

Subject Case Report Forms

Draft 25 version 1.0 MIGPROD 17JAN2018 - 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

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NOT RECOMMENDED FOR SOURCE DOCUMENTATION

Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Enrollment Forms

Form: Demography

Generated On: 15 May 2019 14:40:46

FORM_OID PID3302204_V1_0

Patient Initials (LFM) _____

Patient's Date of Birth _____

Ethnicity Hispanic or Latino
Not Hispanic or Latino
Not Reported
Unknown

Gender of a Person Female Gender
Male Gender
Unknown

Country of Residence _____

ZIP Code _____

Method of Payment PRIVATE INSURANCE
MEDICARE
MEDICARE AND PRIVATE
INSURANCE
MEDICAID
MEDICAID AND MEDICARE
MILITARY OR VETERANS
SPONSORED NOS
MILITARY SPONSORED
(INCLUDING CHAMPUS
&TRICARE)
VETERANS SPONSORED
SELF PAY (NO INSURANCE)

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Folder: Enrollment Forms

Form: Demography

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-
- NO MEANS OF PAYMENT (NO
 - INSURANCE)
 - OTHER
 - Unknown

Race

- American Indian or Alaska 9
- Native
- Asian
- Black or African American
- Native Hawaiian or Other
- Pacific Islander
- White
- Not Reported
- Unknown

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Folder: Enrollment Forms

Form: Demography

Generated On: 15 May 2019 14:40:46

Field Name	Data Type	Units	Values	Include Field OID
① FORM_OID	\$200		PID3302204 _V1_0	FORM_OID
② Participant Initials PID2001039 _V4_0	\$4			PT_INITIALS _NAME
③ Patient's Date of Birth PID793_V5_ 1	dd MMM yyyy			PER_BIR_DT
④ Ethnicity PID2192217 _V2_0	\$22		Hispanic or Latino = Hispanic or Latino Not Hispanic or Latino = Not Hispanic or Latino Not reported = Not Reported Unknown = Unknown	ETHN_GRP_C AT_TXT
⑤ Gender of a Person PID3368866 _V1_0	\$13		Female Gender = Female Gender Male Gender = Male Gender Unknown = Unknown	PERSON_GE NDER

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Folder: Enrollment Forms

Form: Demography

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Field Name	Data Type	Units	Values	Include Field OID
⑥ Country of Residence (if not USA) PID2006183_V2_0	\$5		CNTRY_C_PI D2018396_V D 1_0	COUNTRY_C
⑦ ZIP Code PID2179606_V2_0	\$15			ADDR_POST AL_CD
⑧ Method of Payment PID58384_V2_4	\$51		PRIVATE INSURANCE = PRIVATE INSURANCE MEDICARE = MEDICARE MEDICARE AND PRIVATE INSURANCE = MEDICARE AND PRIVATE INSURANCE MEDICAID = MEDICAID MEDICAID AND MEDICARE = MEDICAID AND MEDICARE	PAYMENT_M ETHOD

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

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Form: Demography

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

MILITARY OR
VETERANS
SPONSORED
NOS =
MILITARY OR
VETERANS
SPONSORED
NOS
MILITARY
SPONSORED
(INCLUDING
CHAMPUS
&TRICARE)
= MILITARY
SPONSORED
(INCLUDING
CHAMPUS
&TRICARE)
VETERANS
SPONSORED
= VETERANS
SPONSORED
SELF PAY
(NO
INSURANCE)
= SELF PAY
(NO
INSURANCE)
NO MEANS
OF PAYMENT
(NO
INSURANCE)
= NO MEANS
OF PAYMENT
(NO
INSURANCE)

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Folder: Enrollment Forms

Form: Demography

Generated On: 15 May 2019 14:40:46

Field Name	Data Type	Units	Values	Include Field OID
			OTHER = OTHER Unknown = Unknown	
⑨ Race PID2192199 _V1_0	\$41		American Indian or Alaska Native = American Indian or Alaska Native Asian = Asian Black or African American = Black or African American Native Hawaiian or other Pacific Islander = Native Hawaiian or Other Pacific Islander White = White Not Reported = Not Reported Unknown = Unknown	RACE_CAT_T XT

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Enrollment Forms

Form: Step Information

Generated On: 15 May 2019 14:40:46

FORM_OID PID3285392_V1_0 **1**

Registration Step **2**

Event Description **3**

Tracking Number **4**

Treating Investigator **5**

Site Registrar **6**

Crediting Group **7**

Crediting Investigator **8**

Arm Name **9**

Event Date **10**

Event Time **11**

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

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Folder: Enrollment Forms

Form: Step Information

Generated On: 15 May 2019 14:40:46

Field Name	Data Type	Units	Values	Include Field OID
① FORM_OID	\$200		PID3285392 _V1_0	FORM_OID
② Step No PID2002093 _V4_0	\$20			REG_STEP_N UM
③ Event Description PID3303110 _V1_0	\$100			EVENT_DESC
④ Tracking Number PID3302859 _V1_0	\$25			TRACKING_N UM
⑤ Treating Physician Or Participating Investigator Name PID2740424 _V1_0	\$100			TX_MD_PAR T_INV_NM
⑥ Registrar PID2172_V3 _0	\$100			PROT_REG_ NAME
⑦ Organization Name PID2152_V3 _0	\$200			ORG_NAME

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Folder: Enrollment Forms

Form: Step Information

Generated On: 15 May 2019 14:40:46

Field Name	Data Type	Units	Values	Include Field OID
⑧ Investigator PID2002224 _V4_0	\$100			INVESTIGAT OR_NAME
⑨ Assigned Treatment Arm PID2001626 _V3_0	\$100			PROT_TX_AR M_ASS_TXT
⑩ Event Date PID3370375 _V1_0	dd MMM yyyy			EVENT_DATE
⑪ 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

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Enrollment Forms

Form: Treatment Assignment

Generated On: 15 May 2019 14:40:46

FORM_OID

PID3285336_V1_0

Arm Name

Step No

Event description

Date of Intervention/Treatment Assignment

Event Time

EST

CST

MST

PST

EDT

CDT

MDT

PDT

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Enrollment Forms

Form: Treatment Assignment

Generated On: 15 May 2019 14:40:46

Field Name	Data Type	Units	Values	Include Field OID
① FORM_OID	\$200		PID3285336 _V1_0	FORM_OID
② Assigned Treatment Arm PID2001626 _V3_0	\$100			PROT_TX_AR M_ASS_TXT
③ Step No PID2002093 _V4_0	\$20			REG_STEP_N UM
④ Event Description PID3303110 _V1_0	\$100			EVENT_DESC
⑤ Date of Intervention/ Treatment Assignment PID3370377 _V1_0	dd MMM yyyy			TRT_ARM_A SGN_DATE
⑥ Event Time PID3412598 _V1_0	hh:mm:ss:rr		EST = EST CST = CST MST = MST PST = PST EDT = EDT CDT = CDT MDT = MDT PDT = PDT	EVENT_TIME

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Folder: Enrollment Forms

Form: Eligibility Checklist

Generated On: 15 May 2019 14:40:46

Demography: Age and Birth Year

Year of Birth _____

Age _____

Inclusion Criteria

Is the patient willing and able to provide written informed consent?

No 5
Yes

Date Informed Consent Signed _____

Is the patient 50 years or older?

No 7
Yes

Does the patient have an initial diagnosis of indeterminate pulmonary nodule (0.7-3.0cm)?

No 8
Yes

Indeterminate pulmonary nodule size _____

Fixed Unit: cm 9

Has the patient had a CT scan within 3 months prior to enrollment?

No 10
Yes

Provide the date of CT scan _____

Is the patient a current or former smoker with > or = 20 pack years?

No 12

Yes

Provide the pack(s) per day smoked:

Fixed Unit: packs per day **13**

Provide the number of year(s) smoked cigarettes

Fixed Unit: years **14**

Pack Years of Smoking

Fixed Unit: pack years **15**

Is the patient willing to undergo fiberoptic bronchoscopy?

No **16**

Yes

Is the patient able to tolerate all biospecimen collection as required by protocol?

No **17**

Yes

Is the patient able to comply with standard of care follow up visits including clinical exams, diagnostic work-ups, and imaging for a minimum of 2 years?

No **18**

Yes

Is the patient able to fill out the Patient Lung History questionnaire?

No **19**

Yes

Exclusion Criteria

Does the patient have a history or previous diagnosis of lung cancer?

No **21**

Yes

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Folder: Enrollment Forms

Form: Eligibility Checklist

Generated On: 15 May 2019 14:40:46

Does the patient have a diagnosis of pure ground glass opacities for the target lesion on chest CT?

No 22
Yes

Does the patient have any contraindications to nasal brushing or fiberoptic bronchoscopy?

No 23
Yes

Does the patient have allergies to any local anesthetic that may be used to obtain biosamples in the study?

No 24
Yes

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Folder: Enrollment Forms

Form: Eligibility Checklist

Generated On: 15 May 2019 14:40:46

Field Name	Data Type	Units	Values	Include Field OID
② YR_BIRTH	yyyy			YR_BIRTH
③ AGE	2			AGE
⑤ PT_SIGN_CN SNT	1		1 = No 2 = Yes	PT_SIGN_CN SNT
⑥ CNSNT_DT	dd MMM yyyy			CNSNT_DT
⑦ PT_AGE_50_1 YN			1 = No 2 = Yes	PT_AGE_50_ YN
⑧ INDT_PULM_1 NOD_YN			1 = No 2 = Yes	INDT_PULM_ NOD_YN
⑨ INDT_PULM_6.2 NOD_SZ				INDT_PULM_ NOD_SZ
⑩ CT_3MOS_Y N	2		1 = No 2 = Yes	CT_3MOS_Y N
⑪ CT_3MOS_D T	dd MMM yyyy			CT_3MOS_D T
⑫ PT_SMK_30P KY_YN	1		1 = No 2 = Yes	PT_SMK_30P KY_YN
⑬ PT_SMK_PK_6.2 DY				PT_SMK_PK_ DY

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Form: Eligibility Checklist

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Field Name	Data Type	Units	Values	Include Field OID
14 PT_SMK_YRS2				PT_SMK_YRS
15 PT_PK_YRS	6.2			PT_PK_YRS
16 FIBOPT_BRO NCH_YN	1		1 = No 2 = Yes	FIBOPT_BRO NCH_YN
17 BIO_SPEC_T OL_YN	1		1 = No 2 = Yes	BIO_SPEC_T OL_YN
18 SOC_COMPL _YN	1		1 = No 2 = Yes	SOC_COMPL _YN
19 LUNG_HX_Q UES_YN	1		1 = No 2 = Yes	LUNG_HX_Q UES_YN
21 HX_DX_LUN G_CX	1		1 = No 2 = Yes	HX_DX_LUN G_CX
22 DX_GLS_OPC _LSN_YN	1		1 = No 2 = Yes	DX_GLS_OPC _LSN_YN
23 CON_IND_N BRSH_FIBBR N_YN	1		1 = No 2 = Yes	CON_IND_N BRSH_FIBBR N_YN
24 ALLG_ANT_Y N	1		1 = No 2 = Yes	ALLG_ANT_Y N

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Date of Registration Visit _____

1

Was the patient lung history questionnaire completed?

No

2

Yes

Unknown

Reason patient lung questionnaire was not completed

Patient Refused

3

Questionnaire Not Distributed to Patient

Site Error

Questionnaire Lost

Unknown

Other, specify

Was the patients medical history obtained?

No

4

Yes

Unknown

Reason medical history not obtained

Patient Refused

5

Site error

Unknown

Other, specify

Was physical exam performed?

No

6

Yes

Unknown

Reason physical exam not performed

Patient Refused

7

Site error

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Patient does not produce sputum on a regular basis
Unknown
Other, specify

Was the SOC Diagnostic Imaging reviewed?

No 8
Yes
Unknown

If yes, indicate the type of imaging used to identify the indeterminate pulmonary nodule used for eligibility (check all that apply)

CT 10

Dynamic contrast-enhanced CT 11

PET 12

MRI 13

X-ray 14

Other, specify 15

Primary reason SOC Diagnostic Imaging not reviewed

Images Lost 16
Site error
Unknown
Other, specify

Was the sputum instructions and sample collection kit distributed to the patient?

- No 17
- Yes
- Unknown

Reason sputum instructions and sample collection kit not distributed to patient

- Patient Refused 18
- Site error
- Patient does not produce sputum on a regular basis
- Unknown
- Other, specify

Date distributed to patient

19

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Eligibility/Registration Visit

Form: Registration Visit

Generated On: 15 May 2019 14:40:46

Field Name	Data Type	Units	Values	Include Field OID
① REG_VST_DTMMM dd yyyy				REG_VST_DT
② PT_COMPL_F 2 ORM_YN			1 = No 2 = Yes 99 = Unknown	PT_COMPL_F ORM_YN
③ PT_COMPL_F 2 ORM_NC_RS			1 = Patient Refused 2 = Questionnaire Not Distributed to Patient 3 = Site Error 4 = Questionnaire Lost 99 = Unknown 88 = Other, specify	PT_COMPL_F ORM_NC_RS
④ MED_HX_FO 2 RM_YN			1 = No 2 = Yes 99 = Unknown	MED_HX_FO RM_YN
⑤ MED_HX_ND 2			1 = Patient Refused 2 = Site error 99 = Unknown 88 = Other, specify	MED_HX_ND

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Folder: Eligibility/Registration Visit

Form: Registration Visit

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Field Name	Data Type	Units	Values	Include Field OID
⑥ PHY_EXAM_Y2 N			1 = No 2 = Yes 99 = Unknown	PHY_EXAM_Y N
⑦ PHY_EXAM_ 2 ND			1 = Patient Refused 2 = Site error 3 = Patient, does not produce sputum on a regular basis 99 = Unknown 88 = Other, specify	PHY_EXAM_ ND
⑧ SOC_DIAG_I 2 MAG_YN			1 = No 2 = Yes 99 = Unknown	SOC_DIAG_I MAG_YN
⑩ DIAG_IMAG_1 CT				DIAG_IMAG_ CT
⑪ DIAG_IMAG_1 DC_CT				DIAG_IMAG_ DC_CT
⑫ DIAG_IMAG_1 PET				DIAG_IMAG_ PET
⑬ DIAG_IMAG_1 MRI				DIAG_IMAG_ MRI

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Form: Registration Visit

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Field Name	Data Type	Units	Values	Include Field OID
14 DIAG_IMAG_1 XRAY				DIAG_IMAG_ XRAY
15 DIAG_IMAG_ \$200 OTH				DIAG_IMAG_ OTH
16 SOC_DIAG_I 2 MAG_ND			1 = Images Lost 2 = Site error 99 = Unknown 88 = Other, specify	SOC_DIAG_I MAG_ND
17 SPT_SAMP_K 2 IT_YN			1 = No 2 = Yes 99 = Unknown	SPT_SAMP_K IT_YN
18 SPT_SAMP_K 2 IT_ND			1 = Patient Refused 2 = Site error 3 = Patient does not produce sputum on a regular basis 99 = Unknown 88 = Other, specify	SPT_SAMP_K IT_ND
19 SPT_SAMP_K MMM dd yyyy IT_DT				SPT_SAMP_K IT_DT

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Folder: Eligibility/Registration Visit

Form: Pre-test Probability

Generated On: 15 May 2019 14:40:46

Instructions: This form captures the physician's assessment of the pre-test probability that the lesion used for eligibility is lung cancer prior to the bronchoscopy.

For subjects that were not able to have the physicians assessment completed prior to bronchoscopy, the reason should be provided in Q1a, and the assessment should be completed using the pre-bronchoscopy data.

1. - Was the pre-test probability completed prior to bronchoscopy? No ②
Yes

1a. - If no, provide primary reason Timing Issues ③
Patient enrolled prior to form implementation
Other, specify

2. - Date of Assessment _____ ④

3. - Time of Assessment _____ ⑤

4. - Pre-test probability Low (<10% probability that lesion is lung cancer) ⑥
Medium (10-60% probability that lesion is lung cancer)
High (>60% probability that lesion is lung cancer)

Initials of Physician Completing Assessment _____ ⑦

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Folder: Eligibility/Registration Visit
Form: Pre-test Probability
Generated On: 15 May 2019 14:40:46

Field Name	Data Type	Units	Values	Include Field OID
② PRE_TST_PR 2 IOR_BRNCH_ YN			1 = No 2 = Yes	PRE_TST_PR IOR_BRNCH_ YN
③ PRE_TST_ND2 _RSN			1 = Timing Issues 2 = Patient enrolled prior to form implementati on 88 = Other, specify	PRE_TST_ND _RSN
④ PRE_TST_AS S_DT	MMM dd yyyy			PRE_TST_AS S_DT
⑤ PRE_TST_AS S_TM	hh:nn			PRE_TST_AS S_TM
⑥ PRE_TST_PR 2 OB			1 = Low (<10% probability that lesion is lung cancer) 2 = Medium (10-60% probability that lesion is lung cancer) 3 = High (>60% probability that lesion is lung cancer)	PRE_TST_PR OB

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Folder: Eligibility/Registration Visit

Form: Pre-test Probability

Generated On: 15 May 2019 14:40:46

Field Name	Data Type	Units	Values	Include Field OID
⑦ TX_PHY_INI TIALS	\$5			TX_PHY_INI TIALS

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Eligibility/Registration Visit

Form: Physical Exam

Generated On: 15 May 2019 14:40:46

Examination Date

Fixed Unit: MMM dd yyyy **1**

Weight

kg **2**

lbs

Height

cm **3**

in

Pulse

Fixed Unit: bpm **4**

Blood pressure

Systolic

Fixed Unit: mmHg **6**

Diastolic

Fixed Unit: mmHg **7**

Temperature

C **8**

F

Respiratory Rate

Fixed Unit: breaths per minute **9**

Instructions Indicate the status of each body system/site under the Body System Column. A response is required for the body system column in each row, including the 'other, specify' rows. If there are no additional sites examined, select 'not examined'

Body System/Site

Head 11

Neck

Chest

Heart

Abdomen

Musculoskeletal

Neurologic

Other, specify

If other, specify _____ 12

Body System

Abnormal 13

Normal

Not Examined

If abnormal, describe _____ 14

Body System/Site

Head 11

Neck

Chest

Heart

Abdomen

Musculoskeletal

Neurologic

Other, specify

If other, specify _____ 12

Body System

Abnormal 13
Normal
Not Examined

If abnormal, describe

14

Body System/Site

Head 11
Neck
Chest
Heart
Abdomen
Musculoskeletal
Neurologic
Other, specify

If other, specify

12

Body System

Abnormal 13
Normal
Not Examined

If abnormal, describe

14

Body System/Site

Head 11
Neck
Chest

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- Heart
- Abdomen
- Musculoskeletal
- Neurologic
- Other, specify

If other, specify _____

12

Body System

- Abnormal
- Normal
- Not Examined

13

If abnormal, describe _____

14

Body System/Site

- Head
- Neck
- Chest
- Heart
- Abdomen
- Musculoskeletal
- Neurologic
- Other, specify

11

If other, specify _____

12

Body System

- Abnormal
- Normal
- Not Examined

13

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If abnormal, describe _____

14

Body System/Site

Head

11

Neck

Chest

Heart

Abdomen

Musculoskeletal

Neurologic

Other, specify

If other, specify _____

12

Body System

Abnormal

13

Normal

Not Examined

If abnormal, describe _____

14

Body System/Site

Head

11

Neck

Chest

Heart

Abdomen

Musculoskeletal

Neurologic

Other, specify

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If other, specify _____

12

Body System

Abnormal
Normal
Not Examined

13

If abnormal, describe _____

14

Body System/Site

Head
Neck
Chest
Heart
Abdomen
Musculoskeletal
Neurologic
Other, specify

11

If other, specify _____

12

Body System

Abnormal
Normal
Not Examined

13

If abnormal, describe _____

14

Body System/Site

Head

11

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- Neck
- Chest
- Heart
- Abdomen
- Musculoskeletal
- Neurologic
- Other, specify

If other, specify _____

12

Body System

- Abnormal
- Normal
- Not Examined

13

If abnormal, describe _____

14

Body System/Site

- Head
- Neck
- Chest
- Heart
- Abdomen
- Musculoskeletal
- Neurologic
- Other, specify

11

If other, specify _____

12

Body System

- Abnormal

13

FOR SITE IRB SUBMISSION ONLY
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Normal
Not Examined

If abnormal, describe _____ **14**

Body System/Site

Head **11**
Neck
Chest
Heart
Abdomen
Musculoskeletal
Neurologic
Other, specify

If other, specify _____ **12**

Body System

Abnormal **13**
Normal
Not Examined

If abnormal, describe _____ **14**

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Eligibility/Registration Visit

Form: Physical Exam

Generated On: 15 May 2019 14:40:46

Field Name	Data Type	Units	Values	Include Field OID
① PHY_EXAM_ DT	MMM dd yyyy			PHY_EXAM_ DT
② PT_WT	7.3	1 = kg 2 = lbs		PT_WT
③ PT_HT	7.3	1 = cm 2 = in		PT_HT
④ PULSE_RATE MSRMT_VA L	3.0			PULSE_RATE MSRMT_VA L
⑥ BLD_PRESS_8 SYSTOLIC				BLD_PRESS_ SYSTOLIC
⑦ BLD_PRESS_8 DIASTOLIC				BLD_PRESS_ DIASTOLIC
⑧ PT_TEMP	5.2	1 = C 2 = F		PT_TEMP
⑨ P_VS_RR_PH3 YSEXM_VAL				P_VS_RR_PH YSEXM_VAL
⑩ BDY_SYS_SI 2 TE_NM			1 = Head 2 = Neck 3 = Chest 4 = Heart 5 = Abdomen	BDY_SYS_SI TE_NM

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Form: Physical Exam

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Field Name	Data Type	Units	Values	Include Field OID
			6 = Musculoskele tal 7 = Neurologic 88 = Other, specify	
12	BDY_SITE_O TH_SPC	\$200		BDY_SITE_O TH_SPC
13	BDY_SYS_IN D	2	1 = Abnormal 3 = Normal 98 = Not Examined	BDY_SYS_IN D
14	BDY_SYS_IN D_ABN_DSC	\$200		BDY_SYS_IN D_ABN_DSC

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Instructions: Provide the medical history for the patient as assessed during registration. If the date of diagnosis is unknown, enter days as UN, months as UNK, and years as 0000.

Has the patient been diagnosed with any other aerodigestive conditions not listed in the table below? Note: This may include additional conditions/events of those conditions listed

No ②
Yes
Unknown

Medical Condition _____ Asbestosis ③

Has patient ever been diagnosed with this condition?

No ④
Yes
Unknown

Date diagnosed _____ ⑤

If yes, provide a description of medical condition _____ ⑥

Medical Condition _____ COPD ③

Has patient ever been diagnosed with this condition?

No ④
Yes
Unknown

Date diagnosed _____ ⑤

If yes, provide a description of medical condition _____ ⑥

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Medical Condition

Chronic Bronchitis 3

Has patient ever been diagnosed with this condition?

No 4

Yes

Unknown

Date diagnosed

5

If yes, provide a description of medical condition

6

Medical Condition

Emphysema 3

Has patient ever been diagnosed with this condition?

No 4

Yes

Unknown

Date diagnosed

5

If yes, provide a description of medical condition

6

Medical Condition

GERD 3

Has patient ever been diagnosed with this condition?

No 4

Yes

Unknown

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Date diagnosed _____ 5

If yes, provide a description of medical condition _____ 6

Medical Condition Barrett's esophagus 3

Has patient ever been diagnosed with this condition? No 4
Yes
Unknown

Date diagnosed _____ 5

If yes, provide a description of medical condition _____ 6

Medical Condition Heart Disease - Heart Attack 3

Has patient ever been diagnosed with this condition? No 4
Yes
Unknown

Date diagnosed _____ 5

If yes, provide a description of medical condition _____ 6

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Medical Condition

Hypertension - High Blood Pressure 3

Has patient ever been diagnosed with this condition?

No 4
Yes
Unknown

Date diagnosed

_____ 5

If yes, provide a description of medical condition

_____ 6

Medical Condition

Lung Infection 3

Has patient ever been diagnosed with this condition?

No 4
Yes
Unknown

Date diagnosed

_____ 5

If yes, provide a description of medical condition

_____ 6

Medical Condition

Occupational Lung Diseases 3

Has patient ever been diagnosed with this condition?

No 4
Yes
Unknown

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Date diagnosed _____ ⑤

If yes, provide a description of medical condition _____ ⑥

Medical Condition Pulmonary Fibrosis ③

Has patient ever been diagnosed with this condition? No ④
Yes
Unknown

Date diagnosed _____ ⑤

If yes, provide a description of medical condition _____ ⑥

Medical Condition Sleep Apnea ③

Has patient ever been diagnosed with this condition? No ④
Yes
Unknown

Date diagnosed _____ ⑤

If yes, provide a description of medical condition _____ ⑥

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Medical Condition

Stroke - Cerebrovascular Disease 3

Has patient ever been diagnosed with this condition?

No 4
Yes
Unknown

Date diagnosed

_____ 5

If yes, provide a description of medical condition

_____ 6

Medical Condition

Thyroid disorders 3

Has patient ever been diagnosed with this condition?

No 4
Yes
Unknown

Date diagnosed

_____ 5

If yes, provide a description of medical condition

_____ 6

Medical Condition

Cystic Fibrosis 3

Has patient ever been diagnosed with this condition?

No 4
Yes
Unknown

Date diagnosed _____ ⑤

If yes, provide a description of medical condition _____ ⑥

Medical Condition _____ Interstitial Lung Disease ③

Has patient ever been diagnosed with this condition? No ④
Yes
Unknown

Date diagnosed _____ ⑤

If yes, provide a description of medical condition _____ ⑥

Medical Condition _____ Bronchiectasis ③

Has patient ever been diagnosed with this condition? No ④
Yes
Unknown

Date diagnosed _____ ⑤

If yes, provide a description of medical condition _____ ⑥

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Medical Condition

Obliterative Bronchiolitis 3

Has patient ever been diagnosed with this condition?

No 4

Yes

Unknown

Date diagnosed

_____ 5

If yes, provide a description of medical condition

_____ 6

Medical Condition

Central Airway
Obstruction/Extrinsic
Compression 3

Has patient ever been diagnosed with this condition?

No 4

Yes

Unknown

Date diagnosed

_____ 5

If yes, provide a description of medical condition

_____ 6

Medical Condition

TB or active Pneumonia 3

Has patient ever been diagnosed with this condition?

No 4

Yes

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Unknown

Date diagnosed

5

If yes, provide a description of medical condition

6

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Folder: Eligibility/Registration Visit

Form: Medical History- Log

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Field Name	Data Type	Units	Values	Include Field OID
② OTH_AERO_ 2 DIG_DX			1 = No 2 = Yes 99 = Unknown	OTH_AERO_ DIG_DX
③ MED_COND_ 2 TYPE			Medical History	MED_COND_ TYPE
④ MED_COND_ 2 YNUNK			1 = No 2 = Yes 99 = Unknown	MED_COND_ YNUNK
⑤ MED_COND_ MMM- dd- DT_DX yyyy				MED_COND_ DT_DX
⑥ MED_COND_ \$200 DESC				MED_COND_ DESC

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Form: Medical History- Other
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History/Condition/Allergy _____

Date of Diagnosis _____

Active/Ongoing

No **3**
Yes
Unknown

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 Folder: Eligibility/Registration Visit
 Form: Medical History- Other
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Field Name	Data Type	Units	Values	Include Field OID
① HIST_COND_ \$90 ALLR				HIST_COND_ ALLR
② DX_DT	MMM- dd- YYYY			DX_DT
③ ACT_ONG_Y 2 NU			1 = No 2 = Yes 99 = Unknown	ACT_ONG_Y NU

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Folder: Eligibility/Registration Visit

Form: Concomitant Medications Yes/No

Generated On: 15 May 2019 14:40:46

Has the participant taken any inhaled medications within the last two weeks?

No ①
Yes
Unknown

Has the participant taken any intranasal medications within the last two weeks?

No ②
Yes
Unknown

Has the participant taken any statins within the last two weeks?

No ③
Yes
Unknown

Has the participant taken any other medications within the last two weeks?

No ④
Yes
Unknown

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Folder: Eligibility/Registration Visit

Form: Concomitant Medications Yes/No

Generated On: 15 May 2019 14:40:46

Field Name	Data Type	Units	Values	Include Field OID
① INH_MED_Y N	2		1 = No 2 = Yes 99 = Unknown	INH_MED_Y N
② INTR_NSL_M ED_YN			1 = No 2 = Yes 99 = Unknown	INTR_NSL_M ED_YN
③ STAT_MED_Y N	2		1 = No 2 = Yes 99 = Unknown	STAT_MED_Y N
④ OTH_MED_Y N	2		1 = No 2 = Yes 99 = Unknown	OTH_MED_Y N

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Provide the details of the inhaled medication taken in the past 2 weeks

Medication
(Generic Name only) _____

②

Start Date _____

③

End Date _____

④

Check If Ongoing _____

⑤

Indication
(Reason for use) _____

⑥

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Folder: Eligibility/Registration Visit

Form: Inhaled Medications

Generated On: 15 May 2019 14:40:46

Field Name	Data Type	Units	Values	Include Field OID
② CONMED_NA ME	\$200			CONMED_NA ME
③ CONMED_ST _DT	MMM- dd- yyyy			CONMED_ST _DT
④ CONMED_EN D_DT	MMM- dd- yyyy			CONMED_EN D_DT
⑤ CONMED_ON G	1			CONMED_ON G
⑥ CONMED_IN D	\$200			CONMED_IN D

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Provide the details of the intranasal medication taken in the past 2 weeks

Medication
(Generic Name only) _____

②

Start Date _____

③

End Date _____

④

Check If Ongoing _____

⑤

Indication
(Reason for use) _____

⑥

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Eligibility/Registration Visit

Form: Intranasal Medications

Generated On: 15 May 2019 14:40:46

Field Name	Data Type	Units	Values	Include Field OID
② CONMED_NA ME	\$200			CONMED_NA ME
③ CONMED_ST _DT	MMM- dd- yyyy			CONMED_ST _DT
④ CONMED_EN D_DT	MMM- dd- yyyy			CONMED_EN D_DT
⑤ CONMED_ON G	1			CONMED_ON G
⑥ CONMED_IN D	\$200			CONMED_IN D

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Provide the details of the statin medication taken in the past 2 weeks

Medication
(Generic Name only)

②

Start Date

③

End Date

④

Check If Ongoing

⑤

Indication
(Reason for use)

⑥

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Folder: Eligibility/Registration Visit

Form: Statin Medications

Generated On: 15 May 2019 14:40:46

Field Name	Data Type	Units	Values	Include Field OID
② CONMED_NA ME	\$200			CONMED_NA ME
③ CONMED_ST _DT	MMM- dd- yyyy			CONMED_ST _DT
④ CONMED_EN D_DT	MMM- dd- yyyy			CONMED_EN D_DT
⑤ CONMED_ON G	1			CONMED_ON G
⑥ CONMED_IN D	\$200			CONMED_IN D

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Provide the details of the other medication taken in the past 2 weeks

Medication
(Generic Name only) _____ ②

Start Date _____ ③

End Date _____ ④

Check If Ongoing _____ ⑤

Indication
(Reason for use) _____ ⑥

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Eligibility/Registration Visit

Form: Other Medications

Generated On: 15 May 2019 14:40:46

Field Name	Data Type	Units	Values	Include Field OID
② CONMED_NA ME	\$200			CONMED_NA ME
③ CONMED_ST _DT	MMM- dd- yyyy			CONMED_ST _DT
④ CONMED_EN D_DT	MMM- dd- yyyy			CONMED_EN D_DT
⑤ CONMED_ON G	1			CONMED_ON G
⑥ CONMED_IN D	\$200			CONMED_IN D

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[Reviewer] What is the quality of the PFT?

- Exemplary Quality ①
- Adequate Quality
- Limited Quality
- Non- adequate Quality

[Reviewer] Do you agree with the data entered?

- Disagree ②
- Agree
- Uncertain

[Reviewer]Comments _____ ③

Was pulmonary function test/spirometry performed?

- No ④
- Yes
- Unknown

Instructions: If PFT performed/collected, provide the details below. If PFT was not performed/collected at registration, but will be done in the future, provide the reason and tentative date.If PFT was not performed/collected and will not be done in the future, provide the reason and leave rest of the form blank.
Note:If PFT was not collected as part of registration but will be done in the future, that PFT data should be entered into this PFT form.

Reason pulmonary function test/spirometry not performed

- Patient Refused ⑥
- Site error
- Equipment Unavailable
- Will be completed after registration
- Unknown
- Other, specify

Provide the tentative date the PFT will be completed _____ ⑦

Upload a de-identified copy of the PFT

8

Date of Spirometry

Fixed Unit: MMM dd yyyy

9

Indicate the timing of the PFT values provided on this page

Pre bronchodilator

10

Post bronchodilator
(preferred)

Unknown

FVC (L-BTPS)

Fixed Unit: actual

11

FVC

Fixed Unit: % predicted

12

FEV₁

Fixed Unit: actual

13

FEV₁

Fixed Unit: % predicted

14

FEV₁/FVC

Fixed Unit: actual

15

FEF 25-75%

Fixed Unit: actual

16

FEF 25-75%

Fixed Unit: predicted

17

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Was full pulmonary function test performed?

No 18
Yes
Unknown

If full pulmonary test was not done, the following questions are not required

If full pulmonary test was done, the following questions are required

Date of full pulmonary test	_____	20
D _{Lco}	_____ Fixed Unit: % of predicted	21
D _{Lco}	_____ Fixed Unit: actual	22
Total Lung Capacity	_____ Fixed Unit: % predicted	23
Total Lung Capacity	_____ Fixed Unit: actual	24
Residual Lung Volume	_____ Fixed Unit: % predicted	25
Residual Lung Volume	_____ Fixed Unit: actual	26
Derived Fev1/Fvc	_____	27

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms
Folder: Eligibility/Registration Visit
Form: Pulmonary Function Test/Spirometry
Generated On: 15 May 2019 14:40:46

Field Name	Data Type	Units	Values	Include Field OID
① RVW_QUALI TY	2		1 = Exemplary Quality 2 = Adequate Quality 3 = Limited Quality 4 = Non-adequate Quality	RVW_QUALI TY
② RVW_AGREE _DATA	2		1 = Disagree 2 = Agree 3 = Uncertain	RVW_AGREE _DATA
③ RVW_COMM	\$200			RVW_COMM
④ PFT_YN	2		1 = No 2 = Yes 99 = Unknown	PFT_YN
⑥ PFT_ND	2		1 = Patient Refused 2 = Site error 3 = Equipment Unavailable 4 = Will be completed after registration	PFT_ND

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms
Folder: Eligibility/Registration Visit
Form: Pulmonary Function Test/Spirometry
Generated On: 15 May 2019 14:40:46

Field Name	Data Type	Units	Values	Include Field OID
			99 = Unknown 88 = Other, specify	
7 PFT_TENT_D T	MMM dd yyyy			PFT_TENT_D T
8 PFT_FILE	\$200			PFT_FILE
9 PFT_DT	MMM dd yyyy			PFT_DT
10 PFT_PREPOS T	2		1 = Pre bronchodilato r 2 = Post bronchodilato r (preferred) 99 = Unknown	PFT_PREPOS T
11 FVC_RS	7.3			FVC_RS
12 FVC_RS_PER	7.3			FVC_RS_PER
13 FEV_RS	7.3			FEV_RS
14 FEV_RS_PER	7.3			FEV_RS_PER
15 FEV_FVC	7.3			FEV_FVC

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms
Folder: Eligibility/Registration Visit
Form: Pulmonary Function Test/Spirometry
Generated On: 15 May 2019 14:40:46

Field Name	Data Type	Units	Values	Include Field OID
16 FEF_2575_V AL	7.3			FEF_2575_V AL
17 FEF_2575_V AL_PER	7.3			FEF_2575_V AL_PER
18 FULL_PULM_2 TST_PRF_YN			1 = No 2 = Yes 99 = Unknown	FULL_PULM_ TST_PRF_YN
20 FULL_PULM_ TST_DT	MMM dd yyyy			FULL_PULM_ TST_DT
21 DLCO_RS	7.3			DLCO_RS
22 DLCO_ACT	7.3			DLCO_ACT
23 TOT_LUNG_ CAP_PR	7.3			TOT_LUNG_ CAP_PR
24 TOT_LUNG_ CAP	7.3			TOT_LUNG_ CAP
25 RES_LUN_VO L	7.3			RES_LUN_VO L
26 RES_LUNG_V OL	7.3			RES_LUNG_V OL

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms
Folder: Eligibility/Registration Visit
Form: Pulmonary Function Test/Spirometry
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Field Name	Data Type	Units	Values	Include Field OID
27 DER_FEV_FV 7.2 C				DER_FEV_FV C

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Date of CT Imaging

Fixed Unit: MMM dd yyyy

1

Indication/Reason for CT Imaging
check all that apply

Chronic Cough

3

Asbestos Exposure

4

Screening

5

Follow up of known nodules

6

Emphysema

7

Abnormal Pulmonary Function Test

8

Other, specify

9

Was IV contrast Administered?

No

Yes

10

Record amount of IV contrast injected

Fixed Unit: mL

11

CT Imaging Report

12

Provide the CT findings nodules Record one nodule/mass per log line

Slice Number _____ **14**

Anatomic location (lobe)

- 15** Right Upper Lobe
- Right Middle Lobe
- Right Lower Lobe
- Left Upper Lobe
- Lingula
- Left Lower Lobe
- Right Hilum
- Left Hilum
- Right Main Stem Bronchus
- Left Main Stem Bronchus
- Carina
- Mediastinum
- Unknown
- Other, specify _____

Size- Longest Diameter

Fixed Unit: mm **16**

Size- Perpendicular Diameter

Fixed Unit: mm **17**

Check if perpendicular diameter is not in the report

18

Margins

- 19** Spiculated (Stellate)
- Smooth
- Poorly Defined
- Not in Report
- Unknown

Predominant Attenuation

Soft Tissue 20

Ground Glass

Mixed (soft tissue and ground glass)

Fluid/water

Fat

Not in Report

Unknown

Other, specify

3 month enrollment day derivation

21

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Eligibility/Registration Visit

Form: CT Imaging

Generated On: 15 May 2019 14:40:46

Field Name	Data Type	Units	Values	Include Field OID
① CT_IMAG_ACMMM Q_DT	dd yyyy			CT_IMAG_AC Q_DT
③ INDCTN_CG H	1			INDCTN_CG H
④ INDCTN_ASB 1				INDCTN_ASB
⑤ INDCTN_SCR 1				INDCTN_SCR
⑥ INDCTN_FU_1 NOD				INDCTN_FU_ NOD
⑦ INDCTN_EMP 1				INDCTN_EMP
⑧ INDCTN_PFT 1				INDCTN_PFT
⑨ INDCTN_OT H	\$200			INDCTN_OT H
⑩ IV_CNTRST_1 ADMIN_YN			1 = No 2 = Yes	IV_CNTRST_ ADMIN_YN
⑪ IV_CNTRST_3 AMT				IV_CNTRST_ AMT
⑫ CT_IMAG_RP RT_DOC	\$200			CT_IMAG_RP RT_DOC

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Eligibility/Registration Visit

Form: CT Imaging

Generated On: 15 May 2019 14:40:46

Field Name	Data Type	Units	Values	Include Field OID
14 CT_SLICE_N UM				CT_SLICE_N UM
15 CT_ANT_LOC2 ATION			1 = Right Upper Lobe 2 = Right Middle Lobe 3 = Right Lower Lobe 4 = Left Upper Lobe 5 = Lingula 6 = Left Lower Lobe 7 = Right Hilum 8 = Left Hilum 9 = Right Main Stem Bronchus 10 = Left Main Stem Bronchus 11 = Carina 12 = Mediastinum 99 = Unknown 88 = Other, specify	CT_ANT_LOC ATION
16 CT_NOD_SIZ 6.2 E_LDIAM				CT_NOD_SIZ E_LDIAM
17 CT_NOD_SIZ 6.2 E_PDIAM				CT_NOD_SIZ E_PDIAM

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Folder: Eligibility/Registration Visit

Form: CT Imaging

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Field Name	Data Type	Units	Values	Include Field OID
18 CT_NOD_SZ _PDIAM_NRP T	1			CT_NOD_SZ _PDIAM_NRP T
19 CT_NOD_MA RGINS	2		1 = Spiculated (Stellate) 2 = Smooth 3 = Poorly Defined 4 = Not in Report 99 = Unknown	CT_NOD_MA RGINS
20 CT_NOD_AT TEN	2		1 = Soft Tissue 2 = Ground Glass 3 = Mixed (soft tissue and ground glass) 4 = Fluid/water 5 = Fat 6 = Not in Report 99 = Unknown 88 = Other, specify	CT_NOD_AT TEN
21 ENROL_DAY_dd DERV	MMM yyyy			ENROL_DAY_ DERV

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Indicate the imaging modality

- CT ①
- Dynamic contrast-enhanced CT
- PET
- MRI
- X-ray
- Other

Date of scan Fixed Unit: MMM dd yyyy ②

Date of Birth ③

Gender of a person Male ④
Female

Mode of image submission Images submitted via TRIAD ⑤
Electronic transfer via sFTP
Other, specify

Telephone # of Technologist ⑥

Email address of technologist at site ⑦

NOW Derivation ⑧

Age Derivation ⑨

Age on ITW Derivation ⑩

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Folder: Eligibility/Registration Visit
Form: Image Transmittal Worksheet
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Time Span Derivation

11

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms
Folder: Eligibility/Registration Visit
Form: Image Transmittal Worksheet
Generated On: 15 May 2019 14:40:46

Field Name	Data Type	Units	Values	Include Field OID
① IMAG_TYPE	2		1 = CT 2 = Dynamic contrast-enhanced CT 3 = PET 4 = MRI 5 = X-ray 88 = Other	IMAG_TYPE
② IMAG_ACQ_S CAN_COMPL _DT	dd yyyy			IMAG_ACQ_S CAN_COMPL _DT
③ YR_BRTH	MMM- dd- YYYY			YR_BRTH
④ GNDR_TP	1		1 = Male 2 = Female	GNDR_TP
⑤ MODE_IMAG _SUBM	2		1 = Images submitted via TRIAD 2 = Electronic transfer via sFTP 88 = Other, specify	MODE_IMAG _SUBM
⑥ PHONE_NUM	\$25			PHONE_NUM
⑦ EMAIL_ADDY	\$100			EMAIL_ADDY

Draft 25 version 1.0 MIGPROD 17JAN2018: All forms
 Folder: Eligibility/Registration Visit
 Form: Image Transmittal Worksheet
 Generated On: 15 May 2019 14:40:46

Field Name	Data Type	Units	Values	Include Field OID
8 NOW_DERV_YYYY YR				NOW_DERV_YYYY
9 DERV_AGE	3			DERV_AGE
10 DERV_AGE_I TW	3			DERV_AGE_I TW
11 DERV_TIME_4 SPN				DERV_TIME_4 SPN

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms
Folder: Eligibility/Registration Visit
Form: Images Received in Core Lab
Generated On: 15 May 2019 14:40:46

Record one imaging modality per form

Date of Imaging _____

Type of Images Received at Core Lab

- CT ③
- Dynamic contrast enhanced CT
- PET
- MRI
- X-ray
- Other

Date Images Initially Received in Core Lab _____ ④

Were images complete?

- No ⑤
- Yes

Date Complete Images Received at Core Lab _____ ⑥

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Eligibility/Registration Visit

Form: Images Received in Core Lab

Generated On: 15 May 2019 14:40:46

Field Name	Data Type	Units	Values	Include Field OID
② Image Acquisition Scan Complete Event Date PID2613966_V1_0	MMM dd yyyy			IMAG_DT
③ Image Received Type PID3436368_V1_0	2		1 = CT 2 = Dynamic contrast-enhanced CT 3 = PET 4 = MRI 5 = X-ray 88 = Other	IMAG_RCVD_ CLAB_TYPE
④ Image Initial Received Date PID3436462_V1_0	MMM dd yyyy			IMAG_INT_R CVD_CLAB_ DT
⑤ Image Received Complete No Yes Coded Indicator PID3436500_V1_0	2		1 = No 2 = Yes	IMAG_RCVD_ CLAB_COMP
⑥ Image Complete Received Date PID3436527_V1_0	MMM dd yyyy			IMAG_COMP _RCVD_CLAB _DT

FOR SOURCE SUBMISSION ONLY
NOT RECOMMENDED FOR SOURCE DOCUMENTATION

Date of Imaging _____ ①

Date of birth _____ Fixed Unit: MMM dd yyyy ②

Reconstruction Type _____ Filtered Backprojection ③
IR
FBP
Other, specify

CT Imaging Data Sets Submitted _____ ④

Slice Spacing of Data Set _____ Fixed Unit: mm ⑤

Slice Thickness of Data Set _____ Fixed Unit: mm ⑥

Collimator Thickness _____ Fixed Unit: mm ⑦

Check if collimator thickness is unknown _____ ⑧

kVp _____ ⑨

Check if kVp is unknown _____ ⑩

Provide the per slice/effective mAs value OR the mAs range

mAs - per slice/effective _____ ⑫

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mAs - range minimum _____ 13

mAs - range maximum _____ 14

Check if mAs is unknown _____ 15

DLP _____ 16

Check if DLP is unknown _____ 17

CTDIvol _____ 18

Check if CTDIvol is unknown _____ 19

Image quality _____ Exemplary Quality 20
Adequate Quality
Limited Quality
Non- adequate Quality

Check the reason(s) image is of limited or non-adequate quality _____

Image acquisition or processing error _____ 22

Incomplete or incorrect imaging protocol _____ 23

Motion-related artifact _____ 24

Patient artifact _____ 25

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Procedural artifact _____ 26

Image noise artifact _____ 27

Other, specify _____ 28

Were any imaging queries issued to the site No 29
Yes
Unknown

Comments _____ 30

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Field Name	Data Type	Units	Values	Include Field OID
① IMAGE_DT	MMM dd yyyy			IMAGE_DT
② YR_BRTH	MMM- dd- YYYY			DT_BRTH
③ RECONTRU_ TYPE			1 = Filtered Backprojectio n 2 = IR 3 = FBP 88 = Other, specify	RECONTRU_ TYPE
④ CT_IMG_DT_2 SETS			CT Imaging Data Sets	CT_IMG_DT_ SETS
⑤ SLC_SPCNG_ DT_SET	6.2			SLC_SPCNG_ DT_SET
⑥ SLC_THKNS_ DT_SET	6.2			SLC_THKNS_ DT_SET
⑦ CT_COL_THC K	6.3			CT_COL_THC K
⑧ CT_COL_THC K_UNK	1			CT_COL_THC K_UNK
⑨ KVP_MEAS	3			KVP_MEAS

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Field Name	Data Type	Units	Values	Include Field OID
10 KVP_MEAS_U1 NK				KVP_MEAS_U NK
12 MAS_SLICE_3 EFF				MAS_SLICE_ EFF
13 MAS_RANGE 3 _MIN				MAS_RANGE _MIN
14 MAS_RANGE 3 _MAX				MAS_RANGE _MAX
15 MAS_UNK 1				MAS_UNK
16 CT_DLP 6.2				CT_DLP
17 CT_DLP_UNK1				CT_DLP_UNK
18 CT_CTDI_VO 6.2 L				CT_CTDI_VO L
19 CT_CTDI_VO1 L_UNK				CT_CTDI_VO L_UNK
20 IMAG_QLTY 1			1 = Exemplary Quality 2 = Adequate Quality	IMAG_QLTY

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Field Name	Data Type	Units	Values	Include Field OID
			3 = Limited Quality 4 = Non- adequate Quality	
22 UNAC_QLTY_1 ACQPROC				UNAC_QLTY_ ACQPROC
23 UNAC_QLTY_1 PROT				UNAC_QLTY_ PROT
24 UNAC_QLTY_1 MOTION				UNAC_QLTY_ MOTION
25 UNAC_QLTY_1 PTART				UNAC_QLTY_ PTART
26 UNAC_QLTY_1 PROCART				UNAC_QLTY_ PROCART
27 UNAC_QLTY_1 NOSART				UNAC_QLTY_ NOSART
28 UNAC_QLTY_1 \$200 OTH				UNAC_QLTY_ OTH
29 QUERY_ISD_2 YN			1 = No 2 = Yes 99 = Unknown	QUERY_ISD_ YN

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Field Name	Data Type	Units	Values	Include Field OID
30 COMM	\$200			COMM

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1. - Indicate your current military status

Active Duty Military _____ ②

Retired Military _____ ③

Veteran _____ ④

Family member of Active Duty/Veteran _____ ⑤

Check if patient left Q1 blank _____ ⑥

2. - Have you ever been deployed?

No ⑦

Yes

Pt Left Field Blank

3. - If you have been deployed, please provide the location of deployment(s)

Check if patient left Q3 blank _____ ⑨

Deployment Country _____ ⑩

Length of Deployment _____ Fixed Unit: weeks ⑪

Length of Deployment _____ Fixed Unit: months ⑫

Length of Deployment _____ Fixed Unit: years ⑬

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Check if pt left deployment length blank

14

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Field Name	Data Type	Units	Values	Include Field OID
② MIL_STS_AC 1 TIVE				MIL_STS_AC TIVE
③ MIL_STS_RT11 RD				MIL_STS_RTI RD
④ MIL_STS_VE 1 T				MIL_STS_VE T
⑤ MIL_STS_FA 1 M				MIL_STS_FA M
⑥ MIL_STS_PT 1 BLANK				MIL_STS_PT BLANK
⑦ PT_COMPL_D2 PLY_YN			1 = No 2 = Yes 77 = Pt Left Field Blank	PT_COMPL_D PLY_YN
⑨ PT_COMPL_D1 PLY_PTBLAN K				PT_COMPL_D PLY_PTBLAN K
⑩ PT_COMPL_D\$5 PLY_CTRY			CNTRY_C_PI PT_COMPL_D D2018396_V PLY_CTRY 1_0_2	
⑪ PT_COMPL_D6.2 PLY_LGTH				PT_COMPL_D PLY_LGTH

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Field Name	Data Type	Units	Values	Include Field OID
12 PT_COMPL_D6.2 PLY_LGTH_M OS				PT_COMPL_D PLY_LGTH_M OS
13 PT_COMPL_D6.2 PLY_LGTH_Y RS				PT_COMPL_D PLY_LGTH_Y RS
14 DPLY_LGTN_1 BLNK				DPLY_LGTN_1 BLNK

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4. - Please check the occupations that you have ever worked

Check if patient left Q4 blank ②

③

Occupation Airline Industry (pilot, flight attendant, and/or flight crew) ④

If other, specify ⑤

Total Number of Months Worked Fixed Unit: months ⑥

Total Number of Years Worked Fixed Unit: years ⑦

Check if the pt left the total number of months/years blank ⑧

Did you wear a respirator? ⑨

No

Yes

Unknown

Pt Left Field Blank

③

Occupation Baking ④

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If other, specify _____

5

Total Number of Months Worked

Fixed Unit: months

6

Total Number of Years Worked

Fixed Unit: years

7

Check if the pt left the total number of months/years blank

8

Did you wear a respirator?

No

9

Yes

Unknown

Pt Left Field Blank

_____ 3

Occupation

Butchering/Meat Packing

4

If other, specify _____

5

Total Number of Months Worked

Fixed Unit: months

6

Total Number of Years Worked

Fixed Unit: years

7

Check if the pt left the total number of months/years blank

8

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Did you wear a respirator?

- No 9
- Yes
- Unknown
- Pt Left Field Blank

Occupation

- Chemical or plastics manufacturing 4

If other, specify

Total Number of Months Worked

Fixed Unit: months 6

Total Number of Years Worked

Fixed Unit: years 7

Check if the pt left the total number of months/years blank

Did you wear a respirator?

- No 9
- Yes
- Unknown
- Pt Left Field Blank

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Occupation Coal Mining 4

If other, specify _____ 5

Total Number of Months Worked Fixed Unit: months 6

Total Number of Years Worked Fixed Unit: years 7

Check if the pt left the total number of months/years blank 8

Did you wear a respirator? No 9
Yes
Unknown
Pt Left Field Blank

_____ 3

Occupation Cotton or jute processing 4

If other, specify _____ 5

Total Number of Months Worked Fixed Unit: months 6

Total Number of Years Worked Fixed Unit: years 7

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Check if the pt left the total number of months/years blank _____ ⑧

Did you wear a respirator? No ⑨
Yes
Unknown
Pt Left Field Blank

_____ ③

Occupation _____ Duty involving exposure to ionizing radiation ④

If other, specify _____ ⑤

Total Number of Months Worked _____ Fixed Unit: months ⑥

Total Number of Years Worked _____ Fixed Unit: years ⑦

Check if the pt left the total number of months/years blank _____ ⑧

Did you wear a respirator? No ⑨
Yes
Unknown
Pt Left Field Blank

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_____ ③

Occupation Farming ④

If other, specify _____ ⑤

Total Number of Months Worked Fixed Unit: months ⑥

Total Number of Years Worked Fixed Unit: years ⑦

Check if the pt left the total number of months/years blank _____ ⑧

Did you wear a respirator? No ⑨
Yes
Unknown
Pt Left Field Blank

_____ ③

Occupation Fire Fighting ④

If other, specify _____ ⑤

Total Number of Months Worked Fixed Unit: months ⑥

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Total Number of Years Worked

Fixed Unit: years

7

Check if the pt left the total number of months/years blank

8

Did you wear a respirator?

No

9

Yes

Unknown

Pt Left Field Blank

Occupation

Flour, feed, or grain milling

4

If other, specify

5

Total Number of Months Worked

Fixed Unit: months

6

Total Number of Years Worked

Fixed Unit: years

7

Check if the pt left the total number of months/years blank

8

Did you wear a respirator?

No

9

Yes

Unknown

Pt Left Field Blank

_____ ③

Occupation Foundry or steel milling ④

If other, specify _____ ⑤

Total Number of Months Worked Fixed Unit: months ⑥

Total Number of Years Worked Fixed Unit: years ⑦

Check if the pt left the total number of months/years blank _____ ⑧

Did you wear a respirator? No ⑨
Yes
Unknown
Pt Left Field Blank

_____ ③

Occupation Hard Rock Mining ④

If other, specify _____ ⑤

Total Number of Months Worked Fixed Unit: months ⑥

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Total Number of Years Worked

Fixed Unit: years

7

Check if the pt left the total number of months/years blank

8

Did you wear a respirator?

No

9

Yes

Unknown

Pt Left Field Blank

Occupation

Painting

4

If other, specify

5

Total Number of Months Worked

Fixed Unit: months

6

Total Number of Years Worked

Fixed Unit: years

7

Check if the pt left the total number of months/years blank

8

Did you wear a respirator?

No

9

Yes

Unknown

Pt Left Field Blank

_____ ③

Occupation Sandblasting ④

If other, specify _____ ⑤

Total Number of Months Worked Fixed Unit: months ⑥

Total Number of Years Worked Fixed Unit: years ⑦

Check if the pt left the total number of months/years blank _____ ⑧

Did you wear a respirator? No ⑨
Yes
Unknown
Pt Left Field Blank

_____ ③

Occupation Welding ④

If other, specify _____ ⑤

Total Number of Months Worked Fixed Unit: months ⑥

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Total Number of Years Worked

Fixed Unit: years

7

Check if the pt left the total number of months/years blank

8

Did you wear a respirator?

No

9

Yes

Unknown

Pt Left Field Blank

Occupation

Wood Working

4

If other, specify

5

Total Number of Months Worked

Fixed Unit: months

6

Total Number of Years Worked

Fixed Unit: years

7

Check if the pt left the total number of months/years blank

8

Did you wear a respirator?

No

9

Yes

Unknown

Pt Left Field Blank

_____ ③

Occupation _____ Other, specify _____ ④

If other, specify _____ ⑤

Total Number of Months Worked _____ Fixed Unit: months ⑥

Total Number of Years Worked _____ Fixed Unit: years ⑦

Check if the pt left the total number of months/years blank _____ ⑧

Did you wear a respirator? No ⑨
Yes
Unknown
Pt Left Field Blank

_____ ③

Occupation _____ None of the above _____ ④

If other, specify _____ ⑤

Total Number of Months Worked _____ Fixed Unit: months ⑥

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Total Number of Years Worked _____

Fixed Unit: years **7**

Check if the pt left the total number of months/years blank _____

8

Did you wear a respirator?

No **9**

Yes

Unknown

Pt Left Field Blank

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② PT_COMPL_O1 CC_PTBLANK				PT_COMPL_O CC_PTBLANK
③ PT_COMPL_ 1 WRK_GRTR_ 1YR				PT_COMPL_ WRK_GRTR_ 1YR
④ PT_COMPL_O2 CC			Occupations	PT_COMPL_O CC
⑤ OCC_OTH_S \$200 PEC				OCC_OTH_S REC
⑥ PT_COMPL_N6.2 UM_MOS_W RK				PT_COMPL_N UM_MOS_W RK
⑦ PT_COMPL_N6.2 UM_YRS_WR K				PT_COMPL_N UM_YRS_WR K
⑧ PT_COMPL_O1 CC_TM_BLN K				PT_COMPL_O CC_TM_BLN K
⑨ PT_COMPL_ 2 WEAR_RESP			1 = No 2 = Yes 88 = Unknown 77 = Pt Left Field Blank	PT_COMPL_ WEAR_RESP

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5. - Please any occupational exposure that you may have had

Check if patient left Q5 blank

Occupation Asbestos

If other, specify _____

Number of Months Exposed _____ Fixed Unit: months

Number of Years Exposed _____ Fixed Unit: years

Check if the pt left the total number of months/ years blank

Indicate the amount of exposure you had
Continuously
Regularly
Occasionally
Pt Left Field Blank

Indicate the effect of the exposure
Not Noticeable
Mild
Moderate
Severe
Pt Left Field Blank

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_____ **3**

Occupation _____ Burn Pits **4**

If other, specify _____ **5**

Number of Months Exposed _____ Fixed Unit: months **6**

Number of Years Exposed _____ Fixed Unit: years **7**

Check if the pt left the total number of months/ years blank _____ **8**

Indicate the amount of exposure you had _____ **9**
Continuously
Regularly
Occasionally
Pt Left Field Blank

Indicate the effect of the exposure _____ **10**
Not Noticeable
Mild
Moderate
Severe
Pt Left Field Blank

_____ **3**

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Occupation

Chemicals/Acids/Solvents 4

If other, specify

Number of Months Exposed

Fixed Unit: months 6

Number of Years Exposed

Fixed Unit: years 7

Check if the pt left the total number of months/ years blank

Indicate the amount of exposure you had

Continuously 9
Regularly
Occasionally
Pt Left Field Blank

Indicate the effect of the exposure

Not Noticeable 10
Mild
Moderate
Severe
Pt Left Field Blank

Occupation

Coal Tar/Asphalt 4

If other, specify _____ 5

Number of Months Exposed _____ Fixed Unit: months 6

Number of Years Exposed _____ Fixed Unit: years 7

Check if the pt left the total number of months/ years blank _____ 8

Indicate the amount of exposure you had _____
Continuously 9
Regularly
Occasionally
Pt Left Field Blank

Indicate the effect of the exposure _____
Not Noticeable 10
Mild
Moderate
Severe
Pt Left Field Blank

_____ 3

Occupation _____ Diesel Engine Exhaust 4

If other, specify _____ 5

Number of Months Exposed _____ Fixed Unit: months 6

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Number of Years Exposed

Fixed Unit: years

7

Check if the pt left the total number of months/ years blank

8

Indicate the amount of exposure you had

Continuously

9

Regularly

Occasionally

Pt Left Field Blank

Indicate the effect of the exposure

Not Noticeable

10

Mild

Moderate

Severe

Pt Left Field Blank

Occupation

Dyes

4

If other, specify

5

Number of Months Exposed

Fixed Unit: months

6

Number of Years Exposed

Fixed Unit: years

7

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Check if the pt left the total number of months/ years blank _____ (8)

Indicate the amount of exposure you had _____

Continuously (9)
Regularly
Occasionally
Pt Left Field Blank

Indicate the effect of the exposure _____

Not Noticeable (10)
Mild
Moderate
Severe
Pt Left Field Blank

_____ (3)

Occupation _____ Explosives (4)

If other, specify _____ (5)

Number of Months Exposed _____ Fixed Unit: months (6)

Number of Years Exposed _____ Fixed Unit: years (7)

Check if the pt left the total number of months/ years blank _____ (8)

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Indicate the amount of exposure you had

- Continuously 9
- Regularly
- Occasionally
- Pt Left Field Blank

Indicate the effect of the exposure

- Not Noticeable 10
- Mild
- Moderate
- Severe
- Pt Left Field Blank

Occupation

Formaldehyde 4

If other, specify

5

Number of Months Exposed

Fixed Unit: months 6

Number of Years Exposed

Fixed Unit: years 7

Check if the pt left the total number of months/ years blank

8

Indicate the amount of exposure you had

- Continuously 9
- Regularly
- Occasionally

Pt Left Field Blank

Indicate the effect of the exposure

Not Noticeable 10

Mild

Moderate

Severe

Pt Left Field Blank

3

Occupation

Gasoline Exhaust 4

If other, specify

5

Number of Months Exposed

Fixed Unit: months 6

Number of Years Exposed

Fixed Unit: years 7

Check if the pt left the total number of months/ years blank

8

Indicate the amount of exposure you had

Continuously 9

Regularly

Occasionally

Pt Left Field Blank

Indicate the effect of the exposure

- Not Noticeable 10
- Mild
- Moderate
- Severe
- Pt Left Field Blank

Occupation

Jet Fuel 4

If other, specify

5

Number of Months Exposed

Fixed Unit: months 6

Number of Years Exposed

Fixed Unit: years 7

Check if the pt left the total number of months/ years blank

8

Indicate the amount of exposure you had

- Continuously 9
- Regularly
- Occasionally
- Pt Left Field Blank

Indicate the effect of the exposure

- Not Noticeable 10
- Mild
- Moderate

Severe
Pt Left Field Blank

3

Occupation

Pesticides/Herbicides (agent orange) 4

If other, specify

5

Number of Months Exposed

Fixed Unit: months 6

Number of Years Exposed

Fixed Unit: years 7

Check if the pt left the total number of months/ years blank

8

Indicate the amount of exposure you had

Continuously 9
Regularly
Occasionally
Pt Left Field Blank

Indicate the effect of the exposure

Not Noticeable 10
Mild
Moderate
Severe
Pt Left Field Blank

3

Occupation _____ Radioactive Materials _____

4

If other, specify _____

5

Number of Months Exposed _____ Fixed Unit: months _____

6

Number of Years Exposed _____ Fixed Unit: years _____

7

Check if the pt left the total number of months/ years blank _____

8

Indicate the amount of exposure you had

Continuously 9
Regularly
Occasionally
Pt Left Field Blank

Indicate the effect of the exposure

Not Noticeable 10
Mild
Moderate
Severe
Pt Left Field Blank

3

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Occupation

Sandstorms 4

If other, specify _____

Number of Months Exposed

Fixed Unit: months 6

Number of Years Exposed

Fixed Unit: years 7

Check if the pt left the total number of months/ years blank

Indicate the amount of exposure you had

- Continuously 9
- Regularly
- Occasionaly
- Pt Left Field Blank

Indicate the effect of the exposure

- Not Noticeable 10
- Mild
- Moderate
- Severe
- Pt Left Field Blank

Occupation

Smoke 4

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If other, specify _____ 5

Number of Months Exposed _____ Fixed Unit: months 6

Number of Years Exposed _____ Fixed Unit: years 7

Check if the pt left the total number of months/ years blank _____ 8

Indicate the amount of exposure you had _____
Continuously 9
Regularly
Occasionally
Pt Left Field Blank

Indicate the effect of the exposure _____
Not Noticeable 10
Mild
Moderate
Severe
Pt Left Field Blank

_____ 3

Occupation _____ Textile Fibers/Dust 4

If other, specify _____ 5

Number of Months Exposed _____ Fixed Unit: months 6

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Number of Years Exposed

Fixed Unit: years

7

Check if the pt left the total number of months/ years blank

8

Indicate the amount of exposure you had

Continuously

9

Regularly

Occasionally

Pt Left Field Blank

Indicate the effect of the exposure

Not Noticeable

10

Mild

Moderate

Severe

Pt Left Field Blank

Occupation

Well Water

4

If other, specify

5

Number of Months Exposed

Fixed Unit: months

6

Number of Years Exposed

Fixed Unit: years

7

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Check if the pt left the total number of months/ years blank _____ **8**

Indicate the amount of exposure you had _____

Continuously **9**
Regularly
Occasionally
Pt Left Field Blank

Indicate the effect of the exposure _____

Not Noticeable **10**
Mild
Moderate
Severe
Pt Left Field Blank

_____ **3**

Occupation _____ Wood Dust **4**

If other, specify _____ **5**

Number of Months Exposed _____ Fixed Unit: months **6**

Number of Years Exposed _____ Fixed Unit: years **7**

Check if the pt left the total number of months/ years blank _____ **8**

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Indicate the amount of exposure you had

- Continuously 9
- Regularly
- Occasionally
- Pt Left Field Blank

Indicate the effect of the exposure

- Not Noticeable 10
- Mild
- Moderate
- Severe
- Pt Left Field Blank

Occupation

Other, specify 4

If other, specify

5

Number of Months Exposed

Fixed Unit: months 6

Number of Years Exposed

Fixed Unit: years 7

Check if the pt left the total number of months/ years blank

8

Indicate the amount of exposure you had

- Continuously 9
- Regularly
- Occasionally

Pt Left Field Blank

Indicate the effect of the exposure

Not Noticeable 10

Mild

Moderate

Severe

Pt Left Field Blank

3

Occupation

None of the above 4

If other, specify

5

Number of Months Exposed

Fixed Unit: months 6

Number of Years Exposed

Fixed Unit: years 7

Check if the pt left the total number of months/ years blank

8

Indicate the amount of exposure you had

Continuously 9

Regularly

Occasionally

Pt Left Field Blank

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Indicate the effect of the exposure

- Not Noticeable 10
 - Mild
 - Moderate
 - Severe
 - Pt Left Field Blank
-

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Field Name	Data Type	Units	Values	Include Field OID
② PT_COMPL_O1 CCE_PTBLAN K				PT_COMPL_O CCE_PTBLAN K
③ PT_COMPL_ WRK_GRTR_ 1YR				PT_COMPL_ WRK_GRTR_ 1YR
④ PT_COMPL_O2 CC_EXP			Occupational Exposure	PT_COMPL_O CC_EXP
⑤ OCC_EXP_OT\$200 H_SPEC				OCC_EXP_OT H_SPEC
⑥ PT_COMPL_N6.2 UM_MOS_EX P				PT_COMPL_N UM_MOS_EX P
⑦ PT_COMPL_N6.2 UM_YRS_EXP				PT_COMPL_N UM_YRS_EXP
⑧ PT_COMPL_E1 XP_TM_BLNK				PT_COMPL_E XP_TM_BLNK
⑨ PT_COMPL_L2 GTH_EXP			1 = Continuously 2 = Regularly 3 = Occasionally 77 = Pt Left Field Blank	PT_COMPL_L GTH_EXP

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Field Name	Data Type	Units	Values	Include Field OID
⑩ PT_COMPL_E XP_EFF			1 = Not Noticeable 2 = Mild 3 = Moderate 4 = Severe 77 = Pt Left Field Blank	PT_COMPL_E XP_EFF

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6. - What is your current weight?

