Logo	**Study Completion/ Early Termination**	**{visit.label}**
		ID: {ID}

This form should be completed only for subjects who are RANDOMIZED in the MIT. (For subjects who are enrolled (signed consent) but are not Randomized, complete the Subject Disposition/Randomization CRF).

1. Did the subject complete the Main Interventional Trial through Week 16? ☐ (TERM:COMPL) No ☐ (TERM:COMPL) Yes

2. If **Yes,** did the subject continue in the Open-Label Follow-Up Phase? ☐ (TERM:OPEN) No ☐ (TERM:OPEN) Yes

If **No:**

- Date of last Main Interventional Trial contact: TERM:CONDA / TERM:CONMO / TERM:CONYR
  Day Month Year
- Date of last dose of study drug: TERM:DRGDA / TERM:DRGMO / TERM:DRGYR
  Day Month Year
- Indicate the **primary** reason the subject did not complete trial through Week 16:

a1. ☐ (TERM:REASON) Study terminated

a2. ☐ (TERM:REASON) Protocol-mandated reason, specify:

☐ (TERM:PROT1) Major bleeding complication

☐ (TERM:PROT2) One episode of severe priapism

☐ (TERM:PROT3) Positive quantitative blood HCG or pregnancy

☐ (TERM:PROT4) New retinal detachment, hemorrhage or clinically significant visual change

☐ (TERM:PROT5) Serious adverse events considered related to study drug

☐ (TERM:PROT6) Specific treatments for pulmonary hypertension

☐ (TERM:PROT7) Initiation of chronic transfusion therapy

☐ (TERM:PROT8) Protease inhibitor treatment for HIV

☐ (TERM:PROT9) Emergency clinical unblinding of treatment assignment

☐ (TERM:PROT10) Initiation of potent CYP3A4 inhibitor therapy, including erythromycin, clarithromycin, saquinovir, or nefazodone

☐ (TERM:PROTO) Other, specify:
TERM:PROTOS

b. ☐ (TERM:REASON) Investigator decision, specify:

☐ (TERM:INV1) Subject non-compliance with protocol

☐ (TERM:INV2) Sickle cell-related clinical deterioration

☐ (TERM:INV3) Clinical deterioration due to pulmonary hypertension

☐ (TERM:INV4) Other, specify:
TERM:INV4SP

c. ☐ (TERM:REASON) Subject or parent/guardian decision, specify:
TERM:SUB_SP

d. ☐ (TERM:REASON) Lost to follow-up

e. ☐ (TERM:REASON) Death

f. ☐ (TERM:REASON) Adverse Event, not listed above, specify:
TERM:AE_SP

g. ☐ (TERM:REASON) Other, specify:
TERM:OTH_SP

3. Although the study is double-blind, individuals sometimes believe they know to which treatment an individual has been assigned. Indicate each individual's "best guess" regarding the subject's treatment assignment.

Subject:	☐ (TERM:ARM_SUB) Placebo	☐ (TERM:ARM_SUB) Sildenafil	☐ (TERM:ARM_SUB) No Opinion
Site Coordinator:	☐ (TERM:ARM_SC) Placebo	☐ (TERM:ARM_SC) Sildenafil	☐ (TERM:ARM_SC) No Opinion
Clinical Investigator:	☐ (TERM:ARM_CI) Placebo	☐ (TERM:ARM_CI) Sildenafil	☐ (TERM:ARM_CI) No Opinion

4. Was there a one-month safety follow-up? ☐ (TERM:SAFTYFU) No ☐ (TERM:SAFTYFU) Yes

If **Yes,** Date of follow-up: TERM:SAFTYDA / TERM:SAFTYMO / TERM:SAFTYYR
Day Month Year

Comments for page:
TERM:COMM

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