Sponsor: WALK-PHASST

Study: MIT

Sponsor: WALK-PHASST

Study: MIT

Sponsor: WALK-PHASST

Study: MIT

FORM LABEL	PHASE	DATASTREAM	PAGE
Echocardiogram (Local)	3000	ECHO	20
Right Heart Catheterization	3000	RHCA	21
6-Minute Walk Test	3000	SIXM	22
Quality of Life	**3000**		
SF-36 Health Survey	3000	SF36	28
Pediatric Quality of Life Inventory Parent Report for Teens (13 Yrs Old)	3000	QP13	30
Pediatric Quality of Life Inventory Teen Report (13 Yrs Old)	3000	QC13	33
Pediatric Quality of Life Inventory Parent Report for Child (12 Yrs Old)	3000	QP12	36
Pediatric Quality of Life Inventory Child Report (12 Yrs Old)	3000	QC12	39
Biomarker/Genotype Sample Collection	3000	BIOM	42
Brief Pain Inventory	3000	BPIQ	44
Study Drug Diary	3000	SDDY	50
Study Completion/ Early Termination	**4000**		
Study Completion/Early Termination	4000	TERM	52
Ongoing	**5000**		
Study Drug Dosing	5000	SDRG, DRLG	54
Study Drug Accountability Log	5000	COMP, DISP, RETR	55
Prior/Concomitant Medications	5000	CMED	57
Adverse Events	5000	AEXP, SAEH, SAEL, SAEM, SAET	58
As Needed			
Protocol Deviation	**5000**		
Protocol Deviation	5000	DEVI	64
Unscheduled Visits	**6000**		
Visit Record	6000	VIST	1
Physical Examination	6000	PHEX	5
Symptoms Documentation	6000	SYMP, SYMA, TRAN	10
Chemistry_	6000	CHEM	12
Hematology_	6000	HEMA	14
Hemoglobin Electrophoresis	6000	HEEL	16
Urinalysis_	6000	URIN	17
Pregnancy Test	6000	PREG	19
Echocardiogram (Local)	6000	ECHO	20
Right Heart Catheterization	6000	RHCA	21
6-Minute Walk Test	6000	SIXM	22
Pulmonary Function Studies	6000	PFTS	24
Chest X-Ray	6000	CXRA	26
SF-36 Health Survey	6000	SF36	28

Sponsor: WALK-PHASST

Study: MIT

Logo	**Visit Record**	**{visit.label}**
Date of Visit: VIST:VISITDA / VIST:VISITMO / VIST:VISITYR (Day / Month / Year)		**ID: {ID}**

1. Did subject come for study visit? ☐ (VIST:VISITYN) Yes ☐ (VIST:VISITYN) No

2. Visit: ☐ (VIST:VISIT) Baseline ☐ (VIST:VISIT) Week 6 ☐ (VIST:VISIT) Week 10
☐ (VIST:VISIT) Week 16 ☐ (VIST:VISIT) Early Termination ☐ (VIST:VISIT) Unscheduled/Repeat Baseline

3. Was this visit or any of the assessments for this visit rescheduled due to transfusion, vaso-occlusive crisis, or acute chest syndrome? ☐ (VIST:RESCHD) Yes ☐ (VIST:RESCHD) No

4. Indicate whether any of the required procedures for **this visit** were either not performed or performed on a different date by checking in the corresponding box. Explain in the Comments for this Page.

Baseline	**Not done**	**Done on a different date**
Vital Signs and Physical Examination	☐ (VIST:PHEX)	☐ (VIST:PHEX)
Blood Chemistry	☐ (VIST:CHEM)	☐ (VIST:CHEM)
Hematology	☐ (VIST:HEMA)	☐ (VIST:HEMA)
Hemoglobin Electrophoresis	☐ (VIST:HEEL)	☐ (VIST:HEEL)
Urinalysis	☐ (VIST:URIN)	☐ (VIST:URIN)
Echocardiogram	☐ (VIST:ECHO)	☐ (VIST:ECHO)
Right Heart Catheterization	☐ (VIST:RHCA)	☐ (VIST:RHCA)
6-Minute Walk Test	☐ (VIST:SIXM)	☐ (VIST:SIXM)
Pulmonary Function Studies	☐ (VIST:PFTS)	☐ (VIST:PFTS)
Pregnancy Test	☐ (VIST:PREG)	☐ (VIST:PREG)
Chest X-Ray	☐ (VIST:CXRA)	☐ (VIST:CXRA)
SF-36 Quality of Life or Peds QOL	☐ (VIST:SFQL)	☐ (VIST:SFQL)
Biomarker and Genotype Sample Collection	☐ (VIST:BIOM)	☐ (VIST:BIOM)
Symptoms Documentation	☐ (VIST:SYMP)	☐ (VIST:SYMP)
Week 6	**Not done**	**Done on a different date**
Vital Signs and Physical Examination	☐ (VIST:PHEX6)	☐ (VIST:PHEX6)
Blood Chemistry	☐ (VIST:CHEM6)	☐ (VIST:CHEM6)
Hematology	☐ (VIST:HEMA6)	☐ (VIST:HEMA6)

Urinalysis	☐ (VIST:URIN6)	☐ (VIST:URIN6)
Echocardiogram	☐ (VIST:ECHO6)	☐ (VIST:ECHO6)
6-Minute Walk Test	☐ (VIST:SIXM6)	☐ (VIST:SIXM6)
Pregnancy Test	☐ (VIST:PREG6)	☐ (VIST:PREG6)
Biomarker and Genotype Sample Collection	☐ (VIST:BIOM6)	☐ (VIST:BIOM6)
Symptoms Documentation	☐ (VIST:SYMP6)	☐ (VIST:SYMP6)
Study Drug Diary	☐ (VIST:SDD6)	☐ (VIST:SDD6)
Brief Pain Inventory	☐ (VIST:BPI6)	☐ (VIST:BPI6)
Week 10	**Not done**	**Done on a different date**
Vital Signs and Physical Examination	☐ (VIST:PHEX10)	☐ (VIST:PHEX10)
Blood Chemistry	☐ (VIST:CHEM10)	☐ (VIST:CHEM10)
Hematology	☐ (VIST:HEMA10)	☐ (VIST:HEMA10)
Urinalysis	☐ (VIST:URIN10)	☐ (VIST:URIN10)
6-Minute Walk Test	☐ (VIST:SIXM10)	☐ (VIST:SIXM10)
Pregnancy Test	☐ (VIST:PREG10)	☐ (VIST:PREG10)
Biomarker and Genotype Sample Collection	☐ (VIST:BIOM10)	☐ (VIST:BIOM10)
Symptoms Documentation	☐ (VIST:SYMP10)	☐ (VIST:SYMP10)
Study Drug Diary	☐ (VIST:SDD10)	☐ (VIST:SDD10)
Brief Pain Inventory	☐ (VIST:BPI10)	☐ (VIST:BPI10)
Week 16	**Not done**	**Done on a different date**
Vital Signs and Physical Examination	☐ (VIST:PHEX16)	☐ (VIST:PHEX16)
Blood Chemistry	☐ (VIST:CHEM16)	☐ (VIST:CHEM16)
Hematology	☐ (VIST:HEMA16)	☐ (VIST:HEMA16)
Urinalysis	☐ (VIST:URIN16)	☐ (VIST:URIN16)
Echocardiogram	☐ (VIST:ECHO16)	☐ (VIST:ECHO16)
Right Heart Catheterization	☐ (VIST:RHCA16)	☐ (VIST:RHCA16)
6-Minute Walk Test	☐ (VIST:SIXM16)	☐ (VIST:SIXM16)
Pregnancy Test	☐ (VIST:PREG16)	☐ (VIST:PREG16)
SF-36 Quality of Life or Peds QOL	☐ (VIST:SFQL16)	☐ (VIST:SFQL16)
Biomarker and Genotype Sample Collection	☐ (VIST:BIOM16)	☐ (VIST:BIOM16)
Symptoms Documentation	☐ (VIST:SYMP16)	☐ (VIST:SYMP16)
Study Drug Diary	☐ (VIST:SDD16)	☐ (VIST:SDD16)
Brief Pain Inventory	☐ (VIST:BPI16)	☐ (VIST:BPI16)
Early Termination	**Not done**	**Done on a different date**

Vital Signs and Physical Examination	☐ (VIST:PHEXET)	☐ (VIST:PHEXET)
Blood Chemistry	☐ (VIST:CHEMET)	☐ (VIST:CHEMET)
Hematology	☐ (VIST:HEMAET)	☐ (VIST:HEMAET)
Urinalysis	☐ (VIST:URINET)	☐ (VIST:URINET)
Echocardiogram	☐ (VIST:ECHOET)	☐ (VIST:ECHOET)
Right Heart Catheterization	☐ (VIST:RHCAET)	☐ (VIST:RHCAET)
6-Minute Walk Test	☐ (VIST:SIXMET)	☐ (VIST:SIXMET)
Pregnancy Test	☐ (VIST:PREGET)	☐ (VIST:PREGET)
SF-36 Quality of Life or Peds QOL	☐ (VIST:SFQLET)	☐ (VIST:SFQLET)
Biomarker and Genotype Sample Collection	☐ (VIST:BIOMET)	☐ (VIST:BIOMET)
Symptoms Documentation	☐ (VIST:SYMPET)	☐ (VIST:SYMPET)
Study Drug Diary	☐ (VIST:SDDET)	☐ (VIST:SDDET)
Brief Pain Inventory	☐ (VIST:BPIET)	☐ (VIST:BPIET)
Unscheduled/Repeat Baseline	**Not done**	**Done on a different date**
Vital Signs and Physical Examination	☐ (VIST:PHEXUN)	☐ (VIST:PHEXUN)
Blood Chemistry	☐ (VIST:CHEMUN)	☐ (VIST:CHEMUN)
Hematology	☐ (VIST:HEMAUN)	☐ (VIST:HEMAUN)
Hemoglobin Electrophoresis	☐ (VIST:HEELUN)	☐ (VIST:HEELUN)
Urinalysis	☐ (VIST:URINUN)	☐ (VIST:URINUN)
Pregnancy Test	☐ (VIST:PREGUN)	☐ (VIST:PREGUN)
Echocardiogram	☐ (VIST:ECHOUN)	☐ (VIST:ECHOUN)
Right Heart Catheterization	☐ (VIST:RHCAUN)	☐ (VIST:RHCAUN)
6-Minute Walk Test	☐ (VIST:SIXMUN)	☐ (VIST:SIXMUN)
Pulmonary Function Studies	☐ (VIST:PFTSUN)	☐ (VIST:PFTSUN)
Chest X-Ray	☐ (VIST:CXRAUN)	☐ (VIST:CXRAUN)
SF-36 Quality of Life or Peds QOL	☐ (VIST:SFQLUN)	☐ (VIST:SFQLUN)
Biomarker and Genotype Sample Collection	☐ (VIST:BIOMUN)	☐ (VIST:BIOMUN)
Brief Pain Inventory	☐ (VIST:BPIUN)	☐ (VIST:BPIUN)
Symptoms Documentation	☐ (VIST:SYMPUN)	☐ (VIST:SYMPUN)

Comments for page:

VIST:COMM

Submit Query Cancel Form Completion Help Print


Rho

Logo	**Physical Examination**	**{visit.label}**
Date of Assessment: PHEX:ASMTDA (Day) / PHEX:ASMTMO (Month) / PHEX:ASMTYR (Year)		**ID: {ID}**

1. Temperature: PHEX:TEMP °C

2. Heart rate: PHEX:HRATE beats/min

3 Oxygen Saturation PHEX:O2 %, measured on: ☐ (PHEX:AIRO2) Air ☐ (PHEX:AIRO2) O_2

If **O_2**, flow rate: PHEX:O2FLOW L/m

4. Respiratory rate: PHEX:RESP breaths/min

5. Sitting blood pressure: (systolic/diastolic) PHEX:SYSBP / PHEX:DIABP mmHg

6. Weight: PHEX:WEIGHT kg

7. Height: PHEX:HEIGHT cm

8. Body surface area[1]: PHEX:BSA m^2 (round to 2 decimal places)

Logo

Category	Status
9. General Appearance	Appearance: ☐ (PHEX:APP) Well appearing ☐ (PHEX:APP) Ill appearing
	Weight: ☐ (PHEX:APPWT) Normal/well nourished ☐ (PHEX:APPWT) Overweight/obese ☐ (PHEX:APPWT) Malnourished/thin
	Comment/ other findings or abnormalities:

PHEX:APPCM

10. HEENT

Scleral icterus: ☐ (PHEX:HEENTSI) None ☐ (PHEX:HEENTSI) Mild ☐ (PHEX:HEENTSI) Moderate

Tonsillar hypertrophy: ☐ (PHEX:HEENTTH) Present ☐ (PHEX:HEENTTH) Absent

Hypopharynx: ☐ (PHEX:HEENTHP) Narrowed ☐ (PHEX:HEENTHP) Normal

`

Comment/ other findings or abnormalities: PHEX:HEENTCM

11. Neurologic – Check all that apply:

☐ (PHEX:NEUR1) Alert and oriented

☐ (PHEX:NEUR2) Normal strength

☐ (PHEX:NEUR3) Normal tone

☐ (PHEX:NEUR4) Normal gait

☐ (PHEX:NEUR5) Stroke sequelae present, describe:

PHEX:STROKE

Comment/ other findings or abnormalities: PHEX:NEURCM

12. Cardiac Heart Sounds

S1 and S2: ☐ (PHEX:CARS12) Normal

S3: ☐ (PHEX:CARS3) Present

S4: ☐ (PHEX:CARS4) Present

P2: ☐ (PHEX:CARP2) Loud

Other Findings ☐ (PHEX:CAROTH) Yes, describe:

PHEX:CARDES

Rate and rhythm: ☐ (PHEX:CARR) Regular ☐ (PHEX:CARR) Irregular, describe:

PHEX:CARRD

Murmur: ☐ (PHEX:CARM) Normal – S1 and S2 with flow mumur heard best at the left upper sternal border

☐ (PHEX:CARM) Other, describe:

PHEX:CARMD

Jugulovenous distension: ☐ (PHEX:CARJD) Present ☐ (PHEX:CARJD) Absent

Comment/ other findings or abnormalities: PHEX:CARCM

13. Pulmonary

Lungs: ☐ (PHEX:PULCL) Clear to ascultation

☐ (PHEX:PULBC) Bibasilar crackles

☐ (PHEX:PULBW) Wheezes

Comment/ other findings or abnormalities: PHEX:PULCM

14. Gastrointestinal – Check all that apply:

Abdomen: ☐ (PHEX:GASTNR) Normal: Belly soft and non-tender

☐ (PHEX:SPL) Splenomegaly:

Size below costal margin: PHEX:SPLSIZE cm

☐ (PHEX:HEP) Hepatomegaly:

Size below costal margin: PHEX:HEPSIZE cm

☐ (PHEX:GASTOT) Other, specify:

Comment/ other findings or abnormalities: PHEX:GASTCM

15. Extremities & Skin

Nails: ☐ (PHEX:EXTNN) Normal ☐ (PHEX:EXTNC) Clubbing ☐ (PHEX:EXTNH) Hyperpigmentation

Lower Extremities

Edema: ☐ (PHEX:EXTED) None ☐ (PHEX:EXTED) + ☐ (PHEX:EXTED) ++ ☐ (PHEX:EXTED) +++ ☐ (PHEX:EXTED) ++++

Pulses: ☐ (PHEX:EXTPL) Normal ☐ (PHEX:EXTPL) Abnormal

If **Abnormal,** describe:

PHEX:EXTPLD

Ulcers: ☐ (PHEX:EXTLUL) None ☐ (PHEX:EXTLUL) Active ☐ (PHEX:EXTLUL) Healed

If **Active** or **Healed,** describe:

PHEX:EXTLULD

Skin

Hyperpigmentation: ☐ (PHEX:SKINHP) Absent ☐ (PHEX:SKINHP) Present

Rashes or skin lesions: ☐ (PHEX:EXTSL) Present ☐ (PHEX:EXTSL) Absent

If **Present,** describe:

PHEX:EXTSLD

Comment/ other findings or abnormalities

PHEX:EXTCM

Comments for page:

PHEX:COMM

Submit Query Cancel Form Completion Help Print Rho

Logo	**Symptoms Documentation**	**{visit.label}**
Date of Assessment: SYMP:ASMTDA / SYMP:ASMTMO / SYMP:ASMTYR (Day / Month / Year)		**ID: {ID}**

1. Since the previous assessment, has the subject experienced any acute events related to sickle cell disease or pulmonary hypertension that led him/her to seek medical care? (SYMP:EVENT) No (SYMP:EVENT) Yes

If **Yes,** add an Acute Event Record for each event and provide details. In addition, complete an Adverse Event form for each acute event.

Treatment location	Acute event/reason for seeking care	
(SYMA:LOC) Physician's office/clinic (SYMA:LOC) Emergency room/day hospital/ urgent care center (SYMA:LOC) Hospital Treatment/admission date: SYMA:TREATDA / SYMA:TREATMO / SYMA:TREATYR (Day / Month / Year)	(SYMA:EVT1) Acute chest syndrome (SYMA:EVT1) (SYMA:EVT2) Chest pain (SYMA:EVT2) (SYMA:EVT3) Dizziness (SYMA:EVT3) (SYMA:EVT4) Edema (SYMA:EVT4) (SYMA:EVT5) Irregular breathing (SYMA:EVT5) (SYMA:EVT6) Pain crisis/vaso-occlusive crisis (SYMA:EVT6) (SYMA:EVT7) Priapism (SYMA:EVT7) (SYMA:EVT8) Shortness of breath (SYMA:EVT8) (SYMA:EVT9) Stroke (SYMA:EVT9) (SYMA:EVT10) Surgical procedure, (SYMA:EVT10) (SYMA:EVT10) specify: SYMA:EVT10SP (SYMA:EVT11) Syncope (SYMA:EVT11) (SYMA:EVTOT) Other, (SYMA:EVTOT) specify: SYMA:EVTOTSP	Remove

Add Acute Event Record

2. Since the previous visit, has the subject had any sickle cell-related pain events that were treated at home? (SYMP:PAIN) No (SYMP:PAIN) Yes

If **Yes:**

Number: SYMP:NUMSCP

Did any of the pain events that were treated at home represent an exacerbation (increased frequency or intensity) of the subject's baseline condition)? (SYMP:PAINEX) No (SYMP:PAINEX) Yes

If **Yes,** complete an Adverse Event form.

3. Since the previous visit, has the subject had any changes in vision? (SYMP:VISION) No (SYMP:VISION) Yes

If **Yes,** describe: SYMP:VISDES

Were the vision changes an Adverse Event? (SYMP:VISAE) No (SYMP:VISAE) Yes

If **Yes,** complete an Adverse Events form.

4. Since the previous visit, has the subject had any headaches? (SYMP:HEAD) No (SYMP:HEAD) Yes

If **Yes:**

Number: SYMP:HEADNUM

Did any of the headaches represent an exacerbation (increased frequency or intensity) of the subject's baseline condition)? (SYMP:HEADEX) No (SYMP:HEADEX) Yes

If **Yes,** complete an Adverse Events form.

