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

1. Adverse Event/Diagnosis: AEXP:AETEXT

1a. This event should be submitted to the Secondary Endpoint Adjudication Committee as a potential (select all that apply):

- ☐ (AEXP:EV_PH) Clinical Deterioration of Pulmonary Hypertension
- ☐ (AEXP:EV_ACS) Acute Chest Syndrome*
- ☐ (AEXP:EV_RHF) Right Heart Failure*
- ☐ (AEXP:EV_NO) None of the above—This event does not require review by the Committee

*Please provide additional event information on the **Adjudication Information Form** below

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 (record on Prior/Concomitant Medication Form)

☐ (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

		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

15. [Question removed]

16. **If medication was given to treat SAE, complete Prior/Concomitant Medications Form.**
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

Adjudication Information Form

If the event for consideration is a POTENTIAL Acute Chest Syndrome or Right Heart failure, provide the following information:

1. Symptoms reported by Subject in association with this event:

Yes **No** **Not done**

Abdominal distention	(AEXP:S1_ABDO)	(AEXP:S1_ABDO)	(AEXP:S1_ABDO)
Chest pain	(AEXP:S1_CHST)	(AEXP:S1_CHST)	(AEXP:S1_CHST)
Cough	(AEXP:S1_CGH)	(AEXP:S1_CGH)	(AEXP:S1_CGH)
Fainting	(AEXP:S1_FNT)	(AEXP:S1_FNT)	(AEXP:S1_FNT)
Shortness of breath	(AEXP:S1_SHBR)	(AEXP:S1_SHBR)	(AEXP:S1_SHBR)
Sputum	(AEXP:S1_SPTM)	(AEXP:S1_SPTM)	(AEXP:S1_SPTM)
Other	(AEXP:S1_OTH)	(AEXP:S1_OTH)	

If **Other,** specify:

AEXP:S1_SP

2. Signs detected upon examination in association with this event:

	Yes	No	Not done
Abnormal heart sounds	(AEXP:S2_AHS)	(AEXP:S2_AHS)	(AEXP:S2_AHS)
Abnormal lung sounds (rales, rhonchi, wheezing, egophony)	(AEXP:S2_ALS)	(AEXP:S2_ALS)	(AEXP:S2_ALS)
Cough	(AEXP:S2_CGH)	(AEXP:S2_CGH)	(AEXP:S2_CGH)
Elevated venous pressure (distended or "pronounced" neck veins)	(AEXP:S2_EVP)	(AEXP:S2_EVP)	(AEXP:S2_EVP)
Enlarged liver	(AEXP:S2_ENLV)	(AEXP:S2_ENLV)	(AEXP:S2_ENLV)
Intercostal retractions, nasal flaring, or use of accessory mucles of respiration	(AEXP:S2_ICR)	(AEXP:S2_ICR)	(AEXP:S2_ICR)
Rapid heart rate	(AEXP:S2_RHR)	(AEXP:S2_RHR)	(AEXP:S2_RHR)
Swelling of feet and/or ankles	(AEXP:S2_SWFA)	(AEXP:S2_SWFA)	(AEXP:S2_SWFA)
Tachypnea (per age-adjusted normal)	(AEXP:S2_TCHY)	(AEXP:S2_TCHY)	(AEXP:S2_TCHY)
Weight gain	(AEXP:S2_WTG)	(AEXP:S2_WTG)	(AEXP:S2_WTG)
Other	(AEXP:S2_OTH)	(AEXP:S2_OTH)	

If **Other,** specify:

AEXP:S2_SP

3. Test results

A) Weight: AEXP:S3_WT kg

B) Temperature: AEXP:S3_TEMP °C

C) Respiration rate: AEXP:S3_RESP breaths/min

D) Chest radiograph or CT Performed? (AEXP:S3_XRAY)Yes (AEXP:S3_XRAY)No

If **Yes:**

Date of chest radiograph or CT: AEXP:S3_XDA / AEXP:S3_XMO / AEXP:S3_XYR

Day Month Year

A new segmental radiographic pulmonary infiltrate (involving at least 1 complete segment): (AEXP:S3_XINF) Yes (AEXP:S3_XINF) No

