HU-Mag Annotated CRF

Table of Contents

Study Phase 1006: Visit 6

Study Phase 1007: Visit 7

Study Phase 1008: Visit 8

Study Phase 1009: Visit 9

Study Phase 1010: Visit 10

Study Phase 1011: Visit 11

Study Phase 1012: Visit 12

Study Phase 1013: Visit 13

Study Phase 1014: Visit 14

Study Phase 1015: Visit 15

Study Phase 1016: Visit 16

Study Phase 2000: Early Termination

Study Phase 3000: Toxicity Visit

Study Phase 2050: Study Completion

Study Phase 4001: Re-screening - Visit 1

Study Phase 4002: 2nd Re-screening - Visit 1

Study Phase 5000: Ongoing

Comprehensive Sickle Cell Centers	**Inclusion Criteria v.6.1**	**{visit.label}**
Hydroxyurea & Magnesium Pidolate (CHAMPS)	Date of Visit: INCL:VISITDA / INCL:VISITMO / INCL:VISITYR (Day / Month / Year)	CSCC ID: {subject.name} Center code: {center.name} Hospital code: {center.hospital.name}

For the subject to be considered eligible for this study, Questions 1 through 6 must be answered Yes.

1. Has the subject been diagnosed with Hb SC disease?	☐ (INCL:INCL1) Yes	☐ (INCL:INCL1) No
2. Is the subject 5 years of age or older?	☐ (INCL:INCL2) Yes	☐ (INCL:INCL2) No
3. Has the subject had at least one vaso-occlusive event (pain crisis[1], acute chest syndrome[2]) in the previous 12 months?	☐ (INCL:INCL3) Yes	☐ (INCL:INCL3) No
4. Has the subject/guardian signed an informed consent/assent form?	☐ (INCL:INCL4) Yes	☐ (INCL:INCL4) No
Date of informed consent: INCL:INFRMDA / INCL:INFRMMO / INCL:INFRMYR (Day / Month / Year)		
5. Does the subject exhibit regular adherence with comprehensive care?[3]	☐ (INCL:INCL5) Yes	☐ (INCL:INCL5) No
6. Is the subject in a steady state and not having an acute complication of sickle cell disease [i.e., no hospitalization, pain event, or episode of acute chest syndrome within the past month (28 days)]?	☐ (INCL:INCL6) Yes	☐ (INCL:INCL6) No

Note: Subjects enrolled under Protocol Version 6.0 are eligible if in steady state within the past 30 days.

1 A pain crisis is defined as the occurrence of pain in the extremities, back, abdomen, chest, or head that lasts at least 2 hours, requires a visit to a hospital, Emergency Department, clinic, or provider's office, and is not explained except by sickle cell disease.

2 Acute chest syndrome is defined as a new pulmonary infiltrate on chest x-ray associated with fever (> 38.5° C), tachypnea, wheezing, cough, or chest pain.

3 A subject has exhibited regular adherence when he/she has consistently shown up for scheduled clinic visits and when he/she has been scheduled for at least one clinic visit per year.

Submit Query | Cancel | Form Completion Help | Print

Comprehensive Sickle Cell Centers	**Exclusion Criteria v.6.1**	**{visit.label}**
Hydroxyurea & Magnesium Pidolate (CHAMPS)		CSCC ID: {subject.name} Center code: {center.name} Hospital code: {center.hospital.name}

For the subject to be considered eligible for this study, Questions 1 through 9 must be answered No.

1. Has the subject had any previous treatment with hydroxyurea within the last 3 months? **Note: Subjects enrolled under Protocol Version 6.0 are excluded if EVER treated with hydroxyurea.**	☐ (EXCL:EXCL1) Yes	☐ (EXCL:EXCL1) No
2. Has the subject had any treatment with magnesium within the past 3 months (including vitamins containing magnesium)?	☐ (EXCL:EXCL2) Yes	☐ (EXCL:EXCL2) No
3. In the investigator's opinion, has the subject exhibited poor adherence with previous treatment	☐ (EXCL:EXCL3) Yes	☐ (EXCL:EXCL3) No

regimens?		
4. Has the subject had hepatic dysfunction (SGPT > 2x upper limit of normal) within the past month?	☐ (EXCL:EXCL4) Yes	☐ (EXCL:EXCL4) No
5. Has the subject had renal dysfunction (creatinine ≥ 1.0 mg/dL, < 18.0 years of age; 1.2 mg/dL, ≥ 18.0 years of age) within the past month?	☐ (EXCL:EXCL5) Yes	☐ (EXCL:EXCL5) No
6. Is the subject pregnant?	☐ (EXCL:EXCL6) Yes	☐ (EXCL:EXCL6) No
7. Has the subject had ≥ 10 hospital admissions (overnight stays) for pain in the last 12 months, or has he/she been using narcotics daily for an extended period of time?[1]	☐ (EXCL:EXCL7) Yes	☐ (EXCL:EXCL7) No
8. Has the subject had treatment with an investigational drug in the last 3 months?	☐ (EXCL:EXCL8) Yes	☐ (EXCL:EXCL8) No
9. Does the subject have any other chronic illness or disorder other than SCD that could adversely affect the subject's performance in the study (e.g., tuberculosis)?	☐ (EXCL:EXCL9) Yes	☐ (EXCL:EXCL9) No

1 For the purposes of this study, "extended period of time" is defined as 6 months of daily use, per the subject's self-report.

Comprehensive Sickle Cell Centers	**Screening**	**{visit.label}**
Hydroxyurea & Magnesium Pidolate (CHAMPS)		CSCC ID: {subject.name} Center code: {center.name} Hospital code: {center.hospital.name}

Expected Date of Next Visit: SCRE:EXVISDA / SCRE:EXVISMO / SCRE:EXVISYR ☐ *Email date to CHAMPS_labs@rhoworld.com*

(Within 1-3 weeks of Visit 1) Day Month Year

1) Red Cell Density:

% Hyperdense cells SCRE:HYPER % *% hyperdense cells will be provided via an e-mail from RhoLAB*

If the subject has ≥ 3 percent RBCs with density > 41 g/dL, he/she is eligible to continue in this study.

2) Hemoglobin Level:

Does the subject have a Hb level between 8-12.5 g/dL? ☐ (SCRE:HGB)Yes ☐ (SCRE:HGB)No

If the subject has a Hb level between 8 – 12.5 g/dL, he/she is eligible to continue in this study.

3) Hb A %:

Has the subject been transfused within the past 3 months? ☐ (SCRE:HGBA)Yes ☐ (SCRE:HGBA)No

☐ **If yes**, is the subject's Hb A ≤ 10%? ☐ (SCRE:YHGBA)Yes ☐ (SCRE:YHGBA)No

If the subject has a Hb A % ≤ 10, he/she is eligible to continue in this study.

4) HIV Status: *(tested within the last 12 months)*

Date tested: SCRE:HIVDA / SCRE:HIVMO / SCRE:HIVYR
Day Month Year

Result: ☐ (SCRE:HIV) Negative ☐ (SCRE:HIV) Positive

If the subject has a negative HIV test, he/she is eligible to continue in this study.

5) Hepatic Dysfunction:

Within the past month, has the subject had SGPT > 2x the upper limit of normal? ☐ (SCRE:HEDYS)Yes ☐ (SCRE:HEDYS)No

Screening SGPT level (U/L) SCRE:HESCR

Local lab upper limit of normal (U/L) SCRE:HEUPL

If the subject has not had SGPT > 2x upper limit of normal within the past month, he/she is eligible to continue in this study.

6) Renal Dysfunction:

Within the past month has subject had creatinine ≥ 1.0 mg/dL (if under age 18.0 years) or ≥ 1.2 mg/dL (if age 18.0 years or above)? ☐ (SCRE:REDYS)Yes ☐ (SCRE:REDYS)No

Screening creatinine level (mg/dL) SCRE:RESCR

Local lab upper limit of normal (mg/dL) SCRE:REUPL

If the subject has not had creatinine ≥ 1.0 mg/dL (if under age 18.0 years) or ≥ 1.2 mg/dL (if 18.0 years or above) within the past month, he/she is eligible to continue in this study.

Demographics

Date of Birth: SCRE:BIRTHDA / SCRE:BIRTHMO / SCRE:BIRTHYR
Day Month Year

Gender: ☐ (SCRE:GENDER)Male ☐ (SCRE:GENDER)Female

Hemoglobinopathy

Date of Results: SCRE:HEMODA / SCRE:HEMOMO / SCRE:HEMOYR
Day Month Year

S (%) SCRE:SPERC

C (%) SCRE:CPERC

A (%) SCRE:APERC

A2 (%) SCRE:A2PERC

F (%) SCRE:FPERC

Include the decimal if provided on the lab report (e.g., 24.6 or 24.0).

If no decimal is provided on the lab report, leave the last box empty (e.g., 24); do not add a zero.

Other (%) SCRE:OTPERC

Other, specify type of electrophoresis: SCRE:OTPSP

If this subject has been re-screened AND had a transfusion within the last 3 months, please repeat the hemoglobin electrophoresis and enter the results here; these results will replace the data that were previously entered.

Submit Query | Cancel | Form Completion Help | Print

Comprehensive Sickle Cell Centers	**Physical Exam**	**{visit.label}**
Hydroxyurea & Magnesium Pidolate (CHAMPS)		CSCC ID: {subject.name} Center code: {center.name} Hospital code: {center.hospital.name}

Physical Exam

☐ (PHEX:PHEXND) Not Done ☐ Specify: PHEX:NDSPEC

1) Weight[1]: PHEX:WEIGHT (kg)

2) Is the spleen palpable? ☐ (PHEX:SPLEEN) Yes ☐ (PHEX:SPLEEN) No

☐ *If **Yes,** what is the current spleen size?* PHEX:SLPESP cm

(at the greatest distance below the left costal margin)

3) Does the subject have any skin lesions? ☐ (PHEX:LESION)Yes ☐ (PHEX:LESION)No

☐ *If **Yes,** where are the lesions located:* PHEX:LESISP

4) Is the subject taking any medication? ☐ (PHEX:MEDIC)Yes ☐ (PHEX:MEDIC)No

☐ *If **Yes,** record information on the Concomitant Medications CRF.*

☐ *Be sure to check "Pre-existing" on the Concomitant Medications CRF.*

1 Weight should be measured with the subject standing still, wearing light clothing (such as a paper exam gown) and no shoes.

Submit Query Cancel Print

Comprehensive Sickle Cell Centers	**Medical History**	**{visit.label}**
Hydroxyurea & Magnesium Pidolate (CHAMPS)		CSCC ID: {subject.name} Center code: {center.name} Hospital code: {center.hospital.name}

Information to be determined by patient interview and review of medical records.