5. Since the previous visit, has the subject had any priapism events that were treated at home? (SYMP:PRIA) No (SYMP:PRIA) Yes

If **Yes:**

Number: SYMP:PRIANUM

Did any of the priapism events represent an exacerbation (increased frequency or intensity) of the subject's baseline condition)? (SYMP:PRIAEX) No (SYMP:PRIAEX) Yes

If **Yes,** complete an Adverse Events form.

6. Has the subject received a transfusion since the previous visit? (SYMP:TRANNA) No (SYMP:TRANNA) Yes

If **Yes,** add a Transfusion Record for each transfusion:

Date of transfusion:	TRAN:TRANDA / TRAN:TRANMO / TRAN:TRANYR (Day / Month / Year)	
Reason for transfusion:	(Check all that apply): (TRAN:REAS1) Anemia associated with chronic renal failure (TRAN:REAS1) (TRAN:REAS2) Acute Chest Syndrome (ACS) (TRAN:REAS2) (TRAN:REAS3) Chronic debilitating pain (TRAN:REAS3) (TRAN:REAS4) Exacerbation of anemia due to an aplastic crisis (TRAN:REAS4) (TRAN:REAS5) Exacerbation of anemia due to splenic sequestration (TRAN:REAS5) (TRAN:REAS6) Fat embolism syndrome (TRAN:REAS6) (TRAN:REAS7) Hyperhemolysis associated with infection (TRAN:REAS7) (TRAN:REAS8) Leg ulcers (TRAN:REAS8) (TRAN:REAS9) Priapism (TRAN:REAS9) (TRAN:REAS10) Pregnancy (TRAN:REAS10) (TRAN:REAS11) Pulmonary hypertension (TRAN:REAS11) (TRAN:REAS_OT) Other, (TRAN:REAS_OT) Specify: TRAN:REAS_SP	Remove Record
Type of transfusion:	(TRAN:TYPE) Exchange (TRAN:TYPE) Simple (TRAN:TYPE) Other	
Number of units transfused:	TRAN:UNITS	

Add Transfusion Record

7. Has the subject changed his/her use of analgesics (medication, dosage, or route)? (SYMP:ANLG) No (SYMP:ANLG) Yes (If **Yes,** complete the Concomitant Medications form.)

If **Yes,** was the change related to an adverse event? (SYMP:ANLGAE) No (SYMP:ANLGAE) Yes (If **Yes,** complete an Adverse Event form.)

Comments for page:

SYMP:COMM

Submit Query Cancel Form Completion Help Print Rho

Logo	**Chemistry**	**{visit.label}**
Date of Collection: CHEM:COLLDA / CHEM:COLLMO / CHEM:COLLYR (Day / Month / Year)		**ID: {ID}**

Test	Lab Value	Unit	Clinical Significance
Albumin	CHEM:ALB	☐ (CHEM:ALBUNIT) g/dL ☐ (CHEM:ALBUNIT) g/L	☐ (CHEM:ALBSG) Clinically significant and a new Adverse Event [1] ☐ (CHEM:ALBSG) Clinically significant, but not a new Adverse Event ☐ (CHEM:ALBSG) Not clinically significant
Alkaline Phosphatase	CHEM:ALK	U/L (IU/L)	☐ (CHEM:ALKSG) Clinically significant and a new Adverse Event [1] ☐ (CHEM:ALKSG) Clinically significant, but not a new Adverse Event ☐ (CHEM:ALKSG) Not clinically significant
ALT	CHEM:ALT	U/L (IU/L)	☐ (CHEM:ALTSG) Clinically significant and a new Adverse Event [1] ☐ (CHEM:ALTSG) Clinically significant, but not a new Adverse Event ☐ (CHEM:ALTSG) Not clinically significant
AST	CHEM:AST	U/L (IU/L)	☐ (CHEM:ASTSG) Clinically significant and a new Adverse Event [1] ☐ (CHEM:ASTSG) Clinically significant, but not a new Adverse Event ☐ (CHEM:ASTSG) Not clinically significant
CO_2	CHEM:CO2	☐ (CHEM:CO2UNIT) mmol/L ☐ (CHEM:CO2UNIT) kPa	☐ (CHEM:CO2SG) Clinically significant and a new Adverse Event [1] ☐ (CHEM:CO2SG) Clinically significant, but not a new Adverse Event ☐ (CHEM:CO2SG) Not clinically significant
BUN	CHEM:BUN	☐ (CHEM:BUNUNIT) mg/dL ☐ (CHEM:BUNUNIT) g/dL ☐ (CHEM:BUNUNIT) mmol/L	☐ (CHEM:BUNSG) Clinically significant and a new Adverse Event [1] ☐ (CHEM:BUNSG) Clinically significant, but not a new Adverse Event ☐ (CHEM:BUNSG) Not clinically significant
Calcium	CHEM:CAL	☐ (CHEM:CALUNIT) mg/dL ☐ (CHEM:CALUNIT) mmol/L	☐ (CHEM:CALSG) Clinically significant and a new Adverse Event [1] ☐ (CHEM:CALSG) Clinically significant, but not a new Adverse Event ☐ (CHEM:CALSG) Not clinically significant
Chloride	CHEM:CHL	mmol/L	☐ (CHEM:CHLSG) Clinically significant and a new Adverse Event [1] ☐ (CHEM:CHLSG) Clinically significant, but not a new Adverse Event ☐ (CHEM:CHLSG) Not clinically significant
Creatinine	CHEM:CRE	☐ (CHEM:CRUNIT) mg/dL ☐ (CHEM:CRUNIT) µmol/L	☐ (CHEM:CRESG) Clinically significant and a new Adverse Event [1] ☐ (CHEM:CRESG) Clinically significant, but not a new Adverse Event ☐ (CHEM:CRESG) Not clinically significant
LDH	CHEM:LDH	IU/L (U/L)	☐ (CHEM:LDHSG) Clinically significant and a new Adverse Event [1] ☐ (CHEM:LDHSG) Clinically significant, but not a new Adverse Event ☐ (CHEM:LDHSG) Not clinically significant
Magnesium	CHEM:MAG	☐ (CHEM:MAGUNIT) mg/dL ☐ (CHEM:MAGUNIT) mmol/L ☐ (CHEM:MAGUNIT) mEq/L	☐ (CHEM:MAGSG) Clinically significant and a new Adverse Event [1] ☐ (CHEM:MAGSG) Clinically significant, but not a new Adverse Event ☐ (CHEM:MAGSG) Not clinically significant
Phosphate/Phosphorus	CHEM:PHOS	☐ (CHEM:PUNIT) mg/dL Phosphorus ☐ (CHEM:PUNIT) mmol/L Phosphate	☐ (CHEM:PHOSSG) Clinically significant and a new Adverse Event [1] ☐ (CHEM:PHOSSG) Clinically significant, but not a new Adverse Event ☐ (CHEM:PHOSSG) Not clinically significant
Potassium	CHEM:POT	mmol/L	☐ (CHEM:POTSG) Clinically significant and a new Adverse Event [1] ☐ (CHEM:POTSG) Clinically significant, but not a new Adverse Event ☐ (CHEM:POTSG) Not clinically significant
Sodium	CHEM:SOD	mmol/L	☐ (CHEM:SODSG) Clinically significant and a new Adverse Event [1] ☐ (CHEM:SODSG) Clinically significant, but not a new Adverse Event ☐ (CHEM:SODSG) Not clinically significant
Total Bilirubin	CHEM:TBIL	☐ (CHEM:TBUNIT) mg/dL ☐ (CHEM:TBUNIT) µmol/L	☐ (CHEM:TBILSG) Clinically significant and a new Adverse Event [1] ☐ (CHEM:TBILSG) Clinically significant, but not a new Adverse Event ☐ (CHEM:TBILSG) Not clinically significant

Total Protein	CHEM:TPROT	☐ (CHEM:TPUNIT) g/dL ☐ (CHEM:TPUNIT) g/L	☐ (CHEM:TPROTSG) Clinically significant and a new Adverse Event [1] ☐ (CHEM:TPROTSG) Clinically significant, but not a new Adverse Event ☐ (CHEM:TPROTSG) Not clinically significant

[1]Complete an Adverse Events form

Comments for page:

CHEM:COMM

Submit Query Cancel Form Completion Help Print Rho

Logo	Hematology	{visit.label}
Date of Collection: HEMA:COLLDA (Day) / HEMA:COLLMO (Month) / HEMA:COLLYR (Year)		ID:{ID}

Test	Lab Value	Units	Clinical Significance
Absolute Neutrophil Count (ANC)	HEMA:ANC	x10^{3}cells/µL (x10^{9}cells/L)	☐ (HEMA:ANCSG) Clinically significant and a new Adverse Event[1] ☐ (HEMA:ANCSG) Clinically significant but not a new Adverse Event ☐ (HEMA:ANCSG) Not clinically significant
Neutrophils (%)	HEMA:NEUT	%	☐ (HEMA:NEUTSG)Clinically significant and a new Adverse Event[1] ☐ (HEMA:NEUTSG) Clinically significant but not a new Adverse Event ☐ (HEMA:NEUTSG) Not clinically significant
Absolute Reticulocyte Count (ARC)	HEMA:ARC	x10^{3}cells/µL (x10^{9}cells/L)	☐ (HEMA:ARCSG) Clinically significant and a new Adverse Event[1] ☐ (HEMA:ARCSG) Clinically significant but not a new Adverse Event ☐ (HEMA:ARCSG) Not clinically significant
Reticulocytes (%)	HEMA:RET	%	☐ (HEMA:RETSG) Clinically significant and a new Adverse Event[1] ☐ (HEMA:RETSG) Clinically significant but not a new Adverse Event ☐ (HEMA:RETSG) Not clinically significant
Hematocrit	HEMA:HCT	☐ (HEMA:HCTUNIT) % ☐ (HEMA:HCTUNIT) 1:1	☐ (HEMA:HCTSG) Clinically significant and a new Adverse Event[1] ☐ (HEMA:HCTSG) Clinically significant but not a new Adverse Event ☐ (HEMA:HCTSG) Not clinically significant
Hemoglobin	HEMA:HGB	☐ (HEMA:HGBUNIT) g/dL ☐ (HEMA:HGBUNIT) g/L	☐ (HEMA:HGBSG)Clinically significant and a new Adverse Event[1] ☐ (HEMA:HGBSG) Clinically significant but not a new Adverse Event ☐ (HEMA:HGBSG) Not clinically significant
Mean Corpuscular Hemoglobin Concentration (MCHC)	HEMA:MCHC	☐ (HEMA:MCHUNIT) g/dL ☐ (HEMA:MCHUNIT) g/L	☐ (HEMA:MCHCSG) Clinically significant and a new Adverse Event[1] ☐ (HEMA:MCHCSG) Clinically significant but not a new Adverse Event ☐ (HEMA:MCHCSG) Not clinically significant
Mean Corpuscular Volume (MCV)	HEMA:MCV	fL	☐ (HEMA:MCVSG) Clinically significant and a new Adverse Event[1] ☐ (HEMA:MCVSG)Clinically significant but not a new Adverse Event ☐ (HEMA:MCVSG) Not clinically significant
Platelet Count	HEMA:PLAT	x10^{3}cells/µL (x10^{9}cells/L)	☐ (HEMA:PLATSG) Clinically significant and a new Adverse Event[1] ☐ (HEMA:PLATSG) Clinically significant but not a new Adverse Event ☐ (HEMA:PLATSG) Not clinically significant
RBC	HEMA:RBC	x10^{6}cells/µL	☐ (HEMA:RBCSG)Clinically significant and a new Adverse Event[1] ☐ (HEMA:RBCSG) Clinically significant but not a new Adverse Event ☐ (HEMA:RBCSG) Not clinically significant
WBC	HEMA:WBC	x10^{3}cells/µL	☐ (HEMA:WBCSG) Clinically significant and a new Adverse Event[1] ☐ (HEMA:WBCSG) Clinically significant but not a new Adverse Event ☐ (HEMA:WBCSG) Not clinically significant
International Normalized Ratio (INR)*	HEMA:INR		☐ (HEMA:INRSG) Clinically significant and a new Adverse Event [1] ☐ (HEMA:INRSG) Clinically significant but not a new Adverse Event ☐ (HEMA:INRSG) Not clinically significant
Activated Partial Thromboplastin Time (aPTT)**	HEMA:APPT		☐ (HEMA:APPTSG) Clinically significant and a new Adverse Event [1] ☐ (HEMA:APPTSG) Clinically significant but not a new Adverse Event ☐ (HEMA:APPTSG) Not clinically significant

* Required if subject is on a Vitamin K antagonist
** Required if subject is on heparin

[1]Complete an Adverse Events form

Comments for page:

HEMA:COMM

Submit Query Cancel Form Completion Help Print Rho

Logo	**Hemoglobin Electrophoresis**	**{visit.label}**
Date of Collection: HEEL:COLLDA (Day) / HEEL:COLLMO (Month) / HEEL:COLLYR (Year)		**ID: {ID}**

1. Was a historical hemoglobin electrophoresis used? (HEEL:HIST) No (HEEL:HIST) Yes
2. A (%): HEEL:HEMA
3. A2 (%): HEEL:HEMA2
4. C (%): HEEL:HEMC
5. F (%): HEEL:HEMF
6. S (%): HEEL:HEMS
7. Other (%): HEEL:HEMOTH If **Other,** specify: HEEL:HEMOSP

Comments for page:

HEEL:COMM

Submit Query | Cancel | Form Completion Help | Print | Rho

Logo	Urinalysis	{visit.label}
		ID: {ID}

1. Date of collection for urinalysis: URIN:COLLDA / URIN:COLLMO / URIN:COLLYR
Day Month Year

Urine Dipstick Chemical Analysis

2. Is the subject menstruating? ☐ (URIN:MENSES) No ☐ (URIN:MENSES) Yes ☐ (URIN:MENSES) Not Applicable (male subject)

3. pH: URIN:PH

4. Specific Gravity: URIN:SPGRAV

For items 5-7, if dipstick result is positive, record code and/or value

Test	Dipstick Results	Code	Value
5. Glucose	☐ (URIN:GLU) Negative ☐ (URIN:GLU) Positive	☐ (URIN:GLUCODE) Trace ☐ (URIN:GLUCODE) 1+ ☐ (URIN:GLUCODE) 2+ ☐ (URIN:GLUCODE) 3+ ☐ (URIN:GLUCODE) 4+	URIN:GLUVAL mg/dL
6. Protein (Proteinuria)	☐ (URIN:PRO) Negative ☐ (URIN:PRO) Positive	☐ (URIN:PROCODE) Trace ☐ (URIN:PROCODE) 1+ ☐ (URIN:PROCODE) 2+ ☐ (URIN:PROCODE) 3+ ☐ (URIN:PROCODE) 4+	URIN:PROVAL mg/dL
7. Blood	☐ (URIN:BLD) Negative ☐ (URIN:BLD) Positive	☐ (URIN:BLDCODE) Trace ☐ (URIN:BLDCODE) 1+ ☐ (URIN:BLDCODE) 2+ ☐ (URIN:BLDCODE) 3+ ☐ (URIN:BLDCODE) 4+	URIN:BLDVAL Ery/µL

Microscopic Exam

8. Was microscopic exam performed? ☐ (URIN:MICROYN) No ☐ (URIN:MICROYN) Yes

If **Yes,** complete the following:

RBC: ☐ (URIN:RBC) 0-5 ☐ (URIN:RBC) 5-10 ☐ (URIN:RBC) 10-25 ☐ (URIN:RBC) 25-50 ☐ (URIN:RBC) 50+ #/HPF

WBC: ☐ (URIN:WBC) 0-5 ☐ (URIN:WBC) 5-10 ☐ (URIN:WBC) 10-25 ☐ (URIN:WBC) 25-50 ☐ (URIN:WBC) 50+ #/HPF

9. Other abnormal findings on microscopic exam? ☐ (URIN:OMICYN) No ☐ (URIN:OMICYN) Yes

If **Yes,** describe: URIN:OMICDES

Overall Assessment of Urinalysis

10. Overall assessment of urinalysis: ☐ (URIN:OVERALL) Normal ☐ (URIN:OVERALL) Abnormal

If **Abnormal,** is this a new AE? ☐ (URIN:NEWAE) No ☐ (URIN:NEWAE) Yes (If **Yes,** report on Adverse Events form.)

Albumin/Creatinine

11. Date of collection for albumin/creatinine: URIN:ACDA (Day) / URIN:ACMO (Month) / URIN:ACYR (Year)

12. Albumin/creatinine URIN:ALB albumin (mg/dL) : URIN:CREAT creatinine (mg/dL) **or** URIN:RATIO ratio

Comments for page:

URIN:COMM

Submit Query Cancel Form Completion Help Print Rho

Logo	Pregnancy Test	{visit.label}
Date of Assessment: PREG:ASMTDA / PREG:ASMTMO / PREG:ASMTYR (Day / Month / Year)		ID: {ID}

1. Result:

- (PREG:RESULT) Negative
- (PREG:RESULT) Positive
- (PREG:RESULT) Not Done

If **Not Done,** specify reason:

- (PREG:REASON) Subject is male
- (PREG:REASON) Subject is pre-menarche or post-menopausal
- (PREG:REASON) Subject is surgically or medically sterile
- (PREG:REASON) Other, specify: PREG:OTH_SP

2. Type of test: (PREG:TYPE) Serum (PREG:TYPE) Urine

If **Serum,** HCG: PREG:HCGSYM PREG:HCG mIU/mL (IU/L) Q2:<; >

Comments for page: PREG:COMM

Submit Query Cancel Form Completion Help Print Rho

Logo	Echocardiogram (Local)	{visit.label}
Date of Procedure: ECHO:PROCDA / ECHO:PROCMO / ECHO:PROCYR (Day / Month / Year)		ID: {ID}

1.Time of procedure: ECHO:PROCHH : ECHO:PROCMM (Hr / Min / (24 hr clock))

1a. Date and time of last dose of study drug: ECHO:DRUGDA / ECHO:DRUGMO / ECHO:DRUGYR (Day / Month / Year) ECHO:DRUGHH : ECHO:DRUGMM (Hr / Min / (24 hr clock)) or (ECHO:NODRUG) Not Applicable (Subject not on study drug)

2. Blood pressure at time of procedure: ECHO:SYSBP / ECHO:DIABP mmHg (Systolic / Diastolic)

3. Tricuspid regurgitant jet velocity: ECHO:TRJV m/s **or** (ECHO:TRJVND) Not detectable

4. Estimated right atrial pressure (mmHg): (ECHO:ERAP)5 (ECHO:ERAP)10 (ECHO:ERAP)15 (ECHO:ERAP)20

5. LV function: (ECHO:LVFUN)Normal (ECHO:LVFUN)Abnormal

6. LV ejection fraction: ECHO:LVEF

	None	Trace	Mild	Mild-Moderate	Moderate	Moderate-Severe	Severe
7. Aortic regurgitation:	(ECHO:AR)	(ECHO:AR)	(ECHO:AR)	(ECHO:AR)	(ECHO:AR)	(ECHO:AR)	(ECHO:AR)
8. Mitral regurgitation:	(ECHO:MR)	(ECHO:MR)	(ECHO:MR)	(ECHO:MR)	(ECHO:MR)	(ECHO:MR)	(ECHO:MR)
9. Tricuspid regurgitation:	(ECHO:TR)	(ECHO:TR)	(ECHO:TR)	(ECHO:TR)	(ECHO:TR)	(ECHO:TR)	(ECHO:TR)

10. Other significant findings:

ECHO:OTHSIG

11. Echo recording bar code(s): ECHO:CODE1 ECHO:CODE2

Comments for page:

ECHO:COMM

Submit Query Cancel Form Completion Help Print Rho

Logo	**Right Heart Catheterization**	**{visit.label}**
		ID: {ID}

1. Was the subject enrolled in the trial with a TR jet velocity ≥ 3.0 m/s? ☐ (RHCA:TRJET) No ☐ (RHCA:TRJET) Yes

If **Yes,** then this procedure is required.
If **No,** then leave the rest of this form blank.