Fixed Unit: lbs

1

Check if pt left Q6 blank

2

7. - How tall are you?

Fixed Unit: feet

4

Fixed Unit: inches

5

Check if pt left Q7 blank

6

8. - Please check if your doctor has every told you that you have the listed conditions or illnesses

Check if pt left Q8 blank

8

NOW Derivation

13

Age Derivation

14

Conditions, Illnesses

Asbestosis

10

If checked, provide your age when the doctor first told you that you had this illness

Fixed Unit: years old **11**

Check if the pt left the age blank

12

Conditions, Illnesses

Asthma - first diagnosed as a child **10**

If checked, provide your age when the doctor first told you that you had this illness

Fixed Unit: years old **11**

Check if the pt left the age blank

12

Conditions, Illnesses

Asthma - first diagnosed as an adult **10**

If checked, provide your age when the doctor first told you that you had this illness

Fixed Unit: years old **11**

Check if the pt left the age blank

12

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_____ 9

Conditions, Illnesses Bronchiectasis 10

If checked, provide your age when the doctor first told you that you had this illness Fixed Unit: years old 11

Check if the pt left the age blank 12

_____ 9

Conditions, Illnesses Chronic Bronchitis 10

If checked, provide your age when the doctor first told you that you had this illness Fixed Unit: years old 11

Check if the pt left the age blank 12

_____ 9

Conditions, Illnesses Chronic Obstructive Pulmonary Disease 10

If checked, provide your age when the doctor first told you that you had this illness Fixed Unit: years old 11

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Check if the pt left the age blank

12

Conditions, Illnesses

Diabetes

10

If checked, provide your age when the doctor first told you that you had this illness

Fixed Unit: years old

11

Check if the pt left the age blank

12

Conditions, Illnesses

Emphysema

10

If checked, provide your age when the doctor first told you that you had this illness

Fixed Unit: years old

11

Check if the pt left the age blank

12

Conditions, Illnesses

Fibrosis of the Lung

10

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If checked, provide your age when the doctor first told you that you had this illness

Fixed Unit: years old **11**

Check if the pt left the age blank

12

Conditions, Illnesses

Heart Disease or Heart Attack **10**

If checked, provide your age when the doctor first told you that you had this illness

Fixed Unit: years old **11**

Check if the pt left the age blank

12

Conditions, Illnesses

High Blood Pressure (Hypertension) **10**

If checked, provide your age when the doctor first told you that you had this illness

Fixed Unit: years old **11**

Check if the pt left the age blank

12

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Conditions, Illnesses

HIV infection

9

10

If checked, provide your age when the doctor first told you that you had this illness

Fixed Unit: years old

11

Check if the pt left the age blank

12

Conditions, Illnesses

Hodgkins Disease

9

10

If checked, provide your age when the doctor first told you that you had this illness

Fixed Unit: years old

11

Check if the pt left the age blank

12

Conditions, Illnesses

Pneumonia

9

10

If checked, provide your age when the doctor first told you that you had this illness

Fixed Unit: years old

11

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Check if the pt left the age blank

12

Conditions, Illnesses

Sarcoidosis

10

If checked, provide your age when the doctor first told you that you had this illness

Fixed Unit: years old

11

Check if the pt left the age blank

12

Conditions, Illnesses

Silicosis

10

If checked, provide your age when the doctor first told you that you had this illness

Fixed Unit: years old

11

Check if the pt left the age blank

12

Conditions, Illnesses

Stroke

10

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If checked, provide your age when the doctor first told you that you had this illness

Fixed Unit: years old **11**

Check if the pt left the age blank

12

Conditions, Illnesses

Tuberculosis (TB) **10**

If checked, provide your age when the doctor first told you that you had this illness

Fixed Unit: years old **11**

Check if the pt left the age blank

12

Conditions, Illnesses

None of the above **10**

If checked, provide your age when the doctor first told you that you had this illness

Fixed Unit: years old **11**

Check if the pt left the age blank

12

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Field Name	Data Type	Units	Values	Include Field OID
① PT_COMPL_3 WT				PT_COMPL_3 WT
② PT_COMPL_1 WT_PTBLAN K				PT_COMPL_1 WT_PTBLAN K
④ PT_COMPL_H1 T_FEET				PT_COMPL_H1 T_FEET
⑤ PT_COMPL_H2 T_INCH				PT_COMPL_H2 T_INCH
⑥ PT_COMPL_H1 T_PTBLANK				PT_COMPL_H1 T_PTBLANK
⑧ PT_COMPL_D1 X_PTBLK				PT_COMPL_D1 X_PTBLK
⑨ PT_COMPL_D1 X				PT_COMPL_D1 X
⑩ COND_ILI 2			Conditions, Illnesses	PT_REP_CON D_ILL
⑪ PT_REP_AGE 3 _FST_DX				PT_REP_AGE _FST_DX
⑫ PT_COMPL_A1 GE_BLNK				PT_COMPL_A1 GE_BLNK

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms
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Form: Pt Questionnaire: Medical History- Conditions and Illnesses
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Field Name	Data Type	Units	Values	Include Field OID
13 NOW_DERV_YYYY YR				NOW_DERV_ YR
14 DERV_AGE	3			DERV_AGE

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9. - Have any of the following blood relatives ever had lung cancer?

Father

No ②
Yes
Unknown
Not Applicable
Pt Left Field Blank

Mother

No ③
Yes
Unknown
Not Applicable
Pt Left Field Blank

Brother(s), including half brothers

No ④
Yes
Unknown
Not Applicable
Pt Left Field Blank

Sister(s), including half sisters

No ⑤
Yes
Unknown
Not Applicable
Pt Left Field Blank

Children (biological)

No ⑥
Yes
Unknown

Not Applicable
Pt Left Field Blank

10. - Please check if your doctor has every told you that you have any of the cancers listed below

Check if pt left Q10 blank _____ 8

NOW Derivation _____ 14

Age Derivation _____ 15

_____ 9

Cancer _____ Bladder Cancer 10

If other, specify _____ 11

If checked, provide age at first diagnosis _____ Fixed Unit: years old 12

Check if the pt left the age blank _____ 13

_____ 9

Cancer _____ Breast Cancer 10

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NOT RECOMMENDED FOR SOURCE DOCUMENTATION

If other, specify _____

11

If checked, provide age at first diagnosis

Fixed Unit: years old

12

Check if the pt left the age blank

13

Cancer

Cervical cancer

10

If other, specify _____

11

If checked, provide age at first diagnosis

Fixed Unit: years old

12

Check if the pt left the age blank

13

Cancer

Colon-Rectal Cancer

10

If other, specify _____

11

If checked, provide age at first diagnosis

Fixed Unit: years old

12

Check if the pt left the age blank

13

Cancer

Esophageal Cancer

10

If other, specify

11

If checked, provide age at first diagnosis

Fixed Unit: years old

12

Check if the pt left the age blank

13

Cancer

Kidney Cancer

10

If other, specify

11

If checked, provide age at first diagnosis

Fixed Unit: years old

12

Check if the pt left the age blank

13

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NOT RECOMMENDED FOR SOURCE DOCUMENTATION

Cancer Larynx Cancer 10

If other, specify _____ 11

If checked, provide age at first diagnosis Fixed Unit: years old 12

Check if the pt left the age blank _____ 13

Cancer Lung cancer 10

If other, specify _____ 11

If checked, provide age at first diagnosis Fixed Unit: years old 12

Check if the pt left the age blank _____ 13

Cancer Mouth (Oral) Cancer 10

If other, specify _____ 11

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If checked, provide age at first diagnosis

Fixed Unit: years old **12**

Check if the pt left the age blank

Cancer

Nasal Cancer **10**

If other, specify

If checked, provide age at first diagnosis

Fixed Unit: years old **12**

Check if the pt left the age blank

Cancer

Pancreatic Cancer **10**

If other, specify

If checked, provide age at first diagnosis

Fixed Unit: years old **12**

Check if the pt left the age blank

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NOT RECOMMENDED FOR SOURCE DOCUMENTATION

_____ 9

Cancer Pharynx Cancer 10

If other, specify _____ 11

If checked, provide age at first diagnosis Fixed Unit: years old 12

Check if the pt left the age blank _____ 13

_____ 9

Cancer Stomach (Gastric) Cancer 10

If other, specify _____ 11

If checked, provide age at first diagnosis Fixed Unit: years old 12

Check if the pt left the age blank _____ 13

_____ 9

Cancer Thyroid Cancer 10

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NOT RECOMMENDED FOR SOURCE DOCUMENTATION

If other, specify _____

11

If checked, provide age at first diagnosis

Fixed Unit: years old

12

Check if the pt left the age blank

13

Cancer

Transition Cell Cancer

10

If other, specify _____

11

If checked, provide age at first diagnosis

Fixed Unit: years old

12

Check if the pt left the age blank

13

Cancer

Other Cancer, Specify

10

If other, specify _____

11

If checked, provide age at first diagnosis

Fixed Unit: years old

12

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NOT RECOMMENDED FOR SOURCE DOCUMENTATION

Check if the pt left the age blank

13

Cancer

Never diagnosed with cancer

10

If other, specify

11

If checked, provide age at first diagnosis

Fixed Unit: years old

12

Check if the pt left the age blank

13

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Field Name	Data Type	Units	Values	Include Field OID
② PT_REP_FAM2 _CX_FAT			1 = No 2 = Yes 99 = Unknown 98 = Not Applicable 77 = Pt Left Field Blank	PT_REP_FAM _CX_FAT
③ PT_REP_FAM2 _CX_MOT			1 = No 2 = Yes 99 = Unknown 98 = Not Applicable 77 = Pt Left Field Blank	PT_REP_FAM _CX_MOT
④ PT_REP_FAM2 _CX_BRO			1 = No 2 = Yes 99 = Unknown 98 = Not Applicable 77 = Pt Left Field Blank	PT_REP_FAM _CX_BRO
⑤ PT_REP_FAM2 _CX_SIS			1 = No 2 = Yes 99 = Unknown 98 = Not Applicable 77 = Pt Left Field Blank	PT_REP_FAM _CX_SIS

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms
Folder: Patient Completed Questionnaire
Form: Pt Questionnaire: Medical History- Cancer
Generated On: 15 May 2019 14:40:46

Field Name	Data Type	Units	Values	Include Field OID
⑥ PT_REP_FAM 2 _CX_CHILD			1 = No 2 = Yes 99 = Unknown 98 = Not Applicable 77 = Pt Left Field Blank	PT_REP_FAM _CX_CHILD
⑧ PT_COMPL_C1 X_PTBLK				PT_COMPL_C X_PTBLK
⑨ PT_COMPL_D1 X				PT_COMPL_D X
⑩ PT_REP_CX 2			Cancer	PT_REP_CX
⑪ CX_OTH_SPE \$200 C				CX_OTH_SPE C
⑫ PT_REP_AGE 3 _FST_DX				PT_REP_AGE _FST_DX
⑬ PT_CX_AGE_1 BLNK				PT_CX_AGE_ BLNK
⑭ NOW_DERV_YYYY YR				NOW_DERV_ YR
⑮ DERV_AGE 3				DERV_AGE

FOR SITE IRB SUBMISSION ONLY
NOT RECOMMENDED FOR SOURCE DOCUMENTATION

Symptom History: Cough

11. - Do you usually have a cough? No ②
Yes
Unknown
Pt Left Field Blank

12. - Do you usually cough as much as 4-6 times a day, 4 or more days out of the week? No ③
Yes
Unknown
Pt Left Field Blank

13. - Do you usually cough at all upon getting up, or first thing in the morning? No ④
Yes
Unknown
Pt Left Field Blank

14. - Do you usually cough at all during the rest of the day or night? No ⑤
Yes
Unknown
Pt Left Field Blank

15. - Do you usually cough like this on most days for 3 consecutive months or more during the year? No ⑥
Yes
Unknown
Pt Left Field Blank

16. - For how many years have you had this cough? Fixed Unit: years ⑦

Check if pt left Q16 blank _____

8

Symptom History: Shortness of Breath

17. - Are you troubled by shortness of breath when hurrying on level ground or walking up a slight hill?

- No
- Yes
- Unknown
- Pt Left Field Blank

10

18. - Do you have to walk slower than people of your age on level ground because of breathlessness?

- No
- Yes
- Unknown
- Pt Left Field Blank

11

19. - Do you ever have to stop for breath after walking about 100 yards (or after a few minutes) on level ground?

- No
- Yes
- Unknown
- Pt Left Field Blank

12

20. - Are you too breathless to leave the house or do you get breathless upon dressing or undressing?

- No
- Yes
- Unknown
- Pt Left Field Blank

13

21. - For how many years have you experienced shortness of breath?

Fixed Unit: years

14

Check if pt left Q21 blank _____

15

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Patient Completed Questionnaire

Form: Pt Questionnaire: Symptom History: Cough, Shortness of Breath, Exacerbations

Generated On: 15 May 2019 14:40:46

Symptom History: Exacerbations

22. - Over the past year, how many times did you require treatment with oral steroids and/or antibiotics for a COPD exacerbation (defined as an increase in dyspnea, sputum production or sputum purulence)?

Fixed Unit: times **17**

Check if pt left Q22 blank

18

23. - Over the past year, how many of these COPD exacerbations required admission to the hospital?

Fixed Unit: admissions to hospital caused by COPD exacerbations **19**

Check if pt left Q23 blank

20

Now Derivation

21

Age Derivation

22

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Patient Completed Questionnaire

Form: Pt Questionnaire: Symptom History: Cough, Shortness of Breath, Exacerbations

Generated On: 15 May 2019 14:40:46

Field Name	Data Type	Units	Values	Include Field OID
② PT_COMPL_C2 GH			1 = No 2 = Yes 88 = Unknown 77 = Pt Left Field Blank	PT_COMPL_C GH
③ PT_COMPL_C2 GH_4_6_YN U			1 = No 2 = Yes 88 = Unknown 77 = Pt Left Field Blank	PT_COMPL_C GH_4_6_YN U
④ PT_COMPL_C2 GH_MORN_Y N			1 = No 2 = Yes 88 = Unknown 77 = Pt Left Field Blank	PT_COMPL_C GH_MORN_Y N
⑤ PT_COMPL_C2 GH_DY_NT_ YN			1 = No 2 = Yes 88 = Unknown 77 = Pt Left Field Blank	PT_COMPL_C GH_DY_NT_ YN
⑥ PT_COMPL_C2 GH_3MOS_Y N			1 = No 2 = Yes 88 = Unknown 77 = Pt Left Field Blank	PT_COMPL_C GH_3MOS_Y N

Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Patient Completed Questionnaire

Form: Pt Questionnaire: Symptom History: Cough, Shortness of Breath, Exacerbations

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Field Name	Data Type	Units	Values	Include Field OID
7 PT_COMPL_C6.2 GH_YRS				PT_COMPL_C GH_YRS
8 CGH_YRS_PT1 BLANK				CGH_YRS_PT BLANK
10 PT_COMPL_S2 BRTH_YN			1 = No 2 = Yes 88 = Unknown 77 = Pt Left Field Blank	PT_COMPL_S BRTH_YN
11 PT_COMPL_S2 BRHT_WSLW _YN			1 = No 2 = Yes 88 = Unknown 77 = Pt Left Field Blank	PT_COMPL_S BRHT_WSLW _YN
12 PT_COMPL_S2 BRTH_100YD S_YN			1 = No 2 = Yes 88 = Unknown 77 = Pt Left Field Blank	PT_COMPL_S BRTH_100YD S_YN
13 PT_COMPL_S2 BRTH_HS_Y N			1 = No 2 = Yes 88 = Unknown 77 = Pt Left Field Blank	PT_COMPL_S BRTH_HS_Y N

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Patient Completed Questionnaire

Form: Pt Questionnaire: Symptom History: Cough, Shortness of Breath, Exacerbations

Generated On: 15 May 2019 14:40:46

	Field Name	Data Type	Units	Values	Include Field OID
14	PT_COMPL_S BRTH_YRS	6.2			PT_COMPL_S BRTH_YRS
15	SBRTH_YRS_1 PTBLNK				SBRTH_YRS_ PTBLNK
17	PT_COMPL_C3 OPD_EX				PT_COMPL_C OPD_EX
18	COPD_EX_PT1 BLNK				COPD_EX_PT BLNK
19	PT_COMPL_C3 OPD_EX_HO S				PT_COMPL_C OPD_EX_HO S
20	COPD_EX_H 1 OS				COPD_EX_H OS
21	NOW_DERV_YYYY YR				NOW_DERV_ YR
22	DERV_AGE 3				DERV_AGE

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Symptom History: Phlegm

24. - Do you usually bring up phlegm from your chest

- No ②
Yes
Unknown
Pt Left Field Blank

24a. - Do you usually bring up phlegm like this as much as twice a day, 4 or more days out of the week?

- No ③
Yes
Unknown
Pt Left Field Blank

25. - Do you usually bring up phlegm at all on getting up, or first thing in the morning?

- No ④
Yes
Unknown
Pt Left Field Blank

26. - Do you usually bring up phlegm at all during the rest of the day or at night?

- No ⑤
Yes
Unknown
Pt Left Field Blank

If yes to any of the above (Q24, Q24a, Q25, Q26), answer the following two questions; if no to all, skip to the next section

27. - Do you bring up phlegm like this on most days for 3 consecutive months or more during the year?

- No ⑦
Yes
Unknown
Pt Left Field Blank
-
-

28. - For how many years have you had trouble with phlegm?

Fixed Unit: years

8

Check if pt left Q28 blank

9

General Alcohol History

29. - Have you ever consumed alcoholic beverages?

No

11

Yes

Unknown

Pt Left Field Blank

30. - Do you presently drink alcoholic beverages?

No

12

Yes

Unknown

Pt Left Field Blank

31. - How long has it been since you last had an alcoholic drink (wine, beer, liquor)?

Less than 1 year

13

1 year to 2 years

More than 3 years

Pt Left Field Blank

32. - For how many years did you drink alcoholic beverages?

Fixed Unit: years

14

Check if pt left Q32 blank

15

33. - What was the usual number of drinks you had per week? (one drink means 1 beer or 1 glass or wine or 1 shot of liquor, record 0 if less than 1 drink per week)

Fixed Unit: per week

16

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Folder: Patient Completed Questionnaire

Form: Pt Questionnaire: Symptom History:Phlegm and Alcohol History

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Check if pt left Q33 blank

17

34. - During the past 24 hours, how many drinks have you had?

Fixed Unit: within last 24 hours

18

Check if pt left Q34 blank

19

35. - Provide your average alcohol consumption

Check if pt left Q35 blank

21

Fixed Unit: drinks per week

22

Fixed Unit: drinks in the last year

23

Fixed Unit: drinks in the last 3 years

24

Year Derivation

25

Age Derivation

26

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Folder: Patient Completed Questionnaire

Form: Pt Questionnaire: Symptom History:Phlegm and Alcohol History

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Field Name	Data Type	Units	Values	Include Field OID
② PT_COMPL_P2 HL_CH_YN			1 = No 2 = Yes 88 = Unknown 77 = Pt Left Field Blank	PT_COMPL_P HL_CH_YN
③ PT_COMPL_P2 HL_OCC			1 = No 2 = Yes 88 = Unknown 77 = Pt Left Field Blank	PT_COMPL_P HL_OCC
④ PT_COMPL_P2 HL_MORN			1 = No 2 = Yes 88 = Unknown 77 = Pt Left Field Blank	PT_COMPL_P HL_MORN
⑤ PT_COMPL_P2 HL_NGT			1 = No 2 = Yes 88 = Unknown 77 = Pt Left Field Blank	PT_COMPL_P HL_NGT
⑦ PT_COMPL_P2 HL_MOS			1 = No 2 = Yes 88 = Unknown 77 = Pt Left Field Blank	PT_COMPL_P HL_MOS

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Patient Completed Questionnaire

Form: Pt Questionnaire: Symptom History:Phlegm and Alcohol History

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Field Name	Data Type	Units	Values	Include Field OID
8 PT_COMPL_P 6.2 HL_YRS				PT_COMPL_P HL_YRS
9 PHL_YRS_PT 1 BLNK				PHL_YRS_PT BLNK
11 PT_COMPL_A2 LC_HX_YN			1 = No 2 = Yes 88 = Unknown 77 = Pt Left Field Blank	PT_COMPL_A LC_HX_YN
12 PT_COMPL_A2 LC_CUR_YN			1 = No 2 = Yes 88 = Unknown 77 = Pt Left Field Blank	PT_COMPL_A LC_CUR_YN
13 PT_COMPL_A2 LC_HX_FRMR			1 = Less than 1 year 2 = 1 year to 2 years 3 = More than 3 years 77 = Pt Left Field Blank	PT_COMPL_A LC_HX_FRMR
14 PT_COMPL_A 6.2 LC_YRS				PT_COMPL_A LC_YRS
15 ALC_YRS_PT 1 BLNK				ALC_YRS_PT BLNK

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Patient Completed Questionnaire

Form: Pt Questionnaire: Symptom History:Phlegm and Alcohol History

Generated On: 15 May 2019 14:40:46

Field Name	Data Type	Units	Values	Include Field OID
16 PT_COMPL_D6.2 RNK_WK				PT_COMPL_D RNK_WK
17 DRNK_WK_P 1 TBNLK				DRNK_WK_P TBNLK
18 PT_COMPL_2 4 4HR_ALC_NU M				PT_COMPL_2 4HR_ALC_NU M
19 H24R_ALC_N1 UM_PTBLNK				H24R_ALC_N UM_PTBLNK
21 ALC_WK_YR 1 _PTBLNK				ALC_WK_YR _PTBLNK
22 PT_COMPL_A6.2 LC_WK				PT_COMPL_A LC_WK
23 PT_COMPL_A62 LC_LST_YR				PT_COMPL_A LC_LST_YR
24 PT_COMPL_A6.2 LC_3YRS				PT_COMPL_A LC_3YRS
25 NOW_DERV_YYYY YR				NOW_DERV_ YR
26 DERV_AGE 3				DERV_AGE

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NOT RECOMMENDED FOR SOURCE DOCUMENTATION

36. - Current smoking status

- Current Smoker (one puff in the last month) ①
- Former Smoker (not smoking for > or = 1 month(not even a puff))
- Never smoked
- Pt Left Field Blank

37. - Please indicate your current smoking habit

- Never Smoked ②
- Former Smoker (not smoking for > or = 1 month(not even a puff))
- Occasional smoker (< or = 6 cigarette per week)
- Regular smoker (> or = 7 cigarettes per week)
- Pt Left Field Blank

38. - Average # cigarettes per day

Fixed Unit: per day ③

Check if pt left Q38 blank ④

39. - Number of Years Smoking

Fixed Unit: years ⑤

Check if pt left Q39 blank ⑥

40. - How old were you the first time you EVER smoked even a puff of a cigarette?

Fixed Unit: years old ⑦

Check if pt left Q40 blank ⑧

41. - When you first started smoking a few cigarettes (between 2-10), how much did you feel dizzy?

- Not at all 9
- A slight amount
- A moderate amount
- An intense amount
- Don't Know
- Pt Left Field Blank

42. - When you first started smoking a few cigarettes (between 2-10), how much did you feel a pleasureable rush or buzz?

- Not at all 10
- A slight amount
- A moderate amount
- An intense amount
- Don't Know
- Pt Left Field Blank

43. - How old were you when you began smoking daily (at least one cigarette per day or more)?

Fixed Unit: years old 11

Check if pt left Q43 blank _____ 12

For the next questions, think about the time period when you smoked most

44. - Think about the time you smoked the most. How many cigarettes did you smoke per day?

Fixed Unit: cigarettes 14

Check if pt left Q44 blank _____ 15

45. - During the time that you smoked, how many different times in your life did you go without smoking for THREE MONTHS or longer?

Fixed Unit: times 16

Check if pt left Q45 blank _____ **17**

46. - Do you find it difficult not to smoke in places where it is forbidden such as in church, at a library, or in a movie theater? **18**

No

Yes

Unknown

Pt Left Field Blank

47. - Do you smoke MORE during the first hours after you woke up or during the rest of the day? **19**

When I first woke up

During the rest of the day

Pt Left Field Blank

NOW Derivation _____ **20**

Age derivation _____ **21**

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Patient Completed Questionnaire

Form: Pt Questionnaire: Smoking History Pt. 1

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Field Name	Data Type	Units	Values	Include Field OID
① PT_COMPL_S2 MOK_STAT			1 = Current Smoker (one puff in the last month) 2 = Former Smoker (not smoking for > or = 1 month(not even a puff)) 3 = Never smoked 77 = Pt Left Field Blank	PT_COMPL_S MOK_STAT
② PT_COMPL_S2 MOK_HAB			1 = Never Smoked 2 = Former Smoker (not smoking for > or = 1 month(not even a puff)) 3 = Occasional smoker (< or = 6 cigarette per week) 4 = Regular smoker (> or = 7 cigarettes per week) 77 = Pt Left Field Blank	PT_COMPL_S MOK_HAB
③ PT_COMPL_C6.2 IG_DAY				PT_COMPL_C IG_DAY

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Form: Pt Questionnaire: Smoking History Pt. 1
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Field Name	Data Type	Units	Values	Include Field OID
④ CIG_DAY_PT 1 BLNK				CIG_DAY_PT BLNK
⑤ PT_COMPL_Y 6.2 RS_SMOKE				PT_COMPL_Y RS_SMOKE
⑥ YRS_SMOKE 1 _PTBLNK				YRS_SMOKE _PTBLNK
⑦ PT_COMPL_1 2 ST_SMOKE				PT_COMPL_1 ST_SMK
⑧ ST1_SMOKE_1 PTBLNK				ST1_SMOKE_ PTBLNK
⑨ PT_COMPL_1 2 ST_SMOKE_ DIZ			1 = Not at all 2 = A slight amount 3 = A moderate amount 4 = An intense amount 5 = Don't Know 77 = Pt Left Field Blank	PT_COMPL_1 ST_SMK_DIZ
⑩ PT_COMPL_1 2 ST_SMK_RU SH			1 = Not at all 2 = A slight amount 3 = A moderate amount	PT_COMPL_1 ST_SMK_RU SH

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Folder: Patient Completed Questionnaire
Form: Pt Questionnaire: Smoking History Pt. 1
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Field Name	Data Type	Units	Values	Include Field OID
			4 = An intense amount 5 = Don't Know 77 = Pt Left Field Blank	
11 PT_COMPL_D2 AILEY_SMK				PT_COMPL_D AILEY_SMK
12 DAILY_SMK_1 PTBLNK				DAILY_SMK_ PTBLNK
14 PT_COMPL_S3 MK_MOST_D AY				PT_COMPL_S MK_MOST_D AY
15 SMK_MOST_1 DAY_PTBLNK				SMK_MOST_ DAY_PTBLNK
16 PT_COMPL_N2 SMK_3MOS				PT_COMPL_N SMK_3MOS
17 NSML_3MOS_1 _PTBLNK				NSML_3MOS _PTBLNK
18 PT_COMPL_N2 SMK_LOC			1 = No 2 = Yes 88 = Unknown 77 = Pt Left Field Blank	PT_COMPL_N SMK_LOC

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Field Name	Data Type	Units	Values	Include Field OID
19 PT_COMPL_S2 MK_MORE			1 = When I first woke up 2 = During the rest of the day 77 = Pt Left Field Blank	PT_COMPL_S MK_MORE
20 NOW_DERV_YYYY YR				NOW_DERV_ YR
21 DERV_AGE	3			DERV_AGE

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48. - How soon after you woke up in the morning did you smoke the first cigarette?

- Within 5 minutes ①
- Within 6 to 14 minutes
- Within 15 to 29 minutes
- Within 30 minutes but less than 1 hour
- Within 1 hour but less than 2 hours
- Within 2 hours but less than 8 hours
- More than 7 hours
- Pt Left Field Blank

49. - Did you smoke even if you were so ill that you were in bed most of the day?

- No ②
- Yes
- Unknown
- Pt Left Field Blank

50. - When you smoked the most, how often did you inhale?

- None of the Time ③
- Some of the Time
- All of the Time
- Pt Left Field Blank

51. - Which cigarette of the day did you hate to give up the most?

- First one in the morning ④
- One later in the morning
- One at mid day
- One in the afternoon
- One after work
- One in the evening
- One late at night
- One before bedtime
- Pt Left Field Blank

52. - When you smoked the most, what was your usual brand of cigarettes? _____

5

The next questions are about your usual brand of cigarette when you were smoking the most

52a. - Was the type

- Regular 7
- Lights
- Ultralights
- Pt Left Field Blank

52b. - Was the flavor

- Regular 8
- Menthol
- Pt Left Field Blank

52c. - Was the packing

- Hard 9
- Soft
- Pt Left Field Blank

52d. - Were the cigarettes

- Filtered 10
- Unfiltered
- Pt Left Field Blank

53. - Have you ever switched to a low tar, low nicotine or ultralight cigarette?

- No 11
- Yes
- Unknown
- Pt Left Field Blank

Complete the following 3 questions only if you answered yes to the having switched to a low tar, low nicotine, or ultralight cigarette

54. - How old were you when you switched?

Fixed Unit: years old 13

Check if pt left Q54 blank

14

55. - During the time that you were smoking low tar, low nicotine, or ultralight cigarettes, about how many cigarettes did you usually smoke per day?

Fixed Unit: per day 15

Check if pt left Q55 blank

16

56. - How many years TOTAL did you smoke low tar, low nicotine, or ultralight cigarettes?

Fixed Unit: years 17

Check if pt left Q56 blank

18

Current Year

19

Age Derivation Using Year

20

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms
Folder: Patient Completed Questionnaire
Form: Pt Questionnaire: Smoking History Pt. 2
Generated On: 15 May 2019 14:40:46

Field Name	Data Type	Units	Values	Include Field OID
① PT_COMPL_ 2 MORN_SMK			1 = Within 5 minutes 2 = Within 6 to 14 minutes 3 = Within 15 to 29 minutes 4 = Within 30 minutes but less than 1 hour 5 = Within 1 hour but less than 2 hours 6 = Within 2 hours but less than 8 hours 7 = More than 7 hours 77 = Pt Left Field Blank	PT_COMPL_ MORN_SMK
② PT_COMPL_I 2 LL_SMK			1 = No 2 = Yes 88 = Unknown 77 = Pt Left Field Blank	PT_COMPL_I LL_SMK
③ PT_COMPL_I 2 NH_SMK			1 = None of the Time 2 = Some of the Time 3 = All of the Time 77 = Pt Left Field Blank	PT_COMPL_I NH_SMK

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms
Folder: Patient Completed Questionnaire
Form: Pt Questionnaire: Smoking History Pt. 2
Generated On: 15 May 2019 14:40:46

Field Name	Data Type	Units	Values	Include Field OID
④ PT_COMPL_S2 MK_GV			1 = First one in the morning 2 = One later in the morning 3 = One at mid day 4 = One in the afternoon 5 = One after work 6 = One in the evening 7 = One late at night 8 = One before bedtime 77 = Pt Left Field Blank	PT_COMPL_S MK_GV
⑤ PT_COMPL_B3 RAND			Cigarette Brand	PT_COMPL_B RAND
⑦ PT_COMPL_B2 RD_TYRE			1 = Regular 2 = Lights 3 = Ultralights 77 = Pt Left Field Blank	PT_COMPL_B RD_TYPE
⑧ PT_COMPL_B2 RD_FLVR			1 = Regular 2 = Menthol 77 = Pt Left Field Blank	PT_COMPL_B RD_FLVR

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Form: Pt Questionnaire: Smoking History Pt. 2
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Field Name	Data Type	Units	Values	Include Field OID
9 PT_COMPL_B2 RD_PCK			1 = Hard 2 = Soft 77 = Pt Left Field Blank	PT_COMPL_B RD_PCK
10 PT_COMPL_B2 RD_FIL			1 = Filtered 2 = Unfiltered 77 = Pt Left Field Blank	PT_COMPL_B RD_FIL
11 PT_COMPL_L 2 OWUTLT_SM K			1 = No 2 = Yes 88 = Unknown 77 = Pt Left Field Blank	PT_COMPL_L OWUTLT_SM K
13 PT_COMPL_A2 GE_LOWULT				PT_COMPL_A GE_LOWULT
14 AGE_LOWUL 1 T_PTBLNK				AGE_LOWUL T_PTBLNK
15 PT_COMPL_L 2 OWULT_SMK _DAY				PT_COMPL_L OWULT_SMK _DAY
16 LOWULT_SM 1 K_PTBLNK				LOWULT_SM K_PTBLNK
17 PT_COMPL_L 6.2 OWULT_YRS				PT_COMPL_L OWULT_YRS

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 Folder: Patient Completed Questionnaire
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Field Name	Data Type	Units	Values	Include Field OID
18 LOWULT_YR 1 S_PTBLNK				LOWULT_YR S_PTBLNK
19 NOW_DERV_YYYY YR				NOW_DERV_ YR
20 DERV_AGE 3				DERV_AGE

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The next question contains statements that smokers have said about quitting.

57. - Please indicate which statement best represents what you think right now
- I enjoy smoking so much I will never consider quitting no matter what happens
 - I never think about quitting but I might someday
 - I rarely think about quitting and have no specific plans to quit
 - I sometimes think about quitting but have no specific plans to quit
 - I often think about quitting but have no specific plans to quit
 - I plan to quit in the next 6 months
 - I plan to quit in the next 30 days
 - I have already begun to cut down and I have set a quit date
 - I have already quit and but I worry about slipping back or relapsing
 - I have quit and I am 100% confident that I will never smoke again
 - I decline to answer
 - Pt left field blank

- 57a. - If you are planning to quit someday, did previous screenings with positive results play a role in your decision?
- No
 - Yes
 - Unknown
 - Not Applicable
 - Pt Left Field Blank

Former Smokers Only

58. - How old were you when you stopped smoking for good?

Fixed Unit: years old

5

Check if pt left Q58 blank

6

59. - When was your last cigarette?

Less than 6 months ago

7

6 months to 1 year ago

1 year to 4 years ago

4 years to 10 years ago

10 years to 15 years ago

More than 15 years ago

Pt Left Field Blank

Current Smokers Only

60. - How many time in the PAST YEAR have you quit smoking for 24 hours or longer?

Fixed Unit: times

9

Check if pt left Q60 blank

10

61. - Since you started smoking, what was the LONGEST period of time that you were able not to smoke cigarettes at all?

Check if pt left Q61 blank

12

Fixed Unit: hours

13

Fixed Unit: days

14

Fixed Unit: weeks **15**

Fixed Unit: years **16**

All Participants

62. - Have you EVER smoked any other forms of tobacco?

- No **18**
Yes
Unknown
Pt Left Field Blank

63. - Do you currently smoke any other forms of tobacco?

- No **19**
Yes
Pt Left Field Blank

64. - Check the form(s) of tobacco you did/do smoke

Check if pt left Q64 blank _____ **21**

NOW Derivation _____ **25**

Age Derivation _____ **26**

Forms of Tobacco

- Pipe **22**
Cigar
Tiparillos

Other

If other, specify

23

24

Forms of Tobacco

Pipe 22

Cigar

Tiparillos

Other

If other, specify

23

24

Forms of Tobacco

Pipe 22

Cigar

Tiparillos

Other

If other, specify

23

24

Forms of Tobacco

Pipe 22

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Cigar
Tiparillos
Other

If other, specify

23

24

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 Folder: Patient Completed Questionnaire
 Form: Pt Questionnaire: Smoking Cessation
 Generated On: 15 May 2019 14:40:46

Field Name	Data Type	Units	Values	Include Field OID
② PT_COMPL_Q2 UIT_STAT			1 = I enjoy smoking so much I will never consider quitting no matter what happens 2 = I never think about quitting but I might someday 3 = I rarely think about quitting and have no specific plans to quit 4 = I sometimes think about quitting but have no specific plans to quit 5 = I often think about quitting but have no specific plans to quit 6 = I plan to quit in the next 6 months 7 = I plan to quit in the next 30 days	PT_COMPL_Q UIT_STAT

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 Folder: Patient Completed Questionnaire
 Form: Pt Questionnaire: Smoking Cessation
 Generated On: 15 May 2019 14:40:46

Field Name	Data Type	Units	Values	Include Field OID
			8 = I have already begun to cut down and I have set a quit date 9 = I have already quit and but I worry about slipping back or relapsing 10 = I have quit and I am 100% confident that I will never smoke again 11 = I decline to answer 77 = Pt left field blank	
③ PT_COMPL_S2 CR_QUIT			1 = No 2 = Yes 99 = Unknown 98 = Not Applicable 77 = Pt Left Field Blank	PT_COMPL_S CR_QUIT
⑤ PT_COMPL_A2 GE_QUIT				PT_COMPL_A GE_QUIT

Draft 25 version 1.0 MIGPROD 17JAN2018: All forms
Folder: Patient Completed Questionnaire
Form: Pt Questionnaire: Smoking Cessation
Generated On: 15 May 2019 14:40:46

Field Name	Data Type	Units	Values	Include Field OID
⑥ AGE_QUIT_P 1 TBLNK				AGE_QUIT_P TBLNK
⑦ PT_COMPL_L 2 ST_CIG			1 = Less than 6 months ago 2 = 6 months to 1 year ago 3 = 1 year to 4 years ago 4 = 4 years to 10 years ago 5 = 10 years to 15 years ago 6 = More than 15 years ago 77 = Pt Left Field Blank	PT_COMPL_L ST_CIG
⑨ PT_COMPL_T 2 IMES_QUIT				PT_COMPL_T IMES_QUIT
⑩ TIMES_QUIT 1 _PT_BLNK				TIMES_QUIT _PT_BLNK
⑪ LTME_QUIT_ 1 PT_BLNK				LTME_QUIT_ PT_BLNK
⑫ PT_COMPL_L 6.2 NGTIME_QUIT				PT_COMPL_L NGTIME_QUIT

Draft 25 version 1.0 MIGPROD 17JAN2018: All forms
Folder: Patient Completed Questionnaire
Form: Pt Questionnaire: Smoking Cessation
Generated On: 15 May 2019 14:40:46

Field Name	Data Type	Units	Values	Include Field OID
14 PT_COMPL_L TME_QUIT_D AY	6.2			PT_COMPL_L TME_QUIT_D AY
15 PT_COMPL_L TME_QUIT_W K	6.2			PT_COMPL_L TME_QUIT_ WK
16 PT_COMPL_L TME_QUIT_Y R	6.2			PT_COMPL_L TME_QUIT_Y R
18 PT_COMPL_O2 TH_TOB_YN			1 = No 2 = Yes 88 = Unknown 77 = Pt Left Field Blank	PT_COMPL_E VR_OTH_TO B_YN
19 PT_COMPL_C2 UR_OTH_TO B_YN			1 = No 2 = Yes 77 = Pt Left Field Blank	PT_COMPL_C UR_OTH_TO B_YN
21 OTH_TOB_P TBLNK	1			OTH_TOB_P TBLNK
22 PT_COMPL_O2 TH_TOB_FO RMS			1 = Pipe 2 = Cigar 3 = Tiparillos 88 = Other	PT_COMPL_O TH_TOB_FO RMS
23 TOB_FORM_ OTH_SPEC	\$200			TOB_FORM_ OTH_SPEC

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Field Name	Data Type	Units	Values	Include Field OID
24 PT_COMPL_O1 TH_TOB_US ED				PT_COMPL_O TH_TOB_US ED
25 NOW_DERV_YYYY YR				NOW_DERV_ YR
26 DERV_AGE	3			DERV_AGE

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The following questions are about exposure to other people's smoking, otherwise known as second hand smoke

65. - Have you EVER lived with someone who smoked in your home? No ②
Yes
Unknown
Pt Left Field Blank

66. - Do you currently live with someone who smokes in your home? No ③
Yes
Unknown
Pt Left Field Blank

67. - Not including yourself, how many people smoke (d) in your home? Fixed Unit: people ④

Check if pt left Q67 blank ⑤

68. - Have you EVER worked in a place where you were exposed to other people's smoking? No ⑥
Yes
Unknown
Pt Left Field Blank

69. - Do you currently work in a place where you are exposed to other people's smoking? No ⑦
Yes
Unknown
Pt Left Field Blank

70. - Not including yourself, how many people smoke(d) at the place that you worked?

Fixed Unit: other smoker(s) 8

Check if pt left Q70 blank

9

71. - Thinking about all of the times that you may have been exposed to other peoples smoking, about how many years in total would you say that you have been exposed to second hand smoke?

Fixed Unit: years 10

Check if pt left Q71 blank

11

NOW Derivation

12

Age derivation

13

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Form: Pt Questionnaire: Secondhand Smoke
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Field Name	Data Type	Units	Values	Include Field OID
② PT_COMPL_L 2 IV_SMKR			1 = No 2 = Yes 88 = Unknown 77 = Pt Left Field Blank	PT_COMPL_L IV_SMKR
③ PT_COMPL_C2 UR_LIV_SMR K			1 = No 2 = Yes 88 = Unknown 77 = Pt Left Field Blank	PT_COMPL_C UR_LIV_SMR K
④ PT_COMPL_N3 UM_SMKR				PT_COMPL_N UM_SMKR
⑤ NUM_SMKR_1 PTBLNK				NUM_SMKR_ PTBLNK
⑥ PT_COMPL_ 2 WRK_SMKR			1 = No 2 = Yes 88 = Unknown 77 = Pt Left Field Blank	PT_COMPL_ WRK_SMKR
⑦ PT_COMPL_C2 UR_WRK_SM KR			1 = No 2 = Yes 88 = Unknown 77 = Pt Left Field Blank	PT_COMPL_C UR_WRK_SM KR

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms
 Folder: Patient Completed Questionnaire
 Form: Pt Questionnaire: Secondhand Smoke
 Generated On: 15 May 2019 14:40:46

Field Name	Data Type	Units	Values	Include Field OID
⑧ PT_COMPL_N8.2 UM_WRK				PT_COMPL_N UM_WRK
⑨ NUM_WRK_P 1 TBLNK				NUM_WRK_P TBLNK
⑩ PT_COMPL_ 6.2 WRK_YRS				PT_COMPL_ WRK_YRS
⑪ WRK_YRS_P 1 TBLNK				WRK_YRS_P TBLNK
⑫ NOW_DERV_ yyyy YR				NOW_DERV_ YR
⑬ DERV_AGE 3				DERV_AGE

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-
72. - Indicate the highest grade or level of schooling completed
- 8th grade or less ①
 - 9-11th grade
 - High school graduate or high school equivalency
 - Post high school training, other than college (for example, Vocational/technical school)
 - Associate degree/some college
 - Bachelors degree
 - Graduate or Professional School
 - Other, specify
 - Unknown/I prefer not to answer
 - Pt Left Field Blank

-
73. - Indicate your marital status
- Never Married ②
 - Married or living as married
 - Widowed
 - Separated
 - Divorced
 - Unknown/I prefer not to answer
 - Pt Left Field Blank

-
74. - Indicate household income(select one which most closely describes the TOTAL average yearly gross income for your household)
- Less than \$8,000 per year ③
 - \$8,000 to 14,999 per year
 - \$15,000 to \$24,999 per year
 - \$25,000 to \$34,999 per year
 - \$35,000 to \$49,999 per year
 - \$50,000 to \$64,999 per year
 - \$65,000 to \$79,999 per year
 - \$80,000 to \$100,000 per year

>\$100,000 per year
Unknown/I prefer not to
answer
Pt Left Field Blank

75. - Including yourself, how many people are supported by
the income listed above? _____

4

Check if pt left Q75 blank _____

5

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Folder: Patient Completed Questionnaire

Form: Pt Questionnaire: Demography

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Field Name	Data Type	Units	Values	Include Field OID
① PT_COMPL_S2 CHOOOL			1 = 8th grade or less 2 = 9-11th grade 3 = High school graduate or high school equivalency 4 = Post high school training, other than college (for example, Vocational/te chnical school) 5 = Associate degree/some college 6 = Bachelors degree 7 = Graduate or Professional School 88 = Other, specify 99 = Unknown/I prefer not to answer 77 = Pt Left Field Blank	PT_COMPL_S CHOOOL

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms
Folder: Patient Completed Questionnaire
Form: Pt Questionnaire: Demography
Generated On: 15 May 2019 14:40:46

Field Name	Data Type	Units	Values	Include Field OID
② PT_COMPL_ MRTL_STS	2		1 = Never Married 2 = Married or living as married 3 = Widowed 4 = Separated 5 = Divorced 99 = Unknown/I prefer not to answer 77 = Pt Left Field Blank	PT_COMPL_ MRTL_STS
③ PT_COMPL_H2 SHLD_INC			1 = Less than \$8,000 per year 2 = \$8,000 to 14,999 per year 3 = \$15,000 to \$24,999 per year 4 = \$25,000 to \$34,999 per year 5 = \$35,000 to \$49,999 per year 6 = \$50,000 to \$64,999 per year 7 = \$65,000 to \$79,999 per year 8 = \$80,000 to \$100,000 per year	PT_COMPL_H SHLD_INC

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms
 Folder: Patient Completed Questionnaire
 Form: Pt Questionnaire: Demography
 Generated On: 15 May 2019 14:40:46

Field Name	Data Type	Units	Values	Include Field OID
			9 = >\$100,000 per year 99 = Unknown/I prefer not to answer 77 = Pt Left Field Blank	
④ PT_COMPL_N2 M_SP_INC				PT_COMPL_N M_SP_INC
⑤ NM_SP_INC_1 PTBLNK				NM_SP_INC_ PTBLNK

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76. - Did you require any assistance completing this questionnaire?

- No ①
- Yes
- Pt Left Field Blank

76a. - Indicate the person who assisted you

- ACRIN-DECAMP Staff Member ②
- Family
- Unknown/I prefer not to answer
- Pt Left Field Blank
- Other

77. - Specify the method used to complete this questionnaire

- At my appointment ③
- By mail
- By telephone
- Unknown/I prefer not to answer
- Other
- Pt Left Field Blank

78. - Comments

_____ ⑦

Date Participant Completed Questionnaire

Fixed Unit: MMM dd yyyy ⑧

Scanned copy of the completed Patient Questionnaire

_____ ⑨

76b. - 76b. Extent of Assistance

- Read items to me ③
- Marked items as I responded
- Other

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Unknown/I prefer not to answer
Pt Left Field Blank

If other, specify _____ ④

Check all that apply _____ ⑤

76b. - 76b. Extent of Assistance
Read items to me ③
Marked items as I responded
Other
Unknown/I prefer not to answer
Pt Left Field Blank

If other, specify _____ ④

Check all that apply _____ ⑤

76b. - 76b. Extent of Assistance
Read items to me ③
Marked items as I responded
Other
Unknown/I prefer not to answer
Pt Left Field Blank

If other, specify _____ ④

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Check all that apply

5

76b. - 76b. Extent of Assistance

Read items to me

3

Marked items as I responded

Other

Unknown/I prefer not to answer

Pt Left Field Blank

If other, specify

4

Check all that apply

5

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Folder: Patient Completed Questionnaire
Form: Pt Questionnaire: Conclusion
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Field Name	Data Type	Units	Values	Include Field OID
① PT_COMPL_A2 SSIS_QST			1 = No 2 = Yes 77 = Pt Left Field Blank	PT_COMPL_A SSIS_QST
② PT_COMPL_P2 RD_ASSIS			1 = ACRIN-DECA MP Staff Member 2 = Family 3 = Unknown/I prefer not to answer 77 = Pt Left Field Blank 88 = Other	PT_COMPL_P RD_ASSIS
③ PT_COMPL_E2 XT_ASSIS			1 = Read items to me 2 = Marked items as I responded 88 = Other 3 = Unknown/I prefer not to answer 77 = Pt Left Field Blank	PT_COMPL_E XT_ASSIS
④ EXT_ASSIT_ OTH_SPEC	\$200			EXT_ASSIT_ OTH_SPEC
⑤ PT_COMPL_E1 XT_ASSIS_C K				PT_COMPL_E XT_ASSIS_C K

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms
 Folder: Patient Completed Questionnaire
 Form: Pt Questionnaire: Conclusion
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Field Name	Data Type	Units	Values	Include Field OID
⑥ PT_COMPL_2 METHOD			1 = At my appointment 2 = By mail 3 = By telephone 4 = Unknown/I prefer not to answer 88 = Other 77 = Pt Left Field Blank	PT_COMPL_ METHOD
⑦ PT_COMPL_C\$1000 OMMENTS				PT_COMPL_C OMMENTS
⑧ PT_COMPL_DMMM dd- ATE	yyyy			PT_COMPL_D ATE
⑨ PT_COMPL_D\$200 OC				PT_COMPL_D OC

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Was bronchoscopy performed?

- No 1
- Yes
- Unknown

Select the primary reason bronchoscopy was performed

- Follow up for lesion seen on imaging exam 2
- Interstitial lung disease
- Coughing up blood
- Cough
- Suspected infection
- Other, specify

If applicable, select one or more secondary reasons bronchoscopy was performed

- Follow up for lesion seen on imaging exam _____ 4
- Interstitial lung disease _____ 5
- Coughing up blood _____ 6
- Cough _____ 7
- Suspected infection _____ 8
- Other reason _____ 9

Primary reason bronchoscopy not performed

- Patient Refused 10
- Site error
- Missing equipment
- Unknown

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Other, specify

Date of Bronchoscopy

Fixed Unit: MMM dd yyyy **11**

Please upload a copy of the bronchoscopy report **12**

Was the bronchoscopy diagnostic?

No **13**
Yes
Uncertain

Was a sedative given?

No **14**
Yes
Unknown

Route of administration

Intravenous **15**
Intramuscular
Other, specify

Type used: **16**

Was a local anesthetic used?

No **17**
Yes
Unknown

Type of local anesthetic **18**

Was endobronchial tissue obtained as part of the bronchoscopy? **19**

No

Yes
Unknown

Were any adverse events that are considered possibly, probably, or definitely related to the study-related biospecimen collection procedures reported?

No 20
Yes
Unknown

Site

right upper lobe (RUL) subsegmental carinas 21
right middle lobe (RML) subsegmental carinas
left upper lobe (LUL) subsegmental carinas

Formalin-fixed 22
Fresh-frozen

Check if collected

23

Fluorescence ratio at biopsy site

24

Check if fluorescence ratio not done

25

Date and Time Into Freezer

26

Freezer Temp

Fixed Unit: °C 27

Did any freeze/thaw occur?

No 28

Yes
Unknown

Freeze/Thaw Comments _____ (29)

Other Comments _____ (30)

Site right upper lobe (RUL) subsegmental carinas (21)
 right middle lobe (RML) subsegmental carinas
 left upper lobe (LUL) subsegmental carinas

Formalin-fixed (22)
Fresh-frozen

Check if collected _____ (23)

Fluorescence ratio at biopsy site _____ (24)

Check if fluorescence ratio not done _____ (25)

Date and Time Into Freezer _____ (26)

Freezer Temp _____ Fixed Unit: °C (27)

Did any freeze/thaw occur? No (28)

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Yes
Unknown

Freeze/Thaw Comments _____ (29)

Other Comments _____ (30)

Site _____ (21)
right upper lobe (RUL) (21)
subsegmental carinas
right middle lobe (RML)
subsegmental carinas
left upper lobe (LUL)
subsegmental carinas

Formalin-fixed (22)
Fresh-frozen

Check if collected _____ (23)

Fluorescence ratio at biopsy site _____ (24)

Check if fluorescence ratio not done _____ (25)

Date and Time Into Freezer _____ (26)

Freezer Temp _____ Fixed Unit: °C (27)

Did any freeze/thaw occur? No (28)

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Yes
Unknown

Freeze/Thaw Comments _____ (29)

Other Comments _____ (30)

Site _____ (21)
right upper lobe (RUL) (21)
subsegmental carinas
right middle lobe (RML)
subsegmental carinas
left upper lobe (LUL)
subsegmental carinas

Formalin-fixed (22)
Fresh-frozen

Check if collected _____ (23)

Fluorescence ratio at biopsy site _____ (24)

Check if fluorescence ratio not done _____ (25)

Date and Time Into Freezer _____ (26)

Freezer Temp _____ Fixed Unit: °C (27)

Did any freeze/thaw occur? No (28)

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Yes
Unknown

Freeze/Thaw Comments _____ (29)

Other Comments _____ (30)

Site

right upper lobe (RUL) (21)
subsegmental carinas
right middle lobe (RML)
subsegmental carinas
left upper lobe (LUL)
subsegmental carinas

Formalin-fixed (22)
Fresh-frozen

Check if collected _____ (23)

Fluorescence ratio at biopsy site _____ (24)

Check if fluorescence ratio not done _____ (25)

Date and Time Into Freezer _____ (26)

Freezer Temp _____

Fixed Unit: °C (27)

Did any freeze/thaw occur? _____

No (28)

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Yes
Unknown

Freeze/Thaw Comments _____ (29)

Other Comments _____ (30)

Site

right upper lobe (RUL) (21)
subsegmental carinas
right middle lobe (RML)
subsegmental carinas
left upper lobe (LUL)
subsegmental carinas

Formalin-fixed (22)
Fresh-frozen

Check if collected _____ (23)

Fluorescence ratio at biopsy site _____ (24)

Check if fluorescence ratio not done _____ (25)

Date and Time Into Freezer _____ (26)

Freezer Temp _____

Fixed Unit: °C (27)

Did any freeze/thaw occur? _____

No (28)

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Yes
Unknown

Freeze/Thaw Comments

29

Other Comments

30

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Field Name	Data Type	Units	Values	Include Field OID
① BRNCHSPY_B2 X_COLL_YN			1 = No 2 = Yes 99 = Unknown	BRNCHSPY_B X_COLL_YN
② BRNCHSPY_ 2 RSN_PRFMD			1 = Follow up for lesion seen on imaging exam 2 = Interstitial lung disease 3 = Coughing up blood 4 = Cough 5 = Suspected infection 88 = Other, specify	BRNCHSPY_ RSN_PRFMD
④ BRNCHSPY_ 1 RSN_IMAG_L SN				BRNCHSPY_ RSN_IMAG_L SN
⑤ BRNCHSPY_ 4 RSN_INT_LG				BRNCHSPY_ RSN_INT_LG
⑥ BRNCHSPY_C1 GH_BLD				BRNCHSPY_C GH_BLD
⑦ BRNCHSPY_C1 GH				BRNCHSPY_C GH

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Field Name	Data Type	Units	Values	Include Field OID
8 BRNCHSPR_ 1 RSN_INFEC				BRNCHSPR_ RSN_INFEC
9 BRNCHSPY_ \$500 OTHER				BRNCHSPY_ OTHER
10 BRNCHSPY_B2 X_COLL_ND			1 = Patient Refused 2 = Site error 3 = Missing equipment 99 = Unknown 88 = Other specify	BRNCHSPY_B X_COLL_ND
11 DT_BRNCHS PY	MMM dd yyyy			BRNCHSPY_B X_COLL_DT
12 BRNCHSPY_ \$200 DX_UPLD				BRNCHSPY_ DX_UPLD
13 BRNCHSPY_ 2 DX_YN			1 = No 2 = Yes 3 = Uncertain	BRNCHSPY_ DX_YN
14 SED_GVN_Y 2 N			1 = No 2 = Yes 99 = Unknown	SED_GVN_Y N

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Field Name	Data Type	Units	Values	Include Field OID
15 RT_SED_AD MIN	2		1 = Intravenous 2 = Intramuscular 88 = Other, specify	RT_SED_AD MIN
16 SED_TYPE	\$60			SED_TYPE
17 LOC_ANEST_2 USED_YN			1 = No 2 = Yes 99 = Unknown	LOC_ANEST_2 USED_YN
18 LOC_ANEST_2 USED_TYPE	\$60			LOC_ANEST_2 USED_TYPE
19 BRNCHSPY_T2 IS_OBT_YN			1 = No 2 = Yes 99 = Unknown	BRNCHSPY_T2 IS_OBT_YN
20 AE_YN	2		1 = No 2 = Yes 99 = Unknown	AE_YN
21 BRNCH_SITE _BP	1		1 = right upper lobe (RUL) subsegmental carinas	BRNCH_SITE _BP

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Field Name	Data Type	Units	Values	Include Field OID
			2 = right middle lobe (RML) subsegmenta l carinas 3 = left upper lobe (LUL) subsegmenta l carinas	
22 BP_SAM_TYP 1			1 = Formalin-fixe d 2 = Fresh-frozen	BP_SAM_TYP
23 BRNCHSPY_B1 P_SLD				BRNCHSPY_B P_SLD
24 BRNCHSPY_F5.3 LR_RT				BRNCHSPY_F LR_RT
25 BRNCHSPY_F1 LR_RT_ND				BRNCHSPY_F LR_RT_ND
26 DT_TM_80_I N	MMM dd yyyy HH nn			DT_TM_80_I N
27 FRZ_TEMP	4.2			FRZ_TEMP
28 SAMP_FRZ_T2 HW			1 = No 2 = Yes	SAMP_FRZ_T HW

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Field Name	Data Type	Units	Values	Include Field OID
			99 = Unknown	
29 SAMP_FRZ_T HW_COMM	\$200			SAMP_FRZ_T HW_COMM
30 ALQ_COMM	\$200			ALQ_COMM

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Was blood collection performed?

- No ①
- Yes
- Unknown

Reason blood collection not performed

- Sample not collected ②
- Collection tubes broken
- Patient Refusal
- Adverse Event
- Site error
- Other, specify

Date of Blood Collection

Fixed Unit: MMM dd yyyy ③

Time of blood collection

Fixed Unit: HH:mm ④

Was fasting blood specimen collected?

- No ⑤
- Yes
- Unknown

Were any adverse events that are considered possibly, probably, or definitely related to the study-related biospecimen collection procedures reported?

- No ⑨
- Yes
- Unknown

Was plasma collection performed?

- No ⑩
- Yes
- Unknown

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Were plasma samples processed and stored within 2 hours of blood collection?

- No 11
- Yes
- Unknown

Did plasma samples undergo centrifugation within 2 hours of blood collection?

- No 12
- Yes
- Unknown

Primary reason plasma collection was not performed

- Sample not collected 13
- Collection tubes broken
- Patient Refusal
- Adverse Event
- Site error
- Other, specify

Was plasma collection performed per protocol?

- No 14
- Yes
- Unknown

Primary reason plasma collection was not performed per protocol

- Collection Tube(s) broke 15
- Missing Materials
- Site error
- Storage not per protocol
- Other, specify

Was buffy coat collection performed?

- No 16
- Yes
- Unknown

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Primary reason buffy coat collection was not performed

- Sample not collected 17
- Collection tubes broken
- Patient Refusal
- Adverse Event
- Site error
- Other, specify

Was buffy coat collection performed per protocol?

- No 18
- Yes
- Unknown

Primary reason buffy coat collection was not performed per protocol

- Collection Tube(s) broke 19
- Missing Materials
- Site error
- Storage not per protocol
- Other, specify

Was serum collection performed?

- No 20
- Yes
- Unknown

Primary reason serum collection was not performed

- Sample not collected 21
- Collection tubes broken
- Patient Refusal
- Adverse Event
- Site error
- Other, specify

Was serum collection performed per protocol?

- No 22

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Yes
Unknown

Primary reason serum collection was not performed per protocol

- Collection Tube(s) broke **23**
- Missing Materials
- Site error
- Storage not per protocol
- Other, specify

Was PAX gene collection performed?

No **24**
Yes
Unknown

Primary reason PAX gene collection was not performed

- Sample not collected **25**
- Collection tubes broken
- Patient Refusal
- Adverse Event
- Site error
- Other, specify

Was PAX gene collection performed per protocol?

No **26**
Yes
Unknown

Primary reason PAX gene collection was not performed per protocol

- Collection Tube(s) broke **27**
- Missing Materials
- Site error
- Storage not per protocol
- Other, specify

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Was streck collection performed?

- No 28
- Yes
- Unknown

Primary reason streck collection was not performed

- Sample not collected 29
- Collection tubes broken
- Patient Refusal
- Adverse Event
- Site error
- Other, specify

Was streck collection performed per protocol?

- No 30
- Yes
- Unknown

Primary reason streck collection was not performed per protocol

- Collection Tube(s) broke 31
- Missing Materials
- Site error
- Storage not per protocol
- Other, specify

Was PBMC collection performed?

- No 32
- Yes
- Unknown

Was PBMC collection performed per protocol?