Medical Conditions

1. Is the subject enrolled in the C-Data study? ☐ (MDHX:CDATA)Yes ☐ (MDHX:CDATA)No

2. Check "Yes", "No" or "Unknown" to indicate whether the subject has been diagnosed with any of the following conditions.

→ For any condition marked "Yes" provide the "Year of First Diagnosis." Also, indicate whether the condition is currently present or occurred in the past year.

Yes	Year of first Diagnosis	No	Unknown	Condition		If yes, Present/ Occurred in past year?
☐ (MDHX:ACS)	MDHX:ACSYR	☐ (MDHX:ACS)	☐ (MDHX:ACS)	(Pulmonary) Acute Chest Syndrome		☐ (MDHX:ACSPRS)
☐ (MDHX:HIP)	MDHX:HIPYR	☐ (MDHX:HIP)	☐ (MDHX:HIP)	(Muscular, Skeletal, Skin) Avascular Necrosis of Hip(s)		☐ (MDHX:HIPPRS)
☐ (MDHX:SHOLDR)	MDHX:SHOYR	☐ (MDHX:SHOLDR)	☐ (MDHX:SHOLDR)	(Muscular, Skeletal, Skin) Avascular Necrosis of Shoulder(s)		☐ (MDHX:SHOPRS)
☐ (MDHX:STROKE)	MDHX:STRYR	☐ (MDHX:STROKE)	☐ (MDHX:STROKE)	(CNS) Stroke		☐ (MDHX:STRPRS)
				(CNS) Other		
	MDHX:CNSYR1			→ Specify: MDHX:CNSOTS1		☐ (MDHX:CNSPRS1)
	MDHX:CNSYR2			→ Specify: MDHX:CNSOTS2		☐ (MDHX:CNSPRS2)
☐ (MDHX:HYPER)	MDHX:HYPYR	☐ (MDHX:HYPER)	☐ (MDHX:HYPER)	(Splenic) Hypersplenism		☐ (MDHX:HYPPRS)
☐ (MDHX:ULCER)	MDHX:ULCYR	☐ (MDHX:ULCER)	☐ (MDHX:ULCER)	(Muscular, Skeletal, Skin) Leg Ulcers		☐ (MDHX:ULCPRS)
☐ (MDHX:PRIAP)	MDHX:PRIYR	☐ (MDHX:PRIAP)	☐ (MDHX:PRIAP)	(Renal/Genitourinary) Priapism	☐ (MDHX:PRIAP) N/A, female subject	☐ (MDHX:PRIPRS)
☐ (MDHX:RETIN)	MDHX:RETYR	☐ (MDHX:RETIN)	☐ (MDHX:RETIN)	(Ocular) Retinopathy		☐ (MDHX:RETPRS)
☐ (MDHX:SPLENIC)	MDHX:SPLYR	☐ (MDHX:SPLENIC)	☐ (MDHX:SPLENIC)	(Anemia) Acute Splenic Sequestration		☐ (MDHX:SPLPRS)

If this subject has been re-screened, please update this form as appropriate to reflect any changes to the subject's medical history since the last time the subject was screened.

Submit Query Cancel Print

Comprehensive Sickle Cell Centers	**Medical History**	**{visit.label}**
Hydroxyurea & Magnesium Pidolate (CHAMPS)		CSCC ID: {subject.name} Center code: {center.name} Hospital code: {center.hospital.name}

Information to be determined by patient interview and review of medical records.

Cancer

Has the subject ever had or ever been diagnosed with cancer? ☐ (CANE:CANCER)Yes ☐ (CANE:CANCER)No

➜ If yes, list the type(s) of cancer below. For each type listed provide year of first diagnosis and indicate whether present in the last year.

Type of Cancer	Year of First Diagnosis	Present in Last Year?
CANE:CANSPEC	CANE:CANYR	☐ (CANE:CANPRS) Yes ☐ (CANE:CANPRS) No
CANE:CANSPE2	CANE:CANYR2	☐ (CANE:CANPRS2) Yes ☐ (CANE:CANPRS2) No
CANE:CANSPE3	CANE:CANYR3	☐ (CANE:CANPRS3) Yes ☐ (CANE:CANPRS3) No

Neuroimaging

In the past year, has **neuroimaging** revealed any significant abnormal findings? ☐ (CANE:NEURO)Yes ☐ (CANE:NEURO)No ☐ (CANE:NEURO)Not Done

➜ **If yes**, click the ADD button, and record details for each test type.

Remove

Date of test:	NEUR:TESTDA / NEUR:TESTMO/ NEUR:TESTYR (Day/Month/Year)
Type of test*:	☐ (NEUR:TYPE)MRI ☐ (NEUR:TYPE)MRA ☐ (NEUR:TYPE)CT ☐ (NEUR:TYPE)Cerebral angiography ☐ (NEUR:TYPE)Other, specify NEUR:TYPEOTS
Briefly describe the findings:	NEUR:FINDING

Add Test

*Information about **"types of tests"** may be downloaded from the CHAMPS web page on the CSCC website.

If this subject has been re-screened, please update this form as appropriate to reflect any changes to the subject's medical history since the last time the subject was screened.

Submit Query Cancel Print

Comprehensive Sickle Cell Centers	**Health History**	**{visit.label}**
Hydroxyurea & Magnesium Pidolate (CHAMPS)		CSCC ID: {subject.name} Center code: {center.name} Hospital code: {center.hospital.name}

All questions relate to events in the past 12 months.

1) Has the subject had acute events that led to a visit to physician's office/clinic/emergency department/ day hospital/urgent care facility, or a hospitalization? ☐ (HLHX:EVENT)Yes ☐ (HLHX:EVENT)No

→**If yes,** click the "ADD" button and record information for each event.

Remove

Treatment Location:		**Date of Encounter:**	
☐ (HTRE:PHYSICN)	Physician's Office / Clinic	HTRE:PHYSDA / HTRE:PHYSMO / HTRE:PHYSYR (Day/Month/Year)	
☐ (HTRE:EDURGCR)	Emergency Department / Day Hospital / Urgent Care	HTRE:EMERDA / HTRE:EMERMO / HTRE:EMERYR (Day/Month/Year)	
		Date Admitted:	**Date Discharged:**
☐ (HTRE:HOSPITL)	Hospital	HTRE:HADMDA / HTRE:HADMMO / HTRE:HADMYR (Day/Month/Year)	HTRE:HDISDA / HTRE:HDISMO / HTRE:HDISYR Day/Month/Year)

Reason(s)[1]:

☐ (HTRE:PAINCRI)	Pain crisis[2]	☐ (HTRE:ACS)	ACS[3]	☐ (HTRE:FEVER)	Fever	☐ (HTRE:SPLENIC) Acute splenic sequestration
☐ (HTRE:STROKE)	Clinical stroke	☐ (HTRE:CANCER)	Cancer	☐ (HTRE:PRIAP)	Priapism	☐ (HTRE:HEPAT) Hepatic sequestration
☐ (HTRE:RSNOT)	Other, specify HTRE:RSNOTS					

Add Visit

2) Has the subject had any pain crisis(es) at home[4] for which there was no hospitalization or emergency department/ day hospital/ urgent care visit? ☐ (HLHX:PCRISIS)Yes ☐ (HLHX:PCRISIS)No

➔**If yes,** how many pain crises were treated at home: HLHX:PCHOME

3) Blood transfusion? ☐ (HLHX:BTRANS) Yes ☐ (HLHX:BTRANS) No

➔**If yes,** click the "ADD" button and record date and number of units or cc's for each transfusion.

	Remove
Date Transfused: TRAN:TRANDA / TRAN:TRANMC / TRAN:TRANYR (Day/Month/Year)	
Number: TRAN:VOLUME	Units/cc's Select one: TRAN:UNIT **OR** ☐ (TRAN:UNITUNK) units/cc's unknown
Reason for Transfusion:	TRAN:REASON
Other, Specify:	TRAN:OTHSP

Add Transfusion

1 Complete AE and/or SAE forms for each reason IF event occurred after the informed consent form was signed.

2 A pain crisis is defined here as the occurrence of pain in the extremities, back, abdomen, chest, or head that lasts at least 2 hours; requires a visit to a hospital, Emergency Department, clinic, or provider's office; and is not explained except by sickle cell disease.

3 Acute chest syndrome is defined as a new pulmonary infiltrate on chest x-ray associated with fever (> 38.5° C), tachypnea, wheezing, cough, or chest pain.

4 A painful crisis at home must be a new event, not a steady state situation. A pain crisis at home is defined as the occurrence of pain in the extremities, back, abdomen, chest, or head that lasts at least 2 hours and is not explained except by sickle cell disease. Ongoing pain at home that occurs every day should not be considered a painful crisis at home.

Comments for page:
HLHX:COMTXT

Submit Query | Cancel | Form Completion Help | Print

If this subject has been re-screened, please update this form as appropriate to reflect any acute events or transfusions since the last time the subject was screened.

Comprehensive Sickle Cell Centers	**Hematology Labs**	**{visit.label}**
Hydroxyurea & Magnesium Pidolate (CHAMPS)		CSCC ID: {subject.name} Center code: {center.name} Hospital code: {center.hospital.name}

*Collection Date: HEMA:COLLDA / HEMA:COLLMC / HEMA:COLLYR

Day Month Year

TEST	VALUE	
Hemoglobin (g/dL)	HEMA:HGB	
Hematocrit (%)	HEMA:HCT	
RBC (x10^6/mm^3)	HEMA:RBC	
WBC (x10^3/mm^3)	HEMA:WBC	
MCV (fl)	HEMA:MCV	
MCHC (g/dL)	HEMA:MCHC	
Platelet count (x10^3/mm^3)	HEMA:PLT	
% Retic **OR** **ARC (x10^3/mm^3)**	HEMA:RET HEMA:ARC	Either % Retic **OR** ARC should be provided. Use the same unit for this subject at all study visits.
ANC (/mm^3)	HEMA:ANC	

*If the collection date differs from the visit date for this visit, explain:
HEMA:DATEDIS

Submit Query Cancel Form Completion Help Print

Comprehensive Sickle Cell Centers	**Chemistry Labs**	**{visit.label}**
Hydroxyurea & Magnesium Pidolate (CHAMPS)		CSCC ID: {subject.name} Center code: {center.name} Hospital code: {center.hospital.name}

*Collection Date: CHEM:COLLDA / CHEM:COLLMO / CHEM:COLLYR

Day Month Year

TEST	VALUE
Sodium (mmol/L)	CHEM:SOD
Potassium (mmol/L)	CHEM:POTAS
Chloride (mmol/L)	CHEM:CHLOR
CO_2 (mmol/L)	CHEM:CO2
BUN (mg/dL)	CHEM:BUN
Creatinine (mg/dL)	CHEM:CREAT
Calcium (mg/dL)	CHEM:CALC
SGPT/ALT (U/L)	CHEM:ALT
Alk phosphatase (U/L)	CHEM:ALKPH
Total bilirubin (mg/dL)	CHEM:TBILI
Total protein (g/dL)	CHEM:TPROT
Albumin (g/dL)	CHEM:ALBUM
LDH (U/L)	CHEM:LDH

