stop Date DD	Stop Date YY	IFU
0.												
1.												
2.												
3.												
4.												
5.												
6.												
7.												
8.												
9.												
10.												
11.												

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

	Brand or Trade Name (Use generic if brand or trade name unknown)	Dose	Unit	Fre-quency	Route	Start Date MM	Start Date DD	Start Date YY	Stop Date MM	Stop Date DD	Stop Date YY	IFU
12.												
13.												
14.												
15.												
16.												
17.												
18.												
19.												
20.												
21.												
22.												
23.												

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

Brand or Trade Name (Use generic if brand or trade name unknown)	Dose	Unit	Fre-quency	Route	Start Date MM	Start Date DD	Start Date YY	Stop Date MM	Stop Date DD	Stop Date YY	IFU

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

Start date of the new study drug dosing regimen (12-14 hour patch) _____/_____/_____
MM DD YY

PATIENT AND VISIT IDENTIFICATION

Patient initials _____ _____ _____
First Middle Last

Visit date _____/_____/_____
MM DD YY

STUDY DRUG : COMPLIANCE

INFORMATION NOT OBTAINED ☐

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

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EXTRAPYRAMIDAL FINDINGS

INFORMATION NOT OBTAINED ☐

1. Masked facies
   - ☐ 0 None
   - ☐ 1 Mild
   - ☐ 2 Moderate
   - ☐ 3 Severe

2. Rigidity of upper extremity
   - ☐ 0 None
   - ☐ 1 Mild
   - ☐ 2 Moderate
   - ☐ 3 Severe

3. Essential tremor
   - ☐ 0 None
   - ☐ 1 Mild
   - ☐ 2 Moderate
   - ☐ 3 Severe

4. Ambulation

   How long did it take the patient to walk 25 yards? _____ seconds

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

INFORMATION NOT OBTAINED ☐

Clinician's initials _____ _____ _____
First Middle Last

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

American Journal of Psychiatry 1984;141:1356-64.

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

INFORMATION NOT OBTAINED ☐

Clinician's initials _____ _____ _____
First Middle Last

Check one box to indicate the extent of change, if any, observed since the initial baseline interview.

☐ 1 Marked improvement

☐ 2 Moderate improvement

☐ 3 Minimal improvement

☐ 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.

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NEUROPSYCHIATRIC INVENTORY - REVISED (NPI-X)

INFORMATION NOT OBTAINED ☐

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.

Item	Not Applicable	Absent	Frequency	Severity	Distress
A. Delusions	96	0	1 2 3 4	1 2 3	0 1 2 3 4 5
B. Hallucinations	96	0	1 2 3 4	1 2 3	0 1 2 3 4 5
C. Agitation/Agression	96	0	1 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 2 3 4 5
E. Anxiety	96	0	1 2 3 4	1 2 3	0 1 2 3 4 5
F. Euphoria/Elation	96	0	1 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 1 2 3 4 5
H. Disinhibition	96	0	1 2 3 4	1 2 3	0 1 2 3 4 5
I. Irritability/Lability	96	0	1 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 2 3 4 5
K. Night-Time Behavior	96	0	1 2 3 4	1 2 3	0 1 2 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)

INFORMATION NOT OBTAINED ☐

Clinician's initials _____ _____ _____
First Middle Last

During the past two weeks, did the patient without help or reminder:

SCORING: **Yes = 1** **No = 0** **Not Applicable = 96**

		Initiation	Planning & Organization	Effective Performance
	HYGIENE			
1.	Undertake to wash himself/herself or to take a bath or a shower			
2.	Undertake to brush his/her teeth or care for his/her dentures			
3.	Decide to care for his/her hair (wash and comb)			
4.	Prepare the water, towels, and soap for washing, taking a bath, or a shower			
5.	Wash and dry completely all parts of his/her body safely			
6.	Brush his/her teeth or care for his/her dentures appropriately			
7.	Care for his/her hair (wash and comb)			
	DRESSING			
8.	Undertake to dress himself/herself			
9.	Choose appropriate clothing (with regard to the occasion, neatness, the weather, and color combination)			
10.	Dress himself/herself in the appropriate order (undergarments, pant/dress, shoes)			
11.	Dress himself/herself completely			
12.	Undress himself/herself completely			
	CONTINENCE			
13.	Decide to use the toilet at appropriate times			
14.	Use the toilet without "accidents"			
	EATING			
15.	Decide that he/she needs to eat			
16.	Choose appropriate utensils and seasonings when eating			
17.	Eat his/her meals at a normal pace and with appropriate manners			
	MEAL PREPARATION			
18.	Undertake to prepare a light meal or snack for himself/herself			
19.	Adequately plan a light meal or snack (ingredients, cookware)			
20.	Prepare or cook a light meal or a snack safely			

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DISABILITY ASSESSMENT FOR DEMENTIA (DAD)

SCORING: **Yes = 1** **No = 0** **Not Applicable = 96**

		Initiation	Planning & Organization	Effective Performance
	TELEPHONING			
21.	Attempt to telephone someone at a suitable time			
22.	Find and dial a telephone number correctly			
23.	Carry out an appropriate telephone conversation			
24.	Write and convey a telephone message adequately			
	GOING ON AN OUTING			
25.	Undertake to go out (walk, visit, shop) at an appropriate time			
26.	Adequately organize an outing with respect to transportation, keys, destination, weather, necessary money, shopping list			
27.	Go out and reach a familiar destination without getting lost			
28.	Safely take the adequate mode of transportation (car, bus, taxi)			
29.	Return from the store with the appropriate items			
	FINANCE AND CORRESPONDENCE			
30.	Show an interest in his/her personal affairs such as his/her finances and written correspondence			
31.	Organize his/her finances to pay his/her bills (cheques, bankbook, bills)			
32.	Adequately organize his/her correspondence with respect to stationery, address, stamps			
33.	Handle adequately his/her money (make change)			
	MEDICATIONS			
34.	Decide to take his/her medications at the correct time			
35.	Take his/her medications as prescribed (according to the right dosage)			
	LEISURE AND HOUSEWORK			
36.	Show an interest in leisure activity(ies)			
37.	Take an interest in household chores that he/she used to perform in the past			
38.	Plan and organize adequately household chores that he/she used to perform in the past			
39.	Complete household chores adequately as he/she used to perform in the past			
40.	Stay safely at home by himself/herself when needed			

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WEIGHT

INFORMATION NOT OBTAINED ☐

Measure with shoes off. Round up or down to the nearest tenth kilogram or tenth pound.

Weight ___ ___ ___ . ___ ☐ kg Kilogram ☐ lb Pound

VITAL SIGNS : HEART RATE AND BLOOD PRESSURE

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) and 3 minutes.

Position
SU = Supine ST = Standing

	(DNDE) Reference Time	Timing Code	Position	Heart Rate (bpm)	Blood Pressure (mmHg) Systolic/Diastolic
0.	5 minutes	815	SU		/
1.	1 minute	816	ST		/
2.	3 minutes	817	ST		/

VITAL SIGNS : TEMPERATURE

INFORMATION NOT OBTAINED ☐

Temperature ___ ___ ___ . ___

Unit of measure ☐ F Fahrenheit ☐ C Centigrade

Method ☐ PO Oral ☐ R Rectal ☐ A Axillary ☐ E Ear ☐ O Other

ELECTROCARDIOGRAM

NOT DONE ☐

Electrocardiogram date _____/_____/_____
MM DD YY

Electrocardiogram result ☐ 12 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

NO COMMENTS ☐

Print legibly and do not use abbreviations or symbols.