- No 33
- Yes
- Unknown

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Primary reason PBMC collection was not performed per protocol	Collection Tube(s) broke <input checked="" type="checkbox"/> 34
	Missing Materials <input type="checkbox"/>
	Site error <input type="checkbox"/>
	Storage not per protocol <input type="checkbox"/>
	Other, specify <input type="checkbox"/>

_____ 35

3 Months after Registration Derivation _____ 36

Tube Type	Purple Top Venous Blood <input checked="" type="checkbox"/> 6
	Collection Tube
	Red Top Venous Blood <input type="checkbox"/>
	Collection Tube
	PAXgene tube <input type="checkbox"/>
	Yellow Top Venous Blood <input type="checkbox"/>
	Collection Tube
	Streck Tube <input type="checkbox"/>

Check if tube collected _____ 7

Reason Tube Not Collected	Patient Refused <input checked="" type="checkbox"/> 8
	Adverse Event <input type="checkbox"/>
	Site Error <input type="checkbox"/>
	Unknown <input type="checkbox"/>
	Other, specify <input type="checkbox"/>

Tube Type	Purple Top Venous Blood <input checked="" type="checkbox"/> 6
	Collection Tube

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Red Top Venous Blood Collection Tube

PAXgene tube

Yellow Top Venous Blood Collection Tube

Streck Tube

Check if tube collected _____

7

Reason Tube Not Collected

Patient Refused

8

Adverse Event

Site Error

Unknown

Other, specify

Tube Type

Purple Top Venous Blood Collection Tube

6

Red Top Venous Blood Collection Tube

PAXgene tube

Yellow Top Venous Blood Collection Tube

Streck Tube

Check if tube collected _____

7

Reason Tube Not Collected

Patient Refused

8

Adverse Event

Site Error

Unknown

Other, specify

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Tube Type

- Purple Top Venous Blood Collection Tube 6
- Red Top Venous Blood Collection Tube
- PAXgene tube
- Yellow Top Venous Blood Collection Tube
- Streck Tube

Check if tube collected

_____ 7

Reason Tube Not Collected

- Patient Refused 8
- Adverse Event
- Site Error
- Unknown
- Other, specify

Tube Type

- Purple Top Venous Blood Collection Tube 6
- Red Top Venous Blood Collection Tube
- PAXgene tube
- Yellow Top Venous Blood Collection Tube
- Streck Tube

Check if tube collected

_____ 7

Reason Tube Not Collected

- Patient Refused 8
- Adverse Event
- Site Error
- Unknown

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Other, specify

Tube Type

- Purple Top Venous Blood Collection Tube 6
- Red Top Venous Blood Collection Tube
- PAXgene tube
- Yellow Top Venous Blood Collection Tube
- Streck Tube

Check if tube collected

7

Reason Tube Not Collected

- Patient Refused 8
- Adverse Event
- Site Error
- Unknown
- Other, specify

Tube Type

- Purple Top Venous Blood Collection Tube 6
- Red Top Venous Blood Collection Tube
- PAXgene tube
- Yellow Top Venous Blood Collection Tube
- Streck Tube

Check if tube collected

7

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Reason Tube Not Collected

- Patient Refused 8
- Adverse Event
- Site Error
- Unknown
- Other, specify

Tube Type

- Purple Top Venous Blood Collection Tube 6
- Red Top Venous Blood Collection Tube
- PAXgene tube
- Yellow Top Venous Blood Collection Tube
- Streck Tube

Check if tube collected

_____ 7

Reason Tube Not Collected

- Patient Refused 8
- Adverse Event
- Site Error
- Unknown
- Other, specify

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Field Name	Data Type	Units	Values	Include Field OID
① BLD_COLL_Y 2 N			1 = No 2 = Yes 99 = Unknown	BLD_COLL_Y N
② BLD_COLL_N 2 D_RSN			1 = Sample not collected 2 = Collection tubes broken 3 = Patient Refusal 4 = Adverse Event 5 = Site error 88 = Other, specify	BLD_COLL_N D_RSN
③ BLD_COLL_D MMM dd yyyy T				BLD_COLL_D T
④ BLD_COLL_T HH mm IME				BLD_COLL_T IME
⑤ BLD_COLL_N 2 PO_YN			1 = No 2 = Yes 99 = Unknown	BLD_COLL_N PO_YN
⑥ BLD_COLL_T 2 B_TYPE			1 = Purple Top Venous Blood Collection Tube	BLD_COLL_T B_TYPE

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Field Name	Data Type	Units	Values	Include Field OID
			2 = Red Top Venous Blood Collection Tube 3 = PAXgene tube 4 = Yellow Top Venous Blood Collection Tube 5 = Streck Tube	
7 BL_COLL_TB 1 _COLL				BL_COLL_TB _COLL
8 BL_COLL_TB 2 _NCLL_RSN			1 = Patient Refused 2 = Adverse Event 3 = Site Error 99 = Unknown 88 = Other, specify	BL_COLL_TB _NCLL_RSN
9 AE_YN	2		1 = No 2 = Yes 99 = Unknown	AE_YN
10 BLD_COLL_P 2 LSM_YN			1 = No 2 = Yes 99 = Unknown	BLD_COLL_P LSM_YN

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Field Name	Data Type	Units	Values	Include Field OID
11 PLSM_PROC_2 2HRS_YN			1 = No 2 = Yes 99 = Unknown	PLSM_PROC_ 2HRS_YN
12 PLSM_CENT_2 IMM_YN			1 = No 2 = Yes 99 = Unknown	PLSM_CENT_ IMM_YN
13 PLSM_NT_PR 2 F_REAS			1 = Sample not collected 2 = Collection tubes broken 3 = Patient Refusal 4 = Adverse Event 5 = Site error 88 = Other, specify	PLSM_NT_PR F_REAS
14 PLSM_PF_PR 2 OT_YN			1 = No 2 = Yes 99 = Unknown	PLSM_PF_PR OT_YN
15 PLSM_PF_PR 2 OT_REAS			1 = Collection Tube(s) broke 2 = Missing Materials 3 = Site error	PLSM_PF_PR OT_REAS

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Field Name	Data Type	Units	Values	Include Field OID
			4 = Storage not per protocol 88 = Other, specify	
16 BLD_COLL_B 2 UFFY_YN			1 = No 2 = Yes 99 = Unknown	BLD_COLL_B UFFY_YN
17 BUFFY_NT_P 2 RF_REAS			1 = Sample not collected 2 = Collection tubes broken 3 = Patient Refusal 4 = Adverse Event 5 = Site error 88 = Other, specify	BUFFY_NT_P RF_REAS
18 BUFFY_PF_P 2 ROT_YN			1 = No 2 = Yes 99 = Unknown	BUFFY_PF_P ROT_YN
19 BUFFY_PF_P 2 ROT_REAS			1 = Collection Tube(s) broke	BUFFY_PF_P ROT_REAS

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Field Name	Data Type	Units	Values	Include Field OID
			2 = Missing Materials 3 = Site error 4 = Storage not per protocol 88 = Other, specify	
20 BLD_COLL_S 2 ERUM_YN			1 = No 2 = Yes 99 = Unknown	BLD_COLL_S ERUM_YN
21 SERUM_NT_ 2 PRF_REAS			1 = Sample not collected 2 = Collection tubes broken 3 = Patient Refusal 4 = Adverse Event 5 = Site error 88 = Other, specify	SERUM_NT_ PRF_REAS
22 SERUM_PF_P 2 ROT_YN			1 = No 2 = Yes 99 = Unknown	SERUM_PF_P ROT_YN

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Field Name	Data Type	Units	Values	Include Field OID
23 SERUM_PF_P 2 ROT_REAS			1 = Collection Tube(s) broke 2 = Missing Materials 3 = Site error 4 = Storage not per protocol 88 = Other, specify	SERUM_PF_P ROT_REAS
24 BLD_COLL_P 2 AX_YN			1 = No 2 = Yes 99 = Unknown	BLD_COLL_P AX_YN
25 PAX_NT_PRF 2 _REAS			1 = Sample not collected 2 = Collection tubes broken 3 = Patient Refusal 4 = Adverse Event 5 = Site error 88 = Other, specify	PAX_NT_PRF _REAS
26 PAX_PF_PRO 2 T_YN			1 = No 2 = Yes 99 = Unknown	PAX_PF_PRO T_YN

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Field Name	Data Type	Units	Values	Include Field OID
27 PAX_PF_PRO 2 T_REAS			1 = Collection Tube(s) broke 2 = Missing Materials 3 = Site error 4 = Storage not per protocol 88 = Other, specify	PAX_PF_PRO T_REAS
28 BLD_COLL_S 2 TRECK_YN			1 = No 2 = Yes 99 = Unknown	BLD_COLL_S TRECK_YN
29 STRECK_NT_2 PRF_REAS			1 = Sample not collected 2 = Collection tubes broken 3 = Patient Refusal 4 = Adverse Event 5 = Site error 88 = Other, specify	STRECK_NT_ PRF_REAS
30 STRECK_PF_2 PROT_YN			1 = No 2 = Yes 99 = Unknown	STRECK_PF_ PROT_YN

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Field Name	Data Type	Units	Values	Include Field OID
31) STRECK_PRO T_REAS	2		1 = Collection Tube(s) broke 2 = Missing Materials 3 = Site error 4 = Storage not per protocol 88 = Other, specify	STRECK_PRO T_REAS
32) BLD_COLL_P BMC_YN	2		1 = No 2 = Yes 99 = Unknown	BLD_COLL_P BMC_YN
33) PBMC_PF_PR OT_YN	2		1 = No 2 = Yes 99 = Unknown	PBMC_PF_PR OT_YN
34) PBMC_PF_PR OT_REAS	2		1 = Collection Tube(s) broke 2 = Missing Materials 3 = Site error 4 = Storage not per protocol 88 = Other, specify	PBMC_PF_PR OT_REAS

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Field Name	Data Type	Units	Values	Include Field OID
35 NOW_1DERI VATION	dd MMM yyyy HH nn			NOW_1DERI VATION
36 DT3_MOS_D ERV	dd MMM yyyy			DT3_MOS_D ERV

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Form: Blood Collection Aliquots-Required

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Total # of Aliquots prepared from the Blood Collection _____ **1**

Did all of the listed aliquots go into the same freezer at the same date/time? No **2**
Yes
Unknown

If yes

If all aliquots listed were put into the same freezer on the same day and same time, please provide that date/time and freezer temp in the fields below. Please leave these columns in the table blank

Date/Time into Freezer for All Aliquots _____ **4**

Temperature of Freezer for All Aliquots _____ **5**

The below table is prefilled with the expected blood collection samples. All fields are editable and the table should reflect the actual samples processed/collected. The total number of items collected should equal the total number of rows in the table. If PBMC preparation and/or Buffy Coat Preparation is performed, details of the aliquots should not be recorded on this form, but should be recorded on the PBMC Blood Collection Form and/or Buffy Coat Collection Form

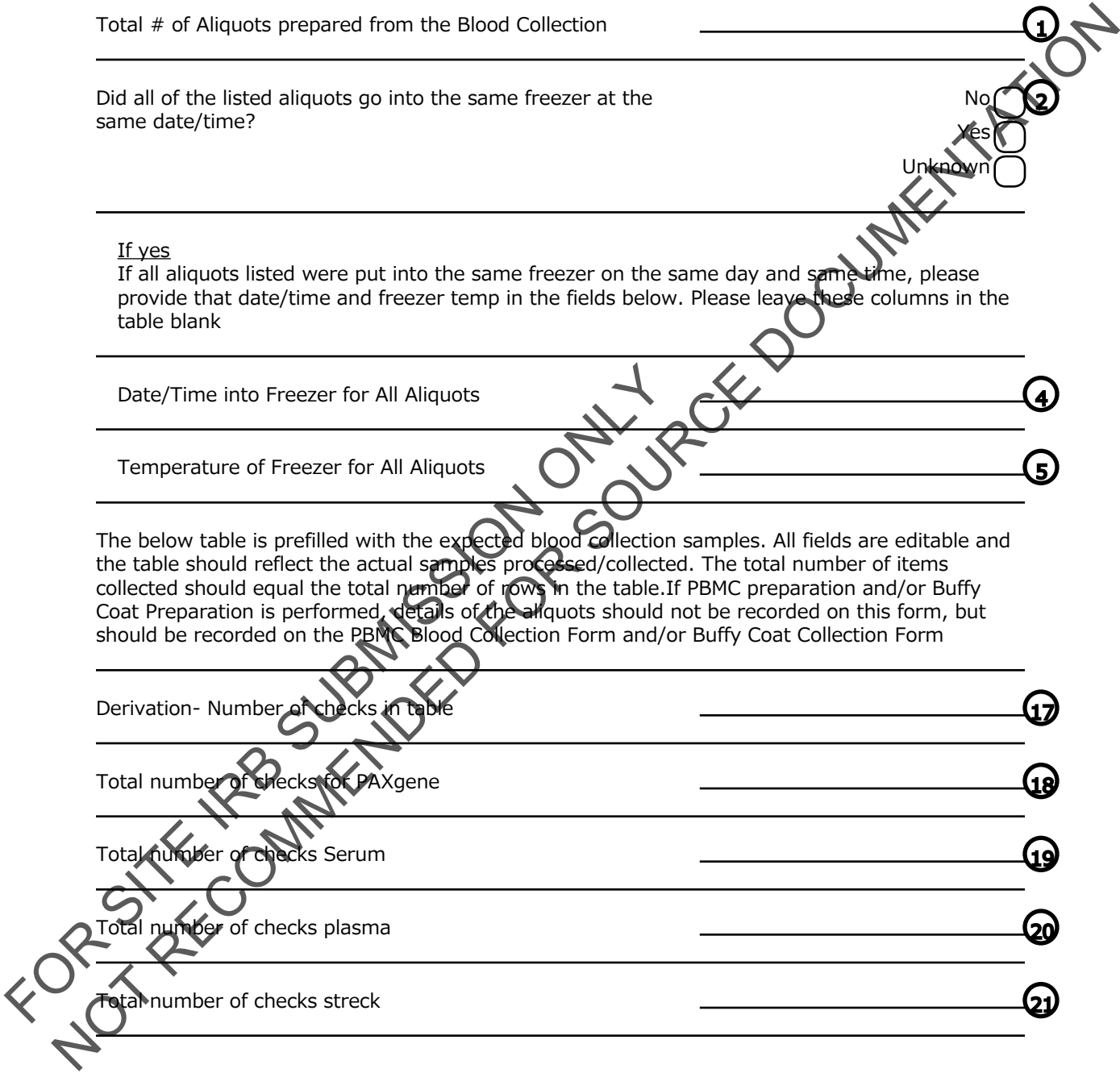
Derivation- Number of checks in table _____ **17**

Total number of checks for PAXgene _____ **18**

Total number of checks Serum _____ **19**

Total number of checks plasma _____ **20**

Total number of checks streck _____ **21**



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Folder: Biospecimen Collection

Form: Blood Collection Aliquots-Required

Generated On: 15 May 2019 14:40:46

Collection Type

Plasma Collection 7

Buffy Coat Collection

Serum Collection

PAX Gene

PBMC

Streck

Check if collected _____ 8

Amount of aliquot in vial/tube _____ 9

Date and Time into -20° Freezer

Fixed Unit: MMM dd yyy HH:MM 10

Temperature of Freezer _____ 11

Data and Time into -80° Freezer

Fixed Unit: MMM dd yyy HH:MM 12

Temperature of freezer _____

Fixed Unit: °C 13

Did any freeze-thaw occur to the sample?

No 14

Yes

Unknown

Comments regarding freeze-thaw _____ 15

Other comments _____ 16

Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Biospecimen Collection

Form: Blood Collection Aliquots-Required

Generated On: 15 May 2019 14:40:46

Collection Type

Plasma Collection 7

Buffy Coat Collection

Serum Collection

PAX Gene

PBMC

Streck

Check if collected _____ 8

Amount of aliquot in vial/tube _____ 9

Date and Time into -20° Freezer

Fixed Unit: MMM dd yyy HH:MM 10

Temperature of Freezer _____ 11

Data and Time into -80° Freezer

Fixed Unit: MMM dd yyy HH:MM 12

Temperature of freezer _____

Fixed Unit: °C 13

Did any freeze-thaw occur to the sample?

No 14

Yes

Unknown

Comments regarding freeze-thaw _____ 15

Other comments _____ 16

Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Biospecimen Collection

Form: Blood Collection Aliquots-Required

Generated On: 15 May 2019 14:40:46

Collection Type

Plasma Collection 7

Buffy Coat Collection

Serum Collection

PAX Gene

PBMC

Streck

Check if collected _____ 8

Amount of aliquot in vial/tube _____ 9

Date and Time into -20° Freezer

Fixed Unit: MMM dd yyy HH:MM _____ 10

Temperature of Freezer _____ 11

Data and Time into -80° Freezer

Fixed Unit: MMM dd yyy HH:MM _____ 12

Temperature of freezer

Fixed Unit: °C _____ 13

Did any freeze-thaw occur to the sample?

No 14

Yes

Unknown

Comments regarding freeze-thaw _____ 15

Other comments _____ 16

Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Biospecimen Collection

Form: Blood Collection Aliquots-Required

Generated On: 15 May 2019 14:40:46

Collection Type

Plasma Collection 7

Buffy Coat Collection

Serum Collection

PAX Gene

PBMC

Streck

Check if collected _____ 8

Amount of aliquot in vial/tube _____ 9

Date and Time into -20° Freezer

Fixed Unit: MMM dd yyy HH:MM _____ 10

Temperature of Freezer _____ 11

Data and Time into -80° Freezer

Fixed Unit: MMM dd yyy HH:MM _____ 12

Temperature of freezer _____

Fixed Unit: °C _____ 13

Did any freeze-thaw occur to the sample?

No 14

Yes

Unknown

Comments regarding freeze-thaw _____ 15

Other comments _____ 16

Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Biospecimen Collection

Form: Blood Collection Aliquots-Required

Generated On: 15 May 2019 14:40:46

Collection Type

Plasma Collection 7

Buffy Coat Collection

Serum Collection

PAX Gene

PBMC

Streck

Check if collected _____ 8

Amount of aliquot in vial/tube _____ 9

Date and Time into -20° Freezer

Fixed Unit: MMM dd yyy HH:MM 10

Temperature of Freezer _____ 11

Data and Time into -80° Freezer

Fixed Unit: MMM dd yyy HH:MM 12

Temperature of freezer _____

Fixed Unit: °C 13

Did any freeze-thaw occur to the sample?

No 14

Yes

Unknown

Comments regarding freeze-thaw _____ 15

Other comments _____ 16

Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Biospecimen Collection

Form: Blood Collection Aliquots-Required

Generated On: 15 May 2019 14:40:46

Collection Type

Plasma Collection 7

Buffy Coat Collection

Serum Collection

PAX Gene

PBMC

Streck

Check if collected _____ 8

Amount of aliquot in vial/tube _____ 9

Date and Time into -20° Freezer

Fixed Unit: MMM dd yyy HH:MM _____ 10

Temperature of Freezer _____ 11

Data and Time into -80° Freezer

Fixed Unit: MMM dd yyy HH:MM _____ 12

Temperature of freezer _____

Fixed Unit: °C _____ 13

Did any freeze-thaw occur to the sample?

No 14

Yes

Unknown

Comments regarding freeze-thaw _____ 15

Other comments _____ 16

Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Biospecimen Collection

Form: Blood Collection Aliquots-Required

Generated On: 15 May 2019 14:40:46

Collection Type

- Plasma Collection 7
- Buffy Coat Collection
- Serum Collection
- PAX Gene
- PBMC
- Streck

Check if collected

8

Amount of aliquot in vial/tube

9

Date and Time into -20° Freezer

Fixed Unit: MMM dd yyy HH:MM 10

Temperature of Freezer

11

Data and Time into -80° Freezer

Fixed Unit: MMM dd yyy HH:MM 12

Temperature of freezer

Fixed Unit: °C 13

Did any freeze-thaw occur to the sample?

- No 14
- Yes
- Unknown

Comments regarding freeze-thaw

15

Other comments

16

Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Biospecimen Collection

Form: Blood Collection Aliquots-Required

Generated On: 15 May 2019 14:40:46

Collection Type

- Plasma Collection 7
- Buffy Coat Collection
- Serum Collection
- PAX Gene
- PBMC
- Streck

Check if collected

8

Amount of aliquot in vial/tube

9

Date and Time into -20° Freezer

Fixed Unit: MMM dd yyy HH:MM 10

Temperature of Freezer

11

Data and Time into -80° Freezer

Fixed Unit: MMM dd yyy HH:MM 12

Temperature of freezer

Fixed Unit: °C 13

Did any freeze-thaw occur to the sample?

- No 14
- Yes
- Unknown

Comments regarding freeze-thaw

15

Other comments

16

Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Biospecimen Collection

Form: Blood Collection Aliquots-Required

Generated On: 15 May 2019 14:40:46

Collection Type

- Plasma Collection 7
- Buffy Coat Collection
- Serum Collection
- PAX Gene
- PBMC
- Streck

Check if collected

8

Amount of aliquot in vial/tube

9

Date and Time into -20° Freezer

Fixed Unit: MMM dd yyy HH:MM 10

Temperature of Freezer

11

Data and Time into -80° Freezer

Fixed Unit: MMM dd yyy HH:MM 12

Temperature of freezer

Fixed Unit: °C 13

Did any freeze-thaw occur to the sample?

- No 14
- Yes
- Unknown

Comments regarding freeze-thaw

15

Other comments

16

Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Biospecimen Collection

Form: Blood Collection Aliquots-Required

Generated On: 15 May 2019 14:40:46

Collection Type

- Plasma Collection 7
- Buffy Coat Collection
- Serum Collection
- PAX Gene
- PBMC
- Streck

Check if collected

8

Amount of aliquot in vial/tube

9

Date and Time into -20° Freezer

Fixed Unit: MMM dd yyy HH:MM 10

Temperature of Freezer

11

Data and Time into -80° Freezer

Fixed Unit: MMM dd yyy HH:MM 12

Temperature of freezer

Fixed Unit: °C 13

Did any freeze-thaw occur to the sample?

- No 14
- Yes
- Unknown

Comments regarding freeze-thaw

15

Other comments

16

Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Biospecimen Collection

Form: Blood Collection Aliquots-Required

Generated On: 15 May 2019 14:40:46

Collection Type

- Plasma Collection 7
- Buffy Coat Collection
- Serum Collection
- PAX Gene
- PBMC
- Streck

Check if collected

8

Amount of aliquot in vial/tube

9

Date and Time into -20° Freezer

Fixed Unit: MMM dd yyy HH:MM 10

Temperature of Freezer

11

Data and Time into -80° Freezer

Fixed Unit: MMM dd yyy HH:MM 12

Temperature of freezer

Fixed Unit: °C 13

Did any freeze-thaw occur to the sample?

- No 14
- Yes
- Unknown

Comments regarding freeze-thaw

15

Other comments

16

Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Biospecimen Collection

Form: Blood Collection Aliquots-Required

Generated On: 15 May 2019 14:40:46

Collection Type

- Plasma Collection 7
- Buffy Coat Collection
- Serum Collection
- PAX Gene
- PBMC
- Streck

Check if collected

8

Amount of aliquot in vial/tube

9

Date and Time into -20° Freezer

Fixed Unit: MMM dd yyy HH:MM 10

Temperature of Freezer

11

Data and Time into -80° Freezer

Fixed Unit: MMM dd yyy HH:MM 12

Temperature of freezer

Fixed Unit: °C 13

Did any freeze-thaw occur to the sample?

- No 14
- Yes
- Unknown

Comments regarding freeze-thaw

15

Other comments

16

Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Biospecimen Collection

Form: Blood Collection Aliquots-Required

Generated On: 15 May 2019 14:40:46

Collection Type

- Plasma Collection 7
- Buffy Coat Collection
- Serum Collection
- PAX Gene
- PBMC
- Streck

Check if collected

8

Amount of aliquot in vial/tube

9

Date and Time into -20° Freezer

Fixed Unit: MMM dd yyy HH:MM 10

Temperature of Freezer

11

Data and Time into -80° Freezer

Fixed Unit: MMM dd yyy HH:MM 12

Temperature of freezer

Fixed Unit: °C 13

Did any freeze-thaw occur to the sample?

- No 14
- Yes
- Unknown

Comments regarding freeze-thaw

15

Other comments

16

Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Biospecimen Collection

Form: Blood Collection Aliquots-Required

Generated On: 15 May 2019 14:40:46

Collection Type

- Plasma Collection 7
- Buffy Coat Collection
- Serum Collection
- PAX Gene
- PBMC
- Streck

Check if collected

8

Amount of aliquot in vial/tube

9

Date and Time into -20° Freezer

Fixed Unit: MMM dd yyy HH:MM 10

Temperature of Freezer

11

Data and Time into -80° Freezer

Fixed Unit: MMM dd yyy HH:MM 12

Temperature of freezer

Fixed Unit: °C 13

Did any freeze-thaw occur to the sample?

- No 14
- Yes
- Unknown

Comments regarding freeze-thaw

15

Other comments

16

Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Biospecimen Collection

Form: Blood Collection Aliquots-Required

Generated On: 15 May 2019 14:40:46

Collection Type

- Plasma Collection 7
- Buffy Coat Collection
- Serum Collection
- PAX Gene
- PBMC
- Streck

Check if collected _____ 8

Amount of aliquot in vial/tube _____ 9

Date and Time into -20° Freezer _____ Fixed Unit: MMM dd yyy HH:MM 10

Temperature of Freezer _____ 11

Data and Time into -80° Freezer _____ Fixed Unit: MMM dd yyy HH:MM 12

Temperature of freezer _____ Fixed Unit: °C 13

Did any freeze-thaw occur to the sample? No 14
Yes
Unknown

Comments regarding freeze-thaw _____ 15

Other comments _____ 16

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NOT RECOMMENDED FOR SOURCE DOCUMENTATION

Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Biospecimen Collection

Form: Blood Collection Aliquots-Required

Generated On: 15 May 2019 14:40:46

Field Name	Data Type	Units	Values	Include Field OID
① TOT_NUM_A LQ	3			TOT_NUM_A LQ
② DT_TM_FZ_Y N			1 = No 2 = Yes 99 = Unknown	DT_TM_FZ_Y N
④ OVRL_DT_T M_80_IN	MMM dd yyyy HH nn			OVRL_DT_T M_80_IN
⑤ OVRL_FRZ_T EMP	6.2			OVRL_FRZ_T EMP
⑦ BLD_COLL_T YPE	2		1 = Plasma Collection 2 = Buffy Coat Collection 3 = Serum Collection 4 = PAX Gene 5 = PBMC 6 = Streck	BLD_COLL_T YPE
⑧ COLL_COMP_ CK				COLL_COMP_ CK
⑨ BLD_ALQ_VO L	08.2			BLD_ALQ_VO L
⑩ DT_TM_20_I N	MMM dd yyyy HH nn			DT_TM_20_I N

Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Biospecimen Collection

Form: Blood Collection Aliquots-Required

Generated On: 15 May 2019 14:40:46

Field Name	Data Type	Units	Values	Include Field OID
11 FRZ_20_TEM P	4.2			FRZ_20_TEM P
12 DT_TM_80_I N	MMM dd yyyy HH nn			DT_TM_80_I N
13 FRZ_TEMP	4.2			FRZ_TEMP
14 SAMP_FRZ_T HW			1 = No 2 = Yes 99 = Unknown	SAMP_FRZ_T HW
15 SAMP_FRZ_T HW_COMM	\$200			SAMP_FRZ_T HW_COMM
16 ALQ_COMM	\$200			ALQ_COMM
17 ALQ_TOT_DE RV				ALQ_TOT_DE RV
18 PAX_ALQ_TO T_DERV				PAX_ALQ_TO T_DERV
19 SERUM_ALQ _TOT_DERV	2			SERUM_ALQ _TOT_DERV
20 PLSM_ALQ_T OT_DERV				PLSM_ALQ_T OT_DERV

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Biospecimen Collection

Form: Blood Collection Aliquots-Required

Generated On: 15 May 2019 14:40:46

Field Name	Data Type	Units	Values	Include Field OID
② STRECK_ALQ2 _TOT_DERV				STRECK_ALQ _TOT_DERV

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NOT RECOMMENDED FOR SOURCE DOCUMENTATION

Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Biospecimen Collection

Form: Blood Collection Aliquots- PBMC

Generated On: 15 May 2019 14:40:46

Date and Time of Start of PBMC Processing

Fixed Unit: MMM dd yyy HH:MM

1

PBMC count

Fixed Unit: 10⁶ cells/mL

2

Total checks for PBMC derivation

13

Collection Type

Plasma Collection

3

Buffy Coat Collection

Serum Collection

PAX Gene

PBMC

Streck

Check if collected

4

Vial/Tube Type

2mL cryovials

5

5mL cryovial

15mL cryovial

PAXgene Blood RNA tube

Number of Cells

6

LTGO volume

7

Date and Time into Freezer

8

Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Biospecimen Collection

Form: Blood Collection Aliquots- PBMC

Generated On: 15 May 2019 14:40:46

Temperature of Freezer

Fixed Unit: °C

Did any freeze-thaw occur to the sample?

No

Yes

Unknown

Comments regarding freeze- thaw

Other comment

Collection Type

Plasma Collection

Buffy Coat Collection

Serum Collection

PAX Gene

PBMC

Streck

Check if collected

Vial/Tube Type

2mL cryovials

5mL cryovial

15mL cryovial

PAXgene Blood RNA tube

Number of Cells

LTGO volume

Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Biospecimen Collection

Form: Blood Collection Aliquots- PBMC

Generated On: 15 May 2019 14:40:46

Date and Time into Freezer _____

8

Temperature of Freezer _____

Fixed Unit: °C

9

Did any freeze-thaw occur to the sample?

No

10

Yes

Unknown

Comments regarding freeze- thaw _____

11

Other comment _____

12

Collection Type

Plasma Collection

3

Buffy Coat Collection

Serum Collection

PAX Gene

PBMC

Streck

Check if collected _____

4

Vial/Tube Type

2mL cryovials

5

5mL cryovial

15mL cryovial

PAXgene Blood RNA tube

Number of Cells _____

6

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Biospecimen Collection

Form: Blood Collection Aliquots- PBMC

Generated On: 15 May 2019 14:40:46

LTGO volume _____

7

Date and Time into Freezer _____

8

Temperature of Freezer _____

Fixed Unit: °C

9

Did any freeze-thaw occur to the sample?

No 10

Yes

Unknown

Comments regarding freeze- thaw _____

11

Other comment _____

12

Collection Type

Plasma Collection 3

Buffy Coat Collection

Serum Collection

PAX Gene

PBMC

Streck

Check if collected _____

4

Vial/Tube Type

2mL cryovials 5

5mL cryovial

15mL cryovial

PAXgene Blood RNA tube

Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Biospecimen Collection

Form: Blood Collection Aliquots- PBMC

Generated On: 15 May 2019 14:40:46

Number of Cells _____ 6

LTGO volume _____ 7

Date and Time into Freezer _____ 8

Temperature of Freezer _____

Fixed Unit: °C 9

Did any freeze-thaw occur to the sample?

- No 10
Yes
Unknown

Comments regarding freeze- thaw _____ 11

Other comment _____ 12

Collection Type

- Plasma Collection 3
Buffy Coat Collection
Serum Collection
PAX Gene
PBMC
Streck

Check if collected _____ 4

Vial/Tube Type

- 2mL cryovials 5
5mL cryovial

Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Biospecimen Collection

Form: Blood Collection Aliquots- PBMC

Generated On: 15 May 2019 14:40:46

15mL cryovial
PAXgene Blood RNA tube

Number of Cells _____ ⑥

LTGO volume _____ ⑦

Date and Time into Freezer _____ ⑧

Temperature of Freezer _____ Fixed Unit: °C ⑨

Did any freeze-thaw occur to the sample? No ⑩
Yes
Unknown

Comments regarding freeze- thaw _____ ⑪

Other comment _____ ⑫

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NOT RECOMMENDED FOR SOURCE DOCUMENTATION

Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Biospecimen Collection

Form: Blood Collection Aliquots- PBMC

Generated On: 15 May 2019 14:40:46

Field Name	Data Type	Units	Values	Include Field OID
① PBMC_DT_T M	MMM dd yyyy HH nn			PBMC_DT_T M
② PBMC_BL_C OUNT	8.2			PBMC_BL_C OUNT
③ PBMC_BLD_C2 OLL_TYPE			1 = Plasma Collection 2 = Buffy Coat Collection 3 = Serum Collection 4 = PAX Gene 5 = PBMC 6 = Streck	PBMC_BLD_C OLL_TYPE
④ COLL_COMP_1 CK				COLL_COMP_ CK
⑤ ALQ_VIAL_S Z	1		1 = 2mL cryovials 2 = 5mL cryovial 3 = 15mL cryovial 4 = PAXgene Blood RNA tube	ALQ_VIAL_S Z
⑥ PBMC_CELL_ CNT	8.4			PBMC_CELL_ CNT

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NOT RECOMMENDED FOR SOURCE DOCUMENTATION

Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Biospecimen Collection

Form: Blood Collection Aliquots- PBMC

Generated On: 15 May 2019 14:40:46

Field Name	Data Type	Units	Values	Include Field OID
7 PBMC_LTGO _VOL	8.4			PBMC_LTGO _VOL
8 DT_TM_80_I N	MMM dd yyyy HH nn			DT_TM_80_I N
9 FRZ_TEMP	4.2			FRZ_TEMP
10 SAMP_FRZ_T HW			1 = No 2 = Yes 99 = Unknown	SAMP_FRZ_T HW
11 SAMP_FRZ_T HW_COMM	\$200			SAMP_FRZ_T HW_COMM
12 ALQ_COMM	\$200			ALQ_COMM
13 PBMC_TOT_ DERV	2			PBMC_TOT_ DERV

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NOT RECOMMENDED FOR SOURCE DOCUMENTATION

Was bronchial airway brushing performed?

- No ①
- Yes
- Unknown

Primary reason not performed

- Patient Refused ②
- Missing Materials
- Adverse Event
- Unknown
- Other, specify

Was bronchial airway brushing performed per protocol?

- No ③
- Yes
- Unknown

Primary reason not performed per protocol

- Missing Materials ④
- Site error
- Adverse Event
- Bronchoscopy not performed
- Unknown
- Other, specify

Date of bronchial airway Brushing

Fixed Unit: MMM dd yyyy ⑤

Were any adverse events that are considered possibly, probably, or definitely related to the study-related biospecimen collection procedures reported?

- No ⑥
- Yes
- Unknown

Type

Tube A 7

Tube B

Tube C

Tube D

Eppendorf tube containing

1mL of RNA protect Cell Reagent 8

1mL of 1X PBS solution for proteomic analysis

1mL of 1X PBS solution for DNA extraction

1mL of RNA protect Cell Reagent

Check if collected

9

Date and Time into Freezer

10

Temperature of Freezer

Fixed Unit: °C 11

Did any freeze-thaw occur to the sample?

No 12

Yes

Unknown

Comments regarding freeze-thaw

13

Other comments

14

Type

Tube A 7

Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Biospecimen Collection

Form: Bronchial Airway Brushing

Generated On: 15 May 2019 14:40:46

Tube B

Tube C

Tube D

Eppendorf tube containing

1mL of RNA protect Cell Reagent 8

1mL of 1X PBS solution for proteomic analysis

1mL of 1X PBS solution for DNA extraction

1mL of RNA protect Cell Reagent

Check if collected

9

Date and Time into Freezer

10

Temperature of Freezer

Fixed Unit: °C 11

Did any freeze-thaw occur to the sample?

No 12

Yes

Unknown

Comments regarding freeze-thaw

13

Other comments

14

Type

Tube A 7

Tube B

FOR SITE IRB SUBMISSION ONLY
NOT RECOMMENDED FOR SOURCE DOCUMENTATION

Tube C

Tube D

Eppendorf tube containing

1mL of RNA protect Cell Reagent 8

1mL of 1X PBS solution for proteomic analysis

1mL of 1X PBS solution for DNA extraction

1mL of RNA protect Cell Reagent

Check if collected 9

Date and Time into Freezer 10

Temperature of Freezer

Fixed Unit: °C 11

Did any freeze-thaw occur to the sample?

No 12

Yes

Unknown

Comments regarding freeze-thaw 13

Other comments 14

Type

Tube A 7

Tube B

Tube C

Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Biospecimen Collection

Form: Bronchial Airway Brushing

Generated On: 15 May 2019 14:40:46

Tube D

Eppendorf tube containing

- 1mL of RNA protect Cell Reagent 8
- 1mL of 1X PBS solution for proteomic analysis
- 1mL of 1X PBS solution for DNA extraction
- 1mL of RNA protect Cell Reagent

Check if collected 9

Date and Time into Freezer 10

Temperature of Freezer

Fixed Unit: °C 11

Did any freeze-thaw occur to the sample?

- No 12
- Yes
- Unknown

Comments regarding freeze-thaw 13

Other comments 14

FOR SITE IRB SUBMISSION ONLY
NOT RECOMMENDED FOR SOURCE DOCUMENTATION

Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Biospecimen Collection

Form: Bronchial Airway Brushing

Generated On: 15 May 2019 14:40:46

Field Name	Data Type	Units	Values	Include Field OID
① ENDOBRON_2 BRSH_COLL_ YN			1 = No 2 = Yes 99 = Unknown	ENDOBRON_ BRSH_COLL_ YN
② ENDOBRON_2 BRSH_ND			1 = Patient Refused 2 = Missing Materials 3 = Adverse Event 99 = Unknown 88 = Other, specify	ENDOBRON_ BRSH_ND
③ ENDOBRON_2 BRSH_PR_YN			1 = No 2 = Yes 99 = Unknown	ENDOBRON_ BRSH_PR_YN
④ ENDOBRON_2 BRSH_PR			1 = Missing Materials 2 = Site error 3 = Adverse Event 4 = Bronchoscopy not performed 99 = Unknown 88 = Other, specify	ENDOBRON_ BRSH_PR

FOR SITE IRB SUBMISSION ONLY
NOT RECOMMENDED FOR SOURCE DOCUMENTATION

Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Biospecimen Collection

Form: Bronchial Airway Brushing

Generated On: 15 May 2019 14:40:46

Field Name	Data Type	Units	Values	Include Field OID
5 ENDOBRON_ BRSH_COLL_ DT				ENDOBRON_ BRSH_COLL_ DT
6 AE_YN	2		1 = No 2 = Yes 99 = Unknown	AE_YN
7 ENDOBRON_2 TYPE			1 = Tube A 2 = Tube B 3 = Tube C 4 = Tube D	ENDOBRON_ TYPE
8 EPPEN_TUBE 2 _CONT			1 = 1mL of RNA protect Cell Reagent 2 = 1mL of 1X PBS solution for proteomic analysis 3 = 1mL of 1X PBS solution for DNA extraction 4 = 1mL of RNA protect Cell Reagent	EPPEN_TUBE _CONT
9 ENDOBRON_1 COLL				ENDOBRON_ COLL
10 DT_TM_80_I N	MMM dd yyyy HH nn			DT_TM_80_I N

Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Biospecimen Collection

Form: Bronchial Airway Brushing

Generated On: 15 May 2019 14:40:46

Field Name	Data Type	Units	Values	Include Field OID
11 FRZ_TEMP	4.2			FRZ_TEMP
12 SAMP_FRZ_T 2 HW			1 = No 2 = Yes 99 = Unknown	SAMP_FRZ_T HW
13 SAMP_FRZ_T \$200 HW_COMM				SAMP_FRZ_T HW_COMM
14 ALQ_COMM	\$200			ALQ_COMM

FOR SITE IRB SUBMISSION ONLY
NOT RECOMMENDED FOR SOURCE DOCUMENTATION

Was urine sample collected?

No ①
Yes
Unknown

Reason urine sample was not collected

Patient Refused ②
Adverse Event
Unknown
Other, specify

Date of Urine Sample Collection

Fixed Unit: MMM dd yyyy ③

Was urine collection performed per protocol?

No ④
Yes
Unknown

Primary reason urine collection was not performed per protocol

Urethral Area Not Cleaned ⑤
Site error
Storage not per protocol
Unknown
Other, specify

Were any adverse events that are considered possibly, probably, or definitely related to the study-related biospecimen collection procedures reported?

No ⑥
Yes
Unknown

Total number of urine cryovials collected

⑭

Draft 25 version 1.0 MIGPROD 17JAN2018: All forms
Folder: Biospecimen Collection
Form: Urine Collection (Midstream Clean Catch)
Generated On: 15 May 2019 14:40:46

Type

Sterile Urine Collection Container 7
Cryovial

Check if collected

8

Date and Time into Freezer

9

Temperature of Freezer

Fixed Unit: °C 10

Did any freeze-thaw occur to the sample?

No 11
Yes
Unknown

Comments regarding freeze-thaw

12

Other comments

13

Type

Sterile Urine Collection Container 7
Cryovial

Check if collected

8

Date and Time into Freezer

9

Temperature of Freezer

Fixed Unit: °C 10

Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Biospecimen Collection

Form: Urine Collection (Midstream Clean Catch)

Generated On: 15 May 2019 14:40:46

Did any freeze-thaw occur to the sample?

No 11
Yes
Unknown

Comments regarding freeze-thaw

12

Other comments

13

Type

Sterile Urine Collection 7
Container
Cryovial

Check if collected

8

Date and Time into Freezer

9

Temperature of Freezer

Fixed Unit: °C 10

Did any freeze-thaw occur to the sample?

No 11
Yes
Unknown

Comments regarding freeze-thaw

12

Other comments

13

Type Sterile Urine Collection Container **7**
 Cryovial

Check if collected _____ **8**

Date and Time into Freezer _____ **9**

Temperature of Freezer _____ Fixed Unit: °C **10**

Did any freeze-thaw occur to the sample? No **11**
Yes
Unknown

Comments regarding freeze-thaw _____ **12**

Other comments _____ **13**

Type Sterile Urine Collection Container **7**
 Cryovial

Check if collected _____ **8**

Date and Time into Freezer _____ **9**

Temperature of Freezer _____ Fixed Unit: °C **10**

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Did any freeze-thaw occur to the sample?

No 11
Yes
Unknown

Comments regarding freeze-thaw

12

Other comments

13

Type

Sterile Urine Collection Container 7
Cryovial

Check if collected

8

Date and Time into Freezer

9

Temperature of Freezer

Fixed Unit: °C 10

Did any freeze-thaw occur to the sample?

No 11
Yes
Unknown

Comments regarding freeze-thaw

12

Other comments

13

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms
Folder: Biospecimen Collection
Form: Urine Collection (Midstream Clean Catch)
Generated On: 15 May 2019 14:40:46

Field Name	Data Type	Units	Values	Include Field OID
① URN_SAMP_2 YN			1 = No 2 = Yes 99 = Unknown	URN_SAMP_ YN
② URN_SAMP_2 NCOLL_REAS			1 = Patient Refused 2 = Adverse Event 99 = Unknown 88 = Other, specify	URN_SAMP_ NCOLL_REAS
③ URN_SAMP_2 DT	MMM dd yyyy			URN_SAMP_ DT
④ URN_SAMP_2 COLL_PR			1 = No 2 = Yes 99 = Unknown	URN_SAMP_ COLL_PR
⑤ URN_NOT_P_2 R_REAS			1 = Urethral Area Not Cleaned 2 = Site error 3 = Storage not per protocol 99 = Unknown 88 = Other, specify	URN_NOT_P R_REAS

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms
Folder: Biospecimen Collection
Form: Urine Collection (Midstream Clean Catch)
Generated On: 15 May 2019 14:40:46

Field Name	Data Type	Units	Values	Include Field OID
6 AE_YN	2		1 = No 2 = Yes 99 = Unknown	AE_YN
7 URN_COLL_T2 YP			1 = Sterile Urine Collection Container 2 = Cryovial	URN_COLL_T YP
8 URN_COLL	1			URN_COLL
9 DT_TM_80_I N	MMM dd yyyy HH nn			DT_TM_80_I N
10 FRZ_TEMP	4.2			FRZ_TEMP
11 SAMP_FRZ_T2 HW			1 = No 2 = Yes 99 = Unknown	SAMP_FRZ_T HW
12 SAMP_FRZ_T HW_COMM	\$200			SAMP_FRZ_T HW_COMM
13 ALQ_COMM	\$200			ALQ_COMM
14 URN_SMP_C L_DERV	2			URN_SMP_C L_DERV

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Was nasal brushing performed?

- No ①
- Yes
- Unknown

Primary reason nasal brushing not performed

- Patient Refused ②
- Adverse Event
- Missing Materials
- Site Error
- Unknown
- Other, specify

Was nasal brushing performed per protocol?

- No ③
- Yes
- Unknown

Primary reason nasal brushing not done per protocol

- Storage Not Per Protocol ④
- Missing Materials
- Site Error
- Unknown
- Other, specify

Date of Nasal Brushing

Fixed Unit: MMM dd yyyy ⑤

Were any adverse events that are considered possibly, probably, or definitely related to the study-related biospecimen collection procedures reported?

- No ⑥
- Yes
- Unknown

Total number types checked

⑭

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Biospecimen Collection

Form: Nasal Brushing

Generated On: 15 May 2019 14:40:46

Type

Tube with RNAprotect Cell Reagent 7

Check if collected

Date and Time into Freezer

Temperature of Freezer

Fixed Unit: °C 10

Did any freeze-thaw occur to the sample?

No 11
Yes
Unknown

Comments regarding freeze-thaw

Other comments

Type

Tube with RNAprotect Cell Reagent 7

Check if collected

Date and Time into Freezer

Temperature of Freezer

Fixed Unit: °C 10

Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Biospecimen Collection

Form: Nasal Brushing

Generated On: 15 May 2019 14:40:46

Did any freeze-thaw occur to the sample?

No 11
Yes
Unknown

Comments regarding freeze-thaw

12

Other comments

13

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Biospecimen Collection

Form: Nasal Brushing

Generated On: 15 May 2019 14:40:46

Field Name	Data Type	Units	Values	Include Field OID
① NAS_BRUSH 2 _YN			1 = No 2 = Yes 99 = Unknown	NAS_BRUSH _YN
② NAS_BRUSH 2 _ND_REAS			1 = Patient Refused 2 = Adverse Event 3 = Missing Materials 4 = Site Error 99 = Unknown 88 = Other, specify	NAS_BRUSH _ND_REAS
③ NAS_BRUSH 2 _PR_YN			1 = No 2 = Yes 99 = Unknown	NAS_BRUSH _PR_YN
④ NAS_BRUSH 2 _ND_PR			1 = Storage Not Per Protocol 2 = Missing Materials 3 = Site Error 99 = Unknown 88 = Other, specify	NAS_BRUSH _ND_PR
⑤ NAS_BRUSH _DT	MMM dd yyyy			NAS_BRUSH _DT

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Biospecimen Collection

Form: Nasal Brushing

Generated On: 15 May 2019 14:40:46

Field Name	Data Type	Units	Values	Include Field OID
6 AE_YN	2		1 = No 2 = Yes 99 = Unknown	AE_YN
7 NAS_BRUSH _TYPE	1		1 = Tube with RNAprotect Cell Reagent	NAS_BRUSH _TYPE
8 NAS_BRUSH _COLL	1			NAS_BRUSH _COLL
9 DT_TM_80_I N	MMM dd yyyy HH nn			DT_TM_80_I N
10 FRZ_TEMP	4.2			FRZ_TEMP
11 SAMP_FRZ_T HW	2		1 = No 2 = Yes 99 = Unknown	SAMP_FRZ_T HW
12 SAMP_FRZ_T HW_COMM	\$200			SAMP_FRZ_T HW_COMM
13 ALQ_COMM	\$200			ALQ_COMM
14 NAS_TOT_D ERV	2			NAS_TOT_D ERV

Was buccal scraping performed?

- No ①
- Yes
- Unknown

Primary reason buccal scraping not performed

- Patient Refused ②
- Adverse Event
- Unknown
- Other, specify

Was buccal scraping performed per protocol?

- No ③
- Yes
- Unknown

Primary reason buccal scraping was not performed per protocol

- Missing Materials ④
- Site error
- Unknown
- Other, specify

Date of Buccal Scraping

Fixed Unit: MMM dd yyyy ⑤

Were any adverse events that are considered possibly, probably, or definitely related to the study-related biospecimen collection procedures reported?

- No ⑥
- Yes
- Unknown

Type

- Microtube ⑦
- Microtube with Scraper

Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Biospecimen Collection

Form: Buccal Scraping

Generated On: 15 May 2019 14:40:46

Check if Collected _____

8

Date and Time into Freezer _____

9

Temperature of Freezer _____

Fixed Unit: °C

10

Did any freeze-thaw occur to the sample?

No

11

Yes

Unknown

Comments regarding freeze thaw _____

12

Other comments _____

13

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Biospecimen Collection

Form: Buccal Scraping

Generated On: 15 May 2019 14:40:46

Field Name	Data Type	Units	Values	Include Field OID
① BUCCAL_SA MP_YN	2		1 = No 2 = Yes 99 = Unknown	BUCCAL_SA MP_YN
② BUCCAL_SA MP_ND_REA S	2		1 = Patient Refused 2 = Adverse Event 99 = Unknown 88 = Other, specify	BUCCAL_SA MP_ND_REA S
③ BUCCAL_ND _PR	2		1 = No 2 = Yes 99 = Unknown	BUCCAL_ND _PR
④ BCCL_ND_PR _REAS	2		1 = Missing Materials 2 = Site error 99 = Unknown 88 = Other, specify	BCCL_ND_PR _REAS
⑤ BUCCAL_SA MP_DT	MMM dd yyyy			BUCCAL_SA MP_DT
⑥ AE_YN	2		1 = No 2 = Yes 99 = Unknown	AE_YN

Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Biospecimen Collection

Form: Buccal Scraping

Generated On: 15 May 2019 14:40:46

Field Name	Data Type	Units	Values	Include Field OID
7 BCCL_TYPE	2		1 = Microtube 2 = Microtube with Scraper	BCCL_TYPE
8 BCCL_COLL	1			BCCL_COLL
9 DT_TM_80_I	MMM dd yyyy N HH nn			DT_TM_80_I N
10 FRZ_TEMP	4.2			FRZ_TEMP
11 SAMP_FRZ_T HW			1 = No 2 = Yes 99 = Unknown	SAMP_FRZ_T HW
12 SAMP_FRZ_T HW_COMM	\$200			SAMP_FRZ_T HW_COMM
13 ALQ_COMM	\$200			ALQ_COMM

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Biospecimen Collection

Form: Sputum Samples

Generated On: 15 May 2019 14:40:46

Was sputum sample collected by the patient and mailed to the core pathology lab?

No ①
Yes
Unknown

Primary reason not collected and/or mailed

Lost kit ②
Sputum kit not distributed to pt
Patient refused
Other Pt related error
Patient does not produce sputum on a regular basis
Other, specify

Date Sputum Sample Mailed _____ ③

Were any adverse events that are considered possibly probably, or definitely related to the study-related biospecimen collection procedures reported?

No ④
Yes
Unknown

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Biospecimen Collection

Form: Sputum Samples

Generated On: 15 May 2019 14:40:46

Field Name	Data Type	Units	Values	Include Field OID
① SPUTUM_SA MP_YN	2		1 = No 2 = Yes 99 = Unknown	SPUTUM_SA MP_YN
② SPUTUM_SA MP_ND	2		1 = Lost kit 2 = Sputum kit not distributed to pt 3 = Patient refused 4 = Other Pt related error 5 = Patient does not produce sputum on a regular basis 88 = Other, specify	SPUTUM_SA MP_ND
③ SPUTUM_SA MP_DT	MMM-dd YYYY			SPUTUM_SA MP_DT
④ AE_YN	2		1 = No 2 = Yes 99 = Unknown	AE_YN

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Was the urine processing for metabolomics study performed?

No ①
Yes
Unknown

If processing not done, provided primary reason

Participant Refused ②
Site error
Missing or Incomplete kit contents
Missing or incomplete material(s) or equipment
Other, specify

Was the urine processing for metabolomics study performed per protocol?

No ③
Yes
Unknown

Primary Reason not performed per protocol

Urethral Area Not Cleaned ④
Site error
Storage not per protocol
Prepared Urine specimen cups not used
Unknown
Other, specify

Date Urine Processed at Site

Fixed Unit: MMM dd yyyy ⑤

Were any adverse events that are considered possibly, probably, or definitely related to the study-related biospecimen collection procedures reported?

No ⑥
Yes
Unknown

Total number of urine checks _____ 14

Type _____

Sterile Conical Tube 7

Eppendorf Tube

Check if Collected _____ 8

Date and Time Into Freezer _____ 9

Freezer Temperature _____

Fixed Unit: °C 10

Did any freeze-thaw occur to the sample?

No 11

Yes

Unknown

Comments regarding freeze thaw _____ 12

Other comments _____ 13

Type _____

Sterile Conical Tube 7

Eppendorf Tube

Check if Collected _____ 8

Date and Time Into Freezer _____ 9

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Freezer Temperature

Fixed Unit: °C **10**

Did any freeze-thaw occur to the sample?

No **11**
Yes
Unknown

Comments regarding freeze thaw

12

Other comments

13

Type

Sterile Conical Tube **7**
Eppendorf Tube

Check if Collected

8

Date and Time Into Freezer

9

Freezer Temperature

Fixed Unit: °C **10**

Did any freeze-thaw occur to the sample?

No **11**
Yes
Unknown

Comments regarding freeze thaw

12

Other comments

13

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NOT RECOMMENDED FOR SOURCE DOCUMENTATION

Type

Sterile Conical Tube 7
Eppendorf Tube

Check if Collected

_____ 8

Date and Time Into Freezer

_____ 9

Freezer Temperature

Fixed Unit: °C 10

Did any freeze-thaw occur to the sample?

No 11
Yes
Unknown

Comments regarding freeze thaw

_____ 12

Other comments

_____ 13

Type

Sterile Conical Tube 7
Eppendorf Tube

Check if Collected

_____ 8

Date and Time Into Freezer

_____ 9

Freezer Temperature

Fixed Unit: °C 10

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Did any freeze-thaw occur to the sample?

No 11
Yes
Unknown

Comments regarding freeze thaw

12

Other comments

13

Type

Sterile Conical Tube 7
Eppendorf Tube

Check if Collected

8

Date and Time Into Freezer

9

Freezer Temperature

Fixed Unit: °C 10

Did any freeze-thaw occur to the sample?

No 11
Yes
Unknown

Comments regarding freeze thaw

12

Other comments

13

Draft 25 version 1.0 MIGPROD 17JAN2018: All forms
Folder: Biospecimen Collection
Form: Urine Processing for Metabolomics Study
Generated On: 15 May 2019 14:40:46

Field Name	Data Type	Units	Values	Include Field OID
① URN_PROC_2 COLL_YN			1 = No 2 = Yes 99 = Unknown	URN_PROC_ COLL_YN
② URN_PROC_2 COLL_ND			1 = Participant Refused 2 = Site error 3 = Missing or incomplete kit contents 4 = Missing or incomplete material(s) or equipment 88 = Other, specify	URN_PROC_ COLL_ND
③ URN_PROC_2 PR_YN			1 = No 2 = Yes 99 = Unknown	URN_PROC_ PR_YN
④ URN_PROC_2 PR_REAS			1 = Urethral Area Not Cleaned 2 = Site error 3 = Storage not per protocol	URN_PROC_ PR_REAS

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms
Folder: Biospecimen Collection
Form: Urine Processing for Metabolomics Study
Generated On: 15 May 2019 14:40:46

Field Name	Data Type	Units	Values	Include Field OID
			4 = Prepared Urine specimen cups not used 99 = Unknown 88 = Other, specify	
⑤ URN_PROC_ SITE_DT	MMM dd yyyy			URN_PROC_ SITE_DT
⑥ AE_YN	2		1 = No 2 = Yes 99 = Unknown	AE_YN
⑦ URN_PROC_ TYPE	2		1 = Sterile Conical Tube 2 = Eppendorf Tube	URN_PROC_ TYPE
⑧ URN_PROC_ COLL	1			URN_PROC_ COLL
⑨ DT_TM_80_I N	MMM dd yyyy HH nn			DT_TM_80_I N
⑩ FRZ_TEMP	4.2			FRZ_TEMP
⑪ SAMP_FRZ_T HW	2		1 = No 2 = Yes	SAMP_FRZ_T HW

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms
 Folder: Biospecimen Collection
 Form: Urine Processing for Metabolomics Study
 Generated On: 15 May 2019 14:40:46

Field Name	Data Type	Units	Values	Include Field OID
			99 = Unknown	
12 SAMP_FRZ_T HW_COMM	\$200			SAMP_FRZ_T HW_COMM
13 ALQ_COMM	\$200			ALQ_COMM
14 URN_PROC_ SITE_TOT	2			URN_PROC_ SITE_TOT

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms
Folder: Biospecimen Collection
Form: Blood Processing at Site
Generated On: 15 May 2019 14:40:46

Date Blood Processed at Site

Fixed Unit: MMM dd yyyy ①

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Biospecimen Collection

Form: Blood Processing at Site

Generated On: 15 May 2019 14:40:46

Field Name	Data Type	Units	Values	Include Field OID
① BLD_PROC_SMMM ITE_DT	dd yyyy			BLD_PROC_S ITE_DT

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Biospecimen Collection

Form: Biospecimen Transmittal-Required

Generated On: 15 May 2019 14:40:46

Kit Barcode _____ ①

Date Specimens Mailed _____ ②

Copy of Biospecimen Transmittal _____ ③

Total Number of Urine Checks _____ ⑫

Total Number of Nasal Epithelium Checks _____ ⑬

Total Number of PAXgene checks _____ ⑭

Total number of serum checks _____ ⑮

Total number of plasma checks _____ ⑯

Total number of streck checks _____ ⑰

Biospecimen Type _____ Blood Collection- Blood ④
Plasma

Barcode Sequence # _____ ⑤

Check if Specimen Included _____ ⑥

Storage Temp _____ Fixed Unit: °C ⑦

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Did any freeze/thaw occur?

No 8
Yes
Unknown

If yes to freeze/thaw- Total # of Times _____ 9

If yes to freeze/thaw- length of each time _____ 10

Comments _____ 11

Biospecimen Type _____

Blood Collection- Blood 4
Plasma

Barcode Sequence # _____ 5

Check if Specimen Included _____ 6

Storage Temp _____

Fixed Unit: °C 7

Did any freeze/thaw occur?

No 8
Yes
Unknown

If yes to freeze/thaw- Total # of Times _____ 9

If yes to freeze/thaw- length of each time _____ 10

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Biospecimen Collection

Form: Biospecimen Transmittal-Required

Generated On: 15 May 2019 14:40:46

Comments

11

Biospecimen Type

Blood Collection- Blood Plasma

4

Barcode Sequence #

9 5

Check if Specimen Included

6

Storage Temp

Fixed Unit: °C

7

Did any freeze/thaw occur?

No

Yes

Unknown

8

If yes to freeze/thaw- Total # of Times

9

If yes to freeze/thaw- length of each time

10

Comments

11

Biospecimen Type

Blood Collection- Blood Plasma

4

Barcode Sequence #

10 5

Check if Specimen Included _____ 6

Storage Temp _____ Fixed Unit: °C 7

Did any freeze/thaw occur? No 8
Yes
Unknown

If yes to freeze/thaw- Total # of Times _____ 9

If yes to freeze/thaw- length of each time _____ 10

Comments _____ 11

Biospecimen Type _____ Blood Collection- Blood 4
Plasma

Barcode Sequence # _____ 11 5

Check if Specimen Included _____ 6

Storage Temp _____ Fixed Unit: °C 7

Did any freeze/thaw occur? No 8
Yes
Unknown

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If yes to freeze/thaw- Total # of Times _____

9

If yes to freeze/thaw- length of each time _____

10

Comments _____

11

Biospecimen Type _____

Blood Collection- Blood
Plasma

4

Barcode Sequence # _____

12

5

Check if Specimen Included _____

6

Storage Temp _____

Fixed Unit: °C

7

Did any freeze/thaw occur?

No

8

Yes

Unknown

If yes to freeze/thaw- Total # of Times _____

9

If yes to freeze/thaw- length of each time _____

10

Comments _____

11

Biospecimen Type _____

Blood Collection- Serum

4

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Biospecimen Collection

Form: Biospecimen Transmittal-Required

Generated On: 15 May 2019 14:40:46

Barcode Sequence # _____ 19 **5**

Check if Specimen Included _____ **6**

Storage Temp _____ Fixed Unit: °C **7**

Did any freeze/thaw occur? No **8**
Yes
Unknown

If yes to freeze/thaw- Total # of Times _____ **9**

If yes to freeze/thaw- length of each time _____ **10**

Comments _____ **11**

Biospecimen Type _____ Blood Collection- Serum **4**

Barcode Sequence # _____ 20 **5**

Check if Specimen Included _____ **6**

Storage Temp _____ Fixed Unit: °C **7**

Did any freeze/thaw occur? No **8**
Yes

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Biospecimen Collection

Form: Biospecimen Transmittal-Required

Generated On: 15 May 2019 14:40:46

Unknown

If yes to freeze/thaw- Total # of Times _____

If yes to freeze/thaw- length of each time _____

Comments _____

Biospecimen Type

Blood Collection- Serum

Barcode Sequence # _____

21

Check if Specimen Included _____

Storage Temp _____

Fixed Unit: °C

Did any freeze/thaw occur?

No

Yes

Unknown

If yes to freeze/thaw- Total # of Times _____

If yes to freeze/thaw- length of each time _____

Comments _____

Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Biospecimen Collection

Form: Biospecimen Transmittal-Required

Generated On: 15 May 2019 14:40:46

Biospecimen Type Blood Collection-PAXgene **4**

Barcode Sequence # **5**

Check if Specimen Included **6**

Storage Temp Fixed Unit: °C **7**

Did any freeze/thaw occur? No **8**
Yes
Unknown

If yes to freeze/thaw- Total # of Times **9**

If yes to freeze/thaw- length of each time **10**

Comments **11**

Biospecimen Type Blood Collection-PAXgene **4**

Barcode Sequence # **5**

Check if Specimen Included **6**

Storage Temp Fixed Unit: °C **7**

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Biospecimen Collection

Form: Biospecimen Transmittal-Required

Generated On: 15 May 2019 14:40:46

Did any freeze/thaw occur?

No 8
Yes
Unknown

If yes to freeze/thaw- Total # of Times

9

If yes to freeze/thaw- length of each time

10

Comments

11

Biospecimen Type

Streck Collection 4

Barcode Sequence #

28 5

Check if Specimen Included

6

Storage Temp

Fixed Unit: °C 7

Did any freeze/thaw occur?

No 8
Yes
Unknown

If yes to freeze/thaw- Total # of Times

9

If yes to freeze/thaw- length of each time

10

Comments

11

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Biospecimen Collection

Form: Biospecimen Transmittal-Required

Generated On: 15 May 2019 14:40:46

Biospecimen Type

Streck Collection ④

Barcode Sequence #

29 ⑤

Check if Specimen Included

⑥

Storage Temp

Fixed Unit: °C ⑦

Did any freeze/thaw occur?

No ⑧

Yes

Unknown

If yes to freeze/thaw- Total # of Times

⑨

If yes to freeze/thaw- length of each time

⑩

Comments

⑪

Biospecimen Type

Streck Collection ④

Barcode Sequence #

30 ⑤

Check if Specimen Included

⑥

Storage Temp

Fixed Unit: °C ⑦

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NOT RECOMMENDED FOR SOURCE DOCUMENTATION

Did any freeze/thaw occur?

No 8
Yes
Unknown

If yes to freeze/thaw- Total # of Times

9

If yes to freeze/thaw- length of each time

10

Comments

11

Biospecimen Type

Streck Collection 4

Barcode Sequence #

31 5

Check if Specimen Included

6

Storage Temp

Fixed Unit: °C 7

Did any freeze/thaw occur?

No 8
Yes
Unknown

If yes to freeze/thaw- Total # of Times

9

If yes to freeze/thaw- length of each time

10

Comments

11

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NOT RECOMMENDED FOR SOURCE DOCUMENTATION

Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Biospecimen Collection

Form: Biospecimen Transmittal-Required

Generated On: 15 May 2019 14:40:46

Biospecimen Type

Bronchial Airway Brushings-
Brush A

4

Barcode Sequence #

60

5

Check if Specimen Included

6

Storage Temp

Fixed Unit: °C

7

Did any freeze/thaw occur?

No

8

Yes

Unknown

If yes to freeze/thaw- Total # of Times

9

If yes to freeze/thaw- length of each time

10

Comments

11

Biospecimen Type

Bronchial Airway Brushings-
Brush B

4

Barcode Sequence #

61

5

Check if Specimen Included

6

Storage Temp

Fixed Unit: °C

7

Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Biospecimen Collection

Form: Biospecimen Transmittal-Required

Generated On: 15 May 2019 14:40:46

Did any freeze/thaw occur?

No 8
Yes
Unknown

If yes to freeze/thaw- Total # of Times _____ 9

If yes to freeze/thaw- length of each time _____ 10

Comments _____ 11

Biospecimen Type

Bronchial Airway Brushings-
Brush C 4

Barcode Sequence #

62 5

Check if Specimen Included _____ 6

Storage Temp

Fixed Unit: °C 7

Did any freeze/thaw occur?

No 8
Yes
Unknown

If yes to freeze/thaw- Total # of Times _____ 9

If yes to freeze/thaw- length of each time _____ 10

FOR SITE IPB SUBMISSION ONLY
NOT RECOMMENDED FOR SOURCE DOCUMENTATION

Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Biospecimen Collection

Form: Biospecimen Transmittal-Required

Generated On: 15 May 2019 14:40:46

Comments

11

Biospecimen Type

Bronchial Biopsy Collection-
RUL Fresh Frozen

4

Barcode Sequence #

68

5

Check if Specimen Included

6

Storage Temp

Fixed Unit: °C

7

Did any freeze/thaw occur?

No

8

Yes

Unknown

If yes to freeze/thaw- Total # of Times

9

If yes to freeze/thaw- length of each time

10

Comments

11

Biospecimen Type

Bronchial Biopsy Collection-
RML Fresh Frozen

4

Barcode Sequence #

70

5

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NOT RECOMMENDED FOR SOURCE DOCUMENTATION

Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Biospecimen Collection

Form: Biospecimen Transmittal-Required

Generated On: 15 May 2019 14:40:46

Check if Specimen Included _____ 6

Storage Temp _____

Fixed Unit: °C 7

Did any freeze/thaw occur?

No 8

Yes

Unknown

If yes to freeze/thaw- Total # of Times _____ 9

If yes to freeze/thaw- length of each time _____ 10

Comments _____ 11

Biospecimen Type _____

Bronchial Biopsy Collection- 4
LUL Fresh Frozen

Barcode Sequence # _____

72 5

Check if Specimen Included _____ 6

Storage Temp _____

Fixed Unit: °C 7

Did any freeze/thaw occur?

No 8

Yes

Unknown

Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Biospecimen Collection

Form: Biospecimen Transmittal-Required

Generated On: 15 May 2019 14:40:46

If yes to freeze/thaw- Total # of Times _____

9

If yes to freeze/thaw- length of each time _____

10

Comments _____

11

Biospecimen Type

Buccal Epithelium Collection

4

Barcode Sequence # _____

51

5

Check if Specimen Included _____

6

Storage Temp _____

Fixed Unit: °C

7

Did any freeze/thaw occur?

No

Yes

Unknown

8

If yes to freeze/thaw- Total # of Times _____

9

If yes to freeze/thaw- length of each time _____

10

Comments _____

11

Biospecimen Type

Nasal Epithelium Collection

4

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Biospecimen Collection

Form: Biospecimen Transmittal-Required

Generated On: 15 May 2019 14:40:46

Barcode Sequence # 54 **5**

Check if Specimen Included **6**

Storage Temp Fixed Unit: °C **7**

Did any freeze/thaw occur? No **8**
Yes
Unknown

If yes to freeze/thaw- Total # of Times **9**

If yes to freeze/thaw- length of each time **10**

Comments **11**

Biospecimen Type Nasal Epithelium Collection **4**

Barcode Sequence # 55 **5**

Check if Specimen Included **6**

Storage Temp Fixed Unit: °C **7**

Did any freeze/thaw occur? No **8**
Yes

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NOT RECOMMENDED FOR SOURCE DOCUMENTATION

Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Biospecimen Collection

Form: Biospecimen Transmittal-Required

Generated On: 15 May 2019 14:40:46

Unknown

If yes to freeze/thaw- Total # of Times _____ 9

If yes to freeze/thaw- length of each time _____ 10

Comments _____ 11

Biospecimen Type _____ Urine Collection 4

Barcode Sequence # _____ 34 5

Check if Specimen Included _____ 6

Storage Temp _____ Fixed Unit: °C 7

Did any freeze/thaw occur? No 8
Yes
Unknown

If yes to freeze/thaw- Total # of Times _____ 9

If yes to freeze/thaw- length of each time _____ 10

Comments _____ 11

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NOT RECOMMENDED FOR SOURCE DOCUMENTATION

Draft 25 version 1.0 MIGPROD 17JAN2018: All forms
Folder: Biospecimen Collection
Form: Biospecimen Transmittal-Required
Generated On: 15 May 2019 14:40:46

Biospecimen Type

Urine Collection ④

Barcode Sequence #

35 ⑤

Check if Specimen Included

⑥

Storage Temp

Fixed Unit: °C ⑦

Did any freeze/thaw occur?

No ⑧
Yes
Unknown

If yes to freeze/thaw- Total # of Times

⑨

If yes to freeze/thaw- length of each time

⑩

Comments

⑪

Biospecimen Type

Urine Collection ④

Barcode Sequence #

36 ⑤

Check if Specimen Included

⑥

Storage Temp

Fixed Unit: °C ⑦

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Biospecimen Collection

Form: Biospecimen Transmittal-Required

Generated On: 15 May 2019 14:40:46

Did any freeze/thaw occur?

No 8
Yes
Unknown

If yes to freeze/thaw- Total # of Times

9

If yes to freeze/thaw- length of each time

10

Comments

11

Biospecimen Type

Urine Collection 4

Barcode Sequence #

37 5

Check if Specimen Included

6

Storage Temp

Fixed Unit: °C 7

Did any freeze/thaw occur?

No 8
Yes
Unknown

If yes to freeze/thaw- Total # of Times

9

If yes to freeze/thaw- length of each time

10

Comments

11

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms
Folder: Biospecimen Collection
Form: Biospecimen Transmittal-Required
Generated On: 15 May 2019 14:40:46

Biospecimen Type

Urine Collection

4

Barcode Sequence #

38

5

Check if Specimen Included

6

Storage Temp

Fixed Unit: °C

7

Did any freeze/thaw occur?

No

8

Yes

Unknown

If yes to freeze/thaw- Total # of Times

9

If yes to freeze/thaw- length of each time

10

Comments

11

Biospecimen Type

Urine Collection

4

Barcode Sequence #

39

5

Check if Specimen Included

6

Storage Temp

Fixed Unit: °C

7

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms
Folder: Biospecimen Collection
Form: Biospecimen Transmittal-Required
Generated On: 15 May 2019 14:40:46

Did any freeze/thaw occur?