*If the collection date differs from the visit date for this visit, explain:
CHEM:DATEDIS

Submit Query Cancel Form Completion Help Print

Comprehensive Sickle Cell Centers	**Pregnancy Test**	**{visit.label}**
Hydroxyurea & Magnesium Pidolate (CHAMPS)		CSCC ID: {subject.name} Center code: {center.name} Hospital code: {center.hospital.name}

Pregnancy Test

☐ (PREG:PREGND) Not done *(Check reason below)*

- ☐ (PREG:NDREAS) Subject male
- ☐ (PREG:NDREAS) Subject has not reached menstruating age
- ☐ (PREG:NDREAS) Postmenopausal
- ☐ (PREG:NDREAS) Hysterectomy
- ☐ (PREG:NDREAS) Tubal ligation
- ☐ (PREG:NDREAS) Other, specifiy: PREG:OTHREAS

*Date of Collection: PREG:COLLDA / PREG:COLLMC / PREG:COLLYR
Day Month Year

Type: ☐ (PREG:TYPE)Serum ☐ (PREG:TYPE)Urine

Result: ☐ (PREG:RESULT)Positive ☐ (PREG:RESULT)Negative

*If the collection date differs from the visit date for this visit, explain:
PREG:DATEDIS

Submit Query | Cancel | Form Completion Help | Print

Comprehensive Sickle Cell Centers	**Screen Failure Log**	**{visit.label}**
Hydroxyurea & Magnesium Pidolate (CHAMPS)		CSCC ID: {subject.name} Center code: {center.name} Hospital code: {center.hospital.name}

This form is to be completed the *first time* the subject discontinues prior to receiving study drug.

Date of last study related contact: SCFL:CONTDA / SCFL:CONTMO / SCFL:CONTYR
Day Month Year

Primary reason the subject will not be enrolled: (Check only one.)

☐ (SCFL:PRIMARY) In the investigator's opinion, the subject's health, safety and/or well-being would be threatened by participation in the study.

☐ (SCFL:PRIMARY) Subject lost to follow-up.

☐ (SCFL:PRIMARY) Subject or subject's legal representative requested to withdraw. ***Specify:*** SCFL:LEGSP

☐ (SCFL:PRIMARY) Subject did not meet inclusion/exclusion criteria.

Is subject no longer in steady state after previously meeting inclusion/exclusion criteria? ☐ (SCFL:NOLONG)Yes ☐ (SCFL:NOLONG)No

☐ **If Yes**, check all that apply and complete the Adverse Event forms.

☐ (SCFL:VASO) Subject experienced one or more vaso-occlusive crises

☐ (SCFL:NONVOC) Subject experienced one or more non-vaso-occlusive sickle events

☐ (SCFL:NONSICK) Subject experienced one or more non-sickle related events

☐ (SCFL:PRIMARY) Other reason, ***Specify:*** SCFL:OTHSP

Did the subject complete Visit 1? ☐ (SCFL:COMPLV1)Yes ☐ (SCFL:COMPLV1)No

☐ **If no,** please provide the Date of Informed Consent.

Date of Informed Consent: SCFL:INFRMDA / SCFL:INFRMMO / SCFL:INFRMYR
Day Month Year

☐ **If yes,** be sure to complete all Visit 1 CRFs.

Is this subject eligible for a Re-screening Visit? ☐ (SCFL:SUBELIG)Yes ☐ (SCFL:SUBELIG)No

☐ **If no,** specify the reason the subject is not eligible.

Reason, ***Specify:*** SCFL:NOELGSP

Investigator's Statement:
I have reviewed the data entries within this CRF and, to the best of my knowledge, the data represent a complete and accurate record of the subject's participation in the study.

☐ (SCFL:PISIG) PI Signature Signature Date: SCFL:SIGDA / SCFL:SIGMO / SCFL:SIGYR
Day Month Year

Submit Query | Cancel | Form Completion Help | Print

Comprehensive Sickle Cell Centers	**Interim Health History**	**{visit.label}**
Hydroxyurea & Magnesium Pidolate (CHAMPS)	**Date of Visit:** IHHX:VISITDA / IHHX:VISITMO / IHHX:VISITYR (Day / Month / Year)	CSCC ID: {subject.name} Center code: {center.name} Hospital code: {center.hospital.name}

All questions relate to events since the previous study visit.

1) Has the subject had acute events that led to a visit to physician's office/clinic/emergency department/ day hospital/urgent care facility, or a hospitalization? ☐ (IHHX:EVENT)Yes ☐ (IHHX:EVENT)No

☐ **If yes**, click the "ADD" button and record information for each event.

Remove

Treatment Location:		**Date of Encounter:**	
☐ (HTRE:PHYSICN)	Physician's Office / Clinic	HTRE:PHYSDA / HTRE:PHYSMO / HTRE:PHYSYR (Day/Month/Year)	
☐ (HTRE:EDURGCR)	Emergency Department / Day Hospital / Urgent Care	HTRE:EMERDA / HTRE:EMERMO / HTRE:EMERYR (Day/Month/Year)	
		Date Admitted:	**Date Discharged:**
☐ (HTRE:HOSPITL)	Hospital	HTRE:HADMDA / HTRE:HADMMO / HTRE:HADMYR (Day/Month/Year)	HTRE:HDISDA / HTRE:HDISMO / HTRE:HDISYR Day/Month/Year)

Reason(s)[1]:

☐ (HTRE:PAINCRI)	Pain crisis[2]	☐ (HTRE:ACS)	ACS[3]	☐ (HTRE:FEVER)	Fever	☐ (HTRE:SPLENIC) Acute splenic sequestration
☐ (HTRE:STROKE)	Clinical stroke	☐ (HTRE:CANCER)	Cancer	☐ (HTRE:PRIAP)	Priapism	☐ (HTRE:HEPAT) Hepatic sequestration
☐ (HTRE:RSNOT)	Other, specify HTRE:RSNOTS					

Add Visit

2) Has the subject had any pain crisis(es) at home[4] for which there was no hospitalization or emergency department/ day hospital/ urgent care visit? ☐ (IHHX:PCRISIS)Yes ☐ (IHHX:PCRISIS)No

☐ **If yes**, how many pain crises were treated at home: IHHX:PCHOME

3) Blood transfusion? ☐ (IHHX:BTRANS) Yes ☐ (IHHX:BTRANS) No

☐ **If yes**, click the "ADD" button and record date and number of units or cc's for each transfusion.

	Remove
Date Transfused: TRAN:TRANDA / TRAN:TRANMO / TRAN:TRANYR (Day/Month/Year)	
Number: TRAN:VOLUME	Units/cc's Select one: TRAN:UNIT **OR** ☐ (TRAN:UNITUNK) units/cc's unknown
Reason for Transfusion:	TRAN:REASON
Other, Specify:	TRAN:OTHSP

Add Transfusion

1 Complete AE and/or SAE forms for each reason.

2 A pain crisis is defined here as the occurrence of pain in the extremities, back, abdomen, chest, or head that lasts at least 2 hours; requires a visit to a hospital, Emergency Department, clinic, or provider's office; and is not explained except by sickle cell disease.

3 Acute chest syndrome is defined as a new pulmonary infiltrate on chest x-ray associated with fever (> 38.5° C), tachypnea, wheezing, cough, or chest pain.

4 A painful crisis at home must be a new event, not a steady state situation. A pain crisis at home is defined as the occurrence of pain in the extremities, back, abdomen, chest, or head that lasts at least 2 hours and is not explained except by sickle cell disease. Ongoing pain at home that occurs every day should not be considered a painful crisis at home.

Comments for page:
IHHX:COMTXT

Submit Query | Cancel | Form Completion Help | Print

Comprehensive Sickle Cell Centers	**Interim Health History**	**{visit.label}**
Hydroxyurea & Magnesium Pidolate (CHAMPS)		CSCC ID: {subject.name} Center code: {center.name} Hospital code: {center.hospital.name}

All questions relate to events since {visit.num}

Cancer

Since {visit.num2} has the subject been diagnosed with cancer? ☐ (CAN1:CANCER)Yes ☐ (CAN1:CANCER)No

☐ **If yes,** record details below and complete a Serious Adverse Event form.

Remove

Date diagnosed:	CANA:DIAGDA / CANA:DIAGMO / CANA:DIAGYR Day Month Year	Type:	CANA:CANTYPE
		Location:	CANA:CANLOC

Add

Neuroimaging

Since {visit.num3} has the subject undergone any neuroimaging procedures? ☐ (CAN1:NEUROPR)Yes ☐ (CAN1:NEUROPR)No

☐ **If yes**, click the ADD button, and record details for each type of test.

☐ Complete one record for each type of test.

Remove

Date of test:	NEU1:TESTDA / NEU1:TESTMO / NEU1:TESTYR (Day/Month/Year)
Type of test[1]:	☐ (NEU1:TYPE) MRI ☐ (NEU1:TYPE) MRA ☐ (NEU1:TYPE) CT ☐ (NEU1:TYPE) Cerebral angiography ☐ (NEU1:TYPE) Other, specify NEU1:TYPEOTS Was this result abnormal? ☐ (NEU1:RSLTABN) Yes[2] ☐ (NEU1:RSLTABN) No ☐ (NEU1:RSLTABN) Equivocal[3] **If yes,** describe brief findings: NEU1:FINDING

Add Test

[1] Information about **"types of tests"** may be downloaded from the CHAMPS web page on the CSCC website.

[2] If **"result abnormal"** is **Yes** or **Equivocal,** fax results to the attention of CHAMPS at the SDMC (Rho, Inc.) 919-287-0126.

[3] If **"result abnormal"** is **Yes** or **Equivocal,** complete Adverse Event form.

Submit Query | Cancel | Print

Comprehensive Sickle Cell Centers	**Physical Exam**	**{visit.label}**
Hydroxyurea & Magnesium Pidolate (CHAMPS)		CSCC ID: {subject.name} Center code: {center.name} Hospital code: {center.hospital.name}

Physical Exam

☐ (PHE2:PHEXND) Not Done ☐ Specify: PHE2:NDSPEC

1) Weight[1]: PHE2:WEIGHT (kg)

2) Is the spleen palpable? ☐ (PHE2:SPLEEN) Yes[2] ☐ (PHE2:SPLEEN)No

☐ *If **Yes,** what is the current spleen size?* PHE2:SLPESP cm

(at the greatest distance below the left costal margin)

3) Does the subject have any new skin lesions? ☐ (PHE2:LESION)Yes[2] ☐ (PHE2:LESION)No

☐ *If **Yes,** where are the lesions located:* PHE2:LESISP

4) Is the subject taking any medication since previous visit? ☐ (PHE2:MEDIC) Yes ☐ (PHE2:MEDIC)No

☐ *If **Yes,** record information on the Concomitant Medications CRF.*

1 Use the weight recorded at this visit to determine if the dose should be adjusted at the next study visit. Refer to the dosing tables in the "Study Drug" section of the Subject Study Binder.

