

**Multiple Sclerosis
IDGN-MS-A07**

I. INCLUSION AND EXCLUSION CRITERIA		
INCLUSION CRITERIA		
	Yes	No
1. Subject is diagnosed with Definite or Probable Multiple Sclerosis according to the Diagnostic Criteria for Multiple Sclerosis.	<input type="checkbox"/>	<input type="checkbox"/>
2. All 4 grandparents are of Ashkenazi Jewish origin as declared by the subject.	<input type="checkbox"/>	<input type="checkbox"/>
3. Subject or subject's legal representative has signed the informed consent form.	<input type="checkbox"/>	<input type="checkbox"/>
EXCLUSION CRITERIA		
	Yes	No
1. Subject is diagnosed with another etiology causing white matter disease: acute disseminated encephalomyelitis (ADEM); Lyme disease; HIV-associated myelopathy; HTLV-1 myelopathy; neurosyphilis; progressive multifocal leukoencephalopathy; systematic lupus erythematosus and/or anti-phospholipid syndrome; polyarteritis nodosa; Sjogren syndrome; Bechet disease; sarcoidosis; paraneoplastic syndromes; subacute myelo-optic neuropathy; adrenomyeloneuropathy; spinocerebellar degenerations; hereditary spastic paraparesis / primary lateral sclerosis; stroke.	<input type="checkbox"/>	<input type="checkbox"/>
2. Subject is a known carrier of a blood transmitted infectious disease or suffers from conditions in which phlebotomy is contra-indicated.	<input type="checkbox"/>	<input type="checkbox"/>
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.		
_____	_____	<input type="checkbox"/> <input type="checkbox"/> / <input type="checkbox"/> <input type="checkbox"/> / <input type="checkbox"/> <input type="checkbox"/>
Investigator's name (printed)	Investigator's signature	Day Month Year

Where appropriate mark like this (not like this)

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II. DEMOGRAPHICS	
1. Sex: <input type="checkbox"/> Male <input type="checkbox"/> Female	3. Country of birth: _____
2. Year of birth: <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	4. Year of immigration: <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>

