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Version 14.00 pushed to PRODUCTION 04.06.2023: All Forms
Form: Subject Enrollment
Generated On: 02 May 2023 16:20:18

FORM_OID	PID3284264_V1_0 (1)
Patient ID	(3)
Enrolling Site CTEP ID	(4)
Lead Organization	(5)
Current Site CTEP ID	(6)
Enrollment Date	(7)
Enrollment Time	**EST** ☐ (8) CST ☐ MST ☐ PST ☐ EDT ☐ CDT ☐ MDT ☐ PDT ☐
Group Data	(9)
Source Application	(10)

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Form: Subject Enrollment
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	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
1	FORM_OID	$200		PID3284264_V1_0		FORM_OID
3	Study Participant Identifier PID2003301_V4_0	$20				PT_ID
4	Enrolling Site CTEP ID PID3314240_V1_0	$25				ENROLLING_SITE_ID
5	Lead Institution PID2192796_V1_0	$100				LEAD_INST_NAME
6	Current Site CTEP ID PID3314243_V1_0	$25				CURRENT_SITE_ID
7	Enrollment Date PID2746541_V1_0	dd MMM yyyy				PARTIC_ENROL_DT

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
8	Enrollment Time PID3412601_V1_0	hh:nn:ss:rr	EST = EST CST = CST MST = MST PST = PST EDT = EDT CDT = CDT MDT = MDT PDT = PDT			ENROLL_TIME
9	Group Type PID3212399_V1_0	$100				GROUP_DATA
10	Source Application PID3302840_V1_0	$100				SRC_APP

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Form: Step Information
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FORM_OID	PID3285392_V1_0 (1)

Registration Step	(3)
Event Description	(4)
Tracking Number	(5)
Treating Investigator	(6)
Site Registrar	(7)
Crediting Group	(8)
Crediting Investigator	(9)
Arm Name	(10)
Event Date	(11)
Event Time	**EST** ☐ (12) CST ☐ MST ☐ PST ☐ EDT ☐ CDT ☐

MDT ☐
PDT ☐

Treatment Assignment Code (TAC): _____ 13

Treatment Assignment Description (TAD): _____ 14

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Form: Step Information
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	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
1	FORM_OID	$200		PID3285392_V1_0		FORM_OID
3	Step No PID2002093_V4_0	$20				REG_STEP_NUM
4	Event Description PID3303110_V1_0	$100				EVENT_DESC
5	Tracking Number PID3302859_V1_0	$25				TRACKING_NUM
6	Treating Physician Or Participating Investigator Name PID2740424_V1_0	$100				TX_MD_PART_INV_NM
7	Registrar PID2172_V3_0	$100				PROT_REG_NAME

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
8	Organization Name PID2152_V3_0	$200				ORG_NAME
9	Investigator PID2002224_V4_0	$100				INVESTIGATOR_NAME
10	Assigned Treatment Arm PID2001626_V3_0	$100				PROT_TX_ARM_ASS_TXT
11	Event Date PID3370375_V1_0	dd MMM yyyy				EVENT_DATE
12	Event Time PID3412598_V1_0	hh:nn:ss:rr	EST = EST CST = CST MST = MST PST = PST EDT = EDT CDT = CDT MDT = MDT PDT = PDT			EVENT_TIME
13	Treatment Assignment Code PID1967_V4_0	$10				TX_ASSIGN_CD

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
14	Other Treatment Assignment PID2002699_V5_0	$1999				TX_ASSIGN_TXT

FORM_OID PID3285336_V1_0 (1)

Arm Name _____ (3)

Step No _____ (4)

Event description _____ (5)

Date of Intervention/Treatment Assignment _____ (6)

Event Time (7)

- **EST** ☐
- CST ☐
- MST ☐
- PST ☐
- EDT ☐
- CDT ☐
- MDT ☐
- PDT ☐

Treatment Assignment Code (TAC): _____ (8)

Treatment Assignment Description (TAD): _____ (9)

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Form: Treatment Assignment
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	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
1	FORM_OID	$200		PID3285336_V1_0		FORM_OID
3	Assigned Treatment Arm PID2001626_V3_0	$100				PROT_TX_ARM_ASS_TXT
4	Step No PID2002093_V4_0	$20				REG_STEP_NUM
5	Event Description PID3303110_V1_0	$100				EVENT_DESC
6	Date of Interventionyyyy /Treatment Assignment PID3370377_V1_0	dd MMM				TRT_ARM_ASGN_DATE
7	Event Time PID3412598_V1_0	hh:nn:ss:rr	EST = EST CST = CST MST = MST PST = PST EDT = EDT CDT = CDT MDT = MDT PDT = PDT			EVENT_TIME

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
8	Treatment Assignment Code PID1967_V4_0	$10				TX_ASSIGN_CD
9	Other Treatment Assignment PID2002699_V5_0	$1999				TX_ASSIGN_TXT

FORM_OID	PID3302204_V1_0 (1)
Patient Initials (LFM)	_____ (3)
Patient's Date of Birth	_____ (4)
Ethnicity	Hispanic or Latino ☐ (5) Not Hispanic or Latino ☐ Not Reported ☐ Unknown ☐
Gender of a Person	Female Gender ☐ (6) Male Gender ☐ Unknown ☐
Country of Residence	_____ (7)
ZIP Code	_____ (8)
Method of Payment	PRIVATE INSURANCE ☐ (9) MEDICARE ☐ MEDICARE AND PRIVATE INSURANCE ☐ MEDICAID ☐ MEDICAID AND MEDICARE ☐ MILITARY OR VETERANS SPONSORED NOS ☐

MILITARY SPONSORED (INCLUDING CHAMPUS &TRICARE) ☐
VETERANS SPONSORED ☐
SELF PAY (NO INSURANCE) ☐
NO MEANS OF PAYMENT (NO INSURANCE) ☐
OTHER ☐
Unknown ☐

Race

American Indian or Alaska Native ☐ 10
Asian ☐
Black or African American ☐
Native Hawaiian or Other Pacific Islander ☐
White ☐
Not Reported ☐
Unknown ☐

Date of planned bone marrow assessments _____ 11

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Form: Demography
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	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
1	FORM_OID	$200		PID3302204_V1_0		FORM_OID
3	Participant Initials PID2001039_V4_0	$4				PT_INITIALS_NAME
4	Patient's Date of Birth PID793_V5_1	dd MMM yyyy				PER_BIR_DT
5	Ethnicity PID2192217_V2_0	$22		Hispanic or Latino = Hispanic or Latino Not Hispanic or Latino = Not Hispanic or Latino Not reported = Not Reported Unknown = Unknown		ETHN_GRP_CAT_TXT
6	Gender of a Person PID3368866_V1_0	$13		Female Gender = Female Gender		PERSON_GENDER

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
				Male Gender = Male Gender Unknown = Unknown		
7	Country of Residence (if not USA) PID2006183_V2_0	$5		COUNTRY_C_PID2018396_V1_0		COUNTRY_CD
8	ZIP Code PID2179606_V2_0	$15				ADDR_POSTAL_CD
9	Method of Payment PID58384_V2_4	$51		PRIVATE INSURANCE = PRIVATE INSURANCE MEDICARE = MEDICARE MEDICARE AND PRIVATE INSURANCE = MEDICARE AND PRIVATE INSURANCE		PAYMENT_METHOD

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			MEDICAID = MEDICAID MEDICAID AND MEDICARE = MEDICAID AND MEDICARE MILITARY OR VETERANS SPONSORED NOS = MILITARY OR VETERANS SPONSORED NOS MILITARY SPONSORED (INCLUDING CHAMPUS &TRICARE) = MILITARY SPONSORED (INCLUDING CHAMPUS &TRICARE)		

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			VETERANS SPONSORED = VETERANS SPONSORED SELF PAY (NO INSURANCE) = SELF PAY (NO INSURANCE) NO MEANS OF PAYMENT (NO INSURANCE) = NO MEANS OF PAYMENT (NO INSURANCE) OTHER = OTHER Unknown = Unknown		

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
10	Race PID2192199_V1_0	$41		American Indian or Alaska Native = American Indian or Alaska Native Asian = Asian Black or African American = Black or African American Native Hawaiian or other Pacific Islander = Native Hawaiian or Other Pacific Islander White = White Not Reported = Not Reported Unknown = Unknown		RACE_CAT_TXT

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
11	Plan Pheresis Or Bone Marrow Collection Occurrence Begin Date PID5002034_V1_0	dd MMM yyyy				PLAN_MARROW_ASSESS_DT

FORM_OID PID4060851_V1_0 1

Participant Subgroup Code _____ 3

Is the Patient currently receiving treatment on study? Yes ☐ 4
No ☐

Performance Status (Zubrod) Normal Activity ☐ 5
Symptoms, but nearly fully ambulatory ☐
Some bed time, but needs to be in bed <50% of normal daytime ☐
Needs to be in bed > 50% of normal daytime ☐
Unable to get out of bed ☐

Date of Last Treatment _____ 6

Baseline Abnormalities Flag No ☐ 7
Yes ☐
Unknown ☐

Response Evaluation Status Yes ☐ 8
No ☐
Too early ☐
Not Applicable ☐

Disease Code _____ 9

Disease Name _____ 10

Is the Subject identified for audit? Yes ☐ 11
No ☐

CTSU Integration Question 1 _____ 12

CTSU Integration Question 2 _____ 13

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
1	PID4060851_V1_0	$200		PID4060851_V1_0		FORM_OID
3	Patient Subgroup Code PID1925_V2_31	$10				PT_SUBGRP_CD
4	Protocol Treatment Current Received Code PID2453595_V1_0	1		1 = Yes 2 = No		PRO_TX_CUR_REC_CD
5	Zubrod Performance Status Score PID2003315_V4_2	$1		0 = Normal Activity 1 = Symptoms, but nearly fully ambulatory 2 = Some bed time, but needs to be in bed <50% of normal daytime		ZUBROD_PERF_STAT_SC

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
				3 = Needs to be in bed > 50% of normal daytime 4 = Unable to get out of bed		
6	Last Treatment Date PID65167_V3_0	dd MMM yyyy				LAST_TX_DT
7	Patient Baseline Abnormality Ind-3 PID2006875_V2_1	$7		1 = No 2 = Yes 99 = Unknown		PT_BSL_ABN_IND3
8	Disease Evaluable Response Code PID2453597_V1_0	$1		1 = Yes 2 = No 3 = Too early 7 = Not Applicable		DZ_EVAL_RESP_CD
9	MedDRA Code PID2004425_V4_0	8				MEDDRA_CODE

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
10	Disease Diagnosis Term Name PID218620 4_V2_0	$100				DZ_DX_NM
11	Is the Subject identified for audit?	$1		1 = Yes 2 = No		REQ_AUDIT
12	CTSU Integration Question 1	$50				CTSU_INT_ Q1
13	CTSU Integration Question 2	$50				CTSU_INT_ Q2

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Form: Patient Characteristics
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FORM_OID	PID3330130_V1_0 (1)
Height (current)	**cm** ☐ (2) in ☐
Maximum adult height	**cm** ☐ (3) in ☐
Weight (current)	**kg** ☐ (4) lb ☐
Maximum adult non-pregnant weight	**kg** ☐ (5) lb ☐
Does the patient have Type I Diabetes?	No ☐ (6) Yes ☐
History of > 90 days steroid use	No ☐ (7) Yes, oral only ☐ Yes, topical only ☐ Yes, oral and topical ☐
Duration at current zipcode	Fixed Unit: Years (8) _____
Duration residing in rural/farm community	Fixed Unit: Years (9) _____

Military Service? No ☐ 10
Yes ☐

Duration of military service Fixed Unit: Years 11

Occupation 12

Length of time Fixed Unit: Years 13

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
1	FORM_OID	$200		PID3330130_V1_0		FORM_OID
2	Height PID649_V4_1	5.1	1 = cm 2 = in			PT_HT
3	Height PID649_V4_1_2	5.1	1 = cm 2 = in			PT_HT_MAX
4	Patient Weight Measurement PID651_V4_0	5.1	1 = kg 2 = lb			PT_WT
5	Patient Weight Measurement PID651_V4_0_5	5.1	1 = kg 2 = lb			PREG_PT_WT
6	DIABETES_YN	1		1 = No 2 = Yes		DIABETES_YN
7	HIST_STEROID	1		1 = No 2 = Yes, oral only 3 = Yes, topical only		HIST_STEROID

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
				4 = Yes, oral and topical		
8	DUR_CURR_ZIP	2				DUR_CURR_ZIP
9	DUR_RURAL	2				DUR_RURAL
10	MILITARY_YN_DYN	1		1 = No 2 = Yes		MILITARY_YN_DYN
11	DUR_MILTARY	2				DUR_MILTARY
12	OCCUPATION	2		OCCUPATION		OCCUPATION
13	DUR_OCCUP	2				DUR_OCCUP

Version 14.00 pushed to PRODUCTION 04.06.2023: All Forms
Form: Prior Malignancy
Generated On: 02 May 2023 16:20:18

FORM_OID _____ 1

Has the patient been diagnosed with any malignancies prior to enrollment? — No ☐ 2 / Yes ☐

Prior malignancy — 3
- ☐ Breast cancer
- ☐ Colon cancer
- ☐ Leukemia, specify
- ☐ Lung
- ☐ Lymphoma, specify
- ☐ Multiple myeloma
- ☐ Prostate cancer
- ☐ Skin cancers (basal, squamous, melanoma)
- ☐ Other, specify

Date of diagnosis _____ 4

Treatment — 5
- ☐ Chemotherapy/Radiation combination, specify
- ☐ Hematopoietic Cell Transplantation
- ☐ Hormonal
- ☐ Immunotherapy
- ☐ Radiation
- ☐ Systemic therapy (chemotherapy), specify
- ☐ Other, specify
- ☐ Unknown
- ☐ None

Date of last treatment or transplant _____ 6

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Form: Prior Malignancy
Generated On: 02 May 2023 16:20:18

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
1	FORM_OID	$200				FORM_OID
2	PRIOR_MAL IG_YN	1		1 = No 2 = Yes		PRIOR_MAL IG_YN
3	PRIOR_MAL IG	2		1 = Breast cancer 2 = Colon cancer 3 = Leukemia, specify 4 = Lung 5 = Lymphoma, specify 6 = Multiple myeloma 7 = Prostate cancer 8 = Skin cancers (basal, squamous, melanoma) 88 = Other, specify		PRIOR_MAL IG
4	DIAG_DT	MMM- yyyy				DIAG_DT

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
5	MALIG_TX	2		1 = Chemotherapy/Radiation combination, specify 2 = Hematopoietic Cell Transplantation 3 = Hormonal 4 = Immunotherapy 5 = Radiation 6 = Systemic therapy (chemotherapy), specify 88 = Other, specify 99 = Unknown 77 = None		MALIG_TX
6	LAST_TREAT_DT	MMM- yyyy				LAST_TREAT_DT

FORM_OID _____ 1

Did the patient have a recent (within past 6 months) biopsy confirming the initial diagnosis of MDS? 2

- ☐ No
- ☐ Yes

Note: Patients with a prior diagnosis of MDS/MPN Overlap Disorder are not eligible for the study.

Has the patient ever had a confirmed diagnosis of MDS 3

- ☐ No
- ☐ Yes

Date of biopsy _____ 4

Is the patient's blood disorder therapy-related? 5

- ☐ No
- ☐ Yes
- ☐ Unknown

Therapy received 6

- ☐ Chemotherapy, specify
- ☐ Radiation
- ☐ Other, specify

Duration of exposure 7

Fixed Unit: Months _____

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
1	FORM_OID	$200				FORM_OID
2	PREV_CONF_DIAG_MDS	1		1 = No 2 = Yes		PREV_CONF_DIAG_MDS
3	EV_CONF_DIAG_MDS	1		1 = No 2 = Yes		EV_CONF_DIAG_MDS
4	DIAG_MDS_DT	dd MMM yyyy				DIAG_MDS_DT
5	TX_MDS_YN	2		1 = No 2 = Yes 99 = Unknown		TX_MDS_YN
6	TX_RCVD	2		1 = Chemotherapy, specify 2 = Radiation 88 = Other, specify		TX_RCVD
7	DUR_EXPO	3				DUR_EXPO

Version 14.00 pushed to PRODUCTION 04.06.2023: All Forms
Form: Prior Hematologic Disorder
Generated On: 02 May 2023 16:20:18

FORM_OID		1
Has the patient been diagnosed with any hematologic disorders prior to enrollment?	No ☐ Yes ☐	2
Prior hematologic disorder		3
Date of diagnosis		4
Treatment		5
Duration of treatment	Fixed Unit: months	6

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
1	FORM_OID	$200				FORM_OID
2	PRIOR_HEM_YN	1		1 = No 2 = Yes		PRIOR_HEM_YN
3	PRIOR_HEM_DX	2		PRIOR_HEM_DX		PRIOR_HEM_DX
4	PRIOR_HEM_DX_DT	MMM- yyyy				PRIOR_HEM_DX_DT
5	PRIOR_HEM_TX	$200				PRIOR_HEM_TX
6	TX_DURATION	3				TX_DURATION

FORM_OID _____ 1

Has the patient been diagnosed with any autoimmune diseases prior to enrollment? 2
- ☐ No
- ☐ Yes

Prior autoimmune disease _____ 3

Date of diagnosis _____ 4

Treatment 5
- ☐ Anti-thymocyte globulin (ATG)
- ☐ Anti-TNF monoclonal
- ☐ Cyclosporins
- ☐ Danazol
- ☐ Intravenous immunoglobulin (IVIG)
- ☐ Methotrexate
- ☐ Sirolimus/mTOR inhibitor
- ☐ Steroids
- ☐ T-Cell costimulator modulators
- ☐ Tacrolimus
- ☐ Other, specify
- ☐ None

Duration of treatment Fixed Unit: months 6
_____

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
1	FORM_OID	$200				FORM_OID
2	PRIOR_AUTO_YN	1		1 = No 2 = Yes		PRIOR_AUTO_YN
3	PRIOR_AUTOIMM_DX	2		PRIOR_AUTOIMM_DX		PRIOR_AUTOIMM_DX
4	PRIOR_AUTOIMM_DX_DT	MMM- yyyy				PRIOR_AUTOIMM_DX_DT
5	PRIOR_AUTOIMM_TX	2		1 = Anti-thymocyte globulin (ATG) 2 = Anti-TNF monoclonal 3 = Cyclosporins 4 = Danazol 5 = Intravenous immunoglobulin (IVIG) 6 = Methotrexate 7 = Sirolimus/mTOR inhibitor		PRIOR_AUTOIMM_TX

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
				8 = Steroids 9 = T-Cell costimulator modulators 10 = Tacrolimus 88 = Other, specify 77 = None		
6	TX_DURATION	3				TX_DURATION_AUTO

FORM_OID _____ 1

Device Type

- Cardiovascular ☐ 2
- Cosmetic ☐
- Dental ☐
- Gastrointestinal ☐
- Genitourinary ☐
- Neurologic ☐
- Orthopedic ☐
- No device placed ☐

Initial Device Placement Date _____ 3

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
1	FORM_OID	$200				FORM_OID
2	DEVICE_PLCMNT	2		1 = Cardiovascular 2 = Cosmetic 3 = Dental 4 = Gastrointestinal 5 = Genitourinary 6 = Neurologic 7 = Orthopedic 99 = No device placed		DEVICE_PLCMNT
3	DEVICE_DT	dd- MMM-yyyy				DEVICE_DT

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Form: Family History
Generated On: 02 May 2023 16:20:18

FORM_OID _____ 1

Form instructions:
Please enter all family members and spouse, if applicable. Select 'None' if the family member or spouse did not have cancer or a blood disorder.