2 If yes, update or add to the AE page as appropriate.

Submit Query | Cancel | Print

Comprehensive Sickle Cell Centers	**Hematology Labs**	**{visit.label}**
Hydroxyurea & Magnesium Pidolate (CHAMPS)		CSCC ID: {subject.name} Center code: {center.name} Hospital code: {center.hospital.name}

*Collection Date: HEM2:COLLDA / HEM2:COLLMO / HEM2:COLLYR

Day Month Year

☐ (HEM2:HEMAND) **Labs not done**

☐ *Specify:* HEM2:NDSPEC

TEST	VALUE	
Hemoglobin (g/dL)	HEM2:HGB	
Hematocrit (%)	HEM2:HCT	
RBC (x10^6/mm^3)	HEM2:RBC	
WBC (x10^3/mm^3)	HEM2:WBC	
MCV (fl)	HEM2:MCV	
MCHC (g/dL)	HEM2:MCHC	
Platelet count (x10^3/mm^3)	HEM2:PLT	
% Retic **OR** **ARC (x10^3/mm^3)**	HEM2:RET HEM2:ARC	Either % Retic **OR** ARC should be provided. Use the same unit for this subject at all study visits.
ANC (/mm^3)	HEM2:ANC	

*If the collection date differs from the visit date for this visit, explain:
HEM2:DATEDIS

Submit Query | Cancel | Form Completion Help | Print

Comprehensive Sickle Cell Centers	**Chemistry Labs**	**{visit.label}**
Hydroxyurea & Magnesium Pidolate (CHAMPS)		CSCC ID: {subject.name} Center code: {center.name} Hospital code: {center.hospital.name}

*Collection Date: CHE2:COLLDA / CHE2:COLLMO / CHE2:COLLYR

Day Month Year

☐ (CHE2:CHEMND) **Labs not done**

☐ *Specify:* CHE2:NDSPEC

TEST	VALUE
Sodium (mmol/L)	CHE2:SOD
Potassium (mmol/L)	CHE2:POTAS
Chloride (mmol/L)	CHE2:CHLOR
CO_2 (mmol/L)	CHE2:CO2
BUN (mg/dL)	CHE2:BUN
Creatinine (mg/dL)	CHE2:CREAT
Calcium (mg/dL)	CHE2:CALC
SGPT/ALT (U/L)	CHE2:ALT
Alk phosphatase (U/L)	CHE2:ALKPH
Total bilirubin (mg/dL)	CHE2:TBILI
Total protein (g/dL)	CHE2:TPROT
Albumin (g/dL)	CHE2:ALBUM
LDH (U/L)	CHE2:LDH

*If the collection date differs from the visit date for this visit, explain:
CHE2:DATEDIS

Comprehensive Sickle Cell Centers	**Urinalysis**	**{visit.label}**
Hydroxyurea & Magnesium Pidolate (CHAMPS)		CSCC ID: {subject.name} Center code: {center.name} Hospital code: {center.hospital.name}

*Collection Date: URIN:COLLDA / URIN:COLLMO / URIN:COLLYR
Day Month Year

☐ (URIN:URINND) **Labs not done**

Specify: URIN:NDSPEC

Protein: *(Select one, as reported by your lab)*:							
☐ (URIN:PROTEIN) Negative	☐ (URIN:PROTEIN) Trace	☐ (URIN:PROTEIN) 100	☐ (URIN:PROTEIN) 200	☐ (URIN:PROTEIN) 300	☐ (URIN:PROTEIN) 1+	☐ (URIN:PROTEIN) 2+	☐ (URIN:PROTEIN) 3+
Microscopic RBC (#/mm^3):							
☐ (URIN:MCRORBC) Negative	☐ (URIN:MCRORBC) 0-5	☐ (URIN:MCRORBC) 5-10	☐ (URIN:MCRORBC) 10-25	☐ (URIN:MCRORBC) 25-50	☐ (URIN:MCRORBC)50+		
Microscopic WBC (#/mm^3):							
☐ (URIN:WBC) Negative	☐ (URIN:WBC)0-5	☐ (URIN:WBC)5-10	☐ (URIN:WBC)10-25	☐ (URIN:WBC)25-50	☐ (URIN:WBC)50+		

*If the collection date differs from the visit date for this visit, explain:
URIN:DATEDIS

Submit Query Cancel Form Completion Help Print

Comprehensive Sickle Cell Centers	**Hematology Labs**	**{visit.label}**
Hydroxyurea & Magnesium Pidolate (CHAMPS)		CSCC ID: {subject.name} Center code: {center.name} Hospital code: {center.hospital.name}

*Collection Date: HEM3:COLLDA / HEM3:COLLMO / HEM3:COLLYR
Day Month Year

☐ (HEM3:HEMAND) **Labs not done**

→ *Specify:* HEM3:NDSPEC

TEST	VALUE
Hemoglobin (g/dL)	HEM3:HGB
Hematocrit (%)	HEM3:HCT
RBC (x10^6/mm^3)	HEM3:RBC
WBC (x10^3/mm^3)	HEM3:WBC
MCV (fl)	HEM3:MCV
MCHC (g/dL)	HEM3:MCHC
Platelet count (x10^3/mm^3)	HEM3:PLT
% Retic **OR** **ARC (x10^3/mm^3)**	HEM3:RET HEM3:ARC
ANC (/mm^3)	HEM3:ANC

Electrophoresis

Hb A (%) HEM3:ELECTRO

☐ (HEM3:ELECND) Not Done– No recent transfusion or Hb A (%) ⩽ 10 at previous visit

☐ (HEM3:ELECND) Not Done– Suspect Hb A (%) > 10

HU/Placebo Toxicity Check!

ANC < 1000/mm^3

Platelet count < 75 x10^3/mm^3

Hb ⩾ 20% ↓ from Visit 1

Total Hb < 5 g/dL or > 13.5 g/dL

Either % Retic **OR** ARC should be provided.

Use the same unit for this subject at all study visits.

*If the collection date differs from the visit date for this visit, explain:
HEM3:DATEDIS

If toxicity occurs, stop the study drug associated with the toxicity.

Submit Query | Cancel | Form Completion Help | Print

Comprehensive Sickle Cell Centers	**Chemistry Labs**	**{visit.label}**
Hydroxyurea & Magnesium Pidolate (CHAMPS)		CSCC ID: {subject.name} Center code: {center.name} Hospital code: {center.hospital.name}

Was a chemistry lab conducted for evaluation of toxicity? ☐ (CHE3:TOXI) Yes ☐ (CHE3:TOXI) No

☐ **If yes,** complete this page.

☐ **If no,** leave the remainder of the page blank.

*Collection Date: CHE3:COLLDA / CHE3:COLLMO / CHE3:COLLYR
Day Month Year

TEST	VALUE	
		HU/Placebo Hepatic Toxicity Check **SGPT** > 2x upper limit of normal
Creatinine (mg/dL)	CHE3:CREAT ☐ (CHE3:CREATNR)Not required	**HU/Placebo Renal Toxicity Check** **Creatinine** ⩾ 1.2 mg/dL subjects < 18 years of age **Creatinine** ⩾ 1.4 mg/dL subjects ⩾ 18 years of age
SGPT/ALT (U/L)	CHE3:ALT ☐ (CHE3:ALTNR)Not required	
		If toxicity occurs, stop the study drug associated with the toxicity.

*If the collection date differs from the visit date for this visit, explain:
CHE3:DATEDIS

Submit Query | Cancel | Form Completion Help | Print

Comprehensive Sickle Cell Centers	**Mg/Placebo Toxicity Check**	**{visit.label}**
Hydroxyurea & Magnesium Pidolate (CHAMPS)		CSCC ID: {subject.name} Center code: {center.name} Hospital code: {center.hospital.name}

All questions relate to events since the previous visit.

1)	**Since the last visit, diarrhea has/is:** ☐ **(MGTX:DIARRNA)** Diarrhea was not evaluated at this visit					
	☐ (MGTX:DIARR) Resolved	☐ (MGTX:DIARR) Ongoing	☐ (MGTX:DIARR) Worsened	☐ (MGTX:DIARR) New	☐ (MGTX:DIARR)Not present at this visit and was not present at the previous visit	
	☐ **If new, ongoing, or worsened:**					
	Grade:	☐ (MGTX:GRADE) **1**	☐ (MGTX:GRADE) **2**	☐ (MGTX:GRADE) **3**	☐ (MGTX:GRADE) **4**	☐ *See CRF Completion Guidelines for grading criteria.*
		☐ *For **all Grades** complete AE form*				
		☐ *For **Grade 3** complete SAE form if subject is hospitalized*				
		☐ *For **Grade 4** complete SAE form*				
	Duration: MGTX:DURDAYS Days MGTX:DURHOUR Hours					

2)	**Since the last visit, abdominal pain has/is:** ☐ **(MGTX:ABDOMNA)** Abdominal pain was not evaluated at this visit				
	☐ (MGTX:ABDOM) Resolved	☐ (MGTX:ABDOM) Ongoing	☐ (MGTX:ABDOM) Worsened	☐ (MGTX:ABDOM) New	☐ (MGTX:ABDOM) Not present at this visit and was not present at the previous visit
	☐ **If ongoing, worsened, or new,** is pain severe enough to interfere with daily activities? ☐ (MGTX:SEVERE)Yes ☐ (MGTX:SEVERE)No				
	☐ ***If resolved** or **ongoing** modify AE Form as appropriate*				
	☐ ***If new,** add AE to AE Form*				

3)	**Since last visit, signs of dehydration have/are?** ☐ **(MGTX:DEHYDNA)** Dehydration was not evaluated at this visit				
	☐ (MGTX:DEHYDR) Resolved	☐ (MGTX:DEHYDR) Ongoing	☐ (MGTX:DEHYDR) Worsened	☐ (MGTX:DEHYDR) New	☐ (MGTX:DEHYDR) Not present at this visit and was not present at the previous visit
	☐ ***If resolved** or **ongoing** modify AE Form as appropriate*				
	☐ ***If new,** add AE to AE Form*				

4)	**Does/did subject meet criteria for Mg/Placebo toxicity*?** ☐ (MGTX:CRITER)Yes ☐ (MGTX:CRITER)No
	☐ ***If yes,** complete AE Form.*

5)	**What action was taken with Mg/Placebo?** ☐ (MGTX:ACTION)No change ☐ (MGTX:ACTION) Withheld ☐ (MGTX:ACTION)Modified
	☐ ***If withheld or modified,*** *update the Mg/Placebo Study Drug Dosing Log.*

*A toxicity exists if the subject has had diarrhea of grade 3 or 4 **OR** if it persists for more than 72 hours **OR** if there are signs of dehydration from diarrhea **OR** if the subject has abdominal pain severe enough to interfere with daily activities.

