

Subject Case Report Forms  
PROD\_22MAR2018\_1.00 - UNIQUE

Signature Prompt: By my dated signature below, I verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject. Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that I intend that this electronic signature is to be the legally binding equivalent of my handwritten signature. To this I do attest by supplying my user name and password and clicking the button below.

**DM = Demographics**

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: Subject Enrollment Form**

**Generated On: 22 Mar 2018 22:20:59**

---

Subject ID

**SUBJID**

**①**

---

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: Subject Enrollment Form**

**Generated On: 22 Mar 2018 22:20:59**

---

Field Name	Data Type	Units	Values	Include Field OID
① SUBJECT	\$9		SUBJECT	

---

**SV = Subject Visits**

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name:** NEKNKTR1726201

**Form:** Visit

**Generated On:** 22 Mar 2018 22:20:59

---

Not Done

**SUPPSV.QVAL where QNAM = VISITND**

**1**

If Not Done, specify reason

Planned - scheduling conflict

**2**

Unplanned

**SUPPSV.QVAL where QNAM = VISREAS**

---

Visit Date (dd-mon-yyyy)

**SVSTDTC**

**SVENDTC**

**3**

---

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name:** NEKNKTR1726201

**Form:** Visit

**Generated On:** 22 Mar 2018 22:20:59

---

Field Name	Data Type	Units	Values	Include Field OID
① VISITND	1		VISITND	
② VISREAS	\$29		Planned - scheduling conflict = Planned - scheduling conflict Unplanned = Unplanned	VISREAS
③ VISDAT	dd MMM yyyy			VISDAT

---

**SV = Subject Visits**

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: Unscheduled**

**Generated On: 22 Mar 2018 22:20:59**

Physical Exam	SVUPDES	1
Vital Signs		2
Echocardiogram		3
Ophthalmology Exam		4
Central Labs		5
NKTR-262 Administration		6
NKTR-214 Administration		7
MOA Sample		8
Biomarker Sample		9
PK Sample NKTR-214 (non-dosing day)		10
PK NKTR-262 (non-dosing day)		11
PK Sample NKTR-262 (Unscheduled)		12
PK Sample NKTR-214 (Unscheduled)		13
Tumor Biopsy		14

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name:** NEKNKTR1726201

**Form:** Unscheduled

**Generated On:** 22 Mar 2018 22:20:59

	Field Name	Data Type	Units	Values	Include Field OID
①	UNS_PE	1			UNS_PE
②	UNS_VS1	1			UNS_VS1
③	UNS_ECHO	1			UNS_ECHO
④	UNS_OA2	1			UNS_OA2
⑤	UNS_CL	1			UNS_CL
⑥	UNS_EX262	1			UNS_EX262
⑦	UNS_EX214	1			UNS_EX214
⑧	UNS_LBMO	1	A		UNS_LBMO A
⑨	UNS_PD	1			UNS_PD
⑩	UNS_PC8	1			UNS_PC8
⑪	UNS_PC2	1			UNS_PC2
⑫	UNS_PC1	1			UNS_PC1

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name:** NEKNKTR1726201

**Form:** Unscheduled

**Generated On:** 22 Mar 2018 22:20:59

---

Field Name	Data Type	Units	Values	Include Field OID
⑬ UNS_PC6	1			UNS_PC6
⑭ UNS_TB	1			UNS_TB

---

DS = Disposition

PROD\_22MAR2018\_1.00: UNIQUE

Project Name: NEKNKTR1726201

DSCAT = PROTOCOL MILESTONE

Form: Re-Consent

DSTERM where DSDECOD = INFORMED CONSENT OBTAINED

Generated On: 22 Mar 2018 22:20:59

DSSCAT = RE-CONSENT

---

Patient Re-Consented to Amendment Number

SUPPDS.QVAL where QNAM = REICFNUM

- 1  ①  
2   
3   
4   
5
- 

Date of Re-Consent (dd-mon-yyyy)

DSSTDTC

②

---

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name:** NEKNKTR1726201

**Form:** Re-Consent

**Generated On:** 22 Mar 2018 22:20:59

---

Field Name	Data Type	Units	Values	Include Field OID
① DSRCAM	1		1 = 1 2 = 2 3 = 3 4 = 4 5 = 5	DSRCAM
② DSDAT	dd MMM yyyy			DSDAT

---

**DS = Disposition**

**DM = Demographics**

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: Patient Information**

**Generated On: 22 Mar 2018 22:20:59**

SUPPDM.QVAL where QNAM = TIVERS if m

Under which protocol version was the patient enrolled?

- Amendment 2  ①  
Amendment 3   
Amendment 4

SUPPDS.QVAL where QNAM = PATAMEND

Phase of Study

- Dose Escalation (Phase 1)  ②  
Dose Expansion (Phase 2)

Used to derive ARM

Cohort Enrolled

SUPPDM.QVAL where QNAM = COHORT

- C-2 Ph1 Cohort -2: 0.008mg  ③  
C-1 Ph1 Cohort -1: 0.015mg   
C01 Ph1 Cohort 1: 0.03mg   
C02 Ph1 Cohort 2: 0.06mg   
C03 Ph1 Cohort 3: 0.06mg   
C04 Ph1 Cohort 4: 0.12mg   
C05 Ph1 Cohort 5: 0.24mg   
CA Ph1 Cohort A: 0.24mg   
CB Ph1 Cohort B: 0.24mg   
MEL-1L Ph2 Melanoma (1L)   
MEL-RR Ph2 Melanoma (RR)   
MCC-1L Ph2 Merkel Cell Carcinoma (MCC-1L)   
MCC-RR Ph2 Merkel Cell Carcinoma (MCC-RR)   
TNBC-1-2L Ph2   
Triple-Negative Breast Cancer (TNBC-1-2L)   
TNBC-RR Ph2   
Triple-Negative Breast Cancer (TNBC-RR)   
OC-2-3L Ph2 Ovarian Cancer (2-3L)   
OC-RR Ph2 Ovarian Cancer (RR)

**DM = Demographics**

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: Patient Information**

**Generated On: 22 Mar 2018 22:20:59**

---

SUPPDM.QVAL where QNAM = COHORT	RCC-1L Ph2 Renal Cell <input type="checkbox"/>
	Carcinoma (RCC-1L) <input type="checkbox"/>
	RCC-RR Ph2 Renal Cell <input type="checkbox"/>
	Carcinoma (RCC-RR) <input type="checkbox"/>
	CRC-2L Ph2 Colorectal <input type="checkbox"/>
	Cancer (2L) <input type="checkbox"/>
	CRC-RR Ph2 Colorectal <input type="checkbox"/>
	Cancer (RR) <input type="checkbox"/>
	URO-1L Ph2 Urothelial <input type="checkbox"/>
	Carcinoma (1L) <input type="checkbox"/>
	URO-RR Ph2 Urothelial <input type="checkbox"/>
	Carcinoma (RR) <input type="checkbox"/>
	SAR-2L Ph2 Sarcoma (2L) <input type="checkbox"/>
	SAR-RR Ph2 Sarcoma (RR) <input type="checkbox"/>

---

DERIVED:NOW

NOT SUBMITTED

④

---

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: Patient Information**

**Generated On: 22 Mar 2018 22:20:59**

---

Field Name	Data Type	Units	Values	Include Field OID
① TIVERS	\$11		Amendment 2 = Amendment 2 Amendment 3 = Amendment 3 Amendment 4 = Amendment 4	TIVERS
② PATPHASE	\$30		Dose Escalation = Dose Escalation (Phase 1) Dose Expansion = Dose Expansion (Phase 2)	PATPHASE

---

**PROD\_22MAR2018\_1.00: UNIQUE****Project Name: NEKNKTR1726201****Form: Patient Information****Generated On: 22 Mar 2018 22:20:59**

Field Name	Data Type	Units	Values	Include Field OID
③ PATCOHE	\$55		C-2 Ph1 Cohort -2: 0.008mg = C-2 Ph1 Cohort -2: 0.008mg C-1 Ph1 Cohort -1: 0.015mg = C-1 Ph1 Cohort -1: 0.015mg C01 Ph1 Cohort 1: 0.03mg = C01 Ph1 Cohort 1: 0.03mg C02 Ph1 Cohort 2: 0.06mg = C02 Ph1 Cohort 2: 0.06mg C03 Ph1 Cohort 3: 0.06mg = C03 Ph1 Cohort 3: 0.06mg	PATCOHE

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: Patient Information**

**Generated On: 22 Mar 2018 22:20:59**

---

Field Name	Data Type	Units	Values	Include Field OID
			C04 Ph1 Cohort 4: 0.12mg = C04 Ph1 Cohort 4: 0.12mg C05 Ph1 Cohort 5: 0.24mg = C05 Ph1 Cohort 5: 0.24mg CA Ph1 Cohort A: 0.24mg = CA Ph1 Cohort A: 0.24mg CB Ph1 Cohort B: 0.24mg = CB Ph1 Cohort B: 0.24mg MEL-1L Ph2 Melanoma (1L) = MEL-1L Ph2 Melanoma (1L)	

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: Patient Information**

**Generated On: 22 Mar 2018 22:20:59**

---

Field Name	Data Type	Units	Values	Include Field OID
			MEL-RR	
			Ph2	
			Melanoma	
			(RR) =	
			MEL-RR	
			Ph2	
			Melanoma	
			(RR)	
			MCC-1L	
			Ph2 Merkel	
			Cell	
			Carcinoma	
			(MCC-1L) =	
			MCC-1L	
			Ph2 Merkel	
			Cell	
			Carcinoma	
			(MCC-1L)	
			MCC-RR	
			Ph2 Merkel	
			Cell	
			Carcinoma	
			(MCC-RR)	

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: Patient Information**

**Generated On: 22 Mar 2018 22:20:59**

---

Field Name	Data Type	Units	Values	Include Field OID
			TNBC-1-2L Ph2 Triple-Negati ve Breast Cancer (TNBC-1-2L )= TNBC-1-2L Ph2 Triple-Negati ve Breast Cancer (TNBC-1-2L ) TNBC-RR Ph2 Triple-Negati ve Breast Cancer (TNBC-RR) = TNBC-RR Ph2 Triple-Negati ve Breast Cancer (TNBC-RR)	

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: Patient Information**

**Generated On: 22 Mar 2018 22:20:59**

---

Field Name	Data Type	Units	Values	Include Field OID
			OC-2-3L Ph2 Ovarian Cancer (2-3L)= OC-2-3L Ph2 Ovarian Cancer (2-3L) OC-RR Ph2 Ovarian Cancer (RR) = OC-RR Ph2 Ovarian Cancer (RR) RCC-1L Ph2 Renal Cell Carcinoma (RCC-1L)= RCC-1L Ph2 Renal Cell Carcinoma (RCC-1L) RCC-RR Ph2 Renal Cell Carcinoma (RCC-RR)= RCC-RR Ph2 Renal Cell Carcinoma (RCC-RR)	

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: Patient Information**

**Generated On: 22 Mar 2018 22:20:59**

---

Field Name	Data Type	Units	Values	Include Field OID
			CRC-2L Ph2	
			Colorectal	
			Cancer (2L)	
			= CRC-2L	
			Ph2	
			Colorectal	
			Cancer (2L)	
			CRC-RR	
			Ph2	
			Colorectal	
			Cancer (RR)	
			= CRC-RR	
			Ph2	
			Colorectal	
			Cancer (RR)	
			URO-1L Ph2	
			Urothelial	
			Carcinoma	
			(1L) =	
			URO-1L Ph2	
			Urothelial	
			Carcinoma	
			(1L)	
			URO-RR	
			Ph2	
			Urothelial	
			Carcinoma	
			(RR) =	
			URO-RR	
			Ph2	
			Urothelial	
			Carcinoma	
			(RR)	

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: Patient Information**

**Generated On: 22 Mar 2018 22:20:59**

---

Field Name	Data Type	Units	Values	Include Field OID
			SAR-2L Ph2 Sarcoma (2L)= SAR-2L Ph2 Sarcoma (2L) SAR-RR Ph2 Sarcoma (RR)= SAR-RR Ph2 Sarcoma (RR)	
④ Z_NOW	dd MMM yyyy HH nn ss		Z_NOW	

---

**DS** = Disposition

**DM** = Demographics

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name:** NEKNKTR1726201

**Form:** Informed Consent

**DSSCAT = INFORMED CONSENT**

**Generated On:** 22 Mar 2018 22:20:59

---

Informed Consent Obtained

INFORMED CONSENT **①**  
OBTAINED

**DSTERM/DSDECOD = INFORMED CONSENT OBTAINED**

---

Protocol Milestone

**DSCAT = PROTOCOL MILESTONE**

PROTOCOL MILESTONE **②**

---

Date of Informed Consent (dd-mon-yyyy)

**RFICDTC DSSTDTC**

**③**

---

Will the subject allow for future use of their tumor tissues  
and/or blood samples in future research?

