

Subject Case Report Forms

Version 12.00 pushed to PRODUCTION 06.16.2020 - All Forms

Signature Prompt: I understand that I am responsible for the data entered into Medidata Clinical Research System under my account name and password. I understand that sharing of passwords is illegal. I hereby confirm that all data is accurate to the best of my knowledge.

Version 12.00 pushed to PRODUCTION 06.16.2020: All Forms
Form: Subject Enrollment
Generated On: 25 Jun 2020 16:25:32

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 _____ **8**

EST
CST
MST
PST
EDT
CDT
MDT
PDT

Group Data _____ **9**

Source Application _____ **10**

Version 12.00 pushed to PRODUCTION 06.16.2020: All Forms

Form: Subject Enrollment

Generated On: 25 Jun 2020 16:25:32

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	FORM_OID	\$200		PID328426 4_V1_0		FORM_OID
③	Study Participant Identifier PID200330 1_V4_0	\$20				PT_ID
④	Enrolling Site CTEP ID PID331424 0_V1_0	\$25				ENROLLING_SITE_ID
⑤	Lead Institution PID219279 6_V1_0	\$100				LEAD_INST_NAME
⑥	Current Site CTEP ID PID331424 3_V1_0	\$25				CURRENT_SITE_ID
⑦	Enrollment Date PID274654 1_V1_0	dd MMM YYYY				PARTIC_ENROL_DT

Version 12.00 pushed to PRODUCTION 06.16.2020: All Forms
Form: Subject Enrollment
Generated On: 25 Jun 2020 16:25:32

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
8 Enrollment Time PID341260 1_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 PID321239 9_V1_0	\$100				GROUP_DATA
10 Source Application PID330284 0_V1_0	\$100				SRC_APP

Version 12.00 pushed to PRODUCTION 06.16.2020: All Forms
Form: Step Information
Generated On: 25 Jun 2020 16:25:32

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 _____ **12**

- EST **12**
- CST
- MST
- PST
- EDT
- CDT

Version 12.00 pushed to PRODUCTION 06.16.2020: All Forms
Form: Step Information
Generated On: 25 Jun 2020 16:25:32

MDT
PDT

Treatment Assignment Code (TAC): _____ 13

Treatment Assignment Description (TAD): _____ 14

Version 12.00 pushed to PRODUCTION 06.16.2020: All Forms

Form: Step Information

Generated On: 25 Jun 2020 16:25:32

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	FORM_OID	\$200		PID328539 2_V1_0		FORM_OID
③	Step No PID200209 3_V4_0	\$20				REG_STEP_NUM
④	Event Description PID330311 0_V1_0	\$100				EVENT_DESC
⑤	Tracking Number PID330285 9_V1_0	\$25				TRACKING_NUM
⑥	Treating Physician Or Participating Investigator Name PID274042 4_V1_0	\$100				TX_MD_PARTICIPATING_INVESTIGATOR_NAME RT_INV_NM
⑦	Registrar PID2172_V 3_0	\$100				PROT_REG_NAME

Version 12.00 pushed to PRODUCTION 06.16.2020: All Forms

Form: Step Information

Generated On: 25 Jun 2020 16:25:32

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
8 Organizational 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

Version 12.00 pushed to PRODUCTION 06.16.2020: All Forms
Form: Step Information
Generated On: 25 Jun 2020 16:25:32

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
① Other Treatment Assignment PID200269 9_V5_0	\$1999				TX_ASSIGN _TXT

Version 12.00 pushed to PRODUCTION 06.16.2020: All Forms
Form: Treatment Assignment
Generated On: 25 Jun 2020 16:25:32

FORM_OID

PID3285336_V1_0 **1**

Arm Name

_____ **3**

Step No

_____ **4**

Event description

_____ **5**

Date of Intervention/Treatment Assignment

_____ **6**

Event Time

EST **7**

CST

MST

PST

EDT

CDT

MDT

PDT

Treatment Assignment Code (TAC):

_____ **8**

Treatment Assignment Description (TAD):

_____ **9**

Version 12.00 pushed to PRODUCTION 06.16.2020: All Forms

Form: Treatment Assignment

Generated On: 25 Jun 2020 16:25:32

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	FORM_OID	\$200		PID328533 6_V1_0		FORM_OID
③	Assigned Treatment Arm PID200162 6_V3_0	\$100				PROT_TX_ARM_ASS_TXT
④	Step No PID200209 3_V4_0	\$20				REG_STEP_NUM
⑤	Event Description PID330311 0_V1_0	\$100				EVENT_DESC
⑥	Date of Intervention /Treatment Assignment PID337037 7_V1_0	dd MMM/yyyy				TRT_ARM_ASSGN_DATE
⑦	Event Time PID341259 8_V1_0	hh:nn:ss:rr	EST = EST CST = CST MST = MST PST = PST EDT = EDT CDT = CDT MDT = MDT PDT = PDT			EVENT_TIME

Version 12.00 pushed to PRODUCTION 06.16.2020: All Forms
Form: Treatment Assignment
Generated On: 25 Jun 2020 16:25:32

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

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Form: Demography

Generated On: 25 Jun 2020 16:25:32

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

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Form: Demography

Generated On: 25 Jun 2020 16:25:32

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

Race

- American Indian or Alaska **10**
Native
 - 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

Generated On: 25 Jun 2020 16:25:32

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
1	FORM_OID	\$200		PID330220 4_V1_0		FORM_OID
3	Participant Initials	\$4		PID200103 9_V4_0		PT_INITIAL S_NAME
4	Patient's Date of Birth	dd MMM yyyy		PID793_V5 _1		PER_BIR_D T
5	Ethnicity	\$22		PID219221 7_V2_0	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	\$13		PID336886 6_V1_0	Female Gender = Female Gender	PERSON_GE NDER

Version 12.00 pushed to PRODUCTION 06.16.2020: All Forms
Form: Demography
Generated On: 25 Jun 2020 16:25:32

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_POS TAL_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

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Form: Demography
Generated On: 25 Jun 2020 16:25:32

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
------------	-----------	-------	--------	-------------------	-------------------

MEDICAID
 =
 MEDICAID
 MEDICAID
 AND
 MEDICARE
 =
 MEDICAID
 AND
 MEDICARE
 MILITARY
 OR
 VETERANS
 SPONSORE
 D NOS =
 MILITARY
 OR
 VETERANS
 SPONSORE
 D NOS
 MILITARY
 SPONSORE
 D
 (INCLUDIN
 G CHAMPUS
 &TRICARE)
 = MILITARY
 SPONSORE
 D
 (INCLUDIN
 G CHAMPUS
 &TRICARE)

Version 12.00 pushed to PRODUCTION 06.16.2020: All Forms
Form: Demography
Generated On: 25 Jun 2020 16:25:32

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

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Form: Demography


Generated On: 25 Jun 2020 16:25:32

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
⑩ Race PID219219 9_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

Version 12.00 pushed to PRODUCTION 06.16.2020: All Forms

Form: Demography

Generated On: 25 Jun 2020 16:25:32

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
 Plan Pheresis Or Bone Marrow Collection Occurrence Begin Date PID500203 4_V1_0	dd MMM yyyy				PLAN_MAR ROW_ASSE SS_DT

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Form: Patient Information for NCI Reporting
Generated On: 25 Jun 2020 16:25:32

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

Version 12.00 pushed to PRODUCTION 06.16.2020: All Forms
Form: Patient Information for NCI Reporting
Generated On: 25 Jun 2020 16:25:32

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**

Version 12.00 pushed to PRODUCTION 06.16.2020: All Forms
Form: Patient Information for NCI Reporting
Generated On: 25 Jun 2020 16:25:32

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
1	PID406085_1_V1_0	\$200		PID406085_1_V1_0		FORM_OID
3	Patient Subgroup Code PID1925_V2_31	\$10				PT_SUBGRP_CD
4	Protocol Treatment Current Received Code PID245359_5_V1_0	1		1 = Yes 2 = No		PRO_TX_CUR_REC_CD
5	Zubrod Performance Status Score PID200331_5_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

Version 12.00 pushed to PRODUCTION 06.16.2020: All Forms
Form: Patient Information for NCI Reporting
Generated On: 25 Jun 2020 16:25:32

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 PID200687_5_V2_1	\$7		1 = No 2 = Yes 99 = Unknown		PT_BSL_ABN_IND3
⑧ Disease Evaluable Response Code PID245359_7_V1_0	\$1		1 = Yes 2 = No 3 = Too early 7 = Not Applicable		DZ_EVAL_RSP_CD
⑨ MedDRA Code PID200442_5_V4_0	8				MEDDRA_CODE

Version 12.00 pushed to PRODUCTION 06.16.2020: All Forms
Form: Patient Information for NCI Reporting
Generated On: 25 Jun 2020 16:25:32

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

Version 12.00 pushed to PRODUCTION 06.16.2020: All Forms
Form: Patient Characteristics
Generated On: 25 Jun 2020 16:25:32

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

Version 12.00 pushed to PRODUCTION 06.16.2020: All Forms

Form: Patient Characteristics

Generated On: 25 Jun 2020 16:25:32

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
① FORM_OID	\$200		PID333013 0_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_1 YN			1 = No 2 = Yes		DIABETES_YN
⑦ HIST_STER OID	1		1 = No 2 = Yes, oral only 3 = Yes, topical only		HIST_STER OID

Version 12.00 pushed to PRODUCTION 06.16.2020: All Forms
Form: Patient Characteristics
Generated On: 25 Jun 2020 16:25:32

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

FORM_OID _____

①

Has the patient been diagnosed with any malignancies prior to enrollment?

No ②
Yes

Prior malignancy

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

Date of diagnosis _____

④

Treatment

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

Date of last treatment or transplant _____

⑥

Version 12.00 pushed to PRODUCTION 06.16.2020: All Forms

Form: Prior Malignancy

Generated On: 25 Jun 2020 16:25:32

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
① FORM_OID	\$200				FORM_OID
② PRIOR_MAL 1 IG_YN			1 = No 2 = Yes		PRIOR_MAL IG_YN
③ PRIOR_MAL 2 IG			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

Version 12.00 pushed to PRODUCTION 06.16.2020: All Forms
Form: Prior Malignancy
Generated On: 25 Jun 2020 16:25:32

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

Version 12.00 pushed to PRODUCTION 06.16.2020: All Forms
Form: MDS Background Form
Generated On: 25 Jun 2020 16:25:32

FORM_OID _____ ①

Did the patient have a recent (within past 6 months) biopsy confirming the initial diagnosis of MDS? No ②
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 No ③
Yes

Date of biopsy _____ ④

Is the patient's blood disorder therapy-related? No ⑤
Yes
Unknown

Therapy received Chemotherapy, specify ⑥
Radiation
Other, specify

Duration of exposure Fixed Unit: Months ⑦

Version 12.00 pushed to PRODUCTION 06.16.2020: All Forms
Form: MDS Background Form
Generated On: 25 Jun 2020 16:25:32

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
① FORM_OID	\$200				FORM_OID
② PREV_CONF1 _DIAG_MD S			1 = No 2 = Yes		PREV_CONF _DIAG_MD S
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_Y N	2		1 = No 2 = Yes 99 = Unknown		TX_MDS_Y N
⑥ TX_RCVD	2		1 = Chemothera py, specify 2 = Radiation 88 = Other, specify		TX_RCVD
⑦ DUR_EXPO	3				DUR_EXPO

Version 12.00 pushed to PRODUCTION 06.16.2020: All Forms
Form: Prior Hematologic Disorder
Generated On: 25 Jun 2020 16:25:32

FORM_OID _____ ①

Has the patient been diagnosed with any hematologic disorders prior to enrollment? No ②
Yes

Prior hematologic disorder _____ ③

Date of diagnosis _____ ④

Treatment _____ ⑤

Duration of treatment _____ Fixed Unit: months ⑥

Version 12.00 pushed to PRODUCTION 06.16.2020: All Forms
Form: Prior Hematologic Disorder
Generated On: 25 Jun 2020 16:25:32

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
① FORM_OID	\$200				FORM_OID
② PRIOR_HEM1_YN			1 = No 2 = Yes		PRIOR_HEM_YN
③ PRIOR_HEM2_DX				PRIOR_HEM_DX	PRIOR_HEM_DX
④ PRIOR_HEMMMM- _DX_DT	yyyy				PRIOR_HEM_DX_DT
⑤ PRIOR_HEM_TX	\$200				PRIOR_HEM_TX
⑥ TX_DURATI ON		3			TX_DURATI ON

FORM_OID _____ ①

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

Prior autoimmune disease _____ ③

Date of diagnosis _____ ④

Treatment

- Anti-thymocyte globulin (ATG) ⑤
- 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

Version 12.00 pushed to PRODUCTION 06.16.2020: All Forms

Form: Prior Autoimmune Disease

Generated On: 25 Jun 2020 16:25:32

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
① FORM_OID	\$200				FORM_OID
② PRIOR_AUT O_YN	1		1 = No 2 = Yes		PRIOR_AUT O_YN
③ PRIOR_AUT OIMM_DX	2		PRIOR_AUT OIMM_DX		PRIOR_AUT OIMM_DX
④ PRIOR_AUT OIMM_DX_DT	MMM- yyyy				PRIOR_AUT OIMM_DX_DT
⑤ PRIOR_AUT OIMM_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_AUT OIMM_TX

Version 12.00 pushed to PRODUCTION 06.16.2020: All Forms
 Form: Prior Autoimmune Disease
 Generated On: 25 Jun 2020 16:25:32

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			8 = Steroids 9 = T-Cell costimulators 10 = Tacrolimus 88 = Other, specify 77 = None		
⑥ TX_DURATI3 ON					TX_DURATI ON_AUTO

Version 12.00 pushed to PRODUCTION 06.16.2020: All Forms
Form: Indwelling Devices or Prostheses
Generated On: 25 Jun 2020 16:25:32

FORM_OID _____ ①

Device Type

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

Initial Device Placement Date _____ ③

Version 12.00 pushed to PRODUCTION 06.16.2020: All Forms
Form: Indwelling Devices or Prostheses
Generated On: 25 Jun 2020 16:25:32

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

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
-

Version 12.00 pushed to PRODUCTION 06.16.2020: All Forms

Form: Family History

Generated On: 25 Jun 2020 16:25:32

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_2 TYPE			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

Version 12.00 pushed to PRODUCTION 06.16.2020: All Forms

Form: Family History

Generated On: 25 Jun 2020 16:25:32

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

Version 12.00 pushed to PRODUCTION 06.16.2020: All Forms
Form: Family History
Generated On: 25 Jun 2020 16:25:32

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		

FORM_OID _____ ①

Has the patient ever smoked cigarettes regularly for six months or longer? No ②
Yes

At what age did the patient start smoking cigarettes regularly? _____ ③

Does the patient smoke regularly now? No ④
Yes

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 ⑥
11-20
21-30
31-40
41-60
61-80
81 or more

Does the patient now or did they ever smoke a pipe regularly for a year or longer? Never smoked a pipe ⑦
Did smoke a pipe but currently do not smoke
Currently do smoke a pipe

Does the patient now or did they ever smoke cigars regularly for a year or longer? Never smoked cigars ⑧
Did smoke cigars but currently do not smoke
Currently smoke cigars

Not including the past two years, has the patient ever lived with someone who regularly smoked cigarettes around them?