Submit Query | Cancel | Form Completion Help | Print

Comprehensive Sickle Cell Centers	**HU/Placebo Toxicity Check**	**{visit.label}**
Hydroxyurea & Magnesium Pidolate (CHAMPS)		CSCC ID: {subject.name} Center code: {center.name} Hospital code: {center.hospital.name}

All questions relate to events <u>since the previous visit.</u>

HU/Placebo Hepatic Toxicity Check				
SGPT > 2x upper limit of normal				
1) Hepatic toxicity? ☐ **(HYTX:HEPNA)** Hepatic toxicity was not evaluated at this visit				
☐ (HYTX:HEPTOX) Resolved	☐ (HYTX:HEPTOX) Ongoing	☐ (HYTX:HEPTOX) Worsened	☐ (HYTX:HEPTOX) New	☐ (HYTX:HEPTOX) Not present at this visit and was not present at the previous visit
HU/Placebo Renal Toxicity Check				
Creatinine ≥ 1.2 mg/dL subjects < 18 years of age **Creatinine** ≥ 1.4 mg/dL subjects ≥ 18 years of age				
2) Renal toxicity? ☐ **(HYTX:RENALNA)** Renal toxicity was not evaluated at this visit				
☐ (HYTX:RENTOX) Resolved	☐ (HYTX:RENTOX) Ongoing	☐ (HYTX:RENTOX) Worsened	☐ (HYTX:RENTOX) New	☐ (HYTX:RENTOX) Not present at this visit and was not present at the previous visit
HU/Placebo Hematologic Toxicity Check *(one or more of the following)*				
1. ANC < 1000/mm^3 **2. Hb** ≥ 20% ☐ from Visit 1 **3. Platelet count** < 75x10^3/mm^3 **4. Total Hb** < 5 or > 13.5 g/dL				
3) Hematologic toxicity? ☐ **(HYTX:HEMANA)** Hematologic toxicity was not evaluated at this visit				
☐ (HYTX:HEMTOX) Resolved	☐ (HYTX:HEMTOX) Ongoing	☐ (HYTX:HEMTOX) Worsened	☐ (HYTX:HEMTOX) New	☐ (HYTX:HEMTOX) Not present at this visit and was not present at the previous visit
*If any toxicity is **new, resolved** or **ongoing** modify AE Form as appropriate*				
What action was taken with Hydroxyurea/placebo? ☐ (HYTX:ACTION)No change ☐ (HYTX:ACTION)Withheld ☐ (HYTX:ACTION)Modified				
☐ ***If withheld or modified**, update the HU/placebo Study Drug Dosing Log*				

Submit Query | Cancel | Form Completion Help | Print

Comprehensive Sickle Cell Centers	**Chemistry Labs**	**{visit.label}**
Hydroxyurea & Magnesium Pidolate (CHAMPS)		CSCC ID: {subject.name} Center code: {center.name} Hospital code: {center.hospital.name}

***Collection Date:** CHE5:COLLDA / CHE5:COLLMO / CHE5:COLLYR

Day Month Year

☐ (CHE5:CHEMND) **Labs not done**

☐ *Specify:* CHE5:NDSPEC

TEST	VALUE
Sodium (mmol/L)	CHE5:SOD
Potassium (mmol/L)	CHE5:POTAS
Chloride (mmol/L)	CHE5:CHLOR
CO_2 (mmol/L)	CHE5:CO2
BUN (mg/dL)	CHE5:BUN
Creatinine (mg/dL)	CHE5:CREAT
Calcium (mg/dL)	CHE5:CALC
SGPT/ALT (U/L)	CHE5:ALT
Alk phosphatase (U/L)	CHE5:ALKPH
Total bilirubin (mg/dL)	CHE5:TBILI
Total protein (g/dL)	CHE5:TPROT

HU/Placebo Hepatic Toxicity Check
SGPT > 2x upper limit of normal

HU/Placebo Renal Toxicity Check
Creatinine ⩾ 1.2 mg/dL subjects < 18 years of age **Creatinine** ⩾ 1.4 mg/dL subjects ⩾ 18 years of age

If toxicity occurs, <u>stop</u> the study drug associated with the toxicity.

Albumin (g/dL)	CHE5:ALBUM
LDH (U/L)	CHE5:LDH

*If the collection date differs from the visit date for this visit, explain:
CHE5:DATEDIS

Submit Query | Cancel | Form Completion Help | Print

Comprehensive Sickle Cell Centers	**Interim Health History**	**{visit.label}**
Hydroxyurea & Magnesium Pidolate (CHAMPS)	**Date of Visit:** IHH2:VISITDA / IHH2:VISITMO / IHH2:VISITYR (Day / Month / Year)	CSCC ID: {subject.name} Center code: {center.name} Hospital code: {center.hospital.name}

Expected Date of Next Visit: IHH2:EXVISDA / IHH2:EXVISMO / IHH2:EXVISYR (Day / Month / Year) ☐ *Email date to CHAMPS_labs@rhoworld.com*

All questions relate to events since the previous study visit.

1) Has the subject had acute events that led to a visit to physician's office/clinic/emergency department/ day hospital/urgent care facility, or a hospitalization? ☐ (IHH2:EVENT)Yes ☐ (IHH2:EVENT)No

☐ **If yes**, click the "ADD" button and record information for each event.

Remove

Treatment Location:		**Date of Encounter:**	
☐ (HTRE:PHYSICN)	Physician's Office / Clinic	HTRE:PHYSDA / HTRE:PHYSMC / HTRE:PHYSYR (Day/Month/Year)	
☐ (HTRE:EDURGCR)	Emergency Department / Day Hospital / Urgent Care	HTRE:EMERDA / HTRE:EMERMO / HTRE:EMERYR (Day/Month/Year)	
		Date Admitted:	**Date Discharged:**
☐ (HTRE:HOSPITL)	Hospital	HTRE:HADMDA / HTRE:HADMMO / HTRE:HADMYR (Day/Month/Year)	HTRE:HDISDA / HTRE:HDISMO / HTRE:HDISYR Day/Month/Year)

Reason(s)[1]:

☐ (HTRE:PAINCRI)	Pain crisis[2]	☐ (HTRE:ACS)	ACS[3]	☐ (HTRE:FEVER)	Fever	☐ (HTRE:SPLENIC) Acute splenic sequestration
☐ (HTRE:STROKE)	Clinical stroke	☐ (HTRE:CANCER)	Cancer	☐ (HTRE:PRIAP)	Priapism	☐ (HTRE:HEPAT) Hepatic sequestration
☐ (HTRE:RSNOT)	Other, specify HTRE:RSNOTS					

Add Visit

2) Has the subject had any pain crisis(es) at home[4] for which there was no hospitalization or emergency department/ day hospital/ urgent care visit? ☐ (IHH2:PCRISIS)Yes ☐ (IHH2:PCRISIS)No

☐ **If yes**, how many pain crises were treated at home: IHH2:PCHOME

3) Blood transfusion? ☐ (IHH2:BTRANS) Yes ☐ (IHH2:BTRANS) No

☐ **If yes**, click the "ADD" button and record date and number of units or cc's for each transfusion.

	Remove
Date Transfused: TRAN:TRANDA / TRAN:TRANMC/ TRAN:TRANYR (Day/Month/Year)	
Number: TRAN:VOLUME	Units/cc's Select one: TRAN:UNIT **OR** ☐ (TRAN:UNITUNK) units/cc's unknown
Reason for Transfusion:	TRAN:REASON
Other, Specify:	TRAN:OTHSP

Add Transfusion

1 Complete AE and/or SAE forms for each reason.

2 A pain crisis is defined here as the occurrence of pain in the extremities, back, abdomen, chest, or head that lasts at least 2 hours; requires a visit to a hospital, Emergency Department, clinic, or provider's office; and is not explained except by sickle cell disease.

3 Acute chest syndrome is defined as a new pulmonary infiltrate on chest x-ray associated with fever (> 38.5° C), tachypnea, wheezing, cough, or chest pain.

4 A painful crisis at home must be a new event, not a steady state situation. A pain crisis at home is defined as the occurrence of pain in the extremities, back, abdomen, chest, or head that lasts at least 2 hours and is not explained except by sickle cell disease. Ongoing pain at home that occurs every day should not be considered a painful crisis at home.

Comments for page:
IHH2:COMTXT

Submit Query | Cancel | Form Completion Help | Print

Comprehensive Sickle Cell Centers	**Chemistry Labs**	**{visit.label}**
Hydroxyurea & Magnesium Pidolate (CHAMPS)		CSCC ID: {subject.name} Center code: {center.name} Hospital code: {center.hospital.name}

*Collection Date: CHE4:COLLDA / CHE4:COLLMO / CHE4:COLLYR

Day Month Year

☐ (CHE4:CHEMND) **Labs not done**

☐ *Specify:* CHE4:NDSPEC

TEST	VALUE
Sodium (mmol/L)	CHE4:SOD
Potassium (mmol/L)	CHE4:POTAS
Chloride (mmol/L)	CHE4:CHLOR
CO_2 (mmol/L)	CHE4:CO2
BUN (mg/dL)	CHE4:BUN
Creatinine (mg/dL)	CHE4:CREAT
Calcium (mg/dL)	CHE4:CALC
SGPT/ALT (U/L)	CHE4:ALT
Alk phosphatase (U/L)	CHE4:ALKPH
Total bilirubin (mg/dL)	CHE4:TBILI
Total protein (g/dL)	CHE4:TPROT

HU/Placebo Hepatic Toxicity Check
SGPT > 2x upper limit of normal

HU/Placebo Renal Toxicity Check
Creatinine ⩾ 1.2 mg/dL subjects < 18 years of age **Creatinine** ⩾ 1.4 mg/dL subjects ⩾ 18 years of age

Albumin (g/dL)	CHE4:ALBUM
LDH (U/L)	CHE4:LDH

*If the collection date differs from the visit date for this visit, explain:
CHE4:DATEDIS

Submit Query | Cancel | Form Completion Help | Print

Comprehensive Sickle Cell Centers	**Hematology Labs**	**{visit.label}**
Hydroxyurea & Magnesium Pidolate (CHAMPS)		CSCC ID: {subject.name} Center code: {center.name} Hospital code: {center.hospital.name}

Hematology Labs only required at this visit for evaluation of unresolved toxicity.

Was a hematology lab conducted for evaluation of toxicity? ☐ (HEM4:TOXI) Yes ☐ (HEM4:TOXI) No

☐ **If yes,** complete this page.

