

TODAY2 Form NEURO, Neuropathy Screening

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Release Participant ID

RELEASEID

Release Visit Number

PVISIT

1. Days since randomization

DAYS

Instructions: Part Ia is a self-administered questionnaire to be completed at annual visits and at the final study visit. Part Ib and Part II are exams completed at annual visits and at the final study visit by trained study staff. Part III is an additional examination completed at the final study visit only by trained study staff.

Instructions for Part Ia: Please take a few minutes to answer the following questions about the feeling in your legs and feet. Check yes or no based on how you usually feel. Thank you.

Part Ia.

History

	Yes	No	
2. Are your legs and/or feet numb?	<input type="checkbox"/> ₁	<input type="checkbox"/> ₀	BBNUMB
3. Do you ever have any burning pain in your legs and/or feet?	<input type="checkbox"/> ₁	<input type="checkbox"/> ₀	BBBURN
4. Are your legs and/or feet too sensitive to touch?	<input type="checkbox"/> ₁	<input type="checkbox"/> ₀	BBTOUCH
5. Do you get muscle cramps in your legs and/or feet?	<input type="checkbox"/> ₁	<input type="checkbox"/> ₀	BBCRAMP
6. Do you ever have any prickling feelings in your legs and/or feet?	<input type="checkbox"/> ₁	<input type="checkbox"/> ₀	BBPRICK
7. Does it hurt when the bed covers touch your skin?	<input type="checkbox"/> ₁	<input type="checkbox"/> ₀	BBSKIN
8. When you get into the tub or shower, are you able to tell the hot water from the cold water?	<input type="checkbox"/> ₁	<input type="checkbox"/> ₀	BBHC
9. Have you ever had an open sore on your foot?	<input type="checkbox"/> ₁	<input type="checkbox"/> ₀	BBSORE
10. Has your doctor ever told you that you have diabetic neuropathy?	<input type="checkbox"/> ₁	<input type="checkbox"/> ₀	BBNEUROP
11. Do you feel weak all over most of the time?	<input type="checkbox"/> ₁	<input type="checkbox"/> ₀	BBWEAK

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12. Are your symptoms worse at night?

₁ ₀

BBNIGHT

13. Do your legs hurt when you walk?

₁ ₀

BBWALK

14. Are you able to sense your feet when you walk?

₁ ₀

BBSENSE

15. Is the skin on your feet so dry that it cracks open?

₁ ₀

BBDRY

Instructions for Part Ib: Completed only after Part Ia has been completed and is an exam performed by trained study staff.

Part Ib.

Examination

a. Appearance and condition

Left Foot: ₁ Normal ₂ Abnormal

MLFOOT

Right Foot: ₁ Normal ₂ Abnormal

MRFOOT

If ABNORMAL Check all that apply

Deformities

Left Foot: ₁

MLDEFORM

Right Foot: ₁

MRDEFORM

Dry skin, callus

Left Foot: ₁

MLDRY

Right Foot: ₁

MRDRY

Infection

Left Foot: ₁

MLINFEC

Right Foot: ₁

MRINFEC

Fissure

Left Foot: ₁

MLFISS

Right Foot: ₁

MRFISS

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b. Ulceration	Left Foot:	<input type="checkbox"/> ₁ Present	<input type="checkbox"/> ₂ Absent	<input type="text"/>	
	Right Foot:	<input type="checkbox"/> ₁ Present	<input type="checkbox"/> ₂ Absent	<input type="text"/>	
c. Ankle reflexes	Left Foot:	<input type="checkbox"/> ₁ Present	<input type="checkbox"/> ₂ Present/ Reinforcement	<input type="checkbox"/> ₃ Absent	<input type="text"/>
	Right Foot:	<input type="checkbox"/> ₁ Present	<input type="checkbox"/> ₂ Present/ Reinforcement	<input type="checkbox"/> ₃ Absent	<input type="text"/>
d. Vibration perception at great toe	Left Foot:	<input type="checkbox"/> ₁ Present (<10 sec)	<input type="checkbox"/> ₂ Reduced (≥ 10 sec)	<input type="checkbox"/> ₃ Absent	<input type="text"/>
	Right Foot:	<input type="checkbox"/> ₁ Present (<10 sec)	<input type="checkbox"/> ₂ Reduced (≥ 10 sec)	<input type="checkbox"/> ₃ Absent	<input type="text"/>

Instructions for Part II: Completed only after Part I has been completed and is a test performed by trained study staff.