ACCEPTABILITY : CAREGIVER'S RESPONSE ABOUT THE PATCH

INFORMATION NOT OBTAINED ☐

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):

☐ 1 Insist that the patient receive an oral pill

☐ 2 Prefer that the patient receive an oral pill

☐ 3 Have no preference (neutral) for an oral or patch formulation

☐ 4 Prefer that the patient receive a patch

☐ 5 Insist that the patient receive a patch

ACCEPTABILITY : CAREGIVER'S RESPONSE ABOUT THE PATCH

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 appearance of the patch while being worn is acceptable:

1	2	3	4	5	6	7
Strongly Disagree			Neutral			Strongly Agree

2. The size of the patch is acceptable:

1	2	3	4	5	6	7
Strongly Disagree			Neutral			Strongly Agree

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

1	2	3	4	5	6	7
Strongly Disagree			Neutral			Strongly Agree

STUDY DRUG THERAPY : DATE OF FINAL DOSE

Date of final dose of study drug _____/_____/_____
MM DD YY

PATIENT SUMMARY

Patient Initials _____ _____ _____
First Middle Last

CHECK ONE PRIMARY REASON FOR ENDING PARTICIPATION IN THE STUDY

☐ 1 Protocol completed

☐ 3 Adverse event E __ __
E__ Code

☐ 4 Death* E __ __
E__ Code

If # **4** is checked, enter date of death.

Date of Death ____/_____/____
MM DD YY

☐ 8 Lack of efficacy, patient/caregiver perception

☐ 9 Lack of efficacy, physician perception

☐ 11 Unable to contact patient (lost to follow-up)

☐ 13 Personal conflict or other patient/caregiver decision _____
Specify

☐ 22 Physician decision _____
Specify

☐ 14 Protocol entry criteria not met _____ (Specify number from entry criteria checklist)
Specify

☐ 243 Protocol violation

☐ 18 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.

COMMENTS : STUDY SUMMARY

NO COMMENTS ☐

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.

All information reported for this patient is accurate and complete.

_____ _____/_____/_____
Investigator Signature MM DD YY

TRIAL – Adverse Event Reporting Form **Page ___ of ___**

International ID No. ____________________ **DEN Mfr. Control No.** ________________

Research Code: **H2Q** Facility Code: **MC** Study Code: **LZZT** | Investigator No: | Indication: **Alzheimer's**

Patient Identification

Patient Number ______________ **Kit Number** ______________

Concomitant Medication(s) Information (Exclude those medications used to treat the event)

Name of Concomitant Medication ____
Dose ________ Unit ________ Frequency________ Route ________

Start Date ____/_______/____ Stop Date ____/_______/____ Indication for Use ____________
(DD MMM YY) (DD MMM YY)
Duration Drug taken____day(s) week(s) month(s) year(s) (circle one unit)

Name of Concomitant Medication ____
Dose ________ Unit ________ Frequency________ Route ________

Start Date ____/_______/____ Stop Date ____/_______/____ Indication for Use ____________
(DD MMM YY) (DD MMM YY)
Duration Drug taken____day(s) week(s) month(s) year(s) (circle one unit)

Name of Concomitant Medication ____
Dose ________ Unit ________ Frequency________ Route ________

Start Date ____/_______/____ Stop Date ____/_______/____ Indication for Use ____________
(DD MMM YY) (DD MMM YY)
Duration Drug taken____day(s) week(s) month(s) year(s) (circle one unit)

Name of Concomitant Medication ____
Dose ________ Unit ________ Frequency________ Route ________

Start Date ____/_______/____ Stop Date ____/_______/____ Indication for Use ____________
(DD MMM YY) (DD MMM YY)
Duration Drug taken____day(s) week(s) month(s) year(s) (circle one unit)

Name of Concomitant Medication ____
Dose ________ Unit ________ Frequency________ Route ________

Start Date ____/_______/____ Stop Date ____/_______/____ Indication for Use ____________
(DD MMM YY) (DD MMM YY)
Duration Drug taken____day(s) week(s) month(s) year(s) (circle one unit)

