

Focal Segmental Glomerulosclerosis (FSGS) Clinical Trial Death Notification Form (Form # 63)

PID

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1. Participant ID number

ALPHCD

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2. Alpha code

Visit Number: VISN
(automatically calculated)

3. Date of death.....(dd/mmm/yyyy) _____ / _____ / _____ DTHDT

	Cause of Death:	MedDRA Code:
4. a. Primary cause of death		mdc11+1
b. Secondary cause of death		mdc11+2

5. Was an autopsy performed?..... (0 = no, 1 = yes-send autopsy report, 9 = unknown) ___ ATPYNY

6. Location of death..... (0 = hospital, 1 = not in a hospital, 9 = unknown) ___ DTHLOC

7. Does the PI believe the death is related to:
a. Randomized medication?..... (0 = no, 1 = yes, provide comments in Q8, 8 = not applicable, 9 = unknown) ___ DTHNY1

b. Other study requirements?.....(0 = no, 1 = yes, provide comments in Q8, 9 = unknown) ___ DTHNY2

c. Underlying disease?.....(0 = no, 1 = yes, provide comments in Q8, 9 = unknown) ___ DTHNY3

d. Other?(0 = no, 1 = yes, provide comments in Q8, 9 = unknown) ___ DTHNY4

8. Provide additional comments: _____ DTHCOM

9. If the death was related to a randomized medication (Q7a = 1), which medication:

a. CSA.....(0 = no, 1 = yes, 8 = NA, 9 = unknown) ___ DTHMED1

b. Dexamethasone.....(0 = no, 1 = yes, 8 = NA, 9 = unknown) ___ DTHMED2

c. Lisinopril/Losartan(0 = no, 1 = yes, 8 = NA, 9 = unknown) ___ DTHMED3

d. MMF(0 = no, 1 = yes, 8 = NA, 9 = unknown) ___ DTHMED4

e. Prednisolone/Prednisone.....(0 = no, 1 = yes, 8 = NA, 9 = unknown) ___ DTHMED5