Relationship _____ 3

Relation type
- Blood ☐ 4
- Non-blood ☐
- Unknown ☐

Cancer
- Breast cancer ☐ 5
- Colon cancer ☐
- Leukemia, specify ☐
- Lung cancer ☐
- Lymphoma, specify ☐
- Multiple myeloma ☐
- Prostate cancer ☐
- Skin cancers (basal, squamous, melanoma) ☐
- Other, specify ☐
- None ☐

Age at diagnosis _____ 6

Blood disorder _____ 7

Age at diagnosis _____ 8

Survival Status

- Alive (9)
- Dead
- Unknown

Age at death _____ (10)

Cause of death

- Accident (11)
- Acute leukemia
- Other cancer
- Bacterial infection
- Chronic Lower Respiratory Disease
- Fungal infection
- Heart Disease
- Hemorrhage
- Stroke
- Viral infection
- Other, specify
- Unknown

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
1	FORM_OID	$200				FORM_OID
3	RELATION	2		RELATION		RELATION
4	RELATION_TYPE	2		1 = Blood 2 = Non-blood 99 = Unknown		RELATION_TYPE
5	CANCER_FT	2		1 = Breast cancer 2 = Colon cancer 3 = Leukemia, specify 4 = Lung cancer 5 = Lymphoma, specify 6 = Multiple myeloma 7 = Prostate cancer 8 = Skin cancers (basal, squamous, melanoma)		CANCER_FT

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
				88 = Other, specify 99 = None		
6	AGE_CANCER_DX	3				AGE_CANCER_DX
7	BLOOD_DZ_FT	2		FAM_HEM_DISORDER		BLOOD_DZ_FT
8	AGE_BLOOD_DZ	3				AGE_BLOOD_DZ
9	RELATIVE_SURVIVAL	2		1 = Alive 2 = Dead 99 = Unknown		RELATIVE_SURVIVAL
10	AGE_DEATH	3				AGE_DEATH
11	RELATIVE_COD	2		1 = Accident 2 = Acute leukemia 3 = Other cancer 4 = Bacterial infection		RELATIVE_COD

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			5 = Chronic Lower Respiratory Disease 6 = Fungal infection 7 = Heart Disease 8 = Hemorrhage 9 = Stroke 10 = Viral infection 88 = Other, specify 99 = Unknown		

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Form: Smoking History
Generated On: 02 May 2023 16:20:18

FORM_OID	_____	1
Has the patient ever smoked cigarettes regularly for six months or longer?	No ☐ Yes ☐	2
At what age did the patient start smoking cigarettes regularly?	_____	3
Does the patient smoke regularly now?	No ☐ Yes ☐	4
At what age did the patient last stop smoking cigarettes regularly?	_____	5
During the periods when the patient smoked, how many cigarettes did they or do they usually smoke per day?	1-10 ☐ 11-20 ☐ 21-30 ☐ 31-40 ☐ 41-60 ☐ 61-80 ☐ 81 or more ☐	6
Does the patient now or did they ever smoke a pipe regularly for a year or longer?	Never smoked a pipe ☐ Did smoke a pipe but currently do not smoke ☐ Currently do smoke a pipe ☐	7
Does the patient now or did they ever smoke cigars regularly for a year or longer?	Never smoked cigars ☐ Did smoke cigars but currently do not smoke ☐ Currently smoke cigars ☐	8

Not including the past two years, has the patient ever lived with someone who regularly smoked cigarettes around them? 9
- No
- Yes

How many years did they smoke cigarettes around the patient regularly? 10 _____

Not including the past two years, has the patient ever worked with someone who regularly smoked cigarettes around them? 11
- No
- Yes

How many years did they smoke cigarettes around the patient regularly? 12 _____

Has the patient ever used smokeless tobacco for 6 months or more? 13
- No
- Yes

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Form: Smoking History
Generated On: 02 May 2023 16:20:18

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
1	FORM_OID	$200				FORM_OID
2	SMOKE_6_MO	1		1 = No 2 = Yes		SMOKE_6_MO_DYN
3	AGE_SMOKE_STRT	2				AGE_SMOKE_STRT
4	CURR_SMOKE_YN	1		1 = No 2 = Yes		CURR_SMOKE_YN_DYN
5	AGE_SMOKE_STOP	2				AGE_SMOKE_STOP
6	SMOKE_DAY_NUM	1		1 = 1-10 2 = 11-20 3 = 21-30 4 = 31-40 5 = 41-60 6 = 61-80 7 = 81 or more		SMOKE_DAY_NUM
7	PIPE_YN	1		1 = Never smoked a pipe 2 = Did smoke a pipe but currently do not smoke		PIPE_YN

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
				3 = Currently do smoke a pipe		
8	CIGAR_YN	1		1 = Never smoked cigars 2 = Did smoke cigars but currently do not smoke 3 = Currently smoke cigars		CIGAR_YN
9	LIVE_CIG_YN	1		1 = No 2 = Yes		LIVE_CIG_YN
10	YRS_LIVE_CIG	2				YRS_LIVE_CIG
11	WORK_CIG_YN	1		1 = No 2 = Yes		WORK_CIG_YN
12	YRS_WORK_CIG	2				YRS_WORK_CIG
13	SMOKELESS_TOB_YN	1		1 = No 2 = Yes		SMOKELESS_TOB_YN

Version 14.00 pushed to PRODUCTION 04.06.2023: All Forms
Form: Alcohol History
Generated On: 02 May 2023 16:20:18

FORM_OID _____ 1

Age
- 18-24 years ☐ 2
- 25-39 years ☐
- 40-54 years ☐
- 55 years or older ☐

12 oz bottle or can of beer
- Never ☐ 3
- 1 per month or fewer ☐
- 2-3 per month ☐
- 1-2 per week ☐
- 3-4 per week ☐
- 5-6 per week ☐
- 1 per day ☐
- 2-3 per day ☐
- 4-5 per day ☐
- 6 or more per day ☐

5 oz glass of wine
- Never ☐ 4
- 1 per month or fewer ☐
- 2-3 per month ☐
- 1-2 per week ☐
- 3-4 per week ☐
- 5-6 per week ☐
- 1 per day ☐
- 2-3 per day ☐
- 4-5 per day ☐
- 6 or more per day ☐

1.5 oz shot of liquor (including mixed drinks)
- Never ☐ 5

1 per month or fewer ☐
2-3 per month ☐
1-2 per week ☐
3-4 per week ☐
5-6 per week ☐
1 per day ☐
2-3 per day ☐
4-5 per day ☐
6 or more per day ☐

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
1	FORM_OID	$200				FORM_OID
2	AGE_ALC	1		1 = 18-24 years 2 = 25-39 years 3 = 40-54 years 4 = 55 years or older	1: 18-24 years 2: 25-39 years 3: 40-54 years 4: 55 years or older	AGE_ALC
3	BEER_FREQ	2		1 = Never 2 = 1 per month or fewer 3 = 2-3 per month 4 = 1-2 per week 5 = 3-4 per week 6 = 5-6 per week 7 = 1 per day 8 = 2-3 per day 9 = 4-5 per day 10 = 6 or more per day		BEER_FREQ

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
4	WINE_FREQ	2		1 = Never 2 = 1 per month or fewer 3 = 2-3 per month 4 = 1-2 per week 5 = 3-4 per week 6 = 5-6 per week 7 = 1 per day 8 = 2-3 per day 9 = 4-5 per day 10 = 6 or more per day		WINE_FREQ
5	LIQUOR_FREQ	2		1 = Never 2 = 1 per month or fewer 3 = 2-3 per month 4 = 1-2 per week 5 = 3-4 per week 6 = 5-6 per week 7 = 1 per day 8 = 2-3 per day		LIQUOR_FREQ

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			9 = 4-5 per day 10 = 6 or more per day		

FORM_OID _____ 1

Has the patient ever been exposed to any of the following substances listed below, for at least 8 hours per week for 1 year or more, either on a job or working on a hobby?

Environmental Exposure Type _____ 3

Environmental Exposure? 4
- ☐ No
- ☐ Yes
- ☐ Unknown

(If yes) Years of exposure — Fixed Unit: Years 5

_____

Has the patient ever been exposed to agent orange? 6
- ☐ No
- ☐ Yes
- ☐ Unknown

Has the patient ever been exposed to other chemicals or solvents? 7
- ☐ No
- ☐ Yes (specify)
- ☐ Unknown

Has the patient ever been exposed to radiation? 8
- ☐ No
- ☐ Yes (specify)
- ☐ Unknown

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
1	FORM_OID	$200				FORM_OID
3	EXP_TYPE	2		EXP_TYPE	1: Cutting oils, motor vehicle oils 2: Asphalt, tar or pitch 3: Benzene 4: Pesticides 5: Herbicides 6: Gasoline 7: Fertilizers 8: Arsenic 9: Mineral Oils 10: Soot 11: Creosote 12: Inks, dyes, tanning solutions 13: Dry cleaning agents 14: Rubber and rubber products 15: Vinyl chloride, plastics 16: Acrylic and oil based paints	EXP_TYPE

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
					17: Varnish, lacquers, or glues 18: Paraffin waxes 19: Coal dust 20: Metals (lead, nickel, zinc) 21: Radioactive materials 22: X-ray machines	
4	EVIRON_EXP_YN	2		1 = No 2 = Yes 99 = Unknown		EVIRON_EXP_YN
5	YRS_EXP	2				YRS_EXP
6	AGENT_ORANGE_YN	2		1 = No 2 = Yes 99 = Unknown		AGENT_ORANGE_YN
7	OTH_CHEM_YN	2		1 = No 2 = Yes (specify) 99 = Unknown		OTH_CHEM_YN

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
RAD_YN	2		1 = No 2 = Yes (specify) 99 = Unknown		RAD_YN

Version 14.00 pushed to PRODUCTION 04.06.2023: All Forms
Form: Military Service Form
Generated On: 02 May 2023 16:20:18

FORM_OID 1

US Military Service Start Year 2

US Military Service End Year 3

What branch of the US military did you serve in (select one)? 4

- Army
- Marine Corps
- Navy
- Air Force
- Coast Guard
- National Guard
- Other

If "Other", explain: 5

Did you serve overseas? 6

- No
- Yes

If 'Yes', indicate the number of countries 7

Countries 8

During your service, did you serve in Vietnam? 9

- No
- Yes
- Unknown

During your service, did you serve aboard a U.S. military vessel that operated in the inland waterways of Vietnam? 10

- No
- Yes

	Unknown ☐
During your service, did you serve on a vessel operating near the demarcation line of the waters of Vietnam and Cambodia?	No ☐ 11 Yes ☐ Unknown ☐
During your service, did you serve on any U.S. or Royal Thai military base in Thailand?	No ☐ 12 Yes ☐ Unknown ☐
During your service, did you serve in Laos?	No ☐ 13 Yes ☐ Unknown ☐
During your service, did you serve in Cambodia at Mimot or Krek, Kampong Cham Province?	No ☐ 14 Yes ☐ Unknown ☐
During your service, did you serve in Guam or American Samoa or in the territorial waters off Guam or American Samoa?	No ☐ 15 Yes ☐ Unknown ☐
During your service, did you serve at Johnston Atoll or on a ship that called at Johnston Atoll?	No ☐ 16 Yes ☐ Unknown ☐
Did you serve in or near the Korean DMZ?	No ☐ 17 Yes ☐ Unknown ☐

While serving or on active duty were you in a regular Air Force unit location where a C-123 aircraft with traces of Agent Orange was assigned, and had repeated contact with this aircraft due to your duties?	No ☐ 18 Yes ☐ Unknown ☐
During your service, were you involved in transporting, testing, storing, or other uses of Agent Orange?	No ☐ 19 Yes ☐ Unknown ☐
During your service, were you assigned as a Reservist to certain flight, ground, or medical crew duties at Lockbourne/Rickenbacker Air Force Base in Ohio, Westover Air Force Base in Massachusetts, and/or Pittsburgh International Airport in Pennsylvania?	No ☐ 20 Yes ☐ Unknown ☐
Have you ever applied for or received disability benefits related to Agent Orange exposure?	No ☐ 21 Yes ☐ Unknown ☐
Did you serve in the Gulf during Operation Desert Shield, Operation Desert Storm, Operation Iraqi Freedom, or Operation New Dawn?	No ☐ 22 Yes ☐ Unknown ☐
During your service in the Gulf War were you exposed to Oil Well Fires?	No ☐ 23 Yes ☐ Unknown ☐
During your service in the Gulf War were you exposed to Chemical or Biological weapons?	No ☐ 24 Yes ☐ Unknown ☐

During your service in the Gulf War were you exposed to Depleted Uranium?

No ☐ 25
Yes ☐
Unknown ☐

Now (derived for dynamic EC) _____ 26

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
1	FORM_OID	$200				FORM_OID
2	SRV_STRT_YR	yyyy-YR				SRV_STRT_YR
3	SRV_END_YR	yyyy-YR				SRV_END_YR
4	SRV_MIL_BRANCH	2		1 = Army 2 = Marine Corps 3 = Navy 4 = Air Force 5 = Coast Guard 6 = National Guard 88 = Other		SRV_MIL_BRANCH
5	SRV_MIL_BRANCH_EXPL	$200				SRV_MIL_BRANCH_EXPL
6	SRV_OVER_SEAS	1		1 = No 2 = Yes		SRV_OVER_SEAS
7	SRV_COUNTRY_NUM	2				SRV_COUNTRY_NUM

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
8	SRV_COUNTRY_XX	$5		COUNTRY_C_PID2018396_V1_0		SRV_COUNTRY_XX
9	SRV_VN	2		1 = No 2 = Yes 99 = Unknown		SRV_VN
10	SRV_US_MIL_VSL_IW_VN	2		1 = No 2 = Yes 99 = Unknown		SRV_US_MIL_VSL_IW_VN
11	SRV_VSL_DW_VN_KH	2		1 = No 2 = Yes 99 = Unknown		SRV_VSL_DW_VN_KH
12	SRV_US_RTH_MIL_BASE	2		1 = No 2 = Yes 99 = Unknown		SRV_US_RTH_MIL_BASE
13	SRV_LA	2		1 = No 2 = Yes 99 = Unknown		SRV_LA
14	SRV_KH_M_K_KCP	2		1 = No 2 = Yes 99 = Unknown		SRV_KH_M_K_KCP

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
15	SRV_GU_AS	2		1 = No 2 = Yes 99 = Unknown		SRV_GU_AS
16	SRV_JA_S_JA	2		1 = No 2 = Yes 99 = Unknown		SRV_JA_S_JA
17	SRV_KR_DMZ	2		1 = No 2 = Yes 99 = Unknown		SRV_KR_DMZ
18	SRV_C123_AGNT_ORNG	2		1 = No 2 = Yes 99 = Unknown		SRV_C123_AGNT_ORNG
19	SRV_TRN_TST_ST_AGNT_ORNG	2		1 = No 2 = Yes 99 = Unknown		SRV_TRN_TST_ST_AGNT_ORNG
20	SRV_R_FL_GR_MC_L_W_P	2		1 = No 2 = Yes 99 = Unknown		SRV_R_FL_GR_MC_L_W_P
21	APL_RCV_DS_BENF_AGNT_ORNG	2		1 = No 2 = Yes		APL_RCV_DS_BENF_AGNT_ORNG

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
				99 = Unknown		
22	SRV_ODSH_ODST_OIF_OND	2		1 = No 2 = Yes 99 = Unknown		SRV_ODSH_ODST_OIF_OND
23	SRV_GF_EXP_OWF	2		1 = No 2 = Yes 99 = Unknown		SRV_GF_EXP_OWF
24	SRV_GF_EXP_CB_WP	2		1 = No 2 = Yes 99 = Unknown		SRV_GF_EXP_CB_WP
25	SRV_GF_EXP_DU	2		1 = No 2 = Yes 99 = Unknown		SRV_GF_EXP_DU
26	ADD_MIL_Q_DATETIME	dd MMM yyyy HH:nn:ss				ADD_MIL_Q_DATETIME

Version 14.00 pushed to PRODUCTION 04.06.2023: All Forms
Form: Agent Orange Exposure Form
Generated On: 02 May 2023 16:20:18

FORM_OID _____ 1

Were you exposed to Agent Orange during Military Service? 2
- ☐ No
- ☐ Yes
- ☐ Unknown

If 'No', how were you exposed? 3
- ☐ Work
- ☐ Residential Proximity
- ☐ Other

If "Other", explain: _____ 4

Type/location of exposure: 5
- ☐ Water
- ☐ Land
- ☐ Air
- ☐ Combination of the above
- ☐ Other

If "Other", explain: _____ 6

Indicate the approximate cumulative duration of exposure to agent orange, choosing the closest unit of the duration. 7

_____

Unit 8
- ☐ Days
- ☐ Weeks
- ☐ Months
- ☐ Years

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
1	FORM_OID	$200				FORM_OID
2	EXP_AGNT_ORNG_MIL_SRV_YN	2		1 = No 2 = Yes 99 = Unknown		EXP_AGNT_ORNG_MIL_SRV_YN
3	HW_EXP_AGNT_ORNG	2		1 = Work 2 = Residential Proximity 88 = Other		HW_EXP_AGNT_ORNG
4	HW_EXP_AGNT_ORNG_EXPL	$200				HW_EXP_AGNT_ORNG_EXPL
5	TL_EXP_AGNT_ORNG	2		1 = Water 2 = Land 3 = Air 4 = Combination of the above 88 = Other		TL_EXP_AGNT_ORNG
6	TL_EXP_AGNT_ORNG_EXPL	$200				TL_EXP_AGNT_ORNG_EXPL
7	DUR_EXP_AGNT_ORNG	4				DUR_EXP_AGNT_ORNG

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
8	DUR_EXP_A1 GNT_ORNG _U			1 = Days 2 = Weeks 3 = Months 4 = Years		DUR_EXP_A GNT_ORNG _U

Version 14.00 pushed to PRODUCTION 04.06.2023: All Forms
Form: Baseline Hematology/Chemistry
Generated On: 02 May 2023 16:20:18

FORM_OID _____ 1

Form instructions:

NOTES: Please note that there are 29 lab tests included within the log line section of this form. If you see less than 29 lab tests, be sure to look at the pagination at the bottom right hand corner of the log line section to access all lab tests.

Lab Test _____ 3

Test not done _____ 4

Lab Value _____ 5

Lab Unit _____ 6

Value Abnormal? 7
- ☐ No
- ☐ Yes

Date Hematology (Blood) Sample Obtained _____ 8

Antinuclear Antibody (ANA), Serum 9
- ☐ Negative
- ☐ Positive
- ☐ Not done

Date obtained _____ 10

T-Cell Receptor Rearrangement 11
- ☐ Negative
- ☐ Positive

Not done ☐

Date obtained _____ 12

Paroxysmal nocturnal hemoglobinuria flow — Negative ☐ 13
Low-level PNH clone positive (.01-<1%) ☐
PNH clone positive (1-20%) ☐
PNH clone positive (>20%) ☐
Not done ☐

PNH flow method:

Granulocytes: CD59 and/or CD55 — No ☐ 15
Yes ☐

Assay type — Screening ☐ 16
High sensitivity ☐

Lower limit of detection — Fixed Unit: % 17
_____

Date obtained _____ 18

Granulocytes: FLAER — No ☐ 19
Yes ☐

Assay type — Screening ☐ 20
High sensitivity ☐

Lower limit of detection — Fixed Unit: % (21)

Date obtained (22)

Monocytes: CD14 — No (23) / Yes

Assay type — Screening (24) / High sensitivity

Lower limit of detection — Fixed Unit: % (25)

Date obtained (26)

Monocytes: FLAER — No (27) / Yes

Assay type — Screening (28) / High sensitivity

Lower limit of detection — Fixed Unit: % (29)

Date obtained (30)

Erythrocytes: CD59 and/or CD55 — No (31)

	Yes ☐
Assay type	Screening ☐ 32 High sensitivity ☐
Lower limit of detection	Fixed Unit: % 33 _____
Date obtained	_____ 34
Mean corpuscular volume	_____ 35
MVC Unit	fL ☐ 36 % ☐
Date of mean corpuscular volume	_____ 37
Red cell distribution width	_____ 38
RCDW Unit	fL ☐ 39 % ☐
Date of red cell distribution width	_____ 40

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
1	FORM PID4761574	$200				FORM_OID
3	Laboratory Finding Test Name PID2003746_V5_0	2		LAB_TEST_PID2182809_V4_0F	1: Creatinine, Serum 2: Alkaline Phosphatase, Serum 3: Aspartate Aminotransferase (AST or SGOT), Serum 4: Alanine Aminotransferase (ALT or SGPT), Serum 5: Lactate Dehydrogenase (LDH), Serum 6: Vitamin B12, Serum 7: Copper, Serum 8: Iron, Serum 9: Total Iron Binding Capacity, Serum	LAB_NAME_XX

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
				10: Iron Saturation, Ratio, Serum 11: Ferritin, Serum 12: Thyrotropin (Thyroid Stimulating Hormone or TSH), Serum 13: Total Protein, Serum 14: Rheumatoid Factor, Serum 15: Hemoglobin, Blood 16: Platelets, Blood 17: White Blood Cells (WBC), #, Blood 18: Absolute Neutrophil Count (ANC), Blood	

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
				19: Monocytes, #, Blood 20: Lymphocytes, #, Blood 21: Eosinophils, #, blood 22: Basophils, #, Blood 23: Reticulocytes, #, Blood 24: Blasts, %, Blood 25: Folate, Serum 26: Folate, Red Blood Cell 27: Albumin, Serum 28: Bilirubin, Total, Serum 29: Direct Antiglobulin Test (Coombs), Red Blood Cells	

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
4	Laboratory Procedure Not Performed Text PID2200616_V1_0	1				TEST_ND_XX
5	Laboratory Test Result Numeric Value PID2183360_V2_0	10.2				LAB_RS_XX
6	Laboratory Test Result Unit of Measure Unified Code for Units of Measure Code PID2787947_V1_0	2		LAB_UOM_PID2015224_V3_0F	1: mg/dL 2: U/L 3: U/L 4: U/L 5: U/L 6: pg/mL 7: µg/dL 8: µg/dL 9: µg/dL 10: % 11: ng/mL 12: mIU/L 13: g/dl 14: U/mL 15: g/dL 16: /µL 17: /µL 18: /µL 19: /µL 20: /µL 21: /µL 22: /µL	LAB_UNIT_XX

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
					23: /µL 24: % 25: ng/mL 26: ng/mL 27: g/dL 28: mg/dL 29:	
7	ABNORMAL_YN	1		1 = No 2 = Yes		ABNORMAL_YN
8	Sample Collection Date PID2004004_V3_0	MMM dd yyyy				LAB_DT_XX
9	ANA	2		1 = Negative 2 = Positive 99 = Not done		ANA
10	ANA_DT	MMM dd yyyy				ANA_DT
11	T_CELL	2		1 = Negative 2 = Positive 99 = Not done		T_CELL

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
12	T_CELL_DT	MMM dd yyyy				T_CELL_DT
13	PNHF	2		1 = Negative 2 = Low-level PNH clone positive (.01-<1%) 3 = PNH clone positive (1-20%) 4 = PNH clone positive (>20%) 99 = Not done		PNHF
15	GRAN_CD59_CD55_YN	1		1 = No 2 = Yes		GRAN_CD59_CD55_YN
16	ASSAY_TYPE1	1		1 = Screening 2 = High sensitivity		ASSAY_TYPE1
17	LL_DET1	4.3				LL_DET1
18	PNHF_DT1	MMM dd yyyy				PNHF_DT1

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
19	GRAN_FLAER_YN	1		1 = No 2 = Yes		GRAN_FLAER_YN
20	ASSAY_TYPE2	1		1 = Screening 2 = High sensitivity		ASSAY_TYPE2
21	LL_DET2	4.3				LL_DET2
22	PNHF_DT2	MMM dd yyyy				PNHF_DT2
23	MON_CD14_YN	1		1 = No 2 = Yes		MON_CD14_YN
24	ASSAY_TYPE3	1		1 = Screening 2 = High sensitivity		ASSAY_TYPE3
25	LL_DET3	4.3				LL_DET3
26	PNHF_DT3	MMM dd yyyy				PNHF_DT3
27	MON_FLAER_YN	1		1 = No 2 = Yes		MON_FLAER_YN

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
28	ASSAY_TYPE4	1		1 = Screening 2 = High sensitivity		ASSAY_TYPE4
29	LL_DET4	4.3				LL_DET4
30	PNHF_DT4	MMM dd yyyy				PNHF_DT4
31	ERY_CD59_CD55_YN	1		1 = No 2 = Yes		ERY_CD59_CD55_YN
32	ASSAY_TYPE5	1		1 = Screening 2 = High sensitivity		ASSAY_TYPE5
33	LL_DET5	4.3				LL_DET5
34	PNHF_DT5	MMM dd yyyy				PNHF_DT5
35	MCV_RS	5.1				MCV_RS
36	MCV_UNIT	1		1 = fL 2 = %		MCV_UNIT
37	MCV_DT	MMM dd yyyy				MCV_DT

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
38	RDW_RS	5.1				RDW_RS
39	RDW_UNIT	1		1 = fL 2 = %		RDW_UNIT
40	RDW_DT	MMM dd yyyy				RDW_DT

Version 14.00 pushed to PRODUCTION 04.06.2023: All Forms
Form: Concomitant Medication Form
Generated On: 02 May 2023 16:20:18

FORM_OID (1)

Form instructions:

At Baseline, please report medications from the previous 12 months. Update this form whenever a medication is started or stopped. Disease-modifying therapy given as part of a treatment cycle for MDS should be reported only on the MDS Disease Modifying Therapy Form and treatment provided for any COVID-19 care should captured on the COVID-19 Medication Form. Report all other medications, growth factors, and iron chelation on this form.