No **9**
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?

No **11**
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?

No **13**
Yes

Version 12.00 pushed to PRODUCTION 06.16.2020: All Forms

Form: Smoking History

Generated On: 25 Jun 2020 16:25:32

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_SMOK_E_STRT	2				AGE_SMOK_E_STRT
④ CURR_SMOKE_YN	1		1 = No 2 = Yes		CURR_SMOKE_YN_DYN
⑤ AGE_SMOK_E_STOP	2				AGE_SMOK_E_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

Version 12.00 pushed to PRODUCTION 06.16.2020: All Forms
Form: Smoking History
Generated On: 25 Jun 2020 16:25:32

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_Y1 N			1 = No 2 = Yes		LIVE_CIG_Y N
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 SMOKELESS1 _TOB_YN			1 = No 2 = Yes		SMOKELESS _TOB_YN

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
-

Version 12.00 pushed to PRODUCTION 06.16.2020: All Forms
 Form: Alcohol History
 Generated On: 25 Jun 2020 16:25:32

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

Version 12.00 pushed to PRODUCTION 06.16.2020: All Forms
Form: Alcohol History
Generated On: 25 Jun 2020 16:25:32

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
④ WINE_FRE Q	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_FRE Q
⑤ LIQUOR_FR EQ	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_FR EQ

Version 12.00 pushed to PRODUCTION 06.16.2020: All Forms
Form: Alcohol History
Generated On: 25 Jun 2020 16:25:32

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

Version 12.00 pushed to PRODUCTION 06.16.2020: All Forms
Form: Environmental Exposure
Generated On: 25 Jun 2020 16:25:32

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?

No ④
Yes
Unknown

(If yes) Years of exposure _____

Fixed Unit: Years ⑤

Has the patient ever been exposed to agent orange?

No ⑥
Yes
Unknown

Has the patient ever been exposed to other chemicals or solvents?

No ⑦
Yes (specify)
Unknown

Has the patient ever been exposed to radiation?

No ⑧
Yes (specify)
Unknown

Version 12.00 pushed to PRODUCTION 06.16.2020: All Forms
 Form: Environmental Exposure
 Generated On: 25 Jun 2020 16:25:32

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

Version 12.00 pushed to PRODUCTION 06.16.2020: All Forms
Form: Environmental Exposure
Generated On: 25 Jun 2020 16:25:32

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_EX P_YN	2		1 = No 2 = Yes 99 = Unknown		EVIRON_EX P_YN
⑤ YRS_EXP	2				YRS_EXP
⑥ AGENT_OR ANGE_YN	2		1 = No 2 = Yes 99 = Unknown		AGENT_OR ANGE_YN
⑦ OTH_CHEM _YN	2		1 = No 2 = Yes (specify) 99 = Unknown		OTH_CHEM _YN

Version 12.00 pushed to PRODUCTION 06.16.2020: All Forms
Form: Environmental Exposure
Generated On: 25 Jun 2020 16:25:32

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
⑧ RAD_YN	2		1 = No 2 = Yes (specify) 99 = Unknown		RAD_YN

Version 12.00 pushed to PRODUCTION 06.16.2020: All Forms
Form: Baseline Hematology/Chemistry
Generated On: 25 Jun 2020 16:25:32

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?

No ⑦
Yes

Date Hematology (Blood) Sample Obtained _____ ⑧

Antinuclear Antibody (ANA), Serum

Negative ⑨
Positive
Not done

Date obtained _____ ⑩

T-Cell Receptor Rearrangement

Negative ⑪
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

Version 12.00 pushed to PRODUCTION 06.16.2020: All Forms
Form: Baseline Hematology/Chemistry
Generated On: 25 Jun 2020 16:25:32

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

Version 12.00 pushed to PRODUCTION 06.16.2020: All Forms
Form: Baseline Hematology/Chemistry
Generated On: 25 Jun 2020 16:25:32

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
① FORM PID476157 4	\$200				FORM_OID
③ Laboratory 2 Finding Test Name PID200374 6_V5_0			LAB_TEST_ 1: PID218280 9_V4_0F	LAB_NAME _XX Creatinine, Serum 2: Alkaline Phosphatas e, Serum 3: Aspartate Aminotransf erases (AST or SGOT), Serum 4: Alanine Aminotransf erases (ALT or SGPT), Serum 5: Lactate Dehydrogen ase (LDH), Serum 6: Vitamin B12, Serum 7: Copper, Serum 8: Iron, Serum 9: Total Iron Binding Capacity, Serum	

Version 12.00 pushed to PRODUCTION 06.16.2020: All Forms
Form: Baseline Hematology/Chemistry
Generated On: 25 Jun 2020 16:25:32

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	

Version 12.00 pushed to PRODUCTION 06.16.2020: All Forms
Form: Baseline Hematology/Chemistry
Generated On: 25 Jun 2020 16:25:32

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
				19:	
				Monocytes,	
				#, Blood	
				20:	
				Lymphocyte	
				s, #, Blood	
				21:	
				Eosinophils,	
				#, blood	
				22:	
				Basophils,	
				#, Blood	
				23:	
				Reticulocyte	
				s, #, 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	

Version 12.00 pushed to PRODUCTION 06.16.2020: All Forms
Form: Baseline Hematology/Chemistry
Generated On: 25 Jun 2020 16:25:32

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
④ Laboratory Procedure Not Performed Text PID220061_6_V1_0	1				TEST_ND_XX
⑤ Laboratory Test Result Numeric Value PID218336_0_V2_0	10.2				LAB_RS_XX
⑥ Laboratory Test Result Unit of Measure Unified Code for Units of Measure Code PID278794_7_V1_0	2		LAB_UOM_1: mg/dL PID201522_4_V3_0F	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

Version 12.00 pushed to PRODUCTION 06.16.2020: All Forms
 Form: Baseline Hematology/Chemistry
 Generated On: 25 Jun 2020 16:25:32

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
				23: / μ L 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 PID200400 4_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

Version 12.00 pushed to PRODUCTION 06.16.2020: All Forms
Form: Baseline Hematology/Chemistry
Generated On: 25 Jun 2020 16:25:32

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_CD5 9_CD55_YN	1		1 = No 2 = Yes		GRAN_CD5 9_CD55_YN
16 ASSAY_TYP E1	1		1 = Screening 2 = High sensitivity		ASSAY_TYP E1
17 LL_DET1	4.3				LL_DET1
18 PNHF_DT1	MMM dd YYYY				PNHF_DT1

Version 12.00 pushed to PRODUCTION 06.16.2020: All Forms
Form: Baseline Hematology/Chemistry
Generated On: 25 Jun 2020 16:25:32

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
16 GRAN_FLAE R_YN	1		1 = No 2 = Yes		GRAN_FLAE R_YN
20 ASSAY_TYP E2	1		1 = Screening 2 = High sensitivity		ASSAY_TYP E2
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_TYP E3	1		1 = Screening 2 = High sensitivity		ASSAY_TYP E3
25 LL_DET3	4.3				LL_DET3
26 PNHF_DT3	MMM dd YYYY				PNHF_DT3
27 MON_FLAE R_YN	1		1 = No 2 = Yes		MON_FLAE R_YN

Version 12.00 pushed to PRODUCTION 06.16.2020: All Forms
Form: Baseline Hematology/Chemistry
Generated On: 25 Jun 2020 16:25:32

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
28 ASSAY_TYP 1 E4			1 = Screening 2 = High sensitivity		ASSAY_TYP E4
29 LL_DET4	4.3				LL_DET4
30 PNHF_DT4	MMM dd YYYY				PNHF_DT4
31 ERY_CD59_1 CD55_YN			1 = No 2 = Yes		ERY_CD59_1 CD55_YN
32 ASSAY_TYP 1 E5			1 = Screening 2 = High sensitivity		ASSAY_TYP E5
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

Version 12.00 pushed to PRODUCTION 06.16.2020: All Forms
 Form: Baseline Hematology/Chemistry
 Generated On: 25 Jun 2020 16:25:32

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 12.00 pushed to PRODUCTION 06.16.2020: All Forms
Form: Concomitant Medication Form
Generated On: 25 Jun 2020 16:25:32

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 be 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 12.00 pushed to PRODUCTION 06.16.2020: All Forms
Form: Concomitant Medication Form
Generated On: 25 Jun 2020 16:25:32

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_REAS_ON	\$200				MED_REAS_ON

Version 12.00 pushed to PRODUCTION 06.16.2020: All Forms
Form: Charlson Comorbidity Index Yes/No
Generated On: 25 Jun 2020 16:25:32

FORM_OID _____

①

Was Charlson Comorbidity Index completed?

No ②
Yes

Version 12.00 pushed to PRODUCTION 06.16.2020: All Forms
Form: Charlson Comorbidity Index Yes/No
Generated On: 25 Jun 2020 16:25:32

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

Version 12.00 pushed to PRODUCTION 06.16.2020: All Forms
Form: Charlson Comorbidity Index
Generated On: 25 Jun 2020 16:25:32

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? No 11
Yes

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

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

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

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

Type of Cancer Lymphoma 16
Leukemia
Solid tumor (specify)

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

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

Version 12.00 pushed to PRODUCTION 06.16.2020: All Forms
Form: Charlson Comorbidity Index
Generated On: 25 Jun 2020 16:25:32

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

Version 12.00 pushed to PRODUCTION 06.16.2020: All Forms
Form: Charlson Comorbidity Index
Generated On: 25 Jun 2020 16:25:32

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 DMENDORG1 AN			1 = No 2 = Yes		DMENDORG AN
⑪ RENAL	1		1 = No 2 = Yes		RENAL

Version 12.00 pushed to PRODUCTION 06.16.2020: All Forms
Form: Charlson Comorbidity Index
Generated On: 25 Jun 2020 16:25:32

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_TY1PE			1 = Lymphoma 2 = Leukemia 3 = Solid tumor (specify)		CANCER_TY1PE
17 METS_YN	1		1 = No 2 = Yes		METS_YN
18 METASTASES			1 = Breast 2 = Colon 3 = Prostate 4 = Lung 5 = Melanoma 88 = Other (specify)		METASTASES

Version 12.00 pushed to PRODUCTION 06.16.2020: All Forms
 Form: Charlson Comorbidity Index
 Generated On: 25 Jun 2020 16:25:32

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 DEPRESSIO N	1		1 = No 2 = Yes		DEPRESSIO N
25 WARFARIN	1		1 = No 2 = Yes		WARFARIN

Version 12.00 pushed to PRODUCTION 06.16.2020: All Forms
Form: Report Period and Vital Status Form
Generated On: 25 Jun 2020 16:25:32

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

Alive ⑤
Dead

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

Date of death _____ ⑦

Primary Cause of Death

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

Version 12.00 pushed to PRODUCTION 06.16.2020: All Forms
Form: Report Period and Vital Status Form
Generated On: 25 Jun 2020 16:25:32

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	FORM PID396493 5	\$200				FORM_OID
③	Treatment Reporting Period Begin Date PID2993_V 4_0	MMM dd yyyy				RP_STRT_DT
④	Treatment Reporting Period End Date PID2992_V 4_0	MMM dd yyyy				RP_END_DT
⑤	Participant Vital Status Type PID284733 0_V1_0	1		1 = Alive 2 = Dead		PT_VT_STA
⑥	Participant Last Known Alive Date PID284728 5_V1_0	MMM dd yyyy				LAST_CONT_ACT_DT
⑦	Death Date PID200415 2_V3_0	MMM dd yyyy				DEATH_DT

Version 12.00 pushed to PRODUCTION 06.16.2020: All Forms
Form: Report Period and Vital Status Form
Generated On: 25 Jun 2020 16:25:32

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 12.00 pushed to PRODUCTION 06.16.2020: All Forms
Form: Study Visit Information
Generated On: 25 Jun 2020 16:25:32

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

Version 12.00 pushed to PRODUCTION 06.16.2020: All Forms

Form: Study Visit Information

Generated On: 25 Jun 2020 16:25:32

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
① FORM_OID	\$200				FORM_OID
② STUDY_VIS IT_YN	1		1 = No 2 = Yes		STUDY_VIS IT_YN
③ STUDY_VIS IT_DT	MMM dd yyyy				STUDY_VIS IT_DT
④ PT_DATA_COLL_YN	C1		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

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? No 19
Yes

Peripheral Inserted central catheter (PICC) or Midline catheter? No 20
Yes

Silicone central venous (e.g., Hickman, Broviac) No 21
Yes

Implantable vascular access device (port) No 22
Yes

Has the patient experienced bleeding or hemorrhage of CTCAE grade 2 or higher? No 23
Yes

Event type Purpura 24
Hematoma
Hemorrhage, gastrointestinal
Hemorrhage, genitourinary
Hemorrhage, pulmonary
Hemorrhage, central nervous system
Hemorrhage, vitreous
Hemorrhage, other, specify

Maximum CTCAE grade 2 25
3
4
5

Has the patient entered hospice care?