***Collection Date:** HEM4:COLLDA / HEM4:COLLMO / HEM4:COLLYR
Day Month Year

TEST	VALUE
Hemoglobin (g/dL)	HEM4:HGB
Hematocrit (%)	HEM4:HCT
RBC ($x10^6/mm^3$)	HEM4:RBC
WBC ($x10^3/mm^3$)	HEM4:WBC
MCV (fl)	HEM4:MCV
MCHC (g/dL)	HEM4:MCHC
Platelet count ($x10^3/mm^3$)	HEM4:PLT

Electrophoresis

Hb A (%)	HEM4:ELECTRC ☐ (HEM4:ELECND) Not Done–No recent transfusion or Hb A (%) ⩽ 10 at previous visit ☐ (HEM4:ELECND) Not Done–Suspect Hb A (%) > 10

HU/Placebo Toxicity Check!

ANC < $1000/mm^3$

Platelet count < $75 x10^3/mm^3$

% Retic **OR** **ARC (x10^3/mm^3)**	HEM4:RET HEM4:ARC	**Hb** ⩾ 20% ☐ from Visit 1 **Total Hb** < 5 g/dL or > 13.5 g/dL Either % Retic **OR** ARC should be provided. Use the same unit for this subject at all study visits.
ANC (/mm^3)	HEM4:ANC	

s

*If the collection date differs from the visit date for this visit, explain:

HEM4:DATEDIS

If toxicity occurs, stop the study drug associated with the toxicity.

Submit Query | Cancel | Form Completion Help | Print

Comprehensive Sickle Cell Centers	**Study Completion**	**{visit.label}**
Hydroxyurea & Magnesium Pidolate (CHAMPS)		CSCC ID: {subject.name} Center code: {center.name} Hospital code: {center.hospital.name}

Date of last visit: COMP:LASTDA / COMP:LASTMC / COMP:LASTYR
Day Month Year

Did the subject complete the study? ☐ (COMP:CMPLT)Yes ☐ (COMP:CMPLT)No

☐ **If no**, record the date of last contact and select the **primary** reason for early withdrawal from below.

Date of last contact: COMP:CONTDA / COMP:CONTMC / COMP:CONTYR
Day Month Year

Reasons for early withdrawal:

☐ (COMP:PRIMARY) In the investigator's opinion the subject's health, safety and/or well-being was threatened by continued participation in the study

☐ (COMP:PRIMARY) Subject was nonadherent. ***Specify:*** COMP:NONASR

☐ (COMP:PRIMARY) Subject lost to follow-up

☐ (COMP:PRIMARY) Subject or subject's legal representative requested to withdraw. ***Specify:*** COMP:LEGSP

☐ (COMP:PRIMARY) Discontinuation *(check all that apply)*

☐ (COMP:DECLINE)Decline in Hb level to < 5 g/dL

☐ (COMP:INCREAS)Increase in Hb level to > 13.5 g/dL (viscosity concerns)

☐ (COMP:CHRONIC)Initiation of chronic transfusion

☐ (COMP:HEPATIC)Hepatic dysfunction (SGPT > 2x upper limit of normal)

☐ (COMP:RENAL)Renal toxicity (creatinine ≥ 1.2 mg/dL if age < 18 years, creatinine ≥ 1.4 mg/dL if age ≥ 18 years)

☐ (COMP:PREG)Pregnancy

☐ (COMP:STROKE)Stroke

☐ (COMP:PULMNRY)Pulmonary failure requiring intubation

☐ (COMP:TOXICTY)Grade 3 or 4 toxicity lasting longer than

two weeks

☐ (COMP:INGEST)Unable to orally ingest the study drug

☐ (COMP:PRIMARY) Other adverse event or significant concurrent illness, ***Specify:*** COMP:OAESP

☐ (COMP:PRIMARY) Other, ***Specify:*** COMP:OTHSP

Investigator:

In your opinion, into which arm was this subject randomized?

☐ (COMP:GUESIN) Hydroxyurea & Magnesium

☐ (COMP:GUESIN) Hydroxyurea Placebo & Magnesium

☐ (COMP:GUESIN) Hydroxyurea & Magnesium Placebo

☐ (COMP:GUESIN) Hydroxyurea Placebo & Magnesium Placebo

☐ (COMP:GUESIN) No opinion

Study Coordinator:

In your opinion, into which arm was this subject randomized?

☐ (COMP:GUESST) Hydroxyurea & Magnesium

☐ (COMP:GUESST) Hydroxyurea Placebo & Magnesium

☐ (COMP:GUESST) Hydroxyurea & Magnesium Placebo

☐ (COMP:GUESST) Hydroxyurea Placebo & Magnesium Placebo

☐ (COMP:GUESST) No opinion

Subject: Ask this question if the Subject is at least 14 years of age; skip to "Parent/Guardian" if the Subject is < 14.
Note that you will also ask this question of the Parent/Guardian for all Subjects under the age of 18.

In your opinion, into which arm were you randomized?

☐ (COMP:GUESSU) Hydroxyurea & Magnesium. If marked:

☐ Would you want to continue using Hydroxyurea?

☐ (COMP:SHYDROX)
Yes ☐ (COMP:SHYDROX)
No ☐ (COMP:SHYDROX)
Don't know

☐ Would you want to continue using Magnesium?

☐ (COMP:SMAGNES)
Yes ☐ (COMP:SMAGNES)
No ☐ (COMP:SMAGNES)
Don't know

☐ (COMP:GUESSU) Hydroxyurea Placebo & Magnesium. If marked:

☐ Would you want to continue using Magnesium?

☐ (COMP:SMGONLY)
Yes ☐ (COMP:SMGONLY)
No ☐ (COMP:SMGONLY)

Don't know

☐ (COMP:GUESSU) Hydroxyurea & Magnesium Placebo. If marked:

☐ Would you want to continue using Hydroxyurea? ☐ (COMP:SHUONLY) Yes ☐ (COMP:SHUONLY) No ☐ (COMP:SHUONLY) Don't know

☐ (COMP:GUESSU) Hydroxyurea Placebo & Magnesium Placebo

☐ (COMP:GUESSU) No opinion

☐ (COMP:GUESSU) *Not asked, subject < 14 years old*

☐ (COMP:GUESSU) *Not asked, other reason:*

Specify: COMP:SUNARE

Parent/Guardian: Ask this question if the Subject is less than 18 years of age.

In your opinion, into which arm was the subject randomized?

☐ (COMP:GUESPG) Hydroxyurea & Magnesium. If marked:

☐ Would you want the subject to continue using Hydroxyurea? ☐ (COMP:PHYDROX) Yes ☐ (COMP:PHYDROX) No ☐ (COMP:PHYDROX) Don't know

☐ Would you want the subject to continue using Magnesium? ☐ (COMP:PMAGNES) Yes ☐ (COMP:PMAGNES) No ☐ (COMP:PMAGNES) Don't know

☐ (COMP:GUESPG) Hydroxyurea Placebo & Magnesium. If marked:

☐ Would you want the subject to continue using Magnesium? ☐ (COMP:PMGONLY) Yes ☐ (COMP:PMGONLY) No ☐ (COMP:PMGONLY) Don't know

☐ (COMP:GUESPG) Hydroxyurea & Magnesium Placebo. If marked:

☐ Would you want the subject to continue using Hydroxyurea? ☐ (COMP:PHUONLY) Yes ☐ (COMP:PHUONLY) No ☐ (COMP:PHUONLY) Don't know

☐ (COMP:GUESPG) Hydroxyurea Placebo & Magnesium Placebo

☐ (COMP:GUESPG) No opinion

Comprehensive Sickle Cell Centers	**HU/Placebo Study Drug Dosing Log**	**{visit.label}**
Hydroxyurea & Magnesium Pidolate (CHAMPS)		CSCC ID: {subject.name} Center code: {center.name} Hospital code: {center.hospital.name}

Initial Dose:

Dose (mg/kg/day)	**Dose** (mg)	**Start Date** DD MMM YYYY	**Stop Date** DD MMM YYYY
HYAD:INDOSE1	HYAD:INDOSE	HYAD:INSTRDA / HYAD:INSTRMO / HYAD:INSTRYR	HYAD:INSTPDA / HYAD:INSTPMO / HYAD:INSTPYR

Dose Changed or Interrupted:

→ If necessary, complete **AE Form** if dose was changed or interrupted.

→ Click the "Add" button **each time** HU/placebo dose is **changed or interrupted** and record the following information.

Dose (mg/kg/day)	**Dose** (mg)	**Start Date** DD MMM YYYY	**Stop Date** DD MMM YYYY
HYLG:DOSECH	HYLG:LGDOSE	HYLG:LGSTRDA / HYLG:LGSTRMO / HYLG:LGSTRYR	HYLG:LGSTPDA / HYLG:LGSTPMO / HYLG:LGSTPYR
			Remove

Add Row

Submit Query | Cancel | Form Completion Help | Print

Comprehensive Sickle Cell Centers	**Mg/Placebo Study Drug Dosing Log**	**{visit.label}**
Hydroxyurea & Magnesium Pidolate (CHAMPS)		CSCC ID: {subject.name} Center code: {center.name} Hospital code: {center.hospital.name}

Initial Dose:

Dose (mEq/kg B.I.D.)	**Dose (B.I.D.)** (mL)	**Start Date** DD MMM YYYY	**Stop Date** DD MMM YYYY
MGAD:INDOSE1	MGAD:INDOSE	MGAD:INSTRDA / MGAD:INSTRMO / MGAD:INSTRYR	MGAD:INSTPDA / MGAD:INSTPMO / MGAD:INSTPYR

Dose Changed or Interrupted:

- If necessary, complete **AE Form** if dose was changed or interrupted.
- Click the "Add" button **each time** Mg/placebo dose is **changed or interrupted** and record the following information.

Dose (mEq/kg B.I.D.)	**Dose (B.I.D.)** (mL)	**Start Date** DD MMM YYYY	**Stop Date** DD MMM YYYY
MGLG:DOSECH	MGLG:LGDOSE	MGLG:LGSTRDA / MGLG:LGSTRMO / MGLG:LGSTRYR	MGLG:LGSTPDA / MGLG:LGSTPMO / MGLG:LGSTPYR
			Remove
*Complete AE Form for each dose change or interruption.			