Medication Name (3)

Medication Start Date (4)

Medication Stop Date (5)

Reason for Medication (6)

Version 14.00 pushed to PRODUCTION 04.06.2023: All Forms
Form: Concomitant Medication Form
Generated On: 02 May 2023 16:20:18

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
1	FORM_OID	$200				FORM_OID
3	MED_NAME	$200				MED_NAME
4	MED_STRT_DT	dd- MMM-yyyy				MED_STRT_DT
5	MED_END_DT	dd- MMM-yyyy				MED_END_DT
6	MED_REASON	$200				MED_REASON

FORM_OID _____ 1

Was Charlson Comorbidity Index completed? No ☐ 2
Yes ☐

Version 14.00 pushed to PRODUCTION 04.06.2023: All Forms
Form: Charlson Comorbidity Index Yes/No
Generated On: 02 May 2023 16:20:18

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
1	FORM_OID	$200				FORM_OID
2	COMORB_C OMPL_YN	1		1 = No 2 = Yes		COMORB_C OMPL_YN

Version 14.00 pushed to PRODUCTION 04.06.2023: All Forms
Form: Charlson Comorbidity Index
Generated On: 02 May 2023 16:20:18

FORM_OID _____ 1

Form instructions:
This form is for data capture and entry purposes. Rave CRA's must rely on info in patient chart to answer the questions on this form.

Has the patient had a myocardial infarction? No ☐ 3 Yes ☐

Has the patient been hospitalized or treated for heart failure? No ☐ 4 Yes ☐

Does the patient have peripheral vascular disease? No ☐ 5 Yes ☐

Has the patient had a CVA or transient ischemic disease? No ☐ 6 Yes ☐

Does the patient have hemiplegia? No ☐ 7 Yes ☐

Does the patient have asthma, chronic lung disease, chronic bronchitis or emphysema? No ☐ 8 Yes ☐

Does the patient have diabetes that requires treatment? No ☐ 9 Yes ☐

Does the patient have end organ damage from diabetes? No ☐ 10 Yes ☐

Does the patient have moderate or severe renal disease? 11
- No ☐
- Yes ☐

Does the patient have a chronic liver disease? 12
- No ☐
- Yes ☐

Does the patient have moderate to severe liver disease? 13
- No ☐
- Yes ☐

Has the patient had gastric or peptic ulcers? 14
- No ☐
- Yes ☐

Has the patient had cancer (other than basal cell skin cancer)? 15
- No ☐
- Yes ☐

Type of Cancer 16
- Lymphoma ☐
- Leukemia ☐
- Solid tumor (specify) ☐

Has the patient had a metastatic solid tumor? 17
- No ☐
- Yes ☐

Type of metastatic solid tumor 18
- Breast ☐
- Colon ☐
- Prostate ☐
- Lung ☐
- Melanoma ☐
- Other (specify) ☐

Does the patient have Alzheimer's, dementia from any etiology or any serious cognitive impairment?	No ☐ 19 Yes ☐
Does the patient have any rheumatic or connective tissue disease?	No ☐ 20 Yes ☐
Does the patient have HIV or AIDS?	No ☐ 21 Yes ☐
Does the patient have hypertension?	No ☐ 22 Yes ☐
Has the patient had decubitus ulcers, peripheral skin ulcers or repeated episodes of cellulitis?	No ☐ 23 Yes ☐
Does the patient have depression?	No ☐ 24 Yes ☐
Is the patient on warfarin or coumadin?	No ☐ 25 Yes ☐

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
1	FORM_OID	$200				FORM_OID
3	MI	1		1 = No 2 = Yes		MI
4	CHF	1		1 = No 2 = Yes		CHF
5	PVD	1		1 = No 2 = Yes		PVD
6	CVA	1		1 = No 2 = Yes		CVA
7	PLEGIA	1		1 = No 2 = Yes		PLEGIA
8	COPD	1		1 = No 2 = Yes		COPD
9	DM	1		1 = No 2 = Yes		DM
10	DMENDORGAN	1		1 = No 2 = Yes		DMENDORGAN
11	RENAL	1		1 = No 2 = Yes		RENAL

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
12	MILDLIVER	1		1 = No 2 = Yes		MILDLIVER
13	SEVERELIVER	1		1 = No 2 = Yes		SEVERELIVER
14	ULCER	1		1 = No 2 = Yes		ULCER
15	CANCER	1		1 = No 2 = Yes		CANCER
16	CANCER_TYPE	1		1 = Lymphoma 2 = Leukemia 3 = Solid tumor (specify)		CANCER_TYPE
17	METS_YN	1		1 = No 2 = Yes		METS_YN
18	METASTASES	2		1 = Breast 2 = Colon 3 = Prostate 4 = Lung 5 = Melanoma 88 = Other (specify)		METASTASES

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
19	DEMENTIA	1		1 = No 2 = Yes		DEMENTIA
20	RHEUMATIC	1		1 = No 2 = Yes		RHEUMATIC
21	HIV	1		1 = No 2 = Yes		HIV
22	HBP	1		1 = No 2 = Yes		HBP
23	SKINULCER	1		1 = No 2 = Yes		SKINULCER
24	DEPRESSION	1		1 = No 2 = Yes		DEPRESSION
25	WARFARIN	1		1 = No 2 = Yes		WARFARIN

Version 14.00 pushed to PRODUCTION 04.06.2023: All Forms
Form: Report Period and Vital Status Form
Generated On: 02 May 2023 16:20:18

FORM_OID _____ 1

Form instructions:
Reporting Period Start Date must be the day after Reporting Period End Date of the previous folder. For the first Visit folder, the Reporting Period Start Date should be the day after all Baseline interviews and assessments are completed.

Reporting Period Start Date (mmm/dd/yyyy) _____ 3

Reporting Period End Date (mmm/dd/yyyy) _____ 4

Patient's Vital Status 5
- ☐ Alive
- ☐ Dead

Date of last contact (mmm/dd/yyyy) _____ 6

Date of death _____ 7

Primary Cause of Death 8
- ☐ Accident
- ☐ Acute leukemia
- ☐ Other cancer
- ☐ Bacterial infection
- ☐ Chronic Lower Respiratory Disease
- ☐ Fungal infection
- ☐ Heart Disease
- ☐ Hemorrhage
- ☐ Stroke
- ☐ Viral infection
- ☐ Other, specify
- ☐ Unknown

Version 14.00 pushed to PRODUCTION 04.06.2023: All Forms
Form: Report Period and Vital Status Form
Generated On: 02 May 2023 16:20:18

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
1	FORM PID3964935	$200				FORM_OID
3	Treatment Reporting Period Begin Date PID2993_V4_0	MMM dd yyyy				RP_STRT_DT
4	Treatment Reporting Period End Date PID2992_V4_0	MMM dd yyyy				RP_END_DT
5	Participant Vital Status Type PID2847330_V1_0	1		1 = Alive 2 = Dead		PT_VT_STAT
6	Participant Last Known Alive Date PID2847285_V1_0	MMM dd yyyy				LAST_CONTACT_DT
7	Death Date PID2004152_V3_0	MMM dd yyyy				DEATH_DT

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
8	Patient Death Primary Reason	2		1 = Accident 2 = Acute leukemia 3 = Other cancer 4 = Bacterial infection 5 = Chronic Lower Respiratory Disease 6 = Fungal infection 7 = Heart Disease 8 = Hemorrhage 9 = Stroke 10 = Viral infection 88 = Other, specify 99 = Unknown		COD

Version 14.00 pushed to PRODUCTION 04.06.2023: All Forms
Form: Study Visit Information
Generated On: 02 May 2023 16:20:18

FORM_OID	_____ 1
Did the required study visit occur during the reporting period?	No ☐ 2 Yes ☐
Study visit date	_____ 3
Was participant data still collected?	No ☐ 4 Yes ☐
Please specify the method of data collection	Remote patient contact ☐ 5 External clinic collaboration ☐ EMR ☐ Phone and EMR ☐ Other, specify ☐

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
1	FORM_OID	$200				FORM_OID
2	STUDY_VISIT_YN	1		1 = No 2 = Yes		STUDY_VISIT_YN
3	STUDY_VISIT_DT	MMM dd yyyy				STUDY_VISIT_DT
4	PT_DATA_COLL_YN	1		1 = No 2 = Yes		PT_DATA_COLL_YN
5	DATA_COLL_METHOD	2		1 = Remote patient contact 2 = External clinic collaboration 3 = EMR 4 = Phone and EMR 88 = Other, specify		DATA_COLL_METHOD

Version 14.00 pushed to PRODUCTION 04.06.2023: All Forms
Form: Status Form
Generated On: 02 May 2023 16:20:18

FORM_OID _____ 1

Form instructions:
At baseline: Report events from the last 6 months unless otherwise specified
At study visits: Report events since the last study visit

ECOG Performance Status
0 ☐ 3
1 ☐
2 ☐
3 ☐
4 ☐

Has the patient progressed to AML?
No ☐ 4
Yes ☐

Date of diagnosis _____ 5

Has the patient been hospitalized or been to the emergency room?
No ☐ 6
Yes ☐

Has the patient been in intensive care unit?
No ☐ 7
Yes ☐

Has the patient had clinic visit(s)?
No ☐ 8
Yes ☐

Has the patient had a packed RBC transfusion?
No ☐ 9
Yes ☐

Has the patient had a platelet transfusion?	No ☐ 10 Yes ☐
Has the patient had any infections requiring therapy?	No ☐ 11 Yes ☐
Therapy type	Antibiotic ☐ 12 Antiviral ☐ Antifungal ☐
Was IV administration route used?	No ☐ 13 Yes ☐
Has the patient had any thromboembolic events (at baseline – within the last 3 years)?	No ☐ 14 Yes ☐
Has the patient had any clots (NOS)? (at baseline – within the last 3 years)	No ☐ 15 Yes ☐
Has the patient had any pulmonary embolisms? (at baseline – within the last 3 years)	No ☐ 16 Yes ☐
Has the patient had any deep vein thrombosis (DVT)? (at baseline – within the last 3 years)	No ☐ 17 Yes ☐
Has the patient had any coronary thrombosis? (at baseline – within the last 3 years)	No ☐ 18 Yes ☐

Has the patient had a central venous access procedure?	19 No ☐ Yes ☐
Peripheral Inserted central catheter (PICC) or Midline catheter?	20 No ☐ Yes ☐
Silicone central venous (e.g., Hickman, Broviac)	21 No ☐ Yes ☐
Implantable vascular access device (port)	22 No ☐ Yes ☐
Has the patient experienced bleeding or hemorrhage of CTCAE grade 2 or higher?	23 No ☐ Yes ☐
Event type	24 Purpura ☐ Hematoma ☐ Hemorrhage, gastrointestinal ☐ Hemorrhage, genitourinary ☐ Hemorrhage, pulmonary ☐ Hemorrhage, central nervous system ☐ Hemorrhage, vitreous ☐ Hemorrhage, other, specify ☐
Maximum CTCAE grade	25 2 ☐ 3 ☐ 4 ☐ 5 ☐

Has the patient entered hospice care? No ☐ 26
Yes ☐

Date entered _____ 27

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
1	FORM_OID	$200				FORM_OID
3	PS	1		0 = 0 1 = 1 2 = 2 3 = 3 4 = 4		PS
4	PROG_AML_YN	1		1 = No 2 = Yes		PROG_AML_YN
5	PROG_AML_DT	dd MMM yyyy				PROG_AML_DT
6	HOSP_YN	1		1 = No 2 = Yes		HOSP_YN
7	ICUYN	1		1 = No 2 = Yes		ICUYN
8	CLINIC_YN	1		1 = No 2 = Yes		CLINIC_YN
9	RBC_TRANSF_YN	1		1 = No 2 = Yes		RBC_TRANSF_YN
10	PLT_TRANSF_YN	1		1 = No 2 = Yes		PLT_TRANSF_YN

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
11	INF_REQ_TX	1		1 = No 2 = Yes		INF_REQ_TX
12	TX_TYPE	1		1 = Antibiotic 2 = Antiviral 3 = Antifungal		TX_TYPE
13	IV_ADMN_YN	1		1 = No 2 = Yes		IV_ADMN_YN
14	HIST_THROMB	1		1 = No 2 = Yes		HIST_THROMB
15	HIST_CLOTS	1		1 = No 2 = Yes		HIST_CLOTS
16	HIST_PUL_EMB	1		1 = No 2 = Yes		HIST_PUL_EMB
17	HIST_DVT	1		1 = No 2 = Yes		HIST_DVT
18	HIST_COR_THROMB	1		1 = No 2 = Yes		HIST_COR_THROMB
19	CVA_YN	1		1 = No 2 = Yes		CVA_YN

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
20	PICC_MIDLINE_YN	1		1 = No 2 = Yes		PICC_MIDLINE_YN
21	SILICONE_CENT_VEN_YN	1		1 = No 2 = Yes		SILICONE_CENT_VEN_YN
22	PORT_YN	1		1 = No 2 = Yes		PORT_YN
23	HEM_GR2_YN	1		1 = No 2 = Yes		HEM_GR2_YN
24	HEM_EVENT	2		1 = Purpura 2 = Hematoma 3 = Hemorrhage, gastrointestinal 4 = Hemorrhage, genitourinary 5 = Hemorrhage, pulmonary 6 = Hemorrhage, central nervous system		HEM_EVENT

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
				7 = Hemorrhage, vitreous 99 = Hemorrhage, other, specify		
25	HEM_EVENT_GR	1		2 = 2 3 = 3 4 = 4 5 = 5		HEM_EVENT_GR
26	HOSPICE_YN	1		1 = No 2 = Yes		HOSPICE_YN
27	HOSPICE_DT	dd-MMM-yyyy				HOSPICE_DT

Version 14.00 pushed to PRODUCTION 04.06.2023: All Forms
Form: Hospitalization/ER Form
Generated On: 02 May 2023 16:20:18

FORM_OID	1
Hospitalization or ER admission date	2
Hospitalization or ER discharge date	3
Reason for hospitalization or ER	4

- ☐ Bleeding
- ☐ Cardiovascular
- ☐ Infection
- ☐ Neurologic
- ☐ Pulmonary
- ☐ Therapy
- ☐ Transfusion
- ☐ Trauma
- ☐ Confirmed COVID-19 or SARS-CoV-2 infection
- ☐ Other, specify

Version 14.00 pushed to PRODUCTION 04.06.2023: All Forms
Form: Hospitalization/ER Form
Generated On: 02 May 2023 16:20:18

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
1	FORM_OID	$200				FORM_OID
2	HOSP_ADM_DT	dd- MMM-yyyy				HOSP_ADM_DT
3	HOSP_DISC_DT	dd- MMM-yyyy				HOSP_DISC_DT
4	HOSP_REAS2			1 = Bleeding 2 = Cardiovascular 3 = Infection 4 = Neurologic 5 = Pulmonary 6 = Therapy 7 = Transfusion 8 = Trauma 9 = Confirmed COVID-19 or SARS-CoV-2 infection 88 = Other, specify		HOSP_REAS

FORM_OID	_____	1
ICU admission date	_____	2
ICU discharge date	_____	3
Was patient intubated?	☐ No ☐ Yes ☐ Unknown	4
Did patient receive vasopressor agents?	☐ No ☐ Yes ☐ Unknown	5
Was the patient treated in ICU for the novel coronavirus (SARS-CoV-2)?	☐ No ☐ Yes ☐ Unknown	6

Version 14.00 pushed to PRODUCTION 04.06.2023: All Forms
Form: ICU Form
Generated On: 02 May 2023 16:20:18

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
1	FORM_OID	$200				FORM_OID
2	ICU_ADM_DT	dd- MMM-yyyy				ICU_ADM_DT
3	ICU_DISC_DT	dd- MMM-yyyy				ICU_DISC_DT
4	INTUBATED_YNU	2		1 = No 2 = Yes 99 = Unknown		INTUBATED_YNU
5	VASPORESSOR_YNU	2		1 = No 2 = Yes 99 = Unknown		VASPORESSOR_YNU
6	CORONA_TX_YNU	2		1 = No 2 = Yes 99 = Unknown		CORONA_TX_YNU

Version 14.00 pushed to PRODUCTION 04.06.2023: All Forms
Form: Clinic Visit Form
Generated On: 02 May 2023 16:20:18

FORM_OID	1
Clinic visit date	2
Reason for clinic visit	3 MDS care ☐ COVID-19 infection ☐ Other, specify ☐

Version 14.00 pushed to PRODUCTION 04.06.2023: All Forms
Form: Clinic Visit Form
Generated On: 02 May 2023 16:20:18

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
1	FORM_OID	$200				FORM_OID
2	CLINIC_DT	dd- MMM-yyyy				CLINIC_DT
3	CLINIC_REAS	2		1 = MDS care 2 = COVID-19 infection 88 = Other, specify		CLINIC_REAS

Version 14.00 pushed to PRODUCTION 04.06.2023: All Forms
Form: RBC Transfusion Form
Generated On: 02 May 2023 16:20:18

FORM_OID	_____ 1
Transfusion date	_____ 2
Blood unit type	Packed ☐ 3 Whole ☐
Number of units	_____ 4

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
1	FORM_OID	$200				FORM_OID
2	RBC_TRANS_DT	dd- MMM-yyyy				RBC_TRANS_DT
3	RBC_UNIT_TYPE	2		1 = Packed 2 = Whole		RBC_UNIT_TYPE
4	NUM_UNITS	2				NUM_UNITS

Version 14.00 pushed to PRODUCTION 04.06.2023: All Forms
Form: Platelet Transfusion Form
Generated On: 02 May 2023 16:20:18

FORM_OID	_____ 1
Transfusion date	_____ 2
Number of bags	_____ 3
Donor type	Pooled ☐ 4 Single ☐

Version 14.00 pushed to PRODUCTION 04.06.2023: All Forms
Form: Platelet Transfusion Form
Generated On: 02 May 2023 16:20:18

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
1	FORM_OID	$200				FORM_OID
2	PLT_TRANS_DT	dd-MMM-yyyy				PLT_TRANS_DT
3	NUM_BAGS	2				NUM_BAGS
4	DONOR_TYPE	1		1 = Pooled 2 = Single		DONOR_TYPE

Version 14.00 pushed to PRODUCTION 04.06.2023: All Forms
Form: Second Primary
Generated On: 02 May 2023 16:20:18

FORM_OID _____ 1

Form instructions:
This form is to be completed and submitted within 14 days of diagnosis of a new primary cancer.

If a digital copy of the requested source documentation is not available for direct upload, this form is set up to utilize the CTSU Document Image Portal integration. To utilize this integration, click "Save" at the bottom of the page after completing all the relevant fields on the form. A link to "Print Cover Sheet" will appear under the upload field. Click on the link, print and follow the directions stated on the coversheet. Any questions regarding this functionality, please contact the CTSU Help Desk at 1-888-823-5923.

Date of Diagnosis of Second Primary Cancer _____ 3

Site of Second Primary Cancer _____ 4

Specify other second primary cancer _____ 5

Is it likely that the second primary cancer is related to any anti-cancer treatment the patient has received? 6
No ☐
Yes ☐

Include information on histologic subtype _____ 7

Please upload copies of any corroborating pathology reports (required). NOTE: If the patient has been diagnosed with AML/MDS, submit a copy of the pathology report and the cytogenetic report on the Marrow Assessment Form. 8 _____

Briefly describe treatment planned or given for the diagnosis of this second primary 9 _____

Version 14.00 pushed to PRODUCTION 04.06.2023: All Forms
Form: Second Primary
Generated On: 02 May 2023 16:20:18

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
1	FORM PID3922837	$200				FORM_OID
3	Second Primary Neoplasm Diagnosis Date PID2003748_V4_0	dd MMM yyyy				PRIM2_DX_DT
4	Second Primary Malignant Neoplasm Anatomic Site Text PID2003749_V3_0	3		SEC_PRIM_SITE		PRIM2_SITE_FT
5	Second Primary Malignant Neoplasm Anatomic Site Specify PID2433974_V1_0	$200				PRIM2_SITE_SP

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
6	Second Primary Neoplasm Cancer Treatment Attribution Diagnosis Ind_2 PID3160811_V1_0	1		1 = No 2 = Yes		PRIM2_TX_RELATE_YN
7	Second Tumor Histologic Subtype Specify PID2003750_V4_0	$100				PRIM2_HISTOL_FT
8	Pathology Report Upload Text PID3914969_V1_0	$200				CYTO_REPORT
9	Second Cancer Therapy Planned Text PID2003752_V4_0	$200				TX_PLANNED_PRIM2_FT

Version 14.00 pushed to PRODUCTION 04.06.2023: All Forms
Form: Hematology/Chemistry
Generated On: 02 May 2023 16:20:18

FORM_OID	1
Lab Test	2
Test not done	3
Lab Value	4
Lab Unit	5
Value Abnormal?	6 No ☐ Yes ☐
Date Hematology (Blood) Sample Obtained	7

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
1	FORM PID476423 5	$200				FORM_OID
2	Laboratory Finding Test Name PID200374 6_V5_0	2		LAB_TEST_ PID218280 9_V4_0F	1: Hemoglobin , Blood 2: Platelets, Blood 3: White Blood Cells (WBC), #, Blood 4: Absolute Neutrophil Count (ANC), Blood 5: Monocytes, #, Blood 6: Lymphocyte s, #, Blood 7: Eosinophils, #, blood 8: Basophils, #, Blood 9: Reticulocyte s, #, Blood 10: Blasts, %, Blood	LAB_NAME _XX

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
③	Laboratory Procedure Not Performed Text PID2200616_V1_0	1				TEST_ND_XX
④	Laboratory Test Result Numeric Value PID2183360_V2_0	10.2				LAB_RS_XX
⑤	Laboratory Test Result Unit of Measure Unified Code for Units of Measure Code PID2787947_V1_0	2		LAB_UOM_PID2015224_V3_0F	1: g/dL 2: /µL 3: /µL 4: /µL 5: /µL 6: /µL 7: /µL 8: /µL 9: /µL 10: %	LAB_UNIT_XX
⑥	ABNORMAL_YN	1		1 = No 2 = Yes		ABNORMAL_YN
⑦	Sample Collection Date PID2004004_V3_0	MMM dd yyyy				LAB_DT_XX

Version 14.00 pushed to PRODUCTION 04.06.2023: All Forms
Form: Marrow Assessment
Generated On: 02 May 2023 16:20:18

FORM_OID _____ 1

Form instructions:

NOTES: When uploading any type of source documentation, please double check to ensure the patient's name and any identifiers, except initials and the patient's ECOG-ACRIN number, have been redacted.
The following PHI should be redacted from the uploaded documentation:

- Subject Name

- Birth Date

- Medical record number or other unique ID assigned by the site

- Personal address and/or zip code

- Personal phone number

- Social security number

- Accession number

NOTE: Please be sure to include the EA patient ID number when uploading any type of source documentation.