Yes  **④**  
No

**SUPPDS.QVAL where QNAM = DSOPT**

---

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name:** NEKNKTR1726201

**Form:** Informed Consent

**Generated On:** 22 Mar 2018 22:20:59

---

	Field Name	Data Type	Units	Values	Include Field OID
①	DSTERM	\$30		INFORMED CONSENT OBTAINED	
②	DSCAT	\$20		PROTOCOL MILESTON E	
③	DSDAT	dd MMM yyyy			DSDAT
④	DSOPT	\$1		Y = Yes N = No	DSOPT

---

**DM = Demographics**

**SC = Subject Characteristics**

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: Demographics**

**Generated On: 22 Mar 2018 22:20:59**

---

Year of Birth  
(Integrated from IRT)

**BRTHDTC**

**①**

---

Age  
(Integrated from IRT)

**AGE**

**②**

---

Age Units

**AGEU**

**YEARS**

**③**

---

Sex  
(Integrated from IRT)

**SEX**

Female



**④**

Male



---

If Female, Reproductive Status

**SCCAT = REPRODUCTIVE STATUS**

Of Child-bearing Potential

Surgically Sterile

Post-menopausal



---

Ethnicity

Hispanic or Latino



Not Hispanic or Latino



Not Reported

**ETHNIC**

Unknown



**⑥**

---

Race

RACEif multiple races are selected the

American Indian or Alaska

Native

Asian



Black or African American



Native Hawaiian or Other

Pacific Islander

White



Other



**SUPPDM.QVAL where QNAM = RACE1 / RACE2 /**

**⑦**

**DM = Demographics**

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: Demographics**

**Generated On: 22 Mar 2018 22:20:59**

---

If Other Race, specify

**SUPPDM.QVAL where QNAM = RACEOTH**

**⑧**

---

**PROD\_22MAR2018\_1.00: UNIQUE****Project Name:** NEKNKTR1726201**Form:** Demographics**Generated On:** 22 Mar 2018 22:20:59

	Field Name	Data Type	Units	Values	Include Field OID
①	BRTHDAT	yyyy			BRTHDAT
②	AGE	3			AGE
③	AGEU	\$5		YEARS	AGEU
④	SEX	\$1		F = Female M = Male	SEX
⑤	SCORRES	\$26		Of Child-bearin g Potential = Of Child-bearin g Potential Surgically Sterile = Surgically Sterile Post-menopa usal = Post-menopa usal	SCORRES
⑥	ETHNIC	\$22		HISPANIC OR LATINO = Hispanic or Latino	ETHNIC

**PROD\_22MAR2018\_1.00: UNIQUE****Project Name:** NEKNKTR1726201**Form:** Demographics**Generated On:** 22 Mar 2018 22:20:59

Field Name	Data Type	Units	Values	Include Field OID
			NOT HISPANIC OR LATINO = Not Hispanic or Latino NOT REPORTED = Not Reported U = Unknown	
⑦ RACE	\$2		1 = American Indian or Alaska Native 2 = Asian 3 = Black or African American 4 = Native Hawaiian or Other Pacific Islander 5 = White 99 = Other	RACE
⑧ RACESPEC	\$50			RACESPEC

IE = Inclusion/Exclusion Criteria Not Met

DS = Disposition

PROD\_22MAR2018\_1.00: UNIQUE

Project Name: NEKNKTR1726201

Form: Inclusion / Exclusion Criteria

Generated On: 22 Mar 2018 22:20:59

DTERM/DSDECOD = ELIGIBILITY CRITERIA MET where DS

Did the subject meet all General Eligibility Criteria?

Yes  1  
No

DTERM/DSDECOD = SCREEN FAILURE where DSCAT =

If No, Please enter all criterion not met below

Criterion Identifier

IETESTCD  
INCL01  3

INCL02

INCL03

INCL04

INCL05

INCL06

INCL07

INCL08

INCL09.a

INCL09.b

INCL09.c

INCL09.d

INCL09.e

INCL09.f

INCL09.g

INCL09.h

INCL10

INCL11

INCL12

INCL13

INCL14

INCL15

INCL16.a

INCL16.b

INCL16.c

IEORRES = N where IECAT = IN

IEORRES = Y where IECAT = E

[IE = Inclusion/Exclusion Criteria Not Met]

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name:** NEKNKTR1726201

**Form:** Inclusion / Exclusion Criteria

**Generated On:** 22 Mar 2018 22:20:59

[IETESTCD]
INCL16.d
INCL16.e
INCL16.f
INCL17
EXCL01
EXCL02
EXCL03
EXCL04
EXCL05
EXCL06
EXCL07
EXCL08
EXCL09
EXCL10
EXCL11
EXCL12
EXCL13
EXCL14
EXCL15
EXCL16
EXCL17
EXCL18
EXCL19
EXCL20.a
EXCL20.b
EXCL20.c
EXCL21
EXCL22
EXCL23
EXCL24

[IEORRES = Y where IECAT = ]

**PROD\_22MAR2018\_1.00: UNIQUE****Project Name:** NEKNKTR1726201**Form:** Inclusion / Exclusion Criteria**Generated On:** 22 Mar 2018 22:20:59

---

Field Name	Data Type	Units	Values	Include Field OID
① IEYN	\$1		Y = Yes N = No	IEYN
③ IETESTCD	\$8		INCL01 = INCL01 INCL02 = INCL02 INCL03 = INCL03 INCL04 = INCL04 INCL05 = INCL05 INCL06 = INCL06 INCL07 = INCL07 INCL08 = INCL08 INCL09.a = INCL09.a INCL09.b = INCL09.b INCL09.c = INCL09.c INCL09.d = INCL09.d INCL09.e = INCL09.e INCL09.f = INCL09.f INCL09.g = INCL09.g	IETESTCD

---

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name:** NEKNKTR1726201

**Form:** Inclusion / Exclusion Criteria

**Generated On:** 22 Mar 2018 22:20:59

---

Field Name	Data Type	Units	Values	Include Field OID
			INCL09.h =	
			INCL09.h	
			INCL10 =	
			INCL10	
			INCL11 =	
			INCL11	
			INCL12 =	
			INCL12	
			INCL13 =	
			INCL13	
			INCL14 =	
			INCL14	
			INCL15 =	
			INCL15	
			INCL16.a =	
			INCL16.a	
			INCL16.b =	
			INCL16.b	
			INCL16.c =	
			INCL16.c	
			INCL16.d =	
			INCL16.d	
			INCL16.e =	
			INCL16.e	
			INCL16.f =	
			INCL16.f	
			INCL17 =	
			INCL17	
			EXCL01 =	
			EXCL01	
			EXCL02 =	
			EXCL02	
			EXCL03 =	
			EXCL03	

---

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name:** NEKNKTR1726201

**Form:** Inclusion / Exclusion Criteria

**Generated On:** 22 Mar 2018 22:20:59

---

Field Name	Data Type	Units	Values	Include Field OID
			EXCL04 =	
			EXCL04	
			EXCL05 =	
			EXCL05	
			EXCL06 =	
			EXCL06	
			EXCL07 =	
			EXCL07	
			EXCL08 =	
			EXCL08	
			EXCL09 =	
			EXCL09	
			EXCL10 =	
			EXCL10	
			EXCL11 =	
			EXCL11	
			EXCL12 =	
			EXCL12	
			EXCL13 =	
			EXCL13	
			EXCL14 =	
			EXCL14	
			EXCL15 =	
			EXCL15	
			EXCL16 =	
			EXCL16	
			EXCL17 =	
			EXCL17	
			EXCL18 =	
			EXCL18	
			EXCL19 =	
			EXCL19	
			EXCL20.a =	
			EXCL20.a	

---

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name:** NEKNKTR1726201

**Form:** Inclusion / Exclusion Criteria

**Generated On:** 22 Mar 2018 22:20:59

---

Field Name	Data Type	Units	Values	Include Field OID
			EXCL20.b =	
			EXCL20.b	
			EXCL20.c =	
			EXCL20.c	
			EXCL21 =	
			EXCL21	
			EXCL22 =	
			EXCL22	
			EXCL23 =	
			EXCL23	
			EXCL24 =	
			EXCL24	

---

DM = Demographics

PROD\_22MAR2018\_1.00: UNIQUE

Project Name: NEKNKTR1726201

Form: Inclusion/Exclusion for Specific Lesion Types

Generated On: 22 Mar 2018 22:20:59

---

Please indicate the tumor type. If necessary, please indicate identifier for the failed specific tumor type criteria as specified in the protocol.

---

Please select tumor type

Colorectal Cancer  ②

Melanoma

Merkel Cell Carcinoma  
(MCC)

Ovarian Cancer

Renal Cell Carcinoma (RCC)

Sarcoma

Triple-Negative Breast Cancer  
(TNBC)

Urothelial Carcinoma

---

Did subject meet all inclusion criteria for specific tumor type?

Yes  ③

No

---

If No, please indicate criterion not met

a  ④

b

c

c. i

c. ii

c. iii

c. iv

c. v

d

e

f

g

---

---

SUPPDM.QVAL where QNAM = IESPTUYN

If multiple criteria are selected, these will be

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: Inclusion/Exclusion for Specific Lesion Types**

**Generated On: 22 Mar 2018 22:20:59**

---

DERIVED:NOW

NOT SUBMITTED

⑤

---

**PROD\_22MAR2018\_1.00: UNIQUE****Project Name: NEKNKTR1726201****Form: Inclusion/Exclusion for Specific Lesion Types****Generated On: 22 Mar 2018 22:20:59**

Field Name	Data Type	Units	Values	Include Field OID
② IECAT	\$25		Colorectal Cancer = Colorectal Cancer Melanoma = Melanoma MCC = Merkel Cell Carcinoma (MCC) Ovarian Cancer = Ovarian Cancer RCC = Renal Cell Carcinoma (RCC) Sarcoma = Sarcoma TNBC = Triple-Negati ve Breast Cancer (TNBC) Urothelial Carcinoma = Urothelial Carcinoma	IECAT
③ IEYN	\$1		Y = Yes N = No	IEYN

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: Inclusion/Exclusion for Specific Lesion Types**

**Generated On: 22 Mar 2018 22:20:59**

---

Field Name	Data Type	Units	Values	Include Field OID
④ IETESTC	\$6		a = a b = b c = c c. i = c. i c. ii = c. ii c. iii = c. iii c. iv = c. iv c. v = c. v d = d e = e f = f g = g	IETESTC
⑤ Z_NOW		dd MMM yyyy HH nn ss		Z_NOW

---

MH = Medical History

PROD\_22MAR2018\_1.00: UNIQUE

Project Name: NEKNKTR1726201

Form: Medical History

Generated On: 22 Mar 2018 22:20:59

MHCAT = MEDICAL HISTORY

Has the subject experienced any past and / or concomitant diseases or non-cancer related surgeries?

NOT SUBMITTED

Yes  ①  
No

Diagnosis

MHTERM

②

Onset Date (dd-mon-yyyy)

MHSTDTC

③

Ongoing

MHENRF

Yes  ④  
No

End Date (dd-mon-yyyy)

MHENDTC

⑤

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name:** NEKNKTR1726201

**Form:** Medical History

**Generated On:** 22 Mar 2018 22:20:59

---

	Field Name	Data Type	Units	Values	Include Field OID
①	MHYN	\$1		Y = Yes N = No	MHYN
②	MHTERM	\$100			MHTERM
③	MHSTDAT	dd- MMM- yyyy			MHSTDAT
④	MHONGO	\$1		Y = Yes N = No	MHONGO
⑤	MHENDAT	dd- MMM- yyyy			MHENDAT

---

SC = Subject Characteristics

PROD\_22MAR2018\_1.00: UNIQUE

Project Name: NEKNKTR1726201

Form: Melanoma Cancer History

SCCAT = CANCER HISTORY

Generated On: 22 Mar 2018 22:20:59

Primary Cancer Diagnosis

SCORRES where SCTESTCD = CHDIAG

Melanoma **1**

M stage at study entry

M0  **2**

M1a

M1b

M1c

SCORRES where SCTESTCD = CHMSTG

BRAF Status

Mutant  **3**

Wild Type

SCORRES where SCTESTCD = CHBRAFPN

If BRAF Status is **Mutant** (check all that apply)

SCORRES where SCTESTCD = CHBRAF

Allele V600E

**5**

Allele V600K

**6**

Other Allele

**7**

If Other, specify Mutant BRAF Alleles

SUPPSC.QVAL where QNAM = CHBRAFSP

**8**

KRAS Status

Mutant  **9**

Wild Type

Unknown

SCORRES where SCTESTCD = CHKRAS

MSI High

Yes  **10**

No

Unknown

SCORRES where SCTESTCD = CHMSI

**SC = Subject Characteristics**

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: Melanoma Cancer History**

**Generated On: 22 Mar 2018 22:20:59**

---

Date of Initial Primary Cancer Diagnosis (dd-mon-yyyy) **SCDTC** **11**

---

Date of Initial Metastasis Diagnosis or Most Recent Local Recurrence (dd-mon-yyyy) **SCDTC** **12**

---

Current Status Metastatic  **13**  
Locally Recurrent   
**SCORRES where SCTESTCD = CHCURST**

---

Stage at Most Recent Recurrence III  **14**  
IV   
**SCORRES where SCTESTCD = CHSTAG2**

---

Brain Metastases History? Yes  **15**  
No   
Unknown   
**SCORRES where SCTESTCD = CHBM**

---

Date of Initial Brain Metastasis Diagnosis (dd-mon-yyyy) **SCDTC** **16**

---

**Last known PD-L1 status**

---

Date of last known PD-L1 status (dd-mon-yyyy) **SCDTC** **18**

---

Assay used 22C3  **19**  
28-8   
**SCORRES where SCTESTCD = CHUSED** SP142   
SP263   
Not Done   
Other

---

---

**SC = Subject Characteristics**

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: Melanoma Cancer History**

**Generated On: 22 Mar 2018 22:20:59**

---

If Other, specify assay used

**SUPPSC.QVAL where QNAM = CHUSEDSP**

**20**

## Results

---

Please enter PD-L1%

**SCORRES where SCTESTCD = CHPD**

**22**

**SCORRESU = %**

Is this result considered?