No 26
Yes

Date entered _____

27

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Form: Status Form

Generated On: 25 Jun 2020 16:25:32

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_TRAN_SF_YN	1		1 = No 2 = Yes		RBC_TRAN_SF_YN
⑩ PLT_TRANSF_YN	1		1 = No 2 = Yes		PLT_TRANSF_YN

Version 12.00 pushed to PRODUCTION 06.16.2020: All Forms

Form: Status Form

Generated On: 25 Jun 2020 16:25:32

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
11 INF_REQ_T X	1		1 = No 2 = Yes		INF_REQ_T X
12 TX_TYPE	1		1 = Antibiotic 2 = Antiviral 3 = Antifungal		TX_TYPE
13 IV_ADMN_Y1 N			1 = No 2 = Yes		IV_ADMN_Y N
14 HIST_THRO MB	1		1 = No 2 = Yes		HIST_THRO MB
15 HIST_CLOT S	1		1 = No 2 = Yes		HIST_CLOT S
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

Version 12.00 pushed to PRODUCTION 06.16.2020: All Forms

Form: Status Form

Generated On: 25 Jun 2020 16:25:32

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
20 PICC_MIDLI1 NE_YN			1 = No 2 = Yes		PICC_MIDLI NE_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_EVEN T	2		1 = Purpura 2 = Hematoma 3 = Hemorrhag e, gastrointest inal 4 = Hemorrhag e, genitourinar y 5 = Hemorrhag e, pulmonary 6 = Hemorrhag e, central nervous system		HEM_EVEN T

Version 12.00 pushed to PRODUCTION 06.16.2020: All Forms

Form: Status Form

Generated On: 25 Jun 2020 16:25:32

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			7 = Hemorrhag e, vitreous 99 = Hemorrhag e, other, specify		
25 HEM_EVEN T_GR	1		2 = 2 3 = 3 4 = 4 5 = 5		HEM_EVEN T_GR
26 HOSPICE_Y N	1		1 = No 2 = Yes		HOSPICE_Y N
27 HOSPICE_D T	dd MMM YYYY				HOSPICE_D T

Version 12.00 pushed to PRODUCTION 06.16.2020: All Forms
Form: Hospitalization/ER Form
Generated On: 25 Jun 2020 16:25:32

FORM_OID _____ ①

Hospitalization or ER admission date _____ ②

Hospitalization or ER discharge date _____ ③

Reason for hospitalization or ER

- Bleeding ④
- Cardiovascular
- Infection
- Neurologic
- Pulmonary
- Therapy
- Transfusion
- Trauma
- Confirmed COVID-19 or SARS-CoV-2 infection
- Other, specify

Version 12.00 pushed to PRODUCTION 06.16.2020: All Forms
Form: Hospitalization/ER Form
Generated On: 25 Jun 2020 16:25:32

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

Version 12.00 pushed to PRODUCTION 06.16.2020: All Forms

Form: ICU Form

Generated On: 25 Jun 2020 16:25:32

FORM_OID _____ ①

ICU admission date _____ ②

ICU discharge date _____ ③

Was patient intubated? No ④
Yes
Unknown

Did patient receive vasopressor agents? No ⑤
Yes
Unknown

Was the patient treated in ICU for the novel coronavirus (SARS-CoV-2)? No ⑥
Yes
Unknown

Version 12.00 pushed to PRODUCTION 06.16.2020: All Forms

Form: ICU Form

Generated On: 25 Jun 2020 16:25:32

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 INTUBATED2_YNU			1 = No 2 = Yes 99 = Unknown		INTUBATED_YNU
⑤ VASPORESS2_OR_YNU			1 = No 2 = Yes 99 = Unknown		VASPORESS_OR_YNU
⑥ CORONA_T2_X_YNU			1 = No 2 = Yes 99 = Unknown		CORONA_T2_X_YNU

Version 12.00 pushed to PRODUCTION 06.16.2020: All Forms
Form: Clinic Visit Form
Generated On: 25 Jun 2020 16:25:32

FORM_OID _____ ①

Clinic visit date _____ ②

Reason for clinic visit

MDS care ③
COVID-19 infection
Other, specify

Version 12.00 pushed to PRODUCTION 06.16.2020: All Forms
Form: Clinic Visit Form
Generated On: 25 Jun 2020 16:25:32

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_RE AS	2		1 = MDS care 2 = COVID-19 infection 88 = Other, specify		CLINIC_RE AS

Version 12.00 pushed to PRODUCTION 06.16.2020: All Forms
Form: RBC Transfusion Form
Generated On: 25 Jun 2020 16:25:32

FORM_OID _____ ①

Transfusion date _____ ②

Blood unit type _____ Packed ③
Whole

Number of units _____ ④

Version 12.00 pushed to PRODUCTION 06.16.2020: All Forms
Form: RBC Transfusion Form
Generated On: 25 Jun 2020 16:25:32

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
① FORM_OID	\$200				FORM_OID
② RBC_TRAN S_DT	dd MMM YYYY				RBC_TRAN S_DT
③ RBC_UNIT_2 TYPE			1 = Packed 2 = Whole		RBC_UNIT_ TYPE
④ NUM_UNIT S	2				NUM_UNIT S

Version 12.00 pushed to PRODUCTION 06.16.2020: All Forms
Form: Platelet Transfusion Form
Generated On: 25 Jun 2020 16:25:32

FORM_OID _____ ①

Transfusion date _____ ②

Number of bags _____ ③

Donor type _____ Pooled ④
Single

Version 12.00 pushed to PRODUCTION 06.16.2020: All Forms
Form: Platelet Transfusion Form
Generated On: 25 Jun 2020 16:25:32

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_TY PE	1		1 = Pooled 2 = Single		DONOR_TY PE

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?

No ⑥
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

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Form: Second Primary

Generated On: 25 Jun 2020 16:25:32

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	FORM PID392283 7	\$200				FORM_OID
③	Second Primary Neoplasm Diagnosis Date PID200374 8_V4_0	dd MMM YYYY				PRIM2_DX_ DT
④	Second Primary Malignant Neoplasm Anatomic Site Text PID200374 9_V3_0	3		SEC_PRIM_ SITE		PRIM2_SIT E_FT
⑤	Second Primary Malignant Neoplasm Anatomic Site Specify PID243397 4_V1_0	\$200				PRIM2_SIT E_SP

Version 12.00 pushed to PRODUCTION 06.16.2020: All Forms

Form: Second Primary

Generated On: 25 Jun 2020 16:25:32

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
⑥ Second Primary Neoplasm Cancer Treatment Attribution Diagnosis Ind_2 PID316081 1_V1_0	1		1 = No 2 = Yes		PRIM2_TX_RELATE_YN
⑦ Second Tumor Histologic Subtype Specify PID200375 0_V4_0	\$100				PRIM2_HISTOL_FT
⑧ Pathology Report Upload Text PID391496 9_V1_0	\$200				CYTO_REPORT
⑨ Second Cancer Therapy Planned Text PID200375 2_V4_0	\$200				TX_PLANNE D_PRIM2_FT

Version 12.00 pushed to PRODUCTION 06.16.2020: All Forms
Form: Hematology/Chemistry
Generated On: 25 Jun 2020 16:25:32

FORM_OID _____ ①

Lab Test _____ ②

Test not done _____ ③

Lab Value _____ ④

Lab Unit _____ ⑤

Value Abnormal? No ⑥
Yes

Date Hematology (Blood) Sample Obtained _____ ⑦

Version 12.00 pushed to PRODUCTION 06.16.2020: All Forms
Form: Hematology/Chemistry
Generated On: 25 Jun 2020 16:25:32

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
① FORM PID476423 5	\$200				FORM_OID
② Laboratory 2 Finding Test Name PID200374 6_V5_0			LAB_TEST_ 1: PID218280 9_V4_0F	LAB_NAME Hemoglobin _XX , 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	

Version 12.00 pushed to PRODUCTION 06.16.2020: All Forms
Form: Hematology/Chemistry
Generated On: 25 Jun 2020 16:25:32

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
③ Laboratory Procedure Not Performed Text PID220061_6_V1_0	1				TEST_ND_XX
④ Laboratory Test Result Numeric Value PID218336_0_V2_0	10.2				LAB_RS_XX
⑤ Laboratory Test Result Unit of Measure Unified Code for Units of Measure Code PID278794_7_V1_0	2		LAB_UOM_1: g/dL PID201522_4_V3_0F	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 PID200400_4_V3_0	MMM dd yyyy				LAB_DT_XX

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?

No ③
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

Were peripheral blood samples submitted to MDS Central Laboratory and Biorespository? No **7**
Yes

Please indicate reason why samples were not collected Procedure performed at another location **8**
Dry tap
Patient refusal
Site error
COVID-19 Related
Other (specify)

Procedure Bone marrow biopsy **9**
Bone marrow aspirate
Both biopsy and aspirate

Date of procedure _____ **10**

Upload report _____ **11**

2008 WHO Category AML **12**
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 13
- 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: % 14

Blast, Bone Marrow, reported within normal limits

15

Cellularity, %, Bone Marrow

Fixed Unit: % 16

Cellularity, Bone Marrow, % unknown

Hypocellular 17
Normocellular
Hypercellular

Molecular diagnostics performed?

No 18
Yes, report uploaded
Yes, report not uploaded

FISH performed?

No 19

Yes, report uploaded
Yes, report not uploaded

Cytogenetic karyotyping performed?

No 20
Yes, report uploaded
Yes, report not uploaded

Upload molecular diagnostics, FISH, and/or cytogenetic reports

21

Version 12.00 pushed to PRODUCTION 06.16.2020: All Forms

Form: Marrow Assessment

Generated On: 25 Jun 2020 16:25:32

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_SA MPL_SUBM _YN	1		1 = No 2 = Yes		BM_BX_SA MPL_SUBM _YN
⑤ REAS_SAMP2 L_NOT_SUB M			1 = Procedure performed at another location 2 = Dry tap 3 = Patient refusal 4 = Site error 5 = COVID-19 Related 88 = Other (specify)		REAS_SAMP L_NOT_SUB M
⑥ BLOOD_DR AWN_YN	1		1 = No 2 = Yes		BLOOD_DR AWN_YN
⑦ BLOOD_SA MPL_SUBM _YN	1		1 = No 2 = Yes		BLOOD_SA MPL_SUBM _YN

Version 12.00 pushed to PRODUCTION 06.16.2020: All Forms

Form: Marrow Assessment

Generated On: 25 Jun 2020 16:25:32

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
8 REAS_BLOO2 D_SAMPL_ 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_BLOO D_SAMPL_ NOT_SUBM
9 BM_PROCE DURE	1		1 = Bone marrow biopsy 2 = Bone marrow aspirate 3 = Both biopsy and aspirate		BM_PROCE DURE
10 BM_BX_DT	dd MMM YYYY				BM_BX_DT
11 BM_DX_UP LOAD	\$200				BM_DX_UP LOAD


Version 12.00 pushed to PRODUCTION 06.16.2020: All Forms
Form: Marrow Assessment
Generated On: 25 Jun 2020 16:25:32

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
DIAG_WHO 2 _CAT			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) 6 = MDS Refractory cytopenia with unilineage dysplasia - refractory Thrombocyt openia (RCUD-RT)		DIAG_WHO _CAT

Version 12.00 pushed to PRODUCTION 06.16.2020: All Forms
Form: Marrow Assessment
Generated On: 25 Jun 2020 16:25:32

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			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)		
			11 = MDS associated with isolated del(5q)		
			12 = Myelodysplastic syndrome unclassified (MDS-U)		

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Form: Marrow Assessment
Generated On: 25 Jun 2020 16:25:32

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			77 = Other Malignancy, specify 88 = Other, specify		
 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) 6 = MDS with multilineage dysplasia (MDS-MLD) 7 = MDS with multilineage dysplasia and ring sideroblasts (MDS-RSMLD)		DIAG_WHO _CAT2


Version 12.00 pushed to PRODUCTION 06.16.2020: All Forms
Form: Marrow Assessment
Generated On: 25 Jun 2020 16:25:32

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			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		
14 BLAST_PCT	3				BLAST_PCT
15 BLAST_RPT _NORM_LI MITS_XX	1				BLAST_RPT _NORM_LI MITS_XX
16 CELL_PCT	3				CELL_PCT

Version 12.00 pushed to PRODUCTION 06.16.2020: All Forms
 Form: Marrow Assessment
 Generated On: 25 Jun 2020 16:25:32

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
17 CELLULARI TY_UNKOW N_TYPE_XX	1		1 = Hypocellular 2 = Normocellular 3 = Hypercellular		CELLULARI TY_UNKOW N_TYPE_XX
18 MOLEC_DIA G	1		1 = No 2 = Yes, report uploaded 3 = Yes, report not uploaded		MOLEC_DIA G
19 FISH	1		1 = No 2 = Yes, report uploaded 3 = Yes, report not uploaded		FISH
20 CYTO_KARY O	1		1 = No 2 = Yes, report uploaded 3 = Yes, report not uploaded		CYTO_KARY O

Version 12.00 pushed to PRODUCTION 06.16.2020: All Forms
Form: Marrow Assessment
Generated On: 25 Jun 2020 16:25:32

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
 CYTOGEN_ RPT_UPLOA D	\$200				CYTOGEN_ RPT_UPLOA D

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?

No ③
Yes

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Form: Baseline Marrow Assessment
Generated On: 25 Jun 2020 16:25:32

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

Were peripheral blood samples submitted to MDS Central Laboratory and Biorespository?

No 7
Yes

Please indicate reason why samples were not collected

Procedure performed at another location 8
Dry tap
Patient refusal
Site error
COVID-19 Related
Other (specify)

Procedure

Bone marrow biopsy 9
Bone marrow aspirate
Both biopsy and aspirate

Date of procedure

_____ 10

Upload report

11

2008 WHO Category

- AML 12
- 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 13

- 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: % **14**

Blast, Bone Marrow, reported within normal limits

15

Cellularity, %, Bone Marrow

Fixed Unit: % **16**

Cellularity, Bone Marrow, % unknown

Hypocellular **17**
Normocellular
Hypercellular

Version 12.00 pushed to PRODUCTION 06.16.2020: All Forms
Form: Baseline Marrow Assessment
Generated On: 25 Jun 2020 16:25:32

Molecular diagnostics performed? No **18**
Yes, report uploaded
Yes, report not uploaded

FISH performed? No **19**
Yes, report uploaded
Yes, report not uploaded

Cytogenetic karyotyping performed? No **20**
Yes, report uploaded
Yes, report not uploaded

Upload molecular diagnostics, FISH, and/or cytogenetic reports **21**

Version 12.00 pushed to PRODUCTION 06.16.2020: All Forms

Form: Baseline Marrow Assessment

Generated On: 25 Jun 2020 16:25:32

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_SA MPL_SUBM _YN	1		1 = No 2 = Yes		BM_BX_SA MPL_SUBM _YN
⑤ REAS_SAMP2 L_NOT_SUB M			1 = Procedure performed at another location 2 = Dry tap 3 = Patient refusal 4 = Site error 5 = COVID-19 Related 88 = Other (specify)		REAS_SAMP L_NOT_SUB M
⑥ BLOOD_DR AWN_YN	1		1 = No 2 = Yes		BLOOD_DR AWN_YN
⑦ BLOOD_SA MPL_SUBM _YN	1		1 = No 2 = Yes		BLOOD_SA MPL_SUBM _YN

Version 12.00 pushed to PRODUCTION 06.16.2020: All Forms
Form: Baseline Marrow Assessment
Generated On: 25 Jun 2020 16:25:32

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
8 REAS_BLOO2 D_SAMPL_ 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_BLOO D_SAMPL_ NOT_SUBM
9 BM_PROCE DURE	1		1 = Bone marrow biopsy 2 = Bone marrow aspirate 3 = Both biopsy and aspirate	1:	BM_PROCE DURE
10 BM_BX_DT	dd MMM YYYY				BM_BX_DT
11 BM_DX_UP LOAD	\$200				BM_DX_UP LOAD


Version 12.00 pushed to PRODUCTION 06.16.2020: All Forms
Form: Baseline Marrow Assessment
Generated On: 25 Jun 2020 16:25:32

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
DIAG_WHO 2 _CAT			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) 6 = MDS Refractory cytopenia with unilineage dysplasia - refractory Thrombocyt openia (RCUD-RT)		DIAG_WHO _CAT

Version 12.00 pushed to PRODUCTION 06.16.2020: All Forms
Form: Baseline Marrow Assessment
Generated On: 25 Jun 2020 16:25:32

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			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)		
			11 = MDS associated with isolated del(5q)		
			12 = Myelodyspla stic syndrome unclassified (MDS-U)		

Version 12.00 pushed to PRODUCTION 06.16.2020: All Forms
Form: Baseline Marrow Assessment
Generated On: 25 Jun 2020 16:25:32