Was a bone marrow procedure done? 3
- [ ] No
- [ ] Yes

Were bone marrow samples submitted to MDS Central Laboratory and Biorepository? 4
- [ ] No
- [ ] Yes

Please indicate reason why samples were not submitted 5
- [ ] Procedure performed at another location
- [ ] Dry tap

	Patient refusal ☐ Site error ☐ COVID-19 Related ☐ Other (specify) ☐
Did the participant have their blood drawn?	No ☐ 6 Yes ☐
Please indicate reason why blood was not drawn	Patient refusal ☐ 7 Site error ☐ COVID-19 Related ☐ Clinic visit did not occur ☐ Other (specify) ☐
Were peripheral blood samples submitted to MDS Central Laboratory and Biorespository?	No ☐ 8 Yes ☐
Please indicate reason why samples were not collected	Procedure performed at another location ☐ 9 Patient refusal ☐ Site error ☐ COVID-19 Related ☐ Other (specify) ☐
Procedure	Bone marrow biopsy ☐ 10 Bone marrow aspirate ☐ Both biopsy and aspirate ☐
Date of procedure	_____ 11

Upload report 12

2008 WHO Category 13

- [ ] AML
- [ ] ICUS
- [ ] MDS/MPN overlap
- [ ] MDS Refractory cytopenia with unilineage dysplasia - refractory anemia (RCUD-RA)
- [ ] MDS Refractory cytopenia with unilineage dysplasia - refractory Neutropenia (RCUD-RN)
- [ ] MDS Refractory cytopenia with unilineage dysplasia - refractory Thrombocytopenia (RCUD-RT)
- [ ] MDS Refractory anemia with ring sideroblasts (RARS)
- [ ] MDS Refractory cytopenia with multilineage dysplasia (RCMD)
- [ ] MDS Refractory anemia with excess blasts-1 (RAEB-1)
- [ ] MDS Refractory anemia with excess blasts-2 (RAEB-2)
- [ ] MDS associated with isolated del(5q)
- [ ] Myelodysplastic syndrome unclassified (MDS-U)
- [ ] Other Malignancy, specify
- [ ] Other, specify

2016 WHO Category 14

- [ ] AML

ICUS ☐
MDS/MPN overlap ☐
MDS with single lineage dysplasia (MDS-SLD) ☐
MDS with single lineage dysplasia and ring sideroblasts (MDS-RSSLD) ☐
MDS with multilineage dysplasia (MDS-MLD) ☐
MDS with multilineage dysplasia and ring sideroblasts (MDS-RSMLD) ☐
MDS with excess blasts-1 (MDS-EB1, 5-9% blasts) ☐
MDS with excess blasts-2 (MDS-EB2, 10-19% blasts) ☐
MDS with isolated del(5q) ☐
MDS, unclassifiable (MDS-U) ☐
Other Malignancy, specify ☐
Other, specify ☐

Blast, %, Bone Marrow — Fixed Unit: % (15)

Blast, Bone Marrow, reported within normal limits (16)

Cellularity, %, Bone Marrow — Fixed Unit: % (17)

Cellularity, Bone Marrow, % unknown (18)
Hypocellular ☐
Normocellular ☐
Hypercellular ☐

Molecular diagnostics performed? (19)
- No ☐
- Yes, report uploaded ☐
- Yes, report not uploaded ☐

FISH performed? (20)
- No ☐
- Yes, report uploaded ☐
- Yes, report not uploaded ☐

Cytogenetic karyotyping performed? (21)
- No ☐
- Yes, report uploaded ☐
- Yes, report not uploaded ☐

Upload molecular diagnostics, FISH, and/or cytogenetic reports (22)

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
1	FORM_OID	$200				FORM_OID
3	BM_BX_YN	1		1 = No 2 = Yes		BM_BX_YN
4	BM_BX_SAMPL_SUBM_YN	1		1 = No 2 = Yes		BM_BX_SAMPL_SUBM_YN
5	REAS_SAMP2L_NOT_SUBM			1 = Procedure performed at another location 2 = Dry tap 3 = Patient refusal 4 = Site error 5 = COVID-19 Related 88 = Other (specify)		REAS_SAMPL_NOT_SUBM
6	BLOOD_DRAWN_YN	1		1 = No 2 = Yes		BLOOD_DRAWN_YN
7	REAS_BLOO2D_NOT_DRAWN			3 = Patient refusal 4 = Site error		REAS_BLOOD_NOT_DRAWN

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
				5 = COVID-19 Related 6 = Clinic visit did not occur 88 = Other (specify)		
8	BLOOD_SAMPL_SUBM_YN	1		1 = No 2 = Yes		BLOOD_SAMPL_SUBM_YN
9	REAS_BLOO2D_SAMPL_NOT_SUBM			1 = Procedure performed at another location 3 = Patient refusal 4 = Site error 5 = COVID-19 Related 88 = Other (specify)		REAS_BLOOD_SAMPL_NOT_SUBM
10	BM_PROCEDURE	1		1 = Bone marrow biopsy 2 = Bone marrow aspirate		BM_PROCEDURE

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
				3 = Both biopsy and aspirate		
11	BM_BX_DT	dd MMM yyyy				BM_BX_DT
12	BM_DX_UPLOAD	$200				BM_DX_UPLOAD
13	DIAG_WHO_CAT	2		1 = AML 2 = ICUS 3 = MDS/MPN overlap 4 = MDS Refractory cytopenia with unilineage dysplasia - refractory anemia (RCUD-RA) 5 = MDS Refractory cytopenia with unilineage dysplasia - refractory Neutropenia (RCUD-RN)		DIAG_WHO_CAT

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			6 = MDS Refractory cytopenia with unilineage dysplasia - refractory Thrombocytopenia (RCUD-RT) 7 = MDS Refractory anemia with ring sideroblasts (RARS) 8 = MDS Refractory cytopenia with multilineage dysplasia (RCMD) 9 = MDS Refractory anemia with excess blasts-1 (RAEB-1) 10 = MDS Refractory anemia with excess blasts-2 (RAEB-2)		

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
				11 = MDS associated with isolated del(5q) 12 = Myelodysplastic syndrome unclassified (MDS-U) 77 = Other Malignancy, specify 88 = Other, specify		
14	DIAG_WHO 2_CAT2			1 = AML 2 = ICUS 3 = MDS/MPN overlap 4 = MDS with single lineage dysplasia (MDS-SLD) 5 = MDS with single lineage dysplasia and ring sideroblasts (MDS-RSSLD)		DIAG_WHO_CAT2

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			6 = MDS with multilineage dysplasia (MDS-MLD) 7 = MDS with multilineage dysplasia and ring sideroblasts (MDS-RSMLD) 8 = MDS with excess blasts-1 (MDS-EB1, 5-9% blasts) 9 = MDS with excess blasts-2 (MDS-EB2, 10-19% blasts) 10 = MDS with isolated del(5q) 11 = MDS, unclassifiable (MDS-U) 77 = Other Malignancy, specify 88 = Other, specify		

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
15	BLAST_PCT	3				BLAST_PCT
16	BLAST_RPT_NORM_LIMITS_XX	1				BLAST_RPT_NORM_LIMITS_XX
17	CELL_PCT	3				CELL_PCT
18	CELLULARITY_UNKOWN_TYPE_XX	1		1 = Hypocellular 2 = Normocellular 3 = Hypercellular		CELLULARITY_UNKOWN_TYPE_XX
19	MOLEC_DIAG	1		1 = No 2 = Yes, report uploaded 3 = Yes, report not uploaded		MOLEC_DIAG
20	FISH	1		1 = No 2 = Yes, report uploaded 3 = Yes, report not uploaded		FISH

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
21	CYTO_KARY1O			1 = No 2 = Yes, report uploaded 3 = Yes, report not uploaded		CYTO_KARYO
22	CYTOGEN_RPT_UPLOAD	$200				CYTOGEN_RPT_UPLOAD

FORM_OID _____ 1

Form instructions:

NOTE: The flow cytometry report submitted under Molecular Diagnostics IS NOT a substitute for the cytogenetic and karyotype report. The cytogenetic report can take 7-10 days post collection before it is complete and ready to be uploaded. Please remember to upload the cytogenetic and karyotype reports when they are complete for central pathology review and study assignment to occur in a timely manner.

NOTE: When uploading any type of source documentation, please double check to ensure the patient's name and any identifiers, except initials and the patient's ECOG-ACRIN number, have been redacted.
The following PHI should be redacted from the uploaded documentation:

- Subject Name

- Birth Date

- Medical record number or other unique ID assigned by the site

- Personal address and/or zip code

- Personal phone number

- Social security number

- Accession number

NOTE: Please be sure to include the EA patient ID number when uploading any type of source documentation.

Was a bone marrow procedure done? 3

☐ No
☐ Yes

Were bone marrow samples submitted to MDS Central Laboratory and Biorepository?	No ☐ 4 Yes ☐
Please indicate reason why samples were not submitted	Procedure performed at another location ☐ 5 Dry tap ☐ Patient refusal ☐ Site error ☐ COVID-19 Related ☐ Other (specify) ☐
Did the participant have their blood drawn?	No ☐ 6 Yes ☐
Please indicate reason why blood was not drawn	Patient refusal ☐ 7 Site error ☐ COVID-19 Related ☐ Clinic visit did not occur ☐ Other (specify) ☐
Were peripheral blood samples submitted to MDS Central Laboratory and Biorespository?	No ☐ 8 Yes ☐
Please indicate reason why samples were not collected	Procedure performed at another location ☐ 9 Patient refusal ☐ Site error ☐ COVID-19 Related ☐ Other (specify) ☐

Procedure	Bone marrow biopsy ☐ 10 Bone marrow aspirate ☐ Both biopsy and aspirate ☐
Date of procedure	_____ 11
Upload report	_____ 12
2008 WHO Category	AML ☐ 13 ICUS ☐ MDS/MPN overlap ☐ MDS Refractory cytopenia with unilineage dysplasia - refractory anemia (RCUD-RA) ☐ MDS Refractory cytopenia with unilineage dysplasia - refractory Neutropenia (RCUD-RN) ☐ MDS Refractory cytopenia with unilineage dysplasia - refractory Thrombocytopenia (RCUD-RT) ☐ MDS Refractory anemia with ring sideroblasts (RARS) ☐ MDS Refractory cytopenia with multilineage dysplasia (RCMD) ☐ MDS Refractory anemia with excess blasts-1 (RAEB-1) ☐ MDS Refractory anemia with excess blasts-2 (RAEB-2) ☐ MDS associated with isolated del(5q) ☐

Myelodysplastic syndrome unclassified (MDS-U) ☐
Other Malignancy, specify ☐
Other, specify ☐

2016 WHO Category

AML ☐ 14
ICUS ☐
MDS/MPN overlap ☐
MDS with single lineage dysplasia (MDS-SLD) ☐
MDS with single lineage dysplasia and ring sideroblasts (MDS-RSSLD) ☐
MDS with multilineage dysplasia (MDS-MLD) ☐
MDS with multilineage dysplasia and ring sideroblasts (MDS-RSMLD) ☐
MDS with excess blasts-1 (MDS-EB1, 5-9% blasts) ☐
MDS with excess blasts-2 (MDS-EB2, 10-19% blasts) ☐
MDS with isolated del(5q) ☐
MDS, unclassifiable (MDS-U) ☐
Other Malignancy, specify ☐
Other, specify ☐

Blast, %, Bone Marrow — Fixed Unit: % 15

Blast, Bone Marrow, reported within normal limits 16

Cellularity, %, Bone Marrow — Fixed Unit: % 17

Cellularity, Bone Marrow, % unknown

- Hypocellular ☐ 18
- Normocellular ☐
- Hypercellular ☐

Molecular diagnostics performed?

- No ☐ 19
- Yes, report uploaded ☐
- Yes, report not uploaded ☐

FISH performed?

- No ☐ 20
- Yes, report uploaded ☐
- Yes, report not uploaded ☐

Cytogenetic karyotyping performed?

- No ☐ 21
- Yes, report uploaded ☐
- Yes, report not uploaded ☐

Upload molecular diagnostics, FISH, and/or cytogenetic reports _____ 22

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
1	FORM_OID	$200				FORM_OID
3	BM_BX_YN	1		1 = No 2 = Yes		BM_BX_YN
4	BM_BX_SAMPL_SUBM_YN	1		1 = No 2 = Yes		BM_BX_SAMPL_SUBM_YN
5	REAS_SAMP2L_NOT_SUBM			1 = Procedure performed at another location 2 = Dry tap 3 = Patient refusal 4 = Site error 5 = COVID-19 Related 88 = Other (specify)		REAS_SAMPL_NOT_SUBM
6	BLOOD_DRAWN_YN	1		1 = No 2 = Yes		BLOOD_DRAWN_YN
7	REAS_BLOO2D_NOT_DRAWN			3 = Patient refusal 4 = Site error		REAS_BLOOD_NOT_DRAWN

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
				5 = COVID-19 Related 6 = Clinic visit did not occur 88 = Other (specify)		
8	BLOOD_SAMPL_SUBM_YN	1		1 = No 2 = Yes		BLOOD_SAMPL_SUBM_YN
9	REAS_BLOO2D_SAMPL_NOT_SUBM			1 = Procedure performed at another location 3 = Patient refusal 4 = Site error 5 = COVID-19 Related 88 = Other (specify)		REAS_BLOOD_SAMPL_NOT_SUBM
10	BM_PROCEDURE	1		1 = Bone marrow biopsy 2 = Bone marrow aspirate	1:	BM_PROCEDURE

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
				3 = Both biopsy and aspirate		
11	BM_BX_DT	dd MMM yyyy				BM_BX_DT
12	BM_DX_UPLOAD	$200				BM_DX_UPLOAD
13	DIAG_WHO_CAT	2		1 = AML 2 = ICUS 3 = MDS/MPN overlap 4 = MDS Refractory cytopenia with unilineage dysplasia - refractory anemia (RCUD-RA) 5 = MDS Refractory cytopenia with unilineage dysplasia - refractory Neutropenia (RCUD-RN)		DIAG_WHO_CAT

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			6 = MDS Refractory cytopenia with unilineage dysplasia - refractory Thrombocytopenia (RCUD-RT) 7 = MDS Refractory anemia with ring sideroblasts (RARS) 8 = MDS Refractory cytopenia with multilineage dysplasia (RCMD) 9 = MDS Refractory anemia with excess blasts-1 (RAEB-1) 10 = MDS Refractory anemia with excess blasts-2 (RAEB-2)		

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
				11 = MDS associated with isolated del(5q) 12 = Myelodysplastic syndrome unclassified (MDS-U) 77 = Other Malignancy, specify 88 = Other, specify		
14	DIAG_WHO 2 _CAT2			1 = AML 2 = ICUS 3 = MDS/MPN overlap 4 = MDS with single lineage dysplasia (MDS-SLD) 5 = MDS with single lineage dysplasia and ring sideroblasts (MDS-RSSLD)		DIAG_WHO _CAT2

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			6 = MDS with multilineage dysplasia (MDS-MLD) 7 = MDS with multilineage dysplasia and ring sideroblasts (MDS-RSMLD) 8 = MDS with excess blasts-1 (MDS-EB1, 5-9% blasts) 9 = MDS with excess blasts-2 (MDS-EB2, 10-19% blasts) 10 = MDS with isolated del(5q) 11 = MDS, unclassifiable (MDS-U) 77 = Other Malignancy, specify 88 = Other, specify		

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
15	BLAST_PCT	3				BLAST_PCT
16	BLAST_RPT_NORM_LIMITS_XX	1				BLAST_RPT_NORM_LIMITS_XX
17	CELL_PCT	3				CELL_PCT
18	CELLULARITY_UNKOWN_TYPE_XX	1		1 = Hypocellular 2 = Normocellular 3 = Hypercellular		CELLULARITY_UNKOWN_TYPE_XX
19	MOLEC_DIAG	1		1 = No 2 = Yes, report uploaded 3 = Yes, report not uploaded		MOLEC_DIAG
20	FISH	1		1 = No 2 = Yes, report uploaded 3 = Yes, report not uploaded		FISH

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
21	CYTO_KARY1O			1 = No 2 = Yes, report uploaded 3 = Yes, report not uploaded		CYTO_KARYO
22	CYTOGEN_RPT_UPLOAD	$200				CYTOGEN_RPT_UPLOAD

Version 14.00 pushed to PRODUCTION 04.06.2023: All Forms
Form: Marrow Assessment Hematology/Chemistry 1
Generated On: 02 May 2023 16:20:18

FORM_OID	1
Lab Test	2
Test not done	3
Lab Value	4
Lab Unit	5
Value Abnormal?	6 No ☐ Yes ☐
Date Hematology (Blood) Sample Obtained	7

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
1	FORM PID4764235	$200				FORM_OID
2	Laboratory Finding Test Name PID2003746_V5_0	2		LAB_TEST_PID2182809_V4_0F	1: Hemoglobin, Blood 2: Platelets, Blood 3: White Blood Cells (WBC), #, Blood 4: Absolute Neutrophil Count (ANC), Blood 5: Monocytes, #, Blood 6: Lymphocytes, #, Blood 7: Eosinophils, #, blood 8: Basophils, #, Blood 9: Reticulocytes, #, Blood 10: Blasts, %, Blood	LAB_NAME_XX

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
3	Laboratory Procedure Not Performed Text PID2200616_V1_0	1				TEST_ND_XX
4	Laboratory Test Result Numeric Value PID2183360_V2_0	10.2				LAB_RS_XX
5	Laboratory Test Result Unit of Measure Unified Code for Units of Measure Code PID2787947_V1_0	2		LAB_UOM_PID2015224_V3_0F	1: g/dL 2: /µL 3: /µL 4: /µL 5: /µL 6: /µL 7: /µL 8: /µL 9: /µL 10: %	LAB_UNIT_XX
6	ABNORMAL_YN	1		1 = No 2 = Yes		ABNORMAL_YN
7	Sample Collection Date PID2004004_V3_0	MMM dd yyyy				LAB_DT_XX

FORM_OID		1
Lab Test		2
Test not done		3
Lab Value		4
Lab Unit		5
Value Abnormal?	No ☐ Yes ☐	6
Date Hematology (Blood) Sample Obtained		7

Version 14.00 pushed to PRODUCTION 04.06.2023: All Forms
Form: Marrow Assessment Hematology/Chemistry 2
Generated On: 02 May 2023 16:20:18

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
1	FORM PID476423 5	$200				FORM_OID
2	Laboratory Finding Test Name PID200374 6_V5_0	2		LAB_TEST_ PID218280 9_V4_0F	1: Hemoglobin , Blood 2: Platelets, Blood 3: White Blood Cells (WBC), #, Blood 4: Absolute Neutrophil Count (ANC), Blood 5: Monocytes, #, Blood 6: Lymphocyte s, #, Blood 7: Eosinophils, #, blood 8: Basophils, #, Blood 9: Reticulocyte s, #, Blood 10: Blasts, %, Blood	LAB_NAME _XX

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
3	Laboratory Procedure Not Performed Text PID2200616_V1_0	1				TEST_ND_XX
4	Laboratory Test Result Numeric Value PID2183360_V2_0	10.2				LAB_RS_XX
5	Laboratory Test Result Unit of Measure Unified Code for Units of Measure Code PID2787947_V1_0	2		LAB_UOM_PID2015224_V3_0F	1: g/dL 2: /µL 3: /µL 4: /µL 5: /µL 6: /µL 7: /µL 8: /µL 9: /µL 10: %	LAB_UNIT_XX
6	ABNORMAL_YN	1		1 = No 2 = Yes		ABNORMAL_YN
7	Sample Collection Date PID2004004_V3_0	MMM dd yyyy				LAB_DT_XX

FORM_OID	1
Lab Test	2
Test not done	3
Lab Value	4
Lab Unit	5
Value Abnormal?	6 No ☐ Yes ☐
Date Hematology (Blood) Sample Obtained	7

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
1	FORM PID476423 5	$200				FORM_OID
2	Laboratory Finding Test Name PID200374 6_V5_0	2		LAB_TEST_ PID218280 9_V4_0F	1: Hemoglobin , Blood 2: Platelets, Blood 3: White Blood Cells (WBC), #, Blood 4: Absolute Neutrophil Count (ANC), Blood 5: Monocytes, #, Blood 6: Lymphocyte s, #, Blood 7: Eosinophils, #, blood 8: Basophils, #, Blood 9: Reticulocyte s, #, Blood 10: Blasts, %, Blood	LAB_NAME _XX

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
3	Laboratory Procedure Not Performed Text PID2200616_V1_0	1				TEST_ND_XX
4	Laboratory Test Result Numeric Value PID2183360_V2_0	10.2				LAB_RS_XX
5	Laboratory Test Result Unit of Measure Unified Code for Units of Measure Code PID2787947_V1_0	2		LAB_UOM_PID2015224_V3_0F	1: g/dL 2: /µL 3: /µL 4: /µL 5: /µL 6: /µL 7: /µL 8: /µL 9: /µL 10: %	LAB_UNIT_XX
6	ABNORMAL_YN	1		1 = No 2 = Yes		ABNORMAL_YN
7	Sample Collection Date PID2004004_V3_0	MMM dd yyyy				LAB_DT_XX

Version 14.00 pushed to PRODUCTION 04.06.2023: All Forms
Form: Marrow Assessment Hematology/Chemistry 4
Generated On: 02 May 2023 16:20:18

FORM_OID	1
Lab Test	2
Test not done	3
Lab Value	4
Lab Unit	5
Value Abnormal?	6 No ☐ Yes ☐
Date Hematology (Blood) Sample Obtained	7

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
1	FORM PID4764235	$200				FORM_OID
2	Laboratory Finding Test Name PID2003746_V5_0	2		LAB_TEST_PID2182809_V4_0F	1: Hemoglobin, Blood 2: Platelets, Blood 3: White Blood Cells (WBC), #, Blood 4: Absolute Neutrophil Count (ANC), Blood 5: Monocytes, #, Blood 6: Lymphocytes, #, Blood 7: Eosinophils, #, blood 8: Basophils, #, Blood 9: Reticulocytes, #, Blood 10: Blasts, %, Blood	LAB_NAME_XX

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
3	Laboratory Procedure Not Performed Text PID2200616_V1_0	1				TEST_ND_XX
4	Laboratory Test Result Numeric Value PID2183360_V2_0	10.2				LAB_RS_XX
5	Laboratory Test Result Unit of Measure Unified Code for Units of Measure Code PID2787947_V1_0	2		LAB_UOM_PID2015224_V3_0F	1: g/dL 2: /µL 3: /µL 4: /µL 5: /µL 6: /µL 7: /µL 8: /µL 9: /µL 10: %	LAB_UNIT_XX
6	ABNORMAL_YN	1		1 = No 2 = Yes		ABNORMAL_YN
7	Sample Collection Date PID2004004_V3_0	MMM dd yyyy				LAB_DT_XX

FORM_OID	1
Lab Test	2
Test not done	3
Lab Value	4
Lab Unit	5
Value Abnormal?	No ☐ Yes ☐ 6
Date Hematology (Blood) Sample Obtained	7

Version 14.00 pushed to PRODUCTION 04.06.2023: All Forms
Form: Marrow Assessment Hematology/Chemistry 5
Generated On: 02 May 2023 16:20:18