No 8
Yes
Unknown

If yes to freeze/thaw- Total # of Times

_____ 9

If yes to freeze/thaw- length of each time

_____ 10

Comments

_____ 11

FOR SITE IRB SUBMISSION ONLY
NOT RECOMMENDED FOR SOURCE DOCUMENTATION

Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Biospecimen Collection

Form: Biospecimen Transmittal-Required

Generated On: 15 May 2019 14:40:46

Field Name	Data Type	Units	Values	Include Field OID
① BSPCM_KIT_ BCD	\$60			BSPCM_KIT_ BCD
② BSPCM_SENTMMM _CLAB_DT	dd yyyy			BSPCM_SENT _CLAB_DT
③ BSPCM_TRA NS_UP	\$200			BSPCM_TRA NS_UP
④ BSPCM_TYPE	2		Required Biospecimen Types	BSPCM_TYPE
⑤ BSPCM_BCD _SEQ	3		7 8 9 10 11 12 19 20 21 25 26 28 2 9 30 31 60 61 62 68 70 72 51 54 5 5 34 35 36 37 38 39	BSPCM_BCD _SEQ
⑥ BSPCM_ST_C R_LB				BSPCM_ST_C R_LB
⑦ BSPCM_ST_T EMP	4.2			BSPCM_ST_T EMP
⑧ BSPCM_FZ_T HAW			1 = No 2 = Yes 99 = Unknown	BSPCM_FZ_T HAW

Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Biospecimen Collection

Form: Biospecimen Transmittal-Required

Generated On: 15 May 2019 14:40:46

	Field Name	Data Type	Units	Values	Include Field OID
9	FZ_THAW_T TL_TME				FZ_THAW_T TL_TME
10	FX_THAW_L NGTH	\$200			FX_THAW_L NGTH
11	BSPCM_TRA NS_COMM	\$200			BSPCM_TRA NS_COMM
12	URN_TOT_D ERV				URN_TOT_D ERV
13	NAS_EP_TOT _DERV	2			NAS_EP_TOT _DERV
14	PAX_TOT_DE RV	2			PAX_TOT_DE RV
15	SERUM_TOT _DERV	2			SERUM_TOT _DERV
16	PLAS_TOT_D ERV	2			PLAS_TOT_D ERV
17	STRECK_TOT _DERV	2			STRECK_TOT _DERV

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Biospecimen Collection

Form: Biospecimen Transmittal- Required- Bronchial Biopsy Formalin Fixed

Generated On: 15 May 2019 14:40:46

Kit Barcode

①

Date Specimens Mailed

②

Copy of Biospecimen Transmittal- Bronchial Biopsy Formalin Fixed

③

Biospecimen Sample

Bronchial Biopsy Collection-
RUL Formalin Fixed

④

Barcode Sequence #

67

⑤

Check if Specimen Included

⑥

Comments

⑦

Biospecimen Sample

Bronchial Biopsy Collection-
RML Formalin Fixed

④

Barcode Sequence #

69

⑤

Check if Specimen Included

⑥

Comments

⑦

Biospecimen Sample

Bronchial Biopsy Collection-
LUL Formalin Fixed

④

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NOT RECOMMENDED FOR SOURCE DOCUMENTATION

Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Biospecimen Collection

Form: Biospecimen Transmittal- Required- Bronchial Biopsy Formalin Fixed

Generated On: 15 May 2019 14:40:46

Barcode Sequence #

71 **5**

Check if Specimen Included

6

Comments

7

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NOT RECOMMENDED FOR SOURCE DOCUMENTATION

Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Biospecimen Collection

Form: Biospecimen Transmittal- Required- Bronchial Biopsy Formalin Fixed

Generated On: 15 May 2019 14:40:46

Field Name	Data Type	Units	Values	Include Field OID
① BSPCM_KIT_ BCD	\$60			BSPCM_KIT_ BCD
② BSPCM_SENTMMM _CLAB_DT	dd yyyy			BSPCM_SENT _CLAB_DT
③ BSPCM_TRA NS_UP	\$200			BSPCM_TRA NS_UP
④ BSPCM_TYPE	2		Required Biospecimen Types	BSPCM_TYPE
⑤ BSPCM_BCD _SEQ	3		67 69 71	BSPCM_BCD _SEQ
⑥ BSPCM_ST_C R_LB	C2			BSPCM_ST_C R_LB
⑦ BSPCM_TRA NS_COMM	\$200			BSPCM_TRA NS_COMM

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms
Folder: Biospecimen Collection
Form: Biospecimen Transmittal- Optional
Generated On: 15 May 2019 14:40:46

Were optional biospecimens sent to the core lab?

No ①
Yes
Unknown

If no optional biospecimens were sent to the core lab, leave the table blank.

If optional specimens were sent, at least one row of the table must be checked as sent.

Date optional biospecimens sent to core lab _____ ③

Total number of Buffy Coat Checks _____ ⑫

Total number of PBMC checks _____ ⑬

Total number of Urine Processing for Metabolomics Study Checks _____ ⑭

Biospecimen Type

Blood Collection- Buffy Coat ④
Blood Collection- PBMC
Bronchial Airway Brushings
Collection- Tube D
Urine Processing for Metabolomics Study

Barcode Sequence # _____ 13 ⑤

Check if Specimen Included _____ ⑥

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Biospecimen Collection

Form: Biospecimen Transmittal- Optional

Generated On: 15 May 2019 14:40:46

Storage Temp _____

Fixed Unit: °C

7

Did any freeze/thaw occur? _____

No

8

Yes

Unknown

If yes to freeze/thaw- Total # of Times _____

9

If yes to freeze/thaw- length of each time _____

10

Comments _____

11

Biospecimen Type _____

Blood Collection- Buffy Coat

4

Blood Collection- PBMC

Bronchial Airway Brushings

Collection- Tube D

Urine Processing for

Metabolomics Study

Barcode Sequence # _____

14

5

Check if Specimen Included _____

6

Storage Temp _____

Fixed Unit: °C

7

Did any freeze/thaw occur? _____

No

8

Yes

Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Biospecimen Collection

Form: Biospecimen Transmittal- Optional

Generated On: 15 May 2019 14:40:46

Unknown

If yes to freeze/thaw- Total # of Times _____

If yes to freeze/thaw- length of each time _____

Comments _____

Biospecimen Type

Blood Collection- Buffy Coat

Blood Collection- PBMC

Bronchial Airway Brushings

Collection- Tube D

Urine Processing for
Metabolomics Study

Barcode Sequence # _____

Check if Specimen Included _____

Storage Temp _____

Fixed Unit: °C _____

Did any freeze/thaw occur?

No

Yes

Unknown

If yes to freeze/thaw- Total # of Times _____

If yes to freeze/thaw- length of each time _____

Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Biospecimen Collection

Form: Biospecimen Transmittal- Optional

Generated On: 15 May 2019 14:40:46

Comments

11

Biospecimen Type

Blood Collection- Buffy Coat

4

Blood Collection- RBMC

Bronchial Airway Brushings

Collection- Tube D

Urine Processing for

Metabolomics Study

Barcode Sequence #

16

5

Check if Specimen Included

6

Storage Temp

Fixed Unit: °C

7

Did any freeze/thaw occur?

No

8

Yes

Unknown

If yes to freeze/thaw- Total # of Times

9

If yes to freeze/thaw- length of each time

10

Comments

11

Biospecimen Type

Blood Collection- Buffy Coat

4

Blood Collection- PBMC

Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Biospecimen Collection

Form: Biospecimen Transmittal- Optional

Generated On: 15 May 2019 14:40:46

Bronchial Airway Brushings
Collection- Tube D
Urine Processing for
Metabolomics Study

Barcode Sequence # 17 **5**

Check if Specimen Included **6**

Storage Temp Fixed Unit: °C **7**

Did any freeze/thaw occur? No **8**
Yes
Unknown

If yes to freeze/thaw- Total # of Times **9**

If yes to freeze/thaw- length of each time **10**

Comments **11**

Biospecimen Type Blood Collection- Buffy Coat **4**
Blood Collection- PBMC
Bronchial Airway Brushings
Collection- Tube D
Urine Processing for
Metabolomics Study

Barcode Sequence # 18 **5**

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Biospecimen Collection

Form: Biospecimen Transmittal- Optional

Generated On: 15 May 2019 14:40:46

Check if Specimen Included _____ ⑥

Storage Temp _____

Fixed Unit: °C ⑦

Did any freeze/thaw occur? _____

No ⑧

Yes

Unknown

If yes to freeze/thaw- Total # of Times _____ ⑨

If yes to freeze/thaw- length of each time _____ ⑩

Comments _____ ⑪

Biospecimen Type _____

Blood Collection- Buffy Coat ④

Blood Collection- PBMC

Bronchial Airway Brushings

Collection- Tube D

Urine Processing for
Metabolomics Study

Barcode Sequence # _____

27 ⑤

Check if Specimen Included _____ ⑥

Storage Temp _____

Fixed Unit: °C ⑦

Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Biospecimen Collection

Form: Biospecimen Transmittal- Optional

Generated On: 15 May 2019 14:40:46

Did any freeze/thaw occur?

No 8
Yes
Unknown

If yes to freeze/thaw- Total # of Times

9

If yes to freeze/thaw- length of each time

10

Comments

11

Biospecimen Type

Blood Collection- Buffy Coat 4
Blood Collection- PBMC
Bronchial Airway Brushings
Collection- Tube D
Urine Processing for
Metabolomics Study

Barcode Sequence #

28 5

Check if Specimen Included

6

Storage Temp

Fixed Unit: °C 7

Did any freeze/thaw occur?

No 8
Yes
Unknown

If yes to freeze/thaw- Total # of Times

9

Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Biospecimen Collection

Form: Biospecimen Transmittal- Optional

Generated On: 15 May 2019 14:40:46

If yes to freeze/thaw- length of each time _____

10

Comments _____

11

Biospecimen Type

Blood Collection- Buffy Coat 4

Blood Collection- PBMC

Bronchial Airway Brushings

Collection- Tube D

Urine Processing for Metabolomics Study

Barcode Sequence # _____

29 5

Check if Specimen Included _____

6

Storage Temp _____

Fixed Unit: °C 7

Did any freeze/thaw occur?

No 8

Yes

Unknown

If yes to freeze/thaw- Total # of Times _____

9

If yes to freeze/thaw- length of each time _____

10

Comments _____

11

Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Biospecimen Collection

Form: Biospecimen Transmittal- Optional

Generated On: 15 May 2019 14:40:46

Biospecimen Type

Blood Collection- Buffy Coat ④

Blood Collection- PBMC

Bronchial Airway Brushings

Collection- Tube D

Urine Processing for

Metabolomics Study

Barcode Sequence #

30 ⑤

Check if Specimen Included

⑥

Storage Temp

Fixed Unit: °C ⑦

Did any freeze/thaw occur?

No ⑧

Yes

Unknown

If yes to freeze/thaw- Total # of Times

⑨

If yes to freeze/thaw- length of each time

⑩

Comments

⑪

Biospecimen Type

Blood Collection- Buffy Coat ④

Blood Collection- PBMC

Bronchial Airway Brushings

Collection- Tube D

Urine Processing for

Metabolomics Study

Draft 25 version 1.0 MIGPROD 17JAN2018: All forms
Folder: Biospecimen Collection
Form: Biospecimen Transmittal- Optional
Generated On: 15 May 2019 14:40:46

Barcode Sequence # 31 **5**

Check if Specimen Included _____ **6**

Storage Temp _____ Fixed Unit: °C **7**

Did any freeze/thaw occur? No **8**
Yes
Unknown

If yes to freeze/thaw- Total # of Times _____ **9**

If yes to freeze/thaw- length of each time _____ **10**

Comments _____ **11**

Biospecimen Type Blood Collection- Buffy Coat **4**
Blood Collection- PBMC
Bronchial Airway Brushings Collection- Tube D
Urine Processing for Metabolomics Study

Barcode Sequence # 63 **5**

Check if Specimen Included _____ **6**

Storage Temp _____ Fixed Unit: °C **7**

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Biospecimen Collection

Form: Biospecimen Transmittal- Optional

Generated On: 15 May 2019 14:40:46

Did any freeze/thaw occur?

No 8
Yes
Unknown

If yes to freeze/thaw- Total # of Times

9

If yes to freeze/thaw- length of each time

10

Comments

11

Biospecimen Type

Blood Collection- Buffy Coat 4
Blood Collection- PBMC
Bronchial Airway Brushings
Collection- Tube D
Urine Processing for
Metabolomics Study

Barcode Sequence #

40 5

Check if Specimen Included

6

Storage Temp

Fixed Unit: °C 7

Did any freeze/thaw occur?

No 8
Yes
Unknown

If yes to freeze/thaw- Total # of Times

9

Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Biospecimen Collection

Form: Biospecimen Transmittal- Optional

Generated On: 15 May 2019 14:40:46

If yes to freeze/thaw- length of each time _____ 10

Comments _____ 11

Biospecimen Type

- Blood Collection- Buffy Coat 4
- Blood Collection- PBMC
- Bronchial Airway Brushings
- Collection- Tube D
- Urine Processing for Metabolomics Study

Barcode Sequence # _____ 41 5

Check if Specimen Included _____ 6

Storage Temp _____

Fixed Unit: °C 7

Did any freeze/thaw occur?

- No 8
- Yes
- Unknown

If yes to freeze/thaw- Total # of Times _____ 9

If yes to freeze/thaw- length of each time _____ 10

Comments _____ 11

Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Biospecimen Collection

Form: Biospecimen Transmittal- Optional

Generated On: 15 May 2019 14:40:46

Biospecimen Type

Blood Collection- Buffy Coat 4

Blood Collection- PBMC

Bronchial Airway Brushings

Collection- Tube D

Urine Processing for Metabolomics Study

Barcode Sequence #

42 5

Check if Specimen Included

6

Storage Temp

Fixed Unit: °C 7

Did any freeze/thaw occur?

No 8

Yes

Unknown

If yes to freeze/thaw- Total # of Times

9

If yes to freeze/thaw- length of each time

10

Comments

11

Biospecimen Type

Blood Collection- Buffy Coat 4

Blood Collection- PBMC

Bronchial Airway Brushings

Collection- Tube D

Urine Processing for Metabolomics Study

Draft 25 version 1.0 MIGPROD 17JAN2018: All forms
Folder: Biospecimen Collection
Form: Biospecimen Transmittal- Optional
Generated On: 15 May 2019 14:40:46

Barcode Sequence # 43 **5**

Check if Specimen Included _____ **6**

Storage Temp _____ Fixed Unit: °C **7**

Did any freeze/thaw occur? No **8**
Yes
Unknown

If yes to freeze/thaw- Total # of Times _____ **9**

If yes to freeze/thaw- length of each time _____ **10**

Comments _____ **11**

Biospecimen Type Blood Collection- Buffy Coat **4**
Blood Collection- PBMC
Bronchial Airway Brushings
Collection- Tube D
Urine Processing for
Metabolomics Study

Barcode Sequence # 44 **5**

Check if Specimen Included _____ **6**

Storage Temp _____ Fixed Unit: °C **7**

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Biospecimen Collection

Form: Biospecimen Transmittal- Optional

Generated On: 15 May 2019 14:40:46

Did any freeze/thaw occur?

No 8
Yes
Unknown

If yes to freeze/thaw- Total # of Times

9

If yes to freeze/thaw- length of each time

10

Comments

11

Biospecimen Type

Blood Collection- Buffy Coat 4
Blood Collection- PBMC
Bronchial Airway Brushings
Collection- Tube D
Urine Processing for
Metabolomics Study

Barcode Sequence #

45 5

Check if Specimen Included

6

Storage Temp

Fixed Unit: °C 7

Did any freeze/thaw occur?

No 8
Yes
Unknown

If yes to freeze/thaw- Total # of Times

9

Draft 25 version 1.0 MIGPROD 17JAN2018: All forms
Folder: Biospecimen Collection
Form: Biospecimen Transmittal- Optional
Generated On: 15 May 2019 14:40:46

If yes to freeze/thaw- length of each time _____

Comments _____

10

11

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Biospecimen Collection

Form: Biospecimen Transmittal- Optional

Generated On: 15 May 2019 14:40:46

Field Name	Data Type	Units	Values	Include Field OID
① OP_BSPCM_2 COLL			1 = No 2 = Yes 99 = Unknown	OP_BSPCM_ COLL
③ BSPCM_SENTMMM _CLAB_DT	dd yyyy			BSPCM_SENT _CLAB_DT
④ BSPCM_OP_T2 YPE			1 = Blood Collection Buffy Coat 2 = Blood Collection- PBMG 3 = Bronchial Airway Brushings Collection- Tube D 4 = Urine Processing for Metabolomics Study	BSPCM_OP_T YPE
⑤ BSPCM_BCD_3 _SEQ			13 14 15 16 17 18 27 2 8 29 30 31 63 40 41 42 43 44 45	BSPCM_BCD _SEQ
⑥ BSPCM_ST_C2 R_LB				BSPCM_ST_C R_LB
⑦ BSPCM_ST_T 4.2 EMP				BSPCM_TEM P

Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Biospecimen Collection

Form: Biospecimen Transmittal- Optional

Generated On: 15 May 2019 14:40:46

Field Name	Data Type	Units	Values	Include Field OID
8 BSPCM_FZ_T HAW			1 = No 2 = Yes 99 = Unknown	BSPCM_FZ_T HAW
9 FZ_THAW_T TL_TME				FZ_THAW_T TL_TME
10 FX_THAW_L NGTH	\$200			FX_THAW_L NGTH
11 BSPCM_TRA NS_COMM	\$200			BSPCM_TRA NS_COMM
12 BUFFY_CT_T OT_DERV				BUFFY_CT_T OT_DERV
13 PBMC_TRAN S_TOT_DERV				PBMC_TRAN S_TOT_DERV
14 URN_MET_T OT_DERV				URN_MET_T OT_DERV

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NOT RECOMMENDED FOR SOURCE DOCUMENTATION

Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Biospecimen Collection

Form: Biospecimen Transmittal- Additional

Generated On: 15 May 2019 14:40:46

Were additional biospecimens sent to the core lab?

No ①
Yes
Unknown

If no additional biospecimens were sent to the core lab, leave the table blank.

If additional specimens were sent, at least one row of the table must be completed.

Biospecimen Type

Blood Collection- Blood Plasma ③
Blood Collection- Buffy Coat
Blood Collection- PBMC
Blood Collection- Serum
Blood Collection-PAXgene
Bronchial Airway Brushings Collection
Bronchial Biopsy Collection
Buccal Epithelium Collection
Nasal Epithelium Collection
Urine Collection
Other, specify

Barcode Sequence # _____ ④

Date Sent to Core Lab _____ ⑤

Storage Temp _____

Fixed Unit: °C ⑥

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Folder: Biospecimen Collection
Form: Biospecimen Transmittal- Additional
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Did any freeze/thaw occur?

No 7
Yes
Unknown

If yes to freeze/thaw- Total # of Times

_____ 8

If yes to freeze/thaw- length of each time

_____ 9

Comments

_____ 10

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Folder: Biospecimen Collection

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Field Name	Data Type	Units	Values	Include Field OID
① ADD_BSPCM 2 _COLL			1 = No 2 = Yes 99 = Unknown	ADD_BSPCM _COLL
③ BSPCM_TYPE 3 _ADD			1 = Blood Collection- Blood Plasma 2 = Blood Collection- Buffy Coat 3 = Blood Collection- PBMG 4 = Blood Collection- Serum 5 = Blood Collection-PA Xgène 6 = Bronchial Airway Brushings Collection 7 = Bronchial Biopsy Collection 8 = Buccal Epithelium Collection 9 = Nasal Epithelium Collection 10 = Urine Collection 88 = Other, specify	BSPCM_TYPE _ADD

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Field Name	Data Type	Units	Values	Include Field OID
④ BSPCM_BCD _SEQ				BSPCM_BCD _SEQ
⑤ BSPCM_SENTMMM _CLAB_DT	dd yyyy			BSPCM_SENT _CLAB_DT
⑥ BSPCM_ST_T EMP	4.2			BSPCM_ST_T EMP
⑦ BSPCM_FZ_T HAW			1 = No 2 = Yes 99 = Unknown	BSPCM_FZ_T HAW
⑧ FZ_THAW_T TL_TME	3			FZ_THAW_T TL_TME
⑨ FX_THAW_L NGTH	\$200			FX_THAW_L NGTH
⑩ BSPCM_TRA NS_COMM	\$200			BSPCM_TRA NS_COMM

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Folder: Adverse Events

Form: Adverse Events

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INSTRUCTION TEXT. (Please refer to your local IRB's policies regarding AEs.)

AE Term

Adverse Event Text Name (CTCAE v4.0)

Adverse Event Grade

1- Mild

2- Moderate

3- Severe

4- Life-threatening or
disabling

5- Death

CTC Adverse Event Attribution Scale

Unrelated

Unlikely

Possible

Probable

Definite

Expectedness

Expected

Unexpected

Serious AE?

No

Yes

Action Taken- Mark all that apply

Action Taken- None

Action Taken- Medication Therapy

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Folder: Adverse Events

Form: Adverse Events

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Action Taken- Procedure _____ 11

Action Taken- Hospitalization _____ 12

Action Taken- Other _____ 13

Outcome _____ 14

Recovered 14

Improved

Ongoing

Death

Unknown

AE Start Date _____ 15

AE End Date _____ 16

Check if ongoing _____ 17

Comments _____ 18

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Folder: Adverse Events

Form: Adverse Events

Generated On: 15 May 2019 14:40:46

Field Name	Data Type	Units	Values	Include Field OID
② AE_TERM	\$200			AE_TERM
③ TOXXX	10		CTCAE_403_ TOXXX TERM	
④ VALXX	2		1 = 1- Mild 2 = 2- Moderate 3 = 3- Severe 4 = 4- Life-threatening or disabling 5 = 5- Death	VALXX
⑤ TOX_RLXX	1		1 = Unrelated 2 = Unlikely 3 = Possible 4 = Probable 5 = Definite	TOX_RLXX
⑥ AE_EXP	2		1 = Expected 2 = Unexpected	AE_EXP
⑦ AER_XX	1		1 = No 2 = Yes	AER_XX
⑨ AE_ACT_TKN _NON	1			AE_ACT_TKN _NON

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Folder: Adverse Events

Form: Adverse Events

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Field Name	Data Type	Units	Values	Include Field OID
10 AE_ACT_TKN1 _MED				AE_ACT_TKN _MED
11 AE_ACT_TKN1 _PROC				AE_ACT_TKN _PROC
12 AE_ACT_TKN1 _HOS				AE_ACT_TKN _HOS
13 AE_ACT_TKN1 _OTH				AE_ACT_TKN _OTH
14 AE_OUTCOM 2 E			1 = Recovered 2 = Improved 3 = Ongoing 4 = Death 5 = Unknown	AE_OUTCOM E
15 AE_START_D T	MMM dd yyyy			AE_START_D T
16 AE_END_DT	MMM dd yyyy			AE_END_DT
17 AE_ONGOIN G	1			AE_ONGOIN G
18 COMTOXOTH	\$200			COMTOXOTH

Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Adverse Events

Form: Serious Adverse Event

Generated On: 15 May 2019 14:40:46

The Serious Adverse Event Form should only be completed for reportable serious adverse events
One Serious Adverse Event Form should be completed per SAE. Any updates to the SAE should be recorded on the original SAE report

Definition of an SAE= any untoward medical occurrence that:

- Results in death;
 - Is life-threatening (at the time of the event);
 - Requires inpatient hospitalization or prolongation of an existing hospitalization;
 - Results in persistent or significant disability or incapacity;
 - Is a congenital anomaly/birth defect;
 - Is considered a medically-important event
- Refer to the 4703 Protocol Section 10.0 for more details

The Site PI must electronically sign off on the eCRF before the form can be considered complete

Check if Final Report (i.e., no additional data will be collected regarding this SAE) _____ **2**

Date of Birth _____ **3**

Patient Gender Male **4**
Female

Describe the serious adverse event (SAE) _____ **5**

Onset Date of Event _____ **6**

Severity of Event Mild **7**
Moderate
Severe
Life threatening
Fatal

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Relationship of the study to the SAE

- Unrelated **8**
- Unlikely
- Possible
- Probable
- Definite

Event Resolution

- Recovered/Resolved **9**
- Ongoing
- Recovered/Resolved with sequelae, specify sequelae
- Fatal
- Unknown

If recovered/resolved, please provide date _____ **10**

If fatal, please provide date of death _____ **11**

Seriousness Criteria for SAE

- Death **12**
- Life threatening
- Hospitalization
- Prolongation of hospitalization
- Congenital anomaly or birth defect
- Persistent or significant disability/incapacity
- Important medical event requiring medical or surgical intervention to prevent serious outcome, please specify:

Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Adverse Events

Form: Serious Adverse Event

Generated On: 15 May 2019 14:40:46

Field Name	Data Type	Units	Values	Include Field OID
② FINAL_REPO RT	1			FINAL_REPO RT
③ PT_DOB_SAE MM- dd- YYYY				PT_DOB_SAE
④ PT_GENDER_2 SAE			1 = Male 2 = Female	PT_GENDER_ SAE
⑤ SAE_DESCRI P	\$600			SAE_DESCRI P
⑥ SAE_ONSET_ DT	MMM dd yyyy			SAE_ONSET_ DT
⑦ SAE_SEVERI TY	2		1 = Mild 2 = Moderate 3 = Severe 4 = Life threatening 5 = Fatal	SAE_SEVERI TY
⑧ SAE_RLTHSP _STUDY	2		1 = Unrelated 2 = Unlikely 3 = Possible 4 = Probable 5 = Definite	SAE_RLTHSP _STUDY

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Folder: Adverse Events

Form: Serious Adverse Event

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Field Name	Data Type	Units	Values	Include Field OID
9 SAE_RESOLU TION			1 = Recovered/R esolved 2 = Ongoing 3 = Recovered/R esolved with sequelae, specify sequelae 4 = Fatal 99 = Unknown	SAE_RESOLU TION
10 SAE_RECRES _DT	MMM dd yyyy			SAE_RECRES _DT
11 SAE_DTH_D T	MMM dd- yyyy			SAE_DTH_D T
12 SAE_CRITERI A			1 = Death 2 = Life threatening 3 = Hospitalizatio n 4 = Prolongation of hospitalizatio n 5 = Congenital anomaly or birth defect	SAE_CRITERI A

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Adverse Events

Form: Serious Adverse Event

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Field Name	Data Type	Units	Values	Include Field OID
			6 = Persistent or significantdis ability/incapa city 7 = Important medical event requiring medical or surgical intervention to prevent serious outcome please specify:	

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Follow up- 1 Year

Form: SOC Follow up

Generated On: 15 May 2019 14:40:46

Was the SOC follow up completed?

No ①
Yes
Unknown

If the SOC follow up was not completed, please provide the primary reason it was not done

Patient Refused ②
Patient Lost to Follow up
Site error
Other, specify

Date of Standard of Care Follow up

Fixed Unit: MMM dd yyyy ③

Were any adverse events that are considered possibly, probably, or definitely related to the study-related biospecimen collection procedures reported?

No ④
Yes
Unknown

Did the patient have any imaging performed as part of follow up?

No ⑤
Yes
Unknown

Provide the date(s) of imaging the patient had as part of follow up

⑥

Did the patient have any surgery performed as part of follow up?

No ⑦
Yes
Unknown

Date of Surgery

⑧

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Follow up- 1 Year

Form: SOC Follow up

Generated On: 15 May 2019 14:40:46

Were surgical tissue samples collected?

- No 9
- Yes
- Unknown

Primary reason surgical tissue samples were not collected

- Site Error 10
- Patient Refused
- Pathology Lab Refused
- Request
- Unknown
- Other, specify

NOW Derivation

11

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Follow up- 1 Year

Form: SOC Follow up

Generated On: 15 May 2019 14:40:46

Field Name	Data Type	Units	Values	Include Field OID
① SOC_FU_YN	2		1 = No 2 = Yes 99 = Unknown	SOC_FU_YN
② SOC_FU_ND _REAS	2		1 = Patient Refused 2 = Patient Lost to Follow up 3 = Site error 88 = Other, specify	SOC_FU_ND _REAS
③ SOC_FU_DT	MMM dd yyyy			SOC_FU_DT
④ AE_FU_YN	2		1 = No 2 = Yes 99 = Unknown	AE_FU_YN
⑤ IMAG_YN	2		1 = No 2 = Yes 99 = Unknown	IMAG_YN
⑥ IMAG_DR_FU	MMM dd yyyy			IMAG_DR_FU
⑦ SURG_YN	2		1 = No 2 = Yes 99 = Unknown	SURG_YN

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Folder: Follow up- 1 Year

Form: SOC Follow up

Generated On: 15 May 2019 14:40:46

Field Name	Data Type	Units	Values	Include Field OID
8 SURG_DT	MMM dd yyyy			SURG_DT
9 SURG_SAMP 2 _YN			1 = No 2 = Yes 99 = Unknown	SURG_SAMP _YN
10 SURG_SAMP 2 _ND_RSN			1 = Site Error 2 = Patient Refused 3 = Pathology Lab Refused Request 99 = Unknown 88 = Other, specify	SURG_SAMP _ND_RSN
11 NOW_4DERI VATION	MMM dd/yyyy HH ss			NOW_4DERI VATION

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NOT RECOMMENDED FOR SOURCE DOCUMENTATION

Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Follow up- 1 Year

Form: Study Evaluation and Diagnosis- Pt I, II, III

Generated On: 15 May 2019 14:40:46

Instructions: The Study Evaluation and Diagnosis Worksheet should be completed by the Treating Physician at each SOC follow up visit for the patient. Any malignancy identified during the two-year follow-up time period will need to be reported on the Study Evaluation and Diagnosis Form.

1. - Was the Study Evaluation and Diagnosis Form completed by the treating physician? No ②
Yes
Unknown

1a. - If no, provide primary reason Patient Refused Follow up ③
Patient Lost to Follow up
Treating physician did not complete form
Other, specify

2. - Date study evaluation and diagnosis completed _____ ④

3. - Is there malignancy in the lung? No, further follow up is required ⑤
No, this is a benign case, follow up will cease
Yes
Uncertain, but presumed malignant
Uncertain

3a. - If yes, provide date established _____ ⑥

3b. - If yes, the malignancy is: Primary Lung ⑦
Metastatic to the Lung
Uncertain
Presumed Cancer- primary lung

Presumed Cancer- metastatic
to the lung
Other, specify

3b1. - If metastatic, provide the primary site of origin: _____ **8**

4. - Did the case have any other cancer diagnosis? No **9**
Yes

4a. - If yes, provide the primary site _____ **10**

Part II. Lung Malignancy complete this section only if Q3b=primary lung

5. - Has the lung malignancy been reported on a previous Study Evaluation and Diagnosis form? No **12**
Yes
Not Applicable
Unknown

5a. - Has the patient developed progressive disease following treatment for lung cancer? No **13**
Yes
Unknown

5a1. If yes, date of first documentation of progressive lung cancer _____ **14**

5a2. List the site(s) of progression of cancer Original lung site **15**
Other lung site(s)
Pleura
Brain
Bone

- Liver
- Adrenal
- Skin/subcutaneous tissue
- N1 regional lymph nodes (ipsilateral hilar/intrapulmonary)
- N2 ipsilateral mediastinal lymph nodes
- N3 distant lymph nodes (contralateral mediastinal or hilar/supraclavicular/scalene)
- Unknown
- Other, specify

6. - Lung Cancer Type

- Small Cell Lung Cancer 16
- Non-Small Cell Lung Cancer
- Carcinoid
- Unknown
- Other, specify

7. - Histologic Class

- Adenocarcinoma 17
- Adenosquamous Carcinoma
- Epidermoid Carcinoma
- Bronchioloalveolar Carcinoma
- Carcinoid
- Large Cell Carcinoma
- Small Cell Carcinoma
- Squamous Cell Carcinoma
- Other, specify
- Unknown

8. - Histologic Subtype

- Acinar 18

- Bronchioalveola
- Papillary
- Solid carcinoma with mucus formation
- Mixed
- Pure small cell carcinoma
- Combined small cell carcinoma
- Large cell neuroendocrine
- Basaloid
- Lymphoepithelial-like
- Large cell with rhabdoid phenotype
- Unknown
- Other, specify

9. - Cancer Stage

- Occult 19
- 0
- IA
- IB
- IIA
- IIB
- IIIA
- IIIB
- IV

Part III. No Malignancy complete this section only if Q3=No, this is a benign case, follow up will cease

10. - Provide the reasoning for the no malignancy diagnosis

- Alternate Diagnosis 21
- Resolution of Abnormality
- Stable mass, no additional FU

Stable mass, additional FU required
Other, specify

11. - If alternative diagnosis, what is the alternate diagnosis?

- Sarcoid 22
- Altelectasis
- Carcinoid
- Infection
- Other, specify

11a. - If the alternative diagnosis is infection, provide the type

- TB 23
- Bacterial Pneumonia
- Fungus
- Viral Pneumonia
- Other, specify

Enrollment Date- Derived

24

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Folder: Follow up- 1 Year
Form: Study Evaluation and Diagnosis- Pt I, II, III
Generated On: 15 May 2019 14:40:46

Field Name	Data Type	Units	Values	Include Field OID
② ST_EV_DX_C2 OM_YN			1 = No 2 = Yes 99 = Unknown	ST_EV_DX_C OM_YN
③ ST_EV_DX_N2 D_RS			1 = Patient Refused Follow up 2 = Patient Lost to Follow up 3 = Treating physician did not complete form 88 = Other, specify	ST_EV_DX_N D_RS
④ ST_EV_DX_CMMM dd yyyy OM_DT				ST_EV_DX_C OM_DT
⑤ MLGNCY_LG 2 _YN			1 = No, further follow up is required 2 = No, this is a benign case, follow up will cease 3 = Yes 5 = Uncertain, but presumed malignant	MLGNCY_LG _YN

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Folder: Follow up- 1 Year

Form: Study Evaluation and Diagnosis- Pt I, II, III

Generated On: 15 May 2019 14:40:46

Field Name	Data Type	Units	Values	Include Field OID
			4 = Uncertain	
⑥ DX_EST_DT	MMM- dd- YYYY			DX_EST_DT
⑦ MLGNCY_LG _TYPE	2		1 = Primary Lung 2 = Metastatic to the Lung 3 = Uncertain 4 = Presumed Cancer- primary lung 5 = Presumed Cancer- metastatic to the lung 88 = Other, specify	MLGNCY_LG _TYPE
⑧ DX_MET_SIT E_ORG	2		Cancer Primary Origin	DX_MET_SIT E_ORG
⑨ OTHER_CX_ DX_YN	2		1 = No 2 = Yes	OTHER_CX_ DX_YN
⑩ OTHER_CX_ DX_SITE	2		Cancer Primary Origin	OTHER_CX_ DX_SITE

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms
 Folder: Follow up- 1 Year
 Form: Study Evaluation and Diagnosis- Pt I, II, III
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Field Name	Data Type	Units	Values	Include Field OID
12 LUNG_CS_PR2 V_REP_YN			1 = No 2 = Yes 98 = Not Applicable 99 = Unknown	LUNG_CS_PR V_REP_YN
13 LG_MLG_PRG2 _DX			1 = No 2 = Yes 99 = Unknown	LG_MLG_PRG _DX
14 LG_MLG_PRGMMM- dd- _DT yyyy				LG_MLG_PRG DT
15 LUNG_CS_PR2 OG_SITE			1 = Original lung site 2 = Other lung site(s) 3 = Pleura 4 = Brain 5 = Bone 6 = Liver 7 = Adrenal 8 = Skin/subcuta neous tissue 9 = N1 regional lymph nodes (ipsilateral hilar/intrapul monary)	LUNG_CS_PR OG_SITE

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Follow up- 1 Year

Form: Study Evaluation and Diagnosis- Pt I, II, III

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Field Name	Data Type	Units	Values	Include Field OID
			10 = N2 ipsilateral mediastinal lymph nodes 11 = N3 distant lymph nodes (contralateral mediastinal or hilar/supracla vicular/scale ne) 99 = Unknown 88 = Other, specify	
16 LG_CX_TYPE 2			1 = Small Cell Lung Cancer 2 = Non-Small Cell Lung Cancer 3 = Carcinoid 99 = Unknown 88 = Other, specify	LG_CX_TYPE
17 LG_CX_HIST 2 _CLS			4 = Adenocarcino ma 8 = Adenosquam ous Carcinoma	LG_CX_HIST

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 Form: Study Evaluation and Diagnosis- Pt I, II, III
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Field Name	Data Type	Units	Values	Include Field OID
			1 = Epidermoid Carcinoma 5 = Bronchioloalveolar Carcinoma 6 = Carcinoid 3 = Large Cell Carcinoma 7 = Small Cell Carcinoma 2 = Squamous Cell Carcinoma 88 = Other, Specify 99 = Unknown	

18 LG_CX_HIST 2 _SBTYP			1 = Acinar 2 = Bronchioalveolar 3 = Papillary 4 = Solid carcinoma with mucus formation 5 = Mixed 6 = Pure small cell carcinoma 7 = Combined small cell carcinoma	LG_CX_HIST _SBTYP
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 Folder: Follow up- 1 Year
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Field Name	Data Type	Units	Values	Include Field OID
			8 = Large cell neuroendocrine 9 = Basaloid 10 = Lymphoepithelial-like 11 = Large cell with rhabdoid phenotype 99 = Unknown 88 = Other, specify	
19 NSM_CELL_L 2 G_CS_STG			1 = Occult 2 = 0 3 = IA 4 = IB 5 = IIA 6 = IIB 7 = IIIA 8 = IIIB 9 = IV	NSM_CELL_L G_CS_STG
21 NMLGY_REA 2 SON			1 = Alternate Diagnosis 2 = Resolution of Abnormality 3 = Stable mass, no additional FU 4 = Stable mass, additional FU required	NMLGY_REA SON

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Field Name	Data Type	Units	Values	Include Field OID
			88 = Other, specify	
22 NMLG_ALT_2 DX_TYPE			1 = Sarcoid 2 = Altelectasis 3 = Carcinoid 4 = Infection 88 = Other, specify	NMLG_ALT_ DX_TYPE
23 NMLGY_ALT_2 DX_TYPE			1 = TB 2 = Bacterial Pneumonia 3 = Fungus 4 = Viral Pneumonia 88 = Other, specify	NMLGY_ALT_ DX_TYPE
24 ENROL_DT_ DERV	dd MMM/yyyy			ENROL_DT_ DERV

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Folder: Follow up- 1 Year

Form: Study Evaluation and Diagnosis- Pt IV

Generated On: 15 May 2019 14:40:46

Part IV. Diagnostic tests performed since the last Study Evaluation and Diagnosis Form was completed required if Q1=yes

Note: All diagnostic tests will need a de-identified copy of the report uploaded into Rave

NOW DERIVATION _____ ⑦

Diagnostic Test Type

Bone Scan ②

Was test performed since last Study Evaluation and Diagnosis form was completed?

No ③

Yes

Unknown

Date of test _____ ④

Was test used to establish diagnosis described above?

No ⑤

Yes

Upload Report _____ ⑥

Diagnostic Test Type

Bronchoscopy ②

Was test performed since last Study Evaluation and Diagnosis form was completed?

No ③

Yes

Unknown

Date of test _____ ④

Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Follow up- 1 Year

Form: Study Evaluation and Diagnosis- Pt IV

Generated On: 15 May 2019 14:40:46

Was test used to establish diagnosis described above?

No 5
Yes

Upload Report _____ 6

Diagnostic Test Type

Chest X Ray 2

Was test performed since last Study Evaluation and Diagnosis form was completed?

No 3
Yes
Unknown

Date of test _____ 4

Was test used to establish diagnosis described above?

No 5
Yes

Upload Report _____ 6

Diagnostic Test Type

CT Scan 2

Was test performed since last Study Evaluation and Diagnosis form was completed?

No 3
Yes
Unknown

Date of test _____ 4

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NOT RECOMMENDED FOR SOURCE DOCUMENTATION

Was test used to establish diagnosis described above?

No 5
Yes

Upload Report _____ 6

Diagnostic Test Type

Lobectomy 2

Was test performed since last Study Evaluation and Diagnosis form was completed?

No 3
Yes
Unknown

Date of test _____ 4

Was test used to establish diagnosis described above?

No 5
Yes

Upload Report _____ 6

Diagnostic Test Type

Mediastinoscopy 2

Was test performed since last Study Evaluation and Diagnosis form was completed?

No 3
Yes
Unknown

Date of test _____ 4

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Was test used to establish diagnosis described above?

No 5
Yes

Upload Report _____ 6

Diagnostic Test Type

MRI 2

Was test performed since last Study Evaluation and Diagnosis form was completed?

No 3
Yes
Unknown

Date of test _____ 4

Was test used to establish diagnosis described above?

No 5
Yes

Upload Report _____ 6

Diagnostic Test Type

PET 2

Was test performed since last Study Evaluation and Diagnosis form was completed?

No 3
Yes
Unknown

Date of test _____ 4

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Form: Study Evaluation and Diagnosis- Pt IV

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Was test used to establish diagnosis described above?

No 5
Yes

Upload Report _____ 6

Diagnostic Test Type

Sputum 2

Was test performed since last Study Evaluation and Diagnosis form was completed?

No 3
Yes
Unknown

Date of test _____ 4

Was test used to establish diagnosis described above?

No 5
Yes

Upload Report _____ 6

Diagnostic Test Type

TBNA 2

Was test performed since last Study Evaluation and Diagnosis form was completed?

No 3
Yes
Unknown

Date of test _____ 4

Was test used to establish diagnosis described above?

No 5
Yes

Upload Report _____ 6

Diagnostic Test Type

Surgical Lung Biopsy 2

Was test performed since last Study Evaluation and Diagnosis form was completed?

No 3
Yes
Unknown

Date of test _____ 4

Was test used to establish diagnosis described above?

No 5
Yes

Upload Report _____ 6

Diagnostic Test Type

TTNA 2

Was test performed since last Study Evaluation and Diagnosis form was completed?

No 3
Yes
Unknown

Date of test _____ 4

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms
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Was test used to establish diagnosis described above?

No 5
Yes

Upload Report

6

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NOT RECOMMENDED FOR SOURCE DOCUMENTATION

Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Follow up- 1 Year

Form: Study Evaluation and Diagnosis- Pt IV

Generated On: 15 May 2019 14:40:46

Field Name	Data Type	Units	Values	Include Field OID
② DX_TSTS_TY PE			Diagnosis Methods	DX_TSTS_TY PE
③ DX_TSTS_US ED_YNU			1 = No 2 = Yes 99 = Unknown	DX_TSTS_US ED_YNU
④ DX_TST_DT	MMM dd yyyy			DX_TST_DT
⑤ DX_TSTS_US ED_DX			1 = No 2 = Yes	DX_TSTS_US ED_DX
⑥ DX_TSTS_FI LE	\$200			DX_TSTS_FI LE
⑦ NOW_2DERI VATION	MMM dd yyyy HH ss			NOW_2DERI VATION

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Follow up- 1 Year

Form: Surgical Lung Specimens- Formalin Fixed

Generated On: 15 May 2019 14:40:46

Kit Barcode

1

Date Specimen Mailed

2

Copy of Surgical Lung Specimen- Formalin Fixed Transmittal Form

3

Biospecimen Type

Formalin Fixed Tumor Tissue

4

Formalin Fixed Normal Tissue

Barcode Sequence #

5

Check if Specimen Included

6

Storage Temp

Fixed Unit: °C

7

Did any freeze/thaw occur?

No

8

Yes

Unknown

If yes to freeze/thaw- Total # of Times

9

If yes to freeze/thaw- length of each time

10

Comments

11

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Follow up- 1 Year

Form: Surgical Lung Specimens- Formalin Fixed

Generated On: 15 May 2019 14:40:46

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Barcode Sequence #

5

Check if Specimen Included

6

Storage Temp

Fixed Unit: °C

7

Did any freeze/thaw occur?

No

8

Yes

Unknown

If yes to freeze/thaw- Total # of Times

9

If yes to freeze/thaw- length of each time

10

Comments

11

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Follow up- 1 Year

Form: Surgical Lung Specimens- Formalin Fixed

Generated On: 15 May 2019 14:40:46

Field Name	Data Type	Units	Values	Include Field OID
① BSPCM_KIT_ BCD	\$60			BSPCM_KIT_ BCD
② BSPCM_SENTMMM _CLAB_DT	dd yyyy			BSPCM_SENT _CLAB_DT
③ SURG_SAMP _FILE	\$200			SURG_SAMP _FILE
④ SURG_SAMP 2 FF_TYPE			1 = Formalin Fixed Tumor Tissue 2 = Formalin Fixed Normal Tissue	SURG_SAMP FF_TYPE
⑤ BSPCM_BCD 3 _SEQ				BSPCM_BCD _SEQ
⑥ BSPCM_ST_C2 R_LB				BSPCM_ST_C R_LB
⑦ BSPCM_ST_T 4.2 EMP				BSPCM_ST_T EMP
⑧ BSPCM_FZ_T 2 HAW			1 = No 2 = Yes 99 = Unknown	BSPCM_FZ_T HAW
⑨ FZ_THAW_T 3 TL_TME				FZ_THAW_T TL_TME

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Follow up- 1 Year

Form: Surgical Lung Specimens- Formalin Fixed

Generated On: 15 May 2019 14:40:46

Field Name	Data Type	Units	Values	Include Field OID
⑩ FX_THAW_L NGTH	\$200			FX_THAW_L NGTH
⑪ BSPCM_TRA NS_COMM	\$200			BSPCM_TRA NS_COMM

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Follow up- 1 Year

Form: Surgical Lung Specimens- Fresh Frozen

Generated On: 15 May 2019 14:40:46

Kit Barcode _____ ①

Date Specimen Mailed _____ ②

Copy of Surgical Lung Specimens- Fresh Frozen Transmittal Form _____ ③

Biospecimen Type
Fresh Frozen Tumor Tissue ④
Fresh Frozen Normal Tissue

Barcode Sequence # _____ ⑤

Check if specimen included _____ ⑥

Storage Temp _____ Fixed Unit: °C ⑦

Did any freeze/thaw occur? No ⑧
Yes
Unknown

If yes to freeze/thaw- Total # of Times _____ ⑨

If yes to freeze/thaw- length of each time _____ ⑩

Comments _____ ⑪

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Follow up- 1 Year

Form: Surgical Lung Specimens- Fresh Frozen

Generated On: 15 May 2019 14:40:46

Biospecimen Type

Fresh Frozen Tumor Tissue ④

Fresh Frozen Normal Tissue

Barcode Sequence # _____ ⑤

Check if specimen included _____ ⑥

Storage Temp _____

Fixed Unit: °C ⑦

Did any freeze/thaw occur?

No ⑧

Yes

Unknown

If yes to freeze/thaw- Total # of Times _____ ⑨

If yes to freeze/thaw- length of each time _____ ⑩

Comments _____ ⑪

FOR SITE IRB SUBMISSION ONLY
NOT RECOMMENDED FOR SOURCE DOCUMENTATION

Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Follow up- 1 Year

Form: Surgical Lung Specimens- Fresh Frozen

Generated On: 15 May 2019 14:40:46

Field Name	Data Type	Units	Values	Include Field OID
① BSPCM_KIT_ BCD	\$60			BSPCM_KIT_ BCD
② BSPCM_SENTMMM _CLAB_DT	dd yyyy			BSPCM_SENT _CLAB_DT
③ SURG_SPEC_ FRZ_UPL	\$200			SURG_SPEC_ FRZ_UPL
④ SURG_SAMP 2 _FFZ_TYPE			1 = Fresh Frozen Tumor Tissue 2 = Fresh Frozen Normal Tissue	SURG_SAMP _FFZ_TYPE
⑤ BSPCM_BCD 3 _SEQ				BSPCM_BCD _SEQ
⑥ BSPCM_ST_C2 R_LB				BSPCM_ST_C R_LB
⑦ BSPCM_ST_T4.2 EMP				BSPCM_ST_T EMP
⑧ BSPCM_FZ_T 2 HAW			1 = No 2 = Yes 99 = Unknown	BSPCM_FZ_T HAW
⑨ FZ_THAW_T 3 TL_TME				FZ_THAW_T TL_TME

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NOT RECOMMENDED FOR SOURCE DOCUMENTATION

Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Follow up- 1 Year

Form: Surgical Lung Specimens- Fresh Frozen

Generated On: 15 May 2019 14:40:46

Field Name	Data Type	Units	Values	Include Field OID
⑩ FX_THAW_L NGTH	\$200			FX_THAW_L NGTH
⑪ BSPCM_TRA NS_COMM	\$200			BSPCM_TRA NS_COMM

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Follow up- 2 Year

Form: SOC Follow up

Generated On: 15 May 2019 14:40:46

Was the SOC follow up completed?

No ①
Yes
Unknown

If the SOC follow up was not completed, please provide the primary reason it was not done

Patient Refused ②
Patient Lost to Follow up
Site error
Other, specify

Date of Standard of Care Follow up

Fixed Unit: MMM dd yyyy ③

Were any adverse events that are considered possibly, probably, or definitely related to the study-related biospecimen collection procedures reported?

No ④
Yes
Unknown

Did the patient have any imaging performed as part of follow up?

No ⑤
Yes
Unknown

Provide the date(s) of imaging the patient had as part of follow up

⑥

Did the patient have any surgery performed as part of follow up?

No ⑦
Yes
Unknown

Date of Surgery

⑧

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Were surgical tissue samples collected?

- No 9
- Yes
- Unknown

Primary reason surgical tissue samples were not collected

- Site Error 10
- Patient Refused
- Pathology Lab Refused
- Request
- Unknown
- Other, specify

NOW Derivation

11

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Follow up- 2 Year

Form: SOC Follow up

Generated On: 15 May 2019 14:40:46

Field Name	Data Type	Units	Values	Include Field OID
① SOC_FU_YN	2		1 = No 2 = Yes 99 = Unknown	SOC_FU_YN
② SOC_FU_ND _REAS	2		1 = Patient Refused 2 = Patient Lost to Follow up 3 = Site error 88 = Other, specify	SOC_FU_ND _REAS
③ SOC_FU_DT	MMM dd yyyy			SOC_FU_DT
④ AE_FU_YN	2		1 = No 2 = Yes 99 = Unknown	AE_FU_YN
⑤ IMAG_YN	2		1 = No 2 = Yes 99 = Unknown	IMAG_YN
⑥ IMAG_DR_FU	MMM dd yyyy			IMAG_DR_FU
⑦ SURG_YN	2		1 = No 2 = Yes 99 = Unknown	SURG_YN

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Follow up- 2 Year

Form: SOC Follow up

Generated On: 15 May 2019 14:40:46

Field Name	Data Type	Units	Values	Include Field OID
8 SURG_DT	MMM dd yyyy			SURG_DT
9 SURG_SAMP 2 _YN			1 = No 2 = Yes 99 = Unknown	SURG_SAMP _YN
10 SURG_SAMP 2 _ND_RSN			1 = Site Error 2 = Patient Refused 3 = Pathology Lab Refused Request 99 = Unknown 88 = Other, specify	SURG_SAMP _ND_RSN
11 NOW_4DERI VATION	MMM dd/yyyy HH ss			NOW_4DERI VATION

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NOT RECOMMENDED FOR SOURCE DOCUMENTATION

Instructions: The Study Evaluation and Diagnosis Worksheet should be completed by the Treating Physician at each SOC follow up visit for the patient. Any malignancy identified during the two-year follow-up time period will need to be reported on the Study Evaluation and Diagnosis Form.

1. - Was the Study Evaluation and Diagnosis Form completed by the treating physician? No ②
Yes
Unknown

1a. - If no, provide primary reason Patient Refused Follow up ③
Patient Lost to Follow up
Treating physician did not complete form
Other, specify

2. - Date study evaluation and diagnosis completed _____ ④

3. - Is there malignancy in the lung? No, further follow up is required ⑤
No, this is a benign case, follow up will cease
Yes
Uncertain, but presumed malignant
Uncertain

3a. - If yes, provide date established _____ ⑥

3b. - If yes, the malignancy is: Primary Lung ⑦
Metastatic to the Lung
Uncertain
Presumed Cancer- primary lung

Presumed Cancer- metastatic
to the lung
Other, specify

3b1. - If metastatic, provide the primary site of origin: _____ (8)

4. - Did the case have any other cancer diagnosis? No (9)
Yes

4a. - If yes, provide the primary site _____ (10)

Part II. Lung Malignancy complete this section only if Q3b=primary lung

5. - Has the lung malignancy been reported on a previous Study Evaluation and Diagnosis form? No (12)
Yes
Not Applicable
Unknown

5a. - Has the patient developed progressive disease following treatment for lung cancer? No (13)
Yes
Unknown

5a1. If yes, date of first documentation of progressive lung cancer _____ (14)

5a2. List the site(s) of progression of cancer Original lung site (15)
Other lung site(s)
Pleura
Brain
Bone

- Liver
- Adrenal
- Skin/subcutaneous tissue
- N1 regional lymph nodes (ipsilateral hilar/intrapulmonary)
- N2 ipsilateral mediastinal lymph nodes
- N3 distant lymph nodes (contralateral mediastinal or hilar/supraclavicular/scalene)
- Unknown
- Other, specify

6. - Lung Cancer Type

- Small Cell Lung Cancer 16
- Non-Small Cell Lung Cancer
- Carcinoid
- Unknown
- Other, specify

7. - Histologic Class

- Adenocarcinoma 17
- Adenosquamous Carcinoma
- Epidermoid Carcinoma
- Bronchioloalveolar Carcinoma
- Carcinoid
- Large Cell Carcinoma
- Small Cell Carcinoma
- Squamous Cell Carcinoma
- Other, specify
- Unknown

8. - Histologic Subtype

- Acinar 18

- Bronchioalveola
- Papillary
- Solid carcinoma with mucus formation
- Mixed
- Pure small cell carcinoma
- Combined small cell carcinoma
- Large cell neuroendocrine
- Basaloid
- Lymphoepithelial-like
- Large cell with rhabdoid phenotype
- Unknown
- Other, specify

9. - Cancer Stage

- Occult 19
- 0
- IA
- IB
- IIA
- IIB
- IIIA
- IIIB
- IV

Part III. No Malignancy complete this section only if Q3=No, this is a benign case, follow up will cease

10. - Provide the reasoning for the no malignancy diagnosis

- Alternate Diagnosis 21
- Resolution of Abnormality
- Stable mass, no additional FU

Stable mass, additional FU required
Other, specify

11. - If alternative diagnosis, what is the alternate diagnosis?

- Sarcoid 22
- Altelectasis
- Carcinoid
- Infection
- Other, specify

11a. - If the alternative diagnosis is infection, provide the type

- TB 23
- Bacterial Pneumonia
- Fungus
- Viral Pneumonia
- Other, specify

Enrollment Date- Derived

24

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms
Folder: Follow up- 2 Year
Form: Study Evaluation and Diagnosis- Pt I, II, III
Generated On: 15 May 2019 14:40:46

Field Name	Data Type	Units	Values	Include Field OID
② ST_EV_DX_C2 OM_YN			1 = No 2 = Yes 99 = Unknown	ST_EV_DX_C OM_YN
③ ST_EV_DX_N2 D_RS			1 = Patient Refused Follow up 2 = Patient Lost to Follow up 3 = Treating physician did not complete form 88 = Other, specify	ST_EV_DX_N D_RS
④ ST_EV_DX_CMMM dd yyyy OM_DT				ST_EV_DX_C OM_DT
⑤ MLGNCY_LG 2 _YN			1 = No, further follow up is required 2 = No, this is a benign case, follow up will cease 3 = Yes 5 = Uncertain, but presumed malignant	MLGNCY_LG _YN

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Follow up- 2 Year

Form: Study Evaluation and Diagnosis- Pt I, II, III

Generated On: 15 May 2019 14:40:46

Field Name	Data Type	Units	Values	Include Field OID
			4 = Uncertain	
⑥ DX_EST_DT	MMM- dd- YYYY			DX_EST_DT
⑦ MLGNCY_LG _TYPE	2		1 = Primary Lung 2 = Metastatic to the Lung 3 = Uncertain 4 = Presumed Cancer- primary lung 5 = Presumed Cancer- metastatic to the lung 88 = Other, specify	MLGNCY_LG _TYPE
⑧ DX_MET_SIT E_ORG	2		Cancer Primary Origin	DX_MET_SIT E_ORG
⑨ OTHER_CX_ DX_YN	2		1 = No 2 = Yes	OTHER_CX_ DX_YN
⑩ OTHER_CX_ DX_SITE	2		Cancer Primary Origin	OTHER_CX_ DX_SITE

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms
 Folder: Follow up- 2 Year
 Form: Study Evaluation and Diagnosis- Pt I, II, III
 Generated On: 15 May 2019 14:40:46

Field Name	Data Type	Units	Values	Include Field OID
12 LUNG_CS_PR2 V_REP_YN			1 = No 2 = Yes 98 = Not Applicable 99 = Unknown	LUNG_CS_PR V_REP_YN
13 LG_MLG_PRG2 _DX			1 = No 2 = Yes 99 = Unknown	LG_MLG_PRG _DX
14 LG_MLG_PRGMMM- dd- _DT yyyy				LG_MLG_PRG DT
15 LUNG_CS_PR2 OG_SITE			1 = Original lung site 2 = Other lung site(s) 3 = Pleura 4 = Brain 5 = Bone 6 = Liver 7 = Adrenal 8 = Skin/subcuta neous tissue 9 = N1 regional lymph nodes (ipsilateral hilar/intrapul monary)	LUNG_CS_PR OG_SITE

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms
 Folder: Follow up- 2 Year
 Form: Study Evaluation and Diagnosis- Pt I, II, III
 Generated On: 15 May 2019 14:40:46

Field Name	Data Type	Units	Values	Include Field OID
			10 = N2 ipsilateral mediastinal lymph nodes 11 = N3 distant lymph nodes (contralateral mediastinal or hilar/supracla vicular/scale ne) 99 = Unknown 88 = Other, specify	
16 LG_CX_TYPE 2			1 = Small Cell Lung Cancer 2 = Non-Small Cell Lung Cancer 3 = Carcinoid 99 = Unknown 88 = Other, specify	LG_CX_TYPE
17 LG_CX_HIST 2 _CLS			4 = Adenocarcino ma 8 = Adenosquam ous Carcinoma	LG_CX_HIST

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms
 Folder: Follow up- 2 Year
 Form: Study Evaluation and Diagnosis- Pt I, II, III
 Generated On: 15 May 2019 14:40:46

Field Name	Data Type	Units	Values	Include Field OID
			1 = Epidermoid Carcinoma 5 = Bronchioloalveolar Carcinoma 6 = Carcinoid 3 = Large Cell Carcinoma 7 = Small Cell Carcinoma 2 = Squamous Cell Carcinoma 88 = Other, Specify 99 = Unknown	

18 LG_CX_HIST 2 _SBTYP			1 = Acinar 2 = Bronchioalveolar 3 = Papillary 4 = Solid carcinoma with mucus formation 5 = Mixed 6 = Pure small cell carcinoma 7 = Combined small cell carcinoma	LG_CX_HIST _SBTYP
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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms
 Folder: Follow up- 2 Year
 Form: Study Evaluation and Diagnosis- Pt I, II, III
 Generated On: 15 May 2019 14:40:46

Field Name	Data Type	Units	Values	Include Field OID
			8 = Large cell neuroendocri ne 9 = Basaloid 10 = Lymphoepith elial-like 11 = Large cell with rhabdoid phenotype 99 = Unknown 88 = Other, specify	
19 NSM_CELL_L 2 G_CS_STG			1 = Occult 2 = 0 3 = IA 4 = IB 5 = IIA 6 = IIB 7 = IIIA 8 = IIIB 9 = IV	NSM_CELL_L G_CS_STG
21 NMLGY_REA 2 SON			1 = Alternate Diagnosis 2 = Resolution of Abnormality 3 = Stable mass, no additional FU 4 = Stable mass, additional FU required	NMLGY_REA SON

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms
 Folder: Follow up- 2 Year
 Form: Study Evaluation and Diagnosis- Pt I, II, III
 Generated On: 15 May 2019 14:40:46

Field Name	Data Type	Units	Values	Include Field OID
			88 = Other, specify	
22 NMLG_ALT_2 DX_TYPE			1 = Sarcoid 2 = Altelectasis 3 = Carcinoid 4 = Infection 88 = Other, specify	NMLG_ALT_ DX_TYPE
23 NMLGY_ALT_2 DX_TYPE			1 = TB 2 = Bacterial Pneumonia 3 = Fungus 4 = Viral Pneumonia 88 = Other, specify	NMLGY_ALT_ DX_TYPE
24 ENROL_DT_ DERV	dd MMM/yyyy			ENROL_DT_ DERV

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Follow up- 2 Year

Form: Study Evaluation and Diagnosis- Pt IV

Generated On: 15 May 2019 14:40:46

Part IV. Diagnostic tests performed since the last Study Evaluation and Diagnosis Form was completed required if Q1=yes

Note: All diagnostic tests will need a de-identified copy of the report uploaded into Rave

NOW DERIVATION _____ ⑦

Diagnostic Test Type

Bone Scan ②

Was test performed since last Study Evaluation and Diagnosis form was completed?

No ③

Yes

Unknown

Date of test _____ ④

Was test used to establish diagnosis described above?

No ⑤

Yes

Upload Report _____ ⑥

Diagnostic Test Type

Bronchoscopy ②

Was test performed since last Study Evaluation and Diagnosis form was completed?

No ③

Yes

Unknown

Date of test _____ ④

Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Follow up- 2 Year

Form: Study Evaluation and Diagnosis- Pt IV

Generated On: 15 May 2019 14:40:46

Was test used to establish diagnosis described above?

No 5
Yes

Upload Report _____ 6

Diagnostic Test Type

Chest X Ray 2

Was test performed since last Study Evaluation and Diagnosis form was completed?

No 3
Yes
Unknown

Date of test _____ 4

Was test used to establish diagnosis described above?

No 5
Yes

Upload Report _____ 6

Diagnostic Test Type

CT Scan 2

Was test performed since last Study Evaluation and Diagnosis form was completed?

No 3
Yes
Unknown

Date of test _____ 4

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Was test used to establish diagnosis described above?

No 5
Yes

Upload Report _____ 6

Diagnostic Test Type

Lobectomy 2

Was test performed since last Study Evaluation and Diagnosis form was completed?

No 3
Yes
Unknown

Date of test _____ 4

Was test used to establish diagnosis described above?

No 5
Yes

Upload Report _____ 6

Diagnostic Test Type

Mediastinoscopy 2

Was test performed since last Study Evaluation and Diagnosis form was completed?

No 3
Yes
Unknown

Date of test _____ 4

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Follow up- 2 Year

Form: Study Evaluation and Diagnosis- Pt IV

Generated On: 15 May 2019 14:40:46

Was test used to establish diagnosis described above?

No 5
Yes

Upload Report _____ 6

Diagnostic Test Type

MRI 2

Was test performed since last Study Evaluation and Diagnosis form was completed?

No 3
Yes
Unknown

Date of test _____ 4

Was test used to establish diagnosis described above?

No 5
Yes

Upload Report _____ 6

Diagnostic Test Type

PET 2

Was test performed since last Study Evaluation and Diagnosis form was completed?

No 3
Yes
Unknown

Date of test _____ 4

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Follow up- 2 Year

Form: Study Evaluation and Diagnosis- Pt IV

Generated On: 15 May 2019 14:40:46

Was test used to establish diagnosis described above?

No 5
Yes

Upload Report _____ 6

Diagnostic Test Type

Sputum 2

Was test performed since last Study Evaluation and Diagnosis form was completed?

No 3
Yes
Unknown

Date of test _____ 4

Was test used to establish diagnosis described above?

No 5
Yes

Upload Report _____ 6

Diagnostic Test Type

TBNA 2

Was test performed since last Study Evaluation and Diagnosis form was completed?

No 3
Yes
Unknown

Date of test _____ 4

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NOT RECOMMENDED FOR SOURCE DOCUMENTATION

Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Follow up- 2 Year

Form: Study Evaluation and Diagnosis- Pt IV

Generated On: 15 May 2019 14:40:46

Was test used to establish diagnosis described above?

No 5
Yes

Upload Report _____ 6

Diagnostic Test Type

Surgical Lung Biopsy 2

Was test performed since last Study Evaluation and Diagnosis form was completed?

No 3
Yes
Unknown

Date of test _____ 4

Was test used to establish diagnosis described above?

No 5
Yes

Upload Report _____ 6

Diagnostic Test Type

TTNA 2

Was test performed since last Study Evaluation and Diagnosis form was completed?

No 3
Yes
Unknown

Date of test _____ 4

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NOT RECOMMENDED FOR SOURCE DOCUMENTATION

Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Follow up- 2 Year

Form: Study Evaluation and Diagnosis- Pt IV

Generated On: 15 May 2019 14:40:46

Was test used to establish diagnosis described above?

No 5

Yes 6

Upload Report

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NOT RECOMMENDED FOR SOURCE DOCUMENTATION

Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Follow up- 2 Year

Form: Study Evaluation and Diagnosis- Pt IV

Generated On: 15 May 2019 14:40:46

Field Name	Data Type	Units	Values	Include Field OID
② DX_TSTS_TY PE			Diagnosis Methods	DX_TSTS_TY PE
③ DX_TSTS_US ED_YNU			1 = No 2 = Yes 99 = Unknown	DX_TSTS_US ED_YNU
④ DX_TST_DT	MMM dd yyyy			DX_TST_DT
⑤ DX_TSTS_US ED_DX			1 = No 2 = Yes	DX_TSTS_US ED_DX
⑥ DX_TSTS_FI LE	\$200			DX_TSTS_FI LE
⑦ NOW_2DERI VATION	MMM dd yyyy HH ss			NOW_2DERI VATION

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Follow up- 2 Year

Form: Surgical Lung Specimens- Formalin Fixed

Generated On: 15 May 2019 14:40:46

Kit Barcode _____ ①

Date Specimen Mailed _____ ②

Copy of Surgical Lung Specimen- Formalin Fixed Transmittal Form _____ ③

Biospecimen Type
Formalin Fixed Tumor Tissue ④
Formalin Fixed Normal Tissue

Barcode Sequence # _____ ⑤

Check if Specimen Included _____ ⑥

Storage Temp _____ Fixed Unit: °C ⑦

Did any freeze/thaw occur? No ⑧
Yes
Unknown

If yes to freeze/thaw- Total # of Times _____ ⑨

If yes to freeze/thaw- length of each time _____ ⑩

Comments _____ ⑪

FOR SITE IRB SUBMISSION ONLY
NOT RECOMMENDED FOR SOURCE DOCUMENTATION

Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Follow up- 2 Year

Form: Surgical Lung Specimens- Formalin Fixed

Generated On: 15 May 2019 14:40:46

Biospecimen Type

Formalin Fixed Tumor Tissue

4

Formalin Fixed Normal Tissue

Barcode Sequence #

5

Check if Specimen Included

6

Storage Temp

Fixed Unit: °C

7

Did any freeze/thaw occur?