2. Visit:

☐ (RHCA:VISIT) Baseline **(Complete Steps 1–5 from protocol)**

☐ (RHCA:VISIT) Week 16/Early Termination Visit **(Complete Steps 1, 4, and 5 from protocol)**

3. Last dose of study drug: RHCA:LDSDDA / RHCA:LDSDMO / RHCA:LDSDYR RHCA:LDSDHH : RHCA:LDSDMM
(Leave blank if Baseline Visit) Day / Month / Year Hr : Min

4. Date of procedure: RHCA:PROCDA / RHCA:PROCMO / RHCA:PROCYR
Day / Month / Year

	Parameter	Step 1 At Rest or Trough Drug Effect	INO Start	Step 2 10 Min Post INO Start	Step 3 10 Min Post Step 2	
5.	Catheterization side: ☐ (RHCA:SIDE) Left ☐ (RHCA:SIDE) Right					
6.	Time of Intervention (hr:min, 24 hr clock)		RHCA:INOHH : RHCA:INOMM			RH
7.	Time of Assessment (hr:min, 24 hr clock)	RHCA:ASMT1HH : RHCA:ASMT1MM		RHCA:ASMT2HH : RHCA:ASMT2MM	RHCA:ASMT3HH : RHCA:ASMT3MM	
8.	Heart Rate (beats/min)	RHCA:HRATE1		RHCA:HRATE2	RHCA:HRATE3	
9.	Systemic Arterial Saturation (%)	RHCA:SAS1		RHCA:SAS2	RHCA:SAS3	
10.	SvO_2 (%)	RHCA:SVOX1		RHCA:SVOX2	RHCA:SVOX3	
11.	Systolic Systemic Pressure (mmHg)	RHCA:SSBP1		RHCA:SSBP2	RHCA:SSBP3	
12.	Diastolic Systemic Pressure (mmHg)	RHCA:DSBP1		RHCA:DSBP2	RHCA:DSBP3	
13.	Mean Systemic Pressure (mmHg)	RHCA:MSP1		RHCA:MSP2	RHCA:MSP3	
14.	Systolic Pulmonary Artery Pressure (mmHg)	RHCA:SPAP1		RHCA:SPAP2	RHCA:SPAP3	
15.	Diastolic Pulmonary Artery Pressure (mmHg)	RHCA:DPAP1		RHCA:DPAP2	RHCA:DPAP3	
16.	Mean Pulmonary Artery Pressure (mmHg)	RHCA:MPAP1		RHCA:MPAP2	RHCA:MPAP3	
17.	Mean Right Atrial Pressure (mmHg)	RHCA:MRAP1		RHCA:MRAP2	RHCA:MRAP3	
18.	Mean Pulmonary Capillary Wedge Pressure (mmHg)	RHCA:MPCWP1		RHCA:MPCWP2	RHCA:MPCWP3	
19.	Left Ventricular End-Diastolic Pressure (mmHg) (if Left Heart Catheterization)	RHCA:LVEDP1		RHCA:LVEDP2	RHCA:LVEDP3	
20.	Cardiac Output (L/min)	RHCA:OUTPUT1		RHCA:OUTPUT2	RHCA:OUTPUT3	
21.	Cardiac Output Method: ☐ (RHCA:METHOD) Fick ☐ (RHCA:METHOD) Thermodilution					

22. Recording bar code: RHCA:CODE or ☐ (RHCA:NOTSENT) Recording not sent

Comments for page:
RHCA:COMM

Submit Query Cancel Form Completion Help Print Rho

Logo	**6-Minute Walk Test**	**{visit.label}**
Date of Assessment: SIXM:ASMTDA / SIXM:ASMTMO / SIXM:ASMTYR (Day / Month / Year)		**ID: {ID}**

Date and time of last dose of study drug: SIXM:DRUGDA / SIXM:DRUGMO / SIXM:DRUGYR (Day / Month / Year) SIXM:DRUGHH : SIXM:DRUGMM (Hr / Min, 24 hr clock)

or ☐ (SIXM:LDNA) Not Applicable (Baseline Visit)

Before Walk

1. Blood pressure (systolic/diastolic): SIXM:SYSPRE / SIXM:DIAPRE mmHg

2. Heart rate: SIXM:HRPRE beats/min

3. O_2 saturation: SIXM:OSPRE %, measured on: ☐ (SIXM:AOPRE) Air ☐ (SIXM:AOPRE) O_2

   If **O_2**, flow rate: SIXM:FRPRE L/m

4. Time walk started (24-hr clock) SIXM:STARTHH : SIXM:STARTMM (Hr Min)

After Walk

5. Blood pressure (systolic/diastolic): SIXM:SYSPOST / SIXM:DIAPOST mmHg

6. Heart rate immediately after: SIXM:HRPOST beats/min

7. O_2 saturation immediately after: SIXM:OSPOST %, measured on: ☐ (SIXM:AOPOST) Air ☐ (SIXM:AOPOST) O_2

   If **O_2**, flow rate: SIXM:FRPOST L/m

8. Distance walked: SIXM:DIST m

9. Did subject stop before 6-minute time limit? ☐ (SIXM:SUBSTOP) No ☐ (SIXM:SUBSTOP) Yes

10. Did subject use oxygen during the test? ☐ (SIXM:USEO2) No ☐ (SIXM:USEO2) Yes

    If **Yes:** Oxygen flow rate: SIXM:FRWALK L/min

    Was oxygen device carried or pushed? ☐ (SIXM:DEVICE) Carried ☐ (SIXM:DEVICE) Pushed

11. Borg dyspnea score:

- ☐ (SIXM:BRGPOST) 0=Nothing at all
- ☐ (SIXM:BRGPOST) 0.5=Very, very slight (just noticeable)
- ☐ (SIXM:BRGPOST) 1=Very slight
- ☐ (SIXM:BRGPOST) 2=Slight
- ☐ (SIXM:BRGPOST) 3=Moderate
- ☐ (SIXM:BRGPOST) 4=Somewhat severe
- ☐ (SIXM:BRGPOST) 5=severe

☐ (SIXM:BRGPOST) 6

☐ (SIXM:BRGPOST) 7=Very severe

☐ (SIXM:BRGPOST) 8

☐ (SIXM:BRGPOST) 9=Very, very severe (almost maximum)

☐ (SIXM:BRGPOST) 10=Maximum

12. NYHA/WHO classification:

☐ (SIXM:CLASS) Class I	Patients with pulmonary hypertension but without resulting limitation of physical activity. Ordinary physical activity does not cause undue dyspnea or fatigue, chest pain, or near syncope.
☐ (SIXM:CLASS) Class II	Patients with pulmonary hypertension resulting in slight limitation of physical activity. They are comfortable at rest. Ordinary physical activity causes undue dyspnea or fatigue, chest pain, or near syncope.
☐ (SIXM:CLASS) Class III	Patients with pulmonary hypertension resulting in marked limitation of physical activity. They are comfortable at rest. Less than ordinary physical activity causes undue dyspnea or fatigue, chest pain, or near syncope.
☐ (SIXM:CLASS) Class IV	Patients with pulmonary hypertension resulting in the inability to carry out any physical activity without symptoms. These patients manifest signs of right heart failure. Dyspnea and/or fatigue may be present at rest, and discomfort is increased by any physical activity.

Comments for page:

SIXM:COMM

Submit Query Cancel Form Completion Help Print ☐ Rho

Logo	**Pulmonary Function Studies**	**{visit.label}**
Date of Assessment: PFTS:ASMTDA / PFTS:ASMTMO / PFTS:ASMTYR Day Month Year		**ID: {ID}**

Spirometry – Pre-bronchodilator	**Absolute Value**	**% Predicted**
FVC (forced vital capacity)	PFTS:A_FVC L	PFTS:A_FVCP %
FEV_1 (forced expiratory volume in 1st second)	PFTS:A_FEV1 L	PFTS:A_FEV1P %
FEV_1/FVC	PFTS:A_DIV %	PFTS:A_DIVP %
$FEF_{25-75\%}$ (forced expiratory flow 25-75%)	PFTS:A_25 L/sec	PFTS:A_25P %
Spirometry – Post-bronchodilator	**Absolute Value**	**% Predicted**
FVC (forced vital capacity)	PFTS:B_FVC L	PFTS:B_FVCP %
FEV_1 (forced expiratory volume in 1st second)	PFTS:B_FEV1 L	PFTS:B_FEV1P %
FEV_1/FVC	PFTS:B_DIV %	PFTS:B_DIVP %
$FEF_{25-75\%}$ (forced expiratory flow 25-75%)	PFTS:B_25	PFTS:B_25P %
Lung Volumes	**Absolute Value**	**% Predicted**
TLC (total lung capacity)	PFTS:TLC L	PFTS:TLCP %
FRC (functional residual capacity)	PFTS:FRC L	PFTS:FRCP %
RV (residual volume)	PFTS:RV L	PFTS:RVP %
IC (inspiratory capacity)	PFTS:IC L	PFTS:ICP %
ERV (expiratory reserve volume)	PFTS:ERV L	PFTS:ERVP %
RV/TLC	PFTS:RDIV %	PFTS:RDIVP %
Diffusion	**Absolute Value**	**% Predicted**
D_{LCO} (diffusion capacity for CO)	PFTS:DLCO mL/min/mmHg	PFTS:DLCOP %
D_{LCOc} (diffusion capacity corrected for hemoglobin level)	PFTS:DLCOC mL/min/mmHg	PFTS:DLCOCP %

V_A (alveolar volume)	PFTS:VA L	PFTS:VAP %
D_{LCO}/V_A	PFTS:D_VA mL/min/mmHg/L	PFTS:D_VAP %
D_{LOCc}/V_A	PFTS:DC_VAC mL/min/mmHg/L	PFTS:DC_VACP %

Comments for page:

PFTS:COMM

Submit Query Cancel Form Completion Help Print Rho

Logo	Chest X-ray	{visit.label}
Date of Procedure: CXRA:PROCDA / CXRA:PROCMO / CXRA:PROCYR (Day / Month / Year)		ID: {ID}

1. Result:

☐ (CXRA:RESULT) Normal

☐ (CXRA:RESULT) Abnormal

If **Abnormal,** check all that apply:

☐ (CXRA:ABN1) Atelectasis, specify location:

Right Lung: ☐ (CXRA:ABN1RSL) superior (upper) lobe ☐ (CXRA:ABN1RML) middle lobe ☐ (CXRA:ABN1RIL) inferior (lower) lobe

Left Lung: ☐ (CXRA:ABN1LSL) superior (upper) lobe ☐ (CXRA:ABN1LIL) inferior (lower) lobe

☐ (CXRA:ABN2) Bony abnormalities

☐ (CXRA:ABN3) Cardiomegaly

☐ (CXRA:ABN4) Effusion

☐ (CXRA:ABN5) Infiltrates, specify location:

Right Lung: ☐ (CXRA:ABN5RSL) superior (upper) lobe ☐ (CXRA:ABN5RML) middle lobe ☐ (CXRA:ABN5RIL) inferior (lower) lobe

Left Lung: ☐ (CXRA:ABN5LSL) superior (upper) lobe ☐ (CXRA:ABN5LIL) inferior (lower) lobe

☐ (CXRA:ABN6) Interstitial changes, specify location:

Right Lung: ☐ (CXRA:ABN6RSL) superior (upper) lobe ☐ (CXRA:ABN6RML) middle lobe ☐ (CXRA:ABN6RIL) inferior (lower) lobe

Left Lung: ☐ (CXRA:ABN6LSL) superior (upper) lobe ☐ (CXRA:ABN6LIL) inferior (lower) lobe

☐ (CXRA:ABN7) Mass, specify location:

Right Lung: ☐ (CXRA:ABN7RSL) superior (upper) lobe ☐ (CXRA:ABN7RML) middle lobe ☐ (CXRA:ABN7RIL)

inferior (lower) lobe

Left Lung: ☐ (CXRA:ABN7LSL) superior (upper) lobe

☐ (CXRA:ABN7LIL) inferior (lower) lobe

☐ (CXRA:ABN8) Pulmonary artery enlargement

☐ (CXRA:ABN9) Soft tissue abnormalities

☐ (CXRA:ABN10) Other abnormality, specify:

CXRA:OTH_SP

2. X-ray bar code: CXRA:CODE **or** ☐ (CXRA:NOCODE) Bar code not used

Comments for page:

CXRA:COMM

Submit Query Cancel Form Completion Help Print Rho

Logo	**SF-36 Health Survey**	**{visit.label}**
Date of Assessment: SF36:ASMTDA / SF36:ASMTMO / SF36:ASMTYR (Day / Month / Year)		**ID: {ID}**

1. In general, would you say your health is:

☐ (SF36:SFQ1) Excellent ☐ (SF36:SFQ1) Very good ☐ (SF36:SFQ1) Good ☐ (SF36:SFQ1) Fair ☐ (SF36:SFQ1) Poor

2. **Compared to one year ago,** how would you rate your health in general **now?**

☐ (SF36:SFQ2) Much better now than 1 year ago ☐ (SF36:SFQ2) Somewhat better now than 1 year ago ☐ (SF36:SFQ2) About the same as 1 year ago ☐ (SF36:SFQ2) Somewhat worse now than 1 year ago ☐ (SF36:SFQ2) Much worse now than 1 year ago

3. The following questions are about activities you might do during a typical day. Does **your health now limit you** in these activities? If so, how much?

	Activity	Yes, limited a lot	Yes, limited a little	No, not limited at all
a.	**Vigorous activities,** such as running, lifting heavy objects, or participating in strenuous sports	☐ (SF36:SFQ3A)	☐ (SF36:SFQ3A)	☐ (SF36:SFQ3A)
b.	**Moderate activities,** such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	☐ (SF36:SFQ3B)	☐ (SF36:SFQ3B)	☐ (SF36:SFQ3B)
c.	Lifting or carrying groceries	☐ (SF36:SFQ3C)	☐ (SF36:SFQ3C)	☐ (SF36:SFQ3C)
d.	Climbing **several** flights of stairs	☐ (SF36:SFQ3D)	☐ (SF36:SFQ3D)	☐ (SF36:SFQ3D)
e.	Climbing **one** flight of stairs	☐ (SF36:SFQ3E)	☐ (SF36:SFQ3E)	☐ (SF36:SFQ3E)
f.	Bending, kneeling, or stooping	☐ (SF36:SFQ3F)	☐ (SF36:SFQ3F)	☐ (SF36:SFQ3F)
g.	Walking **more than a mile**	☐ (SF36:SFQ3G)	☐ (SF36:SFQ3G)	☐ (SF36:SFQ3G)
h.	Walking **several hundred yards**	☐ (SF36:SFQ3H)	☐ (SF36:SFQ3H)	☐ (SF36:SFQ3H)
i.	Walking **one hundred yards**	☐ (SF36:SFQ3I)	☐ (SF36:SFQ3I)	☐ (SF36:SFQ3I)
j.	Bathing or dressing yourself	☐ (SF36:SFQ3J)	☐ (SF36:SFQ3J)	☐ (SF36:SFQ3J)

4. During the **past 4 weeks,** how much of the time have you had any of the following problems with your work or other regular daily activities **as a result of your physical health?**

		All of the time	Most of the time	Some of the time	A little of the time	None of the time
a.	Cut down on the **amount of time** you spent on work or other activities.	☐ (SF36:SFQ4A)	☐ (SF36:SFQ4A)	☐ (SF36:SFQ4A)	☐ (SF36:SFQ4A)	☐ (SF36:SFQ4A)
b.	**Accomplished less** than you would like.	☐ (SF36:SFQ4B)	☐ (SF36:SFQ4B)	☐ (SF36:SFQ4B)	☐ (SF36:SFQ4B)	☐ (SF36:SFQ4B)
c.	Were limited in the **kind** of work or other activities	☐ (SF36:SFQ4C)	☐ (SF36:SFQ4C)	☐ (SF36:SFQ4C)	☐ (SF36:SFQ4C)	☐ (SF36:SFQ4C)
d.	Had **difficulty** performing the work or other activities (for example, it took extra effort).	☐ (SF36:SFQ4D)	☐ (SF36:SFQ4D)	☐ (SF36:SFQ4D)	☐ (SF36:SFQ4D)	☐ (SF36:SFQ4D)

5. During the **past 4 weeks,** how much of the time have you had any of the following problems with your work or other regular daily activities **as a result of any emotional problems** (such as feeling depressed or anxious)?

		All of the time	Most of the time	Some of the time	A little of the time	None of the time
a.	Cut down on the **amount of time** you spent on work or other activities.	☐ (SF36:SFQ5A)	☐ (SF36:SFQ5A)	☐ (SF36:SFQ5A)	☐ (SF36:SFQ5A)	☐ (SF36:SFQ5A)
b.	**Accomplished less** than you would like.	☐ (SF36:SFQ5B)	☐ (SF36:SFQ5B)	☐ (SF36:SFQ5B)	☐ (SF36:SFQ5B)	☐ (SF36:SFQ5B)
c.	Did work or other activities **less carefully than usual**.	☐ (SF36:SFQ5C)	☐ (SF36:SFQ5C)	☐ (SF36:SFQ5C)	☐ (SF36:SFQ5C)	☐ (SF36:SFQ5C)

6. During the **past 4 weeks,** to what extent has your **physical health or emotional problems** interfered with your normal social activities with family, friends, neighbors, or groups?

☐ (SF36:SFQ6) Not at all ☐ (SF36:SFQ6) Slightly ☐ (SF36:SFQ6) Moderately ☐ (SF36:SFQ6) Quite a bit ☐ (SF36:SFQ6) Extremely

7. How much **bodily pain** have you had during the **past 4 weeks?**

☐ (SF36:SFQ7) None ☐ (SF36:SFQ7) Very mild ☐ (SF36:SFQ7) Mild ☐ (SF36:SFQ7) Moderate ☐ (SF36:SFQ7) Severe ☐ (SF36:SFQ7) Very Severe

8. During the **past 4 weeks,** how much did **pain** interfere with your normal work (including both work outside the home and housework)?

☐ (SF36:SFQ8) Not at all ☐ (SF36:SFQ8) A little bit ☐ (SF36:SFQ8) Moderately ☐ (SF36:SFQ8) Quite a bit ☐ (SF36:SFQ8) Extremely

9. These questions are about how you feel and how things have been with you **during the past 4 weeks.** For each question, please give the one answer that comes closest to the way you have been feeling.