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
1	FORM PID476423 5	$200				FORM_OID
2	Laboratory Finding Test Name PID200374 6_V5_0	2		LAB_TEST_ PID218280 9_V4_0F	1: Hemoglobin , Blood 2: Platelets, Blood 3: White Blood Cells (WBC), #, Blood 4: Absolute Neutrophil Count (ANC), Blood 5: Monocytes, #, Blood 6: Lymphocyte s, #, Blood 7: Eosinophils, #, blood 8: Basophils, #, Blood 9: Reticulocyte s, #, Blood 10: Blasts, %, Blood	LAB_NAME _XX

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
3	Laboratory Procedure Not Performed Text PID2200616_V1_0	1				TEST_ND_XX
4	Laboratory Test Result Numeric Value PID2183360_V2_0	10.2				LAB_RS_XX
5	Laboratory Test Result Unit of Measure Unified Code for Units of Measure Code PID2787947_V1_0	2		LAB_UOM_PID2015224_V3_0F	1: g/dL 2: /µL 3: /µL 4: /µL 5: /µL 6: /µL 7: /µL 8: /µL 9: /µL 10: %	LAB_UNIT_XX
6	ABNORMAL_YN	1		1 = No 2 = Yes		ABNORMAL_YN
7	Sample Collection Date PID2004004_V3_0	MMM dd yyyy				LAB_DT_XX

FORM_OID	_____	1
Lab Test	_____	2
Test not done	_____	3
Lab Value	_____	4
Lab Unit	_____	5
Value Abnormal?	No ☐ Yes ☐	6
Date Hematology (Blood) Sample Obtained	_____	7

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
1	FORM PID4764235	$200				FORM_OID
2	Laboratory Finding Test Name PID2003746_V5_0	2		LAB_TEST_PID2182809_V4_0F	1: Hemoglobin, Blood 2: Platelets, Blood 3: White Blood Cells (WBC), #, Blood 4: Absolute Neutrophil Count (ANC), Blood 5: Monocytes, #, Blood 6: Lymphocytes, #, Blood 7: Eosinophils, #, blood 8: Basophils, #, Blood 9: Reticulocytes, #, Blood 10: Blasts, %, Blood	LAB_NAME_XX

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
3	Laboratory Procedure Not Performed Text PID2200616_V1_0	1				TEST_ND_XX
4	Laboratory Test Result Numeric Value PID2183360_V2_0	10.2				LAB_RS_XX
5	Laboratory Test Result Unit of Measure Unified Code for Units of Measure Code PID2787947_V1_0	2		LAB_UOM_PID2015224_V3_0F	1: g/dL 2: /µL 3: /µL 4: /µL 5: /µL 6: /µL 7: /µL 8: /µL 9: /µL 10: %	LAB_UNIT_XX
6	ABNORMAL_YN	1		1 = No 2 = Yes		ABNORMAL_YN
7	Sample Collection Date PID2004004_V3_0	MMM dd yyyy				LAB_DT_XX

Version 14.00 pushed to PRODUCTION 04.06.2023: All Forms
Form: Marrow Assessment Hematology/Chemistry 7
Generated On: 02 May 2023 16:20:18

FORM_OID	1
Lab Test	2
Test not done	3
Lab Value	4
Lab Unit	5
Value Abnormal?	6 ☐ No ☐ Yes
Date Hematology (Blood) Sample Obtained	7

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
1	FORM PID4764235	$200				FORM_OID
2	Laboratory Finding Test Name PID2003746_V5_0	2		LAB_TEST_PID2182809_V4_0F	1: Hemoglobin, Blood 2: Platelets, Blood 3: White Blood Cells (WBC), #, Blood 4: Absolute Neutrophil Count (ANC), Blood 5: Monocytes, #, Blood 6: Lymphocytes, #, Blood 7: Eosinophils, #, blood 8: Basophils, #, Blood 9: Reticulocytes, #, Blood 10: Blasts, %, Blood	LAB_NAME_XX

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
3	Laboratory Procedure Not Performed Text PID2200616_V1_0	1				TEST_ND_XX
4	Laboratory Test Result Numeric Value PID2183360_V2_0	10.2				LAB_RS_XX
5	Laboratory Test Result Unit of Measure Unified Code for Units of Measure Code PID2787947_V1_0	2		LAB_UOM_PID2015224_V3_0F	1: g/dL 2: /µL 3: /µL 4: /µL 5: /µL 6: /µL 7: /µL 8: /µL 9: /µL 10: %	LAB_UNIT_XX
6	ABNORMAL_YN	1		1 = No 2 = Yes		ABNORMAL_YN
7	Sample Collection Date PID2004004_V3_0	MMM dd yyyy				LAB_DT_XX

Version 14.00 pushed to PRODUCTION 04.06.2023: All Forms
Form: Marrow Assessment Hematology/Chemistry 8
Generated On: 02 May 2023 16:20:18

FORM_OID	1
Lab Test	2
Test not done	3
Lab Value	4
Lab Unit	5
Value Abnormal?	6 No ☐ Yes ☐
Date Hematology (Blood) Sample Obtained	7

Version 14.00 pushed to PRODUCTION 04.06.2023: All Forms
Form: Marrow Assessment Hematology/Chemistry 8
Generated On: 02 May 2023 16:20:18

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
1	FORM PID476423 5	$200				FORM_OID
2	Laboratory Finding Test Name PID200374 6_V5_0	2		LAB_TEST_ PID218280 9_V4_0F	1: Hemoglobin , Blood 2: Platelets, Blood 3: White Blood Cells (WBC), #, Blood 4: Absolute Neutrophil Count (ANC), Blood 5: Monocytes, #, Blood 6: Lymphocyte s, #, Blood 7: Eosinophils, #, blood 8: Basophils, #, Blood 9: Reticulocyte s, #, Blood 10: Blasts, %, Blood	LAB_NAME _XX

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
3	Laboratory Procedure Not Performed Text PID2200616_V1_0	1				TEST_ND_XX
4	Laboratory Test Result Numeric Value PID2183360_V2_0	10.2				LAB_RS_XX
5	Laboratory Test Result Unit of Measure Unified Code for Units of Measure Code PID2787947_V1_0	2		LAB_UOM_PID2015224_V3_0F	1: g/dL 2: /µL 3: /µL 4: /µL 5: /µL 6: /µL 7: /µL 8: /µL 9: /µL 10: %	LAB_UNIT_XX
6	ABNORMAL_YN	1		1 = No 2 = Yes		ABNORMAL_YN
7	Sample Collection Date PID2004004_V3_0	MMM dd yyyy				LAB_DT_XX

FORM_OID	_____	1
Lab Test	_____	2
Test not done	_____	3
Lab Value	_____	4
Lab Unit	_____	5
Value Abnormal?	No ☐ Yes ☐	6
Date Hematology (Blood) Sample Obtained	_____	7

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
1	FORM PID4764235	$200				FORM_OID
2	Laboratory Finding Test Name PID2003746_V5_0	2		LAB_TEST_PID2182809_V4_0F	1: Hemoglobin, Blood 2: Platelets, Blood 3: White Blood Cells (WBC), #, Blood 4: Absolute Neutrophil Count (ANC), Blood 5: Monocytes, #, Blood 6: Lymphocytes, #, Blood 7: Eosinophils, #, blood 8: Basophils, #, Blood 9: Reticulocytes, #, Blood 10: Blasts, %, Blood	LAB_NAME_XX

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
3	Laboratory Procedure Not Performed Text PID2200616_V1_0	1				TEST_ND_XX
4	Laboratory Test Result Numeric Value PID2183360_V2_0	10.2				LAB_RS_XX
5	Laboratory Test Result Unit of Measure Unified Code for Units of Measure Code PID2787947_V1_0	2		LAB_UOM_PID2015224_V3_0F	1: g/dL 2: /µL 3: /µL 4: /µL 5: /µL 6: /µL 7: /µL 8: /µL 9: /µL 10: %	LAB_UNIT_XX
6	ABNORMAL_YN	1		1 = No 2 = Yes		ABNORMAL_YN
7	Sample Collection Date PID2004004_V3_0	MMM dd yyyy				LAB_DT_XX

FORM_OID	_____	1
Lab Test	_____	2
Test not done	_____	3
Lab Value	_____	4
Lab Unit	_____	5
Value Abnormal?	No ☐ Yes ☐	6
Date Hematology (Blood) Sample Obtained	_____	7

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
1	FORM PID476423 5	$200				FORM_OID
2	Laboratory Finding Test Name PID200374 6_V5_0	2		LAB_TEST_ PID218280 9_V4_0F	1: Hemoglobin , Blood 2: Platelets, Blood 3: White Blood Cells (WBC), #, Blood 4: Absolute Neutrophil Count (ANC), Blood 5: Monocytes, #, Blood 6: Lymphocyte s, #, Blood 7: Eosinophils, #, blood 8: Basophils, #, Blood 9: Reticulocyte s, #, Blood 10: Blasts, %, Blood	LAB_NAME _XX

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
3	Laboratory Procedure Not Performed Text PID2200616_V1_0	1				TEST_ND_XX
4	Laboratory Test Result Numeric Value PID2183360_V2_0	10.2				LAB_RS_XX
5	Laboratory Test Result Unit of Measure Unified Code for Units of Measure Code PID2787947_V1_0	2		LAB_UOM_PID2015224_V3_0F	1: g/dL 2: /µL 3: /µL 4: /µL 5: /µL 6: /µL 7: /µL 8: /µL 9: /µL 10: %	LAB_UNIT_XX
6	ABNORMAL_YN	1		1 = No 2 = Yes		ABNORMAL_YN
7	Sample Collection Date PID2004004_V3_0	MMM dd yyyy				LAB_DT_XX

Version 14.00 pushed to PRODUCTION 04.06.2023: All Forms
Form: Adverse Event Form
Generated On: 02 May 2023 16:20:18

FORM_OID _____ 1

Form instructions:
Report only severe adverse events (CTCAE Grade 3-5) that are related to the biologic sampling procedures for the study.

During this reporting period, did the patient have any severe adverse events (CTCAE Grade 3-5) that were related to the biologic sampling procedures for this study?

No ☐ 3
Yes ☐

Adverse Event Text Name (CTCAE v4.0) _____ 4

MedDRA Adverse Event Code (v12.0) _____ 5

Adverse Event Grade _____ 6

Adverse Event Grade Description _____ 7

Version 14.00 pushed to PRODUCTION 04.06.2023: All Forms
Form: Adverse Event Form
Generated On: 02 May 2023 16:20:18

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
1	FORM PID3932371	$200				FORM_OID
3	AEYN	1		1 = No 2 = Yes		AEYN
4	Common Terminology Criteria for Adverse Events Version 4.0 Low Level Term Name PID3125302_V1_1	10		CTCAE_403_TERM		TOXXX
5	Common Terminology Criteria for Adverse Events Version 4.0 Mapped Low Level Term MedDRA Code PID3133353_V1_0	$200				MEDRASOCXX

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
6	Adverse Event Severity Grade PID2944515_V1_0	2				VALXX
7	Grade 3 Adverse Event Description Text PID2001857_V4_0	$700				VALDESCXX

Version 14.00 pushed to PRODUCTION 04.06.2023: All Forms
Form: Pre-Treatment Hematology/Chemistry
Generated On: 02 May 2023 16:20:18

FORM_OID	1
Lab Test	2
Test not done	3
Lab Value	4
Lab Unit	5
Value Abnormal?	6 ☐ No ☐ Yes
Date Hematology (Blood) Sample Obtained	7

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
1	FORM PID476423 5	$200				FORM_OID
2	Laboratory Finding Test Name PID200374 6_V5_0	2		LAB_TEST_ PID218280 9_V4_0F	1: Hemoglobin , Blood 2: Platelets, Blood 3: White Blood Cells (WBC), #, Blood 4: Absolute Neutrophil Count (ANC), Blood 5: Monocytes, #, Blood 6: Lymphocyte s, #, Blood 7: Eosinophils, #, blood 8: Basophils, #, Blood 9: Reticulocyte s, #, Blood 10: Blasts, %, Blood	LAB_NAME _XX

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
3	Laboratory Procedure Not Performed Text PID2200616_V1_0	1				TEST_ND_XX
4	Laboratory Test Result Numeric Value PID2183360_V2_0	10.2				LAB_RS_XX
5	Laboratory Test Result Unit of Measure Unified Code for Units of Measure Code PID2787947_V1_0	2		LAB_UOM_PID2015224_V3_0F	1: g/dL 2: /µL 3: /µL 4: /µL 5: /µL 6: /µL 7: /µL 8: /µL 9: /µL 10: %	LAB_UNIT_XX
6	ABNORMAL_YN	1		1 = No 2 = Yes		ABNORMAL_YN
7	Sample Collection Date PID2004004_V3_0	MMM dd yyyy				LAB_DT_XX

Version 14.00 pushed to PRODUCTION 04.06.2023: All Forms
Form: Therapy Yes/No
Generated On: 02 May 2023 16:20:18

FORM_OID _____ 1

Have new therapeutic regimen(s) started or stopped since the patient's last visit? 2

- ☐ Started
- ☐ Stopped
- ☐ Both stopped and started
- ☐ Neither

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Form: Therapy Yes/No
Generated On: 02 May 2023 16:20:18

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
1	FORM_OID	$200				FORM_OID
2	THERAPY_Y N	1		1 = Started 2 = Stopped 3 = Both stopped and started 4 = Neither		THERAPY_Y N

Version 14.00 pushed to PRODUCTION 04.06.2023: All Forms
Form: MDS Disease Modifying Therapy/Hematologic Therapy
Generated On: 02 May 2023 16:20:18

FORM_OID _____ 1

Form instructions:
Report disease-modifying therapy for MDS or hematologic therapy. Growth factors (including erythropoiesis-stimulating agents) and iron chelation should be reported on the Concomitant Medication Form.

Is the patient on an active MDS therapeutic trial or a hematologic therapy which restricts ongoing reporting? 3
- No ☐
- Yes ☐

Regimen start date _____ 4

Agent _____ 5

Agent dose (initial) _____ 6

Agent unit (initial) 7
- mg ☐
- mg/m^2 ☐
- mg/kg ☐

Cycle length (initial) Fixed Unit: days 8
_____

Dosing days/cycle Fixed Unit: days 9
_____

Agent dose (at 6 months) _____ 10

Agent unit (at 6 months) 11
- mg ☐

mg/m^2 ☐
mg/kg ☐

Cycle length (at 6 months) — Fixed Unit: days (12) _____

Dosing days/cycle — Fixed Unit: days (13) _____

Agent dose (at 12 months) _____ (14)

Agent unit (at 12 months) — mg ☐ (15)
mg/m^2 ☐
mg/kg ☐

Cycle length (at 12 months) — Fixed Unit: days (16) _____

Dosing days/cycle — Fixed Unit: days (17) _____

Regimen end date _____ (18)

Reason regimen ended — Death ☐ (19)
Progression ☐
Toxicity ☐
Bone Marrow Transplant ☐
Lack of response ☐
Completed planned course ☐

Other, specify ☐

Total number of cycles delivered _____ 20

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
1	FORM_OID	$200				FORM_OID
3	ACTIVE_TX_TRIAL	1		1 = No 2 = Yes		ACTIVE_TX_TRIAL
4	REG_STRT_DT	dd MMM yyyy				REG_STRT_DT
5	AGENT	2		AGENT		AGENT
6	AGENT_DOSE_INIT	7.2				AGENT_DOSE_INIT
7	AGENT_UNIT_INIT	1		1 = mg 2 = mg/m^2 3 = mg/kg		AGENT_UNIT_INIT
8	CYCLE_LENGTH_INIT	3				CYCLE_LENGTH_INIT
9	DOSE_DAYS_INIT	3				DOSE_DAYS_INIT
10	AGENT_DOSE_6MO	7.2				AGENT_DOSE_6MO
11	AGENT_UNIT_6MO	1		1 = mg 2 = mg/m^2		AGENT_UNIT_6MO

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
				3 = mg/kg		
12	CYCLE_LENGTH_6MO	3				CYCLE_LENGTH_6MO
13	DOSE_DAYS_6MO	3				DOSE_DAYS_6MO
14	AGENT_DOSE_12MO	7.2				AGENT_DOSE_12MO
15	AGENT_UNIT_12MO	1		1 = mg 2 = mg/m^2 3 = mg/kg		AGENT_UNIT_12MO
16	CYCLE_LENGTH_12MO	3				CYCLE_LENGTH_12MO
17	DOSE_DAYS_12MO	3				DOSE_DAYS_12MO
18	REG_END_DT	dd MMM yyyy				REG_END_DT
19	REG_END_REAS	2		1 = Death 2 = Progression 3 = Toxicity		REG_END_REAS

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
				4 = Bone Marrow Transplant 5 = Lack of response 6 = Completed planned course 88 = Other, specify		
20	NUM_CYCLES	3				NUM_CYCLES

Version 14.00 pushed to PRODUCTION 04.06.2023: All Forms
Form: Concomitant Medication Yes/No
Generated On: 02 May 2023 16:20:18

FORM_OID	_____ 1
In the 12 months prior to registration, has the patient taken any non-disease modifying concomitant medications?	No ☐ 2 Yes ☐
Have the patient's non-disease modifying concomitant medications changed since previous visit?	No ☐ 3 Yes ☐

Version 14.00 pushed to PRODUCTION 04.06.2023: All Forms
Form: Concomitant Medication Yes/No
Generated On: 02 May 2023 16:20:18

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
1	FORM_OID	$200				FORM_OID
2	BL_MED_YN	1		1 = No 2 = Yes		BL_MED_YN
3	MEDS_YN	1		1 = No 2 = Yes		MEDS_YN

FORM_OID		1
Did the patient have a hematologic response to this treatment regimen?	No ☐ Yes ☐	2
Lab Test		3
Test not done		4
Lab Value		5
Lab Unit		6
Value Abnormal?	No ☐ Yes ☐	7
Date Hematology (Blood) Sample Obtained		8

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
1	FORM PID4764235	$200				FORM_OID
2	HEM_RESP_1 YN			1 = No 2 = Yes		HEM_RESP_ YN
3	Laboratory Finding Test Name PID2003746_V5_0	2		LAB_TEST_ PID2182809_V4_0F	1: Hemoglobin, Blood 2: Platelets, Blood 3: White Blood Cells (WBC), #, Blood 4: Absolute Neutrophil Count (ANC), Blood 5: Monocytes, #, Blood 6: Lymphocytes, #, Blood 7: Eosinophils, #, blood 8: Basophils, #, Blood 9: Reticulocytes, #, Blood	LAB_NAME _XX

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
					10: Blasts, %, Blood	
④	Laboratory Procedure Not Performed Text PID2200616_V1_0	1				TEST_ND_XX
⑤	Laboratory Test Result Numeric Value PID2183360_V2_0	10.2				LAB_RS_XX
⑥	Laboratory Test Result Unit of Measure Unified Code for Units of Measure Code PID2787947_V1_0	2		LAB_UOM_PID2015224_V3_0F	1: g/dL 2: /µL 3: /µL 4: /µL 5: /µL 6: /µL 7: /µL 8: /µL 9: /µL 10: %	LAB_UNIT_XX
⑦	ABNORMAL_YN	1		1 = No 2 = Yes		ABNORMAL_YN

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
8	Sample Collection Date PID2004004_V3_0	MMM dd yyyy				LAB_DT_XX

FORM_OID _____ 1

Was VES-13 Frailty completed? 2
- ☐ No, assessment was not required at this time point
- ☐ No, assessment was required
- ☐ Yes

Was QUALMS completed? 3
- ☐ No, assessment was not required at this time point
- ☐ No, assessment was required
- ☐ Yes

Was FACT-G completed? 4
- ☐ No, assessment was not required at this time point
- ☐ No, assessment was required
- ☐ Yes

Was EQ-5D-5L completed? 5
- ☐ No, assessment was not required at this time point
- ☐ No, assessment was required
- ☐ Yes

Was PROMIS Short form fatigue 7a completed? 6
- ☐ No, assessment was not required at this time point
- ☐ No, assessment was required
- ☐ Yes

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
1	FORM_OID	$200				FORM_OID
2	Cancer Therapy Functional Assessment Questionnaire Complete Ind_2 PID2200515_V1_0_1	1		1 = No, assessment was not required at this time point 2 = No, assessment was required 3 = Yes		QOL_COMP_YN
3	Cancer Therapy Functional Assessment Questionnaire Complete Ind_2 PID2200515_V1_0_2	1		1 = No, assessment was not required at this time point 2 = No, assessment was required 3 = Yes		QOL_COMP_2_YN
4	Cancer Therapy Functional Assessment Questionnaire Complete Ind_2 PID2200515_V1_0_3	1		1 = No, assessment was not required at this time point		QOL_COMP_3_YN

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
				2 = No, assessment was required 3 = Yes		
5	Cancer Therapy Functional Assessment Questionnaire Complete Ind_2 PID2200515_V1_0_4	1		1 = No, assessment was not required at this time point 2 = No, assessment was required 3 = Yes		QOL_COMP_4_YN
6	Cancer Therapy Functional Assessment Questionnaire Complete Ind_2 PID2200515_V1_0_5	1		1 = No, assessment was not required at this time point 2 = No, assessment was required 3 = Yes		QOL_COMP_5_YN

Version 14.00 pushed to PRODUCTION 04.06.2023: All Forms
Form: Quality of Life Completed Yes/No
Generated On: 02 May 2023 16:20:18

FORM_OID _____ 1

Form instructions:
For patients in the ICUS Longitudinal cohort, the QUALMS and FACT-G assessments are not required and should not be completed.

Was VES-13 Frailty completed?

- No, assessment was not required at this time point ☐ 3
- No, assessment was required ☐
- Yes ☐

Was QUALMS completed?

- No, assessment was not required at this time point ☐ 4
- No, assessment was required ☐
- Yes ☐

Was FACT-G completed?

- No, assessment was not required at this time point ☐ 5
- No, assessment was required ☐
- Yes ☐

Was EQ-5D-5L completed?

- No, assessment was not required at this time point ☐ 6
- No, assessment was required ☐
- Yes ☐

Was PROMIS Short form fatigue 7a completed?

- No, assessment was not required at this time point ☐ 7
- No, assessment was required ☐

Yes ☐

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
1	FORM_OID	$200				FORM_OID
3	Cancer Therapy Functional Assessment Questionnaire Complete Ind_2 PID2200515_V1_0_1	1		1 = No, assessment was not required at this time point 2 = No, assessment was required 3 = Yes		QOL_COMP_YN
4	Cancer Therapy Functional Assessment Questionnaire Complete Ind_2 PID2200515_V1_0_2	1		1 = No, assessment was not required at this time point 2 = No, assessment was required 3 = Yes		QOL_COMP_2_YN
5	Cancer Therapy Functional Assessment Questionnaire Complete Ind_2 PID2200515_V1_0_3	1		1 = No, assessment was not required at this time point		QOL_COMP_3_YN

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
				2 = No, assessment was required 3 = Yes		
6	Cancer Therapy Functional Assessment Questionnaire Complete Ind_2 PID2200515_V1_0_4	1		1 = No, assessment was not required at this time point 2 = No, assessment was required 3 = Yes		QOL_COMP_4_YN
7	Cancer Therapy Functional Assessment Questionnaire Complete Ind_2 PID2200515_V1_0_5	1		1 = No, assessment was not required at this time point 2 = No, assessment was required 3 = Yes		QOL_COMP_5_YN

Version 14.00 pushed to PRODUCTION 04.06.2023: All Forms
Form: QOL Completed
Generated On: 02 May 2023 16:20:18

FORM_OID _____ 1

Where were the forms completed?