Add Row

Submit Query | Cancel | Form Completion Help | Print

Comprehensive Sickle Cell Centers	**HU/Placebo Study Drug Record**	**{visit.label}**
Hydroxyurea & Magnesium Pidolate (CHAMPS)	**Randomization Number:** RAND:RANDNUM	CSCC ID: {subject.name} Center code: {center.name} Hospital code: {center.hospital.name}

Remove

Dispense							**Return**		
Visit #	**Start Date ***	**Not Dispensed**	**Bottle Number**	**Prescribed Dose**	**Capsule Type**	**# Capsules Dispensed**	**Total Capsules Returned/ Bottle**	**Not Returned**	**Return Date**
HYSD:VISIT **OR** (HYSD:UNSCED) Unscheduled	HYSD:DISPDA / HYSD:DISPMO / HYSD:DISPYR Day Month Year		HYSD:BOTNUM	HYSD:PDOSE mg	HYSD:CAPTYP	HYSD:CAPDIS	HYSD:RETRN	(HYSD:NTRETR)	HYSD:RETRDA / HYSD:RETRMC / HYSD:RETRYR Day Month Year
		(HYSD:NOTDIS2)	HYSD:BOTNUM2		HYSD:CAPTYP2	HYSD:CAPDIS2	HYSD:RETRN2	(HYSD:NTRETR2)	HYSD:RETRDA2 / HYSD:RETRMO2 / HYSD:RETRYR2 Day Month Year
							NOTE: Return Information must correspond to the bottle number recorded for this dispensing date.		

Comments: HYSD:COMM

*** If the initial start date is more than one day after the date for Visit 2, please indicate why in the Comments field (i.e., initiation of study drug was delayed).**

Add Visit

Submit Query | Cancel | Form Completion Help

Print

Comprehensive Sickle Cell Centers	**Mg/Placebo Study Drug Record**	**{visit.label}**
Hydroxyurea & Magnesium Pidolate (CHAMPS)		CSCC ID: {subject.name} Center code: {center.name} Hospital code: {center.hospital.name}

Remove

Dispense					Return		
Visit #	**Start Date**	**Not Dispensed**	**Bottle Number**	**Prescribed Dose (B.I.D.)**	**Return Volume**	**Not Returned**	**Return Date** (Day/Month/Year)
MGSD:VISIT **OR** (MGSD:UNSCED) Unscheduled	MGSD:DISPDA / MGSD:DISPMO / MGSD:DISPYR Day Month Year		MGSD:BOTNUM	MGSD:PDOSE mL	MGSD:RETRN MGSD:UNIT	(MGSD:NTRETR)	MGSD:RETRDA / MGSD:RETRMO / MGSD:RETRYR
		(MGSD:NOTDIS2)	MGSD:BOTNUM2		MGSD:RETRN2 MGSD:UNIT2	(MGSD:NTRETR2)	MGSD:RETRDA2 / MGSD:RETRMO2 / MGSD:RETRYR2
		(MGSD:NOTDIS3)	MGSD:BOTNUM3		MGSD:RETRN3 MGSD:UNIT3	(MGSD:NTRETR3)	MGSD:RETRDA3 / MGSD:RETRMO3 / MGSD:RETRYR3
					NOTE: Return Information must correspond to the bottle number recorded for this dispensing date.		
Comments: MGSD:COMM							

Add Visit

Submit Query Cancel Form Completion Help Print

Comprehensive Sickle Cell Centers	**Adverse Events Not for Painful Crisis**	**{visit.label}**
Hydroxyurea & Magnesium Pidolate (CHAMPS)		CSCC ID: {subject.name} Center code: {center.name} Hospital code: {center.hospital.name}

Click **New** on the study menu to create a new page for each AE the subject experienced during the study period.

→If subject experienced a pain crisis, complete *AE for Painful Crisis* page.

Adverse Event/Diagnosis	AEXP:ADVERSE
Sickle Cell Related?	AEXP:SCR
AE Start Date	AEXP:ONSETDA / AEXP:ONSETMO / AEXP:ONSETYR (Day/Month/Year)
AE Stop Date	AEXP:STOPDA / AEXP:STOPMO / AEXP:STOPYR (Day/Month/Year)
Serious?	AEXP:SAE *If Yes, complete SAE form.*
Outcome[1]	AEXP:OUTCOME
Severity[2]	AEXP:SEVERE
Relationship to Study Drug[3]	AEXP:RELAT
Action Taken[4] *Record all that apply.*	☐ (AEXP:ACTION1)None ☐ (AEXP:ACTION2)Study treatment interrupted ☐ (AEXP:ACTION3)Study treatment discontinued ☐ (AEXP:ACTION4)Concomitant medication given ☐ (AEXP:ACTION5)Hospitalization ☐ (AEXP:ACTION6)ER/Day hospital ☐ (AEXP:ACTION7)Other, specify AEXP:ACT7SP

[1]OUTCOME	[2]SEVERITY	[3]RELATIONSHIP	[4]ACTION TAKEN
1 Resolved without	1 Mild	1 Unrelated	1 None

=	sequelae	=		=		=	
2 =	Resolved with sequelae	2 =	Moderate	2 =	Probably not/remote	2 =	Study treatment interrupted/modified
3 =	Medically stable	3 =	Severe	3 =	Possibly related	3 =	Study treatment discontinued
4 =	Present at death, not contributing to death	4 =	Life-threatening	4 =	Probably related	4 =	Concomitant medication given/changed
5 =	Death	5 =	Fatal	5 =	Definitely related	5 =	Hospitalization
6 =	Ongoing					6 =	ER/Day hospital
						7 =	Other, specify

Submit Query | Cancel | Form Completion Help | Print

Comprehensive Sickle Cell Centers	**AE for Painful Crisis**	**{visit.label}**
Hydroxyurea & Magnesium Pidolate (CHAMPS)		CSCC ID: {subject.name} Center code: {center.name} Hospital code: {center.hospital.name}

Complete this form for each pain event.

Was this a Serious Adverse Event? ☐ (PAIN:SAE) Yes ☐ (PAIN:SAE) No ☐ If yes, submit an SAE report to SDMC?

Date of onset: PAIN:ONSETDA / PAIN:ONSETMO / PAIN:ONSETYR (Day / Month / Year)

Date of resolution: PAIN:STOPDA / PAIN:STOPMO / PAIN:STOPYR (Day / Month / Year)

Location of Pain *(Check **all** that apply)*

☐ (PAIN:CHEST)Chest ☐ (PAIN:ABDOM)Abdomen ☐ (PAIN:LEGS) Leg(s)
☐ (PAIN:BACK)Back ☐ (PAIN:ARMS)Arm(s) ☐ (PAIN:HEAD) Head & Neck

Type of Pain

☐ (PAIN:TYPE)Typical ☐ (PAIN:TYPE)Atypical

What was the outcome? *(Check **one**)*

☐ (PAIN:OUTCOME)Resolved without sequelae ☐ (PAIN:OUTCOME)Resolved with sequelae ☐ (PAIN:OUTCOME)Ongoing
☐ (PAIN:OUTCOME)Present at death, not contributing to death ☐ (PAIN:OUTCOME)Death due to this AE

What was the level of severity? *(Check **one**)*

☐ (PAIN:SEVERTY)Mild - Home ☐ (PAIN:SEVERTY)Moderate - ER ☐ (PAIN:SEVERTY) Severe - Hospital

What was the relationship to the study drug(s)? *(Check **one**)*

☐ (PAIN:RELATN) Unrelated ☐ (PAIN:RELATN) Probably not related / remote ☐ (PAIN:RELATN) Possibly related ☐ (PAIN:RELATN) Probably related ☐ (PAIN:RELATN) Definitely related

What action was taken? *(Check **all** that apply)*

☐ (PAIN:ACTION1) No Action
☐ (PAIN:ACTION2) Study Treatment Interrupted
☐ (PAIN:ACTION3) Study Treatment Discontinued
☐ (PAIN:ACTION4) Study Treatment Dose Adjusted
☐ (PAIN:ACTION5) Concomitant Medication Given
☐ (PAIN:ACTION6) ER/Day Hospital
☐ (PAIN:ACTION7) Hospitalization

As a result of this AE, was the subject transfused? ☐ (PAIN:TRANSFU) Yes ☐ (PAIN:TRANSFU) No

☐ **If yes,** complete the transfusion section of the Interim Health History form.

Did the pain event evolve into another adverse event? ☐ (PAIN:ADVER) Yes ☐ (PAIN:ADVER) No

☐ **If yes,** complete an Adverse Event form and specify Adverse Event:

Adverse Event, specify: PAIN:ADVERSP

Submit Query | Cancel | Form Completion Help | Print

Comprehensive Sickle Cell Centers	**Concomitant Medications**	**{visit.label}**
Hydroxyurea & Magnesium Pidolate (CHAMPS)		CSCC ID: {subject.name} Center code: {center.name} Hospital code: {center.hospital.name}

Record all medications from Visit 1 to termination of study. Include start dates prior to the study **only** if the medication continues to be taken at Baseline visit.

Medication	CMED:MEDIC
Indication	CMED:INDICAT
Pre-existing	☐ (CMED:PRE) (Check if pre-existing)
Start Date	CMED:STRTDA / CMED:STRTMO / CMED:STRTYR (Day/Month/Year)
Stop Date	CMED:STOPDA / CMED:STOPMO / CMED:STOPYR (Day/Month/Year)
Ongoing	☐ (CMED:ONG) (Check if ongoing)
Information From:	CMED:INFOFRM ▼

Submit Query | Cancel | Form Completion Help | Print

Comprehensive Sickle Cell Centers	**Screening (Re-screen)**	**{visit.label}**
Hydroxyurea & Magnesium Pidolate (CHAMPS)		CSCC ID: {subject.name} Center code: {center.name} Hospital code: {center.hospital.name}

Expected Date of Next Visit: SCR2:EXVISDA / SCR2:EXVISMO / SCR2:EXVISYR ☐ *Email date to CHAMPS_labs@rhoworld.com*

(Within 1-3 weeks of Visit 1) Day Month Year

1) Red Cell Density:

% Hyperdense cells SCR2:HYPER % *% hyperdense cells will be provided via an e-mail from RhoLAB*

If the subject has ≥ 3 percent RBCs with density > 41 g/dL, he/she is eligible to continue in this study.

2) Hemoglobin Level:

Does the subject have a Hb level between 8-12.5 g/dL? ☐ (SCR2:HGB)Yes ☐ (SCR2:HGB)No

If the subject has a Hb level between 8 – 12.5 g/dL, he/she is eligible to continue in this study.

3) Hb A %:

Has the subject been transfused within the past 3 months? ☐ (SCR2:HGBA)Yes ☐ (SCR2:HGBA)No

☐ **If yes**, is the subject's Hb A ≤ 10%? ☐ (SCR2:YHGBA)Yes ☐ (SCR2:YHGBA)No

If the subject has a Hb A % ≤ 10, he/she is eligible to continue in this study.

4) HIV Status: *(tested within the last 12 months)*

Date tested: SCR2:HIVDA / SCR2:HIVMO / SCR2:HIVYR Day Month Year

Result: ☐ (SCR2:HIV) Negative ☐ (SCR2:HIV) Positive

If the subject has a negative HIV test, he/she is eligible to continue in this study.