How much of the time during the past 4 weeks...		All of the time	Most of the time	Some of the time	A little of the time	None of the time
a.	Did you feel full of life?	☐ (SF36:SFQ9A)	☐ (SF36:SFQ9A)	☐ (SF36:SFQ9A)	☐ (SF36:SFQ9A)	☐ (SF36:SFQ9A)
b.	Have you been very nervous?	☐ (SF36:SFQ9B)	☐ (SF36:SFQ9B)	☐ (SF36:SFQ9B)	☐ (SF36:SFQ9B)	☐ (SF36:SFQ9B)
c.	Have you felt so down in the dumps that nothing could cheer you up?	☐ (SF36:SFQ9C)	☐ (SF36:SFQ9C)	☐ (SF36:SFQ9C)	☐ (SF36:SFQ9C)	☐ (SF36:SFQ9C)
d.	Have you felt calm and peaceful?	☐ (SF36:SFQ9D)	☐ (SF36:SFQ9D)	☐ (SF36:SFQ9D)	☐ (SF36:SFQ9D)	☐ (SF36:SFQ9D)
e.	Did you have a lot of energy?	☐ (SF36:SFQ9E)	☐ (SF36:SFQ9E)	☐ (SF36:SFQ9E)	☐ (SF36:SFQ9E)	☐ (SF36:SFQ9E)
f.	Have you felt downhearted and depressed?	☐ (SF36:SFQ9F)	☐ (SF36:SFQ9F)	☐ (SF36:SFQ9F)	☐ (SF36:SFQ9F)	☐ (SF36:SFQ9F)
g.	Did you feel worn out?	☐ (SF36:SFQ9G)	☐ (SF36:SFQ9G)	☐ (SF36:SFQ9G)	☐ (SF36:SFQ9G)	☐ (SF36:SFQ9G)
h.	Have you been happy?	☐ (SF36:SFQ9H)	☐ (SF36:SFQ9H)	☐ (SF36:SFQ9H)	☐ (SF36:SFQ9H)	☐ (SF36:SFQ9H)
i.	Did you feel tired?	☐ (SF36:SFQ9I)	☐ (SF36:SFQ9I)	☐ (SF36:SFQ9I)	☐ (SF36:SFQ9I)	☐ (SF36:SFQ9I)

10. During the **past 4 weeks,** how much of the time has your **physical health or emotional problems** interfered with your social activities (like visiting friends, relatives, etc.)?

☐ (SF36:SFQ10) All of the time ☐ (SF36:SFQ10) Most of the time ☐ (SF36:SFQ10) Some of the time ☐ (SF36:SFQ10) A little of the time ☐ (SF36:SFQ10) None of the time

11. How TRUE or FALSE is **each** of the following statements for you?

Statement		Definitely True	Mostly True	Don't Know	Mostly False	Definitely False
a.	I seem to get sick a little easier than other people.	☐ (SF36:SFQ11A)	☐ (SF36:SFQ11A)	☐ (SF36:SFQ11A)	☐ (SF36:SFQ11A)	☐ (SF36:SFQ11A)
b.	I am as healthy as anybody I know.	☐ (SF36:SFQ11B)	☐ (SF36:SFQ11B)	☐ (SF36:SFQ11B)	☐ (SF36:SFQ11B)	☐ (SF36:SFQ11B)
c.	I expect my health to get worse.	☐ (SF36:SFQ11C)	☐ (SF36:SFQ11C)	☐ (SF36:SFQ11C)	☐ (SF36:SFQ11C)	☐ (SF36:SFQ11C)
d.	My health is excellent.	☐ (SF36:SFQ11D)	☐ (SF36:SFQ11D)	☐ (SF36:SFQ11D)	☐ (SF36:SFQ11D)	☐ (SF36:SFQ11D)

Comments for page:

SF36:COMM

Submit Query Cancel Form Completion Help Print Rho

Logo	**Pediatric Quality of Life Inventory Parent Report for Teen (13 yrs old)**	**{visit.label}**
Date of Assessment: QP13:ASMTDA / QP13:ASMTMO / QP13:ASMTYR (DD / MMM / YYYY)	**Quality of Life Assessments**	**ID: {ID}**

*In the past **ONE month,** how much of a **problem** has your teen had with...*

Physical Functioning *(problems with...)*	Never	Almost Never	Some-times	Often	Almost Always
1. Walking more than one block	☐ (QP13:PHYFP1) 0	☐ (QP13:PHYFP1) 1	☐ (QP13:PHYFP1) 2	☐ (QP13:PHYFP1) 3	☐ (QP13:PHYFP1) 4
2. Running	☐ (QP13:PHYFP2) 0	☐ (QP13:PHYFP2) 1	☐ (QP13:PHYFP2) 2	☐ (QP13:PHYFP2) 3	☐ (QP13:PHYFP2) 4
3. Participating in sports activity or exercise	☐ (QP13:PHYFP3) 0	☐ (QP13:PHYFP3) 1	☐ (QP13:PHYFP3) 2	☐ (QP13:PHYFP3) 3	☐ (QP13:PHYFP3) 4
4. Lifting something heavy	☐ (QP13:PHYFP4) 0	☐ (QP13:PHYFP4) 1	☐ (QP13:PHYFP4) 2	☐ (QP13:PHYFP4) 3	☐ (QP13:PHYFP4) 4
5. Taking a bath or shower by him or herself	☐ (QP13:PHYFP5) 0	☐ (QP13:PHYFP5) 1	☐ (QP13:PHYFP5) 2	☐ (QP13:PHYFP5) 3	☐ (QP13:PHYFP5) 4
6. Doing chores around the house	☐ (QP13:PHYFP6) 0	☐ (QP13:PHYFP6) 1	☐ (QP13:PHYFP6) 2	☐ (QP13:PHYFP6) 3	☐ (QP13:PHYFP6) 4
7. Having hurts or aches	☐ (QP13:PHYFP7) 0	☐ (QP13:PHYFP7) 1	☐ (QP13:PHYFP7) 2	☐ (QP13:PHYFP7) 3	☐ (QP13:PHYFP7) 4
8. Low energy level	☐ (QP13:PHYFP8) 0	☐ (QP13:PHYFP8) 1	☐ (QP13:PHYFP8) 2	☐ (QP13:PHYFP8) 3	☐ (QP13:PHYFP8) 4

Emotional Functioning *(problems with...)*	Never	Almost Never	Some-times	Often	Almost Always
1. Feeling afraid or scared	☐ (QP13:EMOFP1) 0	☐ (QP13:EMOFP1) 1	☐ (QP13:EMOFP1) 2	☐ (QP13:EMOFP1) 3	☐ (QP13:EMOFP1) 4
2. Feeling sad or blue	☐ (QP13:EMOFP2) 0	☐ (QP13:EMOFP2) 1	☐ (QP13:EMOFP2) 2	☐ (QP13:EMOFP2) 3	☐ (QP13:EMOFP2) 4

3. Feeling angry	☐ (QP13:EMOFP3) 0	☐ (QP13:EMOFP3) 1	☐ (QP13:EMOFP3) 2	☐ (QP13:EMOFP3) 3	☐ (QP13:EMOFP3) 4
4. Trouble sleeping	☐ (QP13:EMOFP4) 0	☐ (QP13:EMOFP4) 1	☐ (QP13:EMOFP4) 2	☐ (QP13:EMOFP4) 3	☐ (QP13:EMOFP4) 4
5. Worrying about what will happen to him or her	☐ (QP13:EMOFP5) 0	☐ (QP13:EMOFP5) 1	☐ (QP13:EMOFP5) 2	☐ (QP13:EMOFP5) 3	☐ (QP13:EMOFP5) 4

Social Functioning *(problems with...)*	Never	Almost Never	Some-times	Often	Almost Always
1. Getting along with other teens	☐ (QP13:SOCFP1) 0	☐ (QP13:SOCFP1) 1	☐ (QP13:SOCFP1) 2	☐ (QP13:SOCFP1) 3	☐ (QP13:SOCFP1) 4
2. Other teens not wanting to be his or her friend	☐ (QP13:SOCFP2) 0	☐ (QP13:SOCFP2) 1	☐ (QP13:SOCFP2) 2	☐ (QP13:SOCFP2) 3	☐ (QP13:SOCFP2) 4
3. Getting teased by other teens	☐ (QP13:SOCFP3) 0	☐ (QP13:SOCFP3) 1	☐ (QP13:SOCFP3) 2	☐ (QP13:SOCFP3) 3	☐ (QP13:SOCFP3) 4
4. Not able to do things that other teens his or her age can do	☐ (QP13:SOCFP4) 0	☐ (QP13:SOCFP4) 1	☐ (QP13:SOCFP4) 2	☐ (QP13:SOCFP4) 3	☐ (QP13:SOCFP4) 4
5. Keeping up with other teens	☐ (QP13:SOCFP5) 0	☐ (QP13:SOCFP5) 1	☐ (QP13:SOCFP5) 2	☐ (QP13:SOCFP5) 3	☐ (QP13:SOCFP5) 4

School Functioning *(problems with...)*	Never	Almost Never	Some-times	Often	Almost Always
1. Paying attention in class	☐ (QP13:SCHFP1) 0	☐ (QP13:SCHFP1) 1	☐ (QP13:SCHFP1) 2	☐ (QP13:SCHFP1) 3	☐ (QP13:SCHFP1) 4
2. Forgetting things	☐ (QP13:SCHFP2) 0	☐ (QP13:SCHFP2) 1	☐ (QP13:SCHFP2) 2	☐ (QP13:SCHFP2) 3	☐ (QP13:SCHFP2) 4
3. Keeping up with schoolwork	☐ (QP13:SCHFP3) 0	☐ (QP13:SCHFP3) 1	☐ (QP13:SCHFP3) 2	☐ (QP13:SCHFP3) 3	☐ (QP13:SCHFP3) 4
4. Missing school because of not feeling well	☐ (QP13:SCHFP4) 0	☐ (QP13:SCHFP4) 1	☐ (QP13:SCHFP4) 2	☐ (QP13:SCHFP4) 3	☐ (QP13:SCHFP4) 4
5. Missing school to go to the doctor or hospital	☐ (QP13:SCHFP5) 0	☐ (QP13:SCHFP5) 1	☐ (QP13:SCHFP5) 2	☐ (QP13:SCHFP5) 3	☐ (QP13:SCHFP5) 4

Comments for page: QP13:COMM

Submit Query | Cancel | Form Completion Help | Print | Rho

Logo	**Pediatric Quality of Life Inventory Teen Report (13 yrs old)**	**{visit.label}**
Date of Assessment: QC13:ASMTDA / QC13:ASMTMO / QC13:ASMTYR (DD / MMM / YYYY)	**Quality of Life Assessments**	**ID: {ID}**

*In the past **ONE month,** how much of a **problem** has this been for you...*

About My Health and Activities *(problems with...)*	Never	Almost Never	Some-times	Often	Almost Always
1. It is hard for me to walk more than one block	☐ (QC13:PHYFC1) 0	☐ (QC13:PHYFC1) 1	☐ (QC13:PHYFC1) 2	☐ (QC13:PHYFC1) 3	☐ (QC13:PHYFC1) 4
2. It is hard for me to run	☐ (QC13:PHYFC2) 0	☐ (QC13:PHYFC2) 1	☐ (QC13:PHYFC2) 2	☐ (QC13:PHYFC2) 3	☐ (QC13:PHYFC2) 4
3. It is hard for me to do sports activity or exercise	☐ (QC13:PHYFC3) 0	☐ (QC13:PHYFC3) 1	☐ (QC13:PHYFC3) 2	☐ (QC13:PHYFC3) 3	☐ (QC13:PHYFC3) 4
4. It is hard for me to lift something heavy	☐ (QC13:PHYFC4) 0	☐ (QC13:PHYFC4) 1	☐ (QC13:PHYFC4) 2	☐ (QC13:PHYFC4) 3	☐ (QC13:PHYFC4) 4
5. It is hard for me to take a bath or shower by myself	☐ (QC13:PHYFC5) 0	☐ (QC13:PHYFC5) 1	☐ (QC13:PHYFC5) 2	☐ (QC13:PHYFC5) 3	☐ (QC13:PHYFC5) 4
6. It is hard for me to do chores around the house	☐ (QC13:PHYFC6) 0	☐ (QC13:PHYFC6) 1	☐ (QC13:PHYFC6) 2	☐ (QC13:PHYFC6) 3	☐ (QC13:PHYFC6) 4
7. I hurt or ache	☐ (QC13:PHYFC7) 0	☐ (QC13:PHYFC7) 1	☐ (QC13:PHYFC7) 2	☐ (QC13:PHYFC7) 3	☐ (QC13:PHYFC7) 4
8. I have low energy	☐ (QC13:PHYFC8) 0	☐ (QC13:PHYFC8) 1	☐ (QC13:PHYFC8) 2	☐ (QC13:PHYFC8) 3	☐ (QC13:PHYFC8) 4

About My Feelings *(problems with...)*	Never	Almost Never	Some-times	Often	Almost Always

1. I feel afraid or scared	☐ (QC13:EMOFC1) 0	☐ (QC13:EMOFC1) 1	☐ (QC13:EMOFC1) 2	☐ (QC13:EMOFC1) 3	☐ (QC13:EMOFC1) 4
2. I feel sad or blue	☐ (QC13:EMOFC2) 0	☐ (QC13:EMOFC2) 1	☐ (QC13:EMOFC2) 2	☐ (QC13:EMOFC2) 3	☐ (QC13:EMOFC2) 4
3. I feel angry	☐ (QC13:EMOFC3) 0	☐ (QC13:EMOFC3) 1	☐ (QC13:EMOFC3) 2	☐ (QC13:EMOFC3) 3	☐ (QC13:EMOFC3) 4
4. I have trouble sleeping	☐ (QC13:EMOFC4) 0	☐ (QC13:EMOFC4) 1	☐ (QC13:EMOFC4) 2	☐ (QC13:EMOFC4) 3	☐ (QC13:EMOFC4) 4
5. I worry about what will happen to me	☐ (QC13:EMOFC5) 0	☐ (QC13:EMOFC5) 1	☐ (QC13:EMOFC5) 2	☐ (QC13:EMOFC5) 3	☐ (QC13:EMOFC5) 4

How I Get Along with Others *(problems with...)*	Never	Almost Never	Some-times	Often	Almost Always
1. I have trouble getting along with other teens	☐ (QC13:SOCFC1) 0	☐ (QC13:SOCFC1) 1	☐ (QC13:SOCFC1) 2	☐ (QC13:SOCFC1) 3	☐ (QC13:SOCFC1) 4
2. Other teens do not want to be my friend	☐ (QC13:SOCFC2) 0	☐ (QC13:SOCFC2) 1	☐ (QC13:SOCFC2) 2	☐ (QC13:SOCFC2) 3	☐ (QC13:SOCFC2) 4
3. Other teens tease me	☐ (QC13:SOCFC3) 0	☐ (QC13:SOCFC3) 1	☐ (QC13:SOCFC3) 2	☐ (QC13:SOCFC3) 3	☐ (QC13:SOCFC3) 4
4. I cannot do things that other teens my age can do	☐ (QC13:SOCFC4) 0	☐ (QC13:SOCFC4) 1	☐ (QC13:SOCFC4) 2	☐ (QC13:SOCFC4) 3	☐ (QC13:SOCFC4) 4
5. It is hard for me to keep up with my peers	☐ (QC13:SOCFC5) 0	☐ (QC13:SOCFC5) 1	☐ (QC13:SOCFC5) 2	☐ (QC13:SOCFC5) 3	☐ (QC13:SOCFC5) 4

About School *(problems with...)*	Never	Almost Never	Some-times	Often	Almost Always
1. It is hard to pay attention in class	☐ (QC13:SCHFC1) 0	☐ (QC13:SCHFC1) 1	☐ (QC13:SCHFC1) 2	☐ (QC13:SCHFC1) 3	☐ (QC13:SCHFC1) 4
2. I forget things	☐ (QC13:SCHFC2) 0	☐ (QC13:SCHFC2) 1	☐ (QC13:SCHFC2) 2	☐ (QC13:SCHFC2) 3	☐ (QC13:SCHFC2) 4
3. I have trouble keeping up	☐ (QC13:SCHFC3) 0	☐ (QC13:SCHFC3) 1	☐ (QC13:SCHFC3) 2	☐ (QC13:SCHFC3) 3	☐ (QC13:SCHFC3) 4

with my schoolwork					
4. I miss school because of not feeling well	(QC13:SCHFC4) 0	(QC13:SCHFC4) 1	(QC13:SCHFC4) 2	(QC13:SCHFC4) 3	(QC13:SCHFC4) 4
5. I miss school to go to the doctor or hospital	(QC13:SCHFC5) 0	(QC13:SCHFC5) 1	(QC13:SCHFC5) 2	(QC13:SCHFC5) 3	(QC13:SCHFC5) 4

Comments for page: QC13:COMM

Submit Query Cancel Form Completion Help Print Rho

Logo	**Pediatric Quality of Life Inventory Parent Report for Child (12 yrs old)**	**{visit.label}**
Date of Assessment: QP12:ASMTDA / QP12:ASMTMO / QP12:ASMTYR (DD / MMM / YYYY)	**Quality of Life Assessments**	**ID: {ID}**

*In the past **ONE month,** how much of a **problem** has your child had with...*

Physical Functioning *(problems with...)*	Never	Almost Never	Some-times	Often	Almost Always
1. Walking more than one block	☐ (QP12:PHYFP1) 0	☐ (QP12:PHYFP1) 1	☐ (QP12:PHYFP1) 2	☐ (QP12:PHYFP1) 3	☐ (QP12:PHYFP1) 4
2. Running	☐ (QP12:PHYFP2) 0	☐ (QP12:PHYFP2) 1	☐ (QP12:PHYFP2) 2	☐ (QP12:PHYFP2) 3	☐ (QP12:PHYFP2) 4
3. Participating in sports activity or exercise	☐ (QP12:PHYFP3) 0	☐ (QP12:PHYFP3) 1	☐ (QP12:PHYFP3) 2	☐ (QP12:PHYFP3) 3	☐ (QP12:PHYFP3) 4
4. Lifting something heavy	☐ (QP12:PHYFP4) 0	☐ (QP12:PHYFP4) 1	☐ (QP12:PHYFP4) 2	☐ (QP12:PHYFP4) 3	☐ (QP12:PHYFP4) 4
5. Taking a bath or shower by him or herself	☐ (QP12:PHYFP5) 0	☐ (QP12:PHYFP5) 1	☐ (QP12:PHYFP5) 2	☐ (QP12:PHYFP5) 3	☐ (QP12:PHYFP5) 4
6. Doing chores, like picking up his or her toys	☐ (QP12:PHYFP6) 0	☐ (QP12:PHYFP6) 1	☐ (QP12:PHYFP6) 2	☐ (QP12:PHYFP6) 3	☐ (QP12:PHYFP6) 4
7. Having hurts or aches	☐ (QP12:PHYFP7) 0	☐ (QP12:PHYFP7) 1	☐ (QP12:PHYFP7) 2	☐ (QP12:PHYFP7) 3	☐ (QP12:PHYFP7) 4
8. Low energy level	☐ (QP12:PHYFP8) 0	☐ (QP12:PHYFP8) 1	☐ (QP12:PHYFP8) 2	☐ (QP12:PHYFP8) 3	☐ (QP12:PHYFP8) 4