Name of Concomitant Medication ____
Dose ________ Unit ________ Frequency________ Route ________

Start Date ____/_______/____ Stop Date ____/_______/____ Indication for Use ____________
(DD MMM YY) (DD MMM YY)
Duration Drug taken____day(s) week(s) month(s) year(s) (circle one unit)

Name of Concomitant Medication ____
Dose ________ Unit ________ Frequency________ Route ________

Start Date ____/_______/____ Stop Date ____/_______/____ Indication for Use ____________
(DD MMM YY) (DD MMM YY)
Duration Drug taken____day(s) week(s) month(s) year(s) (circle one unit)

Comments:

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 changes 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 changed 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 caregiver distress 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 total NPI score 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.

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

A. Delusions

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 convinced that these things are happening to him/her.

NO (If no, proceed to the next screening question) YES (If yes, proceed to subquestions).

1. Does the patient believe that he/she is in danger - that others are planning to hurt him/her? _____
2. Does the patient believe that others are stealing from him/her? _____
3. Does patient believe that his/her spouse is having an affair? _____
4. Does patient believe that unwelcome guests are living in his/her house? _____
5. Does the patient believe that his/her spouse or others are not who they claim to be? _____
6. Does the patient believe that his/her house is not his/her home? _____
7. Does the patient believe that family members plan to abandon him/her? _____
8. Does the patient believe that television or magazine figures are actually present in the home? [Does he/she try to talk or interact with them?] _____
9. Does the he/she believe any other unusual things that I haven't asked about? _____

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

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 - delusions present but seem harmless and produce little distress in the patient.
2. Moderate - delusions are distressing and disruptive.
3. Marked - delusions are very disruptive and are a major source of behavioral disruption. [If PRN medications are prescribed, their use signals that the delusions are of marked severity.]

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

B. Hallucinations

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 to the next screening question) YES (If yes, proceed to subquestions).

1. Does the patient describe 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 patient report smelling odors not smelled by others? _____
5. Does the patient describe feeling things on his/her skin or otherwise appear to be feeling things crawling or toughing him/her? _____
6. Does the patient describe tastes that are without any known cause? _____
7. Does the patient describe any other unusual sensory experiences? _____

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

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 - hallucinations present but seem harmless and produce little distress in the patient.
2. Moderate - hallucinations are distressing and disruptive to the patient.
3. Marked - hallucinations are very disruptive and are a major source of behavioral disturbance. PRN medications may be required to control them.

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

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/her 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 things? _____
7. Does the patient attempt to hurt or hit others? _____
8. Does the patient have any other aggressive or agitated 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.
3. 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

D. Depression/Dysphoria

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

NO (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? _____

If the 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.
4. Very frequently - once or more per day.

Severity:
1. 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.
3. 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

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?

NO (If no, proceed to the next screening question) YES (If yes, proceed to subquestions).

1. Does the patient say 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. Does the patient avoid certain places or situations that make him/her more nervous such as riding in the car, meeting with friends, or being in crowds? _____
6. Does the patient become nervous and upset when separated from you [or his/her caregiver]? [Does he/she cling to you to keep from being separated?] _____
7. Does the patient show any other signs of anxiety? _____

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

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 - anxiety is distressing but usually responds to redirection or reassurance.
2. Moderate - anxiety is distressing, anxiety symptoms are spontaneously voiced by the patient and difficult to alleviate.
3. Marked - anxiety 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

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 abnormally good mood or finds humor where others do not.

NO (If no, proceed to the next screening question) YES (If yes, proceed to subquestions).

1. Does the patient appear to feel too good or to be too happy, different from his/her usual self? _____
2. Does the patient find 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 patient "talk big" or claim to have more abilities or wealth than is true? _____
7. Does the patient show any other signs of feeling too good or being too happy? _____

If the screening question is confirmed, determine the frequency and severity of the elation/euphoria.