- Positive  **23**
- Negative
- Unknown
- Other

**SCORRES where SCTESTCD = CHPDL1**

If Other, specify result status

**SUPPSC.QVAL where QNAM = CHPDL1SP**

**24**

---

**PROD\_22MAR2018\_1.00: UNIQUE****Project Name:** NEKNKTR1726201**Form:** Melanoma Cancer History**Generated On:** 22 Mar 2018 22:20:59

	Field Name	Data Type	Units	Values	Include Field OID
①	CHDIAG	\$29		Melanoma	CHDIAG
②	CHMSTAG	\$3		M0 = M0 M1a = M1a M1b = M1b M1c = M1c	CHMSTAG
③	CHBRAF	\$12		Mutant = Mutant Wild Type = Wild Type	CHBRAF
⑤	CHV600E	1			CHV600E
⑥	CHV600K	1			CHV600K
⑦	CHV6OTH	1			CHV6OTH
⑧	CHOTH	\$20			CHOTH
⑨	CHKRAS	\$12		Mutant = Mutant Wild Type = Wild Type Unknown = Unknown	CHKRAS

**PROD\_22MAR2018\_1.00: UNIQUE****Project Name:** NEKNKTR1726201**Form:** Melanoma Cancer History**Generated On:** 22 Mar 2018 22:20:59

	Field Name	Data Type	Units	Values	Include Field OID
⑩	CHMSI	\$7		Y = Yes N = No U = Unknown	CHMSI
⑪	CHDAT1		dd- MMM- yyyy		CHDAT1
⑫	CHDAT2		dd- MMM- yyyy		CHDAT2
⑬	CHCURST	\$17		Metastatic = CHCURST Metastatic Locally Recurrent = Locally Recurrent	
⑭	CHSTAG2	\$3		III = III IV = IV	CHSTAG2
⑮	CHBM	\$1		Y = Yes N = No U = Unknown	CHBM
⑯	CHDAT3		dd- MMM- yyyy		CHDAT3

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name:** NEKNKTR1726201

**Form:** Melanoma Cancer History

**Generated On:** 22 Mar 2018 22:20:59

---

	Field Name	Data Type	Units	Values	Include Field OID
⑯	PDL1DAT	dd MMM yyyy			PDL1DAT
⑰	CHAS	\$8		22C3 = 22C3CHAS 28-8 = 28-8 SP142 = SP142 SP263 = SP263 NOT DONE = Not Done OTHER = Other	
⑱	CHSP3	\$25			CHSP3
⑲	CHPD	8.3			CHPD
⑳	CHRSTAT	\$8		POSITIVE = CHRSTAT Positive NEGATIVE = Negative UNKNOWN = Unknown OTHER = Other	
㉑	CHSP4	\$25			CHSP4

---

---

**SC = Subject Characteristics**

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: RCC Cancer History**

**SCCAT = CANCER HISTORY**

**Generated On: 22 Mar 2018 22:20:59**

---

Primary Cancer Diagnosis

Renal Cell Carcinoma **1**

**SCORRES where SCTESTCD = CHDIAG**

Karnofsky Status

100 **2**  
90  
80  
70  
<70

**SCORRES where SCTESTCD = CHKAR**

Baseline IMDC prognostic score

0 (favorable) **3**  
1-2 (intermediate)  
3-6 (poor)  
Not reported

**SCORRES where SCTESTCD = CHIMDC**

Prior nephrectomy status

Yes **4**  
No

**SCORRES where SCTESTCD = CHNEPH**

**Histological Sub-type (Check all that apply)**

**SCORRES where SCTESTCD = CHSUBTYP**

Clear cell

**6**

Papillary

**7**

Chromophobe

**8**

Unknown

**9**

Other

**10**

**SC = Subject Characteristics**

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: RCC Cancer History**

**Generated On: 22 Mar 2018 22:20:59**

---

If Other, specify

**SUPPSC.QVAL where QNAM = CHTYPEPSP**

**(11)**

---

MSI High

**SCORRES where SCTESTCD = CHMSI**

Yes

No

Unknown

---

Date of Initial Primary Cancer Diagnosis (dd-mon-yyyy)

**SCDTC**

**(13)**

---

Date of Initial Metastasis Diagnosis or Most Recent Local Recurrence (dd-mon-yyyy)

**SCDTC**

**(14)**

---

Current Status

**SCORRES where SCTESTCD = CHCURST**

Metastatic

Locally Recurrent

**(15)**

---

Stage at Most Recent Recurrence

**SCORRES where SCTESTCD = CHSTAG2**

III

IV

**(16)**

---

Brain Metastases History?

**SCORRES where SCTESTCD = CHBM**

Yes

No

Unknown

**(17)**

---

Date of Initial Brain Metastasis Diagnosis (dd-mon-yyyy)

**SCDTC**

**(18)**

---

**Last known PD-L1 status**

---

Date of last known PD-L1 status (dd-mon-yyyy)

**SCDTC**

**(20)**

**SC = Subject Characteristics**

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: RCC Cancer History**

**Generated On: 22 Mar 2018 22:20:59**

---

Assay used

- 22C3  **21**  
28-8   
SP142   
SP263   
Not Done   
Other

**SCORRES where SCTESTCD = CHUSED**

---

If Other, specify assay used

**SUPPSC.QVAL where QNAM = CHUSEDSP**

---

## Results

---

Please enter PD-L1%

**SCORRES where SCTESTCD = CHPD**

**SCORRESU = %**

---

**24**

Is this result considered?

- Positive  **25**  
Negative   
Unknown   
Other

**SCORRES where SCTESTCD = CHPDL1**

If Other, specify result status

**SUPPSC.QVAL where QNAM = CHPDL1SP**

**26**

---

**PROD\_22MAR2018\_1.00: UNIQUE****Project Name: NEKNKTR1726201****Form: RCC Cancer History****Generated On: 22 Mar 2018 22:20:59**

	Field Name	Data Type	Units	Values	Include Field OID
①	CHDIAG	\$29		Renal Cell Carcinoma	CHDIAG
②	CHKAR	\$3		100 = 100 90 = 90 80 = 80 70 = 70 <70 = <70	CHKAR
③	CHIMDC	\$18		0 (favorable) = 0 (favorable) 1-2 (intermediate ) = 1-2 (intermediate ) 3-6 (poor) = 3-6 (poor) Not reported = Not reported	CHIMDC
④	CHNEPH	\$1		Y = Yes N = No	CHNEPH
⑥	CHCELL	1			CHCELL
⑦	CHPAP	1			CHPAP

**PROD\_22MAR2018\_1.00: UNIQUE****Project Name: NEKNKTR1726201****Form: RCC Cancer History****Generated On: 22 Mar 2018 22:20:59**

	Field Name	Data Type	Units	Values	Include Field OID
⑧	CHCHR	1			CHCHR
⑨	CHUNK	1			CHUNK
⑩	CHOTH2	1			CHOTH2
⑪	CHSP	\$25			CHSP
⑫	CHMSI	\$7		Y = Yes N = No U = Unknown	CHMSI
⑬	CHDAT1	dd- MMM- yyyy			CHDAT1
⑭	CHDAT2	dd- MMM- yyyy			CHDAT2
⑮	CHCURST	\$17		Metastatic = CHCURST Metastatic Locally Recurrent = Locally Recurrent	
⑯	CHSTAG2	\$3		III = III IV = IV	CHSTAG2

**PROD\_22MAR2018\_1.00: UNIQUE****Project Name: NEKNKTR1726201****Form: RCC Cancer History****Generated On: 22 Mar 2018 22:20:59**

	Field Name	Data Type	Units	Values	Include Field OID
⑯	CHBM	\$1		Y = Yes N = No U = Unknown	CHBM
⑰	CHDAT3		dd- MMM- yyyy		CHDAT3
⑲	PDL1DAT		dd MMM yyyy		PDL1DAT
⑳	CHAS	\$8		22C3 = 22C3CHAS 28-8 = 28-8 SP142 = SP142 SP263 = SP263 NOT DONE = Not Done OTHER = Other	CHAS
㉑	CHSP3	\$25			CHSP3
㉒	CHPD	8.3			CHPD
㉓	CHRSTAT	\$8		POSITIVE = CHRSTAT Positive	CHRSTAT

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name:** NEKNKTR1726201

**Form:** RCC Cancer History

**Generated On:** 22 Mar 2018 22:20:59

---

Field Name	Data Type	Units	Values	Include Field OID
			NEGATIVE = Negative	
			UNKNOWN = Unknown	
			OTHER = Other	
<b>26</b>	CHSP4	\$25		CHSP4

---

**SC = Subject Characteristics**

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: TNBC Cancer History**

**SCCAT = CANCER HISTORY**

**Generated On: 22 Mar 2018 22:20:59**

Primary Cancer Diagnosis

Triple Negative Breast Cancer **1**

**SCORRES where SCTESTCD = CHDIAG**

BRCA1

Mutant **2**

Wild Type

Unknown

**SCORRES where SCTESTCD = CHBRC1**

BRCA2

Mutant **3**

Wild Type

Unknown

**SCORRES where SCTESTCD = CHBRC2**

MSI High

Yes **4**

No

Unknown

**SCORRES where SCTESTCD = CHMSI**

Date of Initial Primary Cancer Diagnosis (dd-mon-yyyy)

**SCDTC** **5**

Date of Initial Metastasis Diagnosis or Most Recent Local Recurrence (dd-mon-yyyy)

**SCDTC** **6**

Current Status

Metastatic **7**

Locally Recurrent

**SCORRES where SCTESTCD = CHCURST**

Stage at Most Recent Recurrence

III **8**

IV

**SCORRES where SCTESTCD = CHSTAG2**

Brain Metastases History?

Yes **9**

No

Unknown

**SCORRES where SCTESTCD = CHBM**

**SC = Subject Characteristics**

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: TNBC Cancer History**

**Generated On: 22 Mar 2018 22:20:59**

---

Date of Initial Brain Metastasis Diagnosis (dd-mon-yyyy)

**SCDTC**

**(10)**

**Last known PD-L1 status**

---

Date of last known PD-L1 status (dd-mon-yyyy)

**SCDTC**

**(12)**

Assay used

- 22C3
- 28-8
- SP142
- SP263
- Not Done
- Other

**SCORRES where SCTESTCD = CHUSED**

If Other, specify assay used

**SUPPSC.QVAL where QNAM = CHUSEDSP**

**(14)**

**Results**

---

Please enter PD-L1%

**SCORRES where SCTESTCD = CHPD**

**(16)**

**SCORRESU = %**

Is this result considered?

