Sponsor: WALK-PHASST
Study: Open_Label

FORM LABEL	PHASE	DATASTREAM	PAGE
Subjects			
Open-Label Follow-Up	**8000**		
Adverse Event	8000	AEXP, SAEL, SAEH, SAEM, SAET	1
Study Completion/Early Termination	8000	DISC	4
Study Drug Dosing	8000	SDRG, DRLG	6
Concomitant Medications	8000	CMED	7

Logo	**Adverse Events**	**{visit.label}**
		ID: {ID}

1. Adverse Event/Diagnosis: AEXP:AETEXT

2. AE Start Date: AEXP:STARTDA / AEXP:STARTMO / AEXP:STARTYR
Day Month Year

3. AE Stop Date: AEXP:STOPDA / AEXP:STOPMO / AEXP:STOPYR
Day Month Year

4. Severity: AEXP:SEVRTY — Q4: Death, Life-Threatening, Mild, Moderate, Severe

5. Relationship to sickle cell disease? AEXP:RELSCD

6. Relationship to pulmonary hypertension? AEXP:RELPH

7. Relationship to study drug: AEXP:RELSDRG

Q5-Q8:
Definitely Related;
Possibly Related;
Probably not related/remote;
Probably related;
Unrelated

8. Relationship to study procedure: AEXP:RELSP

If not **Unrelated,** specify: AEXP:SP_SP

9. Outcome: AEXP:OUTCOME — Q9:Death; Ongoing; Ongoing at end of follow-up; Present at death, not contributing to death; Resolved with sequelae; Resolved without sequelae

10. Action taken with study drug: AEXP:ACTION — Q10: None; Study drug interrupted/modified; Study drug permanently discontinued;

11. Serious? ☐ (AEXP:SERIOUS) No ☐ (AEXP:SERIOUS) Yes

If **Yes,** a) Complete the **Serious Adverse Event** section below and have the Clinical Investigator review and electronically sign the form by clicking the Sign button when prompted.

b) When submitting an initial SAE or a follow-up SAE, please notify Rho Product Safety by either sending an email to rho_productsafety@rhoworld.com or calling the SAE hotline at 888-746-7231.

Has Rho Product Safety been notified? ☐ (AEXP:NTFY) No ☐ (AEXP:NTFY) Yes

Complete this section for a Serious Adverse Event only.

12. Seriousness:
(Check all that apply)

☐ (AEXP:SAE1) Life-threatening

☐ (AEXP:SAE2) Required hospitalization or prolongation of existing hospitalization

☐ (AEXP:SAE3) Congenital anomaly

☐ (AEXP:SAE4) Disabling/incapacitating

☐ (AEXP:SAE5) Important medical event

☐ (AEXP:SAE6) Fatal

If **Fatal:**

a. Date of death: AEXP:DEATHDA / AEXP:DEATHMO / AEXP:DEATHYR
Day Month Year

b. Primary cause of death: AEXP:CAUSE

c. Was an autopsy performed? ☐ (AEXP:AUTOP) No ☐ (AEXP:AUTOP) Yes

13. Possible contributing factors to SAE other than study drug:
(Check all that apply)

☐ (AEXP:FACT1) Underlying disease being studied

☐ (AEXP:FACT2) Treatment failure

☐ (AEXP:FACT3) Concurrent illness, specify: AEXP:FACT3SP

☐ (AEXP:FACT4) Concurrent medication (specify in Number 15 below)

☐ (AEXP:FACT5) Study procedure, specify AEXP:FACT5SP

☐ (AEXP:FACT6) Other, specify AEXP:FACT6SP

14. Did subject receive study medication (sildenafil capsules or matching placebo)? ☐ (AEXP:SDYMED) No ☐ (AEXP:SDYMED) Yes