No

8

Yes

Unknown

If yes to freeze/thaw- Total # of Times

9

If yes to freeze/thaw- length of each time

10

Comments

11

FOR SITE IRB SUBMISSION ONLY
NOT RECOMMENDED FOR SOURCE DOCUMENTATION

Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Follow up- 2 Year

Form: Surgical Lung Specimens- Formalin Fixed

Generated On: 15 May 2019 14:40:46

Field Name	Data Type	Units	Values	Include Field OID
① BSPCM_KIT_ BCD	\$60			BSPCM_KIT_ BCD
② BSPCM_SENTMMM _CLAB_DT	dd yyyy			BSPCM_SENT _CLAB_DT
③ SURG_SAMP _FILE	\$200			SURG_SAMP _FILE
④ SURG_SAMP 2 FF_TYPE			1 = Formalin Fixed Tumor Tissue 2 = Formalin Fixed Normal Tissue	SURG_SAMP FF_TYPE
⑤ BSPCM_BCD 3 _SEQ				BSPCM_BCD _SEQ
⑥ BSPCM_ST_C2 R_LB				BSPCM_ST_C R_LB
⑦ BSPCM_ST_T 4.2 EMP				BSPCM_ST_T EMP
⑧ BSPCM_FZ_T 2 HAW			1 = No 2 = Yes 99 = Unknown	BSPCM_FZ_T HAW
⑨ FZ_THAW_T 3 TL_TME				FZ_THAW_T TL_TME

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms
Folder: Follow up- 2 Year
Form: Surgical Lung Specimens- Formalin Fixed
Generated On: 15 May 2019 14:40:46

Field Name	Data Type	Units	Values	Include Field OID
⑩ FX_THAW_L NGTH	\$200			FX_THAW_L NGTH
⑪ BSPCM_TRA NS_COMM	\$200			BSPCM_TRA NS_COMM

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Follow up- 2 Year

Form: Surgical Lung Specimens- Fresh Frozen

Generated On: 15 May 2019 14:40:46

Kit Barcode

1

Date Specimen Mailed

2

Copy of Surgical Lung Specimens- Fresh Frozen Transmittal Form

3

Biospecimen Type

Fresh Frozen Tumor Tissue

4

Fresh Frozen Normal Tissue

Barcode Sequence #

5

Check if specimen included

6

Storage Temp

Fixed Unit: °C

7

Did any freeze/thaw occur?

No

8

Yes

Unknown

If yes to freeze/thaw- Total # of Times

9

If yes to freeze/thaw- length of each time

10

Comments

11

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Follow up- 2 Year

Form: Surgical Lung Specimens- Fresh Frozen

Generated On: 15 May 2019 14:40:46

Biospecimen Type

Fresh Frozen Tumor Tissue ④

Fresh Frozen Normal Tissue

Barcode Sequence # _____ ⑤

Check if specimen included _____ ⑥

Storage Temp _____

Fixed Unit: °C ⑦

Did any freeze/thaw occur?

No ⑧

Yes

Unknown

If yes to freeze/thaw- Total # of Times _____ ⑨

If yes to freeze/thaw- length of each time _____ ⑩

Comments _____ ⑪

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Follow up- 2 Year

Form: Surgical Lung Specimens- Fresh Frozen

Generated On: 15 May 2019 14:40:46

Field Name	Data Type	Units	Values	Include Field OID
① BSPCM_KIT_ BCD	\$60			BSPCM_KIT_ BCD
② BSPCM_SENTMMM _CLAB_DT	dd yyyy			BSPCM_SENT _CLAB_DT
③ SURG_SPEC_ FRZ_UPL	\$200			SURG_SPEC_ FRZ_UPL
④ SURG_SAMP 2 _FFZ_TYPE			1 = Fresh Frozen Tumor Tissue 2 = Fresh Frozen Normal Tissue	SURG_SAMP _FFZ_TYPE
⑤ BSPCM_BCD 3 _SEQ				BSPCM_BCD _SEQ
⑥ BSPCM_ST_C2 R_LB				BSPCM_ST_C R_LB
⑦ BSPCM_ST_T4.2 EMP				BSPCM_ST_T EMP
⑧ BSPCM_FZ_T2 HAW			1 = No 2 = Yes 99 = Unknown	BSPCM_FZ_T HAW
⑨ FZ_THAW_T 3 TL_TME				FZ_THAW_T TL_TME

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Follow up- 2 Year

Form: Surgical Lung Specimens- Fresh Frozen

Generated On: 15 May 2019 14:40:46

Field Name	Data Type	Units	Values	Include Field OID
⑩ FX_THAW_L NGTH	\$200			FX_THAW_L NGTH
⑪ BSPCM_TRA NS_COMM	\$200			BSPCM_TRA NS_COMM

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Post Lg Cx- Initial Treatment

Form: Initial Treatment

Generated On: 15 May 2019 14:40:46

Indicate the type(s) of treatment the patient will be undergoing for lung cancer. If 'yes' is selected, provide the details of the treatment on the corresponding form.

Is the patient undergoing radiation treatment(s) for lung cancer?

No 2
Yes
Unknown

Is the patient undergoing surgical treatment(s) for lung cancer?

No 3
Yes
Unknown

Is the patient undergoing chemotherapy treatment(s) for lung cancer?

No 4
Yes
Unknown

Is the patient undergoing any other treatment(s) administered by a physician for lung cancer?

No 5
Yes
Unknown

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Post Lg Cx- Initial Treatment

Form: Initial Treatment

Generated On: 15 May 2019 14:40:46

Field Name	Data Type	Units	Values	Include Field OID
② RT_TX_YN	2		1 = No 2 = Yes 99 = Unknown	RT_TX_YN
③ SURG_TX_Y N	2		1 = No 2 = Yes 99 = Unknown	SURG_TX_Y N
④ CHEMO_TX_ YN	2		1 = No 2 = Yes 99 = Unknown	CHEMO_TX_ YN
⑤ OTH_TX_YN	2		1 = No 2 = Yes 99 = Unknown	OTH_TX_YN

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Post Lg Cx- Initial Treatment

Form: Chemotherapy

Generated On: 15 May 2019 14:40:46

Instructions: Indicate all the chemotherapeutic agents given, the start and end date, not previously reported on this form

If the exact date is unknown, unknown day should be entered as UN and unknown month as UNK

Chemotherapy Type _____ ②

Start Date _____ ③

Check if Ongoing _____ ④

If ongoing, provide the tentative end date _____ ⑤

Actual End Date _____ ⑥

Check if end date unknown _____ ⑦

Provide the number of cycles given Note If ongoing, provide the planned number of cycles _____ ⑧

Check if the number of cycles is unknown _____ ⑨

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Post Lg Cx- Initial Treatment

Form: Chemotherapy

Generated On: 15 May 2019 14:40:46

Field Name	Data Type	Units	Values	Include Field OID
② CHEMO_TYP E	2		Chemotherap y Type	CHEMO_TYP E
③ CHEMO_ST_ DT	MMM- dd- yyyy			CHEMO_ST_ DT
④ CHEMO_ONG OING	1			CHEMO_ONG OING
⑤ CHEMO_TEN T_END_DT	MMM dd yyyy			CHEMO_TEN T_END_DT
⑥ CHEMO_END _DT	MMM- dd- yyyy			CHEMO_END _DT
⑦ CHEMO_END _DT_UNK	1			CHEMO_END _DT_UNK
⑧ CHEMO_CYC _UNK	4.1			CHEMO_CYC
⑨ CHEMO_CYC _UNK	1			CHEMO_CYC _UNK

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Post Lg Cx- Initial Treatment

Form: Radiation

Generated On: 15 May 2019 14:40:46

Instructions: Provide all the body sites that were treated with radiotherapy, one site per log line, not previously reported on this form.

Indicate the sequence of radiotherapy relative to surgery check all that apply

Pre-operative	_____	3
Post-operative	_____	4
Definitive	_____	5
Unknown	_____	6

Radiotherapy Site

Chest Primary Tumor Volume	<input type="checkbox"/>	7
Hilar/Mediastinal Lymph Nodes	<input type="checkbox"/>	
Prophylactic Brain	<input type="checkbox"/>	
Therapeutic Brain	<input type="checkbox"/>	
Other, specify	<input type="checkbox"/>	
Unknown	<input type="checkbox"/>	

Radiotherapy Type

IMRT (intensity-modulated radiation therapy)	<input type="checkbox"/>	8
SBRT (Stereotactic body radiation therapy)	<input type="checkbox"/>	
Proton Therapy	<input type="checkbox"/>	
Brachytherapy	<input type="checkbox"/>	
Unknown	<input type="checkbox"/>	
Other, specify	<input type="checkbox"/>	

Start Date

_____ **9**

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Post Lg Cx- Initial Treatment

Form: Radiation

Generated On: 15 May 2019 14:40:46

Check if Ongoing _____

10

End Date _____

11

Total Dose _____

Fixed Unit: cGY

12

Check if the total dose is unknown _____

13

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Post Lg Cx- Initial Treatment

Form: Radiation

Generated On: 15 May 2019 14:40:46

Field Name	Data Type	Units	Values	Include Field OID
③ PRE_OP_RT	1			PRE_OP_RT
④ POST_OP_RT	1			POST_OP_RT
⑤ DEF_RT	1			DEF_RT
⑥ UNK_RT	1			UNK_RT
⑦ RT_SITE	2		1 = Chest Primary Tumor Volume 2 = Hilar/Mediast inal Lymph Nodes 3 = Prophylactic Brain 4 = Therapeutic Brain 88 = Other, specify 99 = Unknown	RT_SITE
⑧ RT_TYPE	2		1 = IMRT (intensity-mo dulated radiation therapy)	RT_TYPE

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Post Lg Cx- Initial Treatment

Form: Radiation

Generated On: 15 May 2019 14:40:46

Field Name	Data Type	Units	Values	Include Field OID
			2 = SBRT (Stereotactic body radiation therapy) 3 = Proton Therapy 4 = Brachytherap y 99 = Unknown 88 = Other, specify	
9 RT_ST_DT	MMM- dd- YYYY			RT_ST_DT
10 RT_ONGOIN	1 G			RT_ONGOIN G
11 RT_END_DT	MMM- dd- YYYY			RT_END_DT
12 RT_TOTAL_D	6.2 S			RT_TOTAL_D S
13 RT_TOTAL_D	1 S_UNK			RT_TOTAL_D S_UNK

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Instructions Provide each surgical procedure, the approach, and date, for all surgeries not previously reported on this form

Surgical Procedure

- Lobectomy ②
- Bilobectomy
- Pneumonectomy
- Wedge resection
- Segmentectomy | segmental resection
- Lymphadenectomy | lymph node sampling
- Chest wall resection
- Thoracentesis
- Partial pleurectomy
- Multiple wedge resections
- Multiple segmental resections
- Other surgical procedure (specify)
- Unknown surgical procedure

Approach

- Exploratory thoracotomy without resection ③
- Median Sternotomy
- Thoracotomy
- Thoracoscopy | Video-assisted (VATS)
- Thoracoscopy | Video-assisted (VATS) with conversion to Thoracotomy
- Other surgical approach (specify)
- Unknown surgical approach

Date

④

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Post Lg Cx- Initial Treatment

Form: Surgery

Generated On: 15 May 2019 14:40:46

Field Name	Data Type	Units	Values	Include Field OID
② SURG_PROC 2			1 = Lobectomy 2 = Bilobectomy 3 = Pneumonectomy 4 = Wedge resection 5 = Segmentectomy segmental resection 6 = Lymphadenectomy lymph node sampling 7 = Chest wall resection 8 = Thoracentesis 9 = Partial pleurectomy 10 = Multiple wedge resections 11 = Multiple segmental resections 88 = Other surgical procedure (specify) 99 = Unknown surgical procedure	SURG_PROC

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Post Lg Cx- Initial Treatment

Form: Surgery

Generated On: 15 May 2019 14:40:46

Field Name	Data Type	Units	Values	Include Field OID
③ SURG_APPR OACH	2		1 = Exploratory thoracotomy without resection 2 = Median Sternotomy 3 = Thoracotomy 4 = Thoracoscop y Video-assiste d (VATS) 5 = Thoracoscop y Video-assiste d (VATS) with conversion to Thoracotomy 88 = Other surgical approach (specify) 99 = Unknown surgical approach	SURG_APPR OACH
④ SURGERY_PR OC_DT	dd- yyyy			SURGERY_PR OC_DT

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Post Lg Cx- Initial Treatment

Form: Other Treatment

Generated On: 15 May 2019 14:40:46

Instructions: Provide all other types of treatment not previously reported on this form. Add a new log line for each unique treatment, or each treatment type that has a unique start date.

Type of Treatment

Immune Therapy ②

Radio Frequency Ablation

Thermal Ablation

Chemical Ablation

Unknown

Other, specify

Description of other treatment

③

Treatment Start Date

④

Treatment End Date

⑤

Check if treatment is ongoing

⑥

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Post Lg Cx- Initial Treatment

Form: Other Treatment

Generated On: 15 May 2019 14:40:46

Field Name	Data Type	Units	Values	Include Field OID
② OTH_TX_TYP2 E			1 = Immune Therapy 2 = Radio Frequency Ablation 3 = Thermal Ablation 4 = Chemical Ablation 99 = Unknown 88 = Other, specify	OTH_TX_TYP E
③ OTH_TX_DE SCR	\$200			OTH_TX_DE SCR
④ OTH_TX_ST_ DT	MMM- dd- yyyy			OTH_TX_ST_ DT
⑤ OTH_TX_EN D_DT	MMM- dd- yyyy			OTH_TX_EN D_DT
⑥ OTH_TX_ON G				OTH_TX_ON G

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Was blood collection performed?

No ①
Yes
Unknown

Reason blood collection not performed

Sample not collected ②
Collection tubes broken
Patient Refusal
Adverse Event
Site error
Other, specify

Date of Blood Collection

Fixed Unit: MMM dd yyyy ③

Time of blood collection

Fixed Unit: HH:mm ④

Was fasting blood specimen collected?

No ⑤
Yes
Unknown

Were any adverse events that are considered possibly, probably, or definitely related to the study-related biospecimen collection procedures reported?

No ⑨
Yes
Unknown

Was plasma collection performed?

No ⑩
Yes
Unknown

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Were plasma samples processed and stored within 2 hours of blood collection?

- No 11
- Yes
- Unknown

Did plasma samples undergo centrifugation within 2 hours of blood collection?

- No 12
- Yes
- Unknown

Primary reason plasma collection was not performed

- Sample not collected 13
- Collection tubes broken
- Patient Refusal
- Adverse Event
- Site error
- Other, specify

Was plasma collection performed per protocol?

- No 14
- Yes
- Unknown

Primary reason plasma collection was not performed per protocol

- Collection Tube(s) broke 15
- Missing Materials
- Site error
- Storage not per protocol
- Other, specify

Was buffy coat collection performed?

- No 16
- Yes
- Unknown

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Primary reason buffy coat collection was not performed

- Sample not collected 17
- Collection tubes broken
- Patient Refusal
- Adverse Event
- Site error
- Other, specify

Was buffy coat collection performed per protocol?

- No 18
- Yes
- Unknown

Primary reason buffy coat collection was not performed per protocol

- Collection Tube(s) broke 19
- Missing Materials
- Site error
- Storage not per protocol
- Other, specify

Was serum collection performed?

- No 20
- Yes
- Unknown

Primary reason serum collection was not performed

- Sample not collected 21
- Collection tubes broken
- Patient Refusal
- Adverse Event
- Site error
- Other, specify

Was serum collection performed per protocol?

- No 22

Yes
Unknown

Primary reason serum collection was not performed per protocol

- Collection Tube(s) broke (23)
- Missing Materials
- Site error
- Storage not per protocol
- Other, specify

Was PAX gene collection performed?

No (24)
Yes
Unknown

Primary reason PAX gene collection was not performed

- Sample not collected (25)
- Collection tubes broken
- Patient Refusal
- Adverse Event
- Site error
- Other, specify

Was PAX gene collection performed per protocol?

No (26)
Yes
Unknown

Primary reason PAX gene collection was not performed per protocol

- Collection Tube(s) broke (27)
- Missing Materials
- Site error
- Storage not per protocol
- Other, specify

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Was streck collection performed?

No 28
Yes
Unknown

Primary reason streck collection was not performed

Sample not collected 29
Collection tubes broken
Patient Refusal
Adverse Event
Site error
Other, specify

Was streck collection performed per protocol?

No 30
Yes
Unknown

Primary reason streck collection was not performed per protocol

Collection Tube(s) broke 31
Missing Materials
Site error
Storage not per protocol
Other, specify

Was PBMC collection performed?

No 32
Yes
Unknown

Was PBMC collection performed per protocol?

No 33
Yes
Unknown

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Folder: Post Lg Cx- Biospecimen Collection

Form: Blood Collection

Generated On: 15 May 2019 14:40:46

Primary reason PBMC collection was not performed per protocol

- Collection Tube(s) broke 34
- Missing Materials
- Site error
- Storage not per protocol
- Other, specify

3 Months after Registration Derivation

Tube Type

- Purple Top Venous Blood Collection Tube 6
- Red Top Venous Blood Collection Tube
- PAXgene tube
- Yellow Top Venous Blood Collection Tube
- Streck Tube

Check if tube collected

Reason Tube Not Collected

- Patient Refused 8
- Adverse Event
- Site Error
- Unknown
- Other, specify

Tube Type

- Purple Top Venous Blood Collection Tube 6

Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Post Lg Cx- Biospecimen Collection

Form: Blood Collection

Generated On: 15 May 2019 14:40:46

Red Top Venous Blood

Collection Tube

PAXgene tube

Yellow Top Venous Blood

Collection Tube

Streck Tube

Check if tube collected _____

7

Reason Tube Not Collected

Patient Refused

8

Adverse Event

Site Error

Unknown

Other, specify

Tube Type

Purple Top Venous Blood

6

Collection Tube

Red Top Venous Blood

Collection Tube

PAXgene tube

Yellow Top Venous Blood

Collection Tube

Streck Tube

Check if tube collected _____

7

Reason Tube Not Collected

Patient Refused

8

Adverse Event

Site Error

Unknown

Other, specify

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Post Lg Cx- Biospecimen Collection

Form: Blood Collection

Generated On: 15 May 2019 14:40:46

Tube Type

- Purple Top Venous Blood Collection Tube 6
- Red Top Venous Blood Collection Tube
- PAXgene tube
- Yellow Top Venous Blood Collection Tube
- Streck Tube

Check if tube collected

7

Reason Tube Not Collected

- Patient Refused 8
- Adverse Event
- Site Error
- Unknown
- Other, specify

Tube Type

- Purple Top Venous Blood Collection Tube 6
- Red Top Venous Blood Collection Tube
- PAXgene tube
- Yellow Top Venous Blood Collection Tube
- Streck Tube

Check if tube collected

7

Reason Tube Not Collected

- Patient Refused 8
- Adverse Event
- Site Error
- Unknown

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Post Lg Cx- Biospecimen Collection

Form: Blood Collection

Generated On: 15 May 2019 14:40:46

Other, specify

Tube Type

- Purple Top Venous Blood Collection Tube 6
- Red Top Venous Blood Collection Tube
- PAXgene tube
- Yellow Top Venous Blood Collection Tube
- Streck Tube

Check if tube collected

7

Reason Tube Not Collected

- Patient Refused 8
- Adverse Event
- Site Error
- Unknown
- Other, specify

Tube Type

- Purple Top Venous Blood Collection Tube 6
- Red Top Venous Blood Collection Tube
- PAXgene tube
- Yellow Top Venous Blood Collection Tube
- Streck Tube

Check if tube collected

7

Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Post Lg Cx- Biospecimen Collection

Form: Blood Collection

Generated On: 15 May 2019 14:40:46

Reason Tube Not Collected

- Patient Refused 8
- Adverse Event
- Site Error
- Unknown
- Other, specify

Tube Type

- Purple Top Venous Blood Collection Tube 6
- Red Top Venous Blood Collection Tube
- PAXgene tube
- Yellow Top Venous Blood Collection Tube
- Streck Tube

Check if tube collected

_____ 7

Reason Tube Not Collected

- Patient Refused 8
- Adverse Event
- Site Error
- Unknown
- Other, specify

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Post Lg Cx- Biospecimen Collection

Form: Blood Collection

Generated On: 15 May 2019 14:40:46

Field Name	Data Type	Units	Values	Include Field OID
① BLD_COLL_Y 2 N			1 = No 2 = Yes 99 = Unknown	BLD_COLL_Y N
② BLD_COLL_N 2 D_RSN			1 = Sample not collected 2 = Collection tubes broken 3 = Patient Refusal 4 = Adverse Event 5 = Site error 88 = Other, specify	BLD_COLL_N D_RSN
③ BLD_COLL_D MMM dd yyyy T				BLD_COLL_D T
④ BLD_COLL_T HH mm IME				BLD_COLL_T IME
⑤ BLD_COLL_N 2 PO_YN			1 = No 2 = Yes 99 = Unknown	BLD_COLL_N PO_YN
⑥ BLD_COLL_T 2 B_TYPE			1 = Purple Top Venous Blood Collection Tube	BLD_COLL_T B_TYPE

Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Post Lg Cx- Biospecimen Collection

Form: Blood Collection

Generated On: 15 May 2019 14:40:46

Field Name	Data Type	Units	Values	Include Field OID
			2 = Red Top Venous Blood Collection Tube 3 = PAXgene tube 4 = Yellow Top Venous Blood Collection Tube 5 = Streck Tube	
7 BL_COLL_TB 1 _COLL				BL_COLL_TB _COLL
8 BL_COLL_TB 2 _NCLL_RSN			1 = Patient Refused 2 = Adverse Event 3 = Site Error 99 = Unknown 88 = Other, specify	BL_COLL_TB _NCLL_RSN
9 AE_YN	2		1 = No 2 = Yes 99 = Unknown	AE_YN
10 BLD_COLL_P 2 LSM_YN			1 = No 2 = Yes 99 = Unknown	BLD_COLL_P LSM_YN

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Post Lg Cx- Biospecimen Collection

Form: Blood Collection

Generated On: 15 May 2019 14:40:46

Field Name	Data Type	Units	Values	Include Field OID
11 PLSM_PROC_2 2HRS_YN			1 = No 2 = Yes 99 = Unknown	PLSM_PROC_ 2HRS_YN
12 PLSM_CENT_2 IMM_YN			1 = No 2 = Yes 99 = Unknown	PLSM_CENT_ IMM_YN
13 PLSM_NT_PR 2 F_REAS			1 = Sample not collected 2 = Collection tubes broken 3 = Patient Refusal 4 = Adverse Event 5 = Site error 88 = Other, specify	PLSM_NT_PR F_REAS
14 PLSM_PF_PR 2 OT_YN			1 = No 2 = Yes 99 = Unknown	PLSM_PF_PR OT_YN
15 PLSM_PF_PR 2 OT_REAS			1 = Collection Tube(s) broke 2 = Missing Materials 3 = Site error	PLSM_PF_PR OT_REAS

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Post Lg Cx- Biospecimen Collection

Form: Blood Collection

Generated On: 15 May 2019 14:40:46

Field Name	Data Type	Units	Values	Include Field OID
			4 = Storage not per protocol 88 = Other, specify	
16 BLD_COLL_B 2 UFFY_YN			1 = No 2 = Yes 99 = Unknown	BLD_COLL_B UFFY_YN
17 BUFFY_NT_P 2 RF_REAS			1 = Sample not collected 2 = Collection tubes broken 3 = Patient Refusal 4 = Adverse Event 5 = Site error 88 = Other, specify	BUFFY_NT_P RF_REAS
18 BUFFY_PF_P 2 ROT_YN			1 = No 2 = Yes 99 = Unknown	BUFFY_PF_P ROT_YN
19 BUFFY_PF_P 2 ROT_REAS			1 = Collection Tube(s) broke	BUFFY_PF_P ROT_REAS

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms
 Folder: Post Lg Cx- Biospecimen Collection
 Form: Blood Collection
 Generated On: 15 May 2019 14:40:46

Field Name	Data Type	Units	Values	Include Field OID
			2 = Missing Materials 3 = Site error 4 = Storage not per protocol 88 = Other, specify	
20 BLD_COLL_S 2 ERUM_YN			1 = No 2 = Yes 99 = Unknown	BLD_COLL_S ERUM_YN
21 SERUM_NT_ 2 PRF_REAS			1 = Sample not collected 2 = Collection tubes broken 3 = Patient Refusal 4 = Adverse Event 5 = Site error 88 = Other, specify	SERUM_NT_ PRF_REAS
22 SERUM_PF_P 2 ROT_YN			1 = No 2 = Yes 99 = Unknown	SERUM_PF_P ROT_YN

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Post Lg Cx- Biospecimen Collection

Form: Blood Collection

Generated On: 15 May 2019 14:40:46

Field Name	Data Type	Units	Values	Include Field OID
23 SERUM_PF_P2 ROT_REAS			1 = Collection Tube(s) broke 2 = Missing Materials 3 = Site error 4 = Storage not per protocol 88 = Other, specify	SERUM_PF_P ROT_REAS
24 BLD_COLL_P 2 AX_YN			1 = No 2 = Yes 99 = Unknown	BLD_COLL_P AX_YN
25 PAX_NT_PRF 2 _REAS			1 = Sample not collected 2 = Collection tubes broken 3 = Patient Refusal 4 = Adverse Event 5 = Site error 88 = Other, specify	PAX_NT_PRF _REAS
26 PAX_PF_PRO 2 T_YN			1 = No 2 = Yes 99 = Unknown	PAX_PF_PRO T_YN

FOR SITE IRB SUBMISSION ONLY
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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms
 Folder: Post Lg Cx- Biospecimen Collection
 Form: Blood Collection
 Generated On: 15 May 2019 14:40:46

Field Name	Data Type	Units	Values	Include Field OID
27 PAX_PF_PRO 2 T_REAS			1 = Collection Tube(s) broke 2 = Missing Materials 3 = Site error 4 = Storage not per protocol 88 = Other, specify	PAX_PF_PRO T_REAS
28 BLD_COLL_S 2 TRECK_YN			1 = No 2 = Yes 99 = Unknown	BLD_COLL_S TRECK_YN
29 STRECK_NT_2 PRF_REAS			1 = Sample not collected 2 = Collection tubes broken 3 = Patient Refusal 4 = Adverse Event 5 = Site error 88 = Other, specify	STRECK_NT_ PRF_REAS
30 STRECK_PF_ 2 PROT_YN			1 = No 2 = Yes 99 = Unknown	STRECK_PF_ PROT_YN

FOR SITE IRB SUBMISSION ONLY
NOT RECOMMENDED FOR SOURCE DOCUMENTATION

Draft 25 version 1.0 MIGPROD 17JAN2018: All forms
 Folder: Post Lg Cx- Biospecimen Collection
 Form: Blood Collection
 Generated On: 15 May 2019 14:40:46

Field Name	Data Type	Units	Values	Include Field OID
31) STRECK_PRO T_REAS			1 = Collection Tube(s) broke 2 = Missing Materials 3 = Site error 4 = Storage not per protocol 88 = Other, specify	STRECK_PRO T_REAS
32) BLD_COLL_P BMC_YN			1 = No 2 = Yes 99 = Unknown	BLD_COLL_P BMC_YN
33) PBMC_PF_PR OT_YN			1 = No 2 = Yes 99 = Unknown	PBMC_PF_PR OT_YN
34) PBMC_PF_PR OT_REAS			1 = Collection Tube(s) broke 2 = Missing Materials 3 = Site error 4 = Storage not per protocol 88 = Other, specify	PBMC_PF_PR OT_REAS

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Post Lg Cx- Biospecimen Collection

Form: Blood Collection

Generated On: 15 May 2019 14:40:46

Field Name	Data Type	Units	Values	Include Field OID
35 NOW_1DERI VATION	dd MMM yyyy HH nn			NOW_1DERI VATION
36 DT3_MOS_D ERV	dd MMM yyyy			DT3_MOS_D ERV

FOR SITE IRB SUBMISSION ONLY
NOT RECOMMENDED FOR SOURCE DOCUMENTATION

Draft 25 version 1.0 MIGPROD 17JAN2018: All forms
Folder: Post Lg Cx- Biospecimen Collection
Form: Blood Collection Aliquots-Required
Generated On: 15 May 2019 14:40:46

Total # of Aliquots prepared from the Blood Collection _____ ①

Did all of the listed aliquots go into the same freezer at the same date/time? No ②
Yes
Unknown

If yes

If all aliquots listed were put into the same freezer on the same day and same time, please provide that date/time and freezer temp in the fields below. Please leave these columns in the table blank

Date/Time into Freezer for All Aliquots _____ ④

Temperature of Freezer for All Aliquots _____ ⑤

The below table is prefilled with the expected blood collection samples. All fields are editable and the table should reflect the actual samples processed/collected. The total number of items collected should equal the total number of rows in the table. If PBMC preparation and/or Buffy Coat Preparation is performed, details of the aliquots should not be recorded on this form, but should be recorded on the PBMC Blood Collection Form and/or Buffy Coat Collection Form

Derivation- Number of checks in table _____ ⑰

Total number of checks for PAXgene _____ ⑱

Total number of checks Serum _____ ⑲

Total number of checks plasma _____ ⑳

Total number of checks streck _____ ㉑

Collection Type

- Plasma Collection 7
- Buffy Coat Collection
- Serum Collection
- PAX Gene
- PBMC
- Streck

Check if collected

8

Amount of aliquot in vial/tube

9

Date and Time into -20° Freezer

Fixed Unit: MMM dd yyy HH:MM 10

Temperature of Freezer

11

Data and Time into -80° Freezer

Fixed Unit: MMM dd yyy HH:MM 12

Temperature of freezer

Fixed Unit: °C 13

Did any freeze-thaw occur to the sample?

- No 14
- Yes
- Unknown

Comments regarding freeze-thaw

15

Other comments

16

Collection Type

- Plasma Collection 7
- Buffy Coat Collection
- Serum Collection
- PAX Gene
- PBMC
- Streck

Check if collected

8

Amount of aliquot in vial/tube

9

Date and Time into -20° Freezer

Fixed Unit: MMM dd yyy HH:MM 10

Temperature of Freezer

11

Data and Time into -80° Freezer

Fixed Unit: MMM dd yyy HH:MM 12

Temperature of freezer

Fixed Unit: °C 13

Did any freeze-thaw occur to the sample?

- No 14
- Yes
- Unknown

Comments regarding freeze-thaw

15

Other comments

16

Collection Type

- Plasma Collection 7
- Buffy Coat Collection
- Serum Collection
- PAX Gene
- PBMC
- Streck

Check if collected _____ 8

Amount of aliquot in vial/tube _____ 9

Date and Time into -20° Freezer _____ Fixed Unit: MMM dd yyy HH:MM 10

Temperature of Freezer _____ 11

Data and Time into -80° Freezer _____ Fixed Unit: MMM dd yyy HH:MM 12

Temperature of freezer _____ Fixed Unit: °C 13

Did any freeze-thaw occur to the sample? No 14
Yes
Unknown

Comments regarding freeze-thaw _____ 15

Other comments _____ 16

FOR SITE IRB SUBMISSION ONLY
NOT RECOMMENDED FOR SOURCE DOCUMENTATION

Draft 25 version 1.0 MIGPROD 17JAN2018: All forms
Folder: Post Lg Cx- Biospecimen Collection
Form: Blood Collection Aliquots-Required
Generated On: 15 May 2019 14:40:46

Collection Type

- Plasma Collection 7
- Buffy Coat Collection
- Serum Collection
- PAX Gene
- PBMC
- Streck

Check if collected

8

Amount of aliquot in vial/tube

9

Date and Time into -20° Freezer

Fixed Unit: MMM dd yyy HH:MM 10

Temperature of Freezer

11

Data and Time into -80° Freezer

Fixed Unit: MMM dd yyy HH:MM 12

Temperature of freezer

Fixed Unit: °C 13

Did any freeze-thaw occur to the sample?

- No 14
- Yes
- Unknown

Comments regarding freeze-thaw

15

Other comments

16

Draft 25 version 1.0 MIGPROD 17JAN2018: All forms
Folder: Post Lg Cx- Biospecimen Collection
Form: Blood Collection Aliquots-Required
Generated On: 15 May 2019 14:40:46

Collection Type

- Plasma Collection 7
- Buffy Coat Collection
- Serum Collection
- PAX Gene
- PBMC
- Streck

Check if collected _____ 8

Amount of aliquot in vial/tube _____ 9

Date and Time into -20° Freezer

Fixed Unit: MMM dd yyy HH:MM 10

Temperature of Freezer _____ 11

Data and Time into -80° Freezer

Fixed Unit: MMM dd yyy HH:MM 12

Temperature of freezer _____

Fixed Unit: °C 13

Did any freeze-thaw occur to the sample?

- No 14
- Yes
- Unknown

Comments regarding freeze-thaw _____ 15

Other comments _____ 16

Collection Type

- Plasma Collection 7
- Buffy Coat Collection
- Serum Collection
- PAX Gene
- PBMC
- Streck

Check if collected _____ 8

Amount of aliquot in vial/tube _____ 9

Date and Time into -20° Freezer _____

Fixed Unit: MMM dd yyy HH:MM 10

Temperature of Freezer _____ 11

Data and Time into -80° Freezer _____

Fixed Unit: MMM dd yyy HH:MM 12

Temperature of freezer _____

Fixed Unit: °C 13

Did any freeze-thaw occur to the sample?

- No 14
- Yes
- Unknown

Comments regarding freeze-thaw _____ 15

Other comments _____ 16

Collection Type

- Plasma Collection 7
- Buffy Coat Collection
- Serum Collection
- PAX Gene
- PBMC
- Streck

Check if collected

8

Amount of aliquot in vial/tube

9

Date and Time into -20° Freezer

Fixed Unit: MMM dd yyy HH:MM 10

Temperature of Freezer

11

Data and Time into -80° Freezer

Fixed Unit: MMM dd yyy HH:MM 12

Temperature of freezer

Fixed Unit: °C 13

Did any freeze-thaw occur to the sample?

- No 14
- Yes
- Unknown

Comments regarding freeze-thaw

15

Other comments

16

Collection Type

- Plasma Collection 7
- Buffy Coat Collection
- Serum Collection
- PAX Gene
- PBMC
- Streck

Check if collected

8

Amount of aliquot in vial/tube

9

Date and Time into -20° Freezer

Fixed Unit: MMM dd yyy HH:MM 10

Temperature of Freezer

11

Data and Time into -80° Freezer

Fixed Unit: MMM dd yyy HH:MM 12

Temperature of freezer

Fixed Unit: °C 13

Did any freeze-thaw occur to the sample?

- No 14
- Yes
- Unknown

Comments regarding freeze-thaw

15

Other comments

16

Collection Type

- Plasma Collection 7
- Buffy Coat Collection
- Serum Collection
- PAX Gene
- PBMC
- Streck

Check if collected

8

Amount of aliquot in vial/tube

9

Date and Time into -20° Freezer

Fixed Unit: MMM dd yyy HH:MM 10

Temperature of Freezer

11

Data and Time into -80° Freezer

Fixed Unit: MMM dd yyy HH:MM 12

Temperature of freezer

Fixed Unit: °C 13

Did any freeze-thaw occur to the sample?

- No 14
- Yes
- Unknown

Comments regarding freeze-thaw

15

Other comments

16

Collection Type

- Plasma Collection 7
- Buffy Coat Collection
- Serum Collection
- PAX Gene
- PBMC
- Streck

Check if collected _____ 8

Amount of aliquot in vial/tube _____ 9

Date and Time into -20° Freezer _____ Fixed Unit: MMM dd yyy HH:MM 10

Temperature of Freezer _____ 11

Data and Time into -80° Freezer _____ Fixed Unit: MMM dd yyy HH:MM 12

Temperature of freezer _____ Fixed Unit: °C 13

Did any freeze-thaw occur to the sample? No 14
Yes
Unknown

Comments regarding freeze-thaw _____ 15

Other comments _____ 16

FOR SITE IRB SUBMISSION ONLY
NOT RECOMMENDED FOR SOURCE DOCUMENTATION

Draft 25 version 1.0 MIGPROD 17JAN2018: All forms
Folder: Post Lg Cx- Biospecimen Collection
Form: Blood Collection Aliquots-Required
Generated On: 15 May 2019 14:40:46

Collection Type

- Plasma Collection 7
- Buffy Coat Collection
- Serum Collection
- PAX Gene
- PBMC
- Streck

Check if collected

8

Amount of aliquot in vial/tube

9

Date and Time into -20° Freezer

Fixed Unit: MMM dd yyy HH:MM 10

Temperature of Freezer

11

Data and Time into -80° Freezer

Fixed Unit: MMM dd yyy HH:MM 12

Temperature of freezer

Fixed Unit: °C 13

Did any freeze-thaw occur to the sample?

- No 14
- Yes
- Unknown

Comments regarding freeze-thaw

15

Other comments

16

Collection Type

- Plasma Collection 7
- Buffy Coat Collection
- Serum Collection
- PAX Gene
- PBMC
- Streck

Check if collected _____ 8

Amount of aliquot in vial/tube _____ 9

Date and Time into -20° Freezer _____ Fixed Unit: MMM dd yyy HH:MM 10

Temperature of Freezer _____ 11

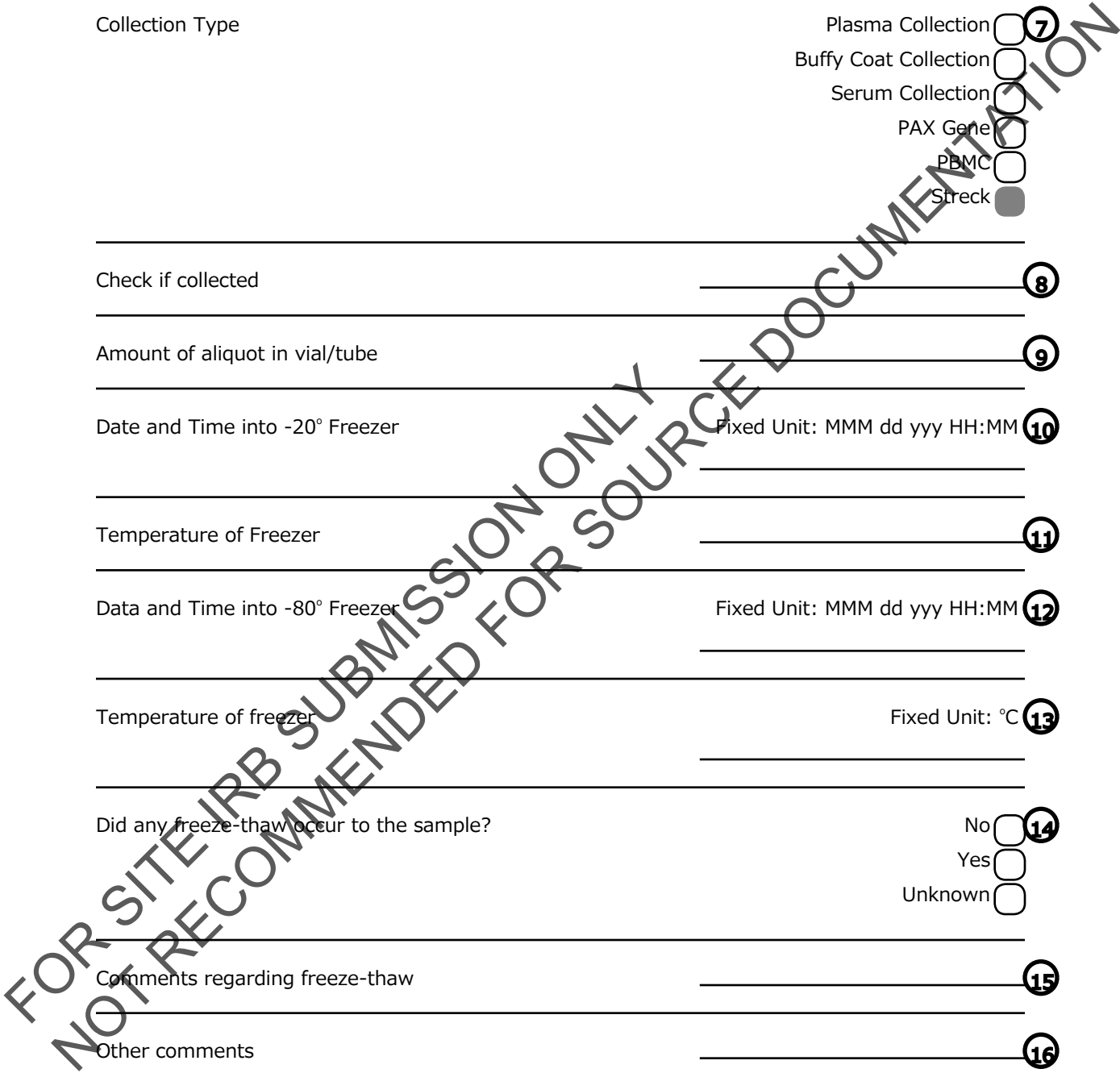
Data and Time into -80° Freezer _____ Fixed Unit: MMM dd yyy HH:MM 12

Temperature of freezer _____ Fixed Unit: °C 13

Did any freeze-thaw occur to the sample? No 14
Yes
Unknown

Comments regarding freeze-thaw _____ 15

Other comments _____ 16



Collection Type

- Plasma Collection 7
- Buffy Coat Collection
- Serum Collection
- PAX Gene
- PBMC
- Streck

Check if collected _____ 8

Amount of aliquot in vial/tube _____ 9

Date and Time into -20° Freezer _____ Fixed Unit: MMM dd yyy HH:MM 10

Temperature of Freezer _____ 11

Data and Time into -80° Freezer _____ Fixed Unit: MMM dd yyy HH:MM 12

Temperature of freezer _____ Fixed Unit: °C 13

Did any freeze-thaw occur to the sample? No 14
Yes
Unknown

Comments regarding freeze-thaw _____ 15

Other comments _____ 16

FOR SITE IRB SUBMISSION ONLY
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Collection Type

- Plasma Collection 7
- Buffy Coat Collection
- Serum Collection
- PAX Gene
- PBMC
- Streck

Check if collected _____ 8

Amount of aliquot in vial/tube _____ 9

Date and Time into -20° Freezer _____ Fixed Unit: MMM dd yyy HH:MM 10

Temperature of Freezer _____ 11

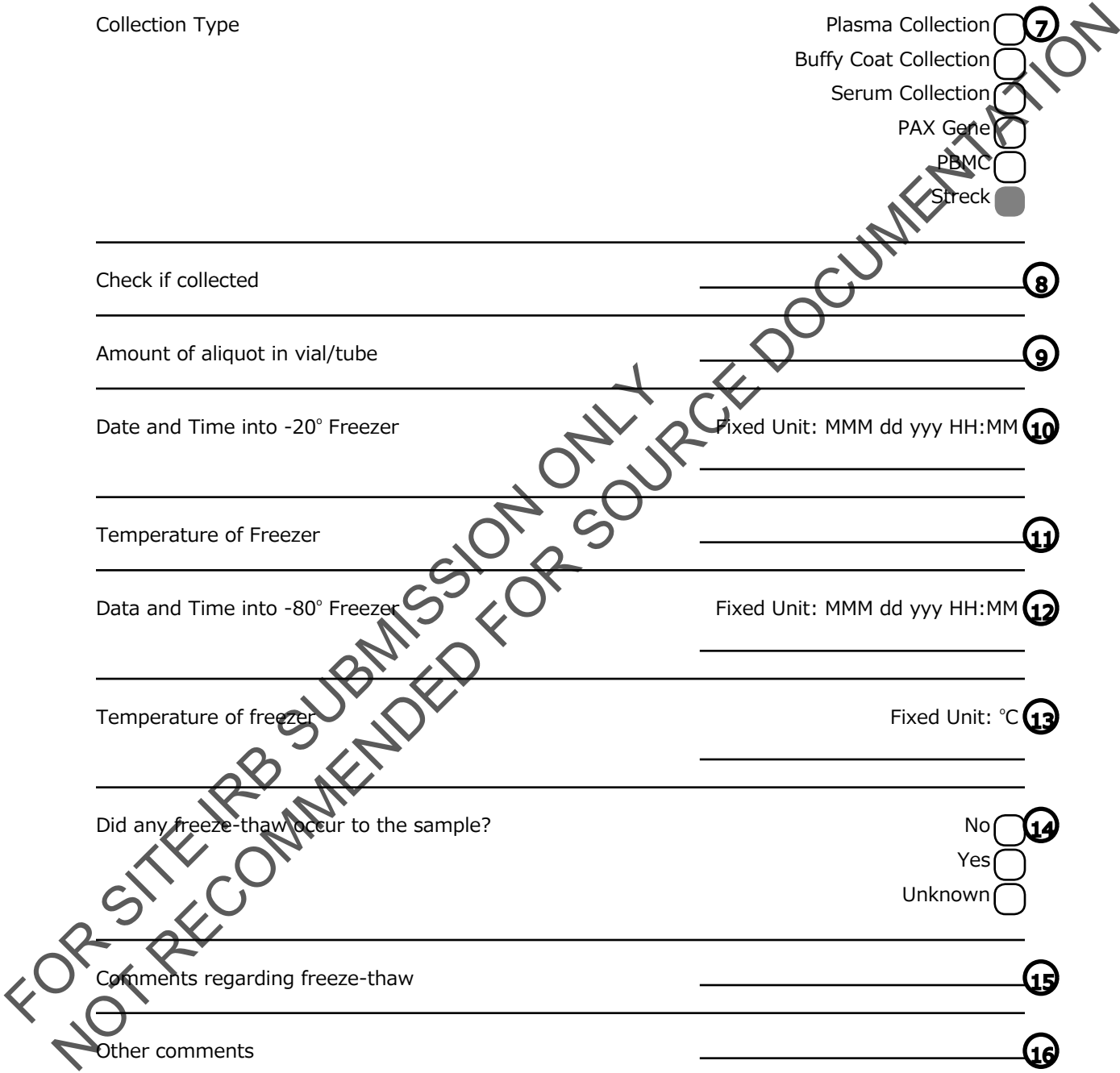
Data and Time into -80° Freezer _____ Fixed Unit: MMM dd yyy HH:MM 12

Temperature of freezer _____ Fixed Unit: °C 13

Did any freeze-thaw occur to the sample? No 14
Yes
Unknown

Comments regarding freeze-thaw _____ 15

Other comments _____ 16



Collection Type

- Plasma Collection 7
- Buffy Coat Collection
- Serum Collection
- PAX Gene
- PBMC
- Streck

Check if collected _____ 8

Amount of aliquot in vial/tube _____ 9

Date and Time into -20° Freezer _____ Fixed Unit: MMM dd yyy HH:MM 10

Temperature of Freezer _____ 11

Data and Time into -80° Freezer _____ Fixed Unit: MMM dd yyy HH:MM 12

Temperature of freezer _____ Fixed Unit: °C 13

Did any freeze-thaw occur to the sample? No 14
Yes
Unknown

Comments regarding freeze-thaw _____ 15

Other comments _____ 16

FOR SITE IRB SUBMISSION ONLY
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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms
Folder: Post Lg Cx- Biospecimen Collection
Form: Blood Collection Aliquots-Required
Generated On: 15 May 2019 14:40:46

Field Name	Data Type	Units	Values	Include Field OID
① TOT_NUM_A LQ				TOT_NUM_A LQ
② DT_TM_FZ_Y N			1 = No 2 = Yes 99 = Unknown	DT_TM_FZ_Y N
④ OVRL_DT_T M_80_IN	MMM dd yyyy HH nn			OVRL_DT_T M_80_IN
⑤ OVRL_FRZ_T EMP	6.2			OVRL_FRZ_T EMP
⑦ BLD_COLL_T YPE			1 = Plasma Collection 2 = Buffy Coat Collection 3 = Serum Collection 4 = PAX Gene 5 = PBMC 6 = Streck	BLD_COLL_T YPE
⑧ COLL_COMP_ CK				COLL_COMP_ CK
⑨ BLD_ALQ_VO L	8.2			BLD_ALQ_VO L
⑩ DT_TM_20_I N	MMM dd yyyy HH nn			DT_TM_20_I N

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms
Folder: Post Lg Cx- Biospecimen Collection
Form: Blood Collection Aliquots-Required
Generated On: 15 May 2019 14:40:46

Field Name	Data Type	Units	Values	Include Field OID
11 FRZ_20_TEM P	4.2			FRZ_20_TEM P
12 DT_TM_80_I N	MMM dd yyyy HH nn			DT_TM_80_I N
13 FRZ_TEMP	4.2			FRZ_TEMP
14 SAMP_FRZ_T HW			1 = No 2 = Yes 99 = Unknown	SAMP_FRZ_T HW
15 SAMP_FRZ_T HW_COMM	\$200			SAMP_FRZ_T HW_COMM
16 ALQ_COMM	\$200			ALQ_COMM
17 ALQ_TOT_DE RV				ALQ_TOT_DE RV
18 PAX_ALQ_TO T_DERV				PAX_ALQ_TO T_DERV
19 SERUM_ALQ _TOT_DERV	2			SERUM_ALQ _TOT_DERV
20 PLSM_ALQ_T OT_DERV				PLSM_ALQ_T OT_DERV

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms
Folder: Post Lg Cx- Biospecimen Collection
Form: Blood Collection Aliquots-Required
Generated On: 15 May 2019 14:40:46

Field Name	Data Type	Units	Values	Include Field OID
② STRECK_ALQ2 _TOT_DERV				STRECK_ALQ _TOT_DERV

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms
Folder: Post Lg Cx- Biospecimen Collection
Form: Blood Collection Aliquots- Buffy Coat
Generated On: 15 May 2019 14:40:46

Total checks for PBMC derivation _____

9

Collection Type

Plasma Collection

1

Buffy Coat Collection

Serum Collection

PAX Gene

PBMC

Streck

Check if collected _____

2

Vial/Tube Type

2mL cryovials

3

5mL cryovial

15mL cryovial

PAXgene Blood RNA tube

Date and Time into Freezer _____

4

Temperature of Freezer _____

Fixed Unit: °C

5

Did any freeze-thaw occur to the sample?

No

6

Yes

Unknown

Comments regarding freeze- thaw _____

7

Other comment _____

8

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms
Folder: Post Lg Cx- Biospecimen Collection
Form: Blood Collection Aliquots- Buffy Coat
Generated On: 15 May 2019 14:40:46

Collection Type

- Plasma Collection ①
- Buffy Coat Collection
- Serum Collection
- PAX Gene
- PBMC
- Streck

Check if collected _____ ②

Vial/Tube Type

- 2mL cryovials ③
- 5mL cryovial
- 15mL cryovial
- PAXgene Blood RNA tube

Date and Time into Freezer _____ ④

Temperature of Freezer

Fixed Unit: °C ⑤

Did any freeze-thaw occur to the sample?

- No ⑥
- Yes
- Unknown

Comments regarding freeze- thaw _____ ⑦

Other comment _____ ⑧

Collection Type

- Plasma Collection ①

Draft 25 version 1.0 MIGPROD 17JAN2018: All forms
Folder: Post Lg Cx- Biospecimen Collection
Form: Blood Collection Aliquots- Buffy Coat
Generated On: 15 May 2019 14:40:46

- Buffy Coat Collection
- Serum Collection
- PAX Gene
- PBMC
- Streck

Check if collected _____ ②

Vial/Tube Type _____ ③

- 2mL cryovials
- 5mL cryovial
- 15mL cryovial
- PAXgene Blood RNA tube

Date and Time into Freezer _____ ④

Temperature of Freezer _____ Fixed Unit: °C ⑤

Did any freeze-thaw occur to the sample? _____ ⑥

- No
- Yes
- Unknown

Comments regarding freeze- thaw _____ ⑦

Other comment _____ ⑧

Collection Type _____ ①

- Plasma Collection
- Buffy Coat Collection

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NOT RECOMMENDED FOR SOURCE DOCUMENTATION

Draft 25 version 1.0 MIGPROD 17JAN2018: All forms
Folder: Post Lg Cx- Biospecimen Collection
Form: Blood Collection Aliquots- Buffy Coat
Generated On: 15 May 2019 14:40:46

Serum Collection
PAX Gene
PBMC
 Streck

Check if collected _____ ②

Vial/Tube Type _____ ③
2mL cryovials
5mL cryovial
15mL cryovial
PAXgene Blood RNA tube

Date and Time into Freezer _____ ④

Temperature of Freezer _____ Fixed Unit: °C ⑤

Did any freeze-thaw occur to the sample? No ⑥
Yes
Unknown

Comments regarding freeze- thaw _____ ⑦

Other comment _____ ⑧

Collection Type _____ ①
Plasma Collection
Buffy Coat Collection
Serum Collection

FOR SITE IRB SUBMISSION ONLY
NOT RECOMMENDED FOR SOURCE DOCUMENTATION

Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Post Lg Cx- Biospecimen Collection

Form: Blood Collection Aliquots- Buffy Coat

Generated On: 15 May 2019 14:40:46

PAX Gene

PBMC

Streck

Check if collected _____

②

Vial/Tube Type

2mL cryovials

③

5mL cryovial

15mL cryovial

PAXgene Blood RNA tube

Date and Time into Freezer _____

④

Temperature of Freezer _____

Fixed Unit: °C

⑤

Did any freeze-thaw occur to the sample? _____

No

⑥

Yes

Unknown

Comments regarding freeze-thaw _____

⑦

Other comment _____

⑧

Collection Type

Plasma Collection

①

Buffy Coat Collection

Serum Collection

PAX Gene

PBMC
Streck

Check if collected _____ **2**

Vial/Tube Type _____ **3**
2mL cryovials
5mL cryovial
15mL cryovial
PAXgene Blood RNA tube

Date and Time into Freezer _____ **4**

Temperature of Freezer _____ Fixed Unit: °C **5**

Did any freeze-thaw occur to the sample? _____ **6**
No
Yes
Unknown

Comments regarding freeze-thaw _____ **7**

Other comment _____ **8**

Collection Type _____ **1**
Plasma Collection
Buffy Coat Collection
Serum Collection
PAX Gene
PBMC

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NOT RECOMMENDED FOR SOURCE DOCUMENTATION

Draft 25 version 1.0 MIGPROD 17JAN2018: All forms
Folder: Post Lg Cx- Biospecimen Collection
Form: Blood Collection Aliquots- Buffy Coat
Generated On: 15 May 2019 14:40:46

Streck

Check if collected _____ ②

Vial/Tube Type
2mL cryovials ③
5mL cryovial
15mL cryovial
PAXgene Blood RNA tube

Date and Time into Freezer _____ ④

Temperature of Freezer _____ Fixed Unit: °C ⑤

Did any freeze-thaw occur to the sample? No ⑥
Yes
Unknown

Comments regarding freeze- thaw _____ ⑦

Other comment _____ ⑧

FOR SITE IRB SUBMISSION ONLY
NOT RECOMMENDED FOR SOURCE DOCUMENTATION

Draft 25 version 1.0 MIGPROD 17JAN2018: All forms
 Folder: Post Lg Cx- Biospecimen Collection
 Form: Blood Collection Aliquots- Buffy Coat
 Generated On: 15 May 2019 14:40:46

Field Name	Data Type	Units	Values	Include Field OID
① BUFF_BLD_C OLL_TYPE			1 = Plasma Collection 2 = Buffy Coat Collection 3 = Serum Collection 4 = PAX Gene 5 = PBMC 6 = Streck	BUFF_BLD_C OLL_TYPE
② COLL_COMP_1 CK				COLL_COMP_ CK
③ ALQ_VIAL_S 1 Z			1 = 2mL cryovials 2 = 5mL cryovial 3 = 15mL cryovial 4 = PAXgene Blood RNA tube	ALQ_VIAL_S Z
④ DT_TM_80_I N	MMMMddyyyy HHmm			DT_TM_80_I N
⑤ FRZ_TEMP	4.2			FRZ_TEMP
⑥ SAMP_FRZ_T HW			1 = No 2 = Yes 99 = Unknown	SAMP_FRZ_T HW

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms
Folder: Post Lg Cx- Biospecimen Collection
Form: Blood Collection Aliquots- Buffy Coat
Generated On: 15 May 2019 14:40:46

Field Name	Data Type	Units	Values	Include Field OID
⑦ SAMP_FRZ_T HW_COMM	\$200			SAMP_FRZ_T HW_COMM
⑧ ALQ_COMM	\$200			ALQ_COMM
⑨ BUFF_TOT_D2 ERV				BUFF_TOT_D ERV

FOR SITE IRB SUBMISSION ONLY
 NOT RECOMMENDED FOR SOURCE DOCUMENTATION

Draft 25 version 1.0 MIGPROD 17JAN2018: All forms
Folder: Post Lg Cx- Biospecimen Collection
Form: Blood Collection Aliquots- PBMC
Generated On: 15 May 2019 14:40:46

Date and Time of Start of PBMC Processing

Fixed Unit: MMM dd yyy HH:MM

1

PBMC count

Fixed Unit: 10^6 cells/mL

2

Total checks for PBMC derivation

13

Collection Type

Plasma Collection

3

Buffy Coat Collection

Serum Collection

PAX Gene

PBMC

Streck

Check if collected

4

Vial/Tube Type

2mL cryovials

5

5mL cryovial

15mL cryovial

PAXgene Blood RNA tube

Number of Cells

6

LTGO volume

7

Date and Time into Freezer

8

Draft 25 version 1.0 MIGPROD 17JAN2018: All forms
Folder: Post Lg Cx- Biospecimen Collection
Form: Blood Collection Aliquots- PBMC
Generated On: 15 May 2019 14:40:46

Temperature of Freezer

Fixed Unit: °C

9

Did any freeze-thaw occur to the sample?

No

10

Yes

Unknown

Comments regarding freeze- thaw

11

Other comment

12

Collection Type

Plasma Collection

3

Buffy Coat Collection

Serum Collection

PAX Gene

PBMC

Streck

Check if collected

4

Vial/Tube Type

2mL cryovials

5

5mL cryovial

15mL cryovial

PAXgene Blood RNA tube

Number of Cells

6

LTGO volume

7

Draft 25 version 1.0 MIGPROD 17JAN2018: All forms
Folder: Post Lg Cx- Biospecimen Collection
Form: Blood Collection Aliquots- PBMC
Generated On: 15 May 2019 14:40:46

Date and Time into Freezer _____

8

Temperature of Freezer _____

Fixed Unit: °C _____

9

Did any freeze-thaw occur to the sample? _____

No

10

Yes

Unknown

Comments regarding freeze- thaw _____

11

Other comment _____

12

Collection Type _____

Plasma Collection

3

Buffy Coat Collection

Serum Collection

PAX Gene

PBMC

Streck

Check if collected _____

4

Vial/Tube Type _____

2mL cryovials

5

5mL cryovial

15mL cryovial

PAXgene Blood RNA tube

Number of Cells _____

6

FOR SITE IRB SUBMISSION ONLY
NOT RECOMMENDED FOR SOURCE DOCUMENTATION

Draft 25 version 1.0 MIGPROD 17JAN2018: All forms
Folder: Post Lg Cx- Biospecimen Collection
Form: Blood Collection Aliquots- PBMC
Generated On: 15 May 2019 14:40:46

LTGO volume _____ 7

Date and Time into Freezer _____ 8

Temperature of Freezer _____ Fixed Unit: °C 9

Did any freeze-thaw occur to the sample? No 10
Yes
Unknown

Comments regarding freeze- thaw _____ 11

Other comment _____ 12

Collection Type Plasma Collection 3
Buffy Coat Collection
Serum Collection
PAX Gene
PBMC
Streck

Check if collected _____ 4

Vial/Tube Type 2mL cryovials 5
5mL cryovial
15mL cryovial
PAXgene Blood RNA tube

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms
Folder: Post Lg Cx- Biospecimen Collection
Form: Blood Collection Aliquots- PBMC
Generated On: 15 May 2019 14:40:46

Number of Cells _____ 6

LTGO volume _____ 7

Date and Time into Freezer _____ 8

Temperature of Freezer _____

Fixed Unit: °C 9

Did any freeze-thaw occur to the sample?

No 10
Yes
Unknown

Comments regarding freeze- thaw _____ 11

Other comment _____ 12

Collection Type

Plasma Collection 3
Buffy Coat Collection
Serum Collection
PAX Gene
PBMC
Streck

Check if collected _____ 4

Vial/Tube Type

2mL cryovials 5
5mL cryovial

Draft 25 version 1.0 MIGPROD 17JAN2018: All forms
Folder: Post Lg Cx- Biospecimen Collection
Form: Blood Collection Aliquots- PBMC
Generated On: 15 May 2019 14:40:46

15mL cryovial
PAXgene Blood RNA tube

Number of Cells _____ ⑥

LTGO volume _____ ⑦

Date and Time into Freezer _____ ⑧

Temperature of Freezer _____ Fixed Unit: °C ⑨

Did any freeze-thaw occur to the sample? No ⑩
Yes
Unknown

Comments regarding freeze- thaw _____ ⑪

Other comment _____ ⑫

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms
Folder: Post Lg Cx- Biospecimen Collection
Form: Blood Collection Aliquots- PBMC
Generated On: 15 May 2019 14:40:46

Field Name	Data Type	Units	Values	Include Field OID
① PBMC_DT_T M	MMM dd yyyy HH nn			PBMC_DT_T M
② PBMC_BL_C OUNT	8.2			PBMC_BL_C OUNT
③ PBMC_BLD_C2 OLL_TYPE			1 = Plasma Collection 2 = Buffy Coat Collection 3 = Serum Collection 4 = PAX Gene 5 = PBMC 6 = Streck	PBMC_BLD_C OLL_TYPE
④ COLL_COMP_1 CK				COLL_COMP_ CK
⑤ ALQ_VIAL_S Z	1		1 = 2mL cryovials 2 = 5mL cryovial 3 = 15mL cryovial 4 = PAXgene Blood RNA tube	ALQ_VIAL_S Z
⑥ PBMC_CELL_ CNT	8.4			PBMC_CELL_ CNT

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms
 Folder: Post Lg Cx- Biospecimen Collection
 Form: Blood Collection Aliquots- PBMC
 Generated On: 15 May 2019 14:40:46

Field Name	Data Type	Units	Values	Include Field OID
7 PBMC_LTGO _VOL	8.4			PBMC_LTGO _VOL
8 DT_TM_80_I N	MMM dd yyyy HH nn			DT_TM_80_I N
9 FRZ_TEMP	4.2			FRZ_TEMP
10 SAMP_FRZ_T HW			1 = No 2 = Yes 99 = Unknown	SAMP_FRZ_T HW
11 SAMP_FRZ_T HW_COMM	\$200			SAMP_FRZ_T HW_COMM
12 ALQ_COMM	\$200			ALQ_COMM
13 PBMC_TOT_ DERV	2			PBMC_TOT_ DERV

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Was urine sample collected?

No ①
Yes
Unknown

Reason urine sample was not collected

Patient Refused ②
Adverse Event
Unknown
Other, specify

Date of Urine Sample Collection

Fixed Unit: MMM dd yyyy ③

Was urine collection performed per protocol?

No ④
Yes
Unknown

Primary reason urine collection was not performed per protocol

Urethral Area Not Cleaned ⑤
Site error
Storage not per protocol
Unknown
Other, specify

Were any adverse events that are considered possibly, probably, or definitely related to the study-related biospecimen collection procedures reported?

No ⑥
Yes
Unknown

Total number of urine cryovials collected

⑭

Type

Sterile Urine Collection Container 7
Cryovial

Check if collected

8

Date and Time into Freezer

9

Temperature of Freezer

Fixed Unit: °C 10

Did any freeze-thaw occur to the sample?

No 11
Yes
Unknown

Comments regarding freeze-thaw

12

Other comments

13

Type

Sterile Urine Collection Container 7
Cryovial

Check if collected

8

Date and Time into Freezer

9

Temperature of Freezer

Fixed Unit: °C 10

Did any freeze-thaw occur to the sample?

No 11
Yes
Unknown

Comments regarding freeze-thaw

12

Other comments

13

Type

Sterile Urine Collection 7
Container
Cryovial

Check if collected

8

Date and Time into Freezer

9

Temperature of Freezer

Fixed Unit: °C 10

Did any freeze-thaw occur to the sample?

No 11
Yes
Unknown

Comments regarding freeze-thaw

12

Other comments

13

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms
Folder: Post Lg Cx- Biospecimen Collection
Form: Urine Collection (Midstream Clean Catch)
Generated On: 15 May 2019 14:40:46

Type

Sterile Urine Collection Container 7
Cryovial

Check if collected

8

Date and Time into Freezer

9

Temperature of Freezer

Fixed Unit: °C 10

Did any freeze-thaw occur to the sample?

No 11
Yes
Unknown

Comments regarding freeze-thaw

12

Other comments

13

Type

Sterile Urine Collection Container 7
Cryovial

Check if collected

8

Date and Time into Freezer

9

Temperature of Freezer

Fixed Unit: °C 10

Did any freeze-thaw occur to the sample?

No 11
Yes
Unknown

Comments regarding freeze-thaw _____ 12

Other comments _____ 13

Type

Sterile Urine Collection 7
Container
Cryovial

Check if collected _____ 8

Date and Time into Freezer _____ 9

Temperature of Freezer

Fixed Unit: °C 10

Did any freeze-thaw occur to the sample?

No 11
Yes
Unknown

Comments regarding freeze-thaw _____ 12

Other comments _____ 13

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms
Folder: Post Lg Cx- Biospecimen Collection
Form: Urine Collection (Midstream Clean Catch)
Generated On: 15 May 2019 14:40:46

Field Name	Data Type	Units	Values	Include Field OID
① URN_SAMP_2 YN			1 = No 2 = Yes 99 = Unknown	URN_SAMP_ YN
② URN_SAMP_2 NCOLL_REAS			1 = Patient Refused 2 = Adverse Event 99 = Unknown 88 = Other, specify	URN_SAMP_ NCOLL_REAS
③ URN_SAMP_2 DT	MMM dd yyyy			URN_SAMP_ DT
④ URN_SAMP_2 COLL_PR			1 = No 2 = Yes 99 = Unknown	URN_SAMP_ COLL_PR
⑤ URN_NOT_P_2 R_REAS			1 = Urethral Area Not Cleaned 2 = Site error 3 = Storage not per protocol 99 = Unknown 88 = Other, specify	URN_NOT_P R_REAS

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms
Folder: Post Lg Cx- Biospecimen Collection
Form: Urine Collection (Midstream Clean Catch)
Generated On: 15 May 2019 14:40:46

Field Name	Data Type	Units	Values	Include Field OID
6 AE_YN	2		1 = No 2 = Yes 99 = Unknown	AE_YN
7 URN_COLL_T2 YP			1 = Sterile Urine Collection Container 2 = Cryovial	URN_COLL_T YP
8 URN_COLL	1			URN_COLL
9 DT_TM_80_I N	MMM dd yyyy HH nn			DT_TM_80_I N
10 FRZ_TEMP	4.2			FRZ_TEMP
11 SAMP_FRZ_T HW	2		1 = No 2 = Yes 99 = Unknown	SAMP_FRZ_T HW
12 SAMP_FRZ_T HW_COMM	\$200			SAMP_FRZ_T HW_COMM
13 ALQ_COMM	\$200			ALQ_COMM
14 URN_SMP_C L_DERV	2			URN_SMP_C L_DERV

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Was nasal brushing performed?