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			77 = Other Malignancy, specify 88 = Other, specify		
 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) 6 = MDS with multilineage dysplasia (MDS-MLD) 7 = MDS with multilineage dysplasia and ring sideroblasts (MDS-RSMLD)		DIAG_WHO _CAT2


Version 12.00 pushed to PRODUCTION 06.16.2020: All Forms
Form: Baseline Marrow Assessment
Generated On: 25 Jun 2020 16:25:32

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			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		
14 BLAST_PCT	3				BLAST_PCT
15 BLAST_RPT _NORM_LI MITS_XX	1				BLAST_RPT _NORM_LI MITS_XX
16 CELL_PCT	3				CELL_PCT

Version 12.00 pushed to PRODUCTION 06.16.2020: All Forms
Form: Baseline Marrow Assessment
Generated On: 25 Jun 2020 16:25:32

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
17 CELLULARI TY_UNKOW N_TYPE_XX	1		1 = Hypocellular 2 = Normocellular 3 = Hypercellular		CELLULARI TY_UNKOW N_TYPE_XX
18 MOLEC_DIA G	1		1 = No 2 = Yes, report uploaded 3 = Yes, report not uploaded		MOLEC_DIA G
19 FISH	1		1 = No 2 = Yes, report uploaded 3 = Yes, report not uploaded		FISH
20 CYTO_KARY O	1		1 = No 2 = Yes, report uploaded 3 = Yes, report not uploaded		CYTO_KARY O

Version 12.00 pushed to PRODUCTION 06.16.2020: All Forms
Form: Baseline Marrow Assessment
Generated On: 25 Jun 2020 16:25:32

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
 CYTOGEN_ RPT_UPLOA D	\$200				CYTOGEN_ RPT_UPLOA D

Version 12.00 pushed to PRODUCTION 06.16.2020: All Forms
Form: Marrow Assessment Hematology/Chemistry 1
Generated On: 25 Jun 2020 16:25:32

FORM_OID _____ ①

Lab Test _____ ②

Test not done _____ ③

Lab Value _____ ④

Lab Unit _____ ⑤

Value Abnormal? No ⑥
Yes

Date Hematology (Blood) Sample Obtained _____ ⑦

Version 12.00 pushed to PRODUCTION 06.16.2020: All Forms
Form: Marrow Assessment Hematology/Chemistry 1
Generated On: 25 Jun 2020 16:25:32

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
① FORM PID476423 5	\$200				FORM_OID
② Laboratory 2 Finding Test Name PID200374 6_V5_0			LAB_TEST_ 1: PID218280 9_V4_0F	LAB_NAME Hemoglobin _XX , 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	

Version 12.00 pushed to PRODUCTION 06.16.2020: All Forms
Form: Marrow Assessment Hematology/Chemistry 1
Generated On: 25 Jun 2020 16:25:32

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
③ Laboratory Procedure Not Performed Text PID220061_6_V1_0	1				TEST_ND_XX
④ Laboratory Test Result Numeric Value PID218336_0_V2_0	10.2				LAB_RS_XX
⑤ Laboratory Test Result Unit of Measure Unified Code for Units of Measure Code PID278794_7_V1_0	2		LAB_UOM_1: g/dL PID201522_4_V3_0F	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 PID200400_4_V3_0	MMM dd yyyy				LAB_DT_XX

Version 12.00 pushed to PRODUCTION 06.16.2020: All Forms
Form: Marrow Assessment Hematology/Chemistry 2
Generated On: 25 Jun 2020 16:25:32

FORM_OID _____ ①

Lab Test _____ ②

Test not done _____ ③

Lab Value _____ ④

Lab Unit _____ ⑤

Value Abnormal? No ⑥
Yes

Date Hematology (Blood) Sample Obtained _____ ⑦

Version 12.00 pushed to PRODUCTION 06.16.2020: All Forms
Form: Marrow Assessment Hematology/Chemistry 2
Generated On: 25 Jun 2020 16:25:32

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
① FORM PID476423 5	\$200				FORM_OID
② Laboratory 2 Finding Test Name PID200374 6_V5_0			LAB_TEST_ 1: PID218280 9_V4_0F	LAB_NAME Hemoglobin_XX , 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	

Version 12.00 pushed to PRODUCTION 06.16.2020: All Forms
Form: Marrow Assessment Hematology/Chemistry 2
Generated On: 25 Jun 2020 16:25:32

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
③ Laboratory Procedure Not Performed Text PID220061_6_V1_0	1				TEST_ND_XX
④ Laboratory Test Result Numeric Value PID218336_0_V2_0	10.2				LAB_RS_XX
⑤ Laboratory Test Result Unit of Measure Unified Code for Units of Measure Code PID278794_7_V1_0	2		LAB_UOM_1: g/dL PID201522_2: /μL 4_V3_0F 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 PID200400_4_V3_0	MMM dd yyyy				LAB_DT_XX

Version 12.00 pushed to PRODUCTION 06.16.2020: All Forms
Form: Marrow Assessment Hematology/Chemistry 3
Generated On: 25 Jun 2020 16:25:32

FORM_OID _____ ①

Lab Test _____ ②

Test not done _____ ③

Lab Value _____ ④

Lab Unit _____ ⑤

Value Abnormal? No ⑥
Yes

Date Hematology (Blood) Sample Obtained _____ ⑦

Version 12.00 pushed to PRODUCTION 06.16.2020: All Forms
Form: Marrow Assessment Hematology/Chemistry 3
Generated On: 25 Jun 2020 16:25:32

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
① FORM PID476423 5	\$200				FORM_OID
② Laboratory 2 Finding Test Name PID200374 6_V5_0			LAB_TEST_ 1: PID218280 9_V4_0F	LAB_NAME Hemoglobin_XX , 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	

Version 12.00 pushed to PRODUCTION 06.16.2020: All Forms
Form: Marrow Assessment Hematology/Chemistry 3
Generated On: 25 Jun 2020 16:25:32

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
③ Laboratory Procedure Not Performed Text PID220061_6_V1_0	1				TEST_ND_XX
④ Laboratory Test Result Numeric Value PID218336_0_V2_0	10.2				LAB_RS_XX
⑤ Laboratory Test Result Unit of Measure Unified Code for Units of Measure Code PID278794_7_V1_0	2		LAB_UOM_1: g/dL PID201522_2: /μL 4_V3_0F 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 PID200400_4_V3_0	MMM dd yyyy				LAB_DT_XX

Version 12.00 pushed to PRODUCTION 06.16.2020: All Forms
Form: Marrow Assessment Hematology/Chemistry 4
Generated On: 25 Jun 2020 16:25:32

FORM_OID _____ ①

Lab Test _____ ②

Test not done _____ ③

Lab Value _____ ④

Lab Unit _____ ⑤

Value Abnormal? No ⑥
Yes

Date Hematology (Blood) Sample Obtained _____ ⑦

Version 12.00 pushed to PRODUCTION 06.16.2020: All Forms
Form: Marrow Assessment Hematology/Chemistry 4
Generated On: 25 Jun 2020 16:25:32

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
① FORM PID476423 5	\$200				FORM_OID
② Laboratory 2 Finding Test Name PID200374 6_V5_0			LAB_TEST_ 1: PID218280 9_V4_0F	LAB_NAME Hemoglobin_XX , 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	

Version 12.00 pushed to PRODUCTION 06.16.2020: All Forms
Form: Marrow Assessment Hematology/Chemistry 4
Generated On: 25 Jun 2020 16:25:32

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
③ Laboratory Procedure Not Performed Text PID220061_6_V1_0	1				TEST_ND_XX
④ Laboratory Test Result Numeric Value PID218336_0_V2_0	10.2				LAB_RS_XX
⑤ Laboratory Test Result Unit of Measure Unified Code for Units of Measure Code PID278794_7_V1_0	2		LAB_UOM_1: g/dL PID201522_4_V3_0F	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 PID200400_4_V3_0	MMM dd yyyy				LAB_DT_XX

Version 12.00 pushed to PRODUCTION 06.16.2020: All Forms
Form: Marrow Assessment Hematology/Chemistry 5
Generated On: 25 Jun 2020 16:25:32

FORM_OID _____ ①

Lab Test _____ ②

Test not done _____ ③

Lab Value _____ ④

Lab Unit _____ ⑤

Value Abnormal? No ⑥
Yes

Date Hematology (Blood) Sample Obtained _____ ⑦

Version 12.00 pushed to PRODUCTION 06.16.2020: All Forms
Form: Marrow Assessment Hematology/Chemistry 5
Generated On: 25 Jun 2020 16:25:32

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
① FORM PID476423 5	\$200				FORM_OID
② Laboratory 2 Finding Test Name PID200374 6_V5_0			LAB_TEST_ 1: PID218280 9_V4_0F	LAB_NAME Hemoglobin_XX , 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	

Version 12.00 pushed to PRODUCTION 06.16.2020: All Forms
Form: Marrow Assessment Hematology/Chemistry 5
Generated On: 25 Jun 2020 16:25:32

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
③ Laboratory Procedure Not Performed Text PID220061_6_V1_0	1				TEST_ND_XX
④ Laboratory Test Result Numeric Value PID218336_0_V2_0	10.2				LAB_RS_XX
⑤ Laboratory Test Result Unit of Measure Unified Code for Units of Measure Code PID278794_7_V1_0	2		LAB_UOM_1: g/dL PID201522_4_V3_0F	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 PID200400_4_V3_0	MMM dd yyyy				LAB_DT_XX

Version 12.00 pushed to PRODUCTION 06.16.2020: All Forms
Form: Marrow Assessment Hematology/Chemistry 6
Generated On: 25 Jun 2020 16:25:32

FORM_OID _____ ①

Lab Test _____ ②

Test not done _____ ③

Lab Value _____ ④

Lab Unit _____ ⑤

Value Abnormal? No ⑥
Yes

Date Hematology (Blood) Sample Obtained _____ ⑦

Version 12.00 pushed to PRODUCTION 06.16.2020: All Forms
Form: Marrow Assessment Hematology/Chemistry 6
Generated On: 25 Jun 2020 16:25:32

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
① FORM PID476423 5	\$200				FORM_OID
② Laboratory 2 Finding Test Name PID200374 6_V5_0			LAB_TEST_ 1: PID218280 9_V4_0F	LAB_NAME Hemoglobin_XX , 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	

Version 12.00 pushed to PRODUCTION 06.16.2020: All Forms
Form: Marrow Assessment Hematology/Chemistry 6
Generated On: 25 Jun 2020 16:25:32

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
③ Laboratory Procedure Not Performed Text PID220061_6_V1_0	1				TEST_ND_XX
④ Laboratory Test Result Numeric Value PID218336_0_V2_0	10.2				LAB_RS_XX
⑤ Laboratory Test Result Unit of Measure Unified Code for Units of Measure Code PID278794_7_V1_0	2		LAB_UOM_1: g/dL PID201522_4_V3_0F	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 PID200400_4_V3_0	MMM dd yyyy				LAB_DT_XX

Version 12.00 pushed to PRODUCTION 06.16.2020: All Forms
Form: Marrow Assessment Hematology/Chemistry 7
Generated On: 25 Jun 2020 16:25:32

FORM_OID _____ ①

Lab Test _____ ②

Test not done _____ ③

Lab Value _____ ④

Lab Unit _____ ⑤

Value Abnormal? No ⑥
Yes

Date Hematology (Blood) Sample Obtained _____ ⑦

Version 12.00 pushed to PRODUCTION 06.16.2020: All Forms
Form: Marrow Assessment Hematology/Chemistry 7
Generated On: 25 Jun 2020 16:25:32

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
① FORM PID476423 5	\$200				FORM_OID
② Laboratory 2 Finding Test Name PID200374 6_V5_0			LAB_TEST_ 1: PID218280 9_V4_0F	LAB_NAME Hemoglobin_XX , 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	

Version 12.00 pushed to PRODUCTION 06.16.2020: All Forms
Form: Marrow Assessment Hematology/Chemistry 7
Generated On: 25 Jun 2020 16:25:32

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
③ Laboratory Procedure Not Performed Text PID220061_6_V1_0	1				TEST_ND_XX
④ Laboratory Test Result Numeric Value PID218336_0_V2_0	10.2				LAB_RS_XX
⑤ Laboratory Test Result Unit of Measure Unified Code for Units of Measure Code PID278794_7_V1_0	2		LAB_UOM_1: g/dL PID201522_2: /μL 4_V3_0F 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 PID200400_4_V3_0	MMM dd yyyy				LAB_DT_XX

Version 12.00 pushed to PRODUCTION 06.16.2020: All Forms
Form: Marrow Assessment Hematology/Chemistry 8
Generated On: 25 Jun 2020 16:25:32

FORM_OID _____ ①

Lab Test _____ ②

Test not done _____ ③

Lab Value _____ ④

Lab Unit _____ ⑤

Value Abnormal? No ⑥
Yes

Date Hematology (Blood) Sample Obtained _____ ⑦

Version 12.00 pushed to PRODUCTION 06.16.2020: All Forms
Form: Marrow Assessment Hematology/Chemistry 8
Generated On: 25 Jun 2020 16:25:32

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
① FORM PID476423 5	\$200				FORM_OID
② Laboratory 2 Finding Test Name PID200374 6_V5_0			LAB_TEST_ 1: PID218280 9_V4_0F	LAB_NAME Hemoglobin_XX , 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	

Version 12.00 pushed to PRODUCTION 06.16.2020: All Forms
Form: Marrow Assessment Hematology/Chemistry 8
Generated On: 25 Jun 2020 16:25:32

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
③ Laboratory Procedure Not Performed Text PID220061_6_V1_0	1				TEST_ND_XX
④ Laboratory Test Result Numeric Value PID218336_0_V2_0	10.2				LAB_RS_XX
⑤ Laboratory Test Result Unit of Measure Unified Code for Units of Measure Code PID278794_7_V1_0	2		LAB_UOM_1: g/dL PID201522_2: /μL 4_V3_0F 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 PID200400_4_V3_0	MMM dd yyyy				LAB_DT_XX

Version 12.00 pushed to PRODUCTION 06.16.2020: All Forms
Form: Marrow Assessment Hematology/Chemistry 9
Generated On: 25 Jun 2020 16:25:32

FORM_OID _____ ①

Lab Test _____ ②

Test not done _____ ③

Lab Value _____ ④

Lab Unit _____ ⑤

Value Abnormal? No ⑥
Yes

Date Hematology (Blood) Sample Obtained _____ ⑦

Version 12.00 pushed to PRODUCTION 06.16.2020: All Forms
Form: Marrow Assessment Hematology/Chemistry 9
Generated On: 25 Jun 2020 16:25:32

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
① FORM PID476423 5	\$200				FORM_OID
② Laboratory 2 Finding Test Name PID200374 6_V5_0			LAB_TEST_ 1: PID218280 9_V4_0F	LAB_NAME Hemoglobin _XX , 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	

Version 12.00 pushed to PRODUCTION 06.16.2020: All Forms
Form: Marrow Assessment Hematology/Chemistry 9
Generated On: 25 Jun 2020 16:25:32