- Positive
- Negative
- Unknown
- Other

**SCORRES where SCTESTCD = CHPDL1**

If Other, specify result status

**SUPPSC.QVAL where QNAM = CHPDL1SP**

**(18)**

**PROD\_22MAR2018\_1.00: UNIQUE****Project Name: NEKNKTR1726201****Form: TNBC Cancer History****Generated On: 22 Mar 2018 22:20:59**

Field Name	Data Type	Units	Values	Include Field OID
① CHDIAG	\$29		Triple Negative Breast Cancer	CHDIAG
② CHBRCA1	\$9		Mutant = Mutant Wild Type = Wild Type Unknown = Unknown	CHBRCA1
③ CHBRCA2	\$9		Mutant = Mutant Wild Type = Wild Type Unknown = Unknown	CHBRCA2
④ CHMSI	\$7		Y = Yes N = No U = Unknown	CHMSI
⑤ CHDAT1	dd- MMM- yyyy			CHDAT1
⑥ CHDAT2	dd- MMM- yyyy			CHDAT2

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: TNBC Cancer History**

**Generated On: 22 Mar 2018 22:20:59**

---

	Field Name	Data Type	Units	Values	Include Field OID
⑦	CHCURST	\$17		Metastatic = CHCURST Metastatic Locally Recurrent = Locally Recurrent	
⑧	CHSTAG2	\$3		III = III IV = IV	CHSTAG2
⑨	CHBM	\$1		Y = Yes N = No U = Unknown	CHBM
⑩	CHDAT3		dd- MMM- yyyy		CHDAT3
⑫	PDL1DAT		dd MMM yyyy		PDL1DAT
⑬	CHAS	\$8		22C3 = 22C3CHAS 28-8 = 28-8 SP142 = SP142 SP263 = SP263 NOT DONE = Not Done	

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name:** NEKNKTR1726201

**Form:** TNBC Cancer History

**Generated On:** 22 Mar 2018 22:20:59

---

Field Name	Data Type	Units	Values	Include Field OID
			OTHER = Other	
<b>(14)</b> CHSP3	\$25			CHSP3
<b>(16)</b> CHPD	8.3			CHPD
<b>(17)</b> CHRSTAT	\$8		POSITIVE = CHRSTAT Positive NEGATIVE = Negative UNKNOWN = Unknown OTHER = Other	
<b>(18)</b> CHSP4	\$25			CHSP4

---

**SC = Subject Characteristics**

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: Urothelial Carcinoma Cancer History**

**SCCAT = CANCER HISTORY**

**Generated On: 22 Mar 2018 22:20:59**

Primary Cancer Diagnosis

Urothelial Carcinoma **1**

**SCORRES where SCTESTCD = CHDIAG**

Initial diagnosis tumor type

Urinary bladder **2**

Renal pelvis

Ureter

Urethra

Other

**SCORRES where SCTESTCD = CHIDT**

If other, specify

**SUPPSC.QVAL where QNAM = CHIDTSP**

**3**

Initial diagnosis classification

Muscle invasive **4**

Non-muscle invasive

Metastatic or advance

unresectable

Not Reported

**SCORRES where SCTESTCD = CHIDC**

Current (study entry) minor histological variants

Yes **5**

No

**SCORRES where SCTESTCD = CHCUR**

If Yes, specify

**SUPPSC.QVAL where QNAM = CHCURSP**

**6**

MSI High

Yes **7**

No

Unknown

**SCORRES where SCTESTCD = CHMSI**

Date of Initial Primary Cancer Diagnosis (dd-mon-yyyy)

**SCDTC**

**8**

SC = Subject Characteristics

PROD\_22MAR2018\_1.00: UNIQUE

Project Name: NEKNKTR1726201

Form: Urothelial Carcinoma Cancer History

Generated On: 22 Mar 2018 22:20:59

Date of Initial Metastasis Diagnosis or Most Recent Local  
Recurrence (dd-mon-yyyy)

SCDTC

⑨

Current Status

Metastatic

⑩

Locally Recurrent

Stage at Most Recent Recurrence

III

⑪

IV

SCORRES where SCTESTCD = CHCURST

Brain Metastases History?

Yes

⑫

No

Unknown

SCORRES where SCTESTCD = CHBM

Date of Initial Brain Metastasis Diagnosis (dd-mon-yyyy)

SCDTC

⑬

Last known PD-L1 status

Date of last known PD-L1 status (dd-mon-yyyy)

SCDTC

⑮

Assay used

22C3

⑯

28-8

SP142

SP263

Not Done

Other

SCORRES where SCTESTCD = CHUSED

If Other, specify assay used

SUPPSC.QVAL where QNAM = CHUSEDSP

⑰

SC = Subject Characteristics

PROD\_22MAR2018\_1.00: UNIQUE

Project Name: NEKNKTR1726201

Form: Urothelial Carcinoma Cancer History

Generated On: 22 Mar 2018 22:20:59

---

## Results

---

Please enter PD-L1%

SCORRES where SCTESTCD = CHPD

(19)

SCORRESU = %

---

Is this result considered?

Positive

(20)

Negative

( )

Unknown

( )

Other

( )

SCORRES where SCTESTCD = CHPDL1

---

If Other, specify result status

SUPPSC.QVAL where QNAM = CHPDL1SP

(21)

---

**PROD\_22MAR2018\_1.00: UNIQUE****Project Name: NEKNKTR1726201****Form: Urothelial Carcinoma Cancer History****Generated On: 22 Mar 2018 22:20:59**

	Field Name	Data Type	Units	Values	Include Field OID
①	CHDIAG	\$29		Urothelial Carcinoma	CHDIAG
②	CHIDT	\$15		URINARY BLADDER = Urinary bladder RENAL PELVIS = Renal pelvis URETER = Ureter URETHRA = Urethra OTHER = Other	CHIDT
③	CHIDTSP	\$200			CHIDTSP
④	CHIDC	\$34		MUSCLE INVASIVE = Muscle invasive NON-MUSC LE INVASIVE = Non-muscle invasive	CHIDC

**PROD\_22MAR2018\_1.00: UNIQUE****Project Name: NEKNKTR1726201****Form: Urothelial Carcinoma Cancer History****Generated On: 22 Mar 2018 22:20:59**

Field Name	Data Type	Units	Values	Include Field OID
			METASTAT IC OR ADVANCE UNRESECT ABLE = Metastatic or advance unresectable NOT REPORTED = Not Reported	
⑤ CHCUR	\$1		Y = Yes N = No	CHCUR
⑥ CHSP2	\$25			CHSP2
⑦ CHMSI	\$7		Y = Yes N = No U = Unknown	CHMSI
⑧ CHDAT1	dd- MMM- yyyy			CHDAT1
⑨ CHDAT2	dd- MMM- yyyy			CHDAT2

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: Urothelial Carcinoma Cancer History**

**Generated On: 22 Mar 2018 22:20:59**

---

	Field Name	Data Type	Units	Values	Include Field OID
⑩	CHCURST	\$17		Metastatic = CHCURST Metastatic Locally Recurrent = Locally Recurrent	
⑪	CHSTAG2	\$3		III = III IV = IV	CHSTAG2
⑫	CHBM	\$1		Y = Yes N = No U = Unknown	CHBM
⑬	CHDAT3		dd- MMM- yyyy		CHDAT3
⑮	PDL1DAT		dd MMM yyyy		PDL1DAT
⑯	CHAS	\$8		22C3 = 22C3CHAS 28-8 = 28-8 SP142 = SP142 SP263 = SP263 NOT DONE = Not Done	

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name:** NEKNKTR1726201

**Form:** Urothelial Carcinoma Cancer History

**Generated On:** 22 Mar 2018 22:20:59

---

Field Name	Data Type	Units	Values	Include Field OID
			OTHER = Other	
<b>(17)</b> CHSP3	\$25			CHSP3
<b>(19)</b> CHPD	8.3			CHPD
<b>(20)</b> CHRSTAT	\$8		POSITIVE = CHRSTAT Positive NEGATIVE = Negative UNKNOWN = Unknown OTHER = Other	
<b>(21)</b> CHSP4	\$25			CHSP4

---

**SC = Subject Characteristics**

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: Colorectal Cancer History**

**SCCAT = CANCER HISTORY**

**Generated On: 22 Mar 2018 22:20:59**

---

Primary Cancer Diagnosis **SCORRES where SCTESTCD = CHDIAG** Colorectal ①

---

BRAF Status **SCORRES where SCTESTCD = CHBRAFPN** Mutant ②  
Wild Type ○

If BRAF Status is **Mutant** (check all that apply)

**SCORRES where SCTESTCD = CHBRAF** ○

Allele V600E ④

Allele V600K ⑤

Other Allele ⑥

If Other, specify Mutant BRAF Alleles **SUPPSC.QVAL where QNAM = CHBRAFSP** ⑦

---

KRAS Status ⑧  
**SCORRES where SCTESTCD = CHKRAS** Mutant ○  
Wild Type ○  
Unknown ○

---

MSI High ⑨  
**SCORRES where SCTESTCD = CHMSI** Yes ○  
No ○  
Unknown ○

---

Date of Initial Primary Cancer Diagnosis (dd-mon-yyyy) **SCDTC** ⑩

---

Date of Initial Metastasis Diagnosis or Most Recent Local  
Recurrence (dd-mon-yyyy) **SCDTC** ⑪

SC = Subject Characteristics

PROD\_22MAR2018\_1.00: UNIQUE

Project Name: NEKNKTR1726201

Form: Colorectal Cancer History

Generated On: 22 Mar 2018 22:20:59

Current Status

Metastatic  12

Locally Recurrent

SCORRES where SCTESTCD = CHCURST

Stage at Most Recent Recurrence

III  13

IV

SCORRES where SCTESTCD = CHSTAG2

Brain Metastases History?

Yes  14

No

Unknown

SCORRES where SCTESTCD = CHBM

Date of Initial Brain Metastasis Diagnosis (dd-mon-yyyy)

SCDTC

15

Last known PD-L1 status

Date of last known PD-L1 status (dd-mon-yyyy)

SCDTC

17

Assay used

22C3  18

28-8

SP142

SP263

Not Done

Other

SCORRES where SCTESTCD = CHUSED

If Other, specify assay used

SUPPSC.QVAL where QNAM = CHUSEDSP

19

Results

Please enter PD-L1%

SCORRES where SCTESTCD = CHPD

21

SCORRESU = %

SC = Subject Characteristics

PROD\_22MAR2018\_1.00: UNIQUE

Project Name: NEKNKTR1726201

Form: Colorectal Cancer History

Generated On: 22 Mar 2018 22:20:59

---

Is this result considered?

Positive  22  
Negative   
Unknown   
Other

SCORRES where SCTESTCD = CHPDL1

If Other, specify result status

SUPPSC.QVAL where QNAM = CHPDL1SP

23

---

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name:** NEKNKTR1726201

**Form:** Colorectal Cancer History

**Generated On:** 22 Mar 2018 22:20:59

---

	Field Name	Data Type	Units	Values	Include Field OID
①	CHDIAG	\$29		Colorectal	CHDIAG
②	CHBRAF	\$12		Mutant = Mutant Wild Type = Wild Type	CHBRAF
④	CHV600E	1			CHV600E
⑤	CHV600K	1			CHV600K
⑥	CHV6OTH	1			CHV6OTH
⑦	CHOTH	\$20			CHOTH
⑧	CHKRAS	\$12		Mutant = Mutant Wild Type = Wild Type Unknown = Unknown	CHKRAS
⑨	CHMSI	\$7		Y = Yes N = No U = Unknown	CHMSI

---

---

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name:** NEKNKTR1726201

**Form:** Colorectal Cancer History

**Generated On:** 22 Mar 2018 22:20:59

---

	Field Name	Data Type	Units	Values	Include Field OID
⑩	CHDAT1	dd- MMM-yyyy			CHDAT1
⑪	CHDAT2	dd- MMM-yyyy			CHDAT2
⑫	CHCURST	\$17		Metastatic = CHCURST Metastatic Locally Recurrent = Locally Recurrent	
⑬	CHSTAG2	\$3		III = III IV = IV	CHSTAG2
⑭	CHBM	\$1		Y = Yes N = No U = Unknown	CHBM
⑮	CHDAT3	dd- MMM-yyyy			CHDAT3
⑯	PDL1DAT	dd MMM-yyyy			PDL1DAT

---

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name:** NEKNKTR1726201

**Form:** Colorectal Cancer History

**Generated On:** 22 Mar 2018 22:20:59

---

Field Name	Data Type	Units	Values	Include Field OID
⑯ CHAS	\$8		22C3 = 22C3CHAS 28-8 = 28-8 SP142 = SP142 SP263 = SP263 NOT DONE = Not Done OTHER = Other	
⑰ CHSP3	\$25			CHSP3
㉑ CHPD	8.3			CHPD
㉒ CHRSTAT	\$8		POSITIVE = CHRSTAT Positive NEGATIVE = Negative UNKNOWN = Unknown OTHER = Other	
㉓ CHSP4	\$25			CHSP4

---

SC = Subject Characteristics

PROD\_22MAR2018\_1.00: UNIQUE

Project Name: NEKNKTR1726201

Form: Sarcoma Cancer History

SCCAT = CANCER HISTORY

Generated On: 22 Mar 2018 22:20:59

Primary Cancer Diagnosis

Sarcoma  1

SCORRES where SCTESTCD = CHDIAG

Predominant Histological Sub-type

Osteosarcoma  2

Chondrosarcoma

Undifferentiated pleomorphic

sarcoma/malignant fibrous  
histiocytoma (UPS/MFH)

Dedifferentiated/pleomorphic   
liposarcoma

Angiosarcoma

Leiomyosarcoma

SCORRES where SCTESTCD = CHHSUBT

MSI High

Yes  3

No

Unknown

SCORRES where SCTESTCD = CHMSI

Date of Initial Primary Cancer Diagnosis (dd-mon-yyyy)

SCDTC  4

Date of Initial Metastasis Diagnosis or Most Recent Local  
Recurrence (dd-mon-yyyy)

SCDTC  5

Current Status

SCORRES where SCTESTCD = CHCURST  6

Locally Recurrent

Metastatic

Stage at Most Recent Recurrence

SCORRES where SCTESTCD = CHSTAG2

III  7

IV

Brain Metastases History?