Consolidation: (AEXP:S3_XCON) Yes (AEXP:S3_XCON) No

Pulmonary edema: (AEXP:S3_XPE) Yes (AEXP:S3_XPE) No

Cardiac enlargement: (AEXP:S3_XCE) Yes (AEXP:S3_XCE) No

Other chest radiograph findings:

AEXP:S3_XFND

E) ECG performed? (AEXP:S3_ECG) Yes (AEXP:S3_ECG) No

If **Yes,** Results:

AEXP:S3_ECGR

F) Echocardiogram performed? (AEXP:S3_ECH) Yes (AEXP:S3_ECH) No

If **Yes,** Results:

AEXP:S3_ECHR

G) Arterial blood gas (AEXP:S3_ABG) Yes (AEXP:S3_ABG) No

If **Yes:**

PaO_2: AEXP:S3_PA02 mmHg

SaO_2: AEXP:S3_SA02 %

CaO_2: AEXP:S3_CA02 %

SpO_2 value: AEXP:S3_SP02

Percent decrease in SpO_2(O_2saturation) from a documented steady-state value in room air: AEXP:S3_PDEC %

Brain natriuretic peptide (BNP) value: AEXP:S3_BNP pg/mL

H) Cardiac enzymes evaluated? (AEXP:S3_CE) Yes (AEXP:S3_CE) No

If **Yes:**

Cardiac troponin value: AEXP:S3_CTP µg/L

Creatine phospokinase value: AEXP:S3_CPH U/L

Aspartate transaminase value: AEXP:S3_AST u/L

Lactate dehydrogenase value: AEXP:S3_LCD U/L

Myoglobin value: AEXP:S3_MYG ng/L

I) Additional hematology assessment? (AEXP:S3_AHA) Yes (AEXP:S3_AHA) No

If **Yes,** please use the "As Needed" section in Rho EDC™ to complete a "Hematology-Unscheduled" Form with these data.

J) Therapies administered in response to event? (AEXP:S3_TH) Yes (AEXP:S3_TH) No

If Yes, completed Questions i) through iv)

i) Transfusion adminstered? (AEXP:S3_TRAN) Yes (AEXP:S3_TRAN) No

If **Yes:**

Pretransfusion hemoglobin value: AEXP:S3_PRHG g/L

Type of transfusion: (AEXP:S3_TYPE) Simple (AEXP:S3_TYPE) Partial exchange (AEXP:S3_TYPE) Exchange

Number of units given: AEXP:S3_UNITS

ii) Oxygen administered? (AEXP:S3_O2) Yes (AEXP:S3_O2) No

If **Yes:**

Highest concentration: AEXP:S3_O2HI L/min

Maximum dose administered: AEXP:S3_O2MX

iii) Medications given? (AEXP:S3_MD) Yes (AEXP:S3_MD) No

If **Yes,** specify: (Ensure that further details are provided on the "Concomitant Medications" Form)

AEXP:S3_MDSP

Did above drug therapies result in symptomatic improvement? (AEXP:S3_MDIM) Yes (AEXP:S3_MDIM) No (AEXP:S3_MDIM) Not applicable

Did above drug therapies result in weight loss? (AEXP:S3_MDWL) Yes (AEXP:S3_MDWL) No (AEXP:S3_MDWL) Not applicable

iv) Other therapies administered? (AEXP:S3_OTH) Yes (AEXP:S3_OTH) No

If **Yes,** specify:

AEXP:S3_OTHS

4. Provide a brief narrative describing this event:

AEXP:ADJ_NAR

Comments for page:

AEXP:COMM

Submit Query Cancel Form Completion Help Print Rho