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
③ Laboratory Procedure Not Performed Text PID220061_6_V1_0	1				TEST_ND_XX
④ Laboratory Test Result Numeric Value PID218336_0_V2_0	10.2				LAB_RS_XX
⑤ Laboratory Test Result Unit of Measure Unified Code for Units of Measure Code PID278794_7_V1_0	2		LAB_UOM_1: g/dL PID201522_2: /µL 4_V3_0F 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 PID200400_4_V3_0	MMM dd yyyy				LAB_DT_XX

Version 12.00 pushed to PRODUCTION 06.16.2020: All Forms
Form: Marrow Assessment Hematology/Chemistry 10
Generated On: 25 Jun 2020 16:25:32

FORM_OID _____ ①

Lab Test _____ ②

Test not done _____ ③

Lab Value _____ ④

Lab Unit _____ ⑤

Value Abnormal? No ⑥
Yes

Date Hematology (Blood) Sample Obtained _____ ⑦

Version 12.00 pushed to PRODUCTION 06.16.2020: All Forms
Form: Marrow Assessment Hematology/Chemistry 10
Generated On: 25 Jun 2020 16:25:32

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
① FORM PID476423 5	\$200				FORM_OID
② Laboratory 2 Finding Test Name PID200374 6_V5_0			LAB_TEST_ 1: PID218280 9_V4_0F	LAB_NAME Hemoglobin_XX , 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	

Version 12.00 pushed to PRODUCTION 06.16.2020: All Forms
Form: Marrow Assessment Hematology/Chemistry 10
Generated On: 25 Jun 2020 16:25:32

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
③ Laboratory Procedure Not Performed Text PID220061_6_V1_0	1				TEST_ND_XX
④ Laboratory Test Result Numeric Value PID218336_0_V2_0	10.2				LAB_RS_XX
⑤ Laboratory Test Result Unit of Measure Unified Code for Units of Measure Code PID278794_7_V1_0	2		LAB_UOM_1: g/dL PID201522_2: /µL 4_V3_0F 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 PID200400_4_V3_0	MMM dd yyyy				LAB_DT_XX

Version 12.00 pushed to PRODUCTION 06.16.2020: All Forms

Form: Adverse Event Form

Generated On: 25 Jun 2020 16:25:32

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 12.00 pushed to PRODUCTION 06.16.2020: All Forms

Form: Adverse Event Form

Generated On: 25 Jun 2020 16:25:32

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
① FORM PID393237 1	\$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 PID312530 2_V1_1	10		CTCAE_403 _TERM		TOXXX
⑤ Common Terminology Criteria for Adverse Events Version 4.0 Mapped Low Level Term MedDRA Code PID313335 3_V1_0	\$200				MEDRASOC XX

Version 12.00 pushed to PRODUCTION 06.16.2020: All Forms
Form: Adverse Event Form
Generated On: 25 Jun 2020 16:25:32

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
⑥ Adverse Event Severity Grade PID294451 5_V1_0	2				VALXX
⑦ Grade 3 Adverse Event Description Text PID200185 7_V4_0	\$700				VALDESCXX

Version 12.00 pushed to PRODUCTION 06.16.2020: All Forms
Form: Pre-Treatment Hematology/Chemistry
Generated On: 25 Jun 2020 16:25:32

FORM_OID _____ ①

Lab Test _____ ②

Test not done _____ ③

Lab Value _____ ④

Lab Unit _____ ⑤

Value Abnormal? No ⑥
Yes

Date Hematology (Blood) Sample Obtained _____ ⑦

Version 12.00 pushed to PRODUCTION 06.16.2020: All Forms
Form: Pre-Treatment Hematology/Chemistry
Generated On: 25 Jun 2020 16:25:32

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
① FORM PID476423 5	\$200				FORM_OID
② Laboratory 2 Finding Test Name PID200374 6_V5_0			LAB_TEST_ 1: PID218280 9_V4_0F	LAB_NAME Hemoglobin _XX , 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	

Version 12.00 pushed to PRODUCTION 06.16.2020: All Forms
Form: Pre-Treatment Hematology/Chemistry
Generated On: 25 Jun 2020 16:25:32

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
③ Laboratory Procedure Not Performed Text PID220061_6_V1_0	1				TEST_ND_XX
④ Laboratory Test Result Numeric Value PID218336_0_V2_0	10.2				LAB_RS_XX
⑤ Laboratory Test Result Unit of Measure Unified Code for Units of Measure Code PID278794_7_V1_0	2		LAB_UOM_ 1: g/dL PID201522 2: /µL 4_V3_0F 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 PID200400_4_V3_0	MMM dd yyyy				LAB_DT_XX

FORM_OID _____

①

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

Started ②

Stopped

Both stopped and started

Neither

Version 12.00 pushed to PRODUCTION 06.16.2020: All Forms
 Form: Therapy Yes/No
 Generated On: 25 Jun 2020 16:25:32

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

Version 12.00 pushed to PRODUCTION 06.16.2020: All Forms
Form: MDS Disease Modifying Therapy/Hematologic Therapy
Generated On: 25 Jun 2020 16:25:32

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?

No ③
Yes

Regimen start date _____ ④

Agent _____ ⑤

Agent dose (initial) _____ ⑥

Agent unit (initial)

mg ⑦
mg/m²
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)

mg ⑪

mg/m²
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/m²
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

Version 12.00 pushed to PRODUCTION 06.16.2020: All Forms
Form: MDS Disease Modifying Therapy/Hematologic Therapy
Generated On: 25 Jun 2020 16:25:32

Other, specify

Total number of cycles delivered

20

Version 12.00 pushed to PRODUCTION 06.16.2020: All Forms
Form: MDS Disease Modifying Therapy/Hematologic Therapy
Generated On: 25 Jun 2020 16:25:32

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_DO SE_INIT	7.2				AGENT_DO SE_INIT
⑦ AGENT_UNI T_INIT	1		1 = mg 2 = mg/m ² 3 = mg/kg		AGENT_UNI T_INIT
⑧ CYCLE_LEN GTH_INIT	3				CYCLE_LEN GTH_INIT
⑨ DOSE_DAY S_INIT	3				DOSE_DAY S_INIT
⑩ AGENT_DO SE_6MO	7.2				AGENT_DO SE_6MO
⑪ AGENT_UNI T_6MO	1		1 = mg 2 = mg/m ²		AGENT_UNI T_6MO

Version 12.00 pushed to PRODUCTION 06.16.2020: All Forms
Form: MDS Disease Modifying Therapy/Hematologic Therapy
Generated On: 25 Jun 2020 16:25:32

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
3 = mg/kg					
12 CYCLE_LEN GTH_6MO	3				CYCLE_LEN GTH_6MO
13 DOSE_DAY S_6MO	3				DOSE_DAY S_6MO
14 AGENT_DO SE_12MO	7.2				AGENT_DO SE_12MO
15 AGENT_UNI T_12MO	1		1 = mg 2 = mg/m ² 3 = mg/kg		AGENT_UNI T_12MO
16 CYCLE_LEN GTH_12MO	3				CYCLE_LEN GTH_12MO
17 DOSE_DAY S_12MO	3				DOSE_DAY S_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

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Form: MDS Disease Modifying Therapy/Hematologic Therapy
Generated On: 25 Jun 2020 16:25:32

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_CYCL ES	3				NUM_CYCL ES

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 12.00 pushed to PRODUCTION 06.16.2020: All Forms
Form: Concomitant Medication Yes/No
Generated On: 25 Jun 2020 16:25:32

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

Version 12.00 pushed to PRODUCTION 06.16.2020: All Forms
Form: Hematologic Response
Generated On: 25 Jun 2020 16:25:32

FORM_OID _____ ①

Did the patient have a hematologic response to this treatment regimen? No ②
Yes

Lab Test _____ ③

Test not done _____ ④

Lab Value _____ ⑤

Lab Unit _____ ⑥

Value Abnormal? No ⑦
Yes

Date Hematology (Blood) Sample Obtained _____ ⑧

Version 12.00 pushed to PRODUCTION 06.16.2020: All Forms
Form: Hematologic Response
Generated On: 25 Jun 2020 16:25:32

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
① FORM PID476423 5	\$200				FORM_OID
② HEM_RESP_1 YN			1 = No 2 = Yes		HEM_RESP_YN
③ Laboratory 2 Finding Test Name PID200374 6_V5_0			LAB_TEST_ 1: PID218280 9_V4_0F	LAB_NAME Hemoglobin_XX , 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	

Version 12.00 pushed to PRODUCTION 06.16.2020: All Forms
Form: Hematologic Response
Generated On: 25 Jun 2020 16:25:32

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
				10: Blasts, %, Blood	
④ Laboratory Procedure Not Performed Text PID220061 6_V1_0	1				TEST_ND_X X
⑤ Laboratory Test Result Numeric Value PID218336 0_V2_0	10.2				LAB_RS_XX
⑥ Laboratory Test Result Unit of Measure Unified Code for Units of Measure Code PID278794 7_V1_0	2		LAB_UOM_ PID201522 4_V3_OF	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

Version 12.00 pushed to PRODUCTION 06.16.2020: All Forms
Form: Hematologic Response
Generated On: 25 Jun 2020 16:25:32

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
⑧ Sample Collection Date PID200400 4_V3_0	MMM dd yyyy				LAB_DT_XX

FORM_OID _____

①

Was VES-13 Frailty completed?

No, assessment was not required at this time point ②
No, assessment was required
Yes

Was QUALMS completed?

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

Was FACT-G completed?

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

Was EQ-5D-5L completed?

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

Was PROMIS Short form fatigue 7a completed?

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

Version 12.00 pushed to PRODUCTION 06.16.2020: All Forms
Form: Baseline Quality of Life Completed Yes/No
Generated On: 25 Jun 2020 16:25:32

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 PID220051 5_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 PID220051 5_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 PID220051 5_V1_0_3	1		1 = No, assessment was not required at this time point		QOL_COMP_3_YN

Version 12.00 pushed to PRODUCTION 06.16.2020: All Forms
Form: Baseline Quality of Life Completed Yes/No
Generated On: 25 Jun 2020 16:25:32

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 PID220051 5_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 PID220051 5_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

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

Version 12.00 pushed to PRODUCTION 06.16.2020: All Forms
Form: Quality of Life Completed Yes/No
Generated On: 25 Jun 2020 16:25:32

Yes

Version 12.00 pushed to PRODUCTION 06.16.2020: All Forms

Form: Quality of Life Completed Yes/No

Generated On: 25 Jun 2020 16:25:32

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 PID220051 5_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 PID220051 5_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 PID220051 5_V1_0_3	1		1 = No, assessment was not required at this time point		QOL_COMP_3_YN

Version 12.00 pushed to PRODUCTION 06.16.2020: All Forms

Form: Quality of Life Completed Yes/No

Generated On: 25 Jun 2020 16:25:32

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

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)

Version 12.00 pushed to PRODUCTION 06.16.2020: All Forms

Form: QOL Completed

Generated On: 25 Jun 2020 16:25:32

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
① FORM_OID	\$200				FORM_OID
③ IN_CLINIC_1 YN			1 = No 2 = Yes		IN_CLINIC_1 YN
④ AT_HOME_1 YN			1 = No 2 = Yes		AT_HOME_1 YN
⑤ COMPL_ME THOD	2		1 = Completed at home and returned through the mail 2 = Completed via a telephone interview 3 = Completed via videoconference 88 = Other		COMPL_ME THOD
⑦ Was Assessment self-administered PID200376_0_V4_0	1		1 = No 2 = Yes		ASSMNT_S ELF_ADMN

Version 12.00 pushed to PRODUCTION 06.16.2020: All Forms

Form: QOL Completed

Generated On: 25 Jun 2020 16:25:32

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_AL OUD
10 Did the patient require clarification of questions or instructions PID242625_7_V1_0	1		1 = No 2 = Yes		PT_REQ_CL RF
11 Did the patient require other assistance PID242625_9_V1_0	1		1 = No 2 = Yes		PT_REQ_OT H_ASSIST
12 Were the forms completed independently by another person PID242626_2_V1_0	1		1 = No 2 = Yes		FORM_COM PL_OTHER_ PRSN

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Form: QOL Completed
Generated On: 25 Jun 2020 16:25:32

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) PID242626 4_V1_0	1		1 = No 2 = Yes (specify)		LANG_DIFF ICULTY
15 Did the patient have a literacy difficulty (patient could not read well enough) PID242626 8_V1_0	1		1 = No 2 = Yes		LITER_DIFF ICULTY
16 Was the patient disabled PID242627 0_V1_0	1		1 = No 2 = Yes (specify)		PT_DISABL ED

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Form: QOL Completed
Generated On: 25 Jun 2020 16:25:32

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
17 Were the forms completed via a telephone interview PID242627 4_V1_0	1		1 = No 2 = Yes		FORM_COM PL_PHONE
18 Other PID242627 6_V1_0	1		1 = No 2 = Yes (specify)		OTHER_RE AS
20 Staff PID242628 0_V1_0	1		1 = No 2 = Yes		STAFF_ASS IST
21 Family PID242628 2_V1_0	1		1 = No 2 = Yes		FAMILY_AS SIST
22 Friend PID242628 4_V1_0	1		1 = No 2 = Yes		FRIEND_AS SIST
23 Other PID242689 6_V1_0	1		1 = No 2 = Yes (specify)		OTHER_AS SIST

Version 12.00 pushed to PRODUCTION 06.16.2020: All Forms
Form: QOL Not Completed Reason
Generated On: 25 Jun 2020 16:25:32

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

Version 12.00 pushed to PRODUCTION 06.16.2020: All Forms
Form: QOL Not Completed Reason
Generated On: 25 Jun 2020 16:25:32

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
① FORM_OID	\$200				FORM_OID
② Assessment Date	MMM dd yyyy		PID200732 1_V1_0		QOL_ASSM NT_DT
④ Patient Refusal	1		PID242612 0_V1_0		PT_REFUSE _YN
⑤ Unable to accommodate disability or language needs	1		PID242612 7		UNABLE_AC CM_DIS_LA NG
⑥ UNABLE_AC	\$200		CM_DIS_LA NG2_SPECI FY		UNABLE_AC CM_DIS_LA NG2_SPECI FY
⑦ Patient did not show up in clinic/office	1		PID242613 5_V1_0		PT_NO_SHOW

Version 12.00 pushed to PRODUCTION 06.16.2020: All Forms
Form: QOL Not Completed Reason
Generated On: 25 Jun 2020 16:25:32

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
8	PT_NO_SH OW2_SPECI FY	\$200				PT_NO_SH OW2_SPECI FY
9	Staff unavailable PID242614 1_V1_0	1				STAFF_UNA VAIL
10	Patient not given form by staff PID242614 9_V1_0	1				PT_NOT_G VN_FORM
11	Patient too ill PID242615 1_V1_0	1				PT_TOO_IL L
12	Patient expried PID242615 3_V1_0	1				PT_EXPRD
13	Staff thought patient too ill PID242622 2_V1_0	1				STAFF_THG HT_PT_TO O_ILL

