Alzheimer's Disease
IDGN-AD-AO5

I. INCLUSION AND EXCLUSION CRITERIA

INCLUSION CRITERIA

	Yes	No
1. Subject is diagnosed with Probable AD according to NINCDS/ADRDA Criteria for Alzheimer's Disease.	☐	☐
2. Onset age ≥ 60.	☐	☐
3. All 4 grandparents are of Ashkenazi Jewish origin as declared by the subject.	☐	☐
4. Subject or subject's legal representative has signed the informed consent form.	☐	☐

EXCLUSION CRITERIA

	Yes	No
1. Subject is diagnosed with Possible AD according to NINCDS/ADRDA Criteria for Alzheimer's Disease.	☐	☐
2. Subject is diagnosed with dementia due to other diseases, or with AD and contribution of other disorders (Mixed dementia): Degenerative dementia such as: frontal lobe dementia, cortical basal dementia, progressive supranuclear palsy and primary progressive aphasia; dementia associated with significant Parkinsonism, e.g. Parkinson's disease, diffuse Lewy body disease; multi-infarct dementia (vascular dementia); primary and secondary brain tumor; genetic disorder associated with dementia (e.g. Huntington's disease, Pick's disease, fronto-temporal dementia, hereditary ataxias, early-onset familial AD); dementia due to sporadic or familiar forms of prion diseases, e.g. Creutzfeldt-Jakob disease; mild cognitive impairment (age associated memory impairment / age related memory decline); diffuse white matter disease; normal-pressure hydrocephalus; head injury leading to cognitive decline; recently diagnosed or untreated thyroid disease; vitamin B12 or folic acid deficiency; drug and medication intoxication; severe depression (pseudodementia); chromosome 21 trisomy (Down syndrome); neurosyphilis; HIV dementia.	☐	☐
3. Brain CT/MRI suggesting alternative diagnoses, such as intracranial space occupying lesions, vascular lesion of the brain, white matter lesion, or hydrocephalus.	☐	☐
4. Subject is a known carrier of a blood transmitted infectious disease or suffers from conditions in which phlebotomy is contra-indicated.	☐	☐

Subject is eligible for the study, if all INCLUSION criteria are YES and all EXCLUSION criteria are NO.

INVESTIGATOR'S STATEMENT

I have verified the data entered in the Case Report Form and have determined that it is complete, accurate and compatible with the source documents.

Investigator's name (printed)	Investigator's signature	Day	Month	Year
_____	_____	☐☐ /	☐☐ /	☐☐

Where appropriate mark like this ☒ (not like this √)

SUBJECT BARCODE STICKER

Alzheimer's Disease
IDGN-AD-AO5

II. DEMOGRAPHICS

1. Sex: ☐ **Male** ☐ **Female**

2. Year of birth: ☐☐☐☐

3. Country of birth: _____

4. Year of immigration: ☐☐☐☐

III. FAMILY HISTORY

1. Mother

	Country of birth
1.1 Mother:	_____
1.2 Grandfather:	_____
1.3 Grandmother:	_____

	Yes	No*
1.4 Mother is alive	☐	☐

*If not, specify age at death: ☐☐

2. Father

	Country of birth
2.1 Father:	_____
2.2 Grandfather:	_____
2.3 Grandmother:	_____

	Yes	No*
2.4 Father is alive	☐	☐

*If not, specify age at death: ☐☐

3. Blood relatives:

3.1 Specify total number of siblings (including patient): ☐☐

3.2 For close relatives suffering from Alzheimer's disease or Dementia, mark appropriate boxes and specify age at onset:

Alzheimer's Disease / Dementia

	Yes	Age at onset
Mother	☐	☐☐
Father	☐	☐☐
Sib. 1	☐	☐☐
Sib. 2	☐	☐☐
Sib. 3	☐	☐☐
Sib. 4	☐	☐☐
Sib. 5	☐	☐☐

SUBJECT BARCODE STICKER

IV. MEDICAL HISTORY

1. Age at diagnosis: ☐☐

2. For the following features, indicate their presence at diagnosis and / or during the disease course:

Clinical Features	At Presentation	During Disease Course	Never or Unknown
Forgetfulness	☐	☐	☐
Language impairment	☐	☐	☐
Perception impairment	☐	☐	☐
Gait disorder	☐	☐	☐
Other motor dysfunction	☐	☐	☐
Spatial impairment	☐	☐	☐
Paranoia or personality change	☐	☐	☐
Depression mandating medications	☐	☐	☐
Disturbed sleep-wake pattern	☐	☐	☐
Incontinence	☐	☐	☐

3. The patient's clinical course can be best described as (choose one):

Continuously progressive ☐

Composed of one or more plateau periods ☐

4. Specify life-long number of smoking years ☐☐

Specify average number of packs a day ☐

	Yes	No	Unknown
5. For women: Is / was the patient treated with post-menopausal hormonal replacement therapy?	☐*	☐	☐

***If yes,** specify approximate age at treatment onset: ☐☐

***If stopped,** specify approximate age at which treatment was discontinued: ☐☐

6. Specify other chronic diseases: _____

_____

SUBJECT BARCODE STICKER

V. MEDICATIONS

	Yes	No
1. Is / was the patient treated with Donepezil (Aricept, Asenta, Memorit)?	☐	☐

If yes, the <u>initial</u> response can be described as:

None ☐ Mild ☐ Significant ☐

Was the drug stopped because of an adverse reaction?	☐	☐

If yes, specify the adverse reaction:

Gastrointestinal intolerance ☐ Headache ☐ Dizziness ☐ Other ☐ *

***Specify**: _____

2. Is / was the patient treated with Rivastigmine (Exelon)?	☐	☐

If yes, the <u>initial</u> response can be described as:

None ☐ Mild ☐ Significant ☐

Was the drug stopped because of an adverse reaction?	☐	☐

If yes, specify the adverse reaction:

Gastrointestinal intolerance ☐ Headache ☐ Dizziness ☐ Other ☐ *

***Specify**: _____

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