If **Yes:**

a. Phase: ☐ (AEXP:DBFU) Double Blind Phase ☐ (AEXP:DBFU) Open Label Follow-Up Phase

b. Dose: AEXP:DOSE mg TID PO

c. Start Date: AEXP:DSTDA / AEXP:DSTMO / AEXP:DSTYR
Day Month Year

d. Stop Date: AEXP:DSPDA / AEXP:DSPMO / AEXP:DSPYR
Day Month Year

e. Ongoing? ☐ (AEXP:ONGO) No ☐ (AEXP:ONGO) Yes

15. Relevant concomitant medications at time of Serious Adverse Event: ☐ (AEXP:CMEDNA) None

☐ (AEXP:CMEDPR) Previously Reported with SAE: AEXP:WITHSAE

		Remove Medication Record			
Name	**Total Daily Dose**	**Units**	**Start Date Stop Date (Day/Month/Year)**	**Ongoing?**	**Suspect Causal Relationship?**
SAEM:NAME	SAEM:MDOSE	SAEM:MUNITS	SAEM:MSTRTDA / SAEM:MSTRTMO / SAEM:MSTRTYR SAEM:MSTPDA / SAEM:MSTPMO / SAEM:MSTPYR	☐ (SAEM:MONGO) No ☐ (SAEM:MONGO) Yes	☐ (SAEM:RELATE) No ☐ (SAEM:RELATE) Yes

Add Medication Record

16. Treatments/procedures for SAE: ☐ (AEXP:TREATNA) None

☐ (AEXP:TREATPR) Previously Reported with SAE: AEXP:TREATSP

	Remove Treatment Record			
Treatment/Procedure	**Total Daily Dose (If Applicable)**	**Units (If Applicable)**	**Start Date Stop Date (Day/Month/Year)**	**Ongoing?**
SAET:TREAT	SAET:TDOSE	SAET:TUNITS	SAET:TSTRTDA / SAET:TSTRTMO / SAET:TSTRTYR SAET:TSTPDA / SAET:TSTPMO / SAET:TSTPYR	☐ (SAET:TONGO) No ☐ (SAET:TONGO) Yes

Add Treatment Record

17. Relevant medical history (Include only relevant past or concurrent medical disorders, surgeries, etc. that may help explain the SAE): ☐ (AEXP:HISTNA) None

☐ (AEXP:HISTPR) Previously Reported with SAE: AEXP:HISTSP

	Remove History Record	
Condition	**Start Date Stop Date (Day/Month/Year)**	**Ongoing?**
SAEH:COND	SAEH:HSTRTDA / SAEH:HSTRTMO / SAEH:HSTRTYR SAEH:HSTPDA / SAEH:HSTPMO / SAEH:HSTPYR	☐ (SAEH:HONGO) No ☐ (SAEH:HONGO) Yes

Add History Record

18. Relevant laboratory/diagnostic tests: ☐ (AEXP:LABNA) None

☐ (AEXP:LABPR) Previously Reported with SAE: AEXP:LABSP

	Remove Lab/Test Record

Lab/Test	Date (Day/Month/Year)	Results/Comment
SAEL:TEST	SAEL:LDATEDA / SAEL:LDATEMO / SAEL:LDATEYR	SAEL:RESULT
	Normal Range (If applicable):	SAEL:RANGE

Add Lab/Test Record

19. Weight: AEXP:WEIGHT ☐ (AEXP:WTUNITS) lb ☐ (AEXP:WTUNITS) kg

20. Height: AEXP:HEIGHT ☐ (AEXP:HTUNITS) in ☐ (AEXP:HTUNITS) cm

21. Narrative/Comments (provide a textual description of the SAE including chronological clinical presentation and evolution of the SAE and associated signs/symptoms):

☐ (AEXP:NARRPR) Previously Reported with SAE: AEXP:NARRSP

Narrative/Comments:

AEXP:NARRATE

Comments for page:

AEXP:COMM

Submit Query Cancel Form Completion Help Print Rho

Logo	**Study Termination**	**{visit.label}**
		ID: {ID}

1. Date of last study-related contact in Open Label Study: DISC:LFUDA / DISC:LFUMO / DISC:LFUYR
   Day Month Year

2. Did subject complete 1 year in Open Label Study? ☐ (DISC:COMPL) No ☐ (DISC:COMPL) Yes

If **No,** indicate **primary** reason:

- ☐ (DISC:REASON) Study terminated
- ☐ (DISC:REASON) Subject or guardian decision, specify: DISC:SUB_SP
- ☐ (DISC:REASON) Subject moved or relocated
- ☐ (DISC:REASON) Lost to follow-up
- ☐ (DISC:REASON) Subject Achieved health insurance coverage for sildenafil
- ☐ (DISC:REASON) Subject rescreened and randomized in Main Interventional Trial
- ☐ (DISC:REASON) Adverse Event, specify: DISC:AE_SP
- ☐ (DISC:REASON) Death