Version 12.00 pushed to PRODUCTION 06.16.2020: All Forms
Form: QOL Not Completed Reason
Generated On: 25 Jun 2020 16:25:32

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
Other PID242622 4_V1_0		1			OTHER_RE AS2
OTHER_RE AS2_SPECI FY	\$200				OTHER_RE AS2_SPECI FY

Version 12.00 pushed to PRODUCTION 06.16.2020: All Forms
Form: VES-13 Frailty Patient Responses
Generated On: 25 Jun 2020 16:25:32

FORM_OID _____ ①

Age _____ ②

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

Poor ③
Fair
Good
Very good
Excellent

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

Stooping, crouching or kneeling? No Difficulty ⑤
A little Difficulty
Some Difficulty
A Lot of Difficulty
Unable to do

Lifting, or carrying objects as heavy as 10 pounds? No Difficulty ⑥
A little Difficulty
Some Difficulty
A Lot of Difficulty
Unable to do

Reaching or extending arms above shoulder level? No Difficulty ⑦
A little Difficulty
Some Difficulty
A Lot of Difficulty
Unable to do

Writing, or handling and grasping small objects? No Difficulty 8
A little Difficulty
Some Difficulty
A Lot of Difficulty
Unable to do

Walking a quarter of a mile? No Difficulty 9
A little Difficulty
Some Difficulty
A Lot of Difficulty
Unable to do

Heavy housework such as scrubbing floors or washing windows? No Difficulty 10
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)? Yes 12
No
Don't do

Do you get help shopping? No 13
Yes

Is that because of your health? No 14
Yes

Version 12.00 pushed to PRODUCTION 06.16.2020: All Forms
Form: VES-13 Frailty Patient Responses
Generated On: 25 Jun 2020 16:25:32

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

Version 12.00 pushed to PRODUCTION 06.16.2020: All Forms
Form: VES-13 Frailty Patient Responses
Generated On: 25 Jun 2020 16:25:32

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
① FORM_OID	\$200				FORM_OID
② AGE	3				AGE
③ HEALTH_C OMP_AGE	1		1 = Poor 2 = Fair 3 = Good 4 = Very good 5 = Excellent		HEALTH_C OMP_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_CARR Y	1		1 = No Difficulty 2 = A little Difficulty 3 = Some Difficulty 4 = A Lot of Difficulty 5 = Unable to do		LIFT_CARR Y

Version 12.00 pushed to PRODUCTION 06.16.2020: All Forms
Form: VES-13 Frailty Patient Responses
Generated On: 25 Jun 2020 16:25:32

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
7 REACH_EXT END			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

Version 12.00 pushed to PRODUCTION 06.16.2020: All Forms
Form: VES-13 Frailty Patient Responses
Generated On: 25 Jun 2020 16:25:32

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_MON_EY	1		1 = No 2 = Yes		HELP_MON_EY
17 DONT_MON_EY_HLTH	1		1 = No 2 = Yes		DONT_MON_EY_HLTH

Version 12.00 pushed to PRODUCTION 06.16.2020: All Forms
Form: VES-13 Frailty Patient Responses
Generated On: 25 Jun 2020 16:25:32

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
18 WALK_ROO M	1		2 = Yes 1 = No 3 = Don't do		WALK_ROO M
19 HELP_WAL K_ROOM	1		1 = No 2 = Yes		HELP_WAL K_ROOM
20 DONT_WAL K_HLTH	1		1 = No 2 = Yes		DONT_WAL K_HLTH
21 LGHT_HSW RK	1		2 = Yes 1 = No 3 = Don't do		LGHT_HSW RK
22 HELP_LGHT _HSWRK_H TLH	1		1 = No 2 = Yes		HELP_LGHT _HSWRK_H TLH
23 DONT_LGH T_HSWRK	1		1 = No 2 = Yes		DONT_LGH T_HSWRK
24 BATH_SHW R	1		2 = Yes 1 = No 3 = Don't do		BATH_SHW R
25 HELP_BATH _SHWR	1		1 = No 2 = Yes		HELP_BATH _SHWR

Version 12.00 pushed to PRODUCTION 06.16.2020: All Forms
Form: VES-13 Frailty Patient Responses
Generated On: 25 Jun 2020 16:25:32

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
26 DONT_BAT 1 H_SHWR_H TLH			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?

Never ③
Rarely
Sometimes
Often
Always

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

Never ④
Rarely
Sometimes
Often
Always

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

Never ⑤
Rarely
Sometimes
Often
Always

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

Never ⑥
Rarely
Sometimes
Often
Always

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

Never ⑦

- 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? Never 17
Rarely
Sometimes
Often
Always

16. Were you worried about bleeding? Never 18
Rarely
Sometimes
Often
Always

17. Did you feel a sense of gratitude for a part of life that you took for granted before? Never 19
Rarely
Sometimes
Often
Always

18. Did you feel nauseated? Never 20
Rarely
Sometimes
Often
Always

19. Did you worry about your MDS progressing or developing into leukemia? Never 21
Rarely
Sometimes
Often
Always

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

- Never 22
Rarely
Sometimes
Often
Always
-

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

- Never 23
Rarely
Sometimes
Often
Always
-

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

- Never 24
Rarely
Sometimes
Often
Always
-

23. Have you felt weak?

- Never 25
Rarely
Sometimes
Often
Always
-

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

- Never 26
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?

- Never 32
Rarely
Sometimes
Often
Always
-

31. Were you concerned about bruising?

- Never 33
Rarely
Sometimes
Often
Always
-

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

- Never 34
Rarely
Sometimes
Often
Always
-

33. Did you experience a change in bowel habits?

- Never 35
Rarely
Sometimes
Often
Always
-

34. Were you afraid of losing your job?

- Never 36
Rarely
Sometimes
Often
Always
Not applicable
-

35. Did you feel too tired to drive?

- Never 37
Rarely
Sometimes
Often
Always
Not applicable
-

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

- Never 38
Rarely
Sometimes
Often
Always
Not applicable
-

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

- Never 39
Rarely
Sometimes
Often
Always
Not applicable
-

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

- Never 40
Rarely
Sometimes
Often
Always
Not applicable
-

Version 12.00 pushed to PRODUCTION 06.16.2020: All Forms
Form: QUALMS Patient Responses
Generated On: 25 Jun 2020 16:25:32

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_UNPRE_DICT	1		1 = Never 2 = Rarely 3 = Sometimes 4 = Often 5 = Always		DZ_UNPRE_DICT
⑦ DIFF_EXPLAIN	1		1 = Never 2 = Rarely 3 = Sometimes		DIFF_EXPLAIN

Version 12.00 pushed to PRODUCTION 06.16.2020: All Forms
Form: QUALMS Patient Responses
Generated On: 25 Jun 2020 16:25:32

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			4 = Often 5 = Always		
8 TRBLE_CON1 CEN			1 = Never 2 = Rarely 3 = Sometimes 4 = Often 5 = Always		TRBLE_CON CEN
9 CHNG_PLA 1 NS			1 = Never 2 = Rarely 3 = Sometimes 4 = Often 5 = Always		CHNG_PLA NS
10 SHRT_BRT 1 H			1 = Never 2 = Rarely 3 = Sometimes 4 = Often 5 = Always		SHRT_BRT H
11 CHNG_SCH 1 ED			1 = Never 2 = Rarely 3 = Sometimes 4 = Often 5 = Always		CHNG_SCH ED
12 ORG_MED_ 1 APPTS			1 = Never 2 = Rarely		ORG_MED_ APPTS

Version 12.00 pushed to PRODUCTION 06.16.2020: All Forms
 Form: QUALMS Patient Responses
 Generated On: 25 Jun 2020 16:25:32

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

Version 12.00 pushed to PRODUCTION 06.16.2020: All Forms
Form: QUALMS Patient Responses
Generated On: 25 Jun 2020 16:25:32

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_BL EED	1		1 = Never 2 = Rarely 3 = Sometimes 4 = Often 5 = Always		WORRY_BLEED
19 SENSE_GRA T	1		1 = Never 2 = Rarely 3 = Sometimes 4 = Often 5 = Always		SENSE_GRA T
20 FEEL_NAUS EATED	1		1 = Never 2 = Rarely 3 = Sometimes 4 = Often 5 = Always		FEEL_NAUS EATED
21 WORRY_PR OGRESS	1		1 = Never 2 = Rarely 3 = Sometimes 4 = Often 5 = Always		WORRY_PR OGRESS

Version 12.00 pushed to PRODUCTION 06.16.2020: All Forms
Form: QUALMS Patient Responses
Generated On: 25 Jun 2020 16:25:32

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
22 TAKE_ACCN1 T_FATIGUE			1 = Never 2 = Rarely 3 = Sometimes 4 = Often 5 = Always		TAKE_ACCN T_FATIGUE
23 CNCRN_FIN1 ANCE			1 = Never 2 = Rarely 3 = Sometimes 4 = Often 5 = Always		CNCRN_FIN ANCE
24 RELATIONS1 HIP_STRND			1 = Never 2 = Rarely 3 = Sometimes 4 = Often 5 = Always		RELATIONS HIP_STRND
25 FELT_WEEK1			1 = Never 2 = Rarely 3 = Sometimes 4 = Often 5 = Always		FELT_WEEK
26 TOO_TIRED1 _RESPNSB			1 = Never 2 = Rarely 3 = Sometimes 4 = Often 5 = Always		TOO_TIRED _RESPNSB

Version 12.00 pushed to PRODUCTION 06.16.2020: All Forms
Form: QUALMS Patient Responses
Generated On: 25 Jun 2020 16:25:32

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
27 BCME_BUR 1 DEN			1 = Never 2 = Rarely 3 = Sometimes 4 = Often 5 = Always		BCME_BUR DEN
28 UNABLE_PA 1 RTIC			1 = Never 2 = Rarely 3 = Sometimes 4 = Often 5 = Always		UNABLE_PA RTIC
29 ANXS_TST_1 RSLTS			1 = Never 2 = Rarely 3 = Sometimes 4 = Often 5 = Always		ANXS_TST_ RSLTS
30 AVOID_CR 1 OWDS			1 = Never 2 = Rarely 3 = Sometimes 4 = Often 5 = Always		AVOID_CR OWDS
31 GRTFUL_TM1 RRW			1 = Never 2 = Rarely 3 = Sometimes 4 = Often 5 = Always		GRTFUL_TM RRW

Version 12.00 pushed to PRODUCTION 06.16.2020: All Forms
Form: QUALMS Patient Responses
Generated On: 25 Jun 2020 16:25:32

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
37 QUALITY_I NFO	1		1 = Never 2 = Rarely 3 = Sometimes 4 = Often 5 = Always		QUALITY_I NFO
33 CNCRN_BR UISING	1		1 = Never 2 = Rarely 3 = Sometimes 4 = Often 5 = Always		CNCRN_BR UISING
34 LACK_ANS WERS	1		1 = Never 2 = Rarely 3 = Sometimes 4 = Often 5 = Always		LACK_ANS WERS
35 CHANGE_B OWEL	1		1 = Never 2 = Rarely 3 = Sometimes 4 = Often 5 = Always		CHANGE_B OWEL
36 AFRD_LOSE _JOB	2		1 = Never 2 = Rarely 3 = Sometimes 4 = Often 5 = Always		AFRD_LOSE _JOB

Version 12.00 pushed to PRODUCTION 06.16.2020: All Forms
 Form: QUALMS Patient Responses
 Generated On: 25 Jun 2020 16:25:32

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			99 = Not applicable		
37 TOO_TIRED2 _DRIVE			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_S2 TOPWRK			1 = Never 2 = Rarely 3 = Sometimes 4 = Often 5 = Always 99 = Not applicable		AFRD_TX_S TOPWRK
40 TOO_TIRED2 _TK_CARE			1 = Never 2 = Rarely 3 = Sometimes		TOO_TIRED _TK_CARE

Version 12.00 pushed to PRODUCTION 06.16.2020: All Forms
Form: QUALMS Patient Responses
Generated On: 25 Jun 2020 16:25:32

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

Version 12.00 pushed to PRODUCTION 06.16.2020: All Forms
Form: FACT-G Physical Well-Being Patient Responses
Generated On: 25 Jun 2020 16:25:32

FORM_OID _____ **1**

Form instructions:

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Assessment date _____ **3**

I have a lack of energy

0 **4**
1
2
3
4

I have nausea

0 **5**
1
2
3
4

Because of my physical condition, I have trouble meeting
the needs of my family

0 **6**
1
2
3
4

I have pain

0 **7**
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

Version 12.00 pushed to PRODUCTION 06.16.2020: All Forms
Form: FACT-G Physical Well-Being Patient Responses
Generated On: 25 Jun 2020 16:25:32

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
① FORM_OID	\$200				FORM_OID
③ Assessment Date	MMM dd YYYY				QOL_ASSM NT_DT
	PID200732 1_V1_0				
④ FACT-G Questionnaire Past Seven Days Lack Energy How True	1		0 = 0 1 = 1 2 = 2 3 = 3 4 = 4		LACK_ENERGY
	Score_5 Point Scale PID314430 7_V2_0				
⑤ FACT-G Questionnaire Past Seven Days Have Nausea How True	1		0 = 0 1 = 1 2 = 2 3 = 3 4 = 4		NAUSEA
	Score_5 Point Scale PID314430 9_V2_0				

Version 12.00 pushed to PRODUCTION 06.16.2020: All Forms
Form: FACT-G Physical Well-Being Patient Responses
Generated On: 25 Jun 2020 16:25:32

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 PID314429 5_V2_0	1		0 = 0 1 = 1 2 = 2 3 = 3 4 = 4		FAM_NEED S
⑦ FACT-G Questionnaire Past Seven Days Have Pain How True Score_5 Point Scale PID314431 1_V2_0	1		0 = 0 1 = 1 2 = 2 3 = 3 4 = 4		PAIN

Version 12.00 pushed to PRODUCTION 06.16.2020: All Forms
Form: FACT-G Physical Well-Being Patient Responses
Generated On: 25 Jun 2020 16:25:32

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 PID314429 6_V2_0	1		0 = 0 1 = 1 2 = 2 3 = 3 4 = 4		SIDE_EFFE CTS
9 FACT-G Questionnaire Past Seven Days Feel Ill How True Score_5 Point Scale PID314430 6_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 PID314430 4_V2_0	1		0 = 0 1 = 1 2 = 2 3 = 3 4 = 4		TIME_BED

Version 12.00 pushed to PRODUCTION 06.16.2020: All Forms
Form: FACT-G Social Well-Being Patient Responses
Generated On: 25 Jun 2020 16:25:32

FORM_OID _____ **1**

Form instructions:

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Assessment date _____ **3**

I feel close to my friends

0 **4**
1
2
3
4

I get emotional support from my family

0 **5**
1
2
3
4

I get support from my friends

0 **6**
1
2
3
4

My family has accepted my illness

0 **7**
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

Version 12.00 pushed to PRODUCTION 06.16.2020: All Forms
Form: FACT-G Social Well-Being Patient Responses
Generated On: 25 Jun 2020 16:25:32

