

FORM252

FSGS Novel Therapies (FONT-II)

Long-term Monitoring Form (Form # 252)

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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. Medical History: Symptoms in the past 4 weeks

Description (Verbatim):	MedDRA Code:
a.	
b. MDVTxx	MDCLLTxx
c.	
d.	

6. a. Does the participant have kidney failure?(0 = no, 1 = yes) ___ ESRD

b. If yes, patient's ESRD treatment modality ESRDRX
 1 = hemodialysis 3 = kidney transplant
 2 = peritoneal dialysis 4 = conservative management

c. Date of ESRD onset.....(dd/mmm/yyyy) ___/___/___ ESRDDT

7. Is the participant pregnant?.....(0 = no, 1 = yes, 8=N/A-male) ___ PREG1
→ complete Adverse Event Form

8. Has the participant been hospitalized since the last visit?.....(0 = no, 1 = yes) ___ HOSPNY
→ complete Adverse Event Form

9. Is the participant currently involved in another clinical trial?.....(0 = no, 1 = yes) ___ OTHTRL

10. Medications: list all medications:

Medication Name	Medication Code (electronically found on code list during data entry)	Frequency on arrival: 0 = Not taken 1 = Taken routinely 2 = Taken as needed	Status when leaving: 2 = Start 3 = Continue 5 = Stop
a.			
b. MEDNAMxx	MEDCDxx	MEDFRQxx	MEDSTxx
c.			
d.			

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

11. Vital Signs

- a. Height(cm) ____ . ____ HEIGHT
- b. Weight..... (kg) ____ . ____ WEIGHT
- c. Blood Pressure, sitting.....(systolic/diastolic) ____ / ____ BP_SYS / BPDIA
- d. Method.....(1=auscultator; 2=oscillometric device) ____ BPMETH

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

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

13. Edema..... (Enter highest code)____

Code: 0 = none, 1 = pretibial, 2 = above knee, 3 = presacral, 4 = ascites, 5 = anasarca

- 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. F252 signed by PI..... (0=no, 1=yes)____
- c. "Username" of PI..... _____
- d. Date form signed by PI..... (dd/mmm/yyyy) ____ / ____ / ____