SCORRES where SCTESTCD = CHBM

Yes  8

No

SC = Subject Characteristics

PROD\_22MAR2018\_1.00: UNIQUE

Project Name: NEKNKTR1726201

Form: Sarcoma Cancer History

Generated On: 22 Mar 2018 22:20:59

---

Unknown

SCORRES where SCTESTCD = CHBM

Date of Initial Brain Metastasis Diagnosis (dd-mon-yyyy)

SCDTC

(9)

---

#### Last known PD-L1 status

Date of last known PD-L1 status (dd-mon-yyyy)

SCDTC

(11)

Assay used

22C3

28-8

SP142

SP263

Not Done

Other

SCORRES where SCTESTCD = CHUSED

If Other, specify assay used

SUPPSC.QVAL where QNAM = CHUSEDSP

(13)

---

#### Results

Please enter PD-L1%

SCORRES where SCTESTCD = CHPD

(15)

SCORRESU = %

Is this result considered?

Positive

(16)

Negative

Unknown

Other

SCORRES where SCTESTCD = CHPDL1

If Other, specify result status

SUPPSC.QVAL where QNAM = CHPDL1SP

(17)

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: Sarcoma Cancer History**

**Generated On: 22 Mar 2018 22:20:59**

---

Field Name	Data Type	Units	Values	Include Field OID
① CHDIAG	\$29		Sarcoma	CHDIAG
② CHHSUBT	\$77		Osteosarcom a = Osteosarcom a Chondrosarc oma = Chondrosarc oma Undifferentia ted pleomorphic sarcoma/mali gnant fibrous histiocytoma (UPS/MFH) = Undifferentia ted pleomorphic sarcoma/mali gnant fibrous histiocytoma (UPS/MFH)	CHHSUBT

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name:** NEKNKTR1726201

**Form:** Sarcoma Cancer History

**Generated On:** 22 Mar 2018 22:20:59

---

Field Name	Data Type	Units	Values	Include Field OID
			Dedifferentiated/pleomorphic liposarcoma = Dedifferentiated/pleomorphic liposarcoma Angiosarcoma = Angiosarcoma Leiomyosarcoma = Leiomyosarcoma	
③ CHMSI	\$7		Y = Yes N = No U = Unknown	CHMSI
④ CHDAT1	dd- MMM-yyyy			CHDAT1
⑤ CHDAT2	dd- MMM-yyyy			CHDAT2

---

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: Sarcoma Cancer History**

**Generated On: 22 Mar 2018 22:20:59**

---

Field Name	Data Type	Units	Values	Include Field OID
⑥ CHCURST	\$17		Metastatic = CHCURST Metastatic Locally Recurrent = Locally Recurrent	
⑦ CHSTAG2	\$3		III = III IV = IV	CHSTAG2
⑧ CHBM	\$1		Y = Yes N = No U = Unknown	CHBM
⑨ CHDAT3		dd- MMM- yyyy		CHDAT3
⑪ PDL1DAT		dd MMM yyyy		PDL1DAT
⑫ CHAS	\$8		22C3 = 22C3CHAS 28-8 = 28-8 SP142 = SP142 SP263 = SP263 NOT DONE = Not Done	

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name:** NEKNKTR1726201

**Form:** Sarcoma Cancer History

**Generated On:** 22 Mar 2018 22:20:59

---

Field Name	Data Type	Units	Values	Include Field OID
			OTHER = Other	
<b>(13)</b> CHSP3	\$25			CHSP3
<b>(15)</b> CHPD	8.3			CHPD
<b>(16)</b> CHRSTAT	\$8		POSITIVE = CHRSTAT Positive NEGATIVE = Negative UNKNOWN = Unknown OTHER = Other	
<b>(17)</b> CHSP4	\$25			CHSP4

---

SC = Subject Characteristics

PROD\_22MAR2018\_1.00: UNIQUE

Project Name: NEKNKTR1726201

Form: Ovarian Cancer History

SCCAT = CANCER HISTORY

Generated On: 22 Mar 2018 22:20:59

Primary Cancer Diagnosis

SCORRES where SCTESTCD = CHDIAG

Ovarian **1**

BRAF Status

SCORRES where SCTESTCD = CHBRAFPN

Mutant **2**

Wild Type

If BRAF Status is **Mutant** (Check all that apply)

SCORRES where SCTESTCD = CHBRAF

Allele V600E

**4**

Allele V600K

**5**

Other Allele

**6**

If Other, specify Mutant BRAF Alleles

SUPPSC.QVAL where QNAM = CHBRAFSP

**7**

KRAS Status

SCORRES where SCTESTCD = CHKRAS

Mutant  **8**

Wild Type

Unknown

MSI High

SCORRES where SCTESTCD = CHMSI

Yes  **9**

No

Unknown

**Histological Sub-type** (check all that apply)

SCORRES where SCTESTCD = CHSUBTYP

Epithelial ovarian

**11**

SC = Subject Characteristics

PROD\_22MAR2018\_1.00: UNIQUE

Project Name: NEKNKTR1726201

Form: Ovarian Cancer History

Generated On: 22 Mar 2018 22:20:59

---

Primary peritoneal \_\_\_\_\_ **(12)**

Fallopian tube carcinoma \_\_\_\_\_ **(13)**

Date of Initial Primary Cancer Diagnosis (dd-mon-yyyy) \_\_\_\_\_ **(SCDTC) (14)**

Date of Initial Metastasis Diagnosis or Most Recent Local Recurrence (dd-mon-yyyy) \_\_\_\_\_ **(SCDTC) (15)**

Current Status  
SCORRES where SCTESTCD = CHCURST \_\_\_\_\_

Metastatic  **(16)**  
Locally Recurrent

Stage at Most Recent Recurrence  
SCORRES where SCTESTCD = CHSTAG2 \_\_\_\_\_

III  **(17)**  
IV

Brain Metastases History?  
SCORRES where SCTESTCD = CHBM \_\_\_\_\_

Yes  **(18)**  
No   
Unknown

Date of Initial Brain Metastasis Diagnosis (dd-mon-yyyy) \_\_\_\_\_ **(SCDTC) (19)**

Last known PD-L1 status

Date of last known PD-L1 status (dd-mon-yyyy) \_\_\_\_\_ **(SCDTC) (21)**

Assay used  
SCORRES where SCTESTCD = CHUSED \_\_\_\_\_

22C3  **(22)**  
28-8   
SP142

**SC = Subject Characteristics**

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: Ovarian Cancer History**

**Generated On: 22 Mar 2018 22:20:59**

---

SP263

Not Done

Other

**SCORRES where SCTESTCD = CHUSED**

If Other, specify assay used

**SUPPSC.QVAL where QNAM = CHUSEDSP**

(23)

## Results

Please enter PD-L1%

**SCORRES where SCTESTCD = CHPD**

(25)

**SCORRESU = %**

Is this result considered?

Positive

(26)

Negative

Unknown

Other

**SCORRES where SCTESTCD = CHPDL1**

If Other, specify result status

**SUPPSC.QVAL where QNAM = CHPDL1SP**

(27)

**PROD\_22MAR2018\_1.00: UNIQUE****Project Name:** NEKNKTR1726201**Form:** Ovarian Cancer History**Generated On:** 22 Mar 2018 22:20:59

Field Name	Data Type	Units	Values	Include Field OID
① CHDIAG	\$29		Ovarian	CHDIAG
② CHBRAF	\$12		Mutant = Mutant Wild Type = Wild Type	CHBRAF
④ CHV600E	1			CHV600E
⑤ CHV600K	1			CHV600K
⑥ CHV6OTH	1			CHV6OTH
⑦ CHOTH	\$20			CHOTH
⑧ CHKRAS	\$12		Mutant = Mutant Wild Type = Wild Type Unknown = Unknown	CHKRAS
⑨ CHMSI	\$7		Y = Yes N = No U = Unknown	CHMSI
⑪ CHOVAR1	1			CHOVAR1

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: Ovarian Cancer History**

**Generated On: 22 Mar 2018 22:20:59**

---

Field Name	Data Type	Units	Values	Include Field OID
⑫ CHOVAR2	1			CHOVAR2
⑬ CHOVAR3	1			CHOVAR3
⑭ CHDAT1	dd- MMM- yyyy			CHDAT1
⑮ CHDAT2	dd- MMM- yyyy			CHDAT2
⑯ CHCURST	\$17		Metastatic = Metastatic Locally Recurrent = Locally Recurrent	CHCURST
⑰ CHSTAG2	\$3		III = III IV = IV	CHSTAG2
⑱ CHBM	\$1		Y = Yes N = No U = Unknown	CHBM
⑲ CHDAT3	dd- MMM- yyyy			CHDAT3

---

---

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: Ovarian Cancer History**

**Generated On: 22 Mar 2018 22:20:59**

---

	Field Name	Data Type	Units	Values	Include Field OID
㉑	PDL1DAT	dd MMM yyyy			PDL1DAT
㉒	CHAS	\$8		22C3 = 22C3CHAS 28-8 = 28-8 SP142 = SP142 SP263 = SP263 NOT DONE = Not Done OTHER = Other	
㉓	CHSP3	\$25			CHSP3
㉔	CHPD	8.3			CHPD
㉕	CHRSTAT	\$8		POSITIVE = CHRSTAT Positive NEGATIVE = Negative UNKNOWN = Unknown OTHER = Other	
㉖	CHSP4	\$25			CHSP4

---

---

**SC = Subject Characteristics**

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: Merkel Cell Carcinoma Cancer History**

**SCCAT = CANCER HISTORY**

**Generated On: 22 Mar 2018 22:20:59**

Primary Cancer Diagnosis

Merkel Cell Carcinoma **1**

**SCORRES where SCTESTCD = CHDIAG**

MCPyV Viral Load

Positive **2**

Negative **2**

**SCORRES where SCTESTCD = CHMCPYV**

MSI High

Yes **3**

No **3**

Unknown **3**

Date of Initial Primary Cancer Diagnosis (dd-mon-yyyy)

**SCDTC** **4**

Date of Initial Metastasis Diagnosis or Most Recent Local Recurrence (dd-mon-yyyy)

**SCDTC** **5**

Current Status

Metastatic **6**

Locally Recurrent **6**

Stage at Most Recent Recurrence

III **7**

IV **7**

**SCORRES where SCTESTCD = CHSTAG2**

Brain Metastases History?

Yes **8**

No **8**

Unknown **8**

Date of Initial Brain Metastasis Diagnosis (dd-mon-yyyy)

**SCDTC** **9**

**Last known PD-L1 status**

SC = Subject Characteristics

PROD\_22MAR2018\_1.00: UNIQUE

Project Name: NEKNKTR1726201

Form: Merkel Cell Carcinoma Cancer History

Generated On: 22 Mar 2018 22:20:59

---

Date of last known PD-L1 status (dd-mon-yyyy)

SCDTC

11

---

Assay used

SCORRES where SCTESTCD = CHUSED

- 22C3   
28-8   
SP142   
SP263   
Not Done   
Other

12

---

If Other, specify assay used

SUPPSC.QVAL where QNAM = CHUSEDSP

13

---

## Results

---

Please enter PD-L1%

SCORRES where SCTESTCD = CHPD

14

SCORRESU = %

---

Is this result considered?

- Positive   
Negative   
Unknown   
Other

15

SCORRES where SCTESTCD = CHPDL1

---

If Other, specify result status

SUPPSC.QVAL where QNAM = CHPDL1SP

16

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: Merkel Cell Carcinoma Cancer History**

**Generated On: 22 Mar 2018 22:20:59**

---

	Field Name	Data Type	Units	Values	Include Field OID
①	CHDIAG	\$29		Merkel Cell Carcinoma	CHDIAG
②	CHMCPYV	\$10		Positive = Positive Negative = Negative	CHMCPYV
③	CHMSI	\$7		Y = Yes N = No U = Unknown	CHMSI
④	CHDAT1	dd- MMM- yyyy			CHDAT1
⑤	CHDAT2	dd- MMM- yyyy			CHDAT2
⑥	CHCURST	\$17		Metastatic = Metastatic Locally Recurrent = Locally Recurrent	CHCURST
⑦	CHSTAG2	\$3		III = III IV = IV	CHSTAG2

---

---

**PROD\_22MAR2018\_1.00: UNIQUE****Project Name: NEKNKTR1726201****Form: Merkel Cell Carcinoma Cancer History****Generated On: 22 Mar 2018 22:20:59**

	Field Name	Data Type	Units	Values	Include Field OID
⑧	CHBM	\$1		Y = Yes N = No U = Unknown	CHBM
⑨	CHDAT3		dd- MMM- yyyy		CHDAT3
⑪	PDL1DAT		dd MMM yyyy		PDL1DAT
⑫	CHAS	\$8		22C3 = 22C3CHAS 28-8 = 28-8 SP142 = SP142 SP263 = SP263 NOT DONE = Not Done OTHER = Other	CHAS
⑬	CHSP3	\$25			CHSP3
⑮	CHPD	8.3			CHPD
⑯	CHRSTAT	\$8		POSITIVE = CHRSTAT Positive	CHRSTAT

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name:** NEKNKTR1726201

**Form:** Merkel Cell Carcinoma Cancer History

**Generated On:** 22 Mar 2018 22:20:59

---

Field Name	Data Type	Units	Values	Include Field OID
			NEGATIVE = Negative	
			UNKNOWN = Unknown	
			OTHER = Other	
<b>(17)</b> CHSP4		\$25		CHSP4

---

**PR = Procedures**

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: Prior Cancer Related Surgery**

**Generated On: 22 Mar 2018 22:20:59**

**PRCAT = PRIOR CANCER RELATED SURGERY**

Has the patient had any cancer related surgery?