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 - elation is notable to friends and family but is not disruptive.
2. Moderate - elation is notably abnormal.
3. Marked - elation is very pronounced; patient is euphoric and finds nearly everything to be humorous.

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

G. Apathy/Indifference

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?

NO (If no, proceed to the next screening question) YES (If yes, proceed to subquestions).

1. Does the patient seem less spontaneous and less active than usual? _____
2. Is the patient less likely to initiate a conversation? _____
3. Is the patient less affectionate or lacking in emotions when compared to his/her usual self? _____
4. Does the patient contribute less to household chores? _____
5. Does the patient seem less interested in the activities and plans of others? _____
6. Has the patient lost interest in friends and family members? _____
7. Is the patient less enthusiastic about his/her usual interests? _____
8. 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

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 to the next screening question) YES (If yes, proceed to subquestions).

1. Does the patient act impulsively without appearing to consider the consequences? _____
2. Does the patient talk 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 patient take liberties or touch or hug others in way that is out of character for him/her? _____
7. Does the patient show any other signs of loss of control of his/her impulses? _____

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

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 - disinhibition is notable but usually responds to redirection and guidance.
2. Moderate - disinhibition is very evident and difficult to overcome by the caregiver.
3. Marked - disinhibition usually fails to respond to any intervention by the caregiver, and is a source of embarrassment or social distress.

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

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 abnormal irritability, impatience, or rapid emotional changes different from his/her usual self.

NO (If no, proceed to the 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 cranky and irritable? _____
6. Is the patient argumentative and difficult to get along with? _____
7. Does the patient show any other signs of irritability? _____

If the screening question is confirmed, determine the frequency and severity of the irritability/ lability.

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 - irritability or lability is notable but usually responds to redirection and reassurance.
2. Moderate - irritability and lability are very evident and difficult to overcome by the caregiver.
3. Marked - irritability and lability are very evident, they usually fail to respond to any intervention by the caregiver, and they are a major source of distress.

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

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?

NO (If no, proceed to the next screening question) YES (If yes, proceed to subquestions).

1. Does the patient pace around the house without apparent purpose? _____
2. Does the patient rummage around opening and unpacking drawers or closets? _____
3. Does the patient repeatedly put 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 patient do any other activities over and over? _____

If the screening question is confirmed, determine the frequency and severity of the aberrant motor activity:

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 - abnormal motor activity is notable but produce little interference with daily routines.
2. Moderate - abnormal motor activity is very evident; can be overcome by the caregiver.
3. Marked - abnormal motor activity is very evident, it usually fails to respond to any intervention by the caregiver and is are a major source of distress.

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

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?

NO (If no, proceed to the next screening question) YES (If yes, proceed to subquestions).

1. Does the patient have difficulty falling asleep? _____
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 patient awaken too early in the morning (earlier that was his/her habit)? _____
7. Does the patient sleep excessively during the day? _____
8. Does the patient have any other night-time behaviors that bother you that we haven't talked about? _____

If the screening question is confirmed, determine the frequency and severity of the night-time behavior disturbance.

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 - night-time behaviors occur but they are not particularly disruptive.
2. Moderate - night-time behaviors occur and disturb the patient and the sleep of the caregiver; more than one type of night-time behavior may be present.
3. Marked - night-time behaviors occur; several types of night-time behaviors may be present; the patient is very distressed during the night and the caregiver's sleep is markedly disturbed.

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

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?

NO (If no, proceed to the next screening question) YES (If yes, proceed to subquestions).

1. Has he/she had a loss of appetite? _____
2. Has he/she had an increase in appetite? _____
3. Has he/she had a loss of weight? _____
4. Has he/she gained weight? _____
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. Has he/she developed eating behaviors such as eating exactly the same types of food each day or eating the food in exactly the same order? _____
8. Have there been any other changes in appetite or eating that I haven't asked about? _____

If the screening question is confirmed, determine the frequency and severity of the changes in eating habits or appetite.