If **Death:**

a. Date of death: DISC:DEATHDA / DISC:DEATHMO / DISC:DEATHYR
   Day Month Year

b. Primary cause of death:

- ☐ (DISC:CAUSE) Cardiac Arrest
- ☐ (DISC:CAUSE) Respiratory Failure/Pneumonia/ Acute Chest Syndrome
- ☐ (DISC:CAUSE) CNS Event/Stroke/ Intracranial hemorrhage
- ☐ (DISC:CAUSE) Sepsis/Infection
- ☐ (DISC:CAUSE) Hepatic Failure
- ☐ (DISC:CAUSE) Severe Anemia
- ☐ (DISC:CAUSE) Malignancy
- ☐ (DISC:CAUSE) Splenic Sequestration
- ☐ (DISC:CAUSE) Multi-System Organ Failure
- ☐ (DISC:CAUSE) Other, specify: DISC:CAUS_SP
- ☐ (DISC:CAUSE) Renal Failure
- ☐ (DISC:CAUSE) Unknown

c. Was the death related to progression of sickle cell disease?

☐ (DISC:RELSC) Unrelated ☐ (DISC:RELSC) Unlikely ☐ (DISC:RELSC) Possibly ☐ (DISC:RELSC) Probably ☐ (DISC:RELSC) Definitely

d. Was the death related to progression of pulmonary hypertension?

(DISC:RELPH) Unrelated (DISC:RELPH) Unlikely (DISC:RELPH) Possibly (DISC:RELPH) Probably (DISC:RELPH) Definitely

e. Was an autopsy performed? (DISC:AUTOP) No (DISC:AUTOP) Yes

(DISC:REASON) Other, specify: DISC:OTH_SP

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

If **Yes,** Date of follow-up: DISC:SAFTYDA / DISC:SAFTYMO / DISC:SAFTYYR

Day Month Year

Comments for page:

DISC:COMM

Submit Query Cancel Form Completion Help Print Rho

Logo	Study Drug Dosing	{visit.label}
		ID: {ID}

Enter a new dose record for any change in study drug dosing during the course of the study.

Total Daily Dose Prescribed	Reason for Dose	Remove Dose Start Date
DRLG:DOSE mg	☐ (DRLG:REASON) As per protocol ☐ (DRLG:REASON) Adverse event and/or lab/test abnormality ☐ (DRLG:REASON) Dosing error ☐ (DRLG:REASON) Other, specify: DRLG:OTH_SP	DRLG:STARTDA / DRLG:STARTMO / DRLG:STARTYR Day Month Year **Dose End Date** DRLG:STOPDA / DRLG:STOPMO / DRLG:STOPYR Day Month Year
Comment: DRLG:DCOMM		

Add New Dose

Comments for page:

SDRG:COMM

Submit Query Cancel Form Completion Help Print Rho

Logo	**Concomitant Medications**	**{visit.label}**
		ID: {ID}

Please note: List medications used for anticoagulation only.

Medication: CMED:MEDNAME

Indication: CMED:IND

Dose: CMED:DOSE

Units: CMED:UNITS If **Other,** specify: CMED:UNIT_SP

Units: Capsule; Drop; Gram; Microgram; Milligram; Milliliter;Other; Tablet;

Frequency: CMED:FREQ If **Other,** specify: CMED:FREQ_SP

Freq: 3 Times Daily; 4 Times Daily; As Needed; Every Day; Every Other Day; Once a Week; Other; Twice Daily

Route: CMED:ROUTE If **Other,** specify: CMED:RTE_SP

Route: By Mouth; Each/Both Eyes; Inhalent; Intra-articular; Intradermal; Intramuscular; Intravenous; Left Eye; Other; Rectal; Right Eye; Subcutaneous; Sublingual; Topical; Vaginal; Suppository

Start Date: CMED:STARTDA / CMED:STARTMO / CMED:STARTYR
Day Month Year

Stop Date: CMED:STOPDA / CMED:STOPMO / CMED:STOPYR
Day Month Year

Associated with a Serious Adverse Event?

- (CMED:SAE) Not related
- (CMED:SAE) Possible cause of SAE
- (CMED:SAE) Medication given in response to SAE

Treatment Status: CMED:STATUS

Status: Continuing at End of Main Interventional Trial; Discontinued; Modified Dose, Frequency, or Route

Comments for page:

CMED:COMM

Submit Query Cancel Form Completion Help Print Rho