**NOT SUBMITTED**

Yes  **1**  
No

Surgical Procedure

**PRTRT**

**2**

Surgery Date (dd-mon-yyyy)

**PRSTDTC**

**3**

**PROD\_22MAR2018\_1.00: UNIQUE**  
**Project Name: NEKNKTR1726201**  
**Form: Prior Cancer Related Surgery**  
**Generated On: 22 Mar 2018 22:20:59**

---

Field Name	Data Type	Units	Values	Include Field OID
① PSPERF	\$1		Y = Yes N = No	PSPERF
② PSTERM	\$100			PSTERM
③ PSSTDAT	dd- MMM- yyyy			PSSTDAT

---

CM = Concomitant Medications

PROD\_22MAR2018\_1.00: UNIQUE

Project Name: NEKNKTR1726201

Form: Prior Systemic Therapy

Generated On: 22 Mar 2018 22:20:59

CMCAT = PRIOR SYSTEMIC THERAPY

Has the patient had any systemic therapies?

NOT SUBMITTED

Yes  ①  
No

Regimen Number

CMSPID

②

Therapy Name

CMTRT

③

Setting of Treatment

Adjuvant   
Neo Adjuvant   
Metastatic   
Locally Recurrent

SUPPCM.QVAL where QNAM = PTLOC

If Metastatic, what line of treatment

First Line   
Second Line   
Third Line   
4+ Line

SUPPCM.QVAL where QNAM = PTLINE

Start Date (dd-mon-yyyy)

CMSTDTC

⑥

Stop Date (dd-mon-yyyy)

CMENDTC

⑦

Reason for Discontinuation

Disease Progression   
Refractory Disease   
Maximum Clinical Benefit   
Toxicity   
Completed Treatment   
Other

SUPPCM.QVAL where QNAM = PTDISC

**CM = Concomitant Medications**

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: Prior Systemic Therapy**

**Generated On: 22 Mar 2018 22:20:59**

---

If Other, specify reason

**SUPPCM.QVAL where QNAM = PTDISC**

**(9)**

Did patient respond to therapy?

Yes

**(10)**

No

Unknown

**SUPPCM.QVAL where QNAM = PTTHER**

What was the best overall response?

Complete Response (CR)

**(11)**

Partial Response (PR)

Stable Disease (SD)

Disease Progression (PD)

Unknown

**SUPPCM.QVAL where QNAM = PTRESP**

Did patient experience Disease Progression with this treatment?

Yes

**(12)**

No

**SUPPCM.QVAL where QNAM = PTPDYN**

If Yes, Date of Disease Progression (dd-mon-yyyy)

**(13)**

**SUPPCM.QVAL where QNAM = PTPDDAT**

Type of Disease Progression

RECIST 1.1

**(14)**

Radiographic Disease

Progression based on Clinical Judgement

Symptomatic Disease

Progression

**SUPPCM.QVAL where QNAM = PTPDTYP**

Date of Clinical Progression, if any (dd-mon-yyyy)**SUPPCM.QVAL where QNAM = PTCPDAT**

---

**PROD\_22MAR2018\_1.00: UNIQUE****Project Name: NEKNKTR1726201****Form: Prior Systemic Therapy****Generated On: 22 Mar 2018 22:20:59**

	Field Name	Data Type	Units	Values	Include Field OID
①	PTPERF	\$1		Y = Yes N = No	PTPERF
②	PTSPID	8			PTSPID
③	PTTRT	\$200			PTTRT
④	PTLOC	\$20		ADJUVANT = Adjuvant NEO ADJUVANT = Neo Adjuvant METASTAT IC = Metastatic LOCALLY RECURREN T = Locally Recurrent	PTLOC
⑤	PTLINE	\$12		First Line = First Line Second Line = Second Line Third Line = Third Line 4+ Line = 4+ Line	PTLINE

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: Prior Systemic Therapy**

**Generated On: 22 Mar 2018 22:20:59**

---

	Field Name	Data Type	Units	Values	Include Field OID
⑥	PTSTDAT	dd- MMM- yyyy			PTSTDAT
⑦	PTENDAT	dd- MMM- yyyy			PTENDAT
⑧	PTDISC	\$25		Disease Progression = Disease Progression Refractory Disease = Refractory Disease Maximum Clinical Benefit = Maximum Clinical Benefit Toxicity = Toxicity Completed Treatment = Completed Treatment Other = Other	PTDISC
⑨	PTDISCSP	\$50			PTDISCSP

---

---

**PROD\_22MAR2018\_1.00: UNIQUE****Project Name: NEKNKTR1726201****Form: Prior Systemic Therapy****Generated On: 22 Mar 2018 22:20:59**

	Field Name	Data Type	Units	Values	Include Field OID
⑩	PTTHER	\$1		Y = Yes N = No U = Unknown	PTTHER
⑪	PTRESP	\$2		CR = Complete Response (CR) PR = Partial Response (PR) SD = Stable Disease (SD) PD = Disease Progression (PD) U = Unknown	PTRESP
⑫	PTPDYN	\$1		Y = Yes N = No	PTPDYN
⑬	PTPDDAT	dd MMM yyyy			PTPDDAT

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: Prior Systemic Therapy**

**Generated On: 22 Mar 2018 22:20:59**

---

Field Name	Data Type	Units	Values	Include Field OID
<b>(14) PTPDTYP</b>	\$60		RECIST 1.1 PTPDTYP = RECIST 1.1 Radiographic Disease Progression based on Clinical Judgement = Radiographic Disease Progression based on Clinical Judgement Symptomatic Disease Progression = Symptomatic Disease Progression	
<b>(15) PTCPDAT</b>	dd- MMM- yyyy		PTCPDAT	

---

**PE = Physical Examination**

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: Physical Exam**

**Generated On: 22 Mar 2018 22:20:59**

**PECAT = Physical Exam**

Was a physical exam performed?

Yes  **1**

No

**PESTAT = NOT DONE if No is checked**

Date of Assessment (dd-mon-yyyy)

**PEDTC**

**2**

**If a condition has worsened since baseline or Cycle 1 Day 1 update the Adverse Event form.**

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name:** NEKNKTR1726201

**Form:** Physical Exam

**Generated On:** 22 Mar 2018 22:20:59

---

	Field Name	Data Type	Units	Values	Include Field OID
①	PEPERF	\$1		Y = Yes N = No	PEPERF
②	PEDAT	dd MMM yyyy			PEDAT

---

VS = Vital Signs

PROD\_22MAR2018\_1.00: UNIQUE

Project Name: NEKNKTR1726201

Form: Vital Signs Screening

Generated On: 22 Mar 2018 22:20:59

Were vital signs collected?

Yes  ①  
No

VSSTAT where VTESTCD = VSALL

Date of Assessment (dd-mon-yyyy)

VSDTC

②

Height

VSORRES where VTESTCD = HEIGHT

③

Height Unit

Centimeter  ④  
VSORRESU Inch

Weight

VSORRES where VTESTCD = WEIGHT

⑤

Weight Unit

Kilogram  ⑥  
VSORRESU Pound

Temperature

VSORRES where VTESTCD = TEMP

⑦

Temperature Unit

C  ⑧  
F  VSORRESU

Respiratory Rate (breaths/min)

VSORRES where VTESTCD = RESP

⑨

VSORRESU

Heart Rate (beats/min)

VSORRES where VTESTCD = HR

⑩

VSORRESU

Oxygen Saturation (%)

VSORRES where VTESTCD = OXYSAT

⑪

VSORRESU

Supine Systolic BP (mmHg)

VSORRES where VTESTCD = SYSBP

⑫

VSORRESU

VS = Vital Signs

PROD\_22MAR2018\_1.00: UNIQUE  
Project Name: NEKNKTR1726201  
Form: Vital Signs Screening  
Generated On: 22 Mar 2018 22:20:59

---

Supine Diastolic BP (mmHg)

VSORRES where VSTESTCD = DIABP

13

VSORRESU

---

**PROD\_22MAR2018\_1.00: UNIQUE****Project Name: NEKNKTR1726201****Form: Vital Signs Screening****Generated On: 22 Mar 2018 22:20:59**

	Field Name	Data Type	Units	Values	Include Field OID
①	VSPERF1	\$1		Y = Yes N = No	VSPERF1
②	VSDAT	dd MMM yyyy			VSDAT
③	HEIGHT	4.1			HEIGHT
④	HEIGHTU	\$2		cm = Centimeter in = Inch	HEIGHTU
⑤	WEIGHT	4.1			WEIGHT
⑥	WEIGHTU	\$2		kg = Kilogram LB = Pound	WEIGHTU
⑦	TEMP	4.1			TEMP
⑧	TEMPU	\$1		C = C F = F	TEMPU
⑨	RESP	8			RESP
⑩	HR	8			HR

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name:** NEKNKTR1726201

**Form:** Vital Signs Screening

**Generated On:** 22 Mar 2018 22:20:59

---

Field Name	Data Type	Units	Values	Include Field OID
⑪ OXYSAT	8			OXYSAT
⑫ SYSBP1	8			SYSBP1
⑬ DIABP1	8			DIABP1

---

PE = Physical Examination

PROD\_22MAR2018\_1.00: UNIQUE

Project Name: NEKNKTR1726201

Form: Ophthalmology Exam Baseline

Generated On: 22 Mar 2018 22:20:59

PECAT = OPHTHALMOLOGY EXAM

Exam Date (dd-mon-yyyy)

PEDTC

1

Was an eye Exam done?

Yes  2

PESTAT where PETESTCD = EYEEEXAM

No

Was fundus photography performed?

Yes  3

SUPPPE.QVAL where QNAM = PEOAFUND

No

Were any clinically significant abnormalities noted?

PEORRES Yes  4

RELREC = Related Records  
If yes, specify clinically significant medical history  
below:

Medical History 1

SUPPPE.QVAL where QNAM = MHNO1

5

Medical History 2

SUPPPE.QVAL where QNAM = MHNO2

6

Medical History 3

SUPPPE.QVAL where QNAM = MHNO3

7

Create RELREC records to connect

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: Ophthalmology Exam Baseline**

**Generated On: 22 Mar 2018 22:20:59**

---

	Field Name	Data Type	Units	Values	Include Field OID
①	OADAT	dd MMM yyyy			OADAT
②	OPAEYEX	\$1		Y = Yes N = No	OPAEYEX
③	OAFUND	\$1		Y = Yes N = No	OAFUND
④	OAABN	\$1		Y = Yes N = No	OAABN
⑤	OAMH1	\$50			OAMH1
⑥	OAMH2	\$50			OAMH2
⑦	OAMH3	\$50			OAMH3

---

QS = Questionnaires

PROD\_22MAR2018\_1.00: UNIQUE

Project Name: NEKNKTR1726201

Form: ECOG

QSCAT = ECOG

Generated On: 22 Mar 2018 22:20:59

---

Not Done

QSSTAT

①

Date of Assessment (dd-mon-yyyy)

QSDTC

②

ECOG Performance Status

0: ABLE TO CARRY OUT

③

ALL NORMAL ACTIVITIES  
WITHOUT RESTRICTION

1: RESTRICTED IN

PHYSICALLY

STRENUOUS ACTIVITY  
BUT AMBULATORY AND  
ABLE TO CARRY OUT  
WORK OF A LIGHT OR  
SEDENTARY NATURE

2: AMBULATORY AND

CAPABLE OF ALL  
SELF-CARE BUT UNABLE  
TO CARRY OUT ANY

WORK ACTIVITIES: UP  
AND ABOUT MORE THAN  
50% OF WAKING HOURS

3: CAPABLE OF LIMITED

SELF-CARE; CONFINED  
TO BED OR CHAIR MORE  
THAN 50% OF WAKING

HOURS

4: COMPLETELY

DISABLED; CANNOT  
CARRY ON SELF-CARE;  
TOTALLY CONFINED TO  
BED OR CHAIR

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name:** NEKNKTR1726201

**Form:** ECOG

**Generated On:** 22 Mar 2018 22:20:59

---

Field Name	Data Type	Units	Values	Include Field OID
① ECOGND	1			ECOGND
② ECOGDAT	dd MMM yyyy			ECOGDAT
③ ECOGRES	\$130		0 = 0: ABLE ECOGRES TO CARRY OUT ALL NORMAL ACTIVITIE S WITHOUT RESTRICTI ON 1 = 1: RESTRICTE D IN PHYSICAL LY STRENUOU S ACTIVITY BUT AMBULAT ORY AND ABLE TO CARRY OUT WORK OF A LIGHT OR SEDENTAR Y NATURE	