5) Hepatic Dysfunction:

Within the past month, has the subject had SGPT > 2x the upper limit of normal?

normal? ☐ (SCR2:HEDYS)Yes ☐ (SCR2:HEDYS)No

Screening SGPT level (U/L) SCR2:HESCR

Local lab upper limit of normal (U/L) SCR2:HEUPL

If the subject has not had SGPT > 2x upper limit of normal within the past month, he/she is eligible to continue in this study.

6) Renal Dysfunction:

Within the past month has subject had creatinine ≥ 1.0 mg/dL (if under age 18.0 years) or ≥ 1.2 mg/dL (if age 18.0 years or above)? ☐ (SCR2:REDYS)Yes ☐ (SCR2:REDYS)No

Screening creatinine level (mg/dL) SCR2:RESCR

Local lab upper limit of normal (mg/dL) SCR2:REUPL

If the subject has not had creatinine ≥ 1.0 mg/dL (if under age 18.0 years) or ≥ 1.2 mg/dL (if 18.0 years or above) within the past month, he/she is eligible to continue in this study.

Submit Query | Cancel | Form Completion Help | Print

Comprehensive Sickle Cell Centers	**Screen Failure Log for Re-screening-Visit 1**	**{visit.label}**
Hydroxyurea & Magnesium Pidolate (CHAMPS)		CSCC ID: {subject.name} Center code: {center.name} Hospital code: {center.hospital.name}

This form is to be completed the *second time* the subject discontinues prior to receiving study drug.

Date of last study related contact: SFL1:CONTDA / SFL1:CONTMO / SFL1:CONTYR
Day Month Year

Primary reason the subject will not be enrolled: (Check only one.)

☐ (SFL1:PRIMARY) In the investigator's opinion the subject's health, safety and/or well-being would be threatened by participation in the study.

☐ (SFL1:PRIMARY) Subject lost to follow-up.

☐ (SFL1:PRIMARY) Subject or subject's legal representative requested to withdraw. ***Specify:*** SFL1:LEGSP

☐ (SFL1:PRIMARY) Subject did not meet inclusion/exclusion criteria.

Is subject no longer in steady state after previously meeting inclusion/exclusion criteria? ☐ (SFL1:NOLONG) Yes ☐ (SFL1:NOLONG) No

☐ **If Yes**, check all that apply and complete the Adverse Event Forms.

☐ (SFL1:VASO) Subject experienced one or more vaso-occlusive crises

☐ (SFL1:NONVOC) Subject experienced one or more non-vaso-occlusive sickle events

☐ (SFL1:NONSICK) Subject experienced one or more non-sickle related events

☐ (SFL1:PRIMARY) Other Reason, ***Specify:*** SFL1:OTHSP

Did the subject complete the Re-screening Visit? ☐ (SFL1:COMPLV1)Yes ☐ (SFL1:COMPLV1)No

☐ **If no**, please provide the Date of Informed Consent for the Re-screening Visit.

Date of Informed Consent: SFL1:INFRMDA / SFL1:INFRMMO / SFL1:INFRMYR
Day Month Year

☐ **If yes**, be sure to complete all Re-screening CRFs. Also update as appropriate, the two Medical History forms and the Health History form under the Visit 1 EDC link.

Is this subject eligible for the 2nd Re-screening Visit? ☐ (SFL1:SUBELIG)Yes ☐ (SFL1:SUBELIG)No

☐ **If no**, specify the reason the subject is not eligible.

Reason, ***Specify:*** SFL1:NOELGSP

Investigator's Statement:
I have reviewed the data entries within this CRF and, to the best of my knowledge, the data represent a complete and accurate record of the subject's participation in the study.

☐ (SFL1:PISIG)PI Signature Signature Date: SFL1:SIGDA / SFL1:SIGMO / SFL1:SIGYR
Day Month Year

Submit Query | Cancel | Form Completion Help | Print

Comprehensive Sickle Cell Centers	**Screen Failure Log for 2nd Re-screening-Visit 1**	**{visit.label}**
Hydroxyurea & Magnesium Pidolate (CHAMPS)		CSCC ID: {subject.name} Center code: {center.name} Hospital code: {center.hospital.name}

This form is to be completed the *3rd time* the subject discontinues prior to receiving study drug. The subject is no longer eligible for this study.

Date of last study related contact: SFL2:CONTDA / SFL2:CONTMO / SFL2:CONTYR
Day Month Year

Primary reason the subject will not be enrolled: (Check only one.)

☐ (SFL2:PRIMARY) In the investigator's opinion the subject's health, safety and/or well-being would be threatened by participation in the study.

☐ (SFL2:PRIMARY) Subject lost to follow-up.

☐ (SFL2:PRIMARY) Subject or subject's legal representative requested to withdraw. ***Specify:*** SFL2:LEGSP

☐ (SFL2:PRIMARY) Subject did not meet inclusion/exclusion criteria.

Is subject no longer in steady state after previously meeting inclusion/exclusion criteria? ☐ (SFL2:NOLONG) Yes ☐ (SFL2:NOLONG) No

☐ **If Yes**, check all that apply and complete the Adverse Event forms.

☐ (SFL2:VASO) Subject experienced one or more vaso-occlusive crises

☐ (SFL2:NONVOC) Subject experienced one or more non-vaso-occlusive sickle events

☐ (SFL2:NONSICK) Subject experienced one or more non-sickle related events

☐ (SFL2:PRIMARY) Other reason, ***Specify:*** SFL2:OTHSP

Did the subject complete the 2nd Re-screening Visit? ☐ (SFL2:COMPLV1)Yes ☐ (SFL2:COMPLV1)No

☐ **If no**, please provide the Date of Informed Consent at the 2nd Re-screening Visit.

Date of Informed Consent: SFL2:INFRMDA / SFL2:INFRMMO / SFL2:INFRMYR
Day Month Year

☐ **If yes**, be sure to complete all 2nd Re-screening CRFs. Also update as appropriate, the two Medical History forms and the Health History form under the Visit 1 EDC link.

Investigator's Statement:
I have reviewed the data entries within this CRF and, to the best of my knowledge, the

data represent a complete and accurate record of the subject's participation in the study.

☐ (SFL2:PISIG) PI Signature Signature Date: SFL2:SIGDA / SFL2:SIGMO / SFL2:SIGYR

Day Month Year

Submit Query Cancel Form Completion Help Print

Comprehensive Sickle Cell Centers	**Protocol Deviation Form**	**{visit.label}**
Hydroxyurea & Magnesium Pidolate (CHAMPS)	Date Form Completed: DEVI:COMPDA (Day) / DEVI:COMPMO (Month) / DEVI:COMPYR (Year) Form Completed by: DEVI:COMPINT	CSCC ID: {subject.name} Center code: {center.name} Hospital code: {center.hospital.name}

Complete a separate form for each deviation from the protocol.

Date of protocol deviation or date when deviation was discovered: DEVI:DEVIDA (DD) / DEVI:DEVIMO (MMM) / DEVI:DEVIYR (YYYY)

Was the subject Randomized? ☐ (DEVI:RANDOMZ)No ☐ (DEVI:RANDOMZ)Yes

Type of Deviation:

☐ (DEVI:DEVITYP) **1. Randomization or Masking Error, Specify:** DEVI:RANDSP

☐ (DEVI:DEVITYP) **2. Dosing Error, Specify:** DEVI:DOSERSP

Did this lead to an overdose? ☐ (DEVI:OVERDOS) No ☐ (DEVI:OVERDOS) Yes

☐ (DEVI:DEVITYP) **3. Missed Visit, Record the Visit Number:** DEVI:MISSVIS

Why was the visit missed?

- ☐ (DEVI:MISSWHY) Caregiver was ill
- ☐ (DEVI:MISSWHY) Transportation problems
- ☐ (DEVI:MISSWHY) Scheduling difficulties
- ☐ (DEVI:MISSWHY) Subject experienced AE requiring hospitalization
- ☐ (DEVI:MISSWHY) Subject experienced AE requiring visit to Clinic or Physician's Office
- ☐ (DEVI:MISSWHY) Subject experienced AE requiring Emergency Dept/Day Hospital/Urgent Care visit
- ☐ (DEVI:MISSWHY) Subject experienced AE not requiring medical attention
- ☐ (DEVI:MISSWHY) Other, specify DEVI:WHY_SP

(If visit was missed due to AE, be sure to complete the AE & SAE forms as appropriate.)

☐ (DEVI:DEVITYP) **4. Mistimed Visit, Record the Visit Number:** DEVI:MISTIME

Did the visit occur too early or too late? ☐ (DEVI:EARLATE) Too early ☐ (DEVI:EARLATE) Too late

How far outside the visit window was the visit? DEVI:OUTWIND days

☐ (DEVI:DEVITYP) **5. Mistimed Procedure or Laboratory Measure, Record the Visit Number:** DEVI:MISPROC

Was the entire assessment mistimed?

- ☐ (DEVI:PARTALL) No: Which part of the assessment was mistimed? DEVI:MISPART
- ☐ (DEVI:PARTALL) Yes: Which assessment was mistimed? DEVI:MISSALL

☐ (DEVI:DEVITYP) **6. Missed Procedure or Laboratory Measure, Record the Visit Number:** DEVI:MISPRO2

Was the entire assessment missed?

- ☐ (DEVI:PARTAL2) No: Which part of the assessment was missed? DEVI:MISPAR2
- ☐ (DEVI:PARTAL2) Yes: Which assessment was missed? DEVI:MISSAL2

(DEVI:DEVITYP) **7. Inclusion Criteria Not Met**

Inclusion Number(s) DEVI:INCL1 DEVI:INCL2 DEVI:INCL3

(DEVI:DEVITYP) **8. Exclusion Criteria Not Met**

Exclusion Number(s) DEVI:EXCL1 DEVI:EXCL2 DEVI:EXCL3

(DEVI:DEVITYP) **9. Informed Consent, Explain:** DEVI:INFORSP

(DEVI:DEVITYP) **10. Other, Specify:** DEVI:OTHERSP

Reason for Deviation: DEVI:DEVIRES

Steps Taken to Resolve and Prevent Recurrence of Deviation: DEVI:DEVIPRV

Did this deviation result in an adverse experience? (DEVI:DEVIAE) No (DEVI:DEVIAE) Yes *(If yes, complete AE form.)*

If yes, was the AE serious? (DEVI:DEVISAE) No (DEVI:DEVISAE) Yes *(If yes, complete AE form.)*

Will the subject continue with the study? (DEVI:CONTINU) No (DEVI:CONTINU) Yes *(If no, complete discontinuation form.)*

Is report to IRB required for this deviation? (DEVI:DEVIIRB) No (DEVI:DEVIIRB) Yes

If yes, Date Reported: DEVI:REPODA / DEVI:REPOMO / DEVI:REPOYR

DD MMM YYYY

If further action is required, describe it: DEVI:OTHACTN

Additional Comments: DEVI:ADDCOMM

Submit Query Cancel Form Completion Help Print