No ①
Yes
Unknown

Primary reason nasal brushing not performed

Patient Refused ②
Adverse Event
Missing Materials
Site Error
Unknown
Other, specify

Was nasal brushing performed per protocol?

No ③
Yes
Unknown

Primary reason nasal brushing not done per protocol

Storage Not Per Protocol ④
Missing Materials
Site Error
Unknown
Other, specify

Date of Nasal Brushing

Fixed Unit: MMM dd yyyy ⑤

Were any adverse events that are considered possibly, probably, or definitely related to the study-related biospecimen collection procedures reported?

No ⑥
Yes
Unknown

Total number types checked

⑭

Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Post Lg Cx- Biospecimen Collection

Form: Nasal Brushing

Generated On: 15 May 2019 14:40:46

Type

Tube with RNAProtect Cell Reagent 7

Check if collected

8

Date and Time into Freezer

9

Temperature of Freezer

Fixed Unit: °C 10

Did any freeze-thaw occur to the sample?

No 11
Yes
Unknown

Comments regarding freeze-thaw

12

Other comments

13

Type

Tube with RNAProtect Cell Reagent 7

Check if collected

8

Date and Time into Freezer

9

Temperature of Freezer

Fixed Unit: °C 10

Draft 25 version 1.0 MIGPROD 17JAN2018: All forms
Folder: Post Lg Cx- Biospecimen Collection
Form: Nasal Brushing
Generated On: 15 May 2019 14:40:46

Did any freeze-thaw occur to the sample?

No 11
Yes
Unknown

Comments regarding freeze-thaw

12

Other comments

13

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Post Lg Cx- Biospecimen Collection

Form: Nasal Brushing

Generated On: 15 May 2019 14:40:46

Field Name	Data Type	Units	Values	Include Field OID
① NAS_BRUSH 2 _YN			1 = No 2 = Yes 99 = Unknown	NAS_BRUSH _YN
② NAS_BRUSH 2 _ND_REAS			1 = Patient Refused 2 = Adverse Event 3 = Missing Materials 4 = Site Error 99 = Unknown 88 = Other, specify	NAS_BRUSH _ND_REAS
③ NAS_BRUSH 2 _PR_YN			1 = No 2 = Yes 99 = Unknown	NAS_BRUSH _PR_YN
④ NAS_BRUSH 2 _ND_PR			1 = Storage Not Per Protocol 2 = Missing Materials 3 = Site Error 99 = Unknown 88 = Other, specify	NAS_BRUSH _ND_PR
⑤ NAS_BRUSH _DT	MMM dd yyyy			NAS_BRUSH _DT

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Post Lg Cx- Biospecimen Collection

Form: Nasal Brushing

Generated On: 15 May 2019 14:40:46

Field Name	Data Type	Units	Values	Include Field OID
6 AE_YN	2		1 = No 2 = Yes 99 = Unknown	AE_YN
7 NAS_BRUSH _TYPE	1		1 = Tube with RNAprotect Cell Reagent	NAS_BRUSH _TYPE
8 NAS_BRUSH _COLL	1			NAS_BRUSH _COLL
9 DT_TM_80_I N	MMM dd yyyy HH nn			DT_TM_80_I N
10 FRZ_TEMP	4.2			FRZ_TEMP
11 SAMP_FRZ_T HW	2		1 = No 2 = Yes 99 = Unknown	SAMP_FRZ_T HW
12 SAMP_FRZ_T HW_COMM	\$200			SAMP_FRZ_T HW_COMM
13 ALQ_COMM	\$200			ALQ_COMM
14 NAS_TOT_D ERV	2			NAS_TOT_D ERV

Was buccal scraping performed?

No ①
Yes
Unknown

Primary reason buccal scraping not performed

Patient Refused ②
Adverse Event
Unknown
Other, specify

Was buccal scraping performed per protocol?

No ③
Yes
Unknown

Primary reason buccal scraping was not performed per protocol

Missing Materials ④
Site error
Unknown
Other, specify

Date of Buccal Scraping

Fixed Unit: MMM dd yyyy ⑤

Were any adverse events that are considered possibly, probably, or definitely related to the study-related biospecimen collection procedures reported?

No ⑥
Yes
Unknown

Type

Microtube ⑦
Microtube with Scraper

Draft 25 version 1.0 MIGPROD 17JAN2018: All forms
Folder: Post Lg Cx- Biospecimen Collection
Form: Buccal Scraping
Generated On: 15 May 2019 14:40:46

Check if Collected _____

8

Date and Time into Freezer _____

9

Temperature of Freezer _____

Fixed Unit: °C

10

Did any freeze-thaw occur to the sample?

No

11

Yes

Unknown

Comments regarding freeze thaw _____

12

Other comments _____

13

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Post Lg Cx- Biospecimen Collection

Form: Buccal Scraping

Generated On: 15 May 2019 14:40:46

Field Name	Data Type	Units	Values	Include Field OID
① BUCCAL_SA MP_YN	2		1 = No 2 = Yes 99 = Unknown	BUCCAL_SA MP_YN
② BUCCAL_SA MP_ND_REA S	2		1 = Patient Refused 2 = Adverse Event 99 = Unknown 88 = Other, specify	BUCCAL_SA MP_ND_REA S
③ BUCCAL_ND _PR	2		1 = No 2 = Yes 99 = Unknown	BUCCAL_ND _PR
④ BCCL_ND_PR _REAS	2		1 = Missing Materials 2 = Site error 99 = Unknown 88 = Other, specify	BCCL_ND_PR _REAS
⑤ BUCCAL_SA MP_DT	MMM dd yyyy			BUCCAL_SA MP_DT
⑥ AE_YN	2		1 = No 2 = Yes 99 = Unknown	AE_YN

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms
 Folder: Post Lg Cx- Biospecimen Collection
 Form: Buccal Scraping
 Generated On: 15 May 2019 14:40:46

Field Name	Data Type	Units	Values	Include Field OID
7 BCCL_TYPE	2		1 = Microtube 2 = Microtube with Scraper	BCCL_TYPE
8 BCCL_COLL	1			BCCL_COLL
9 DT_TM_80_I	MMM dd yyyy N HH nn			DT_TM_80_I N
10 FRZ_TEMP	4.2			FRZ_TEMP
11 SAMP_FRZ_T HW			1 = No 2 = Yes 99 = Unknown	SAMP_FRZ_T HW
12 SAMP_FRZ_T HW_COMM	\$200			SAMP_FRZ_T HW_COMM
13 ALQ_COMM	\$200			ALQ_COMM

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms
Folder: Post Lg Cx- Biospecimen Collection
Form: Biospecimen Transmittal-Required
Generated On: 15 May 2019 14:40:46

Kit Barcode _____ ①

Date Specimens Mailed _____ ②

Copy of Biospecimen Transmittal _____ ③

Total Number of Urine Checks _____ ⑫

Total Number of Nasal Epithelium Checks _____ ⑬

Total Number of PAXgene checks _____ ⑭

Total number of serum checks _____ ⑮

Total number of plasma checks _____ ⑯

Total number of streck checks _____ ⑰

Biospecimen Type _____ Blood Collection- Blood ④
Plasma

Barcode Sequence # _____ ⑤

Check if Specimen Included _____ ⑥

Storage Temp _____ Fixed Unit: °C ⑦

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Did any freeze/thaw occur?

No 8
Yes
Unknown

If yes to freeze/thaw- Total # of Times _____ 9

If yes to freeze/thaw- length of each time _____ 10

Comments _____ 11

Biospecimen Type _____

Blood Collection- Blood 4
Plasma

Barcode Sequence # _____ 5

Check if Specimen Included _____ 6

Storage Temp _____

Fixed Unit: °C 7

Did any freeze/thaw occur?

No 8
Yes
Unknown

If yes to freeze/thaw- Total # of Times _____ 9

If yes to freeze/thaw- length of each time _____ 10

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms
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Form: Biospecimen Transmittal-Required
Generated On: 15 May 2019 14:40:46

Comments _____ 11

Biospecimen Type _____

Blood Collection- Blood Plasma 4

Barcode Sequence # _____ 9 5

Check if Specimen Included _____ 6

Storage Temp _____

Fixed Unit: °C 7

Did any freeze/thaw occur?

No 8
Yes
Unknown

If yes to freeze/thaw- Total # of Times _____ 9

If yes to freeze/thaw- length of each time _____ 10

Comments _____ 11

Biospecimen Type _____

Blood Collection- Blood Plasma 4

Barcode Sequence # _____ 10 5

Check if Specimen Included _____ 6

Storage Temp _____

Fixed Unit: °C 7

Did any freeze/thaw occur?

No 8

Yes

Unknown

If yes to freeze/thaw- Total # of Times _____ 9

If yes to freeze/thaw- length of each time _____ 10

Comments _____ 11

Biospecimen Type _____

Blood Collection- Blood 4
Plasma

Barcode Sequence # _____

11 5

Check if Specimen Included _____ 6

Storage Temp _____

Fixed Unit: °C 7

Did any freeze/thaw occur?

No 8

Yes

Unknown

If yes to freeze/thaw- Total # of Times _____

9

If yes to freeze/thaw- length of each time _____

10

Comments _____

11

Biospecimen Type _____

Blood Collection- Blood Plasma

4

Barcode Sequence # _____

12

5

Check if Specimen Included _____

6

Storage Temp _____

Fixed Unit: °C

7

Did any freeze/thaw occur?

No

8

Yes

Unknown

If yes to freeze/thaw- Total # of Times _____

9

If yes to freeze/thaw- length of each time _____

10

Comments _____

11

Biospecimen Type _____

Blood Collection- Serum

4

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Barcode Sequence # _____ 19 **5**

Check if Specimen Included _____ **6**

Storage Temp _____ Fixed Unit: °C **7**

Did any freeze/thaw occur? No **8**
Yes
Unknown

If yes to freeze/thaw- Total # of Times _____ **9**

If yes to freeze/thaw- length of each time _____ **10**

Comments _____ **11**

Biospecimen Type _____ Blood Collection- Serum **4**

Barcode Sequence # _____ 20 **5**

Check if Specimen Included _____ **6**

Storage Temp _____ Fixed Unit: °C **7**

Did any freeze/thaw occur? No **8**
Yes

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Unknown

If yes to freeze/thaw- Total # of Times _____ 9

If yes to freeze/thaw- length of each time _____ 10

Comments _____ 11

Biospecimen Type _____ Blood Collection- Serum 4

Barcode Sequence # _____ 21 5

Check if Specimen Included _____ 6

Storage Temp _____ Fixed Unit: °C 7

Did any freeze/thaw occur? No 8
Yes
Unknown

If yes to freeze/thaw- Total # of Times _____ 9

If yes to freeze/thaw- length of each time _____ 10

Comments _____ 11

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Biospecimen Type Blood Collection-PAXgene **4**

Barcode Sequence # **5**

Check if Specimen Included **6**

Storage Temp Fixed Unit: °C **7**

Did any freeze/thaw occur? No **8**
Yes
Unknown

If yes to freeze/thaw- Total # of Times **9**

If yes to freeze/thaw- length of each time **10**

Comments **11**

Biospecimen Type Blood Collection-PAXgene **4**

Barcode Sequence # **5**

Check if Specimen Included **6**

Storage Temp Fixed Unit: °C **7**

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Did any freeze/thaw occur?

No 8
Yes
Unknown

If yes to freeze/thaw- Total # of Times _____ 9

If yes to freeze/thaw- length of each time _____ 10

Comments _____ 11

Biospecimen Type _____

Streck Collection 4

Barcode Sequence # _____

28 5

Check if Specimen Included _____ 6

Storage Temp _____

Fixed Unit: °C 7

Did any freeze/thaw occur?

No 8
Yes
Unknown

If yes to freeze/thaw- Total # of Times _____ 9

If yes to freeze/thaw- length of each time _____ 10

Comments _____ 11

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Biospecimen Type

Streck Collection ④

Barcode Sequence #

29 ⑤

Check if Specimen Included

_____ ⑥

Storage Temp

Fixed Unit: °C ⑦

Did any freeze/thaw occur?

No ⑧
Yes
Unknown

If yes to freeze/thaw- Total # of Times

_____ ⑨

If yes to freeze/thaw- length of each time

_____ ⑩

Comments

_____ ⑪

Biospecimen Type

Streck Collection ④

Barcode Sequence #

30 ⑤

Check if Specimen Included

_____ ⑥

Storage Temp

Fixed Unit: °C ⑦

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Did any freeze/thaw occur? No 8
Yes
Unknown

If yes to freeze/thaw- Total # of Times _____ 9

If yes to freeze/thaw- length of each time _____ 10

Comments _____ 11

Biospecimen Type _____ Streck Collection 4

Barcode Sequence # _____ 31 5

Check if Specimen Included _____ 6

Storage Temp _____ Fixed Unit: °C 7

Did any freeze/thaw occur? No 8
Yes
Unknown

If yes to freeze/thaw- Total # of Times _____ 9

If yes to freeze/thaw- length of each time _____ 10

Comments _____ 11

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Biospecimen Type Bronchial Airway Brushings-
Brush A 4

Barcode Sequence # 60 5

Check if Specimen Included 6

Storage Temp Fixed Unit: °C 7

Did any freeze/thaw occur? No 8
Yes
Unknown

If yes to freeze/thaw- Total # of Times 9

If yes to freeze/thaw- length of each time 10

Comments 11

Biospecimen Type Bronchial Airway Brushings-
Brush B 4

Barcode Sequence # 61 5

Check if Specimen Included 6

Storage Temp Fixed Unit: °C 7

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Did any freeze/thaw occur?

No 8
Yes
Unknown

If yes to freeze/thaw- Total # of Times _____ 9

If yes to freeze/thaw- length of each time _____ 10

Comments _____ 11

Biospecimen Type _____

Bronchial Airway Brushings-
Brush C 4

Barcode Sequence # _____

62 5

Check if Specimen Included _____ 6

Storage Temp _____

Fixed Unit: °C 7

Did any freeze/thaw occur?

No 8
Yes
Unknown

If yes to freeze/thaw- Total # of Times _____ 9

If yes to freeze/thaw- length of each time _____ 10

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Comments _____ 11

Biospecimen Type _____

Bronchial Biopsy Collection-
RUL Fresh Frozen 4

Barcode Sequence # _____

68 5

Check if Specimen Included _____ 6

Storage Temp _____

Fixed Unit: °C 7

Did any freeze/thaw occur? _____

No 8
Yes
Unknown

If yes to freeze/thaw- Total # of Times _____ 9

If yes to freeze/thaw- length of each time _____ 10

Comments _____ 11

Biospecimen Type _____

Bronchial Biopsy Collection-
RML Fresh Frozen 4

Barcode Sequence # _____

70 5

Check if Specimen Included _____ 6

Storage Temp _____ Fixed Unit: °C 7

Did any freeze/thaw occur? No 8
Yes
Unknown

If yes to freeze/thaw- Total # of Times _____ 9

If yes to freeze/thaw- length of each time _____ 10

Comments _____ 11

Biospecimen Type _____ Bronchial Biopsy Collection- 4
LUL Fresh Frozen

Barcode Sequence # _____ 72 5

Check if Specimen Included _____ 6

Storage Temp _____ Fixed Unit: °C 7

Did any freeze/thaw occur? No 8
Yes
Unknown

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If yes to freeze/thaw- Total # of Times _____

9

If yes to freeze/thaw- length of each time _____

10

Comments _____

11

Biospecimen Type

Buccal Epithelium Collection

4

Barcode Sequence # _____

51

5

Check if Specimen Included _____

6

Storage Temp _____

Fixed Unit: °C

7

Did any freeze/thaw occur?

No

8

Yes

Unknown

If yes to freeze/thaw- Total # of Times _____

9

If yes to freeze/thaw- length of each time _____

10

Comments _____

11

Biospecimen Type

Nasal Epithelium Collection

4

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NOT RECOMMENDED FOR SOURCE DOCUMENTATION

Barcode Sequence # 54 **5**

Check if Specimen Included _____ **6**

Storage Temp _____ Fixed Unit: °C **7**

Did any freeze/thaw occur? No **8**
Yes
Unknown

If yes to freeze/thaw- Total # of Times _____ **9**

If yes to freeze/thaw- length of each time _____ **10**

Comments _____ **11**

Biospecimen Type Nasal Epithelium Collection **4**

Barcode Sequence # 55 **5**

Check if Specimen Included _____ **6**

Storage Temp _____ Fixed Unit: °C **7**

Did any freeze/thaw occur? No **8**
Yes

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NOT RECOMMENDED FOR SOURCE DOCUMENTATION

Unknown

If yes to freeze/thaw- Total # of Times _____ 9

If yes to freeze/thaw- length of each time _____ 10

Comments _____ 11

Biospecimen Type _____ Urine Collection 4

Barcode Sequence # _____ 34 5

Check if Specimen Included _____ 6

Storage Temp _____ Fixed Unit: °C 7

Did any freeze/thaw occur? No 8
Yes
Unknown

If yes to freeze/thaw- Total # of Times _____ 9

If yes to freeze/thaw- length of each time _____ 10

Comments _____ 11

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NOT RECOMMENDED FOR SOURCE DOCUMENTATION

Biospecimen Type

Urine Collection

4

Barcode Sequence #

35

5

Check if Specimen Included

6

Storage Temp

Fixed Unit: °C

7

Did any freeze/thaw occur?

No

8

Yes

Unknown

If yes to freeze/thaw- Total # of Times

9

If yes to freeze/thaw- length of each time

10

Comments

11

Biospecimen Type

Urine Collection

4

Barcode Sequence #

36

5

Check if Specimen Included

6

Storage Temp

Fixed Unit: °C

7

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Did any freeze/thaw occur?

No 8
Yes
Unknown

If yes to freeze/thaw- Total # of Times _____ 9

If yes to freeze/thaw- length of each time _____ 10

Comments _____ 11

Biospecimen Type _____

Urine Collection 4

Barcode Sequence # _____

37 5

Check if Specimen Included _____ 6

Storage Temp _____

Fixed Unit: °C 7

Did any freeze/thaw occur?

No 8
Yes
Unknown

If yes to freeze/thaw- Total # of Times _____ 9

If yes to freeze/thaw- length of each time _____ 10

Comments _____ 11

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Biospecimen Type

Urine Collection

4

Barcode Sequence #

38

5

Check if Specimen Included

6

Storage Temp

Fixed Unit: °C

7

Did any freeze/thaw occur?

No

8

Yes

Unknown

If yes to freeze/thaw- Total # of Times

9

If yes to freeze/thaw- length of each time

10

Comments

11

Biospecimen Type

Urine Collection

4

Barcode Sequence #

39

5

Check if Specimen Included

6

Storage Temp

Fixed Unit: °C

7

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Folder: Post Lg Cx- Biospecimen Collection
Form: Biospecimen Transmittal-Required
Generated On: 15 May 2019 14:40:46

Did any freeze/thaw occur?

No 8
Yes
Unknown

If yes to freeze/thaw- Total # of Times

_____ 9

If yes to freeze/thaw- length of each time

_____ 10

Comments

_____ 11

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms
Folder: Post Lg Cx- Biospecimen Collection
Form: Biospecimen Transmittal-Required
Generated On: 15 May 2019 14:40:46

Field Name	Data Type	Units	Values	Include Field OID
① BSPCM_KIT_ BCD	\$60			BSPCM_KIT_ BCD
② BSPCM_SENTMMM _CLAB_DT	dd yyyy			BSPCM_SENT _CLAB_DT
③ BSPCM_TRA NS_UP	\$200			BSPCM_TRA NS_UP
④ BSPCM_TYPE	2		Required Biospecimen Types	BSPCM_TYPE
⑤ BSPCM_BCD _SEQ	3		7 8 9 10 11 12 19 20 21 25 26 28 2 9 30 31 60 61 62 68 70 72 51 54 5 5 34 35 36 37 38 39	BSPCM_BCD _SEQ
⑥ BSPCM_ST_C R_LB				BSPCM_ST_C R_LB
⑦ BSPCM_ST_T EMP	4.2			BSPCM_ST_T EMP
⑧ BSPCM_FZ_T HAW			1 = No 2 = Yes 99 = Unknown	BSPCM_FZ_T HAW

Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Post Lg Cx- Biospecimen Collection

Form: Biospecimen Transmittal-Required

Generated On: 15 May 2019 14:40:46

Field Name	Data Type	Units	Values	Include Field OID
9 FZ_THAW_T TL_TME				FZ_THAW_T TL_TME
10 FX_THAW_L NGTH	\$200			FX_THAW_L NGTH
11 BSPCM_TRA NS_COMM	\$200			BSPCM_TRA NS_COMM
12 URN_TOT_D ERV	2			URN_TOT_D ERV
13 NAS_EP_TOT _DERV	2			NAS_EP_TOT _DERV
14 PAX_TOT_DE RV	2			PAX_TOT_DE RV
15 SERUM_TOT _DERV	2			SERUM_TOT _DERV
16 PLAS_TOT_D ERV	2			PLAS_TOT_D ERV
17 STRECK_TOT _DERV	2			STRECK_TOT _DERV

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Were optional biospecimens sent to the core lab?

No ①
Yes
Unknown

If no optional biospecimens were sent to the core lab, leave the table blank.

If optional specimens were sent, at least one row of the table must be checked as sent.

Date optional biospecimens sent to core lab _____ ③

Total number of Buffy Coat Checks _____ ⑫

Total number of PBMC checks _____ ⑬

Total number of Urine Processing for Metabolomics Study Checks _____ ⑭

Biospecimen Type

Blood Collection- Buffy Coat ④
Blood Collection- PBMC
Bronchial Airway Brushings
Collection- Tube D
Urine Processing for Metabolomics Study

Barcode Sequence # _____ 13 ⑤

Check if Specimen Included _____ ⑥

Draft 25 version 1.0 MIGPROD 17JAN2018: All forms
Folder: Post Lg Cx- Biospecimen Collection
Form: Biospecimen Transmittal- Optional
Generated On: 15 May 2019 14:40:46

Storage Temp _____

Fixed Unit: °C

7

Did any freeze/thaw occur? _____

No

8

Yes

Unknown

If yes to freeze/thaw- Total # of Times _____

9

If yes to freeze/thaw- length of each time _____

10

Comments _____

11

Biospecimen Type _____

Blood Collection- Buffy Coat

4

Blood Collection- PBMC

Bronchial Airway Brushings

Collection- Tube D

Urine Processing for

Metabolomics Study

Barcode Sequence # _____

14

5

Check if Specimen Included _____

6

Storage Temp _____

Fixed Unit: °C

7

Did any freeze/thaw occur? _____

No

8

Yes

Unknown

If yes to freeze/thaw- Total # of Times _____

If yes to freeze/thaw- length of each time _____

Comments _____

Biospecimen Type

- Blood Collection- Buffy Coat
- Blood Collection- PBMC
- Bronchial Airway Brushings
- Collection- Tube D
- Urine Processing for
- Metabolomics Study

Barcode Sequence # _____

Check if Specimen Included _____

Storage Temp _____

Fixed Unit: °C _____

Did any freeze/thaw occur?

- No
- Yes
- Unknown

If yes to freeze/thaw- Total # of Times _____

If yes to freeze/thaw- length of each time _____

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms
Folder: Post Lg Cx- Biospecimen Collection
Form: Biospecimen Transmittal- Optional
Generated On: 15 May 2019 14:40:46

Comments _____ 11

Biospecimen Type

- Blood Collection- Buffy Coat 4
- Blood Collection- RBMC
- Bronchial Airway Brushings
- Collection- Tube D
- Urine Processing for
- Metabolomics Study

Barcode Sequence # _____ 16 5

Check if Specimen Included _____ 6

Storage Temp _____

Fixed Unit: °C 7

Did any freeze/thaw occur?

- No 8
- Yes
- Unknown

If yes to freeze/thaw- Total # of Times _____ 9

If yes to freeze/thaw- length of each time _____ 10

Comments _____ 11

Biospecimen Type

- Blood Collection- Buffy Coat 4
- Blood Collection- PBMC

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms
Folder: Post Lg Cx- Biospecimen Collection
Form: Biospecimen Transmittal- Optional
Generated On: 15 May 2019 14:40:46

Bronchial Airway Brushings
Collection- Tube D
Urine Processing for
Metabolomics Study

Barcode Sequence # 17 **5**

Check if Specimen Included _____ **6**

Storage Temp _____ Fixed Unit: °C **7**

Did any freeze/thaw occur? No **8**
Yes
Unknown

If yes to freeze/thaw- Total # of Times _____ **9**

If yes to freeze/thaw- length of each time _____ **10**

Comments _____ **11**

Biospecimen Type Blood Collection- Buffy Coat **4**
Blood Collection- PBMC
Bronchial Airway Brushings
Collection- Tube D
Urine Processing for
Metabolomics Study

Barcode Sequence # 18 **5**

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms
Folder: Post Lg Cx- Biospecimen Collection
Form: Biospecimen Transmittal- Optional
Generated On: 15 May 2019 14:40:46

Check if Specimen Included _____

6

Storage Temp _____

Fixed Unit: °C

7

Did any freeze/thaw occur?

No

8

Yes

Unknown

If yes to freeze/thaw- Total # of Times _____

9

If yes to freeze/thaw- length of each time _____

10

Comments _____

11

Biospecimen Type

Blood Collection- Buffy Coat

4

Blood Collection- PBMC

Bronchial Airway Brushings

Collection- Tube D

Urine Processing for
Metabolomics Study

Barcode Sequence # _____

27 5

Check if Specimen Included _____

6

Storage Temp _____

Fixed Unit: °C

7

Did any freeze/thaw occur?

No 8
Yes
Unknown

If yes to freeze/thaw- Total # of Times

9

If yes to freeze/thaw- length of each time

10

Comments

11

Biospecimen Type

Blood Collection- Buffy Coat 4
Blood Collection- PBMC
Bronchial Airway Brushings
Collection- Tube D
Urine Processing for
Metabolomics Study

Barcode Sequence #

28 5

Check if Specimen Included

6

Storage Temp

Fixed Unit: °C 7

Did any freeze/thaw occur?

No 8
Yes
Unknown

If yes to freeze/thaw- Total # of Times

9

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms
Folder: Post Lg Cx- Biospecimen Collection
Form: Biospecimen Transmittal- Optional
Generated On: 15 May 2019 14:40:46

If yes to freeze/thaw- length of each time _____ 10

Comments _____ 11

Biospecimen Type

- Blood Collection- Buffy Coat 4
- Blood Collection- PBMC
- Bronchial Airway Brushings
- Collection- Tube D
- Urine Processing for Metabolomics Study

Barcode Sequence # _____ 29 5

Check if Specimen Included _____ 6

Storage Temp _____

Fixed Unit: °C 7

Did any freeze/thaw occur?

- No 8
- Yes
- Unknown

If yes to freeze/thaw- Total # of Times _____ 9

If yes to freeze/thaw- length of each time _____ 10

Comments _____ 11

Draft 25 version 1.0 MIGPROD 17JAN2018: All forms
Folder: Post Lg Cx- Biospecimen Collection
Form: Biospecimen Transmittal- Optional
Generated On: 15 May 2019 14:40:46

Biospecimen Type

- Blood Collection- Buffy Coat ④
- Blood Collection- PBMC
- Bronchial Airway Brushings
- Collection- Tube D
- Urine Processing for
- Metabolomics Study

Barcode Sequence #

30 ⑤

Check if Specimen Included

⑥

Storage Temp

Fixed Unit: °C ⑦

Did any freeze/thaw occur?

- No ⑧
- Yes
- Unknown

If yes to freeze/thaw- Total # of Times

⑨

If yes to freeze/thaw- length of each time

⑩

Comments

⑪

Biospecimen Type

- Blood Collection- Buffy Coat ④
- Blood Collection- PBMC
- Bronchial Airway Brushings
- Collection- Tube D
- Urine Processing for
- Metabolomics Study

Barcode Sequence # 31 **5**

Check if Specimen Included _____ **6**

Storage Temp _____ Fixed Unit: °C **7**

Did any freeze/thaw occur? No **8**
Yes
Unknown

If yes to freeze/thaw- Total # of Times _____ **9**

If yes to freeze/thaw- length of each time _____ **10**

Comments _____ **11**

Biospecimen Type Blood Collection- Buffy Coat **4**
Blood Collection- PBMC
Bronchial Airway Brushings Collection- Tube D
Urine Processing for Metabolomics Study

Barcode Sequence # 63 **5**

Check if Specimen Included _____ **6**

Storage Temp _____ Fixed Unit: °C **7**

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Did any freeze/thaw occur?

No 8
Yes
Unknown

If yes to freeze/thaw- Total # of Times

9

If yes to freeze/thaw- length of each time

10

Comments

11

Biospecimen Type

Blood Collection- Buffy Coat 4
Blood Collection- PBMC
Bronchial Airway Brushings
Collection- Tube D
Urine Processing for
Metabolomics Study

Barcode Sequence #

40 5

Check if Specimen Included

6

Storage Temp

Fixed Unit: °C 7

Did any freeze/thaw occur?

No 8
Yes
Unknown

If yes to freeze/thaw- Total # of Times

9

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms
Folder: Post Lg Cx- Biospecimen Collection
Form: Biospecimen Transmittal- Optional
Generated On: 15 May 2019 14:40:46

If yes to freeze/thaw- length of each time _____ 10

Comments _____ 11

Biospecimen Type

- Blood Collection- Buffy Coat 4
- Blood Collection- PBMC
- Bronchial Airway Brushings
- Collection- Tube D
- Urine Processing for Metabolomics Study

Barcode Sequence # _____ 41 5

Check if Specimen Included _____ 6

Storage Temp _____

Fixed Unit: °C 7

Did any freeze/thaw occur?

- No 8
- Yes
- Unknown

If yes to freeze/thaw- Total # of Times _____ 9

If yes to freeze/thaw- length of each time _____ 10

Comments _____ 11

Draft 25 version 1.0 MIGPROD 17JAN2018: All forms
Folder: Post Lg Cx- Biospecimen Collection
Form: Biospecimen Transmittal- Optional
Generated On: 15 May 2019 14:40:46

Biospecimen Type

- Blood Collection- Buffy Coat 4
- Blood Collection- PBMC
- Bronchial Airway Brushings
Collection- Tube D
- Urine Processing for
Metabolomics Study

Barcode Sequence #

42 5

Check if Specimen Included

6

Storage Temp

Fixed Unit: °C 7

Did any freeze/thaw occur?

- No 8
- Yes
- Unknown

If yes to freeze/thaw- Total # of Times

9

If yes to freeze/thaw- length of each time

10

Comments

11

Biospecimen Type

- Blood Collection- Buffy Coat 4
- Blood Collection- PBMC
- Bronchial Airway Brushings
Collection- Tube D
- Urine Processing for
Metabolomics Study

Draft 25 version 1.0 MIGPROD 17JAN2018: All forms
Folder: Post Lg Cx- Biospecimen Collection
Form: Biospecimen Transmittal- Optional
Generated On: 15 May 2019 14:40:46

Barcode Sequence # 43 **5**

Check if Specimen Included _____ **6**

Storage Temp _____ Fixed Unit: °C **7**

Did any freeze/thaw occur? No **8**
Yes
Unknown

If yes to freeze/thaw- Total # of Times _____ **9**

If yes to freeze/thaw- length of each time _____ **10**

Comments _____ **11**

Biospecimen Type Blood Collection- Buffy Coat **4**
Blood Collection- PBMC
Bronchial Airway Brushings
Collection- Tube D
Urine Processing for
Metabolomics Study

Barcode Sequence # 44 **5**

Check if Specimen Included _____ **6**

Storage Temp _____ Fixed Unit: °C **7**

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Did any freeze/thaw occur?

No 8
Yes
Unknown

If yes to freeze/thaw- Total # of Times _____ 9

If yes to freeze/thaw- length of each time _____ 10

Comments _____ 11

Biospecimen Type

Blood Collection- Buffy Coat 4
Blood Collection- PBMC
Bronchial Airway Brushings
Collection- Tube D
Urine Processing for
Metabolomics Study

Barcode Sequence # _____ 45 5

Check if Specimen Included _____ 6

Storage Temp _____

Fixed Unit: °C 7

Did any freeze/thaw occur?

No 8
Yes
Unknown

If yes to freeze/thaw- Total # of Times _____ 9

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Folder: Post Lg Cx- Biospecimen Collection
Form: Biospecimen Transmittal- Optional
Generated On: 15 May 2019 14:40:46

If yes to freeze/thaw- length of each time _____

Comments _____

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Folder: Post Lg Cx- Biospecimen Collection
Form: Biospecimen Transmittal- Optional
Generated On: 15 May 2019 14:40:46

Field Name	Data Type	Units	Values	Include Field OID
① OP_BSPCM_2 COLL			1 = No 2 = Yes 99 = Unknown	OP_BSPCM_ COLL
③ BSPCM_SENTMMM _CLAB_DT	dd yyyy			BSPCM_SENT _CLAB_DT
④ BSPCM_OP_T2 YPE			1 = Blood Collection Buffy Coat 2 = Blood Collection- PBMG 3 = Bronchial Airway Brushings Collection- Tube D 4 = Urine Processing for Metabolomics Study	BSPCM_OP_T YPE
⑤ BSPCM_BCD_3 _SEQ			13 14 15 16 17 18 27 2 8 29 30 31 63 40 41 42 43 44 45	BSPCM_BCD _SEQ
⑥ BSPCM_ST_C2 R_LB				BSPCM_ST_C R_LB
⑦ BSPCM_ST_T 4.2 EMP				BSPCM_TEM P

Draft 25 version 1.0 MIGPROD 17JAN2018: All forms
 Folder: Post Lg Cx- Biospecimen Collection
 Form: Biospecimen Transmittal- Optional
 Generated On: 15 May 2019 14:40:46

Field Name	Data Type	Units	Values	Include Field OID
8 BSPCM_FZ_T 2 HAW			1 = No 2 = Yes 99 = Unknown	BSPCM_FZ_T HAW
9 FZ_THAW_T 3 TL_TME				FZ_THAW_T TL_TME
10 FX_THAW_L \$200 NGTH				FX_THAW_L NGTH
11 BSPCM_TRA \$200 NS_COMM				BSPCM_TRA NS_COMM
12 BUFFY_CT_T 2 OT_DERV				BUFFY_CT_T OT_DERV
13 PBMC_TRAN 2 S_TOT_DERV				PBMC_TRAN S_TOT_DERV
14 URN_MET_T 2 OT_DERV				URN_MET_T OT_DERV

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Were additional biospecimens sent to the core lab?

No ①
Yes
Unknown

If no additional biospecimens were sent to the core lab, leave the table blank.

If additional specimens were sent, at least one row of the table must be completed.

Biospecimen Type

- Blood Collection- Blood Plasma ③
- Blood Collection- Buffy Coat
- Blood Collection- PBMC
- Blood Collection- Serum
- Blood Collection-PAXgene
- Bronchial Airway Brushings Collection
- Bronchial Biopsy Collection
- Buccal Epithelium Collection
- Nasal Epithelium Collection
- Urine Collection
- Other, specify

Barcode Sequence # _____ ④

Date Sent to Core Lab _____ ⑤

Storage Temp _____ Fixed Unit: °C ⑥

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms
Folder: Post Lg Cx- Biospecimen Collection
Form: Biospecimen Transmittal- Additional
Generated On: 15 May 2019 14:40:46

Did any freeze/thaw occur?

No 7
Yes
Unknown

If yes to freeze/thaw- Total # of Times

_____ 8

If yes to freeze/thaw- length of each time

_____ 9

Comments

_____ 10

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms
Folder: Post Lg Cx- Biospecimen Collection
Form: Biospecimen Transmittal- Additional
Generated On: 15 May 2019 14:40:46

Field Name	Data Type	Units	Values	Include Field OID
① ADD_BSPCM 2 _COLL			1 = No 2 = Yes 99 = Unknown	ADD_BSPCM _COLL
③ BSPCM_TYPE 3 _ADD			1 = Blood Collection- Blood Plasma 2 = Blood Collection- Buffy Coat 3 = Blood Collection- PBMG 4 = Blood Collection- Serum 5 = Blood Collection-PA Xgène 6 = Bronchial Airway Brushings Collection 7 = Bronchial Biopsy Collection 8 = Buccal Epithelium Collection 9 = Nasal Epithelium Collection 10 = Urine Collection 88 = Other, specify	BSPCM_TYPE _ADD

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms
 Folder: Post Lg Cx- Biospecimen Collection
 Form: Biospecimen Transmittal- Additional
 Generated On: 15 May 2019 14:40:46

Field Name	Data Type	Units	Values	Include Field OID
④ BSPCM_BCD _SEQ				BSPCM_BCD _SEQ
⑤ BSPCM_SENTMMM _CLAB_DT	dd yyyy			BSPCM_SENT _CLAB_DT
⑥ BSPCM_ST_T EMP	4.2			BSPCM_ST_T EMP
⑦ BSPCM_FZ_T HAW			1 = No 2 = Yes 99 = Unknown	BSPCM_FZ_T HAW
⑧ FZ_THAW_T TL_TME	3			FZ_THAW_T TL_TME
⑨ FX_THAW_L NGTH	\$200			FX_THAW_L NGTH
⑩ BSPCM_TRA NS_COMM	\$200			BSPCM_TRA NS_COMM

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Participant Vital Status

Alive ①
Dead
Unknown

Was the outcome assessment completed for this timepoint?

No ②
Yes

If no, indicate the primary reason not completed

Patient Refused ③
Patient Lost to Follow up
Site error
Other, specify

Date of Assessment

_____ ④

Indicate the person(s) who assessed the patient's status

Site RA

_____ ⑥

Treating Physician

_____ ⑦

Other, specify

_____ ⑧

Indicate the method(s) status was assessed

Medical Records

_____ ⑩

Treating Physician

_____ ⑪

Participant

_____ ⑫

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Folder: Post Lg Cx- 3 month Follow up

Form: Outcomes Assessment

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Other, specify _____

13

Did the participant develop progression at primary site, new lesions, growth of existing lesions, metastases, and/or other recurrence not previously reported?

No 14
Yes
Unknown

Date of first documentation of progressive lung cancer _____

15

Indicate the site(s) of progression of lung cancer

Site

- Original lung site 17
- Other lung site(s)
- Pleura
- Brain
- Bone
- Liver
- Adrenal
- Skin/subcutaneous tissue
- N1 regional lymph nodes (ipsilateral hilar/intrapulmonary)
- N2 ipsilateral mediastinal lymph nodes
- N3 distant lymph nodes (contralateral mediastinal or hilar/supraclavicular/scalene)
- Unknown
- Other, specify

Did the participant develop a second primary lung cancer following treatment for an initial primary lung cancer not previously reported?

No 18
Yes
Unknown

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Folder: Post Lg Cx- 3 month Follow up

Form: Outcomes Assessment

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Date of diagnosis of second primary lung cancer _____

19

Did the participant undergo lung cancer radiation treatment(s) not previously reported?

No

20

Yes

Unknown

Did the participant undergo lung cancer surgical treatment(s) not previously reported?

No

21

Yes

Unknown

Did the participant receive lung cancer chemotherapy not previously reported?

No

22

Yes

Unknown

Did the participant undergo any other lung cancer treatment(s) administered by a physician not previously reported?

No

23

Yes

Unknown

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Folder: Post Lg Cx- 3 month Follow up

Form: Outcomes Assessment

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Field Name	Data Type	Units	Values	Include Field OID
① PT_VT_STS	2		1 = Alive 2 = Dead 99 = Unknown	PT_VT_STS
② OUT_ASSD_ YN	2		1 = No 2 = Yes	OUT_ASSD_ YN
③ OUT_ADD_N D_RSN	2		1 = Patient Refused 2 = Patient Lost to Follow up 3 = Site error 88 = Other, specify	OUT_ADD_N D_RSN
④ ASS_DT	MMM dd yyyy			ASS_DT
⑥ SITE_RA_AS SD	1			SITE_RA_AS SD
⑦ TRTING_PHY _ASS	1			TRTING_PHY _ASS
⑧ OTHER_ASS	\$200			OTHER_ASS
⑩ MTHD_ASS_ MED_REC	1			MTHD_ASS_ MED_REC
⑪ MTHD_ASS_ TRTING_PHY	1			MTHD_ASS_ TRTING_PHY

Draft 25 version 1.0 MIGPROD 17JAN2018: All forms
Folder: Post Lg Cx- 3 month Follow up
Form: Outcomes Assessment
Generated On: 15 May 2019 14:40:46

Field Name	Data Type	Units	Values	Include Field OID
12 MTHD_ASS_ 1 PT				MTHD_ASS_ PT
13 MTHD_ASS_ \$200 OTH				MTHD_ASS_ OTH
14 PRG_DX_YN 2			1 = No 2 = Yes 99 = Unknown	PRG_DX_YN
15 PRG_DX_DT MMM dd yyyy				PRG_DX_DT
17 LUNG_CS_PR2 OG_SITE			1 = Original lung site 2 = Other lung site(s) 3 = Pleura 4 = Brain 5 = Bone 6 = Liver 7 = Adrenal 8 = Skin/subcuta neous tissue 9 = N1 regional lymph nodes (ipsilateral hilar/intrapul monary) 10 = N2 ipsilateral mediastinal lymph nodes	LUNG_CS_PR OG_SITE

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Post Lg Cx- 3 month Follow up

Form: Outcomes Assessment

Generated On: 15 May 2019 14:40:46

Field Name	Data Type	Units	Values	Include Field OID
			11 = N3 distant lymph nodes (contralateral mediastinal or hilar/supracla vicular/scale ne) 99 = Unknown 88 = Other, specify	
18 PRIM_2ND_L G_YN			1 = No 2 = Yes 99 = Unknown	PRIM_2ND_L G_YN
19 PRIM_2ND_L G_DT	MMM dd yyyy			PRIM_2ND_L G_DT
20 RT_TX_YN	2		1 = No 2 = Yes 99 = Unknown	RT_TX_YN
21 SURG_TX_Y N	2		1 = No 2 = Yes 99 = Unknown	SURG_TX_Y N
22 CHEMO_TX_ YN	2		1 = No 2 = Yes 99 = Unknown	CHEMO_TX_ YN

Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Post Lg Cx- 3 month Follow up

Form: Outcomes Assessment

Generated On: 15 May 2019 14:40:46

Field Name	Data Type	Units	Values	Include Field OID
23 OTH_TX_YN	2		1 = No 2 = Yes 99 = Unknown	OTH_TX_YN

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Folder: Post Lg Cx- 3 month Follow up

Form: Chemotherapy

Generated On: 15 May 2019 14:40:46

Instructions: Indicate all the chemotherapeutic agents given, the start and end date, not previously reported on this form

If the exact date is unknown, unknown day should be entered as UN and unknown month as UNK

Chemotherapy Type _____ ②

Start Date _____ ③

Check if Ongoing _____ ④

If ongoing, provide the tentative end date _____ ⑤

Actual End Date _____ ⑥

Check if end date unknown _____ ⑦

Provide the number of cycles given Note If ongoing, provide the planned number of cycles _____ ⑧

Check if the number of cycles is unknown _____ ⑨

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Post Lg Cx- 3 month Follow up

Form: Chemotherapy

Generated On: 15 May 2019 14:40:46

Field Name	Data Type	Units	Values	Include Field OID
② CHEMO_TYP E	2		Chemotherap y Type	CHEMO_TYP E
③ CHEMO_ST_ DT	MMM- dd- yyyy			CHEMO_ST_ DT
④ CHEMO_ONG OING	1			CHEMO_ONG OING
⑤ CHEMO_TEN T_END_DT	MMM dd yyyy			CHEMO_TEN T_END_DT
⑥ CHEMO_END _DT	MMM- dd- yyyy			CHEMO_END _DT
⑦ CHEMO_END _DT_UNK	1			CHEMO_END _DT_UNK
⑧ CHEMO_CYC _UNK	4.1			CHEMO_CYC
⑨ CHEMO_CYC _UNK	1			CHEMO_CYC _UNK

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Post Lg Cx- 3 month Follow up

Form: Radiation

Generated On: 15 May 2019 14:40:46

Instructions: Provide all the body sites that were treated with radiotherapy, one site per log line, not previously reported on this form.

Indicate the sequence of radiotherapy relative to surgery check all that apply

Pre-operative	<input type="checkbox"/>	3
Post-operative	<input type="checkbox"/>	4
Definitive	<input type="checkbox"/>	5
Unknown	<input type="checkbox"/>	6

Radiotherapy Site

Chest Primary Tumor Volume	<input type="checkbox"/>	7
Hilar/Mediastinal Lymph Nodes	<input type="checkbox"/>	
Prophylactic Brain	<input type="checkbox"/>	
Therapeutic Brain	<input type="checkbox"/>	
Other, specify	<input type="checkbox"/>	
Unknown	<input type="checkbox"/>	

Radiotherapy Type

IMRT (intensity-modulated radiation therapy)	<input type="checkbox"/>	8
SBRT (Stereotactic body radiation therapy)	<input type="checkbox"/>	
Proton Therapy	<input type="checkbox"/>	
Brachytherapy	<input type="checkbox"/>	
Unknown	<input type="checkbox"/>	
Other, specify	<input type="checkbox"/>	

Start Date

9

Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Post Lg Cx- 3 month Follow up

Form: Radiation

Generated On: 15 May 2019 14:40:46

Check if Ongoing _____

10

End Date _____

11

Total Dose _____

Fixed Unit: cGY

12

Check if the total dose is unknown _____

13

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Post Lg Cx- 3 month Follow up

Form: Radiation

Generated On: 15 May 2019 14:40:46

Field Name	Data Type	Units	Values	Include Field OID
③ PRE_OP_RT	1			PRE_OP_RT
④ POST_OP_RT	1			POST_OP_RT
⑤ DEF_RT	1			DEF_RT
⑥ UNK_RT	1			UNK_RT
⑦ RT_SITE	2		1 = Chest Primary Tumor Volume 2 = Hilar/Mediast inal Lymph Nodes 3 = Prophylactic Brain 4 = Therapeutic Brain 88 = Other, specify 99 = Unknown	RT_SITE
⑧ RT_TYPE	2		1 = IMRT (intensity-mo dulated radiation therapy)	RT_TYPE

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Post Lg Cx- 3 month Follow up

Form: Radiation

Generated On: 15 May 2019 14:40:46

Field Name	Data Type	Units	Values	Include Field OID
			2 = SBRT (Stereotactic body radiation therapy) 3 = Proton Therapy 4 = Brachytherap y 99 = Unknown 88 = Other, specify	
9 RT_ST_DT	MMM- dd- YYYY			RT_ST_DT
10 RT_ONGOIN	1 G			RT_ONGOIN G
11 RT_END_DT	MMM- dd- YYYY			RT_END_DT
12 RT_TOTAL_D	6.2 S			RT_TOTAL_D S
13 RT_TOTAL_D	1 S_UNK			RT_TOTAL_D S_UNK

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Post Lg Cx- 3 month Follow up

Form: Surgery

Generated On: 15 May 2019 14:40:46

Instructions Provide each surgical procedure, the approach, and date, for all surgeries not previously reported on this form

Surgical Procedure

- Lobectomy ②
- Bilobectomy
- Pneumonectomy
- Wedge resection
- Segmentectomy | segmental resection
- Lymphadenectomy | lymph node sampling
- Chest wall resection
- Thoracentesis
- Partial pleurectomy
- Multiple wedge resections
- Multiple segmental resections
- Other surgical procedure (specify)
- Unknown surgical procedure

Approach

- Exploratory thoracotomy without resection ③
- Median Sternotomy
- Thoracotomy
- Thoracoscopy | Video-assisted (VATS)
- Thoracoscopy | Video-assisted (VATS) with conversion to Thoracotomy
- Other surgical approach (specify)
- Unknown surgical approach

Date

④

Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Post Lg Cx- 3 month Follow up

Form: Surgery

Generated On: 15 May 2019 14:40:46

Field Name	Data Type	Units	Values	Include Field OID
② SURG_PROC	2		1 = Lobectomy 2 = Bilobectomy 3 = Pneumonectomy 4 = Wedge resection 5 = Segmentectomy segmental resection 6 = Lymphadenectomy lymph node sampling 7 = Chest wall resection 8 = Thoracentesis 9 = Partial pleurectomy 10 = Multiple wedge resections 11 = Multiple segmental resections 88 = Other surgical procedure (specify) 99 = Unknown surgical procedure	SURG_PROC

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Post Lg Cx- 3 month Follow up

Form: Surgery

Generated On: 15 May 2019 14:40:46

Field Name	Data Type	Units	Values	Include Field OID
③ SURG_APPR OACH	2		1 = Exploratory thoracotomy without resection 2 = Median Sternotomy 3 = Thoracotomy 4 = Thoracoscop y Video-assiste d (VATS) 5 = Thoracoscop y Video-assiste d (VATS) with conversion to Thoracotomy 88 = Other surgical approach (specify) 99 = Unknown surgical approach	SURG_APPR OACH
④ SURGERY_PR OC_DT	dd- yyyy			SURGERY_PR OC_DT

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Post Lg Cx- 3 month Follow up

Form: Other Treatment

Generated On: 15 May 2019 14:40:46

Instructions: Provide all other types of treatment not previously reported on this form. Add a new log line for each unique treatment, or each treatment type that has a unique start date.

Type of Treatment

Immune Therapy ②

Radio Frequency Ablation

Thermal Ablation

Chemical Ablation

Unknown

Other, specify

Description of other treatment

③

Treatment Start Date

④

Treatment End Date

⑤

Check if treatment is ongoing

⑥

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Post Lg Cx- 3 month Follow up

Form: Other Treatment

Generated On: 15 May 2019 14:40:46

Field Name	Data Type	Units	Values	Include Field OID
② OTH_TX_TYP2 E			1 = Immune Therapy 2 = Radio Frequency Ablation 3 = Thermal Ablation 4 = Chemical Ablation 99 = Unknown 88 = Other, specify	OTH_TX_TYP E
③ OTH_TX_DE SCR	\$200			OTH_TX_DE SCR
④ OTH_TX_ST_ DT	MMM- dd- yyyy			OTH_TX_ST_ DT
⑤ OTH_TX_EN D_DT	MMM- dd- yyyy			OTH_TX_EN D_DT
⑥ OTH_TX_ON G				OTH_TX_ON G

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Participant Vital Status

Alive ①
Dead
Unknown

Was the outcome assessment completed for this timepoint?

No ②
Yes

If no, indicate the primary reason not completed

Patient Refused ③
Patient Lost to Follow up
Site error
Other, specify

Date of Assessment

_____ ④

Indicate the person(s) who assessed the patient's status

Site RA

_____ ⑥

Treating Physician

_____ ⑦

Other, specify

_____ ⑧

Indicate the method(s) status was assessed

Medical Records

_____ ⑩

Treating Physician

_____ ⑪

Participant

_____ ⑫

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Other, specify _____ **13**

Did the participant develop progression at primary site, new lesions, growth of existing lesions, metastases, and/or other recurrence not previously reported? **14**
No
Yes
Unknown

Date of first documentation of progressive lung cancer _____ **15**

Indicate the site(s) of progression of lung cancer

Site _____ **17**
Original lung site
Other lung site(s)
Pleura
Brain
Bone
Liver
Adrenal
Skin/subcutaneous tissue
N1 regional lymph nodes (ipsilateral hilar/intrapulmonary)
N2 ipsilateral mediastinal lymph nodes
N3 distant lymph nodes (contralateral mediastinal or hilar/supraclavicular/scalene)
Unknown
Other, specify

Did the participant develop a second primary lung cancer following treatment for an initial primary lung cancer not previously reported? **18**
No
Yes
Unknown

Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Post Lg Cx- 6 month Follow up

Form: Outcomes Assessment

Generated On: 15 May 2019 14:40:46

Date of diagnosis of second primary lung cancer _____

19

Did the participant undergo lung cancer radiation treatment(s) not previously reported?

No

20

Yes

Unknown

Did the participant undergo lung cancer surgical treatment(s) not previously reported?

No

21

Yes

Unknown

Did the participant receive lung cancer chemotherapy not previously reported?

No

22

Yes

Unknown

Did the participant undergo any other lung cancer treatment(s) administered by a physician not previously reported?

No

23

Yes

Unknown

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Post Lg Cx- 6 month Follow up

Form: Outcomes Assessment

Generated On: 15 May 2019 14:40:46

Field Name	Data Type	Units	Values	Include Field OID
① PT_VT_STS	2		1 = Alive 2 = Dead 99 = Unknown	PT_VT_STS
② OUT_ASSD_ YN	2		1 = No 2 = Yes	OUT_ASSD_ YN
③ OUT_ADD_N D_RSN	2		1 = Patient Refused 2 = Patient Lost to Follow up 3 = Site error 88 = Other, specify	OUT_ADD_N D_RSN
④ ASS_DT	MMM dd yyyy			ASS_DT
⑥ SITE_RA_AS SD	1			SITE_RA_AS SD
⑦ TRTING_PHY _ASS	1			TRTING_PHY _ASS
⑧ OTHER_ASS	\$200			OTHER_ASS
⑩ MTHD_ASS_ MED_REC	1			MTHD_ASS_ MED_REC
⑪ MTHD_ASS_ TRTING_PHY	1			MTHD_ASS_ TRTING_PHY

Draft 25 version 1.0 MIGPROD 17JAN2018: All forms
 Folder: Post Lg Cx- 6 month Follow up
 Form: Outcomes Assessment
 Generated On: 15 May 2019 14:40:46

Field Name	Data Type	Units	Values	Include Field OID
12 MTHD_ASS_ 1 PT				MTHD_ASS_ PT
13 MTHD_ASS_ \$200 OTH				MTHD_ASS_ OTH
14 PRG_DX_YN 2			1 = No 2 = Yes 99 = Unknown	PRG_DX_YN
15 PRG_DX_DT MMM dd yyyy				PRG_DX_DT
17 LUNG_CS_PR2 OG_SITE			1 = Original lung site 2 = Other lung site(s) 3 = Pleura 4 = Brain 5 = Bone 6 = Liver 7 = Adrenal 8 = Skin/subcuta neous tissue 9 = N1 regional lymph nodes (ipsilateral hilar/intrapul monary) 10 = N2 ipsilateral mediastinal lymph nodes	LUNG_CS_PR OG_SITE

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms
 Folder: Post Lg Cx- 6 month Follow up
 Form: Outcomes Assessment
 Generated On: 15 May 2019 14:40:46

Field Name	Data Type	Units	Values	Include Field OID
			11 = N3 distant lymph nodes (contralateral mediastinal or hilar/supracla vicular/scale ne) 99 = Unknown 88 = Other, specify	
18 PRIM_2ND_L G_YN			1 = No 2 = Yes 99 = Unknown	PRIM_2ND_L G_YN
19 PRIM_2ND_L G_DT	MMM dd yyyy			PRIM_2ND_L G_DT
20 RT_TX_YN	2		1 = No 2 = Yes 99 = Unknown	RT_TX_YN
21 SURG_TX_Y N	2		1 = No 2 = Yes 99 = Unknown	SURG_TX_Y N
22 CHEMO_TX_ YN	2		1 = No 2 = Yes 99 = Unknown	CHEMO_TX_ YN

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms
Folder: Post Lg Cx- 6 month Follow up
Form: Outcomes Assessment
Generated On: 15 May 2019 14:40:46

Field Name	Data Type	Units	Values	Include Field OID
23 OTH_TX_YN	2		1 = No 2 = Yes 99 = Unknown	OTH_TX_YN

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Post Lg Cx- 6 month Follow up

Form: Chemotherapy

Generated On: 15 May 2019 14:40:46

Instructions: Indicate all the chemotherapeutic agents given, the start and end date, not previously reported on this form

If the exact date is unknown, unknown day should be entered as UN and unknown month as UNK

Chemotherapy Type _____ ②

Start Date _____ ③

Check if Ongoing _____ ④

If ongoing, provide the tentative end date _____ ⑤

Actual End Date _____ ⑥

Check if end date unknown _____ ⑦

Provide the number of cycles given Note If ongoing, provide the planned number of cycles _____ ⑧

Check if the number of cycles is unknown _____ ⑨

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Post Lg Cx- 6 month Follow up

Form: Chemotherapy

Generated On: 15 May 2019 14:40:46

Field Name	Data Type	Units	Values	Include Field OID
② CHEMO_TYP E	2		Chemotherap y Type	CHEMO_TYP E
③ CHEMO_ST_ DT	MMM- dd- yyyy			CHEMO_ST_ DT
④ CHEMO_ONG OING	1			CHEMO_ONG OING
⑤ CHEMO_TEN T_END_DT	MMM dd yyyy			CHEMO_TEN T_END_DT
⑥ CHEMO_END _DT	MMM- dd- yyyy			CHEMO_END _DT
⑦ CHEMO_END _DT_UNK	1			CHEMO_END _DT_UNK
⑧ CHEMO_CYC _UNK	4.1			CHEMO_CYC
⑨ CHEMO_CYC _UNK	1			CHEMO_CYC _UNK

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Post Lg Cx- 6 month Follow up

Form: Radiation

Generated On: 15 May 2019 14:40:46

Instructions: Provide all the body sites that were treated with radiotherapy, one site per log line, not previously reported on this form.

Indicate the sequence of radiotherapy relative to surgery check all that apply

Pre-operative	<input type="checkbox"/>	③
Post-operative	<input type="checkbox"/>	④
Definitive	<input type="checkbox"/>	⑤
Unknown	<input type="checkbox"/>	⑥

Radiotherapy Site	Chest Primary Tumor Volume	<input type="checkbox"/>	⑦
	Hilar/Mediastinal Lymph Nodes	<input type="checkbox"/>	
	Prophylactic Brain	<input type="checkbox"/>	
	Therapeutic Brain	<input type="checkbox"/>	
	Other, specify	<input type="checkbox"/>	
	Unknown	<input type="checkbox"/>	

Radiotherapy Type	IMRT (intensity-modulated radiation therapy)	<input type="checkbox"/>	⑧
	SBRT (Stereotactic body radiation therapy)	<input type="checkbox"/>	
	Proton Therapy	<input type="checkbox"/>	
	Brachytherapy	<input type="checkbox"/>	
	Unknown	<input type="checkbox"/>	
	Other, specify	<input type="checkbox"/>	

Start Date	<input type="text"/>	⑨
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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Post Lg Cx- 6 month Follow up

Form: Radiation

Generated On: 15 May 2019 14:40:46

Check if Ongoing

10

End Date

11

Total Dose

Fixed Unit: cGY

12

Check if the total dose is unknown

13

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Post Lg Cx- 6 month Follow up

Form: Radiation

Generated On: 15 May 2019 14:40:46

Field Name	Data Type	Units	Values	Include Field OID
③ PRE_OP_RT	1			PRE_OP_RT
④ POST_OP_RT	1			POST_OP_RT
⑤ DEF_RT	1			DEF_RT
⑥ UNK_RT	1			UNK_RT
⑦ RT_SITE	2		1 = Chest Primary Tumor Volume 2 = Hilar/Mediast inal Lymph Nodes 3 = Prophylactic Brain 4 = Therapeutic Brain 88 = Other, specify 99 = Unknown	RT_SITE
⑧ RT_TYPE	2		1 = IMRT (intensity-mo dulated radiation therapy)	RT_TYPE

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Post Lg Cx- 6 month Follow up

Form: Radiation

Generated On: 15 May 2019 14:40:46

Field Name	Data Type	Units	Values	Include Field OID
			2 = SBRT (Stereotactic body radiation therapy) 3 = Proton Therapy 4 = Brachytherap y 99 = Unknown 88 = Other, specify	
9 RT_ST_DT	MMM- dd- YYYY			RT_ST_DT
10 RT_ONGOIN	1 G			RT_ONGOIN G
11 RT_END_DT	MMM- dd- YYYY			RT_END_DT
12 RT_TOTAL_D	6.2 S			RT_TOTAL_D S
13 RT_TOTAL_D	1 S_UNK			RT_TOTAL_D S_UNK

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Post Lg Cx- 6 month Follow up

Form: Surgery

Generated On: 15 May 2019 14:40:46

Instructions Provide each surgical procedure, the approach, and date, for all surgeries not previously reported on this form

Surgical Procedure

- Lobectomy ②
- Bilobectomy
- Pneumonectomy
- Wedge resection
- Segmentectomy | segmental resection
- Lymphadenectomy | lymph node sampling
- Chest wall resection
- Thoracentesis
- Partial pleurectomy
- Multiple wedge resections
- Multiple segmental resections
- Other surgical procedure (specify)
- Unknown surgical procedure

Approach

- Exploratory thoracotomy without resection ③
- Median Sternotomy
- Thoracotomy
- Thoracoscopy | Video-assisted (VATS)
- Thoracoscopy | Video-assisted (VATS) with conversion to Thoracotomy
- Other surgical approach (specify)
- Unknown surgical approach

Date

④

Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Post Lg Cx- 6 month Follow up

Form: Surgery

Generated On: 15 May 2019 14:40:46

Field Name	Data Type	Units	Values	Include Field OID
② SURG_PROC 2			1 = Lobectomy 2 = Bilobectomy 3 = Pneumonectomy 4 = Wedge resection 5 = Segmentectomy segmental resection 6 = Lymphadenectomy lymph node sampling 7 = Chest wall resection 8 = Thoracentesis 9 = Partial pleurectomy 10 = Multiple wedge resections 11 = Multiple segmental resections 88 = Other surgical procedure (specify) 99 = Unknown surgical procedure	SURG_PROC

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Post Lg Cx- 6 month Follow up

Form: Surgery

Generated On: 15 May 2019 14:40:46

Field Name	Data Type	Units	Values	Include Field OID
③ SURG_APPR OACH	2		1 = Exploratory thoracotomy without resection 2 = Median Sternotomy 3 = Thoracotomy 4 = Thoracoscop y Video-assiste d (VATS) 5 = Thoracoscop y Video-assiste d (VATS) with conversion to Thoracotomy 88 = Other surgical approach (specify) 99 = Unknown surgical approach	SURG_APPR OACH
④ SURGERY_PR OC_DT	dd- yyyy			SURGERY_PR OC_DT

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Post Lg Cx- 6 month Follow up

Form: Other Treatment

Generated On: 15 May 2019 14:40:46

Instructions: Provide all other types of treatment not previously reported on this form. Add a new log line for each unique treatment, or each treatment type that has a unique start date.

Type of Treatment

Immune Therapy ②

Radio Frequency Ablation

Thermal Ablation

Chemical Ablation

Unknown

Other, specify

Description of other treatment

③

Treatment Start Date

④

Treatment End Date

⑤

Check if treatment is ongoing

⑥

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Post Lg Cx- 6 month Follow up

Form: Other Treatment

Generated On: 15 May 2019 14:40:46

Field Name	Data Type	Units	Values	Include Field OID
② OTH_TX_TYP2 E			1 = Immune Therapy 2 = Radio Frequency Ablation 3 = Thermal Ablation 4 = Chemical Ablation 99 = Unknown 88 = Other, specify	OTH_TX_TYP E
③ OTH_TX_DE SCR	\$200			OTH_TX_DE SCR
④ OTH_TX_ST_ DT	MMM- dd- yyyy			OTH_TX_ST_ DT
⑤ OTH_TX_EN D_DT	MMM- dd- yyyy			OTH_TX_EN D_DT
⑥ OTH_TX_ON G				OTH_TX_ON G

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Participant Vital Status

Alive ①
Dead
Unknown

Was the outcome assessment completed for this timepoint?

No ②
Yes

If no, indicate the primary reason not completed

Patient Refused ③
Patient Lost to Follow up
Site error
Other, specify

Date of Assessment

_____ ④

Indicate the person(s) who assessed the patient's status

Site RA

_____ ⑥

Treating Physician

_____ ⑦

Other, specify

_____ ⑧

Indicate the method(s) status was assessed

Medical Records

_____ ⑩

Treating Physician

_____ ⑪

Participant

_____ ⑫

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Post Lg Cx- 9 month Follow up

Form: Outcomes Assessment

Generated On: 15 May 2019 14:40:46

Other, specify _____

13

Did the participant develop progression at primary site, new lesions, growth of existing lesions, metastases, and/or other recurrence not previously reported?

No 14
Yes
Unknown

Date of first documentation of progressive lung cancer _____

15

Indicate the site(s) of progression of lung cancer

Site

- Original lung site 17
- Other lung site(s)
- Pleura
- Brain
- Bone
- Liver
- Adrenal
- Skin/subcutaneous tissue
- N1 regional lymph nodes (ipsilateral hilar/intrapulmonary)
- N2 ipsilateral mediastinal lymph nodes
- N3 distant lymph nodes (contralateral mediastinal or hilar/supraclavicular/scalene)
- Unknown
- Other, specify

Did the participant develop a second primary lung cancer following treatment for an initial primary lung cancer not previously reported?

No 18
Yes
Unknown

Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Post Lg Cx- 9 month Follow up

Form: Outcomes Assessment

Generated On: 15 May 2019 14:40:46

Date of diagnosis of second primary lung cancer _____

19

Did the participant undergo lung cancer radiation treatment(s) not previously reported?

No

Yes

Unknown

20

Did the participant undergo lung cancer surgical treatment(s) not previously reported?

No

Yes

Unknown

21

Did the participant receive lung cancer chemotherapy not previously reported?

No

Yes

Unknown

22

Did the participant undergo any other lung cancer treatment(s) administered by a physician not previously reported?