Emotional Functioning *(problems with...)*	Never	Almost Never	Some-times	Often	Almost Always
1. Feeling afraid or scared	☐ (QP12:EMOFP1) 0	☐ (QP12:EMOFP1) 1	☐ (QP12:EMOFP1) 2	☐ (QP12:EMOFP1) 3	☐ (QP12:EMOFP1) 4
2. Feeling sad or blue	☐ (QP12:EMOFP2)	☐ (QP12:EMOFP2)	☐ (QP12:EMOFP2)	☐ (QP12:EMOFP2)	☐ (QP12:EMOFP2)

		0	1	2	3	4
3.	Feeling angry	☐ (QP12:EMOFP3) 0	☐ (QP12:EMOFP3) 1	☐ (QP12:EMOFP3) 2	☐ (QP12:EMOFP3) 3	☐ (QP12:EMOFP3) 4
4.	Trouble sleeping	☐ (QP12:EMOFP4) 0	☐ (QP12:EMOFP4) 1	☐ (QP12:EMOFP4) 2	☐ (QP12:EMOFP4) 3	☐ (QP12:EMOFP4) 4
5.	Worrying about what will happen to him or her	☐ (QP12:EMOFP5) 0	☐ (QP12:EMOFP5) 1	☐ (QP12:EMOFP5) 2	☐ (QP12:EMOFP5) 3	☐ (QP12:EMOFP5) 4

Social Functioning *(problems with...)*	Never	Almost Never	Some-times	Often	Almost Always
1. Getting along with other children	☐ (QP12:SOCFP1) 0	☐ (QP12:SOCFP1) 1	☐ (QP12:SOCFP1) 2	☐ (QP12:SOCFP1) 3	☐ (QP12:SOCFP1) 4
2. Other kids not wanting to be his or her friend	☐ (QP12:SOCFP2) 0	☐ (QP12:SOCFP2) 1	☐ (QP12:SOCFP2) 2	☐ (QP12:SOCFP2) 3	☐ (QP12:SOCFP2) 4
3. Getting teased by other children	☐ (QP12:SOCFP3) 0	☐ (QP12:SOCFP3) 1	☐ (QP12:SOCFP3) 2	☐ (QP12:SOCFP3) 3	☐ (QP12:SOCFP3) 4
4. Not able to do things that other children his or her age can do	☐ (QP12:SOCFP4) 0	☐ (QP12:SOCFP4) 1	☐ (QP12:SOCFP4) 2	☐ (QP12:SOCFP4) 3	☐ (QP12:SOCFP4) 4
5. Keeping up when playing with other children	☐ (QP12:SOCFP5) 0	☐ (QP12:SOCFP5) 1	☐ (QP12:SOCFP5) 2	☐ (QP12:SOCFP5) 3	☐ (QP12:SOCFP5) 4

School Functioning *(problems with...)*	Never	Almost Never	Some-times	Often	Almost Always
1. Paying attention in class	☐ (QP12:SCHFP1) 0	☐ (QP12:SCHFP1) 1	☐ (QP12:SCHFP1) 2	☐ (QP12:SCHFP1) 3	☐ (QP12:SCHFP1) 4
2. Forgetting things	☐ (QP12:SCHFP2) 0	☐ (QP12:SCHFP2) 1	☐ (QP12:SCHFP2) 2	☐ (QP12:SCHFP2) 3	☐ (QP12:SCHFP2) 4
3. Keeping up with schoolwork	☐ (QP12:SCHFP3) 0	☐ (QP12:SCHFP3) 1	☐ (QP12:SCHFP3) 2	☐ (QP12:SCHFP3) 3	☐ (QP12:SCHFP3) 4
4. Missing school because of not feeling well	☐ (QP12:SCHFP4) 0	☐ (QP12:SCHFP4) 1	☐ (QP12:SCHFP4) 2	☐ (QP12:SCHFP4) 3	☐ (QP12:SCHFP4) 4
5. Missing school to go to the doctor or hospital	☐ (QP12:SCHFP5) 0	☐ (QP12:SCHFP5) 1	☐ (QP12:SCHFP5) 2	☐ (QP12:SCHFP5) 3	☐ (QP12:SCHFP5) 4

Comments for page: QP12:COMM

Submit Query | Cancel | Form Completion Help | Print | Rho

Logo	**Pediatric Quality of Life Inventory Child Report (12 yrs old)**	**{visit.label}**
Date of Assessment: QC12:ASMTDA / QC12:ASMTMO / QC12:ASMTYR (DD / MMM / YYYY)	**Quality of Life Assessments**	**ID: {ID}**

*In the past **ONE month,** how much of a **problem** has this been for you...*

About My Health and Activities *(problems with...)*	Never	Almost Never	Some-times	Often	Almost Always
1. It is hard for me to walk more than one block	☐ (QC12:PHYFC1) 0	☐ (QC12:PHYFC1) 1	☐ (QC12:PHYFC1) 2	☐ (QC12:PHYFC1) 3	☐ (QC12:PHYFC1) 4
2. It is hard for me to run	☐ (QC12:PHYFC2) 0	☐ (QC12:PHYFC2) 1	☐ (QC12:PHYFC2) 2	☐ (QC12:PHYFC2) 3	☐ (QC12:PHYFC2) 4
3. It is hard for me to do sports activity or exercise	☐ (QC12:PHYFC3) 0	☐ (QC12:PHYFC3) 1	☐ (QC12:PHYFC3) 2	☐ (QC12:PHYFC3) 3	☐ (QC12:PHYFC3) 4
4. It is hard for me to lift something heavy	☐ (QC12:PHYFC4) 0	☐ (QC12:PHYFC4) 1	☐ (QC12:PHYFC4) 2	☐ (QC12:PHYFC4) 3	☐ (QC12:PHYFC4) 4
5. It is hard for me to take a bath or shower by myself	☐ (QC12:PHYFC5) 0	☐ (QC12:PHYFC5) 1	☐ (QC12:PHYFC5) 2	☐ (QC12:PHYFC5) 3	☐ (QC12:PHYFC5) 4
6. It is hard for me to do chores around the house	☐ (QC12:PHYFC6) 0	☐ (QC12:PHYFC6) 1	☐ (QC12:PHYFC6) 2	☐ (QC12:PHYFC6) 3	☐ (QC12:PHYFC6) 4
7. I hurt or ache	☐ (QC12:PHYFC7) 0	☐ (QC12:PHYFC7) 1	☐ (QC12:PHYFC7) 2	☐ (QC12:PHYFC7) 3	☐ (QC12:PHYFC7) 4
8. I have low energy	☐ (QC12:PHYFC8) 0	☐ (QC12:PHYFC8) 1	☐ (QC12:PHYFC8) 2	☐ (QC12:PHYFC8) 3	☐ (QC12:PHYFC8) 4

About My Feelings *(problems with...)*	Never	Almost Never	Some-times	Often	Almost Always

1. I feel afraid or scared	☐ (QC12:EMOFC1) 0	☐ (QC12:EMOFC1) 1	☐ (QC12:EMOFC1) 2	☐ (QC12:EMOFC1) 3	☐ (QC12:EMOFC1) 4
2. I feel sad or blue	☐ (QC12:EMOFC2) 0	☐ (QC12:EMOFC2) 1	☐ (QC12:EMOFC2) 2	☐ (QC12:EMOFC2) 3	☐ (QC12:EMOFC2) 4
3. I feel angry	☐ (QC12:EMOFC3) 0	☐ (QC12:EMOFC3) 1	☐ (QC12:EMOFC3) 2	☐ (QC12:EMOFC3) 3	☐ (QC12:EMOFC3) 4
4. I have trouble sleeping	☐ (QC12:EMOFC4) 0	☐ (QC12:EMOFC4) 1	☐ (QC12:EMOFC4) 2	☐ (QC12:EMOFC4) 3	☐ (QC12:EMOFC4) 4
5. I worry about what will happen to me	☐ (QC12:EMOFC5) 0	☐ (QC12:EMOFC5) 1	☐ (QC12:EMOFC5) 2	☐ (QC12:EMOFC5) 3	☐ (QC12:EMOFC5) 4

How I Get Along with Others *(problems with...)*	Never	Almost Never	Some-times	Often	Almost Always
1. I have trouble getting along with other kids	☐ (QC12:SOCFC1) 0	☐ (QC12:SOCFC1) 1	☐ (QC12:SOCFC1) 2	☐ (QC12:SOCFC1) 3	☐ (QC12:SOCFC1) 4
2. Other kids do not want to be my friend	☐ (QC12:SOCFC2) 0	☐ (QC12:SOCFC2) 1	☐ (QC12:SOCFC2) 2	☐ (QC12:SOCFC2) 3	☐ (QC12:SOCFC2) 4
3. Other kids tease me	☐ (QC12:SOCFC3) 0	☐ (QC12:SOCFC3) 1	☐ (QC12:SOCFC3) 2	☐ (QC12:SOCFC3) 3	☐ (QC12:SOCFC3) 4
4. I cannot do things that other kids my age can do	☐ (QC12:SOCFC4) 0	☐ (QC12:SOCFC4) 1	☐ (QC12:SOCFC4) 2	☐ (QC12:SOCFC4) 3	☐ (QC12:SOCFC4) 4
5. It is hard for me to keep up when I play with other kids	☐ (QC12:SOCFC5) 0	☐ (QC12:SOCFC5) 1	☐ (QC12:SOCFC5) 2	☐ (QC12:SOCFC5) 3	☐ (QC12:SOCFC5) 4

About School *(problems with...)*	Never	Almost Never	Some-times	Often	Almost Always
1. It is hard to pay attention in class	☐ (QC12:SCHFC1) 0	☐ (QC12:SCHFC1) 1	☐ (QC12:SCHFC1) 2	☐ (QC12:SCHFC1) 3	☐ (QC12:SCHFC1) 4
2. I forget things	☐ (QC12:SCHFC2) 0	☐ (QC12:SCHFC2) 1	☐ (QC12:SCHFC2) 2	☐ (QC12:SCHFC2) 3	☐ (QC12:SCHFC2) 4
3. I have trouble keeping up with my	☐ (QC12:SCHFC3) 0	☐ (QC12:SCHFC3) 1	☐ (QC12:SCHFC3) 2	☐ (QC12:SCHFC3) 3	☐ (QC12:SCHFC3) 4

schoolwork

4. I miss school because of not feeling well	(QC12:SCHFC4) 0	(QC12:SCHFC4) 1	(QC12:SCHFC4) 2	(QC12:SCHFC4) 3	(QC12:SCHFC4) 4
5. I miss school to go to the doctor or hospital	(QC12:SCHFC5) 0	(QC12:SCHFC5) 1	(QC12:SCHFC5) 2	(QC12:SCHFC5) 3	(QC12:SCHFC5) 4

Comments for page: QC12:COMM

Submit Query Cancel Form Completion Help Print Rho

Logo	**Biomarker/Genotype Sample Collection**	**{visit.label}**
		ID: {ID}

1. Date of collection: BIOM:GCOLLDA / BIOM:GCOLLMO / BIOM:GCOLLYR
   Day Month Year

2. Specimen bar codes:

Description	Bar Code Number	Not Collected
Heparin Pellet Sample (2-mL Cryovial)	BIOM:SHPS1	(BIOM:SHPS1NC)
Heparin Pellet Sample (2-mL Cryovial)	BIOM:SHPS2	(BIOM:SHPS2NC)
Heparin Pellet Sample (2-mL Cryovial)	BIOM:SHPS3	(BIOM:SHPS3NC)
Heparin Pellet Sample (2-mL Cryovial)	BIOM:SHPS4	(BIOM:SHPS4NC)
Heparin Pellet Sample (2-mL Cryovial)	BIOM:SHPS5	(BIOM:SHPS5NC)
BNP Sample (2-mL Cryovial)	BIOM:BNP	(BIOM:BNPNC)
Heparin Plasma Sample (2-mL Cryovial)	BIOM:HPS1	(BIOM:HPS1NC)
Heparin Plasma Sample (2-mL Cryovial)	BIOM:HPS2	(BIOM:HPS2NC)
Heparin Plasma Sample (2-mL Cryovial)	BIOM:HPS3	(BIOM:HPS3NC)
Heparin Plasma Sample (2-mL Cryovial)	BIOM:HPS4	(BIOM:HPS4NC)
Citrated Plasma Sample (2-mL Cryovial)	BIOM:CPS1	(BIOM:CPS1NC)
Citrated Plasma Sample (2-mL Cryovial)	BIOM:CPS2	(BIOM:CPS2NC)
Citrated Plasma Sample (2-mL Cryovial)	BIOM:CPS3	(BIOM:CPS3NC)
Citrated Plasma Sample (2-mL Cryovial)	BIOM:CPS4	(BIOM:CPS4NC)
Citrated Plasma Sample (2-mL Cryovial)	BIOM:CPS5	(BIOM:CPS5NC)
Serum Sample (2-mL Cryovial)	BIOM:SS1	(BIOM:SS1NC)
Serum Sample (2-mL Cryovial)	BIOM:SS2	(BIOM:SS2NC)
Serum Sample (2-mL Cryovial)	BIOM:SS3	(BIOM:SS3NC)
Serum Sample (2-mL Cryovial)	BIOM:SS4	(BIOM:SS4NC)
Serum Sample (2-mL Cryovial)	BIOM:SS5	(BIOM:SS5NC)

Comments for page:

BIOM:COMM

Submit Query Cancel Form Completion Help Print Rho

Logo	**Brief Pain Inventory**	**{visit.label}**
Date of Assessment: BPIQ:ASMTDA / BPIQ:ASMTMO / BPIQ:ASMTYR (Day / Month / Year)		**ID: {ID}**

Time of assessment: BPIQ:ASMTHH : BPIQ:ASMTMM (24-hr clock) Hr Min

1. Throughout our lives, most of us have had pain from time to time (such as minor headaches, sprains, and toothaches). Have you had pain other than these everyday kinds of pain today?

   ☐ (BPIQ:Q1) Yes ☐ (BPIQ:Q1) No

2. On the diagram, shade in the areas where you feel pain.

Head/Face	☐ (BPIQ:Q2HEADR) Right	☐ (BPIQ:Q2HEADC) Center	☐ (BPIQ:Q2HEADL) Left	☐ (BPIQ:Q2HEADM) Hurts the most
Neck	☐ (BPIQ:Q2NECK)			☐ (BPIQ:Q2NECKM) Hurts the most
Shoulder	☐ (BPIQ:Q2SHLDR) Right		☐ (BPIQ:Q2SHLDL) Left	☐ (BPIQ:Q2SHLDM) Hurts the most
Upper Arm	☐ (BPIQ:Q2UARMR) Right		☐ (BPIQ:Q2UARML) Left	☐ (BPIQ:Q2UARMM) Hurts the most
Elbow	☐ (BPIQ:Q2ELBR) Right		☐ (BPIQ:Q2ELBL) Left	☐ (BPIQ:Q2ELBM) Hurts the most
Lower Arm	☐ (BPIQ:Q2LARMR) Right		☐ (BPIQ:Q2LARML) Left	☐ (BPIQ:Q2LARMM) Hurts the most
Hand/Fingers	☐ (BPIQ:Q2HANDR) Right		☐ (BPIQ:Q2HANDL) Left	☐ (BPIQ:Q2HANDM) Hurts the most
Chest	☐ (BPIQ:Q2CHSTR) Right	☐ (BPIQ:Q2CHSTC) Center	☐ (BPIQ:Q2CHSTL) Left	☐ (BPIQ:Q2CHSTM) Hurts the most
Upper Back	☐ (BPIQ:Q2UBCKR) Right	☐ (BPIQ:Q2UBCKC) Center	☐ (BPIQ:Q2UBCKL) Left	☐ (BPIQ:Q2UBCKM) Hurts the most
Lower Back	☐ (BPIQ:Q2LBCKR) Right	☐ (BPIQ:Q2LBCKC) Center	☐ (BPIQ:Q2LBCKL) Left	☐ (BPIQ:Q2LBCKM) Hurts the most
Abdomen	☐ (BPIQ:Q2ABDOR) Right	☐ (BPIQ:Q2ABDOC) Center	☐ (BPIQ:Q2ABDOL) Left	☐ (BPIQ:Q2ABDOM) Hurts the most

Genitals	☐ (BPIQ:Q2GEN)			☐ (BPIQ:Q2GENM) Hurts the most
Buttocks	☐ (BPIQ:Q2BUTTR) Right		☐ (BPIQ:Q2BUTTL) Left	☐ (BPIQ:Q2BUTTM) Hurts the most
Upper Leg	☐ (BPIQ:Q2ULEGR) Right		☐ (BPIQ:Q2ULEGL) Left	☐ (BPIQ:Q2ULEGM) Hurts the most
Knee	☐ (BPIQ:Q2KNEER) Right		☐ (BPIQ:Q2KNEEL) Left	☐ (BPIQ:Q2KNEEM) Hurts the most
Lower Leg	☐ (BPIQ:Q2LLEGR) Right		☐ (BPIQ:Q2LLEGL) Left	☐ (BPIQ:Q2LLEGM) Hurts the most
Foot/Ankle	☐ (BPIQ:Q2FOOTR) Right		☐ (BPIQ:Q2FOOTL) Left	☐ (BPIQ:Q2FOOTM) Hurts the most

3. Please rate your pain by marking the box beside the one number that best describes your pain at its **worst** in the last 24 hrs.

BPIQ:Q3 ☐ (BPIQ:Q3NA)Not answered

Q3-Q6:
0; 1; 2; 3; 4; 5; 6; 7; 8; 9; 10;

0 = No pain
10 = Pain as bad as you can imagine

4. Please rate your pain by marking the box beside the one number that best describes your pain at its **least** in the last 24 hrs.

BPIQ:Q4 ☐ (BPIQ:Q4NA)Not answered

0 = No pain
10 = Pain as bad as you can imagine

5. Please rate your pain by marking the box beside the one number that best describes your pain on the **average**.

BPIQ:Q5 ☐ (BPIQ:Q5NA)Not answered

0 = No pain
10 = Pain as bad as you can imagine

6. Please rate your pain by marking the box beside the one number that tells how much pain your have **right now**.

BPIQ:Q6 ☐ (BPIQ:Q6NA)Not answered

0 = No pain
10 = Pain as bad as you can imagine

7. What

☐ (BPIQ:Q7NA) Not answered

treatments or medications are you receiving for your pain?

(Study coordinator: ensure that any medications recorded in the subject's Pain Diary are also reflected on the Concommitant Medications form.)

8. In the last 24 hours, how much relief have pain treatments or medications provided? Please mark the box below the one percentage that most shows how much **relief** you have received.

