FORM261
FSGS Novel Therapies (FONT-II)
Serious Adverse Event Report Form (Form # 261)

1. Participant ID number PID
2. Alpha code ALPHCD VISDT
3. Visit Number CPEVENT / VISIT_NUMBER / SUBEVENT_NUMBER

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

5. Date of initial report..... (dd/mmm/yyyy) ___ ___/___ ___ ___/___ ___ ___ ___REPDT

6. a. Study Physician reporting the event ....____

   b. Phone number .....(___ ___ ___) ___ ___ ___ - ___ ___ ___ ___

Serious Criteria: Code 0 = no, 1 = yes

7. a. Fatal ..... (if yes, complete Death Notification Form #263) ___SERCRT1

   b. Immediately life-threatening .....___SERCRT2

   c. Required hospitalization ..... (if yes, complete Hospitalization Form #262) ___SERCRT3

   d. Prolonged existing hospitalization.....___SERCRT4

   e. Persistent or significant disability/incapacity .....___SERCRT5

   f. Congenital anomaly/birth defect.....___SERCRT6
   (Pregnancy with or without resultant in a birth defect)

   g. Causes cancer.....___SERCRT7

   h. Overdose of study medication .....___SERCRT8

8a. Condition:	**MedDRA Code:**
MDVTxx	MDCLLTxx

b. Prior history of similar event ..... (0 = no, 1 = yes-describe in comments – 8j, 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

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d. Does the PI 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 .....___SAEREL5

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
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 .....___ AEEXP3

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 (complete F245)

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

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

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 (scroll) items a-j. for entry of another condition. To exit the repeating group, press the "page down" key to go to question 200.

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

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

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