No

Yes

Unknown

23

FOR SITE IRB SUBMISSION ONLY
NOT RECOMMENDED FOR SOURCE DOCUMENTATION

Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Post Lg Cx- 9 month Follow up

Form: Outcomes Assessment

Generated On: 15 May 2019 14:40:46

Field Name	Data Type	Units	Values	Include Field OID
① PT_VT_STS	2		1 = Alive 2 = Dead 99 = Unknown	PT_VT_STS
② OUT_ASSD_ YN	2		1 = No 2 = Yes	OUT_ASSD_ YN
③ OUT_ADD_N D_RSN	2		1 = Patient Refused 2 = Patient Lost to Follow up 3 = Site error 88 = Other, specify	OUT_ADD_N D_RSN
④ ASS_DT	MMM dd yyyy			ASS_DT
⑥ SITE_RA_AS SD	1			SITE_RA_AS SD
⑦ TRTING_PHY _ASS	1			TRTING_PHY _ASS
⑧ OTHER_ASS	\$200			OTHER_ASS
⑩ MTHD_ASS_ MED_REC	1			MTHD_ASS_ MED_REC
⑪ MTHD_ASS_ TRTING_PHY	1			MTHD_ASS_ TRTING_PHY

Draft 25 version 1.0 MIGPROD 17JAN2018: All forms
 Folder: Post Lg Cx- 9 month Follow up
 Form: Outcomes Assessment
 Generated On: 15 May 2019 14:40:46

Field Name	Data Type	Units	Values	Include Field OID
12 MTHD_ASS_ 1 PT				MTHD_ASS_ PT
13 MTHD_ASS_ \$200 OTH				MTHD_ASS_ OTH
14 PRG_DX_YN 2			1 = No 2 = Yes 99 = Unknown	PRG_DX_YN
15 PRG_DX_DT MMM dd yyyy				PRG_DX_DT
17 LUNG_CS_PR2 OG_SITE			1 = Original lung site 2 = Other lung site(s) 3 = Pleura 4 = Brain 5 = Bone 6 = Liver 7 = Adrenal 8 = Skin/subcuta neous tissue 9 = N1 regional lymph nodes (ipsilateral hilar/intrapul monary) 10 = N2 ipsilateral mediastinal lymph nodes	LUNG_CS_PR OG_SITE

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Post Lg Cx- 9 month Follow up

Form: Outcomes Assessment

Generated On: 15 May 2019 14:40:46

Field Name	Data Type	Units	Values	Include Field OID
			11 = N3 distant lymph nodes (contralateral mediastinal or hilar/supracla vicular/scale ne) 99 = Unknown 88 = Other, specify	
18 PRIM_2ND_L G_YN			1 = No 2 = Yes 99 = Unknown	PRIM_2ND_L G_YN
19 PRIM_2ND_L G_DT	MMM dd yyyy			PRIM_2ND_L G_DT
20 RT_TX_YN	2		1 = No 2 = Yes 99 = Unknown	RT_TX_YN
21 SURG_TX_Y N	2		1 = No 2 = Yes 99 = Unknown	SURG_TX_Y N
22 CHEMO_TX_ YN	2		1 = No 2 = Yes 99 = Unknown	CHEMO_TX_ YN

Draft 25 version 1.0 MIGPROD 17JAN2018: All forms
Folder: Post Lg Cx- 9 month Follow up
Form: Outcomes Assessment
Generated On: 15 May 2019 14:40:46

Field Name	Data Type	Units	Values	Include Field OID
23 OTH_TX_YN	2		1 = No 2 = Yes 99 = Unknown	OTH_TX_YN

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Post Lg Cx- 9 month Follow up

Form: Chemotherapy

Generated On: 15 May 2019 14:40:46

Instructions: Indicate all the chemotherapeutic agents given, the start and end date, not previously reported on this form

If the exact date is unknown, unknown day should be entered as UN and unknown month as UNK

Chemotherapy Type _____ ②

Start Date _____ ③

Check if Ongoing _____ ④

If ongoing, provide the tentative end date _____ ⑤

Actual End Date _____ ⑥

Check if end date unknown _____ ⑦

Provide the number of cycles given. Note: If ongoing, provide the planned number of cycles _____ ⑧

Check if the number of cycles is unknown _____ ⑨

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Post Lg Cx- 9 month Follow up

Form: Chemotherapy

Generated On: 15 May 2019 14:40:46

Field Name	Data Type	Units	Values	Include Field OID
② CHEMO_TYP E	2		Chemotherap y Type	CHEMO_TYP E
③ CHEMO_ST_ DT	MMM- dd- yyyy			CHEMO_ST_ DT
④ CHEMO_ONG OING	1			CHEMO_ONG OING
⑤ CHEMO_TEN T_END_DT	MMM dd yyyy			CHEMO_TEN T_END_DT
⑥ CHEMO_END _DT	MMM- dd- yyyy			CHEMO_END _DT
⑦ CHEMO_END _DT_UNK	1			CHEMO_END _DT_UNK
⑧ CHEMO_CYC _UNK	4.1			CHEMO_CYC
⑨ CHEMO_CYC _UNK	1			CHEMO_CYC _UNK

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Post Lg Cx- 9 month Follow up

Form: Radiation

Generated On: 15 May 2019 14:40:46

Instructions: Provide all the body sites that were treated with radiotherapy, one site per log line, not previously reported on this form.

Indicate the sequence of radiotherapy relative to surgery check all that apply

Pre-operative	<input type="checkbox"/>	3
Post-operative	<input type="checkbox"/>	4
Definitive	<input type="checkbox"/>	5
Unknown	<input type="checkbox"/>	6

Radiotherapy Site

Chest Primary Tumor Volume	<input type="checkbox"/>	7
Hilar/Mediastinal Lymph Nodes	<input type="checkbox"/>	
Prophylactic Brain	<input type="checkbox"/>	
Therapeutic Brain	<input type="checkbox"/>	
Other, specify	<input type="checkbox"/>	
Unknown	<input type="checkbox"/>	

Radiotherapy Type

IMRT (intensity-modulated radiation therapy)	<input type="checkbox"/>	8
SBRT (Stereotactic body radiation therapy)	<input type="checkbox"/>	
Proton Therapy	<input type="checkbox"/>	
Brachytherapy	<input type="checkbox"/>	
Unknown	<input type="checkbox"/>	
Other, specify	<input type="checkbox"/>	

Start Date

9

Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Post Lg Cx- 9 month Follow up

Form: Radiation

Generated On: 15 May 2019 14:40:46

Check if Ongoing _____

10

End Date _____

11

Total Dose _____

Fixed Unit: cGY

12

Check if the total dose is unknown _____

13

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Post Lg Cx- 9 month Follow up

Form: Radiation

Generated On: 15 May 2019 14:40:46

Field Name	Data Type	Units	Values	Include Field OID
③ PRE_OP_RT	1			PRE_OP_RT
④ POST_OP_RT	1			POST_OP_RT
⑤ DEF_RT	1			DEF_RT
⑥ UNK_RT	1			UNK_RT
⑦ RT_SITE	2		1 = Chest Primary Tumor Volume 2 = Hilar/Mediast inal Lymph Nodes 3 = Prophylactic Brain 4 = Therapeutic Brain 88 = Other, specify 99 = Unknown	RT_SITE
⑧ RT_TYPE	2		1 = IMRT (intensity-mo dulated radiation therapy)	RT_TYPE

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Post Lg Cx- 9 month Follow up

Form: Radiation

Generated On: 15 May 2019 14:40:46

Field Name	Data Type	Units	Values	Include Field OID
			2 = SBRT (Stereotactic body radiation therapy) 3 = Proton Therapy 4 = Brachytherap y 99 = Unknown 88 = Other, specify	
9 RT_ST_DT	MMM- dd- YYYY			RT_ST_DT
10 RT_ONGOIN	1 G			RT_ONGOIN G
11 RT_END_DT	MMM- dd- YYYY			RT_END_DT
12 RT_TOTAL_D	6.2 S			RT_TOTAL_D S
13 RT_TOTAL_D	1 S_UNK			RT_TOTAL_D S_UNK

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Post Lg Cx- 9 month Follow up

Form: Surgery

Generated On: 15 May 2019 14:40:46

Instructions Provide each surgical procedure, the approach, and date, for all surgeries not previously reported on this form

Surgical Procedure

- Lobectomy ②
- Bilobectomy
- Pneumonectomy
- Wedge resection
- Segmentectomy | segmental resection
- Lymphadenectomy | lymph node sampling
- Chest wall resection
- Thoracentesis
- Partial pleurectomy
- Multiple wedge resections
- Multiple segmental resections
- Other surgical procedure (specify)
- Unknown surgical procedure

Approach

- Exploratory thoracotomy without resection ③
- Median Sternotomy
- Thoracotomy
- Thoracoscopy | Video-assisted (VATS)
- Thoracoscopy | Video-assisted (VATS) with conversion to Thoracotomy
- Other surgical approach (specify)
- Unknown surgical approach

Date

④

Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Post Lg Cx- 9 month Follow up

Form: Surgery

Generated On: 15 May 2019 14:40:46

Field Name	Data Type	Units	Values	Include Field OID
② SURG_PROC 2			1 = Lobectomy 2 = Bilobectomy 3 = Pneumonectomy 4 = Wedge resection 5 = Segmentectomy segmental resection 6 = Lymphadenectomy lymph node sampling 7 = Chest wall resection 8 = Thoracentesis 9 = Partial pleurectomy 10 = Multiple wedge resections 11 = Multiple segmental resections 88 = Other surgical procedure (specify) 99 = Unknown surgical procedure	SURG_PROC

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Post Lg Cx- 9 month Follow up

Form: Surgery

Generated On: 15 May 2019 14:40:46

Field Name	Data Type	Units	Values	Include Field OID
③ SURG_APPR OACH	2		1 = Exploratory thoracotomy without resection 2 = Median Sternotomy 3 = Thoracotomy 4 = Thoracoscop y Video-assiste d (VATS) 5 = Thoracoscop y Video-assiste d (VATS) with conversion to Thoracotomy 88 = Other surgical approach (specify) 99 = Unknown surgical approach	SURG_APPR OACH
④ SURGERY_PR OC_DT	dd- yyyy			SURGERY_PR OC_DT

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Post Lg Cx- 9 month Follow up

Form: Other Treatment

Generated On: 15 May 2019 14:40:46

Instructions: Provide all other types of treatment not previously reported on this form. Add a new log line for each unique treatment, or each treatment type that has a unique start date.

Type of Treatment

Immune Therapy ②

Radio Frequency Ablation

Thermal Ablation

Chemical Ablation

Unknown

Other, specify

Description of other treatment

③

Treatment Start Date

④

Treatment End Date

⑤

Check if treatment is ongoing

⑥

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Post Lg Cx- 9 month Follow up

Form: Other Treatment

Generated On: 15 May 2019 14:40:46

Field Name	Data Type	Units	Values	Include Field OID
② OTH_TX_TYP2 E			1 = Immune Therapy 2 = Radio Frequency Ablation 3 = Thermal Ablation 4 = Chemical Ablation 99 = Unknown 88 = Other, specify	OTH_TX_TYP E
③ OTH_TX_DE SCR	\$200			OTH_TX_DE SCR
④ OTH_TX_ST_ DT	MMM- dd- yyyy			OTH_TX_ST_ DT
⑤ OTH_TX_EN D_DT	MMM- dd- yyyy			OTH_TX_EN D_DT
⑥ OTH_TX_ON G				OTH_TX_ON G

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NOT RECOMMENDED FOR SOURCE DOCUMENTATION

Participant Vital Status

Alive ①
Dead
Unknown

Was the outcome assessment completed for this timepoint?

No ②
Yes

If no, indicate the primary reason not completed

Patient Refused ③
Patient Lost to Follow up
Site error
Other, specify

Date of Assessment

_____ ④

Indicate the person(s) who assessed the patient's status

Site RA

_____ ⑥

Treating Physician

_____ ⑦

Other, specify

_____ ⑧

Indicate the method(s) status was assessed

Medical Records

_____ ⑩

Treating Physician

_____ ⑪

Participant

_____ ⑫

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Post Lg Cx- 12 month Follow up

Form: Outcomes Assessment

Generated On: 15 May 2019 14:40:46

Other, specify _____

13

Did the participant develop progression at primary site, new lesions, growth of existing lesions, metastases, and/or other recurrence not previously reported?

No 14
Yes
Unknown

Date of first documentation of progressive lung cancer _____

15

Indicate the site(s) of progression of lung cancer

Site

- Original lung site 17
- Other lung site(s)
- Pleura
- Brain
- Bone
- Liver
- Adrenal
- Skin/subcutaneous tissue
- N1 regional lymph nodes (ipsilateral hilar/intrapulmonary)
- N2 ipsilateral mediastinal lymph nodes
- N3 distant lymph nodes (contralateral mediastinal or hilar/supraclavicular/scalene)
- Unknown
- Other, specify

Did the participant develop a second primary lung cancer following treatment for an initial primary lung cancer not previously reported?

No 18
Yes
Unknown

Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Post Lg Cx- 12 month Follow up

Form: Outcomes Assessment

Generated On: 15 May 2019 14:40:46

Date of diagnosis of second primary lung cancer _____

19

Did the participant undergo lung cancer radiation treatment(s) not previously reported?

No

Yes

Unknown

20

Did the participant undergo lung cancer surgical treatment(s) not previously reported?

No

Yes

Unknown

21

Did the participant receive lung cancer chemotherapy not previously reported?

No

Yes

Unknown

22

Did the participant undergo any other lung cancer treatment(s) administered by a physician not previously reported?

No

Yes

Unknown

23

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Post Lg Cx- 12 month Follow up

Form: Outcomes Assessment

Generated On: 15 May 2019 14:40:46

Field Name	Data Type	Units	Values	Include Field OID
① PT_VT_STS	2		1 = Alive 2 = Dead 99 = Unknown	PT_VT_STS
② OUT_ASSD_ YN	2		1 = No 2 = Yes	OUT_ASSD_ YN
③ OUT_ADD_N D_RSN	2		1 = Patient Refused 2 = Patient Lost to Follow up 3 = Site error 88 = Other, specify	OUT_ADD_N D_RSN
④ ASS_DT	MMM dd yyyy			ASS_DT
⑥ SITE_RA_AS SD	1			SITE_RA_AS SD
⑦ TRTING_PHY _ASS	1			TRTING_PHY _ASS
⑧ OTHER_ASS	\$200			OTHER_ASS
⑩ MTHD_ASS_ MED_REC	1			MTHD_ASS_ MED_REC
⑪ MTHD_ASS_ TRTING_PHY	1			MTHD_ASS_ TRTING_PHY

Draft 25 version 1.0 MIGPROD 17JAN2018: All forms
Folder: Post Lg Cx- 12 month Follow up
Form: Outcomes Assessment
Generated On: 15 May 2019 14:40:46

Field Name	Data Type	Units	Values	Include Field OID
12 MTHD_ASS_ 1 PT				MTHD_ASS_ PT
13 MTHD_ASS_ \$200 OTH				MTHD_ASS_ OTH
14 PRG_DX_YN 2			1 = No 2 = Yes 99 = Unknown	PRG_DX_YN
15 PRG_DX_DT MMM dd yyyy				PRG_DX_DT
17 LUNG_CS_PR2 OG_SITE			1 = Original lung site 2 = Other lung site(s) 3 = Pleura 4 = Brain 5 = Bone 6 = Liver 7 = Adrenal 8 = Skin/subcuta neous tissue 9 = N1 regional lymph nodes (ipsilateral hilar/intrapul monary) 10 = N2 ipsilateral mediastinal lymph nodes	LUNG_CS_PR OG_SITE

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Post Lg Cx- 12 month Follow up

Form: Outcomes Assessment

Generated On: 15 May 2019 14:40:46

Field Name	Data Type	Units	Values	Include Field OID
			11 = N3 distant lymph nodes (contralateral mediastinal or hilar/supracla vicular/scala ne) 99 = Unknown 88 = Other, specify	
18 PRIM_2ND_L G_YN			1 = No 2 = Yes 99 = Unknown	PRIM_2ND_L G_YN
19 PRIM_2ND_L G_DT	MMM dd yyyy			PRIM_2ND_L G_DT
20 RT_TX_YN	2		1 = No 2 = Yes 99 = Unknown	RT_TX_YN
21 SURG_TX_Y N	2		1 = No 2 = Yes 99 = Unknown	SURG_TX_Y N
22 CHEMO_TX_ YN	2		1 = No 2 = Yes 99 = Unknown	CHEMO_TX_ YN

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Post Lg Cx- 12 month Follow up

Form: Outcomes Assessment

Generated On: 15 May 2019 14:40:46

Field Name	Data Type	Units	Values	Include Field OID
23 OTH_TX_YN	2		1 = No 2 = Yes 99 = Unknown	OTH_TX_YN

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Post Lg Cx- 12 month Follow up

Form: Chemotherapy

Generated On: 15 May 2019 14:40:46

Instructions: Indicate all the chemotherapeutic agents given, the start and end date, not previously reported on this form

If the exact date is unknown, unknown day should be entered as UN and unknown month as UNK

Chemotherapy Type _____ ②

Start Date _____ ③

Check if Ongoing _____ ④

If ongoing, provide the tentative end date _____ ⑤

Actual End Date _____ ⑥

Check if end date unknown _____ ⑦

Provide the number of cycles given. Note: If ongoing, provide the planned number of cycles _____ ⑧

Check if the number of cycles is unknown _____ ⑨

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Post Lg Cx- 12 month Follow up

Form: Chemotherapy

Generated On: 15 May 2019 14:40:46

Field Name	Data Type	Units	Values	Include Field OID
② CHEMO_TYP E	2		Chemotherap y Type	CHEMO_TYP E
③ CHEMO_ST_ DT	MMM- dd- yyyy			CHEMO_ST_ DT
④ CHEMO_ONG OING	1			CHEMO_ONG OING
⑤ CHEMO_TEN T_END_DT	MMM dd yyyy			CHEMO_TEN T_END_DT
⑥ CHEMO_END _DT	MMM- dd- yyyy			CHEMO_END _DT
⑦ CHEMO_END _DT_UNK	1			CHEMO_END _DT_UNK
⑧ CHEMO_CYC _UNK	4.1			CHEMO_CYC
⑨ CHEMO_CYC _UNK	1			CHEMO_CYC _UNK

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Post Lg Cx- 12 month Follow up

Form: Radiation

Generated On: 15 May 2019 14:40:46

Instructions: Provide all the body sites that were treated with radiotherapy, one site per log line, not previously reported on this form.

Indicate the sequence of radiotherapy relative to surgery check all that apply

Pre-operative	_____	3
Post-operative	_____	4
Definitive	_____	5
Unknown	_____	6

Radiotherapy Site

Chest Primary Tumor Volume	<input type="checkbox"/>	7
Hilar/Mediastinal Lymph Nodes	<input type="checkbox"/>	
Prophylactic Brain	<input type="checkbox"/>	
Therapeutic Brain	<input type="checkbox"/>	
Other, specify	<input type="checkbox"/>	
Unknown	<input type="checkbox"/>	

Radiotherapy Type

IMRT (intensity-modulated radiation therapy)	<input type="checkbox"/>	8
SBRT (Stereotactic body radiation therapy)	<input type="checkbox"/>	
Proton Therapy	<input type="checkbox"/>	
Brachytherapy	<input type="checkbox"/>	
Unknown	<input type="checkbox"/>	
Other, specify	<input type="checkbox"/>	

Start Date

_____ **9**

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Post Lg Cx- 12 month Follow up

Form: Radiation

Generated On: 15 May 2019 14:40:46

Check if Ongoing _____

10

End Date _____

11

Total Dose _____

Fixed Unit: cGY

12

Check if the total dose is unknown _____

13

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Post Lg Cx- 12 month Follow up

Form: Radiation

Generated On: 15 May 2019 14:40:46

Field Name	Data Type	Units	Values	Include Field OID
③ PRE_OP_RT	1			PRE_OP_RT
④ POST_OP_RT	1			POST_OP_RT
⑤ DEF_RT	1			DEF_RT
⑥ UNK_RT	1			UNK_RT
⑦ RT_SITE	2		1 = Chest Primary Tumor Volume 2 = Hilar/Mediast inal Lymph Nodes 3 = Prophylactic Brain 4 = Therapeutic Brain 88 = Other, specify 99 = Unknown	RT_SITE
⑧ RT_TYPE	2		1 = IMRT (intensity-mo dulated radiation therapy)	RT_TYPE

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Post Lg Cx- 12 month Follow up

Form: Radiation

Generated On: 15 May 2019 14:40:46

Field Name	Data Type	Units	Values	Include Field OID
			2 = SBRT (Stereotactic body radiation therapy) 3 = Proton Therapy 4 = Brachytherap y 99 = Unknown 88 = Other, specify	
9 RT_ST_DT	MMM- dd- YYYY			RT_ST_DT
10 RT_ONGOIN	1 G			RT_ONGOIN G
11 RT_END_DT	MMM- dd- YYYY			RT_END_DT
12 RT_TOTAL_D	6.2 S			RT_TOTAL_D S
13 RT_TOTAL_D	1 S_UNK			RT_TOTAL_D S_UNK

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Post Lg Cx- 12 month Follow up

Form: Surgery

Generated On: 15 May 2019 14:40:46

Instructions Provide each surgical procedure, the approach, and date, for all surgeries not previously reported on this form

Surgical Procedure

- Lobectomy ②
- Bilobectomy
- Pneumonectomy
- Wedge resection
- Segmentectomy | segmental resection
- Lymphadenectomy | lymph node sampling
- Chest wall resection
- Thoracentesis
- Partial pleurectomy
- Multiple wedge resections
- Multiple segmental resections
- Other surgical procedure (specify)
- Unknown surgical procedure

Approach

- Exploratory thoracotomy without resection ③
- Median Sternotomy
- Thoracotomy
- Thoracoscopy | Video-assisted (VATS)
- Thoracoscopy | Video-assisted (VATS) with conversion to Thoracotomy
- Other surgical approach (specify)
- Unknown surgical approach

Date

④

Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Post Lg Cx- 12 month Follow up

Form: Surgery

Generated On: 15 May 2019 14:40:46

Field Name	Data Type	Units	Values	Include Field OID
② SURG_PROC 2			1 = Lobectomy 2 = Bilobectomy 3 = Pneumonectomy 4 = Wedge resection 5 = Segmentectomy segmental resection 6 = Lymphadenectomy lymph node sampling 7 = Chest wall resection 8 = Thoracentesis 9 = Partial pleurectomy 10 = Multiple wedge resections 11 = Multiple segmental resections 88 = Other surgical procedure (specify) 99 = Unknown surgical procedure	SURG_PROC

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Post Lg Cx- 12 month Follow up

Form: Surgery

Generated On: 15 May 2019 14:40:46

Field Name	Data Type	Units	Values	Include Field OID
③ SURG_APPR OACH	2		1 = Exploratory thoracotomy without resection 2 = Median Sternotomy 3 = Thoracotomy 4 = Thoracoscop y Video-assiste d (VATS) 5 = Thoracoscop y Video-assiste d (VATS) with conversion to Thoracotomy 88 = Other surgical approach (specify) 99 = Unknown surgical approach	SURG_APPR OACH
④ SURGERY_PR OC_DT	dd- yyyy			SURGERY_PR OC_DT

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NOT RECOMMENDED FOR SOURCE DOCUMENTATION

Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Post Lg Cx- 12 month Follow up

Form: Other Treatment

Generated On: 15 May 2019 14:40:46

Instructions: Provide all other types of treatment not previously reported on this form. Add a new log line for each unique treatment, or each treatment type that has a unique start date.

Type of Treatment

- Immune Therapy ②
- Radio Frequency Ablation
- Thermal Ablation
- Chemical Ablation
- Unknown
- Other, specify

Description of other treatment

③

Treatment Start Date

④

Treatment End Date

⑤

Check if treatment is ongoing

⑥

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Post Lg Cx- 12 month Follow up

Form: Other Treatment

Generated On: 15 May 2019 14:40:46

Field Name	Data Type	Units	Values	Include Field OID
② OTH_TX_TYP2 E			1 = Immune Therapy 2 = Radio Frequency Ablation 3 = Thermal Ablation 4 = Chemical Ablation 99 = Unknown 88 = Other, specify	OTH_TX_TYP E
③ OTH_TX_DE SCR	\$200			OTH_TX_DE SCR
④ OTH_TX_ST_ DT	MMM- dd- yyyy			OTH_TX_ST_ DT
⑤ OTH_TX_EN D_DT	MMM- dd- yyyy			OTH_TX_EN D_DT
⑥ OTH_TX_ON G				OTH_TX_ON G

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Participant Vital Status

Alive ①
Dead
Unknown

Was the outcome assessment completed for this timepoint?

No ②
Yes

If no, indicate the primary reason not completed

Patient Refused ③
Patient Lost to Follow up
Site error
Other, specify

Date of Assessment

_____ ④

Indicate the person(s) who assessed the patient's status

Site RA

_____ ⑥

Treating Physician

_____ ⑦

Other, specify

_____ ⑧

Indicate the method(s) status was assessed

Medical Records

_____ ⑩

Treating Physician

_____ ⑪

Participant

_____ ⑫

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Post Lg Cx- 15 month Follow up

Form: Outcomes Assessment

Generated On: 15 May 2019 14:40:46

Other, specify _____

13

Did the participant develop progression at primary site, new lesions, growth of existing lesions, metastases, and/or other recurrence not previously reported?

No 14
Yes
Unknown

Date of first documentation of progressive lung cancer _____

15

Indicate the site(s) of progression of lung cancer

Site

- Original lung site 17
- Other lung site(s)
- Pleura
- Brain
- Bone
- Liver
- Adrenal
- Skin/subcutaneous tissue
- N1 regional lymph nodes (ipsilateral hilar/intrapulmonary)
- N2 ipsilateral mediastinal lymph nodes
- N3 distant lymph nodes (contralateral mediastinal or hilar/supraclavicular/scalene)
- Unknown
- Other, specify

Did the participant develop a second primary lung cancer following treatment for an initial primary lung cancer not previously reported?

No 18
Yes
Unknown

Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Post Lg Cx- 15 month Follow up

Form: Outcomes Assessment

Generated On: 15 May 2019 14:40:46

Date of diagnosis of second primary lung cancer _____

19

Did the participant undergo lung cancer radiation treatment(s) not previously reported?

No

20

Yes

Unknown

Did the participant undergo lung cancer surgical treatment(s) not previously reported?

No

21

Yes

Unknown

Did the participant receive lung cancer chemotherapy not previously reported?

No

22

Yes

Unknown

Did the participant undergo any other lung cancer treatment(s) administered by a physician not previously reported?

No

23

Yes

Unknown

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Post Lg Cx- 15 month Follow up

Form: Outcomes Assessment

Generated On: 15 May 2019 14:40:46

Field Name	Data Type	Units	Values	Include Field OID
① PT_VT_STS	2		1 = Alive 2 = Dead 99 = Unknown	PT_VT_STS
② OUT_ASSD_ YN	2		1 = No 2 = Yes	OUT_ASSD_ YN
③ OUT_ADD_N D_RSN	2		1 = Patient Refused 2 = Patient Lost to Follow up 3 = Site error 88 = Other, specify	OUT_ADD_N D_RSN
④ ASS_DT	MMM dd yyyy			ASS_DT
⑥ SITE_RA_AS SD	1			SITE_RA_AS SD
⑦ TRTING_PHY _ASS	1			TRTING_PHY _ASS
⑧ OTHER_ASS	\$200			OTHER_ASS
⑩ MTHD_ASS_ MED_REC	1			MTHD_ASS_ MED_REC
⑪ MTHD_ASS_ TRTING_PHY	1			MTHD_ASS_ TRTING_PHY

Draft 25 version 1.0 MIGPROD 17JAN2018: All forms
Folder: Post Lg Cx- 15 month Follow up
Form: Outcomes Assessment
Generated On: 15 May 2019 14:40:46

Field Name	Data Type	Units	Values	Include Field OID
12 MTHD_ASS_ 1 PT				MTHD_ASS_ PT
13 MTHD_ASS_ \$200 OTH				MTHD_ASS_ OTH
14 PRG_DX_YN 2			1 = No 2 = Yes 99 = Unknown	PRG_DX_YN
15 PRG_DX_DT MMM dd yyyy				PRG_DX_DT
17 LUNG_CS_PR2 OG_SITE			1 = Original lung site 2 = Other lung site(s) 3 = Pleura 4 = Brain 5 = Bone 6 = Liver 7 = Adrenal 8 = Skin/subcuta neous tissue 9 = N1 regional lymph nodes (ipsilateral hilar/intrapul monary) 10 = N2 ipsilateral mediastinal lymph nodes	LUNG_CS_PR OG_SITE

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Post Lg Cx- 15 month Follow up

Form: Outcomes Assessment

Generated On: 15 May 2019 14:40:46

Field Name	Data Type	Units	Values	Include Field OID
			11 = N3 distant lymph nodes (contralateral mediastinal or hilar/supracla vicular/scale ne) 99 = Unknown 88 = Other, specify	
18 PRIM_2ND_L G_YN			1 = No 2 = Yes 99 = Unknown	PRIM_2ND_L G_YN
19 PRIM_2ND_L G_DT	MMM dd yyyy			PRIM_2ND_L G_DT
20 RT_TX_YN	2		1 = No 2 = Yes 99 = Unknown	RT_TX_YN
21 SURG_TX_Y N	2		1 = No 2 = Yes 99 = Unknown	SURG_TX_Y N
22 CHEMO_TX_ YN	2		1 = No 2 = Yes 99 = Unknown	CHEMO_TX_ YN

Draft 25 version 1.0 MIGPROD 17JAN2018: All forms
Folder: Post Lg Cx- 15 month Follow up
Form: Outcomes Assessment
Generated On: 15 May 2019 14:40:46

Field Name	Data Type	Units	Values	Include Field OID
23 OTH_TX_YN	2		1 = No 2 = Yes 99 = Unknown	OTH_TX_YN

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Post Lg Cx- 15 month Follow up

Form: Chemotherapy

Generated On: 15 May 2019 14:40:46

Instructions: Indicate all the chemotherapeutic agents given, the start and end date, not previously reported on this form

If the exact date is unknown, unknown day should be entered as UN and unknown month as UNK

Chemotherapy Type _____ ②

Start Date _____ ③

Check if Ongoing _____ ④

If ongoing, provide the tentative end date _____ ⑤

Actual End Date _____ ⑥

Check if end date unknown _____ ⑦

Provide the number of cycles given. Note: If ongoing, provide the planned number of cycles _____ ⑧

Check if the number of cycles is unknown _____ ⑨

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Post Lg Cx- 15 month Follow up

Form: Chemotherapy

Generated On: 15 May 2019 14:40:46

Field Name	Data Type	Units	Values	Include Field OID
② CHEMO_TYP E	2		Chemotherap y Type	CHEMO_TYP E
③ CHEMO_ST_ DT	MMM- dd- yyyy			CHEMO_ST_ DT
④ CHEMO_ONG OING	1			CHEMO_ONG OING
⑤ CHEMO_TEN T_END_DT	MMM dd yyyy			CHEMO_TEN T_END_DT
⑥ CHEMO_END _DT	MMM- dd- yyyy			CHEMO_END _DT
⑦ CHEMO_END _DT_UNK	1			CHEMO_END _DT_UNK
⑧ CHEMO_CYC	4.1			CHEMO_CYC
⑨ CHEMO_CYC _UNK	1			CHEMO_CYC _UNK

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Post Lg Cx- 15 month Follow up

Form: Radiation

Generated On: 15 May 2019 14:40:46

Instructions: Provide all the body sites that were treated with radiotherapy, one site per log line, not previously reported on this form.

Indicate the sequence of radiotherapy relative to surgery check all that apply

Pre-operative	<input type="checkbox"/>	③
Post-operative	<input type="checkbox"/>	④
Definitive	<input type="checkbox"/>	⑤
Unknown	<input type="checkbox"/>	⑥

Radiotherapy Site

Chest Primary Tumor Volume	<input type="checkbox"/>	⑦
Hilar/Mediastinal Lymph Nodes	<input type="checkbox"/>	
Prophylactic Brain	<input type="checkbox"/>	
Therapeutic Brain	<input type="checkbox"/>	
Other, specify	<input type="checkbox"/>	
Unknown	<input type="checkbox"/>	

Radiotherapy Type

IMRT (intensity-modulated radiation therapy)	<input type="checkbox"/>	⑧
SBRT (Stereotactic body radiation therapy)	<input type="checkbox"/>	
Proton Therapy	<input type="checkbox"/>	
Brachytherapy	<input type="checkbox"/>	
Unknown	<input type="checkbox"/>	
Other, specify	<input type="checkbox"/>	

Start Date

<input type="text"/>	⑨
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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms
Folder: Post Lg Cx- 15 month Follow up
Form: Radiation
Generated On: 15 May 2019 14:40:46

Check if Ongoing _____

10

End Date _____

11

Total Dose _____

Fixed Unit: cGY

12

Check if the total dose is unknown _____

13

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Post Lg Cx- 15 month Follow up

Form: Radiation

Generated On: 15 May 2019 14:40:46

Field Name	Data Type	Units	Values	Include Field OID
③ PRE_OP_RT	1			PRE_OP_RT
④ POST_OP_RT	1			POST_OP_RT
⑤ DEF_RT	1			DEF_RT
⑥ UNK_RT	1			UNK_RT
⑦ RT_SITE	2		1 = Chest Primary Tumor Volume 2 = Hilar/Mediast inal Lymph Nodes 3 = Prophylactic Brain 4 = Therapeutic Brain 88 = Other, specify 99 = Unknown	RT_SITE
⑧ RT_TYPE	2		1 = IMRT (intensity-mo dulated radiation therapy)	RT_TYPE

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Post Lg Cx- 15 month Follow up

Form: Radiation

Generated On: 15 May 2019 14:40:46

Field Name	Data Type	Units	Values	Include Field OID
			2 = SBRT (Stereotactic body radiation therapy) 3 = Proton Therapy 4 = Brachytherap y 99 = Unknown 88 = Other, specify	
9 RT_ST_DT	MMM- dd- YYYY			RT_ST_DT
10 RT_ONGOIN	1 G			RT_ONGOIN G
11 RT_END_DT	MMM- dd- YYYY			RT_END_DT
12 RT_TOTAL_D	6.2 S			RT_TOTAL_D S
13 RT_TOTAL_D	1 S_UNK			RT_TOTAL_D S_UNK

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Post Lg Cx- 15 month Follow up

Form: Surgery

Generated On: 15 May 2019 14:40:46

Instructions Provide each surgical procedure, the approach, and date, for all surgeries not previously reported on this form

Surgical Procedure

- Lobectomy ②
- Bilobectomy
- Pneumonectomy
- Wedge resection
- Segmentectomy | segmental resection
- Lymphadenectomy | lymph node sampling
- Chest wall resection
- Thoracentesis
- Partial pleurectomy
- Multiple wedge resections
- Multiple segmental resections
- Other surgical procedure (specify)
- Unknown surgical procedure

Approach

- Exploratory thoracotomy without resection ③
- Median Sternotomy
- Thoracotomy
- Thoracoscopy | Video-assisted (VATS)
- Thoracoscopy | Video-assisted (VATS) with conversion to Thoracotomy
- Other surgical approach (specify)
- Unknown surgical approach

Date

④

Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Post Lg Cx- 15 month Follow up

Form: Surgery

Generated On: 15 May 2019 14:40:46

Field Name	Data Type	Units	Values	Include Field OID
② SURG_PROC	2		1 = Lobectomy 2 = Bilobectomy 3 = Pneumonectomy 4 = Wedge resection 5 = Segmentectomy segmental resection 6 = Lymphadenectomy lymph node sampling 7 = Chest wall resection 8 = Thoracentesis 9 = Partial pleurectomy 10 = Multiple wedge resections 11 = Multiple segmental resections 88 = Other surgical procedure (specify) 99 = Unknown surgical procedure	SURG_PROC

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Post Lg Cx- 15 month Follow up

Form: Surgery

Generated On: 15 May 2019 14:40:46

Field Name	Data Type	Units	Values	Include Field OID
③ SURG_APPR OACH	2		1 = Exploratory thoracotomy without resection 2 = Median Sternotomy 3 = Thoracotomy 4 = Thoracoscopy Video-assisted (VATS) 5 = Thoracoscopy Video-assisted (VATS) with conversion to Thoracotomy 88 = Other surgical approach (specify) 99 = Unknown surgical approach	SURG_APPR OACH
④ SURGERY_PR OC_DT	dd- yyyy			SURGERY_PR OC_DT

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Post Lg Cx- 15 month Follow up

Form: Other Treatment

Generated On: 15 May 2019 14:40:46

Instructions: Provide all other types of treatment not previously reported on this form. Add a new log line for each unique treatment, or each treatment type that has a unique start date.

Type of Treatment

Immune Therapy ②

Radio Frequency Ablation

Thermal Ablation

Chemical Ablation

Unknown

Other, specify

Description of other treatment

③

Treatment Start Date

④

Treatment End Date

⑤

Check if treatment is ongoing

⑥

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Post Lg Cx- 15 month Follow up

Form: Other Treatment

Generated On: 15 May 2019 14:40:46

Field Name	Data Type	Units	Values	Include Field OID
② OTH_TX_TYP2 E			1 = Immune Therapy 2 = Radio Frequency Ablation 3 = Thermal Ablation 4 = Chemical Ablation 99 = Unknown 88 = Other, specify	OTH_TX_TYP E
③ OTH_TX_DE SCR	\$200			OTH_TX_DE SCR
④ OTH_TX_ST_ DT	MMM- dd- yyyy			OTH_TX_ST_ DT
⑤ OTH_TX_EN D_DT	MMM- dd- yyyy			OTH_TX_EN D_DT
⑥ OTH_TX_ON G				OTH_TX_ON G

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Participant Vital Status

Alive ①
Dead
Unknown

Was the outcome assessment completed for this timepoint?

No ②
Yes

If no, indicate the primary reason not completed

Patient Refused ③
Patient Lost to Follow up
Site error
Other, specify

Date of Assessment

_____ ④

Indicate the person(s) who assessed the patient's status

Site RA

_____ ⑥

Treating Physician

_____ ⑦

Other, specify

_____ ⑧

Indicate the method(s) status was assessed

Medical Records

_____ ⑩

Treating Physician

_____ ⑪

Participant

_____ ⑫

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Other, specify _____

13

Did the participant develop progression at primary site, new lesions, growth of existing lesions, metastases, and/or other recurrence not previously reported?

No
Yes
Unknown

14

Date of first documentation of progressive lung cancer _____

15

Indicate the site(s) of progression of lung cancer

Site

- Original lung site
- Other lung site(s)
- Pleura
- Brain
- Bone
- Liver
- Adrenal
- Skin/subcutaneous tissue
- N1 regional lymph nodes (ipsilateral hilar/intrapulmonary)
- N2 ipsilateral mediastinal lymph nodes
- N3 distant lymph nodes (contralateral mediastinal or hilar/supraclavicular/scalene)
- Unknown
- Other, specify

17

Did the participant develop a second primary lung cancer following treatment for an initial primary lung cancer not previously reported?

No
Yes
Unknown

18

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Post Lg Cx- 18 month Follow up

Form: Outcomes Assessment

Generated On: 15 May 2019 14:40:46

Date of diagnosis of second primary lung cancer _____

19

Did the participant undergo lung cancer radiation treatment(s) not previously reported?

No

Yes

Unknown

20

Did the participant undergo lung cancer surgical treatment(s) not previously reported?

No

Yes

Unknown

21

Did the participant receive lung cancer chemotherapy not previously reported?

No

Yes

Unknown

22

Did the participant undergo any other lung cancer treatment(s) administered by a physician not previously reported?

No

Yes

Unknown

23

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Post Lg Cx- 18 month Follow up

Form: Outcomes Assessment

Generated On: 15 May 2019 14:40:46

Field Name	Data Type	Units	Values	Include Field OID
① PT_VT_STS	2		1 = Alive 2 = Dead 99 = Unknown	PT_VT_STS
② OUT_ASSD_ YN	2		1 = No 2 = Yes	OUT_ASSD_ YN
③ OUT_ADD_N D_RSN	2		1 = Patient Refused 2 = Patient Lost to Follow up 3 = Site error 88 = Other, specify	OUT_ADD_N D_RSN
④ ASS_DT	MMM dd yyyy			ASS_DT
⑥ SITE_RA_AS SD	1			SITE_RA_AS SD
⑦ TRTING_PHY _ASS	1			TRTING_PHY _ASS
⑧ OTHER_ASS	\$200			OTHER_ASS
⑩ MTHD_ASS_ MED_REC	1			MTHD_ASS_ MED_REC
⑪ MTHD_ASS_ TRTING_PHY	1			MTHD_ASS_ TRTING_PHY

Draft 25 version 1.0 MIGPROD 17JAN2018: All forms
 Folder: Post Lg Cx- 18 month Follow up
 Form: Outcomes Assessment
 Generated On: 15 May 2019 14:40:46

Field Name	Data Type	Units	Values	Include Field OID
12 MTHD_ASS_ 1 PT				MTHD_ASS_ PT
13 MTHD_ASS_ \$200 OTH				MTHD_ASS_ OTH
14 PRG_DX_YN 2			1 = No 2 = Yes 99 = Unknown	PRG_DX_YN
15 PRG_DX_DT MMM dd yyyy				PRG_DX_DT
17 LUNG_CS_PR2 OG_SITE			1 = Original lung site 2 = Other lung site(s) 3 = Pleura 4 = Brain 5 = Bone 6 = Liver 7 = Adrenal 8 = Skin/subcuta neous tissue 9 = N1 regional lymph nodes (ipsilateral hilar/intrapul monary) 10 = N2 ipsilateral mediastinal lymph nodes	LUNG_CS_PR OG_SITE

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Post Lg Cx- 18 month Follow up

Form: Outcomes Assessment

Generated On: 15 May 2019 14:40:46

Field Name	Data Type	Units	Values	Include Field OID
			11 = N3 distant lymph nodes (contralateral mediastinal or hilar/supracla vicular/scale ne) 99 = Unknown 88 = Other, specify	
18 PRIM_2ND_L G_YN			1 = No 2 = Yes 99 = Unknown	PRIM_2ND_L G_YN
19 PRIM_2ND_L G_DT	MMM dd yyyy			PRIM_2ND_L G_DT
20 RT_TX_YN	2		1 = No 2 = Yes 99 = Unknown	RT_TX_YN
21 SURG_TX_Y N	2		1 = No 2 = Yes 99 = Unknown	SURG_TX_Y N
22 CHEMO_TX_ YN	2		1 = No 2 = Yes 99 = Unknown	CHEMO_TX_ YN

Draft 25 version 1.0 MIGPROD 17JAN2018: All forms
Folder: Post Lg Cx- 18 month Follow up
Form: Outcomes Assessment
Generated On: 15 May 2019 14:40:46

Field Name	Data Type	Units	Values	Include Field OID
23 OTH_TX_YN	2		1 = No 2 = Yes 99 = Unknown	OTH_TX_YN

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Post Lg Cx- 18 month Follow up

Form: Chemotherapy

Generated On: 15 May 2019 14:40:46

Instructions: Indicate all the chemotherapeutic agents given, the start and end date, not previously reported on this form

If the exact date is unknown, unknown day should be entered as UN and unknown month as UNK

Chemotherapy Type _____ ②

Start Date _____ ③

Check if Ongoing _____ ④

If ongoing, provide the tentative end date _____ ⑤

Actual End Date _____ ⑥

Check if end date unknown _____ ⑦

Provide the number of cycles given Note If ongoing, provide the planned number of cycles _____ ⑧

Check if the number of cycles is unknown _____ ⑨

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Post Lg Cx- 18 month Follow up

Form: Chemotherapy

Generated On: 15 May 2019 14:40:46

Field Name	Data Type	Units	Values	Include Field OID
② CHEMO_TYP E	2		Chemotherap y Type	CHEMO_TYP E
③ CHEMO_ST_ DT	MMM- dd- yyyy			CHEMO_ST_ DT
④ CHEMO_ONG OING	1			CHEMO_ONG OING
⑤ CHEMO_TEN T_END_DT	MMM dd yyyy			CHEMO_TEN T_END_DT
⑥ CHEMO_END _DT	MMM- dd- yyyy			CHEMO_END _DT
⑦ CHEMO_END _DT_UNK	1			CHEMO_END _DT_UNK
⑧ CHEMO_CYC	4.1			CHEMO_CYC
⑨ CHEMO_CYC _UNK	1			CHEMO_CYC _UNK

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Post Lg Cx- 18 month Follow up

Form: Radiation

Generated On: 15 May 2019 14:40:46

Instructions: Provide all the body sites that were treated with radiotherapy, one site per log line, not previously reported on this form.

Indicate the sequence of radiotherapy relative to surgery check all that apply

Pre-operative	<input type="checkbox"/>	③
Post-operative	<input type="checkbox"/>	④
Definitive	<input type="checkbox"/>	⑤
Unknown	<input type="checkbox"/>	⑥

Radiotherapy Site	Chest Primary Tumor Volume	<input type="checkbox"/>	⑦
	Hilar/Mediastinal Lymph Nodes	<input type="checkbox"/>	
	Prophylactic Brain	<input type="checkbox"/>	
	Therapeutic Brain	<input type="checkbox"/>	
	Other, specify	<input type="checkbox"/>	
	Unknown	<input type="checkbox"/>	

Radiotherapy Type	IMRT (intensity-modulated radiation therapy)	<input type="checkbox"/>	⑧
	SBRT (Stereotactic body radiation therapy)	<input type="checkbox"/>	
	Proton Therapy	<input type="checkbox"/>	
	Brachytherapy	<input type="checkbox"/>	
	Unknown	<input type="checkbox"/>	
	Other, specify	<input type="checkbox"/>	

Start Date	<input type="text"/>	⑨
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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Post Lg Cx- 18 month Follow up

Form: Radiation

Generated On: 15 May 2019 14:40:46

Check if Ongoing

10

End Date

11

Total Dose

Fixed Unit: cGY

12

Check if the total dose is unknown

13

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Post Lg Cx- 18 month Follow up

Form: Radiation

Generated On: 15 May 2019 14:40:46

Field Name	Data Type	Units	Values	Include Field OID
③ PRE_OP_RT	1			PRE_OP_RT
④ POST_OP_RT	1			POST_OP_RT
⑤ DEF_RT	1			DEF_RT
⑥ UNK_RT	1			UNK_RT
⑦ RT_SITE	2		1 = Chest Primary Tumor Volume 2 = Hilar/Mediast inal Lymph Nodes 3 = Prophylactic Brain 4 = Therapeutic Brain 88 = Other, specify 99 = Unknown	RT_SITE
⑧ RT_TYPE	2		1 = IMRT (intensity-mo dulated radiation therapy)	RT_TYPE

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Post Lg Cx- 18 month Follow up

Form: Radiation

Generated On: 15 May 2019 14:40:46

Field Name	Data Type	Units	Values	Include Field OID
			2 = SBRT (Stereotactic body radiation therapy) 3 = Proton Therapy 4 = Brachytherap y 99 = Unknown 88 = Other, specify	
9 RT_ST_DT	MMM- dd- YYYY			RT_ST_DT
10 RT_ONGOIN	1 G			RT_ONGOIN G
11 RT_END_DT	MMM- dd- YYYY			RT_END_DT
12 RT_TOTAL_D	6.2 S			RT_TOTAL_D S
13 RT_TOTAL_D	1 S_UNK			RT_TOTAL_D S_UNK

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Post Lg Cx- 18 month Follow up

Form: Surgery

Generated On: 15 May 2019 14:40:46

Instructions Provide each surgical procedure, the approach, and date, for all surgeries not previously reported on this form

Surgical Procedure

- Lobectomy ②
- Bilobectomy
- Pneumonectomy
- Wedge resection
- Segmentectomy | segmental resection
- Lymphadenectomy | lymph node sampling
- Chest wall resection
- Thoracentesis
- Partial pleurectomy
- Multiple wedge resections
- Multiple segmental resections
- Other surgical procedure (specify)
- Unknown surgical procedure

Approach

- Exploratory thoracotomy without resection ③
- Median Sternotomy
- Thoracotomy
- Thoracoscopy | Video-assisted (VATS)
- Thoracoscopy | Video-assisted (VATS) with conversion to Thoracotomy
- Other surgical approach (specify)
- Unknown surgical approach

Date

④

Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Post Lg Cx- 18 month Follow up

Form: Surgery

Generated On: 15 May 2019 14:40:46

Field Name	Data Type	Units	Values	Include Field OID
② SURG_PROC 2			1 = Lobectomy 2 = Bilobectomy 3 = Pneumonectomy 4 = Wedge resection 5 = Segmentectomy segmental resection 6 = Lymphadenectomy lymph node sampling 7 = Chest wall resection 8 = Thoracentesis 9 = Partial pleurectomy 10 = Multiple wedge resections 11 = Multiple segmental resections 88 = Other surgical procedure (specify) 99 = Unknown surgical procedure	SURG_PROC

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Post Lg Cx- 18 month Follow up

Form: Surgery

Generated On: 15 May 2019 14:40:46

Field Name	Data Type	Units	Values	Include Field OID
③ SURG_APPR OACH	2		1 = Exploratory thoracotomy without resection 2 = Median Sternotomy 3 = Thoracotomy 4 = Thoracoscopy Video-assisted (VATS) 5 = Thoracoscopy Video-assisted (VATS) with conversion to Thoracotomy 88 = Other surgical approach (specify) 99 = Unknown surgical approach	SURG_APPR OACH
④ SURGERY_PR OC_DT	dd- yyyy			SURGERY_PR OC_DT

FOR SITE IRB SUBMISSION ONLY
NOT RECOMMENDED FOR SOURCE DOCUMENTATION

Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Post Lg Cx- 18 month Follow up

Form: Other Treatment

Generated On: 15 May 2019 14:40:46

Instructions: Provide all other types of treatment not previously reported on this form. Add a new log line for each unique treatment, or each treatment type that has a unique start date.

Type of Treatment

- Immune Therapy ②
- Radio Frequency Ablation
- Thermal Ablation
- Chemical Ablation
- Unknown
- Other, specify

Description of other treatment

③

Treatment Start Date

④

Treatment End Date

⑤

Check if treatment is ongoing

⑥

FOR SITE IRB SUBMISSION ONLY
NOT RECOMMENDED FOR SOURCE DOCUMENTATION

Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Post Lg Cx- 18 month Follow up

Form: Other Treatment

Generated On: 15 May 2019 14:40:46

Field Name	Data Type	Units	Values	Include Field OID
② OTH_TX_TYP2 E			1 = Immune Therapy 2 = Radio Frequency Ablation 3 = Thermal Ablation 4 = Chemical Ablation 99 = Unknown 88 = Other, specify	OTH_TX_TYP E
③ OTH_TX_DE SCR	\$200			OTH_TX_DE SCR
④ OTH_TX_ST_ DT	MMM- dd- yyyy			OTH_TX_ST_ DT
⑤ OTH_TX_EN D_DT	MMM- dd- yyyy			OTH_TX_EN D_DT
⑥ OTH_TX_ON G				OTH_TX_ON G

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Participant Vital Status

Alive ①
Dead
Unknown

Was the outcome assessment completed for this timepoint?

No ②
Yes

If no, indicate the primary reason not completed

Patient Refused ③
Patient Lost to Follow up
Site error
Other, specify

Date of Assessment

_____ ④

Indicate the person(s) who assessed the patient's status

Site RA

_____ ⑥

Treating Physician

_____ ⑦

Other, specify

_____ ⑧

Indicate the method(s) status was assessed

Medical Records

_____ ⑩

Treating Physician

_____ ⑪

Participant

_____ ⑫

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Other, specify _____ **13**

Did the participant develop progression at primary site, new lesions, growth of existing lesions, metastases, and/or other recurrence not previously reported? **14**

No

Yes

Unknown

Date of first documentation of progressive lung cancer _____ **15**

Indicate the site(s) of progression of lung cancer

Site

Original lung site **17**

Other lung site(s)

Pleura

Brain

Bone

Liver

Adrenal

Skin/subcutaneous tissue

N1 regional lymph nodes (ipsilateral hilar/intrapulmonary)

N2 ipsilateral mediastinal lymph nodes

N3 distant lymph nodes (contralateral mediastinal or hilar/supraclavicular/scalene)

Unknown

Other, specify

Did the participant develop a second primary lung cancer following treatment for an initial primary lung cancer not previously reported? **18**

No

Yes

Unknown

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Folder: Post Lg Cx- 21 month Follow up

Form: Outcomes Assessment

Generated On: 15 May 2019 14:40:46

Date of diagnosis of second primary lung cancer _____

19

Did the participant undergo lung cancer radiation treatment(s) not previously reported?

No 20
Yes
Unknown

Did the participant undergo lung cancer surgical treatment(s) not previously reported?

No 21
Yes
Unknown

Did the participant receive lung cancer chemotherapy not previously reported?

No 22
Yes
Unknown

Did the participant undergo any other lung cancer treatment(s) administered by a physician not previously reported?

No 23
Yes
Unknown

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Post Lg Cx- 21 month Follow up

Form: Outcomes Assessment

Generated On: 15 May 2019 14:40:46

Field Name	Data Type	Units	Values	Include Field OID
① PT_VT_STS	2		1 = Alive 2 = Dead 99 = Unknown	PT_VT_STS
② OUT_ASSD_ YN	2		1 = No 2 = Yes	OUT_ASSD_ YN
③ OUT_ADD_N D_RSN	2		1 = Patient Refused 2 = Patient Lost to Follow up 3 = Site error 88 = Other, specify	OUT_ADD_N D_RSN
④ ASS_DT	MMM dd yyyy			ASS_DT
⑥ SITE_RA_AS SD	1			SITE_RA_AS SD
⑦ TRTING_PHY _ASS	1			TRTING_PHY _ASS
⑧ OTHER_ASS	\$200			OTHER_ASS
⑩ MTHD_ASS_ MED_REC	1			MTHD_ASS_ MED_REC
⑪ MTHD_ASS_ TRTING_PHY	1			MTHD_ASS_ TRTING_PHY

Draft 25 version 1.0 MIGPROD 17JAN2018: All forms
Folder: Post Lg Cx- 21 month Follow up
Form: Outcomes Assessment
Generated On: 15 May 2019 14:40:46

Field Name	Data Type	Units	Values	Include Field OID
12 MTHD_ASS_ 1 PT				MTHD_ASS_ PT
13 MTHD_ASS_ \$200 OTH				MTHD_ASS_ OTH
14 PRG_DX_YN 2			1 = No 2 = Yes 99 = Unknown	PRG_DX_YN
15 PRG_DX_DT MMM dd yyyy				PRG_DX_DT
17 LUNG_CS_PR2 OG_SITE			1 = Original lung site 2 = Other lung site(s) 3 = Pleura 4 = Brain 5 = Bone 6 = Liver 7 = Adrenal 8 = Skin/subcuta neous tissue 9 = N1 regional lymph nodes (ipsilateral hilar/intrapul monary) 10 = N2 ipsilateral mediastinal lymph nodes	LUNG_CS_PR OG_SITE

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Post Lg Cx- 21 month Follow up

Form: Outcomes Assessment

Generated On: 15 May 2019 14:40:46

Field Name	Data Type	Units	Values	Include Field OID
			11 = N3 distant lymph nodes (contralateral mediastinal or hilar/supracla vicular/scale ne) 99 = Unknown 88 = Other, specify	
18 PRIM_2ND_L G_YN			1 = No 2 = Yes 99 = Unknown	PRIM_2ND_L G_YN
19 PRIM_2ND_L G_DT	MMM dd yyyy			PRIM_2ND_L G_DT
20 RT_TX_YN	2		1 = No 2 = Yes 99 = Unknown	RT_TX_YN
21 SURG_TX_Y N	2		1 = No 2 = Yes 99 = Unknown	SURG_TX_Y N
22 CHEMO_TX_ YN	2		1 = No 2 = Yes 99 = Unknown	CHEMO_TX_ YN

Draft 25 version 1.0 MIGPROD 17JAN2018: All forms
Folder: Post Lg Cx- 21 month Follow up
Form: Outcomes Assessment
Generated On: 15 May 2019 14:40:46

Field Name	Data Type	Units	Values	Include Field OID
23 OTH_TX_YN	2		1 = No 2 = Yes 99 = Unknown	OTH_TX_YN

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Post Lg Cx- 21 month Follow up

Form: Chemotherapy

Generated On: 15 May 2019 14:40:46

Instructions: Indicate all the chemotherapeutic agents given, the start and end date, not previously reported on this form

If the exact date is unknown, unknown day should be entered as UN and unknown month as UNK

Chemotherapy Type _____ ②

Start Date _____ ③

Check if Ongoing _____ ④

If ongoing, provide the tentative end date _____ ⑤

Actual End Date _____ ⑥

Check if end date unknown _____ ⑦

Provide the number of cycles given Note If ongoing, provide the planned number of cycles _____ ⑧

Check if the number of cycles is unknown _____ ⑨

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Post Lg Cx- 21 month Follow up

Form: Chemotherapy

Generated On: 15 May 2019 14:40:46

Field Name	Data Type	Units	Values	Include Field OID
② CHEMO_TYP E	2		Chemotherap y Type	CHEMO_TYP E
③ CHEMO_ST_ DT	MMM- dd- yyyy			CHEMO_ST_ DT
④ CHEMO_ONG OING	1			CHEMO_ONG OING
⑤ CHEMO_TEN T_END_DT	MMM dd yyyy			CHEMO_TEN T_END_DT
⑥ CHEMO_END _DT	MMM- dd- yyyy			CHEMO_END _DT
⑦ CHEMO_END _DT_UNK	1			CHEMO_END _DT_UNK
⑧ CHEMO_CYC	4.1			CHEMO_CYC
⑨ CHEMO_CYC _UNK	1			CHEMO_CYC _UNK

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Post Lg Cx- 21 month Follow up

Form: Radiation

Generated On: 15 May 2019 14:40:46

Instructions: Provide all the body sites that were treated with radiotherapy, one site per log line, not previously reported on this form.

Indicate the sequence of radiotherapy relative to surgery check all that apply

Pre-operative	<input type="checkbox"/>	③
Post-operative	<input type="checkbox"/>	④
Definitive	<input type="checkbox"/>	⑤
Unknown	<input type="checkbox"/>	⑥

Radiotherapy Site

Chest Primary Tumor Volume	<input type="checkbox"/>	⑦
Hilar/Mediastinal Lymph Nodes	<input type="checkbox"/>	
Prophylactic Brain	<input type="checkbox"/>	
Therapeutic Brain	<input type="checkbox"/>	
Other, specify	<input type="checkbox"/>	
Unknown	<input type="checkbox"/>	

Radiotherapy Type

IMRT (intensity-modulated radiation therapy)	<input type="checkbox"/>	⑧
SBRT (Stereotactic body radiation therapy)	<input type="checkbox"/>	
Proton Therapy	<input type="checkbox"/>	
Brachytherapy	<input type="checkbox"/>	
Unknown	<input type="checkbox"/>	
Other, specify	<input type="checkbox"/>	

Start Date

<input type="text"/>	⑨
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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Post Lg Cx- 21 month Follow up

Form: Radiation

Generated On: 15 May 2019 14:40:46

Check if Ongoing _____

10

End Date _____

11

Total Dose _____

Fixed Unit: cGY

12

Check if the total dose is unknown _____

13

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Post Lg Cx- 21 month Follow up

Form: Radiation

Generated On: 15 May 2019 14:40:46

Field Name	Data Type	Units	Values	Include Field OID
③ PRE_OP_RT	1			PRE_OP_RT
④ POST_OP_RT	1			POST_OP_RT
⑤ DEF_RT	1			DEF_RT
⑥ UNK_RT	1			UNK_RT
⑦ RT_SITE	2		1 = Chest Primary Tumor Volume 2 = Hilar/Mediast inal Lymph Nodes 3 = Prophylactic Brain 4 = Therapeutic Brain 88 = Other, specify 99 = Unknown	RT_SITE
⑧ RT_TYPE	2		1 = IMRT (intensity-mo dulated radiation therapy)	RT_TYPE

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Post Lg Cx- 21 month Follow up

Form: Radiation

Generated On: 15 May 2019 14:40:46

Field Name	Data Type	Units	Values	Include Field OID
			2 = SBRT (Stereotactic body radiation therapy) 3 = Proton Therapy 4 = Brachytherap y 99 = Unknown 88 = Other, specify	
9 RT_ST_DT	MMM- dd- YYYY			RT_ST_DT
10 RT_ONGOIN	1 G			RT_ONGOIN G
11 RT_END_DT	MMM- dd- YYYY			RT_END_DT
12 RT_TOTAL_D	6.2 S			RT_TOTAL_D S
13 RT_TOTAL_D	1 S_UNK			RT_TOTAL_D S_UNK

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Post Lg Cx- 21 month Follow up

Form: Surgery

Generated On: 15 May 2019 14:40:46

Instructions Provide each surgical procedure, the approach, and date, for all surgeries not previously reported on this form

Surgical Procedure

- Lobectomy ②
- Bilobectomy
- Pneumonectomy
- Wedge resection
- Segmentectomy | segmental resection
- Lymphadenectomy | lymph node sampling
- Chest wall resection
- Thoracentesis
- Partial pleurectomy
- Multiple wedge resections
- Multiple segmental resections
- Other surgical procedure (specify)
- Unknown surgical procedure

Approach

- Exploratory thoracotomy without resection ③
- Median Sternotomy
- Thoracotomy
- Thoracoscopy | Video-assisted (VATS)
- Thoracoscopy | Video-assisted (VATS) with conversion to Thoracotomy
- Other surgical approach (specify)
- Unknown surgical approach

Date

④

Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Post Lg Cx- 21 month Follow up

Form: Surgery

Generated On: 15 May 2019 14:40:46

Field Name	Data Type	Units	Values	Include Field OID
② SURG_PROC 2			1 = Lobectomy 2 = Bilobectomy 3 = Pneumonectomy 4 = Wedge resection 5 = Segmentectomy segmental resection 6 = Lymphadenectomy lymph node sampling 7 = Chest wall resection 8 = Thoracentesis 9 = Partial pleurectomy 10 = Multiple wedge resections 11 = Multiple segmental resections 88 = Other surgical procedure (specify) 99 = Unknown surgical procedure	SURG_PROC

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Post Lg Cx- 21 month Follow up

Form: Surgery

Generated On: 15 May 2019 14:40:46

Field Name	Data Type	Units	Values	Include Field OID
③ SURG_APPR OACH	2		1 = Exploratory thoracotomy without resection 2 = Median Sternotomy 3 = Thoracotomy 4 = Thoracoscopy Video-assisted (VATS) 5 = Thoracoscopy Video-assisted (VATS) with conversion to Thoracotomy 88 = Other surgical approach (specify) 99 = Unknown surgical approach	SURG_APPR OACH
④ SURGERY_PR OC_DT	dd- yyyy			SURGERY_PR OC_DT

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Post Lg Cx- 21 month Follow up

Form: Other Treatment

Generated On: 15 May 2019 14:40:46

Instructions: Provide all other types of treatment not previously reported on this form. Add a new log line for each unique treatment, or each treatment type that has a unique start date.

Type of Treatment

- Immune Therapy ②
- Radio Frequency Ablation
- Thermal Ablation
- Chemical Ablation
- Unknown
- Other, specify

Description of other treatment

③

Treatment Start Date

④

Treatment End Date

⑤

Check if treatment is ongoing

⑥

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Post Lg Cx- 21 month Follow up

Form: Other Treatment

Generated On: 15 May 2019 14:40:46

Field Name	Data Type	Units	Values	Include Field OID
② OTH_TX_TYP2 E			1 = Immune Therapy 2 = Radio Frequency Ablation 3 = Thermal Ablation 4 = Chemical Ablation 99 = Unknown 88 = Other, specify	OTH_TX_TYP E
③ OTH_TX_DE SCR	\$200			OTH_TX_DE SCR
④ OTH_TX_ST_ DT	MMM- dd- yyyy			OTH_TX_ST_ DT
⑤ OTH_TX_EN D_DT	MMM- dd- yyyy			OTH_TX_EN D_DT
⑥ OTH_TX_ON G				OTH_TX_ON G

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Participant Vital Status

Alive ①
Dead
Unknown

Was the outcome assessment completed for this timepoint?

No ②
Yes

If no, indicate the primary reason not completed

Patient Refused ③
Patient Lost to Follow up
Site error
Other, specify

Date of Assessment

_____ ④

Indicate the person(s) who assessed the patient's status

Site RA

_____ ⑥

Treating Physician

_____ ⑦

Other, specify

_____ ⑧

Indicate the method(s) status was assessed

Medical Records

_____ ⑩

Treating Physician

_____ ⑪

Participant

_____ ⑫

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Folder: Post Lg Cx- 24 month Follow up

Form: Outcomes Assessment

Generated On: 15 May 2019 14:40:46

Other, specify _____

13

Did the participant develop progression at primary site, new lesions, growth of existing lesions, metastases, and/or other recurrence not previously reported?

No

Yes

Unknown

14

Date of first documentation of progressive lung cancer _____

15

Indicate the site(s) of progression of lung cancer

Site

Original lung site

Other lung site(s)

Pleura

Brain

Bone

Liver

Adrenal

Skin/subcutaneous tissue

N1 regional lymph nodes

(ipsilateral hilar/intrapulmonary)

N2 ipsilateral mediastinal lymph nodes

N3 distant lymph nodes

(contralateral mediastinal or hilar/supraclavicular/scalene)

Unknown

Other, specify

17

Did the participant develop a second primary lung cancer following treatment for an initial primary lung cancer not previously reported?

No

Yes

Unknown

18

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Folder: Post Lg Cx- 24 month Follow up

Form: Outcomes Assessment

Generated On: 15 May 2019 14:40:46

Date of diagnosis of second primary lung cancer _____

19

Did the participant undergo lung cancer radiation treatment(s) not previously reported?

No

20

Yes

Unknown

Did the participant undergo lung cancer surgical treatment(s) not previously reported?

No

21

Yes

Unknown

Did the participant receive lung cancer chemotherapy not previously reported?

No

22

Yes

Unknown

Did the participant undergo any other lung cancer treatment(s) administered by a physician not previously reported?