BPIQ:Q8 % ☐ (BPIQ:Q8NA)Not answered

0% = No Relief
100% =Complete Relief

Q8:
0%; 10%; 20%; 30%; 40%; 50%; 60%; 70%; 80%; 90%; 100%;

9. Mark the box beside the one number that describes how, during the past 24 hours, pain has interfered with your:

(0 = Does not Interfere, 10 = Completely Interferes)

Q9A-G:
0; 1; 2; 3; 4; 5; 6; 7; 8; 9; 10;

A. General Activity BPIQ:Q9A ☐ (BPIQ:Q9ANA)Not answered

B. Mood BPIQ:Q9B ☐ (BPIQ:Q9BNA)Not answered

C. Walking Ability BPIQ:Q9C ☐ (BPIQ:Q9CNA)Not answered

D. Normal Work (includes both work outside the home and housework) BPIQ:Q9D ☐ (BPIQ:Q9DNA)Not answered

E. Relations with other people BPIQ:Q9E ☐ (BPIQ:Q9ENA)Not answered

F. Sleep BPIQ:Q9F ☐ (BPIQ:Q9FNA)Not answered

G. Enjoyment of life BPIQ:Q9G ☐ (BPIQ:Q9GNA)Not answered

Comments for page:

BPIQ:COMM

Submit Query Cancel Form Completion Help Print Rho

Logo	**Randomization/ Subject Disposition**	**{visit.label}**
		ID: {ID}

1. Date of Main Interventional Trial Informed Consent: RAND:MITDA / RAND:MITMO / RAND:MITYR
   Day Month Year

2. Subject disposition after **Baseline:**
   - ☐ (RAND:DISP) Subject Randomized in Main Interventional Trial
   - ☐ (RAND:DISP) Subject Not Randomized and has been discontinued from the Main Interventional Trial/Subject Enrolled In Observational Follow-Up Study

3. For subjects randomized in the **Main Interventional Trial:**
   Date of randomization: RAND:RANDDA / RAND:RANDMO / RAND:RANDYR
   Day Month Year

   TRV Stratum:
   - ☐ (RAND:TRV) ≥2.7 but <3.0 m/s
   - ☐ (RAND:TRV) ≥3.0 m/s

3a. Is the subject currently taking heparin or a Vitamin K antagonist?
   - ☐ (RAND:HEPVKA) No
   - ☐ (RAND:HEPVKA) Yes

4. For subjects not randomized in the **Main Interventional Trial**:
   Reason not randomized:
   - ☐ (RAND:REASON) Study Terminated
   - ☐ (RAND:REASON) Adverse Event, specify:
     RAND:AE_SP
   - ☐ (RAND:REASON) Investigator decision, specify:
     RAND:ID_SP
   - ☐ (RAND:REASON) Subject or parent/guardian decision
   - ☐ (RAND:REASON) TRV < 2.7 m/s
   - ☐ (RAND:REASON) Disqualified based on wedge pressure
   - ☐ (RAND:REASON) Lost to follow-up

☐ (RAND:REASON) 6-Minute Walk <150 m or >500 m

☐ (RAND:REASON) 6-Minute Walk >15% variability

☐ (RAND:REASON) Other, specify:

RAND:OT_SP

Comments for page:

RAND:COMM

Submit Query | Cancel | Form Completion Help | Print | Rho

Logo	**Study Drug Diary**	**{visit.label}**
		ID: {ID}

Day	Date	Dose	Time (24 hr clock)	Number of Pills Taken	Pills Not Taken or Missed Dose
1	SDDY:D1_DA / SDDY:D1_MO / SDDY:D1_YR Day Month Year	Morning	SDDY:D1_AMHH : SDDY:D1_AMMM Hr Min	SDDY:D1_AMPT	☐ (SDDY:D1_AMNT)
		Midday	SDDY:D1_MDHH : SDDY:D1_MDMM Hr Min	SDDY:D1_MDPT	☐ (SDDY:D1_MDNT)
		Evening	SDDY:D1_PMHH : SDDY:D1_PMMM Hr Min	SDDY:D1_PMPT	☐ (SDDY:D1_PMNT)
2	SDDY:D2_DA / SDDY:D2_MO / SDDY:D2_YR Day Month Year	Morning	SDDY:D2_AMHH : SDDY:D2_AMMM Hr Min	SDDY:D2_AMPT	☐ (SDDY:D2_AMNT)
		Midday	SDDY:D2_MDHH : SDDY:D2_MDMM Hr Min	SDDY:D2_MDPT	☐ (SDDY:D2_MDNT)
		Evening	SDDY:D2_PMHH : SDDY:D2_PMMM Hr Min	SDDY:D2_PMPT	☐ (SDDY:D2_PMNT)
3	SDDY:D3_DA / SDDY:D3_MO / SDDY:D3_YR Day Month Year	Morning	SDDY:D3_AMHH : SDDY:D3_AMMM Hr Min	SDDY:D3_AMPT	☐ (SDDY:D3_AMNT)
		Midday	SDDY:D3_MDHH : SDDY:D3_MDMM Hr Min	SDDY:D3_MDPT	☐ (SDDY:D3_MDNT)
		Evening	SDDY:D3_PMHH : SDDY:D3_PMMM Hr Min	SDDY:D3_PMPT	☐ (SDDY:D3_PMNT)
4	SDDY:D4_DA / SDDY:D4_MO / SDDY:D4_YR Day Month Year	Morning	SDDY:D4_AMHH : SDDY:D4_AMMM Hr Min	SDDY:D4_AMPT	☐ (SDDY:D4_AMNT)
		Midday	SDDY:D4_MDHH : SDDY:D4_MDMM Hr Min	SDDY:D4_MDPT	☐ (SDDY:D4_MDNT)
		Evening	SDDY:D4_PMHH : SDDY:D4_PMMM Hr Min	SDDY:D4_PMPT	☐ (SDDY:D4_PMNT)
5	SDDY:D5_DA / SDDY:D5_MO / SDDY:D5_YR Day Month Year	Morning	SDDY:D5_AMHH : SDDY:D5_AMMM Hr Min	SDDY:D5_AMPT	☐ (SDDY:D5_AMNT)
		Midday	SDDY:D5_MDHH : SDDY:D5_MDMM Hr Min	SDDY:D5_MDPT	☐ (SDDY:D5_MDNT)
		Evening	SDDY:D5_PMHH : SDDY:D5_PMMM Hr Min	SDDY:D5_PMPT	☐ (SDDY:D5_PMNT)

6	SDDY:D6_DA / SDDY:D6_MO / SDDY:D6_YR Day Month Year		Morning	SDDY:D6_AMHH : SDDY:D6_AMMM Hr Min	SDDY:D6_AMPT	☐	(SDDY:D6_AMNT)
			Midday	SDDY:D6_MDHH : SDDY:D6_MDMM Hr Min	SDDY:D6_MDPT	☐	(SDDY:D6_MDNT)
			Evening	SDDY:D6_PMHH : SDDY:D6_PMMM Hr Min	SDDY:D6_PMPT	☐	(SDDY:D6_PMNT)
7	SDDY:D7_DA / SDDY:D7_MO / SDDY:D7_YR Day Month Year		Morning	SDDY:D7_AMHH : SDDY:D7_AMMM Hr Min	SDDY:D7_AMPT	☐	(SDDY:D7_AMNT)
			Midday	SDDY:D7_MDHH : SDDY:D7_MDMM Hr Min	SDDY:D7_MDPT	☐	(SDDY:D7_MDNT)
			Evening	SDDY:D7_PMHH : SDDY:D7_PMMM Hr Min	SDDY:D7_PMPT	☐	(SDDY:D7_PMNT)

Comments for page:

SDDY:COMM

Submit Query Cancel Form Completion Help Print Rho

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

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
Bottle Number Used For This Dose		**Dose End Date**
DRLG:BOTNUM		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	**Study Drug Accountability Log**	**{visit.label}**
		ID: {ID}

Bottles Dispensed

Add a record for each bottle dispensed.

Visit

- (DISP:DVIST) Baseline
- (DISP:DVIST) Week 6
- (DISP:DVIST) Week 10
- (DISP:DVIST) Other

If Visit is **Other,** explanation: DISP:DOTH_SP

Remove Record

Dispense Date	Bottle Number	Pill Strength	# Pills in Bottle
DISP:DISPDA (Day) / DISP:DISPMO (Month) / DISP:DISPYR (Year)	DISP:DBTLNUM	(DISP:STREN) 20 mg (DISP:STREN) 80 mg	DISP:DNUM

Comment: DISP:DCOMM

Add Dispense Record

Bottles Returned

Add a record for each bottle returned.

Visit

- (RETR:RVIST) Week 6
- (RETR:RVIST) Week 10
- (RETR:RVIST) Week 16
- (RETR:RVIST) Early Termination Visit
- (RETR:RVIST) Other

If Visit is **Other,** explanation: RETR:ROTH_SP

Remove Record

Return Date	Bottle Number	# Pills in Bottle	Bottle Not Returned	# Missed Doses (based on patient report)	# Missed Doses (based on pill count)
RETR:RETDA (Day) / RETR:RETMO (Month) / RETR:RETYR (Year)	RETR:RBTLNUM	RETR:RNUM	(RETR:NOTRTN) (RETR:NOTRTN)	RETR:MISSSUB	RETR:MISSPC

Comment: RETR:RCOMM

Add Return Record

Comments for page:

COMP:COMM

Submit Query Cancel Form Completion Help Print Rho

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

Please note: If the subject is on anticoagulation, the corresponding Vitamin K antagonist must also be documented. If anticoagulant changes during MIT, enter a new record with the alternate dose.

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

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

Logo	**Protocol Deviation**	**{visit.label}**
		ID: {ID}

Complete a separate form for each protocol deviation.

1. Date protocol deviation occurred: DEVI:DEVDA / DEVI:DEVMO / DEVI:DEVYR
   Day Month Year

2. Type of deviation:

- ☐ (DEVI:TYPE) Randomization or masking error
- ☐ (DEVI:TYPE) Dosing error: Did dosing error result in overdose? ☐ (DEVI:OD) No ☐ (DEVI:OD) Yes
- ☐ (DEVI:TYPE) Missed visit
- ☐ (DEVI:TYPE) Missed study procedure/lab test
- ☐ (DEVI:TYPE) Visit out of window: **Early by** DEVI:VISTEA days or **Late by** DEVI:VISTLA days
- ☐ (DEVI:TYPE) Study procedure/lab test out of window: **Early by** DEVI:PROCEA days or **Late by** DEVI:PROCLA days
- ☐ (DEVI:TYPE) Study drug not returned
- ☐ (DEVI:TYPE) Study Drug Diary not returned
- ☐ (DEVI:TYPE) Brief Pain Inventory not returned
- ☐ (DEVI:TYPE) Error in Informed Consent
- ☐ (DEVI:TYPE) Inclusion or exclusion criteria not met, **specify:**

	Check all unmet criteria for this deviation	
	Inclusion Criteria	**Exclusion Criteria**
Screening	☐ (DEVI:INCSC1) 1. Male or female, 12 years of age or older ☐ (DEVI:INCSC2) 2. Diagnosis of sickle cell disease ☐ (DEVI:INCSC3) 3. Provision of informed consent and, where applicable, assent	
Main	1. Male or	1. Current pregnancy or

Interventional Study	☐ (DEVI:INCMS1) female, 12 years of age or older ☐ (DEVI:INCMS2) 2. If female, reliable birth control or not able to bear children ☐ (DEVI:INCMS3) 3. Electrophoretic documentation of sickle cell disease ☐ (DEVI:INCMS4) 4. At least mild pulmonary hypertension ☐ (DEVI:INCMS5) 5. If undergoing right heart catherterization, pulmonary capillary wedge pressure ≤24 mmHg ☐ (DEVI:INCMS6) 6. Six-minute walk distance of 150-500 m ☐ (DEVI:INCMS7) 7. Ability to complete protocol-scheduled assessments during 16-week, double-blind phase ☐ (DEVI:INCMS8) 8. Provision of informed consent and, where applicable, assent	☐ (DEVI:EXCMS1) lacation ☐ (DEVI:EXCMS2) 2. Any of: • Stroke within last 6 weeks • New diagnosis of pulmonary embolism within last 3 months • History of retinal detachment/hemorrhage in last 6 months • History of sustained priapism • Non-arteritic anterior ischemic optic neuropathy (NAION) in one or both eyes • Any unstable (chronic or acute) condition that will prevent study completion ☐ (DEVI:EXCMS3) 3. Subject taking nitrate-based vasodilator(s) (including, but not limited to nicorandil [available in the UK only]), prostacyclin (inhaled, subcutaneous or intravenous) or endothelin antagonists. Subjects taking calcium channel blockers will be allowed to participate provided they are on a stable dose for ≥ 3 months. ☐ (DEVI:EXCMS4) 4. Left ventricular ejection fraction < 40% or CS ischemic, valvular or constrictive heart disease ☐ (DEVI:EXCMS5) 5. In other research study with investigational drug except hydroxyurea ☐ (DEVI:EXCMS6) 6. Acute or chronic impairment (other than dyspnea) limiting ability to comply ☐ (DEVI:EXCMS7) 7. Tonsillectomies for sleep apnea within 3 months prior to randomization ☐ (DEVI:EXCMS8) 8. Active therapy for pulmonary hypertension ☐ (DEVI:EXCMS9) 9. Protease inhibitor therapy for HIV treatment ☐ (DEVI:EXCMS10) 10. Potent CYP3A4 inhibitor therapy (e.g., itraconazol, rintonavir, ketoconazole)
Observational Follow-up	☐ (DEVI:INCFU1) 1. Satisfaction of screening criteria	

Study	☐ (DEVI:INCFU2)	2. Ability to maintain follow-up contact	
	☐ (DEVI:INCFU3)	3. Failure to satisfy eligibility requirements of Main Interventional Trial	
	☐ (DEVI:INCFU4)	4. Provision of informed consent and, where applicable, assent	

☐ (DEVI:TYPE) `Other type of deviation,` specify: `DEVI:OTDV_SP`

3. Description of deviation and reason it occurred:

`DEVI:DESC`

4. Was a protocol waiver granted for the deviation?

☐ (DEVI:WAIVER) `No` ☐ (DEVI:WAIVER) `Yes`

5. Study visit at which deviation occurred:

☐ (DEVI:VISIT) `Screening`

☐ (DEVI:VISIT) `Baseline`

☐ (DEVI:VISIT) `Week 6`

☐ (DEVI:VISIT) `Week 10`

☐ (DEVI:VISIT) `Week 16`

☐ (DEVI:VISIT) `Early Termination Visit`

☐ (DEVI:VISIT) `Observational Follow-Up Study`

☐ (DEVI:VISIT) `Open-Label Follow-Up Study`

☐ (DEVI:VISIT) `Not Applicable`

☐ (DEVI:VISIT) `Other,` specify: `DEVI:VISITSP`

6. Steps taken to resolve and prevent

recurrence: DEVI:STEPS

7. Did protocol deviation result in an adverse event? ☐ (DEVI:AE) No ☐ (DEVI:AE) Yes

If **Yes,** report on the Adverse Events form.

8. Will the subject continue in the study? ☐ (DEVI:CONT) No ☐ (DEVI:CONT) Yes

9. Did deviation meet reporting requirements for your site's IRB? ☐ (DEVI:IRB) No ☐ (DEVI:IRB) Yes

If **Yes,** date reported to IRB: DEVI:IRBDA / DEVI:IRBMO / DEVI:IRBYR

Day Month Year

Comments for page: DEVI:COMM

Submit Query Cancel Form Completion Help Print Rho

EDC COMPLETION GUIDELINES

walk-PHaSST Protocol

Adverse Events

Adverse Events Form	During **Screening**, adverse events should be reported if they either begin or worsen from the time the subject signs informed consent for Screening/Observational Follow-Up Study through 7 days after the last Screening procedure **and** if they are considered by the investigator to be possibly associated with a study procedure. During the **Main Interventional Trial and Open-Label Follow-Up**, adverse events should be reported if they begin or worsen from the time the subject signs informed consent for Main Interventional Trial through either the last dose of study drug OR until study discontinuation (for those consented subjects who were never treated).
AE/Diagnosis	Enter the diagnostic term for the Adverse Event, if a diagnosis is available.. If a definitive diagnostic term is not available, enter a description of the condition, such as its symptoms, signs, and/or findings. If a definitive diagnosis becomes available at a later time, update the form with that diagnosis.
AE Start Date	Record the date of onset for the AE, providing as complete a date as possible.

AE Stop Date	Record the stop date for each AE, providing as complete a date as possible. If the AE is continuing, leave the Stop Date blank.
Severity	Enter the response that corresponds to the severity of the adverse event, using the following scale: 1. Mild. Awareness of sign, symptom, or event, but easily tolerated; does not interfere with usual daily activities or tasks. 2. Moderate. Discomfort enough to cause interference with usual daily activity; may warrant therapeutic intervention. 3. Severe. Incapacitating; inability to perform usual activities and daily tasks; significantly affects clinical status; requires therapeutic intervention. 4. Life-threatening. Adverse event is life-threatening. 5. Death. Adverse event causes death.
Related to Sickle Cell?	Enter the response that best describes the relationship of the adverse event to sickle cell disease.
Related to Pulmonary Hypertension?	Enter the response that best describes the relationship of the adverse event to pulmonary hypertension.
Relationship to Study Drug	Enter the response that best describes the relationship of the adverse event to use of the study drugl.

Relationship to Study Procedure	Enter the response that best describes the relationship of the adverse event to any study procedure. If Relationship to Study Procedure is any thing except Unrelated, specify the study procedure.
Outcome	Use the drop-down box to select the response that best describes the outcome of the adverse event. If the adverse event is ongoing and the outcome is yet to be determined, leave Outcome blank. The resulting query will serve as a reminder that the AE should be reviewed at the subject's next visit.
Action Taken with Study Drug	Enter the response that best describes what action was taken with the study drug. If the study drug was temporarily or permanently discontinued, there should be a corresponding entry on the Study Drug Dosing form.
Serious?	Indicate whether the adverse event meets the definition of serious by checking No or Yes. If Yes (Adverse Event is Serious): • Complete the Serious Adverse Event (SAE) section of the form. • Have the Clinical Investigator review and electronically sign the form in RhoEDC. • Notify Rho Product Safety of the Serious Adverse Event. If No (AE is not Serious), the Serious Adverse Event (SAE) section of the form should be left blank.

SAE - Seriousness	Check the criteria for "seriousness" met by the SAE. Check all that apply. At least one criteria must be met in order for the AE to be considered an SAE. If the AE was Fatal, provide: • Date of death • Primary cause of death • Whether an autopsy was performed.
SAE - Contributing Factors	Check any factors other than study drug that possibly contributed to the SAE. Check all that apply. If Concurrent Illness, specify the suspected illness. If Study Procedure, specify the suspected procedure. If a possible contributing factor is not listed, check Other and describe the suspected the other contributing factor.
SAE - Study Medication	Check No or Yes to indicate if the subject received study medication (either sildenafil capsules or matching placebo). If Yes, provide: • The phase of the study (either Double Blind Phase or Open Label Follow-Up Phase) • Dose in Mg TID PO • Study drug start date • Study drug end date (if drug not ongoing) • Whether the subject is currently taking study medication

SAE - Relevant Concomitant Medications	Concomitant Medications should be recorded on this form **only** if the investigator considers them to be relevant to the SAE. Check None if there are no concomitant medications relevant to the SAE. If there are relevant concomitant medications, provide for each one: • Medication name • Total daily dose • Dosage units • Start date and stop date • Whether the medication is ongoing • Whether a causal relationship between the medication and the SAE is suspected Use the Add Medication Record button to create a row for each relevant medication. Use the Previously Reported checkbox if this information was reported with a previous SAE report. If so, identify the previous SAE.
SAE - Treatments/ Procedures	Check None if no treatments or procedures were prescribed with this SAE. If there were treatment or procedures to report for this SAE, provide for each one: • Name of treatment or procedure • Total daily dose (if applicable) • Units (if applicable) • Start date and stop date • Whether the treatment/procedure is ongoing Use the Add Treatment Record button to create a row for each treatment or procedure.

