	RELEASEID		PVISIT
Release Participant ID	Rel	ease Visit Number	
·			

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.

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

Relea	RELEASEID	Release Visit Number	PVISI	-	
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:	Normal	2 Abnormal	MLFOOT
	Right Foot:	Normal		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

Release Participant ID	RELEASEID	PVISIT Release Visit Number	
b. Ulceration	Left Foot:	sent2 Absent	MLULCER
	Right Foot:1 Pres	sent2 Absent	MRULCER
c. Ankle reflexes	Left Foot:1 Present	Present/	MLANKLE
	Right Foot:1 Present	$\square_2 \frac{\text{Present}}{\text{Reinforcement}} \qquad \square_3 \frac{\text{Absent}}{1}$	MRANKLE
d. Vibration perception at great toe	Left Foot:1 Present 1 (<10 sec)	Reduced \square_2 (≥ 10 sec) \square_3 Absent	MLTOE
	Right Foot: 1 (<10 sec)	Reduced \square_2 (≥ 10 sec) \square_3 Absent	MRTOE

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

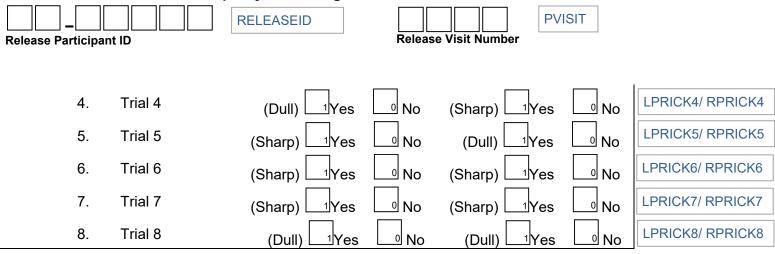
Part II.

Monofilament Test				
10 gm filament (number of applications detected)	Left Foot:	$\square_1 \text{ ($\geq 8$)} \text{ Present } \square_2 \text{ Reduced}$	Absent 3 (0)	MLFILAM
	Right Foot:	$\square_1 \text{ ($\geq 8$)} \qquad \square_2 \text{ Reduced}$	Absent 3 (0)	MRFILAM

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

Part IIIa.

Left Foot Right Foot
1. Trial 1 (Dull) Yes No (Sharp) Yes No
2. Trial 2 (Dull) Yes No (Dull) Yes No
3. Trial 3 (Sharp) 1Yes 0No (Dull) 1Yes No



Part IIIb.

ibratory Sen	sation Test		
		Yes No	Cessation
1.	Left foot vibration detection Trial 1	1 0	
2.	Left foot vibration detection Trial 2	1 0	
3.	Right foot vibration detection Trial 1	1 0	
4.	Right foot vibration detection Trial 2	1 0	