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
① FORM_OID	\$200				FORM_OID
③ Assessment Date	MMM dd YYYY				QOL_ASSM NT_DT
PID200732 1_V1_0					
④ FACT-G Questionnaire Past Seven Days Feel Close to Friends How True Score_5 Point Scale	1		0 = 0 1 = 1 2 = 2 3 = 3 4 = 4		CLOSE_FRI ENDS
PID314429 7					
⑤ FACT-G Questionnaire Past Seven Days Emotional Support From Family How True Score_5 Point Scale	1		0 = 0 1 = 1 2 = 2 3 = 3 4 = 4		EMOT_SPPR T_FAM
PID314429 9_V2_0					


Version 12.00 pushed to PRODUCTION 06.16.2020: All Forms
Form: FACT-G Social Well-Being Patient Responses
Generated On: 25 Jun 2020 16:25:32

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 PID314431 8_V2_0	1		0 = 0 1 = 1 2 = 2 3 = 3 4 = 4		SPPRT_FRN DS
⑦ FACT-G Questionnaire Past Seven Days Family Accepts Illness How True Score_5 Point Scale PID314430 2_V2_0	1		0 = 0 1 = 1 2 = 2 3 = 3 4 = 4		FAM_ACCEP T_ILLNESS

Version 12.00 pushed to PRODUCTION 06.16.2020: All Forms
Form: FACT-G Social Well-Being Patient Responses
Generated On: 25 Jun 2020 16:25:32

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 PID314430 3_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 PID314431 2_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 PID364590 9_V1_0	1				REFUSE_SEX_LIFE

Version 12.00 pushed to PRODUCTION 06.16.2020: All Forms
Form: FACT-G Social Well-Being Patient Responses
Generated On: 25 Jun 2020 16:25:32

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
 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

Version 12.00 pushed to PRODUCTION 06.16.2020: All Forms
Form: FACT-G Emotional Well-Being Patient Responses
Generated On: 25 Jun 2020 16:25:32

FORM_OID _____ **1**

Form instructions:

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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

Version 12.00 pushed to PRODUCTION 06.16.2020: All Forms
Form: FACT-G Emotional Well-Being Patient Responses
Generated On: 25 Jun 2020 16:25:32

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
① FORM_OID	\$200				FORM_OID
③ Assessment Date	MMM dd YYYY				QOL_ASSM NT_DT
PID200732 1_V1_0					
④ FACT-G Questionnaire Past Seven Days Feel Sad How True Score_5 Point Scale	1		0 = 0 1 = 1 2 = 2 3 = 3 4 = 4		FEEL_SAD
PID314431 4_V2_0					
⑤ FACT-G Questionnaire Past Seven Days Satisfied with Coping with Illness How True Score_5 Point Scale	1		0 = 0 1 = 1 2 = 2 3 = 3 4 = 4		SATIS_COP ING
PID314431 5_V2_0					

Version 12.00 pushed to PRODUCTION 06.16.2020: All Forms
Form: FACT-G Emotional Well-Being Patient Responses
Generated On: 25 Jun 2020 16:25:32

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 PID314431 0_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 PID314432 1_V2_0	1		0 = 0 1 = 1 2 = 2 3 = 3 4 = 4		WORRY_DYING

Version 12.00 pushed to PRODUCTION 06.16.2020: All Forms
Form: FACT-G Emotional Well-Being Patient Responses
Generated On: 25 Jun 2020 16:25:32

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 PID314432 0_V2_0	1		0 = 0 1 = 1 2 = 2 3 = 3 4 = 4		WORRY_WORSE

Version 12.00 pushed to PRODUCTION 06.16.2020: All Forms
Form: FACT-G Functional Well-Being Patient Responses
Generated On: 25 Jun 2020 16:25:32

FORM_OID _____ **1**

Form instructions:

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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

Version 12.00 pushed to PRODUCTION 06.16.2020: All Forms
Form: FACT-G Functional Well-Being Patient Responses
Generated On: 25 Jun 2020 16:25:32

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
① FORM_OID	\$200				FORM_OID
③ Assessment Date	MMM dd YYYY				QOL_ASSM NT_DT
PID200732 1_V1_0					
④ FACT-G Questionnaire Past Seven Days Able to Work How True	1		0 = 0 1 = 1 2 = 2 3 = 3 4 = 4		ABLE_WOR K
Score_5 Point Scale PID314429 3_V2_0					
⑤ FACT-G Questionnaire Past Seven Days Work is Fulfilling How True	1		0 = 0 1 = 1 2 = 2 3 = 3 4 = 4		WORK_FUL FILL
Score_5 Point Scale PID314431 9_V2_0					

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Form: FACT-G Functional Well-Being Patient Responses
Generated On: 25 Jun 2020 16:25:32

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 PID314430 0_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 PID314429 4_V2_0	1		0 = 0 1 = 1 2 = 2 3 = 3 4 = 4		ACCEPT_IL LNESS
⑧ FACT-G Questionnaire Past Seven Days Sleeping Well How True Score_5 Point Scale PID314431 7_V2_0	1		0 = 0 1 = 1 2 = 2 3 = 3 4 = 4		SLEEP_WEL L

Version 12.00 pushed to PRODUCTION 06.16.2020: All Forms
 Form: FACT-G Functional Well-Being Patient Responses
 Generated On: 25 Jun 2020 16:25:32

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 PID314430 1_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 PID314429 8_V2_0	1		0 = 0 1 = 1 2 = 2 3 = 3 4 = 4		CONTENT_QOL

Version 12.00 pushed to PRODUCTION 06.16.2020: All Forms
Form: EQ-5D-5L Health Questionnaire Patient Responses
Generated On: 25 Jun 2020 16:25:32

FORM_OID _____

①

Form instructions:

This form is for data capture and entry purposes only. Patients should not enter responses in Medidata Rave. Rave CRAs must abstract the information from paper versions and enter it into Rave. The paper versions of the QOL forms for patient completion are available on the ECOG/CTSU websites.

Assessment date _____

③

MOBILITY

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

④

SELF-CARE

- I have no problems washing or dressing myself
- 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

⑤

USUAL ACTIVITIES

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

⑥

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

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Form: EQ-5D-5L Health Questionnaire Patient Responses
Generated On: 25 Jun 2020 16:25:32

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
① FORM_OID	\$200				FORM_OID
③ Assessment Date	MMM dd yyyy				QOL_ASSM NT_DT
	PID200732 1_V1_0				
④ EQ5D5L_M	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_M OB_SCL
	OB_SCL_PI D3540318_ V1				
⑤ EQ5D5L_SL	1		1 = I have no problems washing or dressing myself		EQ5D5L_SL FCR_SCL
	FCR_SCL_P ID3540322_ _V1				

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 Form: EQ-5D-5L Health Questionnaire Patient Responses
 Generated On: 25 Jun 2020 16:25:32

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_AC1 TV_SCL_PI D3540323_ V1			1 = I have no problems doing my usual activities 2 = I have slight problems doing my usual activities		EQ5D5L_AC TV_SCL

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 Form: EQ-5D-5L Health Questionnaire Patient Responses
 Generated On: 25 Jun 2020 16:25:32

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_S CL_PID354 0325_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_PN1_DSCMF_S CL

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Form: EQ-5D-5L Health Questionnaire Patient Responses
Generated On: 25 Jun 2020 16:25:32

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
8 EQ5D5L_AN1 X_DPRS_SC L_PID3540 326_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_AN X_DPRS_SC L
9 EQ5D5L_HE3 ALTH_SCL_ PID356333 0_V1					HEALTH_SC ALE

FORM_OID _____

①

In the past 7 days...

How often did you feel tired?

- Never ③
Rarely
Sometimes
Often
Always
-

How often did you experience extreme exhaustion?

- Never ④
Rarely
Sometimes
Often
Always
-

How often did you run out of energy?

- Never ⑤
Rarely
Sometimes
Often
Always
-

How often did your fatigue limit you at work (include work at home)?

- Never ⑥
Rarely
Sometimes
Often
Always
-

How often were you too tired to think clearly?

- Never ⑦
-

- Rarely
 - Sometimes
 - Often
 - Always
-

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

- Never 8
 - Rarely
 - Sometimes
 - Often
 - Always
-

How often did you have enough energy to exercise strenuously?

- Never 9
 - Rarely
 - Sometimes
 - Often
 - Always
-

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Form: PROMIS Fatigue Short Form 7a Patient Responses
Generated On: 25 Jun 2020 16:25:32

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
① FORM_OID	\$	200			FORM_OID
③ FEEL_TIRE D	1		1 = Never 2 = Rarely 3 = Sometimes 4 = Often 5 = Always		FEEL_TIRE D
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_WOR K	1		1 = Never 2 = Rarely 3 = Sometimes 4 = Often 5 = Always		LIMIT_WOR K
⑦ THINK_CLE AR	1		1 = Never 2 = Rarely 3 = Sometimes		THINK_CLE AR

Version 12.00 pushed to PRODUCTION 06.16.2020: All Forms
 Form: PROMIS Fatigue Short Form 7a Patient Responses
 Generated On: 25 Jun 2020 16:25:32

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			4 = Often 5 = Always		
8 TIREDBAT1	H		1 = Never 2 = Rarely 3 = Sometimes 4 = Often 5 = Always		TIREDBAT H
9 EXERSTRE1	N		1 = Never 2 = Rarely 3 = Sometimes 4 = Often 5 = Always		EXERSTRE N

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Form: Transplant Evaluation Form
Generated On: 25 Jun 2020 16:25:32

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.

-
- Yes, the patient is clinically HCT eligible (continue to question 2) ③
- 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

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Form: Transplant Evaluation Form
Generated On: 25 Jun 2020 16:25:32

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

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Form: Transplant Evaluation Form
Generated On: 25 Jun 2020 16:25:32

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

Version 12.00 pushed to PRODUCTION 06.16.2020: All Forms
Form: Transplant Evaluation Form
Generated On: 25 Jun 2020 16:25:32

If "other" was checked, please explain _____



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Form: Transplant Evaluation Form
Generated On: 25 Jun 2020 16:25:32

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
① FORM_OID	\$	200			FORM_OID
③ CLIN_HCT_1 ELIG			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_1 ELIG
⑤ OLD_AGE1_1 CB					OLD_AGE1_1 CB
⑥ HIGH_BR_C1 MB1_CB					HIGH_BR_C1 MB1_CB
⑦ POOR_ECO 1 G_PS1_CB					POOR_ECO G_PS1_CB
⑧ OVRL_FRAI 1 L1_CB					OVRL_FRAI L1_CB

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Form: Transplant Evaluation Form
Generated On: 25 Jun 2020 16:25:32

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_E VAL	1		2 = Yes, patient was referred for HCT evaluation and HCT was recommend ed 3 = Yes, patient was referred for HCT evaluation however, HCT was not recommend ed 1 = No		REF_HCT_E VAL
13 OLD_AGE2_1 CB					OLD_AGE2_ CB
14 HIGH_BR_C1 MB2_CB					HIGH_BR_C MB2_CB
15 POOR_ECO G_PS2_CB	1				POOR_ECO G_PS2_CB

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Form: Transplant Evaluation Form
Generated On: 25 Jun 2020 16:25:32

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
16 OVRL_FRAI L2_CB					OVRL_FRAI L2_CB
17 PT_PREF1_ CB					PT_PREF1_ CB
18 INSURANCE1 1_CB					INSURANCE 1_CB
19 CG_ABS1_C1 B					CG_ABS1_C B
20 LOWRISK_ DZ1_CB					LOWRISK_ DZ1_CB
21 LR_HR_DZ11 _CB					LR_HR_DZ1 _CB
22 NO_DONOR1 1_CB					NO_DONOR 1_CB
23 OTH2_CB	1				OTH2_CB
24 OTH2_EXP	\$1999				OTH2_EXP
26 PT_PREF2_ CB					PT_PREF2_ CB

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Form: Transplant Evaluation Form
Generated On: 25 Jun 2020 16:25:32

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
27 INSURANCE1 2_CB					INSURANCE 2_CB
28 CG_ABS2_C1 B					CG_ABS2_C B
29 LOWRISK_ DZ2_CB					LOWRISK_ DZ2_CB
30 LR_HR_DZ21 _CB					LR_HR_DZ2 _CB
31 NO_DONOR1 2_CB					NO_DONOR 2_CB
32 OTH3_CB	1				OTH3_CB
33 OTH3_EXP	\$1999				OTH3_EXP

Version 12.00 pushed to PRODUCTION 06.16.2020: All Forms
Form: Cohort Assignment
Generated On: 25 Jun 2020 16:25:32

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:

- Cross-sectional cohort ③
MDS/AML Longitudinal cohort
ICUS Longitudinal cohort
At-Risk cohort

Please check the box to acknowledge the patient's assignment.

④

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 Form: Cohort Assignment
 Generated On: 25 Jun 2020 16:25:32

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

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Form: Rescreening Yes_No

Generated On: 25 Jun 2020 16:25:32

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

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Form: Rescreening Yes_No
Generated On: 25 Jun 2020 16:25:32

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_1 YN			1 = No 2 = Yes		RESCREEN_ YN

Version 12.00 pushed to PRODUCTION 06.16.2020: All Forms
Form: Transplant
Generated On: 25 Jun 2020 16:25:32

Date of transplant _____ ①

Transplant type _____ Allogeneic ②
Autologous

CIBMTR ID _____ ③

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Form: Transplant

Generated On: 25 Jun 2020 16:25:32

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

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Form: Lost to Follow-Up
Generated On: 25 Jun 2020 16:25:32

FORM_OID _____ ①

Patient Lost to Follow-Up

Was the study participant unable to be contacted for follow-up per defined criteria?

No ③
Yes

Date of last contact _____ ④

Methods of Contact

Contact study participant by phone ⑤
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?

No ⑧
Yes

Date [site](#) stopped participating _____ ⑨

Reason [site](#) stopped participating

IRB terminated study ⑩

Version 12.00 pushed to PRODUCTION 06.16.2020: All Forms

Form: Lost to Follow-Up

Generated On: 25 Jun 2020 16:25:32

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?

No 12
Yes

Date most recent contact

_____ 13

Lost to Follow-Up Internal Review

Study participant lost to follow-up approved?