	Use the Previously Reported checkbox if this information was reported with a previous SAE report. If so, identify the previous SAE.
SAE - Relevant Medical History	Medical History should be recorded on this form **only** if the investigator considers it to be relevant to the SAE. Check None if there is no relevant medical history that would help explain the SAE. Use the Add History button to create a row for each relevant medical history item. Provide for each one: • The medical condition • Start date and stop date. • Whether the condition is ongoing. Use the Previously Reported checkbox if this information was reported with a previous SAE report. If so, identify the previous SAE.
SAE - Relevant Laboratory/ Diagnostic Tests	Laboratory and/or diagnostic tests should be recorded on this form **only** if the investigator considers them to be relevant to the SAE. Check None if there are no relevant tests to report with this SAE. Use the Add Lab/Test Record to create a row for each relevant test. Provide for each: • Name of the test • Result/lab value • Units for the result/lab value • Normal range for the test Use the Previously Reported checkbox if this information was reported with a previous SAE report. If so, identify the previous SAE.

SAE - Weight and Height	Record the subject's weight and height at the time of the SAE and the appropriate unit for each.
SAE - Narrative/ Comments	Record the narrative description of the SAE, including chronological clinical presentation and evolution of the SAE and associated signs/symptoms. Use the Previously Reported checkbox if this information was reported with a previous SAE report. If so, identify the previous SAE.
Comments for page	Record any pertinent comments for this page only.
See also Chapter 15 of the MOO	

EDC COMPLETION GUIDELINES

walk-PHaSST Protocol

Biomarker/Genotype Sample Collection

Date of Collection	Record the date the samples were collected. **Note**: If no sample was collected, provide an explanation in the Comments field at the bottom of the form.
Is this the Screening Visit?	Answer No or Yes.
Specimen Bar Code	Record the specimen bar code number from each sample collected.
Comments for page	Record any pertinent comments for this page only.

EDC COMPLETION GUIDELINES

walk-PHaSST Protocol

Brief Pain Inventory

Date of Assessment	Record the date of the pain assessment.
Time of Assessment	Record the time of the pain assessment using a 24 hour clock. For month and day, ALWAYS enter the leading 0.
Unusual Pain?	Record the subject's Yes or No response. **Note**: The BPI is meant to be used to assess acute pain, not chronic pain. The subject's responses should be related to acute pain.
Pain Diagram	Check the box or boxes that correspond to where the subject indicated feeling pain on the BPI diagram. Check the box that corresponds to where the subject indicated feeling the **most** pain on the BPI diagram.
Questions 3-6 (Pain Ratings)	Select the response that matches the pain rating reported by the subject. **Note:** The scale is 0 to 10, where 0=No Pain and 10=Pain as Bad as You can Imagine.
Question 7 (Treatments)	The treatments and/or medications reported on the BPI should be reported on the Concomitant Medications form.

Question 8 (Treatment Effectiveness)	Select the response that matches the treatment effectiveness rating reported by the subject. **Note:** The scale is 0 to 10, where 0=No Relief and 10=Complete Relief.
Question 9	For each category of activity, select the response that matches the impact rating reported by the subject. **Note:** The scale is 0 to 10, where 10=Does not Interfere and 10=Completely Interferes.
Comments for page	Record any pertinent comments for this page only.

EDC COMPLETION GUIDELINES

walk-PHaSST Protocol

Chemistry

Date of Collection	Record the date the sample was collected for analysis.
Lab Value	Record the result for each test.
Unit	Confirm that the unit reported on the lab slip is the same as the unit on the form. If the unit on the lab slip is unequal to a unit on the form, contact the coordinating center. For help with SI conversions: http://nephron.com/cgi-bin/SI.cgi AND http://www.unc.edu/~rowlett/units/scales/clinical_data.html **Note:** The following units are equivalent:
	10^3cells/µL, 1000/µL, th/µL, K/µL, 10^3/mm^3, 1000/mm^3, th/mm^3, K/mm^3, and 10^9/L
	10^6/µL, mil/µL, M/µL, 10^6/mm^3, mil/mm^3, M/mm^3, 10^{12}/L, and mil/mcL

Clinical Significance	Check the one box that best describes the clinical significance of each result. Clinical significance should be determined by the investigator based on his or her judgment and knowledge of the individual subject and the study population. Generally, a result is deemed "clinically significant" if it requires treatment, re-testing or other follow-up. If the test result is judged clinically significant **and** a new Adverse Event, complete an Adverse Event form.
Comments for page	Record any pertinent comments for this page only.

EDC COMPLETION GUIDELINES

walk-PHaSST Protocol

Concomitant Medications

Medication	At **Screening**, list all medications taken by the subject in the XXX months prior to screening, with particular focus on medications that may exclude the subject. Include medications requiring a wash-out period, if applicable. At **subsequent visits**, record only medications that are new or modified in dose, frequency or route.
Indication	Record the reason the medication was prescribed. **Note:** The indication listed for each medication should be consistent with either the subject's medical history or adverse events.
Dose	Use the drop-down box to enter the prescribed dose for each medication.
Frequency	Use the drop-down box to indicate how often the medication was prescribed to be taken. If the prescribed frequency is not listed, select Other and specify the frequency in the space provided.
Units	Use the drop-down box to indicate the unit for the dose. If the prescribed unit is not listed, select Other and specify the unit in the space provided.

Route	Use the drop-down box to indicate how the medication is taken or administered. If the prescribed route is not listed, check the box for Other and specify the route in the space provided.
Start Date	Record the first date the medication was taken. Provide as complete a date as possible. If a complete date is not known, enter as much of the date as can be determined and leave blank any parts that are unknown. **Note**: Blank date parts will cause an automatic query. If the date part is blank because a complete date is unknown and is impossible to determine, override the automatic query. Provide an appropriate override reason, such as "Start Day Unknown" or "Month Unknown."
Stop Date	Record the last date the medication was taken. Provide as complete a date as possible. If a complete date is not known, enter as much of the date as can be determined and leave blank any parts that are unknown. **Note**: If the medication is ongoing and the subject is still on study, leave Stop Date and Treatment Status blank. This will cause an automatic query. This query will serve as a reminder for the site to review the status of the medication at the subject's next visit and should not be overridden. If the medication is ongoing when the subject completes the study, update the Treatment Status to "Continuing at end of Main Interventional Trial" and leave the Stop Date blank.

Treatment Status	Use the drop-down box to indicate the treatment status. If the Treatment Status is "Modified dose, frequency, or route," remember to enter a new record for the medication with the changes dose, frequency or route. **Note**: If the medication is ongoing and the subject is still on study, leave Treatment Status blank. This will cause an automatic query. This query will serve as a reminder for the site to review the status of the medication at the subject's next visit and should not be overridden. If the medication is ongoing when the subject completes the study, update the Treatment Status to "Continuing at end of Main Interventional Trial" and continue to leave the Stop Date blank.
Comments for Page	Record any pertinent comments for this page only.

EDC COMPLETION GUIDELINES

walk-PHaSST Protocol

Study Drug Accountability Log

Study Drug Accountability Log	The Study Drug Accountability Log keeps track of every bottle of study drug dispensed and returned during the course of the Main Interventional Trial.
Bottles Dispensed	Click the Add Dispense Record button to create a form for the first bottle of study drug dispensed. Use the Add Dispense Record button as needed for each additional bottle dispensed. Use the Remove Record button to delete any bottle records that are created in error. Use caution in deleting records, as deleted records cannot be recovered after the form is updated.
Visit	Use the drop-down box to select the visit at which the bottle was dispensed. If a bottle was dispensed at a time other than a scheduled study visit, select "Other" from the drop-down list and enter an explanation of when the bottle was dispensed in the space provided.
Dispense Date	Record the date the bottle was dispensed.
Bottle Number	Enter the bottle number. The bottle number may be entered by typing in the number or by scanning the bottle's bar code with a hand-held scanner. If scanning, check to see that the cursor is in the Bottle Number field before scanning the bar code.

Pill Strength	Check the box that corresponds to the medication strength of the pills in the dispensed bottle, either 20 mg or 80 mg.
# Pills In Bottle	Enter the number of pills in the dispensed bottle.
Comment	If needed, use the Comment field to record additional information about this bottle and the reason for it being dispensed.
Bottles Returned	Click the Add Return Record button to create a form each bottle of study drug returned, as well for any bottle of study drug that should have been returned but was not. **Note:** At the end of the study, there should be a "Bottle Returned" record corresponding to each "Bottle Dispensed" record. Use the Remove Record button to delete any bottle records that are created in error. Use caution in deleting records, as deleted records cannot be recovered after the form is updated.
Visit	Use the drop-down box to select the visit at which the bottle was returned. If a bottle was returned at a time other than a scheduled study visit, select "Other" from the drop-down list and enter an explanation of when the bottle was returned.
Return Date	Record the date the bottle was returned.

Bottle Number	Enter the bottle number. The bottle number may be entered by typing in the number or by scanning the bottle's bar code with a hand-held scanner. If scanning, check to see that the cursor is in the Bottle Number field before scanning the bar code.
# Pills In Bottle	Enter the number of pills remaining in the returned bottle.
Bottle Not Returned	Check if the subject never returned the bottle.
# of Missed Doses (based on patient report)	Enter the number of doses the subject reports having missed since the previous visit.
# of Missed Doses (based on Patient Report)	Enter the number of doses the subject appears to have missed based on the number of days since the previous visit, the prescribed dose, and the number of pills returned in the bottle. If the bottle was not returned, leave this field blank.
Comment	If needed, use the Comment field to record additional information about this bottle and its return.
Comments for Page	Record any pertinent comments for this page only.

EDC COMPLETION GUIDELINES

walk-PHaSST Protocol

Chest X-ray

Date of Procedure	Record the date the chest x-ray was performed. **Note:** The chest x-ray does not need to be repeated at Screening if one has been performed within the previous 3 months.
Result	Check Normal or Abnormal to indicate the overall result of the x-ray.
Abnormalities	If the result was Abnormal, check the abnormalities found. Check all that apply. For Atelectasis, Infiltrates, Interstitial or Mass results, also enter the location of the abnormality. Check all that apply. If the abnormality found on x-ray is not listed, check Other and specify results in the space provided.
X-ray Bar Code	If the x-ray was shipped, enter the bar code from the label used to track the shipment. If the x-ray was not shipped, check 'Bar code not used.' The bar code may be entered by typing in the number or by scanning the bar code with a hand-held scanner. If scanning, check to see that the cursor is in the Bar Code field before scanning.

Comments for Page	Record any pertinent comments for this page only.

EDC COMPLETION GUIDELINES

walk-PHaSST Protocol

Protocol Deviation

Protocol Deviation Form	The Protocol Deviation form should be completed to document any departure from the study protocol. Complete a separate form for each deviation.
Protocol Deviation Date	Record the date the protocol deviation occurred.
Type of Deviation	Check the one box that best describes the protocol deviation being reported. **Dosing error:** If the deviation was a dosing error, check No or Yes to indicate whether the dosing error resulted in an overdose. **Visit out of window:** If the deviation was a study visit occurring outside of the protocol window, enter the number of days by which the visit was either early or late. **Procedure/test out of window:** If the deviation was a procedure or testing occurring outside of the protocol window, enter the number of days by which it was either early or late. **Inclusion/Exclusion criteria not met:** If the deviation was that protocol inclusion or exclusion criteria were not met, indicate which criteria were not met. Check all that apply. **Other:** If the protocol deviation is of a type not listed, check Other and specify in the space provided.

Deviation Description	Enter a description of the deviation and the reason it occurred.
Protocol Waiver Granted?	Check No or Yes to record whether a protocol waiver was granted.
Study Visit at Which Deviation Occurred	Check the one box to indicate at which study visit the protocol deviation occurred. If the deviation did not occur at a study visit, check Other and specify in the space provided.
Steps Taken to Resolve and Prevent Recurrence	Describe any steps that were taken to resolve the deviation and to prevent it from occurring again.
Adverse Event?	Check No or Yes to indicate whether the protocol deviation resulted in an Adverse Event. If the deviation occurred while the subject was enrolled in the Observational Follow-Up Study, which does not include monitoring for Adverse Events, check Not Applicable. **Note:** If the deviation resulted in an Adverse Event, be sure to report it on an Adverse Events form.
Will Subject Continue in Study?	Check No or Yes to indicate whether the subject will continue in the study despite the deviation. If No, be sure to complete the Study Completion/Early Termination form.

Reporting Deviation to IRB?	Check No or Yes to indicate whether the deviation meets the reporting requirement for your site's IRB. If Yes, record the date the deviation was reported to the IRB.
Comments for Page	Record any pertinent comments for this page only.

EDC COMPLETION GUIDELINES

walk-PHaSST Protocol

Echocardiogram (Local)

Date of Procedure	Record the date the echocardiogram was performed.
Last Study Drug Dose	Record the date and time of the subject's last dose of study drug before the echo procedure. (At Screening, this question is not applicable and does not appear on the form.) **Note**: The echocardiogram should be performed when the subject is on peak dose of study drug dose, which is be 1-1.5 hours after taking the medication.
Time of Procedure	Record the time the echocardiogram was performed, using 24-hour clock. **Note**: The echocardiogram should be performed when the subject is on peak dose of study drug dose, which is be 1-1.5 hours after taking the medication.
Blood Pressure	Record subject's blood pressure at the time of the procedure.

Tricuspid Regurgitant Jet Velocity	Enter the Tricuspid Regurgitant Jet Velocity (TRV) recorded by the echo. If the TRV could not be determined, check Not Detectable. **Note:** Not Detectable is not an acceptable response at Screening and Baseline. In order to be enrolled in the Main Interventional Trial, the subject must have a TRV ≥ 2.7 m/s.
Right Atrial Pressure	Check the box that corresponds to the subject's estimated right atrial pressure in mmHg.
LV Function	Check Normal or Abnormal.
LV Ejection Fraction	Enter the subject's LV ejection fraction.
Regurgitation Findings	Enter aortic, mitral and tricuspid regurgitation findings by checking None, Trace, Mild, Mild-Moderate, Moderate, Moderate-Severe or Severe for each.
Other Significant Findings	Enter any other relevant findings from the echocardiogram.
Bar Code	Enter the bar code(s) from the label used to track the shipment of the echo recording. The bar code may be entered by typing in the number or by scanning the bar code with a hand-held scanner. If scanning, check to see that the cursor is in the Bar Code field before scanning.
Comments for Page	Record any pertinent comments for this page only.

EDC COMPLETION GUIDELINES

walk-PHaSST Protocol

Hematology

Date of Collection	Record the date the sample was collected for analysis.
Lab Value	Record the result for each test.
Unit	Confirm that the unit reported on the lab slip is the same as the unit on the form. If the unit on the lab slip is unequal to a unit on the form, contact the coordinating center. Note: Formula for MCHC is Hb x 100/Hct, if not on print out from lab. For help with conversions: http://nephron.com/cgi-bin/SI.cgi AND http://www.unc.edu/~rowlett/units/scales/clinical_data.html **Note:** The following units are equivalent:
	10^3cells/µL, 1000/µL, th/µL, K/µL, 10^3/mm^3, 1000/mm^3, th/mm^3, K/mm^3, and 10^9/L
	10^6/µL, mil/µL, M/µL, 10^6/mm^3, mil/mm^3, M/mm^3, 10^{12}/L, and mil/mcL

Clinical Significance	Check the one box that best describes the clinical significance of each result. Clinical significance should be determined by the investigator based on his or her judgment and knowledge of the individual subject and the study population. Generally, a result is deemed "clinically significant" if it requires treatment, re-testing or other follow-up. If the test result is judged clinically significant **and** a new Adverse Event, complete an Adverse Event form.
Comments for Page	Record any pertinent comments for this page only.

EDC COMPLETION GUIDELINES

walk-PHaSST Protocol

Pulmonary Function Studies

Date of Assessment	Enter the date the pulmonary function tests were performed. **Note**: Pulmonary function tests do not need to be repeated at Screening if they have been performed within the previous 3 months.
Spirometry	Perform spirometry before and after use of a bronchodilator. For each measurement, enter the result in both absolute terms and in terms of the percent-predicted for this subject.
Lung Volumes	For each measurement, enter the result in both absolute terms and in terms of the percent-predicted for this subject.
Diffusion	For each measurement, enter the result in both absolute terms and in terms of the percent-predicted for this subject.
Comments for page	Record any pertinent comments for this page only.

EDC COMPLETION GUIDELINES

walk-PHaSST Protocol

Physical Examination

Date of Assessment	Record the date of the examination.
Vital Signs	Record the subject's vital signs: • Temperature in degrees Celsius. • Heart rate in beats/minute. • Oxygen saturation and whether the reading was taken with the subject on room air or supplemental oxygen. If the subject was using supplemental oxygen, enter the oxygen flow rate. • Respiratory rate in breaths/minute. • Sitting blood pressure. • Weight in kilograms • Height in centimeters • Body surface area in square meters, using the Mosteller formula. For help with BSA or metric conversions: http://www.halls.md/body-surface-area/bsa.htm AND http://www.teaching-english-in-japan.net/conversion/feet_inches

Body System Categories	Assess the subject's physical condition as it relates to each of the listed body systems. Answer the specific questions related to each body system by checking the boxes or boxes that correspond to the subject's condition. Enter any other findings or comments for each body system in the corresponding Comment/Other findings or abnormalities box.
Comments for Page	Record any pertinent comments for this page only.

EDC COMPLETION GUIDELINES

walk-PHaSST Protocol

Pregnancy Test

Date of Assessment	Record the date the pregnancy test was performed. If the pregnancy test was not performed, the date may be left blank.
Pregnancy Test Result	Check Negative, Positive, or Not Done. If Not Done, check the box that best describes why the test was not performed. If the reason is not listed, check Other and specify in the space provided.
Type of Test	Enter the type of pregnancy test used, either Urine or Serum. If a serum pregnancy test was performed, record the HCG result of the test. **Note:** The following units are equivalent: mIU/ML and IU/L
Comments for Page	Record any pertinent comments for this page only.

EDC COMPLETION GUIDELINES

walk-PHaSST Protocol

Pediatric Quality of Life Inventory Child Report (12 yrs old)

Quality of Life Inventory	The subject should complete the same Quality of Life instrument at each study visit, even if the subject has a birthday between visits. For example, a 12-year-old subject who completes the Quality of Life inventory for 12-year-olds at Screening should complete the Quality of Life inventory for 12-year-olds at the Week 16 or Early Termination visit, even if the subject had a birthday and is 13 at the end of study.
Date of Assessment	Record the date the questionnaire was answered by the subject.
Quality of Life Questions	Enter the subject's self-reported response to each question on the form.
Comments for Page	Record any pertinent comments for this page only.

EDC COMPLETION GUIDELINES

walk-PHaSST Protocol

Pediatric Quality of Life Inventory Teen Report (13 yrs old)

Quality of Life Inventory	The subject should complete the same Quality of Life instrument at each study visit, even if the subject has a birthday between visits. For example, a 13-year-old subject who completes the Quality of Life inventory for 13-year-olds at Screening should complete the Quality of Life inventory for 13-year-olds at the Week 16 or Early Termination visit, even if the subject had a birthday and is 14 at the end of study.
Date of Assessment	Record the date the questionnaire was answered by the subject.
Quality of Life Questions	Enter the subject's self-reported response to each question on the form.
Comments for Page	Record any pertinent comments for this page only.

