

FORM216

FSGS Novel Therapies (FONT-II)

Visit Form (Form # 216)

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1. Participant ID Number
PID

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2. Alpha Code
ALPHCD

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3. Visit Number
CPEVENT /
VISIT_NUMBER /
SUBEVENT_NUMBER

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4. Date of Visit (dd/mmm/yyyy)
VISDT

5. Primary reason for this visit..... __VISRSN
- 1 = protocol visit
 - 2 = adverse event
 - 3 = laboratory
 - 4 = dispensing medication
 - 5 = questions/counseling

Medical History: Symptoms since last visit

Other Symptoms:	MedDRA Code:
6. MDVT	MDCLLT
7.	
8.	
9.	

If a significant/severe symptom is new, increased, unexpected, and/or precipitates a study medication change, complete the Adverse Event Form (Form #260). Use the Serious Adverse Event Form (Form #261) for serious events that are life threatening.

17. Vital Signs
- a. Height(cm) ____ . ____ HEIGHT
 - b. Weight.....(kg) ____ . ____ WEIGHT
 - c. Blood Pressure:
 - 1. Sitting.....(systolic/diastolic) ____ / ____ BP_SYS / BPDIA
 - 2. Method.....(1=auscultator; 2=oscillometric device) ____ BPMETH

- d. Heart rate per minute _____ HRTR
- e. Respiratory rate per minute _____ RESPR
- f. Temperature(°C) _____ . _____ TEMP

18. Physical Exam: Circle Result (N, A, or ND for each)

NOTE: Items A, B and C are required per protocol at each visit (exam)

SYMNA_{xx} : 0 = NORMAL, 1 = ABNORMAL, 2 = NOT DONE

	Normal	Abnormal, specify	MedDRA Code (Data Entry only)	Not Done
a. Lymph Nodes	N SYMNA1	A : _____SYMDS1_____	SYMMD1	ND
b. Liver	N SYMNA2	A : _____SYMDS2_____	SYMMD2	ND
c. Spleen	N SYMNA3	A : _____SYMDS3_____	SYMMD3	ND
d. Head and Neck	N SYMNA4	A : _____SYMDS4_____	SYMMD4	ND
e. Eyes	N SYMNA5	A : _____SYMDS5_____	SYMMD5	ND
f. Ears, Nose, Throat	N SYMNA6	A : _____SYMDS6_____	SYMMD6	ND
g. Abdomen	N SYMNA7	A : _____SYMDS7_____	SYMMD7	ND
h. Genitalia	N SYMNA8	A : _____SYMDS8_____	SYMMD8	ND
i. Extremities/Joints	N SYMNA9	A : _____SYMDS9_____	SYMMD9	ND
j. Neurological Status	N SYMNA10	A : _____SYMDS10_____	SYMMD10	ND
k. Skin	N SYMNA11	A : _____SYMDS11_____	SYMMD11	ND

- 19. Edema(Enter highest code)___EDEMA
Code: 0 = none, 1 = pretibial, 2 = above knee, 3 = presacral, 4 = ascites, 5 = anasarca

**FAX COMPLETED FORM TO FONT STUDY DESK
UMich (734) 232-2353 NYU (212) 263-4053**

- 20. a. Was the PROMIS Short Form(s) completed at this visit?.....__PROMIS
 - 1 = yes, for the first time 2 = yes, not the first time
 - 3 = no, participant is <8yo 4 = no, participant is not English speaking
 - 5 = no, PROMIS is not required at this visit 6 = no, other reason (specify: _____)

PROMIS forms to be completed for participants 8 years old and older at W00, W26, W52, M18 & M24

- b. If Q20a = 1 (yes, for the first time), what was the assigned login:
 - 1. Username
 - 2. Password

- 200. a. Form Completed By(Print name)_____
 - Q200a is not entered into database
- b. "Username" of person completing this form
- c. Date this form completed.....(dd/mmm/yyyy) ____ / ____ / ____

- 201. a. Principal Investigator (PI) Signature ..._____
 - Q201a is not entered into database
- b. F216 signed by PI (0=no, 1=yes)___PSIGN
- c. "Username" of PI.....
- d. Date form signed by PI.....(dd/mmm/yyyy) ____ / ____ / ____ PIDT