Were the forms completed in clinic? No ☐ 3
Yes ☐

Were the forms completed at home? No ☐ 4
Yes ☐

What was the method of completion? Completed at home and returned through the mail ☐ 5
Completed via a telephone interview ☐
Completed via videoconference ☐
Other ☐

Assistance

Did the patient require assistance completing the QOL forms? No ☐ 7
Yes ☐

How was the patient assisted?

Were the questions read aloud to patient? No ☐ 9
Yes ☐

Did the patient require clarification of questions or instructions? No ☐ 10
Yes ☐

Did the patient require other assistance?	No ☐ 11 Yes ☐
Were the forms completed independently by another person?	No ☐ 12 Yes ☐

What was the reason for assistance?

Did the patient have a language difficulty? (questions needed to be translated)	No ☐ 14 Yes (specify) ☐
Did the patient have a literacy difficulty? (patient could not read well enough)	No ☐ 15 Yes ☐
Was the patient disabled?	No ☐ 16 Yes (specify) ☐
Were the forms completed via a telephone interview?	No ☐ 17 Yes ☐
Other	No ☐ 18 Yes (specify) ☐

Who assisted or completed the assessment?

Staff	No ☐ 20 Yes ☐

Family	No ☐ 21 Yes ☐
Friend	No ☐ 22 Yes ☐
Other	No ☐ 23 Yes (specify) ☐

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
1	FORM_OID	$200				FORM_OID
3	IN_CLINIC_YN	1		1 = No 2 = Yes		IN_CLINIC_YN
4	AT_HOME_YN	1		1 = No 2 = Yes		AT_HOME_YN
5	COMPL_METHOD	2		1 = Completed at home and returned through the mail 2 = Completed via a telephone interview 3 = Completed via videoconference 88 = Other		COMPL_METHOD
7	Was Assessment self-administered PID2003760_V4_0	1		1 = No 2 = Yes		ASSMNT_SELF_ADMN

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
9	Were the questions read aloud to patient PID242253_V1_0	1		1 = No 2 = Yes		Q_READ_ALOUD
10	Did the patient require clarification of questions or instructions PID242625 7_V1_0	1		1 = No 2 = Yes		PT_REQ_CLRF
11	Did the patient require other assistance PID242625 9_V1_0	1		1 = No 2 = Yes		PT_REQ_OTH_ASSIST
12	Were the forms completed independently by another person PID242626 2_V1_0	1		1 = No 2 = Yes		FORM_COMPL_OTHER_PRSN

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
14	Did the patient have a language difficulty (questions needed to be translated) PID2426264_V1_0	1		1 = No 2 = Yes (specify)		LANG_DIFFICULTY
15	Did the patient have a literacy difficulty (patient could not read well enough) PID2426268_V1_0	1		1 = No 2 = Yes		LITER_DIFFICULTY
16	Was the patient disabled PID2426270_V1_0	1		1 = No 2 = Yes (specify)		PT_DISABLED

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
17	Were the forms completed via a telephone interview PID2426274_V1_0	1		1 = No 2 = Yes		FORM_COMPL_PHONE
18	Other PID2426276_V1_0	1		1 = No 2 = Yes (specify)		OTHER_REAS
20	Staff PID2426280_V1_0	1		1 = No 2 = Yes		STAFF_ASSIST
21	Family PID2426282_V1_0	1		1 = No 2 = Yes		FAMILY_ASSIST
22	Friend PID2426284_V1_0	1		1 = No 2 = Yes		FRIEND_ASSIST
23	Other PID2426896_V1_0	1		1 = No 2 = Yes (specify)		OTHER_ASSIST

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Form: QOL Not Completed Reason
Generated On: 02 May 2023 16:20:18

FORM_OID	1
(Scheduled) Assessment date	2
Indicate reason(s) why form was not completed (check all that apply)	
Patient refusal	4
Unable to accommodate disability or language needs	5
Specify disability or language	6
Patient did not show up in clinic/office	7
Specify reason patient did not show up	8
Staff unavailable	9
Patient not given form by staff	10
Patient too ill	11
Patient expired	12
Staff thought patient too ill	13
Other	14
Specify other reason	15

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Form: QOL Not Completed Reason
Generated On: 02 May 2023 16:20:18

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
1	FORM_OID	$200				FORM_OID
2	Assessment Date PID2007321_V1_0	MMM-dd-yyyy				QOL_ASSMNT_DT
4	Patient Refusal PID2426120_V1_0	1				PT_REFUSE_YN
5	Unable to accommodate disability or language needs PID2426127	1				UNABLE_ACCM_DIS_LANG
6	UNABLE_ACCM_DIS_LANG2_SPECIFY	$200				UNABLE_ACCM_DIS_LANG2_SPECIFY
7	Patient did not show up in clinic/office PID2426135_V1_0	1				PT_NO_SHOW

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
8	PT_NO_SHOW2_SPECIFY	$200				PT_NO_SHOW2_SPECIFY
9	Staff unavailable PID2426141_V1_0	1				STAFF_UNAVAIL
10	Patient not given form by staff PID2426149_V1_0	1				PT_NOT_GVN_FORM
11	Patient too ill PID2426151_V1_0	1				PT_TOO_ILL
12	Patient expried PID2426153_V1_0	1				PT_EXPRD
13	Staff thought patient too ill PID2426222_V1_0	1				STAFF_THGHT_PT_TOO_ILL

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
14	Other PID2426224_V1_0	1				OTHER_REAS2
15	OTHER_REAS2_SPECIFY	$200				OTHER_REAS2_SPECIFY

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Form: VES-13 Frailty Patient Responses
Generated On: 02 May 2023 16:20:18

FORM_OID _____ 1

Age _____ 2

In general, compared to other people your age, would you say that your health is: 3

- ☐ Poor
- ☐ Fair
- ☐ Good
- ☐ Very good
- ☐ Excellent

How much difficulty on average, do you have with the following physical activities:

Stooping, crouching or kneeling? 5

- ☐ No Difficulty
- ☐ A little Difficulty
- ☐ Some Difficulty
- ☐ A Lot of Difficulty
- ☐ Unable to do

Lifting, or carrying objects as heavy as 10 pounds? 6

- ☐ No Difficulty
- ☐ A little Difficulty
- ☐ Some Difficulty
- ☐ A Lot of Difficulty
- ☐ Unable to do

Reaching or extending arms above shoulder level? 7

- ☐ No Difficulty
- ☐ A little Difficulty
- ☐ Some Difficulty
- ☐ A Lot of Difficulty
- ☐ Unable to do

Writing, or handling and grasping small objects? (8)

- No Difficulty
- A little Difficulty
- Some Difficulty
- A Lot of Difficulty
- Unable to do

Walking a quarter of a mile? (9)

- No Difficulty
- A little Difficulty
- Some Difficulty
- A Lot of Difficulty
- Unable to do

Heavy housework such as scrubbing floors or washing windows? (10)

- No Difficulty
- A little Difficulty
- Some Difficulty
- A Lot of Difficulty
- Unable to do

Because of your health or a physical condition, do you have difficulty:

Shopping for personal items (like toilet items or medicines)? (12)

- Yes
- No
- Don't do

Do you get help shopping? (13)

- No
- Yes

Is that because of your health? (14)

- No
- Yes

Managing money (like keeping track of expenses or paying bills)? — Yes ☐ 15 / No ☐ / Don't do ☐

Do you get help with managing money? — No ☐ 16 / Yes ☐

Is that because of your health? — No ☐ 17 / Yes ☐

Walking across the room? USE OF CANE OR WALKER IS OK — Yes ☐ 18 / No ☐ / Don't do ☐

Do you get help with walking? — No ☐ 19 / Yes ☐

Is that because of your health? — No ☐ 20 / Yes ☐

Doing light housework (like washing dishes, straightening up, or light cleaning)? — Yes ☐ 21 / No ☐ / Don't do ☐

Do you get help with light housework? — No ☐ 22 / Yes ☐

Is that because of your health? — No ☐ 23

	Yes ☐
Bathing or showering?	Yes ☐ 24 No ☐ Don't do ☐
Do you get help bathing or showering?	No ☐ 25 Yes ☐
Is that because of your health?	No ☐ 26 Yes ☐

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
1	FORM_OID	$200				FORM_OID
2	AGE	3				AGE
3	HEALTH_COMP_AGE	1		1 = Poor 2 = Fair 3 = Good 4 = Very good 5 = Excellent		HEALTH_COMP_AGE
5	ST_CR_KN	1		1 = No Difficulty 2 = A little Difficulty 3 = Some Difficulty 4 = A Lot of Difficulty 5 = Unable to do		ST_CR_KN
6	LIFT_CARRY	1		1 = No Difficulty 2 = A little Difficulty 3 = Some Difficulty 4 = A Lot of Difficulty 5 = Unable to do		LIFT_CARRY

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
7	REACH_EXT END	1		1 = No Difficulty 2 = A little Difficulty 3 = Some Difficulty 4 = A Lot of Difficulty 5 = Unable to do		REACH_EXT END
8	WRITE_GR ASP	1		1 = No Difficulty 2 = A little Difficulty 3 = Some Difficulty 4 = A Lot of Difficulty 5 = Unable to do		WRITE_GR ASP
9	WALK	1		1 = No Difficulty 2 = A little Difficulty 3 = Some Difficulty 4 = A Lot of Difficulty 5 = Unable to do		WALK
10	HEAVY_HS WRK	1		1 = No Difficulty		HEAVY_HS WRK

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
				2 = A little Difficulty 3 = Some Difficulty 4 = A Lot of Difficulty 5 = Unable to do		
12	SHP_PERSONAL	1		2 = Yes 1 = No 3 = Don't do		SHP_PERSONAL
13	HELP_SHOP	1		1 = No 2 = Yes		HELP_SHOP
14	DONT_SHOP_HLTH	1		1 = No 2 = Yes		DONT_SHOP_HLTH
15	MANAGE_MONEY	1		2 = Yes 1 = No 3 = Don't do		MANAGE_MONEY
16	HELP_MONEY	1		1 = No 2 = Yes		HELP_MONEY
17	DONT_MONEY_HLTH	1		1 = No 2 = Yes		DONT_MONEY_HLTH

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
18	WALK_ROOM	1		2 = Yes 1 = No 3 = Don't do		WALK_ROOM
19	HELP_WALK_ROOM	1		1 = No 2 = Yes		HELP_WALK_ROOM
20	DONT_WALK_HLTH	1		1 = No 2 = Yes		DONT_WALK_HLTH
21	LGHT_HSWRK	1		2 = Yes 1 = No 3 = Don't do		LGHT_HSWRK
22	HELP_LGHT_HSWRK_HTLH	1		1 = No 2 = Yes		HELP_LGHT_HSWRK_HTLH
23	DONT_LGHT_HSWRK	1		1 = No 2 = Yes		DONT_LGHT_HSWRK
24	BATH_SHWR	1		2 = Yes 1 = No 3 = Don't do		BATH_SHWR
25	HELP_BATH_SHWR	1		1 = No 2 = Yes		HELP_BATH_SHWR

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
26	DONT_BAT H_SHWR_H TLH	1		1 = No 2 = Yes		DONT_BAT H_SHWR_H TLH

FORM_OID _____ 1

During the past week, how often…

1. Did you feel as though there was a lack of clear information about your disease? 3

- ☐ Never
- ☐ Rarely
- ☐ Sometimes
- ☐ Often
- ☐ Always

2. Have you felt there was limited emotional support available for patients with MDS beyond their families? 4

- ☐ Never
- ☐ Rarely
- ☐ Sometimes
- ☐ Often
- ☐ Always

3. Did you feel as though you couldn't do anything about your disease? 5

- ☐ Never
- ☐ Rarely
- ☐ Sometimes
- ☐ Often
- ☐ Always

4. Did you feel the course of your disease was unpredictable? 6

- ☐ Never
- ☐ Rarely
- ☐ Sometimes
- ☐ Often
- ☐ Always

5. Did you have difficulty explaining MDS to your friends or family? 7

- ☐ Never

Rarely ☐
Sometimes ☐
Often ☐
Always ☐

6. Did you have trouble concentrating?

Never ☐ 8
Rarely ☐
Sometimes ☐
Often ☐
Always ☐

7. Have you considered changing long-term plans due to health concerns?

Never ☐ 9
Rarely ☐
Sometimes ☐
Often ☐
Always ☐

8. Have you experienced shortness of breath?

Never ☐ 10
Rarely ☐
Sometimes ☐
Often ☐
Always ☐

9. Did low energy levels cause you to change your schedule?

Never ☐ 11
Rarely ☐
Sometimes ☐
Often ☐
Always ☐

10. Did you feel as though your life was organized around medical appointments?

- Never (12)
- Rarely
- Sometimes
- Often
- Always

11. Have you felt a sense of hopelessness?

- Never (13)
- Rarely
- Sometimes
- Often
- Always

12. Have you been worried about getting an infection?

- Never (14)
- Rarely
- Sometimes
- Often
- Always

13. Have you had sufficient energy for routine tasks?

- Never (15)
- Rarely
- Sometimes
- Often
- Always

14. Were you afraid of dying?

- Never (16)
- Rarely
- Sometimes
- Often
- Always

15. Did you feel angry about your diagnosis? (17)

- ☐ Never
- ☐ Rarely
- ☐ Sometimes
- ☐ Often
- ☐ Always

16. Were you worried about bleeding? (18)

- ☐ Never
- ☐ Rarely
- ☐ Sometimes
- ☐ Often
- ☐ Always

17. Did you feel a sense of gratitude for a part of life that you took for granted before? (19)

- ☐ Never
- ☐ Rarely
- ☐ Sometimes
- ☐ Often
- ☐ Always

18. Did you feel nauseated? (20)

- ☐ Never
- ☐ Rarely
- ☐ Sometimes
- ☐ Often
- ☐ Always

19. Did you worry about your MDS progressing or developing into leukemia? (21)

- ☐ Never
- ☐ Rarely
- ☐ Sometimes
- ☐ Often
- ☐ Always

20. Did you take into account that you might be fatigued when planning your activities? 22

- Never
- Rarely
- Sometimes
- Often
- Always

21. Were you concerned that your MDS caused a financial burden for you or your family? 23

- Never
- Rarely
- Sometimes
- Often
- Always

22. Did you feel your family relationships were strained by your disease? 24

- Never
- Rarely
- Sometimes
- Often
- Always

23. Have you felt weak? 25

- Never
- Rarely
- Sometimes
- Often
- Always

24. Have you been too tired to take on the responsibilities you used to have? 26

- Never
- Rarely
- Sometimes
- Often
- Always

25. Did you worry about becoming a burden to your friends or family?

Never ☐ 27
Rarely ☐
Sometimes ☐
Often ☐
Always ☐

26. Were you unable to participate in activities you are used to doing?

Never ☐ 28
Rarely ☐
Sometimes ☐
Often ☐
Always ☐

27. Have you felt anxious about test or lab results?

Never ☐ 29
Rarely ☐
Sometimes ☐
Often ☐
Always ☐

28. Did you avoid crowds because of fear of getting an infection?

Never ☐ 30
Rarely ☐
Sometimes ☐
Often ☐
Always ☐

29. Did you find yourself grateful for tomorrow?

Never ☐ 31
Rarely ☐
Sometimes ☐
Often ☐
Always ☐

30. Did you feel you were able to find quality information about MDS treatments? 32

- Never
- Rarely
- Sometimes
- Often
- Always

31. Were you concerned about bruising? 33

- Never
- Rarely
- Sometimes
- Often
- Always

32. Did you feel as though there were a lack of concrete answers about what will happen with your MDS? 34

- Never
- Rarely
- Sometimes
- Often
- Always

33. Did you experience a change in bowel habits? 35

- Never
- Rarely
- Sometimes
- Often
- Always

34. Were you afraid of losing your job? 36

- Never
- Rarely
- Sometimes
- Often
- Always
- Not applicable

35. Did you feel too tired to drive? 37

- Never
- Rarely
- Sometimes
- Often
- Always
- Not applicable

36. Were you afraid to have sex due to your blood counts? 38

- Never
- Rarely
- Sometimes
- Often
- Always
- Not applicable

37. Were you afraid that your MDS treatment would stop working? 39

- Never
- Rarely
- Sometimes
- Often
- Always
- Not applicable

38. Have you been too tired to take care of a family member or loved one? 40

- Never
- Rarely
- Sometimes
- Often
- Always
- Not applicable

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
1	FORM_OID	$200				FORM_OID
3	LACK_INFO	1		1 = Never 2 = Rarely 3 = Sometimes 4 = Often 5 = Always		LACK_INFO
4	LIMIT_EMO_SPRT	1		1 = Never 2 = Rarely 3 = Sometimes 4 = Often 5 = Always		LIMIT_EMO_SPRT
5	DO_NOTHING	1		1 = Never 2 = Rarely 3 = Sometimes 4 = Often 5 = Always		DO_NOTHING
6	DZ_UNPREDICT	1		1 = Never 2 = Rarely 3 = Sometimes 4 = Often 5 = Always		DZ_UNPREDICT
7	DIFF_EXPLAIN	1		1 = Never 2 = Rarely 3 = Sometimes		DIFF_EXPLAIN

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
				4 = Often 5 = Always		
8	TRBLE_CONCEN	1		1 = Never 2 = Rarely 3 = Sometimes 4 = Often 5 = Always		TRBLE_CONCEN
9	CHNG_PLANS	1		1 = Never 2 = Rarely 3 = Sometimes 4 = Often 5 = Always		CHNG_PLANS
10	SHRT_BRTH	1		1 = Never 2 = Rarely 3 = Sometimes 4 = Often 5 = Always		SHRT_BRTH
11	CHNG_SCHED	1		1 = Never 2 = Rarely 3 = Sometimes 4 = Often 5 = Always		CHNG_SCHED
12	ORG_MED_APPTS	1		1 = Never 2 = Rarely		ORG_MED_APPTS

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
				3 = Sometimes 4 = Often 5 = Always		
13	HOPELESS	1		1 = Never 2 = Rarely 3 = Sometimes 4 = Often 5 = Always		HOPELESS
14	WORRY_IN FECT	1		1 = Never 2 = Rarely 3 = Sometimes 4 = Often 5 = Always		WORRY_IN FECT
15	ROUTINE_T ASKS	1		1 = Never 2 = Rarely 3 = Sometimes 4 = Often 5 = Always		ROUTINE_T ASKS
16	AFRD_DYIN G	1		1 = Never 2 = Rarely 3 = Sometimes 4 = Often 5 = Always		AFRD_DYIN G

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
17	ANGRY_DX	1		1 = Never 2 = Rarely 3 = Sometimes 4 = Often 5 = Always		ANGRY_DX
18	WORRY_BLEED	1		1 = Never 2 = Rarely 3 = Sometimes 4 = Often 5 = Always		WORRY_BLEED
19	SENSE_GRAT	1		1 = Never 2 = Rarely 3 = Sometimes 4 = Often 5 = Always		SENSE_GRAT
20	FEEL_NAUSEATED	1		1 = Never 2 = Rarely 3 = Sometimes 4 = Often 5 = Always		FEEL_NAUSEATED
21	WORRY_PROGRESS	1		1 = Never 2 = Rarely 3 = Sometimes 4 = Often 5 = Always		WORRY_PROGRESS

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
22	TAKE_ACCNT_FATIGUE	1		1 = Never 2 = Rarely 3 = Sometimes 4 = Often 5 = Always		TAKE_ACCNT_FATIGUE
23	CNCRN_FINANCE	1		1 = Never 2 = Rarely 3 = Sometimes 4 = Often 5 = Always		CNCRN_FINANCE
24	RELATIONS HIP_STRND	1		1 = Never 2 = Rarely 3 = Sometimes 4 = Often 5 = Always		RELATIONS HIP_STRND
25	FELT_WEEK	1		1 = Never 2 = Rarely 3 = Sometimes 4 = Often 5 = Always		FELT_WEEK
26	TOO_TIRED_RESPNSB	1		1 = Never 2 = Rarely 3 = Sometimes 4 = Often 5 = Always		TOO_TIRED_RESPNSB

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
27	BCME_BUR DEN	1		1 = Never 2 = Rarely 3 = Sometimes 4 = Often 5 = Always		BCME_BUR DEN
28	UNABLE_PA RTIC	1		1 = Never 2 = Rarely 3 = Sometimes 4 = Often 5 = Always		UNABLE_PA RTIC
29	ANXS_TST_ RSLTS	1		1 = Never 2 = Rarely 3 = Sometimes 4 = Often 5 = Always		ANXS_TST_ RSLTS
30	AVOID_CR OWDS	1		1 = Never 2 = Rarely 3 = Sometimes 4 = Often 5 = Always		AVOID_CR OWDS
31	GRTFUL_TM RRW	1		1 = Never 2 = Rarely 3 = Sometimes 4 = Often 5 = Always		GRTFUL_TM RRW

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
32	QUALITY_INFO	1		1 = Never 2 = Rarely 3 = Sometimes 4 = Often 5 = Always		QUALITY_INFO
33	CNCRN_BRUISING	1		1 = Never 2 = Rarely 3 = Sometimes 4 = Often 5 = Always		CNCRN_BRUISING
34	LACK_ANSWERS	1		1 = Never 2 = Rarely 3 = Sometimes 4 = Often 5 = Always		LACK_ANSWERS
35	CHANGE_BOWEL	1		1 = Never 2 = Rarely 3 = Sometimes 4 = Often 5 = Always		CHANGE_BOWEL
36	AFRD_LOSE_JOB	2		1 = Never 2 = Rarely 3 = Sometimes 4 = Often 5 = Always		AFRD_LOSE_JOB

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
				99 = Not applicable		
37	TOO_TIRED_DRIVE	2		1 = Never 2 = Rarely 3 = Sometimes 4 = Often 5 = Always 99 = Not applicable		TOO_TIRED_DRIVE
38	AFRD_SEX	2		1 = Never 2 = Rarely 3 = Sometimes 4 = Often 5 = Always 99 = Not applicable		AFRD_SEX
39	AFRD_TX_STOPWRK	2		1 = Never 2 = Rarely 3 = Sometimes 4 = Often 5 = Always 99 = Not applicable		AFRD_TX_STOPWRK
40	TOO_TIRED_TK_CARE	2		1 = Never 2 = Rarely 3 = Sometimes		TOO_TIRED_TK_CARE