EDC COMPLETION GUIDELINES

walk-PHaSST Protocol

Pediatric Quality of Life Inventory Parent Report for Child (12 yrs old)

Quality of Life Inventory	The subject's parent or guardian should complete the same Quality of Life instrument at each study visit, even if the subject has a birthday between visits. For example, the parent/guardian of a 12-year-old subject who completes the Quality of Life inventory for parents of 12-year-olds at Screening should complete the Quality of Life inventory for parents of 12-year-olds at the Week 16 or Early Termination visit, even if the subject had a birthday and is 13 at the end of study.
Date of Assessment	Record the date the questionnaire was answered by the subject's parent or guardian.
Quality of Life Questions	Enter the parent or guardian's self-reported response to each question on the form.
Comments for Page	Record any pertinent comments for this page only.

EDC COMPLETION GUIDELINES

walk-PHaSST Protocol

Pediatric Quality of Life Inventory Parent Report for Teen (13 yrs old)

Quality of Life Inventory	The subject's parent or guardian should complete the same Quality of Life instrument at each study visit, even if the subject has a birthday between visits. For example, the parent/guardian of a 13-year-old subject who completes the Quality of Life inventory for parents of 13-year-olds at Screening should complete the Quality of Life inventory for parents of 13-year-olds at the Week 16 or Early Termination visit, even if the subject had a birthday and is 14 at the end of study.
Date of Assessment	Record the date the questionnaire was answered by the subject's parent or guardian.
Quality of Life Questions	Enter the parent or guardian's self-reported response to each question on the form.
Comments for Page	Record any pertinent comments for this page only.

EDC COMPLETION GUIDELINES

walk-PHaSST Protocol

Randomization/Subject Disposition

Randomization/ Subject Disposition Form	The Randomization/Subject Disposition form should be completed after the subject has completed the Baseline visit in the Main Interventional Trial.
Date of MIT Informed Consent	Enter the date the subject signed informed consent for the Main Interventional Trial.
Subject Disposition after Baseline	Indicate the subject's status as regards randomization into the Main Interventional Trial after the Baseline visit. Check either: • Subject Randomized in Main Interventional Trial • Subject Not Randomized In Main Interventional Trial/Subject Enrolled In Observational Follow-Up Study
Date Randomized and Randomization Stratum	If the subject was randomized, enter the date of randomization and check the TRV Statrum for the subject.

Reason Not Randomized	If the subject was not randomized, check the reason why not. If the reason was Adverse Event, Investigator Decision or Other, specify the details.
Comments for Page	Record any pertinent comments for this page only.

EDC COMPLETION GUIDELINES

walk-PHaSST Protocol

Right Heart Catheterization

Subject's TRV for Enrollment in MIT	Check No or Yes to indicate whether the subject's tricuspid regurgitant jet velocity for enrollment in the Main Interventional Trial was ≥ 3.0 m/s. If Yes, the results of the required right heart catherization procedure should be recorded on this form. If No (subject's TRV < 3.0 m/s), the right heart catherization procedure was not required and the rest of this form should be left blank.
Study Visit	Check the box that corresponds to the study visit for which the right heart cath was performed, either Baseline or Week 16/Early Termination.
Last Dose of Study Drug	If this is the subject's Week 16 or Early Termination visit, record the date and time of the subject's last dose of study drug. Use a 24-hour clock. If this is the subject's Baseline visit, the question is not applicable and should be left blank.
Date of Procedure	Record the date the right heart catherization was performed.

Catheterization Side	Check Left or Right to indicate whether the procedure was performed on the right or left side of the heart. If a left heart catherization was performed, enter an explanation in the comment field at the bottom of the form.
Steps 1-5	Steps 1 through 5 should be completed at the Baseline visit. Step 1, 4 and 5 should be completed at the Week 16 or Early Termination visit. Leave Step 2 and Step 3 blank at the Week 16 or Early Termination visit. For each step performed, record the values corresponding to each of the parameters listed. See protocol section XXX or Chapter XX of the Manual of Operations for details.
Bar Code	If the right heart cath recording was shipped, enter the bar code from the label used to track the shipment. If the recording was not shipped, check 'Recording not sent.' The bar code may be entered by typing in the number or by scanning the bar code with a hand-held scanner. If scanning, check to see that the cursor is in the Bar Code field before scanning.
Comments for Page	Record any pertinent comments for this page only.

EDC COMPLETION GUIDELINES

walk-PHaSST Protocol

Study Drug Diary

Study Drug Diary Form	Complete the Study Drug Diary form from the subject's entries on his/her study drug diary card. The study drug diary card should be completed for 7 consecutive days before the subject's scheduled study visit.
Date	Enter the dates for Diary Days 1 through 7. Enter the diary date even if the subject did not complete the diary on that date.
Daily Entry	For each Diary Day, record the times the subject took his/her morning, midday, and evening doses using a 24-hour clock. Enter the number of pills taken at each timepoint. If the subject missed the study drug dose, check the corresponding box. Leave Time blank and enter 0 (zero) for Number of Pills Taken.
Comments for Page	Record any pertinent comments for this page only.

EDC COMPLETION GUIDELINES

walk-PHaSST Protocol

Study Drug Dosing

Study Drug Dosing Form	The Study Drug Dosing form keeps track of the prescribed dose of study drug during the course of the Main Interventional Trial. Click the Add New Dose button to create a record for the initial dose of study drug prescribed. Use the Add New Dose button to create an additional record any time the prescribed dose changes during the course of the study. Use the Remove button to delete any dosing record that is created in error. Use caution in deleting records, as deleted records cannot be recovered after the form is updated.
Total Daily Dose Prescribed	Enter the total dose prescribed to be taken per day, in miligrams.
Reason for Dose	Check the box that corresponds to the reason for the amount of study drug prescribed. The initial record is expected to have 'As per protocol' as the Reason for Dose. Changes in dose due to the dose escalation outlined in the protocol also are expected to have 'As per protocol' as the Reason for Dose. Other possible reasons for the prescribed dose changing include 'Adverse event/lab abnormality' (in which case the dose might be reduced until the AE or abnormality resolves) or 'Dosing error,' (in which case

	the dose might be changed again when the error is discovered.) If there is another reason for changing the prescribed dose, check Other and specify the reason.
Dose Start Date	Enter the date the precribed dose on this record was started.
Dose End Date	Enter the date the precribed dose on this record was stopped. If the dose is ongoing, leave Dose End Date blank. The resulting query will serve as a reminder that the record will need to be reviewed and updated at the subject's next visit. Use the Add New Dose button to create an additional record if the subject is continuing on the study medication in the Main Interventional Trial. There should be no gaps in the dates recorded during the time the subject is in the Main Interventional Trial. **Note:** If the subject has completed the Main Interventional Trial, the last Dose End Date on this form should be equal to the Date of Last Dose of Study Drug entered on the Study Completion/ Early Termination form.
Bottle Number Used For This Dose	Enter the number of the bottle the subject is expected to use for this dosing regimen. The bottle number may be entered by typing in the number or by scanning the bottle's bar code with a hand-held scanner. If scanning, check to see that the cursor is in the Bottle Number field before scanning the bar code.

Comments for page	Record any pertinent comments for this page only.

EDC COMPLETION GUIDELINES

walk-PHaSST Protocol

SF-36 Health Survey

Date of Assessment	Record the date the subject completed the health survey.
Question 1	Check the one box that best indicates the subject's current health status.
Question 2	Check the one box that best indicates the subject's current health status.
Question 3	For each activity, check the one box that best indicates the current extent of limitation due to the subject's health for a typical day.
Question 4	For each problem listed, check the one box that best indicates the degree to which the subject's physical health during the past 4 weeks has impacted work or other regular daily activities.
Question 5	For each problem listed, check the one box that best indicates the degree to which the subject's emotional health during the past 4 weeks has impacted work or other regular daily activities.
Question 6	Check the one box that best indicates the degree to which the subject's physical or emotional health during the past 4 weeks has impacted normal social activities.
Question 7	Check the one box that best indicates the degree of body pain the subject has experienced during the past 4 weeks.

Question 8	Check the one box that best indicates the degree to which pain has interfered with the subject's normal work during the past 4 weeks.
Question 9	For each question, check the one box that best indicates how frequently the subject has experienced the specified mood during the past 4 weeks.
Question 10	Check the one box that best indicates how much of the time the subject's physical health or emotional problems during the past 4 weeks has interfered with social activities.
Question 11	For each statement, check the one box that best indicates how true or false the statement is regarding the subject's health.
Comments Associated With This Page	Record any pertinent comments for this page only.

EDC COMPLETION GUIDELINES

walk-PHaSST Protocol

6-Minute Walk Test

6-Minute Walk Test Form	The 6-minute walk is the Main Interventional Trial's primary endpoint and must be performed as outlined in Chapter XX of the Manual of Operations. **Language about repeat walk at baseline if not within 15% of Screening.**
Date of Assessment	Record the date the 6-minute walk was performed.
Date/ Time of Last Dose of Study Drug	At visits other than Screening and Baseline, enter the date and time of the subject's last dose of study drug. At Screening and Baseline visits, check Not Applicable for date and time of last study drug dose.
Before Walk	Enter the following from before the start of the walk test: 1. Subject's blood pressure. 2. Subject's heart rate. 3. Subject's oxygen saturation and whether the reading was taken with the subject on room air or supplemental oxygen. If the subject was using supplemental oxygen, enter the oxygen flow rate.

	4. The time the walk started, using a 24-hour clock.
After Walk	Enter the following from after the end of the walk test: 5. Subject's blood pressure. 6. Subject's heart rate. 7. Subject's oxygen saturation and whether the reading was taken with the subject on room air or supplemental oxygen. If the subject was using supplemental oxygen, enter the oxygen flow rate. 8. Distance walked, in meters. 9. Whether the subject stopped before the 6-minute time limit was over. 10. Whether the subject used oxygen during the walk test. If Yes, enter the flow rate and whether the subject carried or pushed the oxygen device during the test. 11. Use the drop-down box to select the correct value for the Borg dyspnea score. 12. Use the drop-down box to select the correct value for the NYHA/WHO classification.
11. Borg Dyspnea Score	Select the value that corresponds to the subject's Borg dyspnea score at the end of the walk.
12. NYHA/ WHO Classification	Check the box that corresponds to the subject's NYHA/ WHO classification at the end of the walk.

Comments for page	Record any pertinent comments for this page only.

EDC COMPLETION GUIDELINES

walk-PHaSST Protocol

Symptoms Documentation

Date of Assessment	Record the date the subject's symptoms were assessed. Usually, this is the same date as the study visit.
Acute Events	Check No or Yes to indicate whether the subject -- since the previous assessment -- has experienced any acute medical events **related to either sickle cell disease or pulmonary hypertension** that caused him/her to seek medical care at a physician's office, clinic, emergency room, day hospital, urgent care center, or hospital.. **Note:** If the subject experienced an acute event for a medical condition **not** related to sickle cell disease or pulmonary hypertension, check No here but record the acute event on the Adverse Events form. If Yes, click the Add Acute Event Record button for each event and provide the following details: **Treatment Location:** Check the box that indicates the location where the subject sought medical treatment. If the subject sought treatment at multiple locations for the same event, check the box for the location that represents the most intensive medical intervention. For example, if the subject went to the emergency room and eventually was admitted to the hospital, Hospital should be checked. **Treatment Date:** Record the date the subject sought treatment. If the subject was admitted to a hospital, record the date of admission.

	Acute event/reason for seeking care : Check the condition that prompted the subject to see medical care. If the reason is either Surgical Procedure or Other, specify the procedure or other condition. Use the Add Acute Event Record button as needed in order to record the details of each acute event since the previous assessment. Use the Remove button to delete any records that are created in error. Use caution in deleting records, as deleted records cannot be recovered after the form is updated. **Note:** Details about each acute event reported on this form must also be reported on the Adverse Event form.
Pain Events	Check No or Yes to indicate whether the subject -- since the previous assessment -- has experienced any sickle cell-related pain events that were treated at home. If Yes, record the number of events treated at home. **Note:** The count of pain events that were treated at home should not include any that were reported as Acute Events at the top of this form. Check No or Yes to indicate if any of the pain events that were treated at home represented an exacerbation -- increased frequency or intensity -- of the subject's baseline condition and hence would be considered Adverse Events. If Yes, report on an Adverse Event form.
Changes in Vision	Check No or Yes to indicate if the subject -- since the previous assessment -- experienced any changes in vision. If Yes, enter a description of the change. Check No or Yes to indicate if the vision change were an Adverse Event. If Yes, complete an Adverse Event form.

Headaches	Check No or Yes to indicate if the subject -- since the previous assessment -- has experienced any headaches. If Yes, record the number of headaches. **Note:** The count of headaches should not include any that were reported as Acute Events at the top of this form. Check No or Yes to indicate if any of the headaches represented an exacerbation -- increased frequency or intensity -- of the subject's baseline condition and hence would be considered Adverse Events. If Yes, report on an Adverse Event form.
Priapism Events	Check No or Yes to indicate whether the subject -- since the previous assessment -- has experienced any priapism events that were treated at home. If Yes, record the number of events treated at home. **Note:** The count of priapism events that were treated at home should not include any that were reported as Acute Events at the top of this form. Check No or Yes to indicate if any of the priapism events that were treated at home represented an exacerbation -- increased frequency or intensity -- of the subject's baseline condition and hence would be considered Adverse Events. If Yes, report on an Adverse Event form.

Transfusion	Check No or Yes to indicate if the subject -- since the previous assessment -- received any transfusions. If Yes, click the Add Transfusion Record button for each transfusion received and provide the following details on each: **Date of Transfusion:** Enter the date **Reason for tranfusion:** Check the box or boxes to indicate the reason for transfusion. If Other, specify the reason. **Type of Transfusion:** Select the type of transfusion given, Simple, Exchange or Other. **Number of Units Tranfused:** Enter the number. Use the Add Transfusion Record button as needed in order to record the details of each transfusion since the previous assessment. Use the Remove Record button to delete any records that are created in error. Use caution in deleting records, as deleted records cannot be recovered after the form is updated.
Analgesics	Check No or Yes to indicate if the subject -- since the previous assessment -- has changed his/her use of analgesics by adding a new medication, changing dosage or route of an existing medication, or stopping a medication. If Yes, record the details of the change on a Concomitant Medications form. Also if Yes, check No or Yes to indicate whether the change was related to an adverse event. If Yes, be sure the AE is reported on an Adverse Event form.

Comments for page	Record any pertinent comments for this page only.

EDC COMPLETION GUIDELINES

walk-PHaSST Protocol

Study Completion/ Early Termination

Study Completion/ Early Termination Form	The Study Completion/ Early Termination form should be completed for every subject randomized in the Main Interventional Trial. If the subject completes the Main Interventional Trial through Week 16, the form should be completed after the Week 16 visit. If the subject terminates early from the Main Interventional Trial, the form should be completed after the subject's last study visit.
Did the Subject Complete MIT through Week 16?	Check No or Yes to indicate whether the subject completed the Main Interventional Trial through Week 16. If **Yes**, check No or Yes to indicate whether the subject continued in the Open-Label Follow-up Phase.
If Subject Did Not Complete MIT through Week 16	If **No** (subject terminated early and did not complete study through Week 16) , provide the following: • Date of the last Main Interventional Trial contact. • Date of the last dose of study drug. • Primary reason the subject did not complete trial through Week 16.

Treatment Arm	Although this study is double-blinded, individuals may sometimes believe they know to which treatment an individual has been assigned. For the Subject (or Parent/Guardian), Site Coordinator, and Clinical Investigator, check the box indicating his/her best guess of the subject's treatment assignment.
Comments for page	Record any pertinent comments for this page only.

EDC COMPLETION GUIDELINES

walk-PHaSST Protocol

Urinalysis

Date of Collection	Record the urine sample was collected for urinalysis.
Urine Dipstick Chemical Analysis	Check No, Yes or Not Applicable (male subject) to indicate whether the subject is menstruating. Enter the pH value. Enter the Specific Gravity value. Enter the dipstick result for glucose, protein and blood by checking Negative or Positive. If any result is Positive, use the drop-down box to select the code for the result and/or enter the positive value (depending on how the result is reported by the lab). For help with conversions: http://nephron.com/cgi-bin/SI.cgi AND http://www.unc.edu/~rowlett/units/scales/clinical_data.html
Microscopic Exam	Check No or Yes to indicate whether a microscopic exam was performed. If Yes, use the drop-down boxes to enter the value that corresponds to the lab's findings for RBC and WBC. Check No or Yes box for whether there were other abnormal findings on the microscopic exam. If Yes, provide a description of the other abnormal findings.

Overall Assessment of Urinalysis	Check Normal or Abnormal to report the overall assessment of the urinalysis. If Abnormal, check No or Yes to indicate whether the finding represents a new Adverse Event. If Yes, report the AE on the Adverse Event form.
Albumin/ Creatinine Ratio	Record the date the sample was collected for the albumin/creatinine ratio test. Enter the albumin and creatinine values, or enter the ratio itself (depending on how the result is reported by the lab).
Comments for page	Record any pertinent comments for this page only.

EDC COMPLETION GUIDELINES

walk-PHaSST Protocol

Visit Record

Date of Visit	Record the date of the study visit. If the subject missed the study visit, date of visit can be left blank.
Did subject come for study visit?	Check Yes or No to indicate whether the subject came for the study visit. **Note:** If the subject missed a study visit, also complete a protocol deviation form.
Study Visit	Check the box that corresponds to this study visit.
Was visit or any visit assessment delayed or rescheduled?	Check Yes or No to indicate whether this visit or any of the assessments for this visit were delayed or rescheduled due to transfusion, vaso-occlusive crisis, or acute chest syndrome. **Note:** Per the protocol, study assessments should not be performed until after 2-3 weeks have passed since a blood transfusion. Also, endpoint assessments (including hemodynamic assessment) should not be performed until 2 weeks after a transfusion and after any VOC or ACS event has resolved.

Were any study procedures not done or done on a different date?	Check the appropriate box if any of the required study procedures for **this** visit were either not performed or were performed on a different date. For example, if all study procedures for Baseline were performed on the same day, except the Right Heart Catherization was scheduled on a different day, Done on a Different Day would be checked for it. If all study procedures were performed and all were on the same day, no boxes should be checked. Enter any explanation for procedures not performed or performed on different dates from the rest of the study visit in the Comments field at the bottom of the form. This information will help to explain missing data or data where a date is different than expected. **Note:** If a required procedure was not performed, also complete a protocol deviation form.
Comments for page	Record any pertinent comments for this page only.

EDC COMPLETION GUIDELINES

walk-PHaSST Protocol

Hemoglobin Electrophoresis

Date of Collection	Record the date the sample for hemoglobin electrophoresis was collected. **Note:** If the subject has had hemoglobin electrophoresis performed in the past, it is not necessary to repeat the procedure. If a historical hemoglobin electrophoresis is used for the study, record the date the sample was collected for the previous procedure.
Historical Hemoglobin Electrophoresis	Check No or Yes to indicate whether a historical hemoglobin electrophoresis is being reported for this study.
Results	Enter the results of the hemoglobin electrophoresis. Enter the percentage of Hemoglobin A, A2, C, F, and S. Record any other hemoglobin results under Other, and specify the reading.
Comments for Page	Record any pertinent comments for this page only.