III. FAMILY HISTORY																																			
1. Mother <div style="text-align: right; margin-right: 20px;">Country of birth</div> <p>1.1 Mother: _____</p> <p>1.2 Grandfather: _____</p> <p>1.3 Grandmother: _____</p> <p>1.4 Mother is alive <input type="checkbox"/> Yes <input type="checkbox"/> No*</p> <p>*If not, specify age at death: <input type="text"/> <input type="text"/></p>	2. Father <div style="text-align: right; margin-right: 20px;">Country of birth</div> <p>2.1 Father: _____</p> <p>2.2 Grandfather: _____</p> <p>2.3 Grandmother: _____</p> <p>2.4 Father is alive <input type="checkbox"/> Yes <input type="checkbox"/> No*</p> <p>*If not, specify age at death: <input type="text"/> <input type="text"/></p>																																		
3. Blood relatives:																																			
<p>3.1 Specify total number of siblings (including patient): <input type="text"/> <input type="text"/></p> <p style="margin-left: 40px;">Specify birth order of patient: <input type="text"/></p> <p>3.2 For close relatives suffering from Multiple Sclerosis, mark gender and age at onset:</p> <table border="1" style="width: 100%; border-collapse: collapse; margin-top: 10px;"> <thead> <tr> <th rowspan="2"></th> <th colspan="2" style="text-align: center;">Gender</th> <th rowspan="2" style="text-align: center;">Age</th> </tr> <tr> <th style="text-align: center;">M</th> <th style="text-align: center;">F</th> </tr> </thead> <tbody> <tr> <td>Mother</td> <td></td> <td></td> <td style="text-align: center;"><input type="text"/> <input type="text"/></td> </tr> <tr> <td>Father</td> <td></td> <td></td> <td style="text-align: center;"><input type="text"/> <input type="text"/></td> </tr> <tr> <td>Sib. 1</td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="text"/> <input type="text"/></td> </tr> <tr> <td>Sib. 2</td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="text"/> <input type="text"/></td> </tr> <tr> <td>Sib. 3</td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="text"/> <input type="text"/></td> </tr> <tr> <td>Sib. 4</td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="text"/> <input type="text"/></td> </tr> <tr> <td>Sib. 5</td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="text"/> <input type="text"/></td> </tr> </tbody> </table>			Gender		Age	M	F	Mother			<input type="text"/> <input type="text"/>	Father			<input type="text"/> <input type="text"/>	Sib. 1	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/> <input type="text"/>	Sib. 2	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/> <input type="text"/>	Sib. 3	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/> <input type="text"/>	Sib. 4	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/> <input type="text"/>	Sib. 5	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/> <input type="text"/>
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IV. MEDICAL HISTORY			
1. Age at diagnosis: <input type="text"/> <input type="text"/>		2. Age at symptom / sign onset: <input type="text"/> <input type="text"/>	
3. The diagnosis of Multiple Sclerosis at present is:			
Clinically definite MS <input type="checkbox"/>	Laboratory supported definite MS <input type="checkbox"/>		
Clinically probable MS <input type="checkbox"/>	Laboratory supported probable MS <input type="checkbox"/>		
4. The disease course can be characterized at present as (choose one):			
Relapsing-remitting		<input type="checkbox"/>	
Secondary progressive (relapsing-remitting evolving into progressive)		<input type="checkbox"/>	
Progressive-relapsing (progressive with superimposed relapses)		<input type="checkbox"/>	
Primary progressive		<input type="checkbox"/>	
5. The disease <u>presenting</u> symptoms and signs included (mark as many as appropriate):			
Limb paresthesia / hypesthesia <input type="checkbox"/>	Diplopia (Internuclear ophthalmoplegia) <input type="checkbox"/>		
Ataxia <input type="checkbox"/>	Optic neuritis <input type="checkbox"/>	*If yes, specify: unilateral <input type="checkbox"/> bilateral <input type="checkbox"/>	
Lhermitte's sign <input type="checkbox"/>	Trigeminal neuralgia <input type="checkbox"/>	Limb(s) weakness <input type="checkbox"/>	
Urinary incontinence / retention <input type="checkbox"/>	Paroxysmal attacks (any kind) <input type="checkbox"/>	Vertigo <input type="checkbox"/>	
6. Were the <u>presenting</u> symptoms / signs asymmetric?		Yes <input type="checkbox"/>	No <input type="checkbox"/>
7. During the disease course, which of the following C.N.S. areas became involved, including presenting symptoms (mark as many as appropriate):			
Pyramidal tracts <input type="checkbox"/>	Ocular motility <input type="checkbox"/>		
Cerebellar / vestibular pathways <input type="checkbox"/>	Optic nerves <input type="checkbox"/>		
Posterior column <input type="checkbox"/>	Cognitive function <input type="checkbox"/>		
Autonomic system (including urinary) <input type="checkbox"/>	Affective function <input type="checkbox"/>		
	Yes	No	Unknown
8. Do the patient's symptoms worsen with high body temperature?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9. <u>For women</u> : Specify number of pregnancies <input type="text"/> <input type="text"/>			
10. <u>For women</u> : If relevant, was there a disease exacerbation during pregnancy or up to six months post-partum?	<input type="checkbox"/>	<input type="checkbox"/>	
11. Specify other chronic diseases: _____ _____ _____			

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V. MEDICATIONS

For the listed medications specify relevant adverse events if they caused drug discontinuation:

	Interferon beta-1b (Betaseron)	Interferon beta-1a (Avonex)	Interferon beta-1a (Rebif)	Glatiramer acetate (Copaxone)
Never tried	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Injection site reaction ¹	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Flu-like symptoms ²	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
G.I. Intolerance ³	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Dysmenorrhagia	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Headache / Dizziness	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Mental disorder ⁴	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Abnormal liver function test ⁵	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Neutropenia ⁶	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Immediate post injection reaction ⁷	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Other, specify: _____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

¹ Pain, erythema, induration, hypersensitivity, necrosis

² Fever, chills, myalgia, malaise

³ Vomiting, diarrhea, constipation

⁴ Depression, anxiety, nervousness, somnolence

⁵ AST>5 times baseline or Bilirubin>2.5 times baseline

⁶ Neutrophil count<1500 cells / mm³

⁷ Flushing, chest tightness, palpitations, dyspnea

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