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name:** NEKNKTR1726201

**Form:** ECOG

**Generated On:** 22 Mar 2018 22:20:59

---

Field Name	Data Type	Units	Values	Include Field OID
			2 = 2: AMBULAT ORY AND CAPABLE OF ALL SELF-CARE BUT UNABLE TO CARRY OUT ANY WORK ACTIVITIE S: UP AND ABOUT MORE THAN 50% OF WAKING HOURS	

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name:** NEKNKTR1726201

**Form:** ECOG

**Generated On:** 22 Mar 2018 22:20:59

---

Field Name	Data Type	Units	Values	Include Field OID
			3 = 3: CAPABLE OF LIMITED SELF-CARE ; CONFINED TO BED OR CHAIR MORE THAN 50% OF WAKING HOURS 4 = 4: COMPLETE LY DISABLED; CANNOT CARRY ON SELF-CARE ; TOTALLY CONFINED TO BED OR CHAIR	

---

[ZE = Diagnostic Procedures]

PROD\_22MAR2018\_1.00: UNIQUE

Project Name: NEKNKTR1726201

Form: Echocardiogram [ZEMETHOD]

Generated On: 22 Mar 2018 22:20:59

---

Not Done

[ZESTAT where ZETESTCD = ZEALL]

(1)

Date of Assessment (dd-mon-yyyy)

[ZEDTC]

(2)

Result

[ZEORRES where ZETESTCD = STRSTEST]

Normal

(3)

Abnormal

If Abnormal, specify

[SUPPZE.QVAL where QNAM = STRSP]

(4)

Left Ventricular Ejection Fraction

Fixed Unit: % (5)

[ZEORRES where ZETESTCD = LVEF]

[ZEORRESU]

---

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name:** NEKNKTR1726201

**Form:** Echocardiogram

**Generated On:** 22 Mar 2018 22:20:59

---

	Field Name	Data Type	Units	Values	Include Field OID
①	CEPERF	1			CEPERF
②	CEDAT	dd MMM yyyy			CEDAT
③	CEORRES	\$8		Normal = Normal Abnormal = Abnormal	CEORRES
④	CESPEC	\$200			CESPEC
⑤	CEORRES2	4.1			CEORRES2

---

LB = Laboratory Test Results

PROD\_22MAR2018\_1.00: UNIQUE

Project Name: NEKNKTR1726201

Form: Stool Sample

Generated On: 22 Mar 2018 22:20:59

LBCAT = STOOL SAMPLE ANALYSIS

Was a stool sample collected?

LBSPEC = STOOL

LBSTAT = NOT DONE if No is checked

Yes  1  
No

Collection Date (dd-mon-yyyy)

LBDTC

2

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name:** NEKNKTR1726201

**Form:** Stool Sample

**Generated On:** 22 Mar 2018 22:20:59

---

	Field Name	Data Type	Units	Values	Include Field OID
①	LPERF	\$1		Y = Yes N = No	LPERF
②	LBDAT	dd MMM yyyy			LBDAT

---

**LB = Laboratory Test Results**

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: Central Labs**

**Generated On: 22 Mar 2018 22:20:59**

---

Was a hematology sample collected?

**LBCAT = HEMATOLOGY**

**LBSTAT = NOT DONE if No is checked**

Yes  1  
No

Was a serum chemistry sample collected?

**LBCAT = CHEMISTRY**

**LBSTAT = NOT DONE if No is checked**

Yes  2  
No

Was a PT/PTT sample collected?

**LBCAT = COAGULATION**

**LBSTAT = NOT DONE if No is checked**

Yes  3  
No

Was a sample collected for TSH, T4, lipase, amylase, and CK?

**LBCAT = CHEMISTRY**

**LBSTAT = NOT DONE if No is checked**

Yes  4  
No

Was a urinalysis (dipstick) sample collected?

**LBCAT = URINALYSIS**

**LBSTAT = NOT DONE if No is checked**

Yes  5  
No

Was a sample collected for HBsAG, anti-HCV antibody, and HIV antibody?

**LBCAT = SEROLOGY**

**LBSTAT = NOT DONE if No is checked**

Yes  6  
No

Was a pregnancy test sample collected?

**LBCAT = CHEMISTRY**

**LBREASND Not Applicable**

**LBSTAT = NOT DONE if No/Not Applicable is checked**

Yes  7  
No

Date of Collection (dd-mon-yyyy)

**LBDTC**

8

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name:** NEKNKTR1726201

**Form:** Central Labs

**Generated On:** 22 Mar 2018 22:20:59

	Field Name	Data Type	Units	Values	Include Field OID
①	HEMAYN	\$1		Y = Yes N = No	HEMAYN
②	CHEMYN	\$1		Y = Yes N = No	CHEMYN
③	COAGYN	\$1		Y = Yes N = No	COAGYN
④	LBADDYN	\$1		Y = Yes N = No	LBADDYN
⑤	URINYN	\$1		Y = Yes N = No	URINYN
⑥	SERYN	\$1		Y = Yes N = No	SERYN
⑦	PGYN	\$2		Y = Yes N = No NA = Not Applicable	PGYN
⑧	CLABDAT	dd MMM yyyy			CLABDAT

PR = Procedures

PROD\_22MAR2018\_1.00: UNIQUE

Project Name: NEKNKTR1726201

Form: Archival Tumor Tissue

Generated On: 22 Mar 2018 22:20:59

PRTRT = ARCHIVAL TUMOR TISSUE

PRCAT = BIOPSY

PRPRESP = Y

---

Was an archived tumor tissue sample obtained?

PROCCUR

Yes  ①  
No

---

Archived Sample Date (dd-mon-yyyy)

(Date the archived tissue sample was actually collected  
from the patient)

PRSTDTC

②

---

Archived Sample type

PRSCAT

Slides  ③  
Blocks

---

If Slides, specify number of slides obtained SUPPPR.QVAL where QNAM = ATTSAMOB

④

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name:** NEKNKTR1726201

**Form:** Archival Tumor Tissue

**Generated On:** 22 Mar 2018 22:20:59

---

	Field Name	Data Type	Units	Values	Include Field OID
①	ATPERF	\$1		Y = Yes N = No	ATPERF
②	ATDAT	dd MMM yyyy			ATDAT
③	ATTSAM	\$6		Slides = Slides Blocks = Blocks	ATTSAM
④	ATTSAMO	2 B			ATTSAMO B

---

**PR = Procedures**

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: Tumor Biopsy**

**Generated On: 22 Mar 2018 22:20:59**

**PRTTRT = TUMOR BIOPSY**

**PRCAT = BIOPSY**

**PRPRESPI = Y**

Date Biopsy Collected (dd-mon-yyyy)

**PRSTDTC**

**1**

Was the tumor biopsy from the injected lesion collected?

**PROCCUR**

Yes  **2**  
No

If yes, record the most recently injected lesion.

Injected Biopsy Lesion

**SUPPPR.QVAL where QNAM = INLESNO**

**3**

Injected Biopsy Location

**PRLOC**

Adrenal Gland  **4**

Bone

Brain

Breast

Chest Wall

Colon/Large Intestine

Esophagus/Oesophagus

Gall bladder/Bile duct

Head and Neck

Heart/Pericardium

Kidney

Leptomeningeal

Liver

Lung - RUL

Lung - RML

Lung - RLL

Lung - LUL

Lung - LLL

Lung - Hilum

Lung - Other

Lymph Nodes

Ovary/Fallopian tube

**PR = Procedures**

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: Tumor Biopsy**

**Generated On: 22 Mar 2018 22:20:59**

---

- |                     |                          |
|---------------------|--------------------------|
| Pancreas            | <input type="checkbox"/> |
| Pelvis (non-bone)   | <input type="checkbox"/> |
| Peritoneum          | <input type="checkbox"/> |
| Pleura              | <input type="checkbox"/> |
| Rectum              | <input type="checkbox"/> |
| Skin - Scalp        | <input type="checkbox"/> |
| Skin - Trunk        | <input type="checkbox"/> |
| Skin - Back         | <input type="checkbox"/> |
| Skin - RU Extremity | <input type="checkbox"/> |
| Skin - RL Extremity | <input type="checkbox"/> |
| Skin - LU Extremity | <input type="checkbox"/> |
| Skin - LL Extremity | <input type="checkbox"/> |
| Skin - Other        | <input type="checkbox"/> |
| Small intestine     | <input type="checkbox"/> |
| Soft tissue         | <input type="checkbox"/> |
| Spleen              | <input type="checkbox"/> |
| Stomach             | <input type="checkbox"/> |
| Trachea/Bronchi     | <input type="checkbox"/> |
| Urinary Bladder     | <input type="checkbox"/> |
| Uterus              | <input type="checkbox"/> |
| Other               | <input type="checkbox"/> |

---

If Other, specify biopsy location of injected lesion **SUPPPR.QVAL where QNAM = PRLOCSP**

---

Was the tumor biopsy from the non-injected lesion collected?

**PRSCAT = NON-INJECTED LESION**

Yes  **6**  
No

---

Non-injected Biopsy Lesion

**SUPPPR.QVAL where QNAM = NINLESNO** **7**

---

---

**PR = Procedures**

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: Tumor Biopsy**

**Generated On: 22 Mar 2018 22:20:59**

---

Non-injected biopsy location

**PRLOC**

Adrenal Gland  8  
Bone   
Brain   
Breast   
Chest Wall   
Colon/Large Intestine   
Esophagus/Oesophagus   
Gall bladder/Bile duct   
Head and Neck   
Heart/Pericardium   
Kidney   
Leptomeningeal   
Liver   
Lung - RUL   
Lung - RML   
Lung - RLL   
Lung - LUL   
Lung - LLL   
Lung - Hilum   
Lung - Other   
Lymph Nodes   
Ovary/Fallopian tube   
Pancreas   
Pelvis (non-bone)   
Peritoneum   
Pleura   
Rectum   
Skin - Scalp   
Skin - Trunk   
Skin - Back

**PR = Procedures**

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: Tumor Biopsy**

**Generated On: 22 Mar 2018 22:20:59**

---

- |                     |                          |
|---------------------|--------------------------|
| Skin - RU Extremity | <input type="checkbox"/> |
| Skin - RL Extremity | <input type="checkbox"/> |
| Skin - LU Extremity | <input type="checkbox"/> |
| Skin - LL Extremity | <input type="checkbox"/> |
| Skin - Other        | <input type="checkbox"/> |
| Small intestine     | <input type="checkbox"/> |
| Soft tissue         | <input type="checkbox"/> |
| Spleen              | <input type="checkbox"/> |
| Stomach             | <input type="checkbox"/> |
| Trachea/Bronchi     | <input type="checkbox"/> |
| Urinary Bladder     | <input type="checkbox"/> |
| Uterus              | <input type="checkbox"/> |
| Other               | <input type="checkbox"/> |

---

If Other, specify non-injected site location

**SUPPPR.QVAL where QNAM = PRLOCSP**

⑨

---

**PROD\_22MAR2018\_1.00: UNIQUE****Project Name: NEKNKTR1726201****Form: Tumor Biopsy****Generated On: 22 Mar 2018 22:20:59**

	Field Name	Data Type	Units	Values	Include Field OID
①	TBDAT	dd MMM yyyy			TBDAT
②	TBPERF	\$1		Y = Yes N = No	TBPERF
③	TBNLMID	\$100			TBNLMID
④	TBLOC	\$22		Adrenal Gland = Adrenal Gland Bone = Bone Brain = Brain Breast = Breast Chest Wall = Chest Wall Colon/Large Intestine = Colon/Large Intestine Esophagus/O esophagus = Esophagus/O esophagus Gall bladder/Bile duct = Gall bladder/Bile duct	TBLOC

**PROD\_22MAR2018\_1.00: UNIQUE****Project Name:** NEKNKTR1726201**Form:** Tumor Biopsy**Generated On:** 22 Mar 2018 22:20:59

---

Field Name	Data Type	Units	Values	Include Field OID
			Head and Neck = Head and Neck Heart/Pericar dium = Heart/Pericar dium Kidney = Kidney Leptomening eal = Leptomening eal Liver = Liver Lung - RUL = Lung - RUL Lung - RML = Lung - RML Lung - RLL = Lung - RLL Lung - LUL = Lung - LUL Lung - LLL = Lung - LLL Lung - Hilum = Lung - Hilum	

---

**PROD\_22MAR2018\_1.00: UNIQUE****Project Name: NEKNKTR1726201****Form: Tumor Biopsy****Generated On: 22 Mar 2018 22:20:59**