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			4 = Often 5 = Always 99 = Not applicable		

FORM_OID _____ 1

Form instructions:
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Assessment date _____ 3

I have a lack of energy 4
0 ☐
1 ☐
2 ☐
3 ☐
4 ☐

I have nausea 5
0 ☐
1 ☐
2 ☐
3 ☐
4 ☐

Because of my physical condition, I have trouble meeting the needs of my family 6
0 ☐
1 ☐
2 ☐
3 ☐
4 ☐

I have pain 7
0 ☐
1 ☐
2 ☐

	3 ☐ 4 ☐
I am bothered by side effects of treatment	0 ☐ (8) 1 ☐ 2 ☐ 3 ☐ 4 ☐
I feel ill	0 ☐ (9) 1 ☐ 2 ☐ 3 ☐ 4 ☐
I am forced to spend time in bed	0 ☐ (10) 1 ☐ 2 ☐ 3 ☐ 4 ☐

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
1	FORM_OID	$200				FORM_OID
3	Assessment Date PID2007321_V1_0	MMM-dd-yyyy				QOL_ASSMNT_DT
4	FACT-G Questionnaire Past Seven Days Lack Energy How True Score_5 Point Scale PID3144307_V2_0	1		0 = 0 1 = 1 2 = 2 3 = 3 4 = 4		LACK_ENERGY
5	FACT-G Questionnaire Past Seven Days Have Nausea How True Score_5 Point Scale PID3144309_V2_0	1		0 = 0 1 = 1 2 = 2 3 = 3 4 = 4		NAUSEA

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
6	FACT-G Questionnaire Past Seven Days Trouble Meeting Family Needs Because of Physical Condition How True Score_5 Point Scale PID3144295_V2_0	1		0 = 0 1 = 1 2 = 2 3 = 3 4 = 4		FAM_NEEDS
7	FACT-G Questionnaire Past Seven Days Have Pain How True Score_5 Point Scale PID3144311_V2_0	1		0 = 0 1 = 1 2 = 2 3 = 3 4 = 4		PAIN

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
8	FACT-G Questionnaire Past Seven Days Bothered By Side Effects How True Score_5 Point Scale PID3144296_V2_0	1		0 = 0 1 = 1 2 = 2 3 = 3 4 = 4		SIDE_EFFECTS
9	FACT-G Questionnaire Past Seven Days Feel Ill How True Score_5 Point Scale PID3144306_V2_0	1		0 = 0 1 = 1 2 = 2 3 = 3 4 = 4		FEEL_ILL
10	FACT-G Questionnaire Past Seven Days Forced to be in Bed How True Score_5 Point Scale PID3144304_V2_0	1		0 = 0 1 = 1 2 = 2 3 = 3 4 = 4		TIME_BED

FORM_OID _____ 1

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Assessment date _____ 3

I feel close to my friends 4
- 0 ☐
- 1 ☐
- 2 ☐
- 3 ☐
- 4 ☐

I get emotional support from my family 5
- 0 ☐
- 1 ☐
- 2 ☐
- 3 ☐
- 4 ☐

I get support from my friends 6
- 0 ☐
- 1 ☐
- 2 ☐
- 3 ☐
- 4 ☐

My family has accepted my illness 7
- 0 ☐
- 1 ☐
- 2 ☐

	3 ☐ 4 ☐
I am satisfied with family communication about my illness	0 ☐ 8 1 ☐ 2 ☐ 3 ☐ 4 ☐
I feel close to my partner (or the person who is my main support)	0 ☐ 9 1 ☐ 2 ☐ 3 ☐ 4 ☐
Regardless of your current level of sexual activity, please answer the following question. If you prefer not to answer it, please mark this box. ☐	10
I am satisfied with my sex life	0 ☐ 11 1 ☐ 2 ☐ 3 ☐ 4 ☐

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
1	FORM_OID	$200				FORM_OID
3	Assessment Date PID2007321_V1_0	MMM- dd-yyyy				QOL_ASSMNT_DT
4	FACT-G Questionnaire Past Seven Days Feel Close to Friends How True Score _5 Point Scale PID3144297	1		0 = 0 1 = 1 2 = 2 3 = 3 4 = 4		CLOSE_FRIENDS
5	FACT-G Questionnaire Past Seven Days Emotional Support From Family How True Score_5 Point Scale PID3144299_V2_0	1		0 = 0 1 = 1 2 = 2 3 = 3 4 = 4		EMOT_SPPRT_FAM

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
6	FACT-G Questionnaire Past Seven Days Support from Friends How True Score_5 Point Scale PID3144318_V2_0	1		0 = 0 1 = 1 2 = 2 3 = 3 4 = 4		SPPRT_FRNDS
7	FACT-G Questionnaire Past Seven Days Family Accepts Illness How True Score_5 Point Scale PID3144302_V2_0	1		0 = 0 1 = 1 2 = 2 3 = 3 4 = 4		FAM_ACCEPT_ILLNESS

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
8	FACT-G Questionnaire Past Seven Days Satisfied with Family Communication How True Score_5 Point Scale PID3144303_V2_0	1		0 = 0 1 = 1 2 = 2 3 = 3 4 = 4		FAM_CMM_ILLNESS
9	FACT-G Questionnaire Past Seven Days Feel Close to Partner How True Score_5 Point Scale PID3144312_V2_0	1		0 = 0 1 = 1 2 = 2 3 = 3 4 = 4		CLOSE_PRTNR
10	FACT-G Questionnaire Satisfied with Sex Life No Answer Preference Checkbox Indicator PID3645909_V1_0	1				REFUSE_SEX_LIFE

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
11	FACT-G Questionnaire Past Seven Days Satisfied with Sex Life How True Score_5 Point Scale PID3144316_V2_0	1		0 = 0 1 = 1 2 = 2 3 = 3 4 = 4		SEX_LIFE

FORM_OID _____ 1

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Assessment date _____ 3

I feel sad 4
0 ☐
1 ☐
2 ☐
3 ☐
4 ☐

I am satisfied with how I am coping with my illness 5
0 ☐
1 ☐
2 ☐
3 ☐
4 ☐

I am losing hope in the fight against my illness 6
0 ☐
1 ☐
2 ☐
3 ☐
4 ☐

I feel nervous 7
0 ☐
1 ☐
2 ☐

	3 ☐ 4 ☐
I worry about dying	0 ☐ (8) 1 ☐ 2 ☐ 3 ☐ 4 ☐
I worry that my condition will get worse	0 ☐ (9) 1 ☐ 2 ☐ 3 ☐ 4 ☐

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
1	FORM_OID	$200				FORM_OID
3	Assessment Date PID2007321_V1_0	MMM-dd-yyyy				QOL_ASSMNT_DT
4	FACT-G Questionnaire Past Seven Days Feel Sad How True Score_5 Point Scale PID3144314_V2_0	1		0 = 0 1 = 1 2 = 2 3 = 3 4 = 4		FEEL_SAD
5	FACT-G Questionnaire Past Seven Days Satisfied with Coping with Illness How True Score_5 Point Scale PID3144315_V2_0	1		0 = 0 1 = 1 2 = 2 3 = 3 4 = 4		SATIS_COPING

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
6	FACT-G Questionnaire Past Seven Days Losing Hope Against Illness How True Score_5 Point Scale	1		0 = 0 1 = 1 2 = 2 3 = 3 4 = 4		LOSING_HOPE
7	FACT-G Questionnaire Past Seven Days Feel Nervous How True Score_5 Point Scale PID3144310_V2_0	1		0 = 0 1 = 1 2 = 2 3 = 3 4 = 4		NERVOUS
8	FACT-G Questionnaire Past Seven Days Worry Dying How True Score_5 Point Scale PID3144321_V2_0	1		0 = 0 1 = 1 2 = 2 3 = 3 4 = 4		WORRY_DYING

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
9	FACT-G Questionnaire Past Seven Days Worry Worsening Condition How True Score_5 Point Scale PID3144320_V2_0	1		0 = 0 1 = 1 2 = 2 3 = 3 4 = 4		WORRY_WORSE

FORM_OID _____ 1

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Assessment date _____ 3

I am able to work (include work at home) 4
- 0 ☐
- 1 ☐
- 2 ☐
- 3 ☐
- 4 ☐

My work (include work at home) is fulfilling 5
- 0 ☐
- 1 ☐
- 2 ☐
- 3 ☐
- 4 ☐

I am able to enjoy life 6
- 0 ☐
- 1 ☐
- 2 ☐
- 3 ☐
- 4 ☐

I have accepted my illness 7
- 0 ☐
- 1 ☐
- 2 ☐

	3 ☐ 4 ☐
I am sleeping well	0 ☐ (8) 1 ☐ 2 ☐ 3 ☐ 4 ☐
I am enjoying the things I usually do for fun	0 ☐ (9) 1 ☐ 2 ☐ 3 ☐ 4 ☐
I am content with the quality of my life right now	0 ☐ (10) 1 ☐ 2 ☐ 3 ☐ 4 ☐

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
1	FORM_OID	$200				FORM_OID
3	Assessment Date PID2007321_V1_0	MMM- dd-yyyy				QOL_ASSMNT_DT
4	FACT-G Questionnaire Past Seven Days Able to Work How True Score_5 Point Scale PID3144293_V2_0	1		0 = 0 1 = 1 2 = 2 3 = 3 4 = 4		ABLE_WORK
5	FACT-G Questionnaire Past Seven Days Work is Fulfilling How True Score_5 Point Scale PID3144319_V2_0	1		0 = 0 1 = 1 2 = 2 3 = 3 4 = 4		WORK_FULFILL

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
6	FACT-G Questionnaire Past Seven Days Able to Enjoy Life How True Score_5 Point Scale PID3144300_V2_0	1		0 = 0 1 = 1 2 = 2 3 = 3 4 = 4		ENJOY_LIFE
7	FACT-G Questionnaire Past Seven Days Accepted Illness How True Score_5 Point Scale PID3144294_V2_0	1		0 = 0 1 = 1 2 = 2 3 = 3 4 = 4		ACCEPT_ILLNESS
8	FACT-G Questionnaire Past Seven Days Sleeping Well How True Score_5 Point Scale PID3144317_V2_0	1		0 = 0 1 = 1 2 = 2 3 = 3 4 = 4		SLEEP_WELL

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
9	FACT-G Questionnaire Past Seven Days Enjoy Things for Fun How True Score_5 Point Scale PID3144301_V2_0	1		0 = 0 1 = 1 2 = 2 3 = 3 4 = 4		ENJOY_FUN
10	FACT-G Questionnaire Past Seven Days Content with Quality of Life How True Score_5 Point Scale PID3144298_V2_0	1		0 = 0 1 = 1 2 = 2 3 = 3 4 = 4		CONTENT_QOL

FORM_OID _____ 1

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Assessment date _____ 3

MOBILITY

- ☐ I have no problems walking 4
- ☐ I have slight problems walking
- ☐ I have moderate problems walking
- ☐ I have severe problems walking
- ☐ I am unable to walk

SELF-CARE

- ☐ I have no problems washing or dressing myself 5
- ☐ I have slight problems washing or dressing myself
- ☐ I have moderate problems washing or dressing myself
- ☐ I have severe problems washing or dressing myself
- ☐ I am unable to wash or dress myself

USUAL ACTIVITIES

- ☐ I have no problems doing my usual activities 6
- ☐ I have slight problems doing my usual activities
- ☐ I have moderate problems doing my usual activities

	I have severe problems doing my usual activities ☐ I am unable to do my usual activities ☐
PAIN / DISCOMFORT	I have no pain or discomfort ☐ 7 I have slight pain or discomfort ☐ I have moderate pain or discomfort ☐ I have severe pain or discomfort ☐ I have extreme pain or discomfort ☐
ANXIETY / DEPRESSION	I am not anxious or depressed ☐ 8 I am slightly anxious or depressed ☐ I am moderately anxious or depressed ☐ I am severely anxious or depressed ☐ I am extremely anxious or depressed ☐
Your health today	_____ 9

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
1	FORM_OID	$200				FORM_OID
3	Assessment Date PID2007321_V1_0	MMM-dd-yyyy				QOL_ASSMNT_DT
4	EQ5D5L_MOB_SCL_PID3540318_V1	1		1 = I have no problems walking 2 = I have slight problems walking 3 = I have moderate problems walking 4 = I have severe problems walking 5 = I am unable to walk		EQ5D5L_MOB_SCL
5	EQ5D5L_SLFCR_SCL_PID3540322_V1	1		1 = I have no problems washing or dressing myself		EQ5D5L_SLFCR_SCL

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
				2 = I have slight problems washing or dressing myself 3 = I have moderate problems washing or dressing myself 4 = I have severe problems washing or dressing myself 5 = I am unable to wash or dress myself		
6	EQ5D5L_AC TV_SCL_PI D3540323_ V1	1		1 = I have no problems doing my usual activities 2 = I have slight problems doing my usual activities		EQ5D5L_AC TV_SCL

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
				3 = I have moderate problems doing my usual activities 4 = I have severe problems doing my usual activities 5 = I am unable to do my usual activities		
7	EQ5D5L_PN1_DSCMF_SCL_PID3540325_V1			1 = I have no pain or discomfort 2 = I have slight pain or discomfort 3 = I have moderate pain or discomfort 4 = I have severe pain or discomfort 5 = I have extreme pain or discomfort		EQ5D5L_PN_DSCMF_SCL

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
8	EQ5D5L_ANX_DPRS_SCL_PID354032 6_V1			1 = I am not anxious or depressed 2 = I am slightly anxious or depressed 3 = I am moderately anxious or depressed 4 = I am severely anxious or depressed 5 = I am extremely anxious or depressed		EQ5D5L_ANX_DPRS_SCL
9	EQ5D5L_HEALTH_SCL_PID3563330_V1					HEALTH_SCALE

FORM_OID _____ 1

In the past 7 days…

How often did you feel tired? 3
- Never
- Rarely
- Sometimes
- Often
- Always

How often did you experiece extreme exhaustion? 4
- Never
- Rarely
- Sometimes
- Often
- Always

How often did you run out of energy? 5
- Never
- Rarely
- Sometimes
- Often
- Always

How often did your fatigue limit you at work (include work at home)? 6
- Never
- Rarely
- Sometimes
- Often
- Always

How often were you too tired to think clearly? 7
- Never

Rarely ☐
Sometimes ☐
Often ☐
Always ☐

How often were you too tired to take a bath or shower? (8)

Never ☐
Rarely ☐
Sometimes ☐
Often ☐
Always ☐

How often did you have enough energy to exercise strenuously? (9)

Never ☐
Rarely ☐
Sometimes ☐
Often ☐
Always ☐

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
1	FORM_OID	$200				FORM_OID
3	FEEL_TIRED	1		1 = Never 2 = Rarely 3 = Sometimes 4 = Often 5 = Always		FEEL_TIRED
4	EXP_EXH	1		1 = Never 2 = Rarely 3 = Sometimes 4 = Often 5 = Always		EXP_EXH
5	RUN_OUT_ENERGY	1		1 = Never 2 = Rarely 3 = Sometimes 4 = Often 5 = Always		RUN_OUT_ENERGY
6	LIMIT_WORK	1		1 = Never 2 = Rarely 3 = Sometimes 4 = Often 5 = Always		LIMIT_WORK
7	THINK_CLEAR	1		1 = Never 2 = Rarely 3 = Sometimes		THINK_CLEAR

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
				4 = Often 5 = Always		
8	TIRED_BAT H	1		1 = Never 2 = Rarely 3 = Sometimes 4 = Often 5 = Always		TIRED_BAT H
9	EXER_STRE N	1		1 = Never 2 = Rarely 3 = Sometimes 4 = Often 5 = Always		EXER_STRE N

FORM_OID (1)

Form instructions:

NOTES: This form is intended to capture the process surrounding the decision to go to transplant or not, and it should be filled out by the investigator.

(3)
- ☐ Yes, the patient is clinically HCT eligible (continue to question 2)
- ☐ No, not eligible even for reduced intensity conditioning regimen
- ☐ Participant not seen during this assessment period

If patient is not clinically Hematopoietic Cell Transplantation (HCT) eligible, select reason (select all that apply):

Older Age (5)

High burden of co-morbidities (6)

Poor ECOG performance status (7)

Overall frailty (8)

Other (9)

If "other" was checked, please explain _____ 10

Yes, patient was referred for HCT evaluation and HCT was recommended ☐ 11
Yes, patient was referred for HCT evaluation however, HCT was not recommended ☐
No ☐

If patient was referred for HCT evaluation however, HCT was not recommended, choose the reason (select all that apply):

Older Age _____ 13

High burden of co-morbidities _____ 14

Poor ECOG performance status _____ 15

Overall frailty _____ 16

Patient preference _____ 17

Insurance _____ 18

Caregiver absence _____ 19

Low risk disease that is followed conservatively with no or minimal intervention _____ 20

Patient with low risk disease or high-risk disease receiving another treatment	21
Preliminary donor search indicates no appropriate donors available	22
Other	23
If "other" was checked, please explain	24

If patient was not referred for HCT evaluation, select reason (select all that apply):

Patient preference	26
Insurance	27
Caregiver absence	28
Low risk disease that is followed conservatively with no or minimal intervention	29
Patient with low risk disease or high-risk disease receiving another treatment	30
Preliminary donor search indicates no appropriate donors available	31
Other	32

If "other" was checked, please explain _____ 33

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
1	FORM_OID	$200				FORM_OID
3	CLIN_HCT_ELIG	1		2 = Yes, the patient is clinically HCT eligible (continue to question 2) 1 = No, not eligible even for reduced intensity conditioning regimen 3 = Participant not seen during this assessment period		CLIN_HCT_ELIG
5	OLD_AGE1_CB	1				OLD_AGE1_CB
6	HIGH_BR_CMB1_CB	1				HIGH_BR_CMB1_CB
7	POOR_ECOG_PS1_CB	1				POOR_ECOG_PS1_CB
8	OVRL_FRAIL1_CB	1				OVRL_FRAIL1_CB

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
9	OTH1_CB	1				OTH1_CB
10	OTH1_EXP	$1999				OTH1_EXP
11	REF_HCT_EVAL	1		2 = Yes, patient was referred for HCT evaluation and HCT was recommended 3 = Yes, patient was referred for HCT evaluation however, HCT was not recommended 1 = No		REF_HCT_EVAL
13	OLD_AGE2_CB	1				OLD_AGE2_CB
14	HIGH_BR_CMB2_CB	1				HIGH_BR_CMB2_CB
15	POOR_ECOG_PS2_CB	1				POOR_ECOG_PS2_CB

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
16	OVRL_FRAIL2_CB	1				OVRL_FRAIL2_CB
17	PT_PREF1_CB	1				PT_PREF1_CB
18	INSURANCE11_CB	1				INSURANCE11_CB
19	CG_ABS1_CB	1				CG_ABS1_CB
20	LOWRISK_DZ1_CB	1				LOWRISK_DZ1_CB
21	LR_HR_DZ1_CB	1				LR_HR_DZ1_CB
22	NO_DONOR11_CB	1				NO_DONOR11_CB
23	OTH2_CB	1				OTH2_CB
24	OTH2_EXP	$1999				OTH2_EXP
26	PT_PREF2_CB	1				PT_PREF2_CB

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
27	INSURANCE2_CB	1				INSURANCE2_CB
28	CG_ABS2_CB	1				CG_ABS2_CB
29	LOWRISK_DZ2_CB	1				LOWRISK_DZ2_CB
30	LR_HR_DZ2_CB	1				LR_HR_DZ2_CB
31	NO_DONOR2_CB	1				NO_DONOR2_CB
32	OTH3_CB	1				OTH3_CB
33	OTH3_EXP	$1999				OTH3_EXP

Version 14.00 pushed to PRODUCTION 04.06.2023: All Forms
Form: Cohort Assignment
Generated On: 02 May 2023 16:20:18

FORM_OID (1)

Form instructions:
The eligibility field below will be populated by the system after central pathology review. After eligibility is determined, please navigate back to this form to acknowledge the patient's assignment. Patients in the longitudinal cohort will be followed long term with study visits every 6 months. Patients in the cross-sectional cohort will not have study visits after baseline.

The patient is eligible for the: (3)

- ☐ Cross-sectional cohort
- ☐ MDS/AML Longitudinal cohort
- ☐ ICUS Longitudinal cohort
- ☐ At-Risk cohort

Please check the box to acknowledge the patient's assignment. (4)

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
1	FORM_OID	$200				FORM_OID
3	ELIG_LONG_YN	1		1 = Cross-sectional cohort 2 = MDS/AML Longitudinal cohort 3 = ICUS Longitudinal cohort 4 = At-Risk cohort		ELIG_LONG_YN
4	ACK_LONG	1				ACK_LONG

Version 14.00 pushed to PRODUCTION 04.06.2023: All Forms
Form: Rescreening Yes_No
Generated On: 02 May 2023 16:20:18

FORM_OID _____ 1

Form instructions:

NOTE: Subjects that are not entered in the longitudinal study are eligible to be rescreened for participation in this study if progression of signs or symptoms provides evidence to support a probable diagnosis of MDS, MDS/MPN overlap disorders or ICUS. Since this patient was not assigned to the longitudinal cohort, they have the option to be rescreened at a later date. If this patient will be rescreened, please complete this form appropriately.

Did this patient have progression of signs or symptoms that provide evidence to support a probable diagnosis of MDS, MDS/MPN overlap disorders or ICUS?

☐ No 3
☐ Yes

Will this patient be re-screened on the NHLBI-MDS trial?