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 - changes in appetite or eating are present but have not led to changes in weight and are not disturbing
2. Moderate - changes in appetite or eating are present and cause minor fluctuations in weight.
3. Marked - obvious changes in appetite or eating are present and cause fluctuations in weight, are embarrassing, or otherwise disturb 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

WORKSHEET (DNDE)
H2Q-MC-LZZT

Investigator No. _____
Patient No. _____
Visit _____

DISABILITY ASSESSMENT FOR DEMENTIA (DAD)

INFORMATION NOT OBTAINED ☐

Clinician's initials _____ _____ _____
First Middle Last

During the past two weeks, did the patient without help or reminder:

SCORING: **Yes = 1** **No = 0** **Not Applicable = 96**

		Initiation	Planning & Organization	Effective Performance
	HYGIENE			
1.	Undertake to wash himself/herself or to take a bath or a shower			
2.	Undertake to brush his/her teeth or care for his/her dentures			
3.	Decide to care for his/her hair (wash and comb)			
4.	Prepare the water, towels, and soap for washing, taking a bath, or a shower			
5.	Wash and dry completely all parts of his/her body safely			
6.	Brush his/her teeth or care for his/her dentures appropriately			
7.	Care for his/her hair (wash and comb)			
	DRESSING			
8.	Undertake to dress himself/herself			
9.	Choose appropriate clothing (with regard to the occasion, neatness, the weather, and color combination)			
10.	Dress himself/herself in the appropriate order (undergarments, pant/dress, shoes)			
11.	Dress himself/herself completely			
12.	Undress himself/herself completely			
	CONTINENCE			
13.	Decide to use the toilet at appropriate times			
14.	Use the toilet without "accidents"			
	EATING			
15.	Decide that he/she needs to eat			
16.	Choose appropriate utensils and seasonings when eating			
17.	Eat his/her meals at a normal pace and with appropriate manners			
	MEAL PREPARATION			
18.	Undertake to prepare a light meal or snack for himself/herself			
19.	Adequately plan a light meal or snack (ingredients, cookware)			
20.	Prepare or cook a light meal or a snack safely			

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WORKSHEET (DNDE)
H2Q-MC-LZZT

DISABILITY ASSESSMENT FOR DEMENTIA (DAD)

SCORING: **Yes = 1** **No = 0** **Not Applicable = 96**

		Initiation	Planning & Organization	Effective Performance
	TELEPHONING			
21.	Attempt to telephone someone at a suitable time			
22.	Find and dial a telephone number correctly			
23.	Carry out an appropriate telephone conversation			
24.	Write and convey a telephone message adequately			
	GOING ON AN OUTING			
25.	Undertake to go out (walk, visit, shop) at an appropriate time			
26.	Adequately organize an outing with respect to transportation, keys, destination, weather, necessary money, shopping list			
27.	Go out and reach a familiar destination without getting lost			
28.	Safely take the adequate mode of transportation (car, bus, taxi)			
29.	Return from the store with the appropriate items			
	FINANCE AND CORRESPONDENCE			
30.	Show an interest in his/her personal affairs such as his/her finances and written correspondence			
31.	Organize his/her finances to pay his/her bills (cheques, bankbook, bills)			
32.	Adequately organize his/her correspondence with respect to stationery, address, stamps			
33.	Handle adequately his/her money (make change)			
	MEDICATIONS			
34.	Decide to take his/her medications at the correct time			
35.	Take his/her medications as prescribed (according to the right dosage)			
	LEISURE AND HOUSEWORK			
36.	Show an interest in leisure activity(ies)			
37.	Take an interest in household chores that he/she used to perform in the past			
38.	Plan and organize adequately household chores that he/she used to perform in the past			
39.	Complete household chores adequately as he/she used to perform in the past			
40.	Stay safely at home by himself/herself when needed			

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