FORM260
FSGS Novel Therapies (FONT-II)
Adverse Event Report Form (Form # 260)

1. Participant ID number PID

2. Alpha code ALPHCD

3. Visit Number VISDT

CPEVENT / VISIT_NUMBER / SUBEVENT_NUMBER

4. a. Date of onset ..... (dd/mmm/yyyy) ___ ___ /___ ___ ___ /___ ___ ___ ___AEDT

b. Source of adverse event ..... ___AESRCE
(1 = central lab results, 2 = local lab results, 3 = other, 4 = two consecutive high BP measurements documented on F216 or F279)

5. Date of initial report..... (dd/mmm/yyyy) ___ ___ /___ ___ ___ /___ ___ ___ ___RPDT
(Note: For high BP, enter the date of the second measurement)

Description: (record diagnoses and/or signs and or symptoms below)

6a. Condition:	**MedDRA Code:**
MDVTxx	MDCLLTxx

b. Prior history of similar event ..... (0 = no, 1 = yes-describe in comments – 6j, 9 = unknown)

___PEVENT

c. Severity of event .....___SAESEV
1 = mild, awareness of the sign or symptom, but easily tolerated
2 = moderate, enough discomfort to interfere with usual activity
3 = severe, incapacitating, with inability to do usual work or activity
4 = life-threatening
5 = fatal (if fatal, complete Death Form F263)

d. Does the Principal Investigator believe that the event may have been caused by study drug?

0 = no	2 = possibly	4 = definitely
1 = unlikely	3 = probably	8 = not applicable

d1. Adalimumab.....___SAEREL1

d2. Galactose..... ___SAEREK5

d3. Atorvastatin.....___SAEREL3

d4. Lisinopril..... ___SAEREL6

d5. Losartan.....___SAEREL7

e. If the event is related to study drug, what is the expectedness of the event?
1 = unexpected – not mentioned in the drug labeling

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2 = expected, but of greater severity than mentioned in the drug labeling
3 = expected and accurately described in the drug labeling

e1. Adalimumab.....___AEEXP1

e2. Galactose.....___AEEXP5

e3. Atorvastatin.....___AEEXO3

e4. Lisinopril.....___AEEXP6

e5. Losartan .....___AEEXP7

f. Action taken

0 = none 2 = study drug temporarily held 4 = other
1 = study drug reduced 3 = study drug discontinued

f1. Adalimumab.....___AEACT1

f2. Galactose.....___AEACT5

f3. Atorvastatin.....___AEACT3

f4. Lisinopril.....___AEACT6

f5. Losartan.....___AEACT7

f6. If any of the items f1 to f5 is "Other", specify

_____ACTOTHxx_____

_____

g. Outcome of event.....___AEOUT

0 = recovered without treatment
1 = recovered with treatment
2 = event continuing without treatment
3 = event continuing and controlled with treatment
4 = event continuing and not controlled with treatment
5 = participant died
6 = not yet available

h. Date of outcome..... (dd/mmm/yyyy) ___ ___/___ ___ ___/___ ___ ___ ___AEOCST

i. Date outcome entered .....(dd/mmm/yyyy) ___ ___/___ ___ ___/___ ___ ___ ___AECCDT

j. Comments: _____ ACTOTHxx_____

_____

Note: for data entry purposes, the database screen is a REPEATING GROUP. Multiple entries are permitted for items a-j. Pressing the "enter" key will clear items a-j. for entry of another condition. To exit the repeating group, press the "page down" key to go to question 200.

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200. Date this form completed.....(dd/mmm/yyyy) ___ ___ /___ ___ ___ /___ ___ ___ ___

201. Username of person completing this form.....___ ___ ___ ___ ___ ___ ___ ___

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