

Focal Segmental Glomerulosclerosis (FSGS) Clinical Trial Medication Stop Point Form (Form # 72)

Once a Stop Point has been confirmed by Clinical Management Subcommittee Review, a measurement of serum SMA 18, cyclosporine level, CBC, lipids, and Up/c will be obtained. Refer to the Protocol section 11.2 for further information pertaining to Medication Stop Points.

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1. Participant ID Number
PID

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2. Alpha Code
ALPHCD

W				
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3. Visit Number
VISN

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

Reason for Stop Point:

- 5. a. Pregnancy(0 = no, 1 = yes) PREG
 - 1) Date of positive pregnancy test(dd/mmm/yyyy) ___/___/___ PREGDT
 - b. Decline in GFR: 50% decline from baseline in estimated GFR to $GFR \leq 75 \text{ ml/min/1.73m}^2$ (0 = no, 1 = yes) DECGFR
 - 1) Date of blood specimen collection that determined Stop Point.....(dd/mmm/yyyy) ___/___/___ DRAWDT
 - c. Does the participant have kidney failure?(0 = no, 1 = yes) ESRD
If yes and if applicable, complete an SAE (F61) and hospitalization (F62) form
 - 1) If yes, patient's ESRD treatment modality.....ESRDRX
 - 1 = hemodialysis
 - 2 = peritoneal dialysis
 - 3 = kidney transplant
 - 4 = untreated (refusing dialysis)
 - 8 = not applicable
 - 9 = unknown
 - 2) Date of ESRD onset.....(dd/mmm/yyyy) ___/___/___ ESRDDT
 - d. Medication related toxicity(0 = no, 1 = yes) MEDTOX
If yes, complete the appropriate toxicity CRF
 - e. Other(0 = no, 1 = yes) OTHER
 - 1) if 5e, "Other" is yes, specify.....OTHSP
- 6. Since the participant's last visit, did an Adverse Event possibly related to study drug(s) occur?(0 = no, 1 = yes) AEOCC
If yes, complete the appropriate AE form(s) – F60 and/or F61
 - 7. Has the participant been hospitalized since the last visit?.....(0 = no, 1 = yes) HOSPNY
If yes, complete F62 (Hospitalization Form) and F61 (SAE)
 - 8. Date Clinical Management Committee confirmed Stop Point..... (dd/mmm/yyyy) ___/___/___ SPCFDT
(DCC to enter once confirmation notification received from Clinical Management Committee)
 - 200. Date this form completed.....(dd/mmm/yyyy) ___/___/___
 - 201. Username of person completing this form.....