No

23

Yes

Unknown

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Post Lg Cx- 24 month Follow up

Form: Outcomes Assessment

Generated On: 15 May 2019 14:40:46

Field Name	Data Type	Units	Values	Include Field OID
① PT_VT_STS	2		1 = Alive 2 = Dead 99 = Unknown	PT_VT_STS
② OUT_ASSD_ YN	2		1 = No 2 = Yes	OUT_ASSD_ YN
③ OUT_ADD_N D_RSN	2		1 = Patient Refused 2 = Patient Lost to Follow up 3 = Site error 88 = Other, specify	OUT_ADD_N D_RSN
④ ASS_DT	MMM dd yyyy			ASS_DT
⑥ SITE_RA_AS SD	1			SITE_RA_AS SD
⑦ TRTING_PHY _ASS	1			TRTING_PHY _ASS
⑧ OTHER_ASS	\$200			OTHER_ASS
⑩ MTHD_ASS_ MED_REC	1			MTHD_ASS_ MED_REC
⑪ MTHD_ASS_ TRTING_PHY	1			MTHD_ASS_ TRTING_PHY

Draft 25 version 1.0 MIGPROD 17JAN2018: All forms
Folder: Post Lg Cx- 24 month Follow up
Form: Outcomes Assessment
Generated On: 15 May 2019 14:40:46

Field Name	Data Type	Units	Values	Include Field OID
12 MTHD_ASS_ 1 PT				MTHD_ASS_ PT
13 MTHD_ASS_ \$200 OTH				MTHD_ASS_ OTH
14 PRG_DX_YN 2			1 = No 2 = Yes 99 = Unknown	PRG_DX_YN
15 PRG_DX_DT MMM dd yyyy				PRG_DX_DT
17 LUNG_CS_PR2 OG_SITE			1 = Original lung site 2 = Other lung site(s) 3 = Pleura 4 = Brain 5 = Bone 6 = Liver 7 = Adrenal 8 = Skin/subcuta neous tissue 9 = N1 regional lymph nodes (ipsilateral hilar/intrapul monary) 10 = N2 ipsilateral mediastinal lymph nodes	LUNG_CS_PR OG_SITE

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Folder: Post Lg Cx- 24 month Follow up

Form: Outcomes Assessment

Generated On: 15 May 2019 14:40:46

Field Name	Data Type	Units	Values	Include Field OID
			11 = N3 distant lymph nodes (contralateral mediastinal or hilar/supracla vicular/scala ne) 99 = Unknown 88 = Other, specify	
18 PRIM_2ND_L G_YN			1 = No 2 = Yes 99 = Unknown	PRIM_2ND_L G_YN
19 PRIM_2ND_L G_DT	MMM dd yyyy			PRIM_2ND_L G_DT
20 RT_TX_YN	2		1 = No 2 = Yes 99 = Unknown	RT_TX_YN
21 SURG_TX_Y N	2		1 = No 2 = Yes 99 = Unknown	SURG_TX_Y N
22 CHEMO_TX_ YN	2		1 = No 2 = Yes 99 = Unknown	CHEMO_TX_ YN

Draft 25 version 1.0 MIGPROD 17JAN2018: All forms
Folder: Post Lg Cx- 24 month Follow up
Form: Outcomes Assessment
Generated On: 15 May 2019 14:40:46

Field Name	Data Type	Units	Values	Include Field OID
23 OTH_TX_YN	2		1 = No 2 = Yes 99 = Unknown	OTH_TX_YN

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Post Lg Cx- 24 month Follow up

Form: Chemotherapy

Generated On: 15 May 2019 14:40:46

Instructions: Indicate all the chemotherapeutic agents given, the start and end date, not previously reported on this form

If the exact date is unknown, unknown day should be entered as UN and unknown month as UNK

Chemotherapy Type _____ ②

Start Date _____ ③

Check if Ongoing _____ ④

If ongoing, provide the tentative end date _____ ⑤

Actual End Date _____ ⑥

Check if end date unknown _____ ⑦

Provide the number of cycles given. Note: If ongoing, provide the planned number of cycles _____ ⑧

Check if the number of cycles is unknown _____ ⑨

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Post Lg Cx- 24 month Follow up

Form: Chemotherapy

Generated On: 15 May 2019 14:40:46

Field Name	Data Type	Units	Values	Include Field OID
② CHEMO_TYP E	2		Chemotherap y Type	CHEMO_TYP E
③ CHEMO_ST_ DT	MMM- dd- YYYY			CHEMO_ST_ DT
④ CHEMO_ONG OING	1			CHEMO_ONG OING
⑤ CHEMO_TEN T_END_DT	MMM dd yyyy			CHEMO_TEN T_END_DT
⑥ CHEMO_END _DT	MMM- dd- YYYY			CHEMO_END _DT
⑦ CHEMO_END _DT_UNK	1			CHEMO_END _DT_UNK
⑧ CHEMO_CYC _UNK	4.1			CHEMO_CYC
⑨ CHEMO_CYC _UNK	1			CHEMO_CYC _UNK

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Post Lg Cx- 24 month Follow up

Form: Radiation

Generated On: 15 May 2019 14:40:46

Instructions: Provide all the body sites that were treated with radiotherapy, one site per log line, not previously reported on this form.

Indicate the sequence of radiotherapy relative to surgery check all that apply

Pre-operative	_____	3
Post-operative	_____	4
Definitive	_____	5
Unknown	_____	6

Radiotherapy Site

Chest Primary Tumor Volume	<input type="checkbox"/>	7
Hilar/Mediastinal Lymph Nodes	<input type="checkbox"/>	
Prophylactic Brain	<input type="checkbox"/>	
Therapeutic Brain	<input type="checkbox"/>	
Other, specify	<input type="checkbox"/>	
Unknown	<input type="checkbox"/>	

Radiotherapy Type

IMRT (intensity-modulated radiation therapy)	<input type="checkbox"/>	8
SBRT (Stereotactic body radiation therapy)	<input type="checkbox"/>	
Proton Therapy	<input type="checkbox"/>	
Brachytherapy	<input type="checkbox"/>	
Unknown	<input type="checkbox"/>	
Other, specify	<input type="checkbox"/>	

Start Date

_____ **9**

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Post Lg Cx- 24 month Follow up

Form: Radiation

Generated On: 15 May 2019 14:40:46

Check if Ongoing _____

10

End Date _____

11

Total Dose _____

Fixed Unit: cGY

12

Check if the total dose is unknown _____

13

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Post Lg Cx- 24 month Follow up

Form: Radiation

Generated On: 15 May 2019 14:40:46

Field Name	Data Type	Units	Values	Include Field OID
③ PRE_OP_RT	1			PRE_OP_RT
④ POST_OP_RT	1			POST_OP_RT
⑤ DEF_RT	1			DEF_RT
⑥ UNK_RT	1			UNK_RT
⑦ RT_SITE	2		1 = Chest Primary Tumor Volume 2 = Hilar/Mediast inal Lymph Nodes 3 = Prophylactic Brain 4 = Therapeutic Brain 88 = Other, specify 99 = Unknown	RT_SITE
⑧ RT_TYPE	2		1 = IMRT (intensity-mo dulated radiation therapy)	RT_TYPE

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Post Lg Cx- 24 month Follow up

Form: Radiation

Generated On: 15 May 2019 14:40:46

Field Name	Data Type	Units	Values	Include Field OID
			2 = SBRT (Stereotactic body radiation therapy) 3 = Proton Therapy 4 = Brachytherap y 99 = Unknown 88 = Other, specify	
9 RT_ST_DT	MMM- dd- YYYY			RT_ST_DT
10 RT_ONGOIN	1 G			RT_ONGOIN G
11 RT_END_DT	MMM- dd- YYYY			RT_END_DT
12 RT_TOTAL_D	6.2 S			RT_TOTAL_D S
13 RT_TOTAL_D	1 S_UNK			RT_TOTAL_D S_UNK

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Post Lg Cx- 24 month Follow up

Form: Surgery

Generated On: 15 May 2019 14:40:46

Instructions Provide each surgical procedure, the approach, and date, for all surgeries not previously reported on this form

Surgical Procedure

- Lobectomy ②
- Bilobectomy
- Pneumonectomy
- Wedge resection
- Segmentectomy | segmental resection
- Lymphadenectomy | lymph node sampling
- Chest wall resection
- Thoracentesis
- Partial pleurectomy
- Multiple wedge resections
- Multiple segmental resections
- Other surgical procedure (specify)
- Unknown surgical procedure

Approach

- Exploratory thoracotomy without resection ③
- Median Sternotomy
- Thoracotomy
- Thoracoscopy | Video-assisted (VATS)
- Thoracoscopy | Video-assisted (VATS) with conversion to Thoracotomy
- Other surgical approach (specify)
- Unknown surgical approach

Date

④

Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Post Lg Cx- 24 month Follow up

Form: Surgery

Generated On: 15 May 2019 14:40:46

Field Name	Data Type	Units	Values	Include Field OID
② SURG_PROC 2			1 = Lobectomy 2 = Bilobectomy 3 = Pneumonectomy 4 = Wedge resection 5 = Segmentectomy segmental resection 6 = Lymphadenectomy lymph node sampling 7 = Chest wall resection 8 = Thoracentesis 9 = Partial pleurectomy 10 = Multiple wedge resections 11 = Multiple segmental resections 88 = Other surgical procedure (specify) 99 = Unknown surgical procedure	SURG_PROC

FOR SITE IRB SUBMISSION ONLY
NOT RECOMMENDED FOR SOURCE DOCUMENTATION

Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Post Lg Cx- 24 month Follow up

Form: Surgery

Generated On: 15 May 2019 14:40:46

Field Name	Data Type	Units	Values	Include Field OID
③ SURG_APPR OACH	2		1 = Exploratory thoracotomy without resection 2 = Median Sternotomy 3 = Thoracotomy 4 = Thoracoscop y Video-assiste d (VATS) 5 = Thoracoscop y Video-assiste d (VATS) with conversion to Thoracotomy 88 = Other surgical approach (specify) 99 = Unknown surgical approach	SURG_APPR OACH
④ SURGERY_PR OC_DT	dd- yyyy			SURGERY_PR OC_DT

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Post Lg Cx- 24 month Follow up

Form: Other Treatment

Generated On: 15 May 2019 14:40:46

Instructions: Provide all other types of treatment not previously reported on this form. Add a new log line for each unique treatment, or each treatment type that has a unique start date.

Type of Treatment

- Immune Therapy ②
- Radio Frequency Ablation
- Thermal Ablation
- Chemical Ablation
- Unknown
- Other, specify

Description of other treatment

③

Treatment Start Date

④

Treatment End Date

⑤

Check if treatment is ongoing

⑥

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Post Lg Cx- 24 month Follow up

Form: Other Treatment

Generated On: 15 May 2019 14:40:46

Field Name	Data Type	Units	Values	Include Field OID
② OTH_TX_TYP2 E			1 = Immune Therapy 2 = Radio Frequency Ablation 3 = Thermal Ablation 4 = Chemical Ablation 99 = Unknown 88 = Other, specify	OTH_TX_TYP E
③ OTH_TX_DE SCR	\$200			OTH_TX_DE SCR
④ OTH_TX_ST_ DT	MMM- dd- yyyy			OTH_TX_ST_ DT
⑤ OTH_TX_EN D_DT	MMM- dd- yyyy			OTH_TX_EN D_DT
⑥ OTH_TX_ON G				OTH_TX_ON G

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Participant Vital Status

Alive ①
Dead
Unknown

Was the outcome assessment completed for this timepoint?

No ②
Yes

If no, indicate the primary reason not completed

Patient Refused ③
Patient Lost to Follow up
Site error
Other, specify

Date of Assessment

_____ ④

Indicate the person(s) who assessed the patient's status

Site RA

_____ ⑥

Treating Physician

_____ ⑦

Other, specify

_____ ⑧

Indicate the method(s) status was assessed

Medical Records

_____ ⑩

Treating Physician

_____ ⑪

Participant

_____ ⑫

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Post Lg Cx- 30 Month Follow up

Form: Outcomes Assessment

Generated On: 15 May 2019 14:40:46

Other, specify _____

13

Did the participant develop progression at primary site, new lesions, growth of existing lesions, metastases, and/or other recurrence not previously reported?

No 14
Yes
Unknown

Date of first documentation of progressive lung cancer _____

15

Indicate the site(s) of progression of lung cancer

Site

- Original lung site 17
- Other lung site(s)
- Pleura
- Brain
- Bone
- Liver
- Adrenal
- Skin/subcutaneous tissue
- N1 regional lymph nodes (ipsilateral hilar/intrapulmonary)
- N2 ipsilateral mediastinal lymph nodes
- N3 distant lymph nodes (contralateral mediastinal or hilar/supraclavicular/scalene)
- Unknown
- Other, specify

Did the participant develop a second primary lung cancer following treatment for an initial primary lung cancer not previously reported?

No 18
Yes
Unknown

Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Post Lg Cx- 30 Month Follow up

Form: Outcomes Assessment

Generated On: 15 May 2019 14:40:46

Date of diagnosis of second primary lung cancer _____

19

Did the participant undergo lung cancer radiation treatment(s) not previously reported?

No

20

Yes

Unknown

Did the participant undergo lung cancer surgical treatment(s) not previously reported?

No

21

Yes

Unknown

Did the participant receive lung cancer chemotherapy not previously reported?

No

22

Yes

Unknown

Did the participant undergo any other lung cancer treatment(s) administered by a physician not previously reported?

No

23

Yes

Unknown

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms
Folder: Post Lg Cx- 30 Month Follow up
Form: Outcomes Assessment
Generated On: 15 May 2019 14:40:46

Field Name	Data Type	Units	Values	Include Field OID
① PT_VT_STS	2		1 = Alive 2 = Dead 99 = Unknown	PT_VT_STS
② OUT_ASSD_ YN	2		1 = No 2 = Yes	OUT_ASSD_ YN
③ OUT_ADD_N D_RSN	2		1 = Patient Refused 2 = Patient Lost to Follow up 3 = Site error 88 = Other, specify	OUT_ADD_N D_RSN
④ ASS_DT	MMM dd yyyy			ASS_DT
⑥ SITE_RA_AS SD	1			SITE_RA_AS SD
⑦ TRTING_PHY _ASS	1			TRTING_PHY _ASS
⑧ OTHER_ASS	\$200			OTHER_ASS
⑩ MTHD_ASS_ MED_REC	1			MTHD_ASS_ MED_REC
⑪ MTHD_ASS_ TRTING_PHY	1			MTHD_ASS_ TRTING_PHY

Draft 25 version 1.0 MIGPROD 17JAN2018: All forms
Folder: Post Lg Cx- 30 Month Follow up
Form: Outcomes Assessment
Generated On: 15 May 2019 14:40:46

Field Name	Data Type	Units	Values	Include Field OID
12 MTHD_ASS_ 1 PT				MTHD_ASS_ PT
13 MTHD_ASS_ \$200 OTH				MTHD_ASS_ OTH
14 PRG_DX_YN 2			1 = No 2 = Yes 99 = Unknown	PRG_DX_YN
15 PRG_DX_DT MMM dd yyyy				PRG_DX_DT
17 LUNG_CS_PR2 OG_SITE			1 = Original lung site 2 = Other lung site(s) 3 = Pleura 4 = Brain 5 = Bone 6 = Liver 7 = Adrenal 8 = Skin/subcuta neous tissue 9 = N1 regional lymph nodes (ipsilateral hilar/intrapul monary) 10 = N2 ipsilateral mediastinal lymph nodes	LUNG_CS_PR OG_SITE

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms
 Folder: Post Lg Cx- 30 Month Follow up
 Form: Outcomes Assessment
 Generated On: 15 May 2019 14:40:46

Field Name	Data Type	Units	Values	Include Field OID
			11 = N3 distant lymph nodes (contralateral mediastinal or hilar/supracla vicular/scale ne) 99 = Unknown 88 = Other, specify	
18 PRIM_2ND_L G_YN			1 = No 2 = Yes 99 = Unknown	PRIM_2ND_L G_YN
19 PRIM_2ND_L G_DT	MMM dd yyyy			PRIM_2ND_L G_DT
20 RT_TX_YN	2		1 = No 2 = Yes 99 = Unknown	RT_TX_YN
21 SURG_TX_Y N	2		1 = No 2 = Yes 99 = Unknown	SURG_TX_Y N
22 CHEMO_TX_ YN	2		1 = No 2 = Yes 99 = Unknown	CHEMO_TX_ YN

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms
Folder: Post Lg Cx- 30 Month Follow up
Form: Outcomes Assessment
Generated On: 15 May 2019 14:40:46

Field Name	Data Type	Units	Values	Include Field OID
23 OTH_TX_YN	2		1 = No 2 = Yes 99 = Unknown	OTH_TX_YN

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Post Lg Cx- 30 Month Follow up

Form: Chemotherapy

Generated On: 15 May 2019 14:40:46

Instructions: Indicate all the chemotherapeutic agents given, the start and end date, not previously reported on this form

If the exact date is unknown, unknown day should be entered as UN and unknown month as UNK

Chemotherapy Type _____ ②

Start Date _____ ③

Check if Ongoing _____ ④

If ongoing, provide the tentative end date _____ ⑤

Actual End Date _____ ⑥

Check if end date unknown _____ ⑦

Provide the number of cycles given. Note: If ongoing, provide the planned number of cycles _____ ⑧

Check if the number of cycles is unknown _____ ⑨

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Post Lg Cx- 30 Month Follow up

Form: Chemotherapy

Generated On: 15 May 2019 14:40:46

Field Name	Data Type	Units	Values	Include Field OID
② CHEMO_TYP E	2		Chemotherap y Type	CHEMO_TYP E
③ CHEMO_ST_ DT	MMM- dd- yyyy			CHEMO_ST_ DT
④ CHEMO_ONG OING	1			CHEMO_ONG OING
⑤ CHEMO_TEN T_END_DT	MMM dd yyyy			CHEMO_TEN T_END_DT
⑥ CHEMO_END _DT	MMM- dd- yyyy			CHEMO_END _DT
⑦ CHEMO_END _DT_UNK	1			CHEMO_END _DT_UNK
⑧ CHEMO_CYC _UNK	4.1			CHEMO_CYC
⑨ CHEMO_CYC _UNK	1			CHEMO_CYC _UNK

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Post Lg Cx- 30 Month Follow up

Form: Radiation

Generated On: 15 May 2019 14:40:46

Instructions: Provide all the body sites that were treated with radiotherapy, one site per log line, not previously reported on this form.

Indicate the sequence of radiotherapy relative to surgery check all that apply

Pre-operative	<input type="checkbox"/>	3
Post-operative	<input type="checkbox"/>	4
Definitive	<input type="checkbox"/>	5
Unknown	<input type="checkbox"/>	6

Radiotherapy Site

Chest Primary Tumor Volume	<input type="checkbox"/>	7
Hilar/Mediastinal Lymph Nodes	<input type="checkbox"/>	
Prophylactic Brain	<input type="checkbox"/>	
Therapeutic Brain	<input type="checkbox"/>	
Other, specify	<input type="checkbox"/>	
Unknown	<input type="checkbox"/>	

Radiotherapy Type

IMRT (intensity-modulated radiation therapy)	<input type="checkbox"/>	8
SBRT (Stereotactic body radiation therapy)	<input type="checkbox"/>	
Proton Therapy	<input type="checkbox"/>	
Brachytherapy	<input type="checkbox"/>	
Unknown	<input type="checkbox"/>	
Other, specify	<input type="checkbox"/>	

Start Date

9

Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Post Lg Cx- 30 Month Follow up

Form: Radiation

Generated On: 15 May 2019 14:40:46

Check if Ongoing _____

10

End Date _____

11

Total Dose _____

Fixed Unit: cGY

12

Check if the total dose is unknown _____

13

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Post Lg Cx- 30 Month Follow up

Form: Radiation

Generated On: 15 May 2019 14:40:46

Field Name	Data Type	Units	Values	Include Field OID
③ PRE_OP_RT	1			PRE_OP_RT
④ POST_OP_RT	1			POST_OP_RT
⑤ DEF_RT	1			DEF_RT
⑥ UNK_RT	1			UNK_RT
⑦ RT_SITE	2		1 = Chest Primary Tumor Volume 2 = Hilar/Mediast inal Lymph Nodes 3 = Prophylactic Brain 4 = Therapeutic Brain 88 = Other, specify 99 = Unknown	RT_SITE
⑧ RT_TYPE	2		1 = IMRT (intensity-mo dulated radiation therapy)	RT_TYPE

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Post Lg Cx- 30 Month Follow up

Form: Radiation

Generated On: 15 May 2019 14:40:46

Field Name	Data Type	Units	Values	Include Field OID
			2 = SBRT (Stereotactic body radiation therapy) 3 = Proton Therapy 4 = Brachytherap y 99 = Unknown 88 = Other, specify	
9 RT_ST_DT	MMM- dd- YYYY			RT_ST_DT
10 RT_ONGOIN	1 G			RT_ONGOIN G
11 RT_END_DT	MMM- dd- YYYY			RT_END_DT
12 RT_TOTAL_D	6.2 S			RT_TOTAL_D S
13 RT_TOTAL_D	1 S_UNK			RT_TOTAL_D S_UNK

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Post Lg Cx- 30 Month Follow up

Form: Surgery

Generated On: 15 May 2019 14:40:46

Instructions Provide each surgical procedure, the approach, and date, for all surgeries not previously reported on this form

Surgical Procedure

- Lobectomy ②
- Bilobectomy
- Pneumonectomy
- Wedge resection
- Segmentectomy | segmental resection
- Lymphadenectomy | lymph node sampling
- Chest wall resection
- Thoracentesis
- Partial pleurectomy
- Multiple wedge resections
- Multiple segmental resections
- Other surgical procedure (specify)
- Unknown surgical procedure

Approach

- Exploratory thoracotomy without resection ③
- Median Sternotomy
- Thoracotomy
- Thoracoscopy | Video-assisted (VATS)
- Thoracoscopy | Video-assisted (VATS) with conversion to Thoracotomy
- Other surgical approach (specify)
- Unknown surgical approach

Date

④

Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Post Lg Cx- 30 Month Follow up

Form: Surgery

Generated On: 15 May 2019 14:40:46

Field Name	Data Type	Units	Values	Include Field OID
② SURG_PROC 2			1 = Lobectomy 2 = Bilobectomy 3 = Pneumonectomy 4 = Wedge resection 5 = Segmentectomy segmental resection 6 = Lymphadenectomy lymph node sampling 7 = Chest wall resection 8 = Thoracentesis 9 = Partial pleurectomy 10 = Multiple wedge resections 11 = Multiple segmental resections 88 = Other surgical procedure (specify) 99 = Unknown surgical procedure	SURG_PROC

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Post Lg Cx- 30 Month Follow up

Form: Surgery

Generated On: 15 May 2019 14:40:46

Field Name	Data Type	Units	Values	Include Field OID
③ SURG_APPR OACH	2		1 = Exploratory thoracotomy without resection 2 = Median Sternotomy 3 = Thoracotomy 4 = Thoracoscop y Video-assiste d (VATS) 5 = Thoracoscop y Video-assiste d (VATS) with conversion to Thoracotomy 88 = Other surgical approach (specify) 99 = Unknown surgical approach	SURG_APPR OACH
④ SURGERY_PR OC_DT	dd- yyyy			SURGERY_PR OC_DT

FOR SITE IRB SUBMISSION ONLY
NOT RECOMMENDED FOR SOURCE DOCUMENTATION

Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Post Lg Cx- 30 Month Follow up

Form: Other Treatment

Generated On: 15 May 2019 14:40:46

Instructions: Provide all other types of treatment not previously reported on this form. Add a new log line for each unique treatment, or each treatment type that has a unique start date.

Type of Treatment

Immune Therapy ②

Radio Frequency Ablation

Thermal Ablation

Chemical Ablation

Unknown

Other, specify

Description of other treatment

③

Treatment Start Date

④

Treatment End Date

⑤

Check if treatment is ongoing

⑥

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Post Lg Cx- 30 Month Follow up

Form: Other Treatment

Generated On: 15 May 2019 14:40:46

Field Name	Data Type	Units	Values	Include Field OID
② OTH_TX_TYP2 E			1 = Immune Therapy 2 = Radio Frequency Ablation 3 = Thermal Ablation 4 = Chemical Ablation 99 = Unknown 88 = Other, specify	OTH_TX_TYP E
③ OTH_TX_DE SCR	\$200			OTH_TX_DE SCR
④ OTH_TX_ST_ DT	MMM- dd- yyyy			OTH_TX_ST_ DT
⑤ OTH_TX_EN D_DT	MMM- dd- yyyy			OTH_TX_EN D_DT
⑥ OTH_TX_ON G				OTH_TX_ON G

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Participant Vital Status

Alive ①
Dead
Unknown

Was the outcome assessment completed for this timepoint?

No ②
Yes

If no, indicate the primary reason not completed

Patient Refused ③
Patient Lost to Follow up
Site error
Other, specify

Date of Assessment

_____ ④

Indicate the person(s) who assessed the patient's status

Site RA

_____ ⑥

Treating Physician

_____ ⑦

Other, specify

_____ ⑧

Indicate the method(s) status was assessed

Medical Records

_____ ⑩

Treating Physician

_____ ⑪

Participant

_____ ⑫

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Post Lg Cx- 36 Month Follow up

Form: Outcomes Assessment

Generated On: 15 May 2019 14:40:46

Other, specify _____

13

Did the participant develop progression at primary site, new lesions, growth of existing lesions, metastases, and/or other recurrence not previously reported?

No 14
Yes
Unknown

Date of first documentation of progressive lung cancer _____

15

Indicate the site(s) of progression of lung cancer

Site

- Original lung site 17
- Other lung site(s)
- Pleura
- Brain
- Bone
- Liver
- Adrenal
- Skin/subcutaneous tissue
- N1 regional lymph nodes (ipsilateral hilar/intrapulmonary)
- N2 ipsilateral mediastinal lymph nodes
- N3 distant lymph nodes (contralateral mediastinal or hilar/supraclavicular/scalene)
- Unknown
- Other, specify

Did the participant develop a second primary lung cancer following treatment for an initial primary lung cancer not previously reported?

No 18
Yes
Unknown

Date of diagnosis of second primary lung cancer _____

19

Did the participant undergo lung cancer radiation treatment(s) not previously reported? No Yes Unknown

20

Did the participant undergo lung cancer surgical treatment(s) not previously reported? No Yes Unknown

21

Did the participant receive lung cancer chemotherapy not previously reported? No Yes Unknown

22

Did the participant undergo any other lung cancer treatment(s) administered by a physician not previously reported? No Yes Unknown

23

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms
Folder: Post Lg Cx- 36 Month Follow up
Form: Outcomes Assessment
Generated On: 15 May 2019 14:40:46

Field Name	Data Type	Units	Values	Include Field OID
① PT_VT_STS	2		1 = Alive 2 = Dead 99 = Unknown	PT_VT_STS
② OUT_ASSD_ YN	2		1 = No 2 = Yes	OUT_ASSD_ YN
③ OUT_ADD_N D_RSN	2		1 = Patient Refused 2 = Patient Lost to Follow up 3 = Site error 88 = Other, specify	OUT_ADD_N D_RSN
④ ASS_DT	MMM dd yyyy			ASS_DT
⑥ SITE_RA_AS SD	1			SITE_RA_AS SD
⑦ TRTING_PHY _ASS	1			TRTING_PHY _ASS
⑧ OTHER_ASS	\$200			OTHER_ASS
⑩ MTHD_ASS_ MED_REC	1			MTHD_ASS_ MED_REC
⑪ MTHD_ASS_ TRTING_PHY	1			MTHD_ASS_ TRTING_PHY

Draft 25 version 1.0 MIGPROD 17JAN2018: All forms
Folder: Post Lg Cx- 36 Month Follow up
Form: Outcomes Assessment
Generated On: 15 May 2019 14:40:46

Field Name	Data Type	Units	Values	Include Field OID
12 MTHD_ASS_ 1 PT				MTHD_ASS_ PT
13 MTHD_ASS_ \$200 OTH				MTHD_ASS_ OTH
14 PRG_DX_YN 2			1 = No 2 = Yes 99 = Unknown	PRG_DX_YN
15 PRG_DX_DT MMM dd yyyy				PRG_DX_DT
17 LUNG_CS_PR2 OG_SITE			1 = Original lung site 2 = Other lung site(s) 3 = Pleura 4 = Brain 5 = Bone 6 = Liver 7 = Adrenal 8 = Skin/subcuta neous tissue 9 = N1 regional lymph nodes (ipsilateral hilar/intrapul monary) 10 = N2 ipsilateral mediastinal lymph nodes	LUNG_CS_PR OG_SITE

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Post Lg Cx- 36 Month Follow up

Form: Outcomes Assessment

Generated On: 15 May 2019 14:40:46

Field Name	Data Type	Units	Values	Include Field OID
			11 = N3 distant lymph nodes (contralateral mediastinal or hilar/supracla vicular/scale ne) 99 = Unknown 88 = Other, specify	
18 PRIM_2ND_L G_YN			1 = No 2 = Yes 99 = Unknown	PRIM_2ND_L G_YN
19 PRIM_2ND_L G_DT	MMM dd yyyy			PRIM_2ND_L G_DT
20 RT_TX_YN	2		1 = No 2 = Yes 99 = Unknown	RT_TX_YN
21 SURG_TX_Y N	2		1 = No 2 = Yes 99 = Unknown	SURG_TX_Y N
22 CHEMO_TX_ YN	2		1 = No 2 = Yes 99 = Unknown	CHEMO_TX_ YN

Draft 25 version 1.0 MIGPROD 17JAN2018: All forms
Folder: Post Lg Cx- 36 Month Follow up
Form: Outcomes Assessment
Generated On: 15 May 2019 14:40:46

Field Name	Data Type	Units	Values	Include Field OID
23 OTH_TX_YN	2		1 = No 2 = Yes 99 = Unknown	OTH_TX_YN

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Post Lg Cx- 36 Month Follow up

Form: Chemotherapy

Generated On: 15 May 2019 14:40:46

Instructions: Indicate all the chemotherapeutic agents given, the start and end date, not previously reported on this form

If the exact date is unknown, unknown day should be entered as UN and unknown month as UNK

Chemotherapy Type _____ ②

Start Date _____ ③

Check if Ongoing _____ ④

If ongoing, provide the tentative end date _____ ⑤

Actual End Date _____ ⑥

Check if end date unknown _____ ⑦

Provide the number of cycles given Note If ongoing, provide the planned number of cycles _____ ⑧

Check if the number of cycles is unknown _____ ⑨

FOR SITE IRB SUBMISSION ONLY
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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Post Lg Cx- 36 Month Follow up

Form: Chemotherapy

Generated On: 15 May 2019 14:40:46

Field Name	Data Type	Units	Values	Include Field OID
② CHEMO_TYP E	2		Chemotherap y Type	CHEMO_TYP E
③ CHEMO_ST_ DT	MMM- dd- yyyy			CHEMO_ST_ DT
④ CHEMO_ONG OING	1			CHEMO_ONG OING
⑤ CHEMO_TEN T_END_DT	MMM dd yyyy			CHEMO_TEN T_END_DT
⑥ CHEMO_END _DT	MMM- dd- yyyy			CHEMO_END _DT
⑦ CHEMO_END _DT_UNK	1			CHEMO_END _DT_UNK
⑧ CHEMO_CYC _UNK	4.1			CHEMO_CYC
⑨ CHEMO_CYC _UNK	1			CHEMO_CYC _UNK

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Post Lg Cx- 36 Month Follow up

Form: Radiation

Generated On: 15 May 2019 14:40:46

Instructions: Provide all the body sites that were treated with radiotherapy, one site per log line, not previously reported on this form.

Indicate the sequence of radiotherapy relative to surgery check all that apply

Pre-operative	_____	3
Post-operative	_____	4
Definitive	_____	5
Unknown	_____	6

Radiotherapy Site

Chest Primary Tumor Volume	<input type="checkbox"/>	7
Hilar/Mediastinal Lymph Nodes	<input type="checkbox"/>	
Prophylactic Brain	<input type="checkbox"/>	
Therapeutic Brain	<input type="checkbox"/>	
Other, specify	<input type="checkbox"/>	
Unknown	<input type="checkbox"/>	

Radiotherapy Type

IMRT (intensity-modulated radiation therapy)	<input type="checkbox"/>	8
SBRT (Stereotactic body radiation therapy)	<input type="checkbox"/>	
Proton Therapy	<input type="checkbox"/>	
Brachytherapy	<input type="checkbox"/>	
Unknown	<input type="checkbox"/>	
Other, specify	<input type="checkbox"/>	

Start Date

_____ **9**

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Post Lg Cx- 36 Month Follow up

Form: Radiation

Generated On: 15 May 2019 14:40:46

Check if Ongoing _____

10

End Date _____

11

Total Dose _____

Fixed Unit: cGY

12

Check if the total dose is unknown _____

13

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NOT RECOMMENDED FOR SOURCE DOCUMENTATION

Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Post Lg Cx- 36 Month Follow up

Form: Radiation

Generated On: 15 May 2019 14:40:46

Field Name	Data Type	Units	Values	Include Field OID
③ PRE_OP_RT	1			PRE_OP_RT
④ POST_OP_RT	1			POST_OP_RT
⑤ DEF_RT	1			DEF_RT
⑥ UNK_RT	1			UNK_RT
⑦ RT_SITE	2		1 = Chest Primary Tumor Volume 2 = Hilar/Mediast inal Lymph Nodes 3 = Prophylactic Brain 4 = Therapeutic Brain 88 = Other, specify 99 = Unknown	RT_SITE
⑧ RT_TYPE	2		1 = IMRT (intensity-mo dulated radiation therapy)	RT_TYPE

FOR SITE IRB SUBMISSION ONLY
NOT RECOMMENDED FOR SOURCE DOCUMENTATION

Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Post Lg Cx- 36 Month Follow up

Form: Radiation

Generated On: 15 May 2019 14:40:46

Field Name	Data Type	Units	Values	Include Field OID
			2 = SBRT (Stereotactic body radiation therapy) 3 = Proton Therapy 4 = Brachytherap y 99 = Unknown 88 = Other, specify	
9 RT_ST_DT	MMM- dd- YYYY			RT_ST_DT
10 RT_ONGOIN	1 G			RT_ONGOIN G
11 RT_END_DT	MMM- dd- YYYY			RT_END_DT
12 RT_TOTAL_D	6.2 S			RT_TOTAL_D S
13 RT_TOTAL_D	1 S_UNK			RT_TOTAL_D S_UNK

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Folder: Post Lg Cx- 36 Month Follow up

Form: Surgery

Generated On: 15 May 2019 14:40:46

Instructions Provide each surgical procedure, the approach, and date, for all surgeries not previously reported on this form

Surgical Procedure

- Lobectomy ②
- Bilobectomy
- Pneumonectomy
- Wedge resection
- Segmentectomy | segmental resection
- Lymphadenectomy | lymph node sampling
- Chest wall resection
- Thoracentesis
- Partial pleurectomy
- Multiple wedge resections
- Multiple segmental resections
- Other surgical procedure (specify)
- Unknown surgical procedure

Approach

- Exploratory thoracotomy without resection ③
- Median Sternotomy
- Thoracotomy
- Thoracoscopy | Video-assisted (VATS)
- Thoracoscopy | Video-assisted (VATS) with conversion to Thoracotomy
- Other surgical approach (specify)
- Unknown surgical approach

Date

④

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Folder: Post Lg Cx- 36 Month Follow up

Form: Surgery

Generated On: 15 May 2019 14:40:46

Field Name	Data Type	Units	Values	Include Field OID
② SURG_PROC	2		1 = Lobectomy 2 = Bilobectomy 3 = Pneumonectomy 4 = Wedge resection 5 = Segmentectomy segmental resection 6 = Lymphadenectomy lymph node sampling 7 = Chest wall resection 8 = Thoracentesis 9 = Partial pleurectomy 10 = Multiple wedge resections 11 = Multiple segmental resections 88 = Other surgical procedure (specify) 99 = Unknown surgical procedure	SURG_PROC

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Post Lg Cx- 36 Month Follow up

Form: Surgery

Generated On: 15 May 2019 14:40:46

Field Name	Data Type	Units	Values	Include Field OID
③ SURG_APPR OACH	2		1 = Exploratory thoracotomy without resection 2 = Median Sternotomy 3 = Thoracotomy 4 = Thoracoscop y Video-assiste d (VATS) 5 = Thoracoscop y Video-assiste d (VATS) with conversion to Thoracotomy 88 = Other surgical approach (specify) 99 = Unknown surgical approach	SURG_APPR OACH
④ SURGERY_PR OC_DT	dd- yyyy			SURGERY_PR OC_DT

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Folder: Post Lg Cx- 36 Month Follow up

Form: Other Treatment

Generated On: 15 May 2019 14:40:46

Instructions: Provide all other types of treatment not previously reported on this form. Add a new log line for each unique treatment, or each treatment type that has a unique start date.

Type of Treatment

- Immune Therapy ②
- Radio Frequency Ablation
- Thermal Ablation
- Chemical Ablation
- Unknown
- Other, specify

Description of other treatment

③

Treatment Start Date

④

Treatment End Date

⑤

Check if treatment is ongoing

⑥

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Folder: Post Lg Cx- 36 Month Follow up

Form: Other Treatment

Generated On: 15 May 2019 14:40:46

Field Name	Data Type	Units	Values	Include Field OID
② OTH_TX_TYP2 E			1 = Immune Therapy 2 = Radio Frequency Ablation 3 = Thermal Ablation 4 = Chemical Ablation 99 = Unknown 88 = Other, specify	OTH_TX_TYP E
③ OTH_TX_DE SCR	\$200			OTH_TX_DE SCR
④ OTH_TX_ST_ DT	MMM- dd- yyyy			OTH_TX_ST_ DT
⑤ OTH_TX_EN D_DT	MMM- dd- yyyy			OTH_TX_EN D_DT
⑥ OTH_TX_ON G				OTH_TX_ON G

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Provide reason for study disposition by selecting one of the following

- Protocol defined follow up completed ①
- Participant lost to follow up
- Participant refused follow up/withdrew
- Death
- Adverse Event/Side Effects/Complications
- Disease progression
- Study terminated by sponsor
- Protocol violation-did not meet eligibility
- Protocol violation-technical problems
- Protocol violation-related to study visits
- Protocol violation-related to imaging
- Protocol violation-related to biospecimen collection
- Other, specify

Date of Death

Fixed Unit: MMM dd yyyy ②

Cause of Death

- Disease progression ③
- Other, specify

Date of disposition

Fixed Unit: MMM dd yyyy ④

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

① REAS_DISP_N 2			1 = Protocol defined follow up completed 2 = Participant lost to follow up 3 = Participant refused follow up/withdrew 4 = Death 5 = Adverse Event/Side Effects/Complications 6 = Disease progression 7 = Study terminated by sponsor 8 = Protocol violation-did not meet eligibility 9 = Protocol violation-technical problems 10 = Protocol violation-related to study visits 11 = Protocol violation-related to imaging	REAS_DISP_N
-----------------	--	--	---	-------------

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Form: Off Study

Generated On: 15 May 2019 14:40:46

Field Name	Data Type	Units	Values	Include Field OID
			12 = Protocol violation-related to biospecimen collection 88 = Other, specify	
② DT_DEATH	MMM- dd- YYYY			DT_DEATH
③ COD	2		1 = Disease progression 88 = Other, specify	COD
④ DT_DISP	MMM dd yyyy			DT_DISP

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Form: Case Review

Generated On: 15 May 2019 14:40:46

[DM] Check if the case is ready for adjudication review _____ ①

[DM] Date of Follow up with Diagnosis that Needs Review _____ ②

[DM] Site reported diagnosis from Follow up

Lung Cancer ③

Presumed Cancer

Metastatic

Benign

Presumed Benign

Adjudication Review: This form is completed each time the adjudicator reviews the diagnosis as reported during follow up and/or at the end of the study.

Select uncertain for the dx and details of dx questions if additional followup timepoints need to be collected.

Select disagree if the diagnosis has been determined and it does not match the site reported diagnosis

Any cases with disagree selected for dx and/or details will be sent for full adjudication committee review.

Case Reviewer Initials _____ Fixed Unit: FirstMiddleLast ⑤

Do you agree with the final diagnosis as reported on the Study Evaluation and Diagnosis forms? Disagree ⑥

Agree

Uncertain

Do you agree with the cell type, stage, and the histologic class/subtype of the cancer diagnosis? Disagree ⑦

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Agree
Uncertain

Do you agree with the site of origin?

Disagree 8
Agree
Uncertain

If disagree or uncertain, provide the primary site of origin _____

9

Do you agree with the reasoning and the alternative diagnosis for the non cancer diagnosis?

Disagree 10
Agree
Uncertain

Comments _____

11

If uncertain or disagree for dx and/or details of dx, please indicate the next steps.

Full adjudication committee review required 12
Additional SOC Follow up Needed
Adjudicator to Provide Definitive Diagnosis and/orDetails

Are additional medical records required for the definitive diagnosis?

No 13
Yes

Provide comments related to the additional documentation needed _____

14

Adjudication Committee Review: For applicable cases, this section appears when 'disagree' or 'uncertain' is selected by the adjudication reviewer. This section is completed after the adjudication committee completes their review.

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Has the case been reviewed by the adjudication committee? No 16
Yes

Date of Adjudication Committee Review _____ 17

Committee decision Additional SOC Follow up 18
Needed
Definitive Diagnosis
Determined

Indicate the timeframe the case should be re-reviewed by the adjudication committee 0 to 3 months 19
3 to 6 months
6 to 9 months
9 months to 1 year
1 to 1 1/2 years
study 2 year follow up

Adjudication Committee Comments _____ 20

Details of Diagnosis This section of the form should be completed for all cases with a lung cancer diagnosis.

Is the malignancy Primary Lung 22
Metastatic to the Lung
Uncertain
Presumed Cancer- primary lung
Presumed Cancer- metastatic to the lung
Other, specify

Lung Cancer Type Small Cell Lung Cancer 23
Non-Small Cell Lung Cancer

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-
- Carcinoid
 - Unknown
 - Other, specify

Histologic Class

- Adenocarcinoma (24)
- Adenosquamous Carcinoma
- Epidermoid Carcinoma
- Bronchioloalveolar Carcinoma
- Carcinoid
- Large Cell Carcinoma
- Small Cell Carcinoma
- Squamous Cell Carcinoma
- Other, specify
- Unknown

Histologic Subtype

- Acinar (25)
- Bronchioalveola
- Papillary
- Solid carcinoma with mucus formation
- Mixed
- Pure small cell carcinoma
- Combined small cell carcinoma
- Large cell neuroendocrine
- Basaloid
- Lymphoepithelial-like
- Large cell with rhabdoid phenotype
- Unknown
- Other, specify

If metastatic, provide the site of primary origin _____

(26)

Cancer Stage

- Occult 27
- 0
- IA
- IB
- IIA
- IIB
- IIIA
- IIIB
- IV

Provide the reasoning for the no malignancy diagnosis

- Alternate Diagnosis 28
- Resolution of Abnormality
- Stable Mass
- Other, specify

If alternative diagnosis, what is the alternate diagnosis?

- Sarcoid 29
- Altelectasis
- Carcinoid
- Infection
- Other, specify

Provide the type of infection

- TB 30
- Bacterial Pneumonia
- Fungus
- Viral Pneumonia
- Other, specify

Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Form: Case Review

Generated On: 15 May 2019 14:40:46

Field Name	Data Type	Units	Values	Include Field OID
① DM_ADJ_REA1 DU_Y				DM_ADJ_REA DU_Y
② DM_STUDY_ EVAL_DX_DT	MMM dd yyyy			DM_STUDY_ EVAL_DX_DT
③ SITE_REP_D X	2		2 = Lung Cancer 3 = Presumed Cancer 5 = Metastatic 1 = Benign 4 = Presumed Benign	SITE_REP_D X
⑤ CS_RVW_IN T	\$3			CS_RVW_IN T
⑥ CS_RVW_FD X_AGR	2		1 = Disagree 2 = Agree 3 = Uncertain	CS_RVW_FD X_AGR
⑦ CS_RVW_CX DX_AGR	2		1 = Disagree 2 = Agree 3 = Uncertain	CS_RVW_CX DX_AGR
⑧ CS_RVW_ME T_CX_DX_AG R	2		1 = Disagree 2 = Agree 3 = Uncertain	CS_RVW_ME T_CX_DX_AG R

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Form: Case Review

Generated On: 15 May 2019 14:40:46

Field Name	Data Type	Units	Values	Include Field OID
9 DX_MET_SIT 2 E_ORG			Cancer Primary Origin	DX_MET_SIT E_ORG
10 CS_RVW_NC 2 X_DX_AGR			1 = Disagree 2 = Agree 3 = Uncertain	CS_RVW_NC X_DX_AGR
11 CS_RVW_DI \$1999 SAGR_COMM				CS_RVW_DI SAGR_COMM
12 CS_RVW_DC 2 _FU_ADJ			1 = Full adjudication committee review required 2 = Additional SOC Follow up Needed 3 = Adjudicator to Provide Definitive Diagnosis and/orDetails	CS_RVW_DC _FU_ADJ
13 ADD_DOC_R 2 QD_YN			1 = No 2 = Yes	ADD_DOC_R QD_YN
14 ADD_DOC_R \$1999 QD_COMM				ADD_DOC_R QD_COMM
16 CS_RVW_AD 2 J_COMM_YN			1 = No 2 = Yes	CS_RVW_AD J_COMM_YN

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Form: Case Review

Generated On: 15 May 2019 14:40:46

Field Name	Data Type	Units	Values	Include Field OID
17 CS_RVW_AD J_DT	MMM dd yyyy			CS_RVW_AD J_DT
18 ADJ_COMM_ DEC	2		1 = Additional SOC Follow up Needed 2 = Definitive Diagnosis Determined	ADJ_COMM_ DEC
19 ADD_SOC_T ME	2		1 = 0 to 3 months 2 = 3 to 6 months 3 = 6 to 9 months 4 = 9 months to 1 year 5 = 1 to 1 1/2 years 6 = study 2 year follow up	ADD_SOC_T ME
20 ADJ_COMM_ COMMENTS	\$1999			ADJ_COMM_ COMMENTS
22 CS_MLGY_LU NG_ORG	2		1 = Primary Lung 2 = Metastatic to the Lung 3 = Uncertain	CS_MLGY_LU NG_ORG

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Field Name	Data Type	Units	Values	Include Field OID
			4 = Presumed Cancer- primary lung 5 = Presumed Cancer- metastatic to the lung 88 = Other, specify	
23 CS_LG_CX_T YPE			1 = Small Cell Lung Cancer 2 = Non-Small Cell Lung Cancer 3 = Carcinoid 99 = Unknown 88 = Other, specify	CS_LG_CX_T YPE
24 CS_LG_CX_H IST_CLS			4 = Adenocarcino ma 8 = Adenosquam ous Carcinoma 1 = Epidermoid Carcinmoa 5 = Bronchioloalv eolar Carcinoma	CS_LG_CX_H IST_CLS

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Form: Case Review

Generated On: 15 May 2019 14:40:46

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

6 = Carcinoid
 3 = Large
 Cell
 Carcinoma
 7 = Small
 Cell
 Carcinoma
 2 =
 Squamous
 Cell
 Carcinoma
 88 = Other,
 specify
 99 =
 Unknown

25 CS_LG_CX_H2
 IST_SBTYP

1 = Acinar CS_LG_CX_H
 2 = IST_SBTYP
 Bronchioalve
 ola
 3 = Papillary
 4 = Solid
 carcinoma
 with mucus
 formation
 5 = Mixed
 6 = Pure
 small cell
 carcinoma
 7 =
 Combined
 small cell
 carcinoma
 8 = Large
 cell
 neuroendocri
 ne
 9 = Basaloid
 10 =
 Lymphoepith
 elial-like

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Field Name	Data Type	Units	Values	Include Field OID
			11 = Large cell with rhabdoid phenotype 99 = Unknown 88 = Other, specify	
26 CS_CN_SITE 2 _ORG			Cancer Primary Origin	CS_CN_SITE _ORG
27 CS_NSM_CEL2 L_LG_CS_ST G			1 = Occult 2 = 0 3 = IA 4 = IB 5 = IIA 6 = IIB 7 = IIIA 8 = IIIB 9 = IV	CS_NSM_CEL L_LG_CS_ST G
28 CS_NMLGY_ 2 REASON			1 = Alternate Diagnosis 2 = Resolution of Abnormality 3 = Stable Mass 88 = Other, specify	CS_NMLGY_ REASON
29 CS_NMLG_AL2 T_DX_TYPE			1 = Sarcoid 2 = Alvelectasis 3 = Carcinoid 4 = Infection	CS_NMLG_AL T_DX_TYPE

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Form: Case Review

Generated On: 15 May 2019 14:40:46

Field Name	Data Type	Units	Values	Include Field OID
			88 = Other, specify	
30 CS_NMLGY_ 2 ALT_DX_TYP E			1 = TB 2 = Bacterial Pneumonia 3 = Fungus 4 = Viral Pneumonia 88 = Other, specify	CS_NMLGY_ ALT_DX_TYP E

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Date Learning Diagnosis Made _____ ①

Can the diagnosis the case is leaning towards be identified? No ②
Yes
Uncertain

If no or uncertain, provide comment _____ ③

If yes, indicate the diagnosis the case is leaning towards Lung Cancer ④
Presumed Cancer
Metastatic
Benign
Presumed Benign

Indicate the primary reason the case is leaning towards a benign diagnosis Alternate Diagnosis ⑤
Resolution of Abnormality
Stable Mass
Other, specify

If alternative diagnosis, what is the alternate diagnosis? Sarcoid ⑥
Atelectasis
Carcinoid
Infection
Other, specify

Provide the type of infection TB ⑦
Bacterial Pneumonia
Fungus
Viral Pneumonia
Other, specify

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Form: Case Review- No Cx no 2 yr
Generated On: 15 May 2019 14:40:46

Comments

8

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Form: Case Review- No Cx no 2 yr

Generated On: 15 May 2019 14:40:46

Field Name	Data Type	Units	Values	Include Field OID
① ADJ_LFDX_D T	MMM dd yyyy			ADJ_LFDX_D T
② ADJ_ABILITY_2 _FDX			1 = No 2 = Yes 3 = Uncertain	ADJ_ABILITY _FDX
③ ADJ_FDX_UN K	\$200			ADJ_FDX_UN K
④ ADJ_FDX	2		2 = Lung Cancer 3 = Presumed Cancer 5 = Metastatic 1 = Benign 4 = Presumed Benign	ADJ_FDX
⑤ ADJ_NMLGY_2 REASON			1 = Alternate Diagnosis 2 = Resolution of Abnormality 3 = Stable Mass 88 = Other, specify	ADJ_NMLGY_ REASON
⑥ ADJ_NMLG_A LT_DX_TYPE			1 = Sarcoid 2 = Altelectasis	ADJ_NMLG_A LT_DX_TYPE

Draft 25 version 1.0 MIGPROD 17JAN2018: All forms
 Form: Case Review- No Cx no 2 yr
 Generated On: 15 May 2019 14:40:46

Field Name	Data Type	Units	Values	Include Field OID
			3 = Carcinoid 4 = Infection 88 = Other, specify	
⑦ ADJ_NMLGY_2 ALT_DX_TYP E			1 = TB 2 = Bacterial Pneumonia 3 = Fungus 4 = Viral Pneumonia 88 = Other, specify	ADJ_NMLGY_ ALT_DX_TYP E
⑧ ADJ_COMME NTS	\$1999			ADJ_COMME NTS

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Definitive diagnosis for the case This will not appear for cases requiring additional adjudication committee review and/or SOC follow up

Date Definitive Diagnosis was Determined _____ ②

Definitive Diagnosis

Benign/Non-cancerous lesion	<input type="checkbox"/>	③
Malignant, primary	<input type="checkbox"/>	
Malignant, metastatic	<input type="checkbox"/>	
Presumed Cancer- primary	<input type="checkbox"/>	
Presumed Cancer- metastatic	<input type="checkbox"/>	
Presumed Benign	<input type="checkbox"/>	

If presumed cancer, provide the reason

Undergoing treatment for suspicion of cancer	<input type="checkbox"/>	④
Patient Lost to Follow up	<input type="checkbox"/>	
Other, specify	<input type="checkbox"/>	

Please indicate if the study bronchoscopy was diagnostic.

No	<input type="checkbox"/>	⑤
Yes	<input type="checkbox"/>	
Unknown	<input type="checkbox"/>	

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Form: Definitive Diagnosis

Generated On: 15 May 2019 14:40:46

Field Name	Data Type	Units	Values	Include Field OID
② DEF_DX_DT	MMM dd yyyy			DEF_DX_DT
③ DEF_DX	2		1 = Benign/Non-cancerous lesion 2 = Malignant, primary 3 = Malignant, metastatic 4 = Presumed Cancer-primary 5 = Presumed Cancer-metastatic 6 = Presumed Benign	DEF_DX
④ PRE_CX_RSN2			1 = Undergoing treatment for suspicion of cancer 2 = Patient Lost to Follow up 88 = Other, specify	PRE_CX_RSN
⑤ BRONCH_DI AG	2		1 = No 2 = Yes 99 = Unknown	BRONCH_DI AG

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Select the protocol event being reported

- Inclusion / exclusion criteria not met at time of registration **1**
- Imaging-related deviation
- Study activity performed prior to participant signing study consent form
- Visit or follow-up assessments/procedures not performed per protocol
- Case enrolled under expired IRB approval / FWA
- Biospecimen Collection not performed per protocol
- Patient Lung Questionnaire Not Completed
- Other

Provide Reason for Imaging Protocol Deviation

- Missing exam series. Study is incomplete per protocol **2**
- Inconsistent subject identifier
- Image artifact - rendering series non-diagnostic
- Incorrect case number assigned to images
- Incomplete image transfer
- Body weight is incorrect or unknown
- Images lost / unavailable
- Other

Protocol Deviation Occurrence Date

3

Date the Protocol Deviation was Discovered

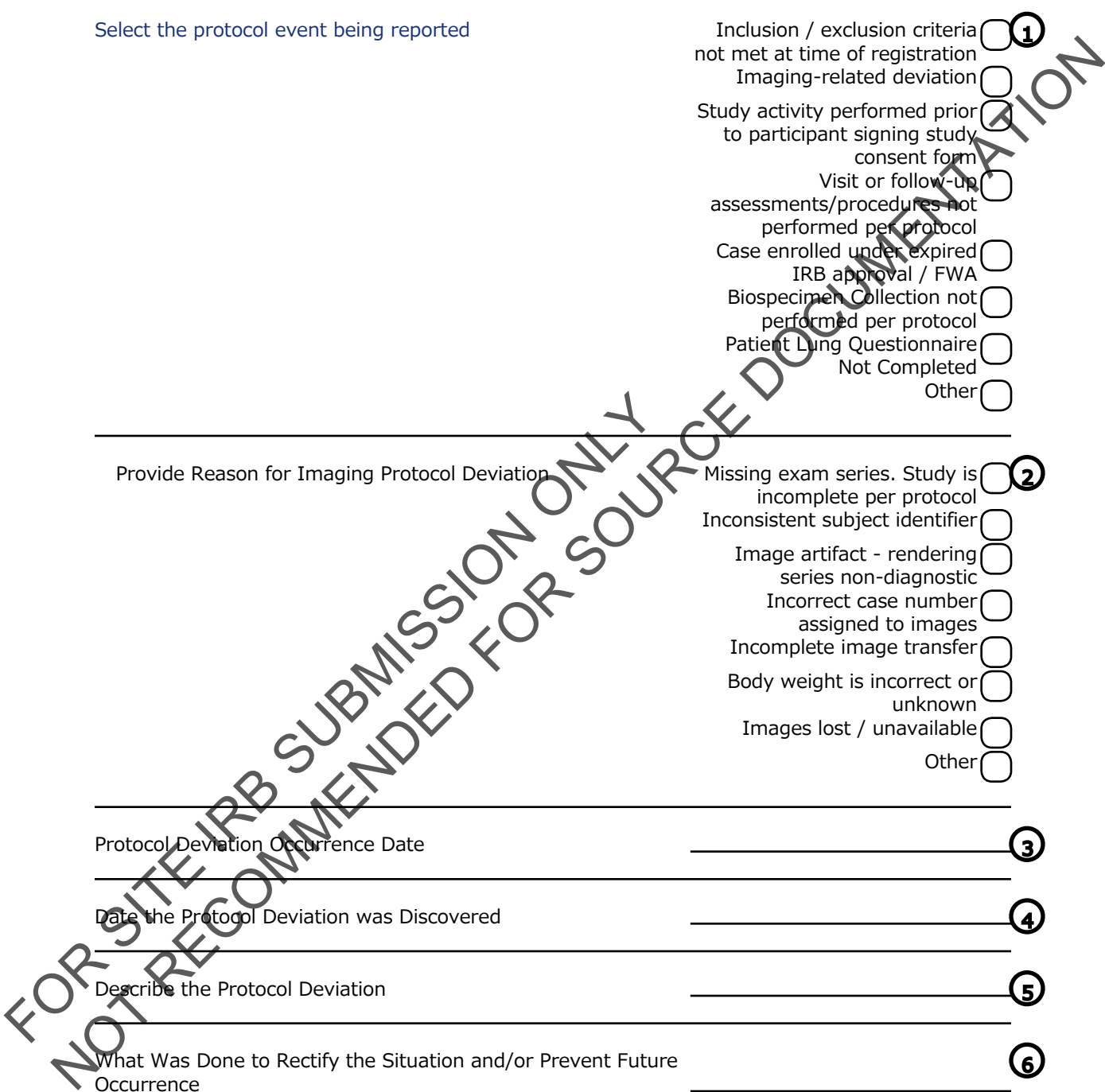
4

Describe the Protocol Deviation

5

What Was Done to Rectify the Situation and/or Prevent Future Occurrence

6



At what reporting period did this Study Deviation Occur

- Eligibility / Registration 7
 - Bronchoscopy
 - Blood Collection
 - Bronchial Airway Brushings
 - Urine Collection (Midstream Clean Catch)
 - Nasal Brushing
 - Buccal Scraping
 - Sputum Samples
 - Urine Processing for Metabolomics Study
 - Biospecimen Transmittal
 - SOC Follow up
 - Follow up- 2 year
 - Baseline Biospecimen Collection [all]
 - Post Lg Cx Biospecimen Collection [all]
 - Other, specify
-

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Form: Protocol Deviation

Generated On: 15 May 2019 14:40:46

Field Name	Data Type	Units	Values	Include Field OID
① RPORT_PROT2 _EVNT			1 = Inclusion / exclusion criteria not met at time of registration 2 = Imaging-relat ed deviation 3 = Study activity performed prior to participant signing study consent form 4 = Visit or follow-up assessments/ procedures not performed per protocol 5 = Case enrolled under expired IRB approval / FWA 6 = Biospecimen Collection not performed per protocol 7 = Patient Lung Questionnair e Not Completed	

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Form: Protocol Deviation

Generated On: 15 May 2019 14:40:46

Field Name	Data Type	Units	Values	Include Field OID
			88 = Other	
② Image Exam 2 Protocol Deviation Reason			1 = Missing exam series. Study is incomplete per protocol 2 = Inconsistent subject identifier 3 = Image artifact-rendering series non-diagnostic 4 = Incorrect case number assigned to images 5 = Incomplete image transfer 6 = Body weight is incorrect or unknown 7 = Images lost / unavailable 88 = Other	RSN_PROT_D DVIAT
③ Protocol Deviation Occurrence Date	MMM dd yyyy			DT_PROT_D VIAT_OCCUR

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Form: Protocol Deviation

Generated On: 15 May 2019 14:40:46

Field Name	Data Type	Units	Values	Include Field OID
④ DT_PROT_D VIAT_DISC	MMM dd yyyy			DT_PROT_D VIAT_DISC
⑤ DESC_PROT_ DVIAT	\$500			DESC_PROT_ DVIAT
⑥ RECT_SITU	\$500			RECT_SITU
⑦ TMPNT_DVIA2 T_OCCUR			1 = Eligibility / Registration 2 = Bronchoscop Y 3 = Blood Collection 4 = Bronchial Airway Brushings 5 = Urine Collection (Midstream Clean Catch) 6 = Nasal Brushing 7 = Buccal Scraping 8 = Sputum Samples 9 = Urine Processing for Metabolomics Study 10 = Biospecimen Transmittal 11 = SOC Follow up	

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms
Form: Protocol Deviation
Generated On: 15 May 2019 14:40:46

Field Name	Data Type	Units	Values	Include Field OID
			12 = Follow up- 2 year 13 = Baseline Biospecimen Collection [all] 14 = Post Lg Cx Biospecimen Collection [all] 88 = Other, specify	

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Instructions: This form appears when the case has had a diagnosis entered on the Study Evaluation and Diagnosis form in one or more of the follow up folders. This form will remain blank until the adjudication committee completes their review. Once their review is completed, this form will automatically populate with the outcome- either the SOC follow up should continue to be entered or the case has been completed per protocol and can be taken off study.

All cases should remain on study and the SOC Follow up entered per protocol until this form indicates the case has been completed per protocol and should be taken off study OR the 2 year follow up time frame has been met

Participant Status Per Adjudication Committee:

Continue to Collect and Enter SOC Followup ②
Diagnosis Confirmed by Adj

Date Adjudication Completed _____ ③

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms
Form: Pt Study Status- ADJ Committee Outcome
Generated On: 15 May 2019 14:40:46

Field Name	Data Type	Units	Values	Include Field OID
② ADJ_COM_D EC_SITE	2		1 = Continue to Collect and Enter SOC Followup 2 = Diagnosis Confirmed by Adj	ADJ_COM_D EC_SITE
③ DT_ADJ_DER V	MMM dd yyyy			DT_ADJ_DER V

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SECTION I. Withdrawal of Consent.

Please complete this form on behalf of your patient whenever your patient withdraws consent to participate in the study.

There is a distinction between discontinuing biospecimen collection and withdrawing consent to submit further data.

Discontinuation of Biospecimen Collection occurs when patient has had at least one biospecimen collection performed, but declines additional biospecimens to be collected. Details related to this type of withdrawal are recorded on the protocol deviation form

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 off study form is also required to be submitted.

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

No 2
Yes

Date study participant withdrew consent _____ 3

Please select the reason(s) for withdrawal: select all that apply

Transportation problems _____ 5

Concerned about privacy _____ 6

Physical illness/cognitive impairment _____ 7

Concerned about medical costs responsibility _____ 8

Concerned about health care effects _____ 9

No reason given _____ 10

Other reason _____ 11

Complete this section only if the patient re-consents to participate in study. Note: All inactivated forms will be re-activated and the target dates of the visits and follow up will re-trigger off the re-consent date

Date of re-consent _____ 13

Reason for change _____ 14

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Form: Withdrawal of Consent

Generated On: 15 May 2019 14:40:46

Field Name	Data Type	Units	Values	Include Field OID
② Patient Withdrawn Consent Clinical Ind-2 PID2199777 _V1_0	1		1 = No 2 = Yes	CLIN_WD_Y N
③ Patient Withdraw Consent Date PID2199780 _V1_0	MMM dd yyyy			WD_CONSEN T_DT
⑤ WOC_RSN_T 1 RANSPORT				WOC_RSN_T RANSPORT
⑥ WOC_RSN_P 1 RIVACY				WOC_RSN_P RIVACY
⑦ WOC_RSN_I 1 LL				WOC_RSN_I LL
⑧ WOC_RSN_C 1 OSTS				WOC_RSN_C OSTS
⑨ WOC_RSN_H EALTH				WOC_RSN_H EALTH
⑩ WOC_RSN_N 1 ONE				WOC_RSN_N ONE
⑪ WOC_RSN_O \$500 THER				WOC_RSN_O THER

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Form: Withdrawal of Consent

Generated On: 15 May 2019 14:40:46

Field Name	Data Type	Units	Values	Include Field OID
13 Patient Amended Consent Date PID3613143_V1_0	MMM dd yyyy			AMEND_CONSENT_DT
14 Consent Withdrawn Change Reason PID4386152_V1_0	\$500			REAS_CHNG_CNSNT

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Subjects diagnosed with lung cancer will be followed for outcomes for three years, per the new study procedures introduced in Amendment 7 of the protocol. Consent will need to be separately obtained for participants enrolled prior to this amendment who have had a lung cancer diagnosis.

Did the participant consent to the outcomes collection of the trial?

No ②
Yes

Indicate the primary reason consent was not given

Amendment not Approved at Site ③
Site error
Participant refused
Other, specify

Derived Date of Diagnosis

④

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Draft 25 version 1.0 MIGPROD 17JAN2018: All forms

Form: Outcomes Consent

Generated On: 15 May 2019 14:40:46

Field Name	Data Type	Units	Values	Include Field OID
② OUT_CON_Y N	2		1 = No 2 = Yes	OUT_CON_Y N
③ OUT_CON_N _RSN	2		1 = Amendment not Approved at Site 2 = Site error 3 = Participant refused 88 = Other, specify	OUT_CON_N _RSN
④ DATE_DX_D ERV	MMM- dd- yyyy			DATE_DX_D ERV

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Each item below must be assessed within XX hours of the study procedure. All other AEs that are possibly, probably, or definitely related to the study procedure that are a grade 3-5 should be reported on the Other Adverse Event Form.

Did the patient experience any other adverse events that were possibly, probably, or definitely related to the study procedure?

No 12
Yes

CTCAE term

Anemia 2

Check if AE not reported by patient

3

Check if AE not evaluated

4

Grade

1- Mild 5
2- Moderate
3- Severe
4- Life-threatening or disabling
5- Death

CTC Adverse Event Attribution Scale

Unrelated 6
Unlikely
Possible
Probable
Definite

Serious AE?

No 7
Yes

Start Date _____ **8**

End Date _____ **9**

Check if ongoing _____ **10**

Comments _____ **11**

CTCAE term _____ Pericardial effusion **2**

Check if AE not reported by patient _____ **3**

Check if AE not evaluated _____ **4**

Grade _____

- 1- Mild **5**
- 2- Moderate
- 3- Severe
- 4- Life-threatening or disabling
- 5- Death

CTC Adverse Event Attribution Scale _____

- Unrelated **6**
- Unlikely
- Possible
- Probable
- Definite

Serious AE? _____

- No **7**
- Yes

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Start Date _____ **8**

End Date _____ **9**

Check if ongoing _____ **10**

Comments _____ **11**

CTCAE term _____ Vertigo **2**

Check if AE not reported by patient _____ **3**

Check if AE not evaluated _____ **4**

Grade _____

- 1- Mild **5**
- 2- Moderate
- 3- Severe
- 4- Life-threatening or disabling
- 5- Death

CTC Adverse Event Attribution Scale _____

- Unrelated **6**
- Unlikely
- Possible
- Probable
- Definite

Serious AE? _____

- No **7**
- Yes

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Form: Solicited AEs
Generated On: 15 May 2019 14:40:46

Start Date _____ ⑧

End Date _____ ⑨

Check if ongoing _____ ⑩

Comments _____ ⑪

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Form: Solicited AEs

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Field Name	Data Type	Units	Values	Include Field OID
② TOXXX	10		CTCAE_403_ TOXXX TERM	
③ AE_NOT_EXP1				AE_NOT_EXP
④ AE_EVAL_YN 1				AE_EVAL_YN
⑤ VALOTH	2		1 = 1- Mild 2 = 2- Moderate 3 = 3- Severe 4 = 4- Life-threatening or disabling 5 = 5- Death	VALOTH
⑥ TOX_RLXX	1		1 = Unrelated 2 = Unlikely 3 = Possible 4 = Probable 5 = Definite	TOX_RLXX
⑦ AER_XX	1		1 = No 2 = Yes	AER_XX
⑧ AE_START_D T	DDMMYY			AE_START_D T
⑨ AE_END_DT	DDMMYY			AE_END_DT

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Form: Solicited AEs

Generated On: 15 May 2019 14:40:46

Field Name	Data Type	Units	Values	Include Field OID
⑩ AE_ONGOIN G	1			AE_ONGOIN G
⑪ COMTOXOTH	\$200			COMTOXOTH
⑫ OTH_SAE_Y N	2		1 = No 2 = Yes	OTH_SAE_Y N

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