☐ No 4
☐ Yes

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
1	FORM_OID	$200				FORM_OID
3	PD_YN	1		1 = No 2 = Yes		PD_YN
4	RESCREEN_YN	1		1 = No 2 = Yes		RESCREEN_YN

Version 14.00 pushed to PRODUCTION 04.06.2023: All Forms
Form: Transplant
Generated On: 02 May 2023 16:20:18

Date of transplant	_____ 1
Transplant type	Allogeneic ☐ 2 Autologous ☐
CIBMTR ID	_____ 3

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
1	TRANSP_DT	dd MMM yyyy				TRANSP_DT
2	TRANSP_TYPE	1		1 = Allogeneic 2 = Autologous		TRANSP_TYPE
3	CIBMTR_ID	9				CIBMTR_ID

Version 14.00 pushed to PRODUCTION 04.06.2023: All Forms
Form: Lost to Follow-Up
Generated On: 02 May 2023 16:20:18

FORM_OID _____ 1

Patient Lost to Follow-Up

Was the study participant unable to be contacted for follow-up per defined criteria? 3
- ☐ No
- ☐ Yes

Date of last contact _____ 4

Methods of Contact 5
- ☐ Contact study participant by phone
- ☐ Search medical record
- ☐ Contact study participant's primary care physician
- ☐ Search registries for region
- ☐ Contact people listed for study participant
- ☐ Contact study participant by registered or certified letter

Date of most recent attempt _____ 6

Institution Lost to Follow-up

Has the site stopped participating in this ECOG-ACRIN study? 8
- ☐ No
- ☐ Yes

Date site stopped participating _____ 9

Reason site stopped participating 10
- ☐ IRB terminated study

Site dissolved / no longer conducting clinical studies ☐
Budgetary reasons ☐
Other ☐

Study Participant Found

Was a study participant previously deemed lost to follow-up able to be contacted? (12)
No ☐
Yes ☐

Date most recent contact _____ (13)

Lost to Follow-Up Internal Review

Study participant lost to follow-up approved? (15)
No ☐
Yes ☐

Date of Approval _____ (16)

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
1	FORM PID392389 2	$200				FORM_OID
3	Patient Lost Follow-up Ind_2 PID61333_ V3_0	1		1 = No 2 = Yes		UNABLE_C ONTACT_Y N
4	Participant Last Known Alive Date PID284728 5_V1_0	MMM dd yyyy				LTFU_LAST _CONTACT _DT
5	Communica tion Contact Technique Type PID361298 1_V1_0	1		1 = Contact study participant by phone 2 = Search medical record 3 = Contact study participant's primary care physician 4 = Search registries for region		CONTACT_ METH

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
				5 = Contact people listed for study participant 6 = Contact study participant by registered or certified letter		
6	Communication Contact Attempt Most Recent Date PID3613053_V1_0	MMM dd yyyy				RECENT_ATTMPT_DT
8	Study Site Stop Clinical Study Participation Code PID5695710_V1_0	2		1 = No 2 = Yes		SITE_NO_PARTICP_YN
9	Study Site Stop Clinical Study Participation Date PID5695719_V1_0	MMM dd yyyy				SITE_LEFT_DT

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
10	Study Site Stop Clinical Study Participation Reason PID5695945_V1_0	2		1 = IRB terminated study 2 = Site dissolved / no longer conducting clinical studies 3 = Budgetary reasons 88 = Other		SITE_NONPART_REAS
12	Patient Prior Lost Follow-up Yes No Indicator PID3613073_V1_0	1		1 = No 2 = Yes		PT_FOUND_YN
13	Communication Contact Technique Most Recent Date PID3613057_V1_0	MMM dd yyyy				PT_FOUND_DT

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
15	Patient Lost to Institutional Review Board Approval Follow-up Yes No Indicator PID361307 8_V1_0	1		1 = No 2 = Yes		LOST_FU_A PPRV_YN
16	Patient Lost to Institutional Review Board Approval Follow-up Date PID361307 9_V1_0	MMM dd yyyy				LOST_FU_A PPRV_DT

FORM_OID _____ 1

SECTION I. Clinical Withdrawal of Consent.
Please complete this form on behalf of your patient whenever your patient withdraws consent to participate in the study.

Clinical Withdrawal of Consent occurs when patient withdraws consent to participate further in the study and does not wish future medical information to be used in research.

The patient withdraws consent to participate further in study and does not wish FUTURE medical information to be used in research.

No ☐ 3
Yes ☐

Date study participant withdrew clinical consent _____ 4

SECTION II. Changing of Participation in Biological Specimen Collection
Option 1 is chosen if a patient wishes to discontinue any future specimen collection. Specimens which were previously collected but not submitted should be submitted, but no future collections will be made. Specimens previously submitted will be used as the patient originally consented.

(Option 1) Patient withdraws consent to all further specimen collection.

No ☐ 6
Yes ☐

Date of amended consent _____ 7

Option 2 is chosen if the consent was reported incorrectly at the time of patient registration or the patient is requesting destruction of previously submitted samples.

Documentation must be uploaded. Examples of appropriate documentation are a copy of the revised or original consent, a registration checklist with the information indicating corrections and date of correction, or written request for destruction of available samples that have not been distributed to researchers.

(Option 2) Patient is changing ORIGINAL consent. ☐ No ☐ Yes (9)

Date of amended consent _____ (10)

Reason for change ☐ Information provided at registration incorrect ☐ Patient consent change - Written Reconsent ☐ Patient consent change - Withdrawal (verbal or written) (11)

Upload Documentation of specific changes _____ (12)

Clinical Withdrawal of Consent Internal Review

Clinical withdrawal of consent approved? ☐ No ☐ Yes (14)

Date of approval _____ (15)

Specimen Change of Participation Internal Review

Specimen change of participation approved? No ☐ 17
Yes ☐

Date of approval _____ 18

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Form: Withdrawal of Consent
Generated On: 02 May 2023 16:20:18

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
1	FORM PID4419411	$200				FORM_OID
3	Patient Withdrawn Consent Clinical Ind_2 PID2199777_V1_0	1		1 = No 2 = Yes		CLIN_WD_YN
4	Withdrawn consent date PID2199780_V1_0	MMM dd yyyy				WD_CONSENT_DT
6	Patient Specimen Consent Withdrawn Yes No Indicator PID3521329_V1_0	1		1 = No 2 = Yes		SPECIMEN_WD_YN
7	Patient Amended Consent Date PID3613143_V1_0	MMM dd yyyy				AMEND_CONSENT_DT

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
9	Patient Amended Consent Yes No Indicator PID3613145_V1_0	1		1 = No 2 = Yes		SPECIMEN_WD_CHNG_YN
10	Patient Amended Consent Date PID3613143_V1_0_1	MMM dd yyyy				OPT2_AMEND_CONSENT_DT
11	Consent Withdrawn Change Reason PID4386152_V1_0	1		1 = Information provided at registration incorrect 2 = Patient consent change - Written Reconsent 3 = Patient consent change - Withdrawal (verbal or written)		REAS_CHNG_CNSNT
12	Document Upload Text PID3421437_V1_0	$200				UPLOAD_CHNG_DOC_XX

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
14	Patient Follow-up Clinical Institutional Review Board Approval Consent Withdrawn Yes No Indicator PID361316 1_V1_0	1		1 = No 2 = Yes		WD_CONSENT_APPRV_YN
15	Patient Follow_up Clinical Institutional Review Board Approval Consent Withdrawn Date PID361316 2_V1_0	MMM dd yyyy				WD_CONSENT_APPRV_DT

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
17	Patient Specimen Institutional Review Board Approval Consent Withdrawn Yes No Indicator PID3613171_V1_0	1		1 = No 2 = Yes		LAB_WOC_APPRV_YN_DV
18	Patient Follow_up Clinical Institutional Review Board Approval Consent Withdrawn Date PID3613162_V1_0_1	MMM dd yyyy				LAB_WOC_APPRV_DT_DV

Version 14.00 pushed to PRODUCTION 04.06.2023: All Forms
Form: COVID-19 Trigger Form
Generated On: 02 May 2023 16:20:18

FORM_OID	①
Was the participant in contact with someone who tested positive for the novel corona virus SARS-CoV-2 that causes COVID-19?	② No ☐ Yes ☐
Was the participant tested for COVID-19?	③ No ☐ Yes ☐
Were there any COVID-19 related protocol deviations to report?	④ No ☐ Yes ☐

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Form: COVID-19 Trigger Form
Generated On: 02 May 2023 16:20:18

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
1	FORM_OID	$200				FORM_OID
2	PT_CONTACT_POS_YN	1		1 = No 2 = Yes		PT_CONTACT_POS_YN
3	COVID19_TEST_YN	1		1 = No 2 = Yes		COVID19_TEST_YN
4	COVID19_DEVIATIONS_YN	1		1 = No 2 = Yes		COVID19_DEVIATIONS_YN

Version 14.00 pushed to PRODUCTION 04.06.2023: All Forms
Form: Coronavirus Disease 2019 (COVID-19) Evaluation Form
Generated On: 02 May 2023 16:20:18

FORM_OID _____ 1

INSTRUCTIONS: This form is intended to capture the COVID-19 status of the patient.

* A patient can be considered 'recovered' if they have had no fever for at least 72 hours (without the use of medicine that reduces fevers), and other symptoms have improved, and it has been at least 7 days since their symptoms first appeared.

Test date _____ 3

Type of test
- PCR (specify) ☐ 4
- Serological (specify) ☐
- Other (specify) ☐

Specify type of test _____ 5

Result
- Negative ☐ 6
- Positive ☐

Outcome (If Positive)*
- Recovering or Resolving ☐ 7
- Recovered or Resolved ☐
- Recovered or Resolved with Sequelae ☐
- Fatal ☐
- Unknown ☐

Did the patient receive treatment in response to a COVID-19 infection
- No ☐ 8
- Yes ☐

Was the patient hospitalized as a result of COVID-19? No ☐ Yes ☐ 9

Duration of hospitalazation (in days) _____ 10

Day of death _____ 11

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
1	FORM_OID	$200				FORM_OID
3	COVID19_TEST_DT_XX	dd- MMM-yyyy				COVID19_TEST_DT_XX
4	COVID19_TEST_TYPE_XX	2		1 = PCR (specify) 2 = Serological (specify) 88 = Other (specify)		COVID19_TEST_TYPE_XX
5	COVID19_TEST_TYPE_SP_XX	$200				COVID19_TEST_TYPE_SP_XX
6	COVID19_TEST_RS_XX	2		1 = Negative 2 = Positive		COVID19_TEST_RS_XX
7	COVID19_TEST_OUTCM_XX	2		1 = Recovering or Resolving 2 = Recovered or Resolved 3 = Recovered or Resolved with Sequelae		COVID19_TEST_OUTCM_XX

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
				4 = Fatal 99 = Unknown		
8	COVID19_TEST_TX_YN_XX	1		1 = No 2 = Yes		COVID19_TEST_TX_YN_XX
9	COVID19_PT_HOSP_YN_XX	1		1 = No 2 = Yes		COVID19_PT_HOSP_YN_XX
10	COVID19_HOSP_DUR_XX	3				COVID19_HOSP_DUR_XX
11	DEATH_DT	MMM dd yyyy				DEATH_DT

Version 14.00 pushed to PRODUCTION 04.06.2023: All Forms
Form: COVID-19 Medication Form
Generated On: 02 May 2023 16:20:18

FORM_OID	1
Medication name	2
Medication start date	3
Medication stop date	4

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Form: COVID-19 Medication Form
Generated On: 02 May 2023 16:20:18

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
1	FORM_OID	$200				FORM_OID
2	COVID19_MED_NAME_FT_XX	$200				COVID19_MED_NAME_FT_XX
3	COVID19_MED_STRT_DT_XX	dd- MMM-yyyy				COVID19_MED_STRT_DT_XX
4	COVID19_MED_END_DT_XX	dd- MMM-yyyy				COVID19_MED_END_DT_XX

Version 14.00 pushed to PRODUCTION 04.06.2023: All Forms
Form: COVID-19 Deviation Log
Generated On: 02 May 2023 16:20:18

Please Note:

Protocol requirements conducted by a Local Healthcare Provider on an intermittent/short-term basis as specified by the protocol under oversight of a Responsible Investigator do NOT need to be reported as protocol deviations

All Minor Deviations need to be reported to EA. EA will report all minor deviations to the CIRB at the time of next annual review of the protocol. Please report all deviations to the local IRB per local policy

---

Type of Deviation

- [ ] Late or Missed Study Lab (2)
- [ ] Late or Missed Correlative Lab
- [ ] Late or Missed Study Procedure
- [ ] Late or Missed QOL/PRO
- [ ] Cycle treatment given early
- [ ] Cycle treatment given late
- [ ] Cycle treatment missed
- [ ] Missed Study Visit
- [ ] Phone or Virtual Visit
- [ ] Informed Consent
- [ ] Other

Reason for Deviation

- [ ] Diagnosis of COVID-19 (3)
- [ ] Suspected COVID-19 Infection
- [ ] Travel Restrictions
- [ ] Participant Decision
- [ ] Physician Decision
- [ ] Institutional Resource Restrictions
- [ ] Other

Start Date	4
End Date	5
Brief Summary of Deviation (Please indicate Cycle or Visit at which the deviation occurred)	6
Notified CIRB For Major Deviation	No ☐ 7 Yes ☐
Date CIRB notified of Major Deviation	8
Notified Local IRB for Major Deviation	No ☐ 9 Yes ☐
Date Local IRB notified of Major Deviation	10

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
2	DEVIA_TYPE_XX	2		1 = Late or Missed Study Lab 2 = Late or Missed Correlative Lab 3 = Late or Missed Study Procedure 4 = Late or Missed QOL/PRO 5 = Cycle treatment given early 6 = Cycle treatment given late 7 = Cycle treatment missed 8 = Missed Study Visit 9 = Phone or Virtual Visit 10 = Informed Consent 88 = Other		DEVIA_TYPE_XX
3	DEVIA_REAS_XX	2		1 = Diagnosis of COVID-19		DEVIA_REAS_XX

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
				2 = Suspected COVID-19 Infection 3 = Travel Restrictions 4 = Participant Decision 5 = Physician Decision 6 = Institutional Resource Restrictions 88 = Other		
4	DEVIA_ST_DT_XX	MMM dd yyyy				DEVIA_ST_DT_XX
5	DEVIA_END_DT_XX	MMM dd yyyy				DEVIA_END_DT_XX
6	DEVIA_SUMMARY_XX	$200				DEVIA_SUMMARY_XX
7	DEVIA_NOTI_CIRB_YN_XX	1		1 = No 2 = Yes		DEVIA_NOTI_CIRB_YN_XX
8	DEVIA_NOTI_CIRB_DT_XX	MMM dd yyyy				DEVIA_NOTI_CIRB_DT_XX

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
9	DEVIA_NOTI_LIRB_YN_XX	1		1 = No 2 = Yes		DEVIA_NOTI_LIRB_YN_XX
10	DEVIA_NOTI_LIRB_DT_yyyyXX	MMM dd				DEVIA_NOTI_LIRB_DT_XX

Site Reported Best Response (derived) 1
- CR ☐
- PR ☐
- SD ☐
- PD ☐
- not assessed ■

Site Reported Worst Response (derived) 2
- CR ☐
- PR ☐
- SD ☐
- PD ☐
- not assessed ■

Folder worst response reported (derived) 3 _____

Folder number where worst response reported 4 _____

Has the patient progressed to AML (derived) 5
- No ☐
- Yes ☐
- Not applicable ■

Date of diagnosis (derived) 6 _____

Folder where progression to AML reported (derived) 7 _____

Folder number where progression to AML reported (derived) 8 _____

Patient Vital Status(derived) 9
- Alive ■
- Dead ☐

Institution Lost to Follow-up ☐
Patient Refused Follow-up ☐
Officially Lost to Follow-up ☐

Date of last contact or death(derived) _____ 10

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
1	OBJECT_RESP_BEST_DV	1		1 = CR 2 = PR 3 = SD 4 = PD -1 = not assessed		OBJECT_RESP_BEST_DV
2	OBJECT_RESP_STAT_DV	1		1 = CR 2 = PR 3 = SD 4 = PD -1 = not assessed		OBJECT_RESP_STAT_DV
3	PD_FOLDER_OID_DV	$50				PD_FOLDER_OID_DV
4	PD_FOLDER_RPT_NUM_DV	3				PD_FOLDER_RPT_NUM_DV
5	PROG_AML_YN_DV	1		1 = No 2 = Yes -1 = Not applicable		PROG_AML_YN_DV
6	PROG_AML_DT_DV	MMM dd yyyy				PROG_AML_DT_DV
7	PROG_AML_FLDR_OID_DV	$50				PROG_AML_FLDR_OID_DV

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
8	PROG_AML_FLDR_RPT_NUM_DV	3				PROG_AML_FLDR_RPT_NUM_DV
9	PT_VT_STAT_DV	1		1 = Alive 2 = Dead 6 = Institution Lost to Follow-up 7 = Patient Refused Follow-up 8 = Officially Lost to Follow-up		PT_VT_STAT_DV
10	LAST_CONTACT_DT_DV	MMM dd yyyy				LAST_CONTACT_DT_DV

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Form: Internal Communications
Generated On: 02 May 2023 16:20:18

Date of communication ①

Type of communication ②
- ☐ Email
- ☐ Phone call
- ☐ Memo
- ☐ Other (specify)

Communication notes ③

Upload file (if applicable) ④

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
1	COMM_DT_XX	MMM dd yyyy				COMM_DT_XX
2	INT_COMM_TYPE_XX	2		1 = Email 2 = Phone call 3 = Memo 98 = Other (specify)		INT_COMM_TYPE_XX
3	NOTES_XX	$200				NOTES_XX
4	UPLOAD_XX	$200				UPLOAD_XX

Version 14.00 pushed to PRODUCTION 04.06.2023: All Forms
Form: Eligibility Evaluation (Step 1)
Generated On: 02 May 2023 16:20:18

Has the patient been diagnosed with any solid tumor or hematologic malignancy that would exclude them from this trial? (1)
- No
- Yes

Does the patient have a known primary diagnosis of a hematologic disorder that would exclude them from this trial? (2)
- No
- Yes

Did the patient receive any prohibited prior therapies that would exclude them from this trial? (3)
- No
- Yes

Was a bone marrow aspirate performed within 4 weeks after enrollment? (4)
- No
- Yes

Were the required baseline labs performed within the protocol specified time frame? (5)
- No
- Yes

Was the patient eligible for this study? (6)
- No
- Yes
- Questionable

Specify reason patient ineligible or questionable (7)

Was an eligibility override/waiver obtained? (8)
- No
- Yes

Upload documentation (9)

Data Management Review

Data Management review date _____ 11

Data Management comments _____ 12

Is Study Chair review required? 13
- ☐ No
- ☐ Yes

Review Status

Review Status 15
- ☐ Final, Completed and reviewed by the study chair. No open discrepancies or requests to the institutions.
- ☐ Unresolved with SC, Eligibility Eval was reviewed by the SC but there are still unresolved coding issues with the SC.
- ☐ Unresolved with Inst, Eligibility Eval was reviewed by the SC but there are still unresolved open requests to the institutions.

Date finalized _____ 16

Study Chair Review

Study Chair: Do you agree with this eligibility assessment? 18
- ☐ No
- ☐ Yes

Study Chair comments _____ 19

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
1	PRIOR_MALIG_EXCL_YN	1		1 = No 2 = Yes		PRIOR_MALIG_EXCL_YN
2	HEM_DX_EXCL_YN	1		1 = No 2 = Yes		HEM_DX_EXCL_YN
3	PRIOR_TX_EXCL_YN	1		1 = No 2 = Yes		PRIOR_TX_EXCL_YN
4	BM_ASP_YN	1		1 = No 2 = Yes		BM_ASP_YN
5	ELIG_LAB_YN	1		1 = No 2 = Yes		ELIG_LAB_YN
6	PT_ELIG_YN	1		1 = No 2 = Yes 3 = Questionable		PT_ELIG_YN
7	INELIG_QUES_FT	$200				INELIG_QUES_FT
8	ELIG_OVRD_WVR_YN	1		1 = No 2 = Yes		ELIG_OVRD_WVR_YN
9	UPLOAD	$200				UPLOAD

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
11	DM_REVIEW_DT	MMM dd yyyy				DM_REVIEW_DT
12	DA_COMMENT	$200				DA_COMMENT
13	SC_REV_REQ_YN	1		1 = No 2 = Yes		SC_REV_REQ_YN
15	ELIG_REVIEW_STAT	1		1 = Final, Completed and reviewed by the study chair. No open discrepancies or requests to the institutions. 2 = Unresolved with SC, Eligibility Eval was reviewed by the SC but there are still unresolved coding issues with the SC.		ELIG_REVIEW_STAT

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
				3 = Unresolved with Inst, Eligibility Eval was reviewed by the SC but there are still unresolved open requests to the institutions.		
16	ELIG_FINAL_DT	MMM dd yyyy				ELIG_FINAL_DT
18	Study Chair: Do you agree with this eligibility assessment ?	1		1 = No 2 = Yes		SC_AGREE_YN
19	SC_COMMENT	$200				SC_COMMENT

Version 14.00 pushed to PRODUCTION 04.06.2023: All Forms
Form: Eligibility Evaluation Signature (Step 1)
Generated On: 02 May 2023 16:20:18

FORM_OID	1
Study Chair Review	
Study Chair Review Date	3
Study Chair Signature	4

Version 14.00 pushed to PRODUCTION 04.06.2023: All Forms
Form: Eligibility Evaluation Signature (Step 1)
Generated On: 02 May 2023 16:20:18

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
1	FORM_OID	$200				FORM_OID
3	SC_EE_REV_DT	MMM dd yyyy				SC_EE_REV_DT
4	Study Chair Signature (Eligibility Evaluation)	eSigPage				SC_EE_SIG

Deviation type

- ☐ NPT or prohibited concomitant medication while on-study (1)
- ☐ Patient's treatment was administered/prescribed/modified not in accordance with protocol guidelines
- ☐ Failure to discontinue treatment
- ☐ Patient ineligible
- ☐ Patient was stratified incorrectly
- ☐ Patient was unable to complete QOL forms due to site's error
- ☐ Patient's labs/tests/scans/assessments were not obtained as required per protocol
- ☐ Other

Comments _____ (2)

Who identified deviation

- ☐ Data Manager (3)
- ☐ Site Monitor
- ☐ Study Chair
- ☐ Other (specify)

Data Management Review

Data Management Comments _____ (5)

Study Chair Review

Do you agree with this deviation assessment? (7)

- ☐ No
- ☐ Yes

Study Chair Comments (8)

Review Status

Review status (10)

- ☐ Final, Completed and reviewed by the study chair. No open discrepancies or requests to the institutions.
- ☐ Unresolved with SC, Case Eval was reviewed by the SC but there are still unresolved coding issues with the SC
- ☐ Unresolved with Inst, Case Eval was reviewed by the SC but there are still unresolved open requests to the institutions.
- ☐ Not applicable - patient never started treatment

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
DEVIATION 2 _XX			1 = NPT or prohibited concomitant medication while on-study 2 = Patient's treatment was administered/prescribed/modified not in accordance with protocol guidelines 3 = Failure to discontinue treatment 4 = Patient ineligible 5 = Patient was stratified incorrectly 6 = Patient was unable to complete QOL forms due to site's error		DEVIATION _XX

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
				7 = Patient's labs/tests/scans/assessments were not obtained as required per protocol 88 = Other		
②	DEVIATION_SP_XX	$200				DEVIATION_SP_XX
③	DEV_IDENT_XX	2		1 = Data Manager 2 = Site Monitor 3 = Study Chair 88 = Other (specify)		DEV_IDENT_XX
⑤	DA_COMMENT	$200				DA_COMMENT
⑦	SC_AGREE_YN	1		1 = No 2 = Yes		SC_AGREE_YN
⑧	SC_COMMENT	$200				SC_COMMENT

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
10	REVIEW_STAT	1		1 = Final, Completed and reviewed by the study chair. No open discrepancies or requests to the institutions. 2 = Unresolved with SC, Case Eval was reviewed by the SC but there are still unresolved coding issues with the SC 3 = Unresolved with Inst, Case Eval was reviewed by the SC but there are still unresolved open requests to the institutions.		REVIEW_STAT

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			4 = Not applicable - patient never started treatment		