No 15
Yes

Date of Approval

_____ 16

Version 12.00 pushed to PRODUCTION 06.16.2020: All Forms

Form: Lost to Follow-Up

Generated On: 25 Jun 2020 16:25:32

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	FORM PID392389 2	\$200				FORM_OID
③	Patient Lost 1 Follow-up Ind_2 PID61333_ V3_0			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 1 tion Contact Technique Type PID361298 1_V1_0			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

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Form: Lost to Follow-Up
Generated On: 25 Jun 2020 16:25:32

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_AT TMPT_DT
8 Study Site Stop Clinical Study Participation Code PID5695710_V1_0	2		1 = No 2 = Yes		SITE_NO_P ARTICP_YN
9 Study Site Stop Clinical Study Participation Date PID5695719_V1_0	MMM dd yyyy				SITE_LEFT_ DT



Version 12.00 pushed to PRODUCTION 06.16.2020: All Forms
Form: Lost to Follow-Up
Generated On: 25 Jun 2020 16:25:32

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_NONP ART_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	dd				PT_FOUND_DT

Version 12.00 pushed to PRODUCTION 06.16.2020: All Forms

Form: Lost to Follow-Up

Generated On: 25 Jun 2020 16:25:32

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

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Form: Withdrawal of Consent
Generated On: 25 Jun 2020 16:25:32

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 **9**
Yes

Date of amended consent _____ **10**

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

Upload Documentation of specific changes _____ **12**

Clinical Withdrawal of Consent Internal Review

Clinical withdrawal of consent approved? No **14**
Yes

Date of approval _____ **15**

Specimen Change of Participation Internal Review

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Form: Withdrawal of Consent
Generated On: 25 Jun 2020 16:25:32

Specimen change of participation approved?

No 17
Yes

Date of approval _____

18

Version 12.00 pushed to PRODUCTION 06.16.2020: All Forms
Form: Withdrawal of Consent
Generated On: 25 Jun 2020 16:25:32

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	FORM PID441941 1	\$200				FORM_OID
③	Patient Withdrawn Consent Clinical Ind_2 PID219977 7_V1_0	1		1 = No 2 = Yes		CLIN_WD_Y N
④	Withdrawn consent date PID219978 0_V1_0	MMM dd yyyy				WD_CONSE NT_DT
⑥	Patient Specimen Consent Withdrawn Yes No Indicator PID352132 9_V1_0	1		1 = No 2 = Yes		SPECIMEN_ WD_YN
⑦	Patient Amended Consent Date PID361314 3_V1_0	MMM dd yyyy				AMEND_CO NSENT_DT

Version 12.00 pushed to PRODUCTION 06.16.2020: All Forms
Form: Withdrawal of Consent
Generated On: 25 Jun 2020 16:25:32

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
9 Patient Amended Consent Yes No Indicator PID361314 5_V1_0	1		1 = No 2 = Yes		SPECIMEN_ WD_CHNG_ YN
10 Patient Amended Consent Date PID361314 3_V1_0_1	MMM dd yyyy				OPT2_AME ND_CONSE NT_DT
11 Consent Withdrawn Change Reason PID438615 2_V1_0	1		1 = Information provided at registration incorrect 2 = Patient consent change - Written Reconsent 3 = Patient consent change - Withdrawal (verbal or written)		REAS_CHN G_CNSNT
12 Document Upload Text PID342143 7_V1_0	\$200				UPLOAD_C HNG_DOC_ XX

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Form: Withdrawal of Consent
Generated On: 25 Jun 2020 16:25:32

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_CONSE NT_APPRV_ YN
15 Patient Follow_up Clinical Institutional Review Board Approval Consent Withdrawn Date PID361316 2_V1_0	MMM dd yyyy				WD_CONSE NT_APPRV_ DT

Version 12.00 pushed to PRODUCTION 06.16.2020: All Forms
Form: Withdrawal of Consent
Generated On: 25 Jun 2020 16:25:32

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
17 Patient Specimen Institutional Review Board Approval Consent Withdrawn Yes No Indicator PID361317 1_V1_0	1		1 = No 2 = Yes		LAB_WOC_ APPRV_YN_ DV
18 Patient Follow_up Clinical Institutional Review Board Approval Consent Withdrawn Date PID361316 2_V1_0_1	MMM dd yyyy				LAB_WOC_ APPRV_DT_ DV

Version 12.00 pushed to PRODUCTION 06.16.2020: All Forms
Form: COVID-19 Trigger Form
Generated On: 25 Jun 2020 16:25:32

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?

No ②
Yes

Was the participant tested for COVID-19?

No ③
Yes

Were there any COVID-19 related protocol deviations to report?

No ④
Yes

Version 12.00 pushed to PRODUCTION 06.16.2020: All Forms
Form: COVID-19 Trigger Form
Generated On: 25 Jun 2020 16:25:32

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
① FORM_OID	\$200				FORM_OID
② PT_CONTA CT_POS_YN	1		1 = No 2 = Yes		PT_CONTA CT_POS_YN
③ COVID19_T EST_YN	1		1 = No 2 = Yes		COVID19_T EST_YN
④ COVID19_D EVIATIONS _YN	1		1 = No 2 = Yes		COVID19_D EVIATIONS _YN

Version 12.00 pushed to PRODUCTION 06.16.2020: All Forms
Form: Coronavirus Disease 2019 (COVID-19) Evaluation Form
Generated On: 25 Jun 2020 16:25:32

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 text _____ 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 9
Yes

Duration of hospitalization (in days)

_____ 10

Day of death

_____ 11

Version 12.00 pushed to PRODUCTION 06.16.2020: All Forms
Form: Coronavirus Disease 2019 (COVID-19) Evaluation Form
Generated On: 25 Jun 2020 16:25:32

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
① FORM_OID	\$200				FORM_OID
③ COVID19_T EST_DT_XXyyyy	MMM dd				COVID19_T EST_DT_XX
④ COVID19_T 2 EST_TYPE_ XX			1 = PCR (specify) 2 = Serological (specify) 88 = Other (specify)		COVID19_T EST_TYPE_ XX
⑤ COVID19_T \$200 EST_TYPE_ SP_XX					COVID19_T EST_TYPE_ SP_XX
⑥ COVID19_T 2 EST_RS_XX			1 = Negative 2 = Positive		COVID19_T EST_RS_XX
⑦ COVID19_T 2 EST_OUTC M_XX			1 = Recovering or Resolving 2 = Recovered or Resolved 3 = Recovered or Resolved with Sequelae		COVID19_T EST_OUTC M_XX

Version 12.00 pushed to PRODUCTION 06.16.2020: All Forms
Form: Coronavirus Disease 2019 (COVID-19) Evaluation Form
Generated On: 25 Jun 2020 16:25:32

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			4 = Fatal 99 = Unknown		
8 COVID19_T 1 EST_TX_YN _XX			1 = No 2 = Yes		COVID19_T EST_TX_YN _XX
9 COVID19_P 1 T_HOSP_YN _XX			1 = No 2 = Yes		COVID19_P T_HOSP_YN _XX
10 COVID19_H 3 OSP_DUR_ XX					COVID19_H OSP_DUR_ XX
11 DEATH_DT	MMM dd YYYY				DEATH_DT

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Form: COVID-19 Medication Form
Generated On: 25 Jun 2020 16:25:32

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: 25 Jun 2020 16:25:32

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
① FORM_OID	\$200				FORM_OID
② COVID19_M ED_NAME_ FT_XX	\$200				COVID19_M ED_NAME_ FT_XX
③ COVID19_Mdd ED_STRT_D T_XX	MMM				COVID19_M ED_STRT_D T_XX
④ COVID19_Mdd ED_END_D T_XX	MMM				COVID19_M ED_END_D T_XX

Version 12.00 pushed to PRODUCTION 06.16.2020: All Forms
Form: COVID-19 Deviation Log
Generated On: 25 Jun 2020 16:25:32

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
-

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Form: COVID-19 Deviation Log
Generated On: 25 Jun 2020 16:25:32

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

Version 12.00 pushed to PRODUCTION 06.16.2020: All Forms
Form: COVID-19 Deviation Log
Generated On: 25 Jun 2020 16:25:32

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
② DEVIA_TYP 2 E_XX			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_TYP E_XX
③ DEVIA_REA 2 S_XX			1 = Diagnosis of COVID-19		DEVIA_REA S_XX

Version 12.00 pushed to PRODUCTION 06.16.2020: All Forms
Form: COVID-19 Deviation Log
Generated On: 25 Jun 2020 16:25:32

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 DE VIA_ST_ DT_XX	MMM dd yyyy				DE VIA_ST_ DT_XX
⑤ DE VIA_END_ DT_XX	MMM dd yyyy				DE VIA_END_ DT_XX
⑥ DE VIA_SUM_ MARY_XX	\$200				DE VIA_SUM_ MARY_XX
⑦ DE VIA_NOT1_ I_CIRB_YN_ XX			1 = No 2 = Yes		DE VIA_NOT1_ I_CIRB_YN_ XX
⑧ DE VIA_NOT_ I_CIRB_DT_ XX	MMM dd yyyy				DE VIA_NOT_ I_CIRB_DT_ XX

Version 12.00 pushed to PRODUCTION 06.16.2020: All Forms
Form: COVID-19 Deviation Log
Generated On: 25 Jun 2020 16:25:32

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
9 DEVIA_NOT1 I_LIRB_YN_ XX			1 = No 2 = Yes		DEVIA_NOT I_LIRB_YN_ XX
10 DEVIA_NOTMMM dd I_LIRB_DT_YYYY XX					DEVIA_NOT I_LIRB_DT_ XX

Site Reported Best Response (derived)

CR ①
PR
SD
PD
not assessed

Site Reported Worst Response (derived)

CR ②
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)

No ⑤
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)

Alive ⑨
Dead

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Form: Case Summary: Global
Generated On: 25 Jun 2020 16:25:32

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

Date of last contact or death(derived)

10

Version 12.00 pushed to PRODUCTION 06.16.2020: All Forms

Form: Case Summary: Global

Generated On: 25 Jun 2020 16:25:32

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
① OBJECT_RE 1 SP_BEST_D V			1 = CR 2 = PR 3 = SD 4 = PD -1 = not assessed		OBJECT_RE SP_BEST_D V
② OBJECT_RE 1 SP_STAT_D V			1 = CR 2 = PR 3 = SD 4 = PD -1 = not assessed		OBJECT_RE SP_STAT_D V
③ PD_FOLDER _OID_DV	\$50				PD_FOLDER _OID_DV
④ PD_FOLDER3 _RPT_NUM _DV					PD_FOLDER _RPT_NUM _DV
⑤ PROG_AML 1 _YN_DV			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

Version 12.00 pushed to PRODUCTION 06.16.2020: All Forms
 Form: Case Summary: Global
 Generated On: 25 Jun 2020 16:25:32

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_STA T_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_STA T_DV
10 LAST_CONTMMM ACT_DT_D yyyy V	dd yyyy V				LAST_CONT ACT_DT_D V

Version 12.00 pushed to PRODUCTION 06.16.2020: All Forms
Form: Internal Communications
Generated On: 25 Jun 2020 16:25:32

Date of communication _____ ①

Type of communication _____

Email ②
Phone call
Memo
Other (specify)

Communication notes _____ ③

Upload file (if applicable) _____ ④

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Form: Internal Communications
Generated On: 25 Jun 2020 16:25:32

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_X	\$200				UPLOAD_X

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Form: Eligibility Evaluation (Step 1)
Generated On: 25 Jun 2020 16:25:32

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

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

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

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

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

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

Specify reason patient ineligible or questionable _____ ⑦

Was an eligibility override/waiver obtained? No ⑧
Yes

Upload documentation _____ ⑨

Data Management Review

Version 12.00 pushed to PRODUCTION 06.16.2020: All Forms
Form: Eligibility Evaluation (Step 1)
Generated On: 25 Jun 2020 16:25:32

Data Management review date _____ **11**

Data Management comments _____ **12**

Is Study Chair review required? No **13**
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? No **18**
Yes

Study Chair comments _____ **19**

Version 12.00 pushed to PRODUCTION 06.16.2020: All Forms

Form: Eligibility Evaluation (Step 1)

Generated On: 25 Jun 2020 16:25:32

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
① PRIOR_MAL IG_EXCL_Y N	1		1 = No 2 = Yes		PRIOR_MAL IG_EXCL_Y N
② HEM_DX_E XCL_YN	1		1 = No 2 = Yes		HEM_DX_E XCL_YN
③ PRIOR_TX_ EXCL_YN	1		1 = No 2 = Yes		PRIOR_TX_ EXCL_YN
④ BM_ASP_Y N	1		1 = No 2 = Yes		BM_ASP_Y N
⑤ ELIG_LAB_ YN	1		1 = No 2 = Yes		ELIG_LAB_ YN
⑥ PT_ELIG_Y N	1		1 = No 2 = Yes 3 = Questionabl e		PT_ELIG_Y N
⑦ INELIG_QU ES_FT	\$200				INELIG_QU ES_FT
⑧ ELIG_OVRD _WVR_YN	1		1 = No 2 = Yes		ELIG_OVRD _WVR_YN
⑨ UPLOAD	\$200				UPLOAD

Version 12.00 pushed to PRODUCTION 06.16.2020: All Forms
Form: Eligibility Evaluation (Step 1)
Generated On: 25 Jun 2020 16:25:32

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
11 DM_REVIEW_DT	MMM dd yyyy				DM_REVIEW_DT
12 DA_COMMENTS	\$200 NT				DA_COMMENTS
13 SC_REVIEW_REQUIRED	1 Q_YN		1 = No 2 = Yes		SC_REVIEW_REQUIRED
15 ELIG_REVIEW_STATUS	1 W_STAT		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_STATUS

Version 12.00 pushed to PRODUCTION 06.16.2020: All Forms
Form: Eligibility Evaluation (Step 1)
Generated On: 25 Jun 2020 16:25:32

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 yyyy				ELIG_FINAL_DT
18 Study Chair: Do you agree with this eligibility assessment ?	1		1 = No 2 = Yes		SC_AGREE_YN
19 SC_COMME_NT	\$200				SC_COMME_NT

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Form: Eligibility Evaluation Signature (Step 1)
Generated On: 25 Jun 2020 16:25:32

FORM_OID _____

①

Study Chair Review

Study Chair Review Date _____

③

Study Chair Signature _____

④

Version 12.00 pushed to PRODUCTION 06.16.2020: All Forms
Form: Eligibility Evaluation Signature (Step 1)
Generated On: 25 Jun 2020 16:25:32

	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?

No 7
Yes

Study Chair Comments

8

Review Status

Review status

Final, Completed and reviewed by the study chair. No open discrepancies or requests to the institutions. 10
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

Version 12.00 pushed to PRODUCTION 06.16.2020: All Forms
Form: Case Summary: Deviations (Step 1)
Generated On: 25 Jun 2020 16:25:32

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
① 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

Version 12.00 pushed to PRODUCTION 06.16.2020: All Forms
Form: Case Summary: Deviations (Step 1)
Generated On: 25 Jun 2020 16:25:32

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			7 = Patient's labs/tests/s cans/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_COMME_NT	\$200				DA_COMME_NT
⑦ SC_AGREE_1_YN			1 = No 2 = Yes		SC_AGREE_1_YN
⑧ SC_COMME_NT	\$200				SC_COMME_NT

Version 12.00 pushed to PRODUCTION 06.16.2020: All Forms
Form: Case Summary: Deviations (Step 1)
Generated On: 25 Jun 2020 16:25:32

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
10 REVIEW_ST1 AT			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_ST AT

Version 12.00 pushed to PRODUCTION 06.16.2020: All Forms
Form: Case Summary: Deviations (Step 1)
Generated On: 25 Jun 2020 16:25:32

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