Part II.

Monofilament Test					
10 gm filament (number of applications detected)	Left Foot:	<input type="checkbox"/> ₁ Present (≥ 8)	<input type="checkbox"/> ₂ Reduced (1 - 7)	<input type="checkbox"/> ₃ Absent (0)	<input type="text"/>
	Right Foot:	<input type="checkbox"/> ₁ Present (≥ 8)	<input type="checkbox"/> ₂ Reduced (1 - 7)	<input type="checkbox"/> ₃ Absent (0)	<input type="text"/>

Instructions for Part III: Test performed by trained study staff.

Part IIIa.

Pinprick Sensation Test						
		Left Foot		Right Foot		
1.	Trial 1	(Dull) <input type="checkbox"/> ₁ Yes	<input type="checkbox"/> ₀ No	(Sharp) <input type="checkbox"/> ₁ Yes	<input type="checkbox"/> ₀ No	<input type="text"/>
2.	Trial 2	(Dull) <input type="checkbox"/> ₁ Yes	<input type="checkbox"/> ₀ No	(Dull) <input type="checkbox"/> ₁ Yes	<input type="checkbox"/> ₀ No	<input type="text"/>
3.	Trial 3	(Sharp) <input type="checkbox"/> ₁ Yes	<input type="checkbox"/> ₀ No	(Dull) <input type="checkbox"/> ₁ Yes	<input type="checkbox"/> ₀ No	<input type="text"/>

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4.	Trial 4	(Dull)	<input type="checkbox"/> 1 Yes	<input type="checkbox"/> 0 No	(Sharp)	<input type="checkbox"/> 1 Yes	<input type="checkbox"/> 0 No	LPRICK4/ RPRICK4
5.	Trial 5	(Sharp)	<input type="checkbox"/> 1 Yes	<input type="checkbox"/> 0 No	(Dull)	<input type="checkbox"/> 1 Yes	<input type="checkbox"/> 0 No	LPRICK5/ RPRICK5
6.	Trial 6	(Sharp)	<input type="checkbox"/> 1 Yes	<input type="checkbox"/> 0 No	(Sharp)	<input type="checkbox"/> 1 Yes	<input type="checkbox"/> 0 No	LPRICK6/ RPRICK6
7.	Trial 7	(Sharp)	<input type="checkbox"/> 1 Yes	<input type="checkbox"/> 0 No	(Sharp)	<input type="checkbox"/> 1 Yes	<input type="checkbox"/> 0 No	LPRICK7/ RPRICK7
8.	Trial 8	(Dull)	<input type="checkbox"/> 1 Yes	<input type="checkbox"/> 0 No	(Dull)	<input type="checkbox"/> 1 Yes	<input type="checkbox"/> 0 No	LPRICK8/ RPRICK8

Part IIIb.

Vibratory Sensation Test		Yes	No	Cessation
1.	Left foot vibration detection Trial 1	<input type="checkbox"/> 1	<input type="checkbox"/> 0	<input type="checkbox"/> . <input type="checkbox"/>
2.	Left foot vibration detection Trial 2	<input type="checkbox"/> 1	<input type="checkbox"/> 0	<input type="checkbox"/> . <input type="checkbox"/>
3.	Right foot vibration detection Trial 1	<input type="checkbox"/> 1	<input type="checkbox"/> 0	<input type="checkbox"/> . <input type="checkbox"/>
4.	Right foot vibration detection Trial 2	<input type="checkbox"/> 1	<input type="checkbox"/> 0	<input type="checkbox"/> . <input type="checkbox"/>

LVIB1/ LCESS1

LVIB2/ LCESS2

RVIB1/ RCESS1

RVIB2/ RCESS2