---

Field Name	Data Type	Units	Values	Include Field OID
			Lung - Other = Lung - Other Lymph Nodes = Lymph Nodes Ovary/Fallop ian tube = Ovary/Fallop ian tube Pancreas = Pancreas Pelvis (non-bone) = Pelvis (non-bone) Peritoneum = Peritoneum Pleura = Pleura Rectum = Rectum Skin - Scalp = Skin - Scalp Skin - Trunk = Skin - Trunk Skin - Back = Skin - Back	

---

**PROD\_22MAR2018\_1.00: UNIQUE****Project Name: NEKNKTR1726201****Form: Tumor Biopsy****Generated On: 22 Mar 2018 22:20:59**

---

Field Name	Data Type	Units	Values	Include Field OID
			Skin - RU	
			Extremity =	
			Skin - RU	
			Extremity	
			Skin - RL	
			Extremity =	
			Skin - RL	
			Extremity	
			Skin - LU	
			Extremity =	
			Skin - LU	
			Extremity	
			Skin - LL	
			Extremity =	
			Skin - LL	
			Extremity	
			Skin - Other	
			= Skin -	
			Other	
			Small	
			intestine =	
			Small	
			intestine	
			Soft tissue =	
			Soft tissue	
			Spleen =	
			Spleen	
			Stomach =	
			Stomach	
			Trachea/Bro	
			nchi =	
			Trachea/Bro	
			nchi	

---

**PROD\_22MAR2018\_1.00: UNIQUE****Project Name: NEKNKTR1726201****Form: Tumor Biopsy****Generated On: 22 Mar 2018 22:20:59**

Field Name	Data Type	Units	Values	Include Field OID
			Urinary Bladder = Urinary Bladder Uterus = Uterus Other = Other	
⑤ TBLOCOTH	\$200			TBLOCOTH
⑥ TBPERF2	\$1		Y = Yes N = No	TBPERF2
⑦ TBNLMID2	\$100			TBNLMID2
⑧ TBLOC2	\$22		Adrenal Gland = Adrenal Gland Bone = Bone Brain = Brain Breast = Breast Chest Wall = Chest Wall Colon/Large Intestine = Colon/Large Intestine	TBLOC2

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: Tumor Biopsy**

**Generated On: 22 Mar 2018 22:20:59**

---

Field Name	Data Type	Units	Values	Include Field OID
			Esophagus/O esophagus = Esophagus/O esophagus Gall bladder/Bile duct = Gall bladder/Bile duct Head and Neck = Head and Neck Heart/Pericar dium = Heart/Pericar dium Kidney = Kidney Leptomening eal = Leptomening eal Liver = Liver Lung - RUL = Lung - RUL Lung - RML = Lung - RML Lung - RLL = Lung - RLL	

**PROD\_22MAR2018\_1.00: UNIQUE****Project Name: NEKNKTR1726201****Form: Tumor Biopsy****Generated On: 22 Mar 2018 22:20:59**

---

Field Name	Data Type	Units	Values	Include Field OID
			Lung - LUL	
			= Lung -	
			LUL	
			Lung - LLL	
			= Lung -	
			LLL	
			Lung -	
			Hilum =	
			Lung -	
			Hilum	
			Lung - Other	
			= Lung -	
			Other	
			Lymph	
			Nodes =	
			Lymph	
			Nodes	
			Ovary/Fallop	
			ian tube =	
			Ovary/Fallop	
			ian tube	
			Pancreas =	
			Pancreas	
			Pelvis	
			(non-bone) =	
			Pelvis	
			(non-bone)	
			Peritoneum =	
			Peritoneum	
			Pleura =	
			Pleura	
			Rectum =	
			Rectum	

---

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name:** NEKNKTR1726201

**Form:** Tumor Biopsy

**Generated On:** 22 Mar 2018 22:20:59

---

Field Name	Data Type	Units	Values	Include Field OID
			Skin - Scalp	
			= Skin -	
			Scalp	
			Skin - Trunk	
			= Skin -	
			Trunk	
			Skin - Back	
			= Skin -	
			Back	
			Skin - RU	
			Extremity =	
			Skin - RU	
			Extremity	
			Skin - RL	
			Extremity =	
			Skin - RL	
			Extremity	
			Skin - LU	
			Extremity =	
			Skin - LU	
			Extremity	
			Skin - LL	
			Extremity =	
			Skin - LL	
			Extremity	
			Skin - Other	
			= Skin -	
			Other	
			Small	
			intestine =	
			Small	
			intestine	

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name:** NEKNKTR1726201

**Form:** Tumor Biopsy

**Generated On:** 22 Mar 2018 22:20:59

---

Field Name	Data Type	Units	Values	Include Field OID
			Soft tissue =	
			Soft tissue	
			Spleen =	
			Spleen	
			Stomach =	
			Stomach	
			Trachea/Bro	
			nchi =	
			Trachea/Bro	
			nchi	
			Urinary	
			Bladder =	
			Urinary	
			Bladder	
			Uterus =	
			Uterus	
			Other =	
			Other	
<hr/>				
(9)	TBLOTH	\$200		TBLOTH
<hr/>				

ZB = Biomarkers

PROD\_22MAR2018\_1.00: UNIQUE

Project Name: NEKNKTR1726201

Form: Biomarker Sample

ZBCAT = BIOMARKER

Generated On: 22 Mar 2018 22:20:59

---

Was the biomarker sample collected?

ZBSTAT

Yes  ①  
No

---

Date of Collection (dd-mon-yyyy)

②

---

Time of Collection (24-hour Clock)

ZBDTC

③

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name:** NEKNKTR1726201

**Form:** Biomarker Sample

**Generated On:** 22 Mar 2018 22:20:59

---

	Field Name	Data Type	Units	Values	Include Field OID
①	PDPERF	\$1		Y = Yes N = No	PDPERF
②	PDDAT	dd MMM yyyy			PDDAT
③	PDTIM	HH:nn			PDTIM

---

TU = Tumor Identification

TR = Tumor Results

PROD\_22MAR2018\_1.00: UNIQUE

Project Name: NEKNKTR1726201

Form: Target Lesion Measurement Baseline

Generated On: 22 Mar 2018 22:20:59

TUORRES = TARGET

TUTESTCD = TUMIDENT

TUTEST = Tumor Identification

Lesion

TULNKID T01  ①  
TRLNKID T02   
T03   
T04   
T05

Anatomical Site

TULOC Adrenal Gland  ②  
Bone   
Brain   
Breast   
Chest Wall   
Colon/Large Intestine   
Esophagus/Oesophagus   
Gall bladder/Bile duct   
Head and Neck   
Heart/Pericardium   
Kidney   
Leptomeningeal   
Liver   
Lung - RUL   
Lung - RML   
Lung - RLL   
Lung - LUL   
Lung - LLL   
Lung - Hilum   
Lung - Other   
Lymph Nodes   
Ovary/Fallopian tube   
Pancreas   
Pelvis (non-bone)

TU = Tumor Identification

TR = Tumor Results

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: Target Lesion Measurement Baseline**

**Generated On: 22 Mar 2018 22:20:59**

---

Peritoneum	<input type="checkbox"/>
Pleura	<input type="checkbox"/>
Rectum	<input type="checkbox"/>
Skin - Scalp	<input type="checkbox"/>
Skin - Trunk	<input type="checkbox"/>
Skin - Back	<input type="checkbox"/>
Skin - RU Extremity	<input type="checkbox"/>
Skin - RL Extremity	<input type="checkbox"/>
Skin - LU Extremity	<input type="checkbox"/>
Skin - LL Extremity	<input type="checkbox"/>
Skin - Other	<input type="checkbox"/>
Small intestine	<input type="checkbox"/>
Soft tissue	<input type="checkbox"/>
Spleen	<input type="checkbox"/>
Stomach	<input type="checkbox"/>
Trachea/Bronchi	<input type="checkbox"/>
Urinary Bladder	<input type="checkbox"/>
Uterus	<input type="checkbox"/>
Other	<input type="checkbox"/>

---

If Other, specify

**SUPPTU.QVAL where QNAM = TUATOTH**

**3**

---

Anatomical Description

**SUPPTU.QVAL where QNAM = TUDESC**

**4**

---

Method of Assessment

**TUMETHOD**

**TRMETHOD**

Conventional CT

Spiral CT

MRI

PET/CT

X-ray

**5**

TU = Tumor Identification

TR = Tumor Results

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: Target Lesion Measurement Baseline**

**Generated On: 22 Mar 2018 22:20:59**

---

Digital Photography with  Calipers

Date of Assessment (dd-mon-yyyy)

**TUDTC** **TRDTC**

**6**

Lymph Node Short Axis (mm)

**TRORRES where TRTESTCD = SAXIS**

**7**

**TRORRESU**

Longest Measurement (mm)

**TRORRES where TRTESTCD = LDIAM**

**8**

**TRORRESU**

DERIVED:NOW

**NOT SUBMITTED**

**9**

**PROD\_22MAR2018\_1.00: UNIQUE****Project Name: NEKNKTR1726201****Form: Target Lesion Measurement Baseline****Generated On: 22 Mar 2018 22:20:59**

Field Name	Data Type	Units	Values	Include Field OID
① LMID	\$3		T01 = T01 T02 = T02 T03 = T03 T04 = T04 T05 = T05	LMID
② LMSITE	\$22		Adrenal Gland = Adrenal Gland Bone = Bone Brain = Brain Breast = Breast Chest Wall = Chest Wall Colon/Large Intestine = Colon/Large Intestine Esophagus/O esophagus = Esophagus/O esophagus Gall bladder/Bile duct = Gall bladder/Bile duct	LMSITE

**PROD\_22MAR2018\_1.00: UNIQUE****Project Name: NEKNKTR1726201****Form: Target Lesion Measurement Baseline****Generated On: 22 Mar 2018 22:20:59**

Field Name	Data Type	Units	Values	Include Field OID
			Head and Neck = Head and Neck Heart/Pericar dium = Heart/Pericar dium Kidney = Kidney Leptomening eal = Leptomening eal Liver = Liver Lung - RUL = Lung - RUL Lung - RML = Lung - RML Lung - RLL = Lung - RLL Lung - LUL = Lung - LUL Lung - LLL = Lung - LLL Lung - Hilum = Lung - Hilum	

**PROD\_22MAR2018\_1.00: UNIQUE****Project Name: NEKNKTR1726201****Form: Target Lesion Measurement Baseline****Generated On: 22 Mar 2018 22:20:59**

Field Name	Data Type	Units	Values	Include Field OID
			Lung - Other = Lung - Other Lymph Nodes = Lymph Nodes Ovary/Fallop ian tube = Ovary/Fallop ian tube Pancreas = Pancreas Pelvis (non-bone) = Pelvis (non-bone) Peritoneum = Peritoneum Pleura = Pleura Rectum = Rectum Skin - Scalp = Skin - Scalp Skin - Trunk = Skin - Trunk Skin - Back = Skin - Back	

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: Target Lesion Measurement Baseline**

**Generated On: 22 Mar 2018 22:20:59**

---

Field Name	Data Type	Units	Values	Include Field OID
			Skin - RU	
			Extremity =	
			Skin - RU	
			Extremity	
			Skin - RL	
			Extremity =	
			Skin - RL	
			Extremity	
			Skin - LU	
			Extremity =	
			Skin - LU	
			Extremity	
			Skin - LL	
			Extremity =	
			Skin - LL	
			Extremity	
			Skin - Other	
			= Skin -	
			Other	
			Small	
			intestine =	
			Small	
			intestine	
			Soft tissue =	
			Soft tissue	
			Spleen =	
			Spleen	
			Stomach =	
			Stomach	
			Trachea/Bronchi =	
			Trachea/Bronchi	
			nchi	

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: Target Lesion Measurement Baseline**

**Generated On: 22 Mar 2018 22:20:59**

---

Field Name	Data Type	Units	Values	Include Field OID
			Urinary Bladder = Urinary Bladder Uterus = Uterus Other = Other	
③ LMOTH1	\$200			LMOTH1
④ LMDESC	\$200			LMDESC
⑤ LMMETHO	\$33	D	Conventional CT = D Conventional CT Spiral CT = Spiral CT MRI = MRI PET/CT = PET/CT X-ray = X-ray Digital Photography with Calipers = Digital Photography with Calipers	LMMETHO

---

---

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: Target Lesion Measurement Baseline**

**Generated On: 22 Mar 2018 22:20:59**

---

	Field Name	Data Type	Units	Values	Include Field OID
⑥	LMSCDAT	dd MMM yyyy			LMSCDAT
⑦	LMSD	8			LMSD
⑧	LMBIDI	8			LMBIDI
⑨	Z_NOW	dd MMM yyyy HH nn ss			Z_NOW

---

TU = Tumor Identification

TR = Tumor Results

**PROD\_22MAR2018\_1.00: UNIQUE**  
**Project Name: NEKNKTR1726201**  
**Form: Non-Target Lesion Baseline**  
**Generated On: 22 Mar 2018 22:20:59**

TUORRES = NON-TARGET

TUTESTCD = TUMIDENT

TUTEST = Tumor Identification

Lesion

NT01   
NT02   
NT03   
NT04   
NT05   
NT06   
NT07   
NT08   
NT09   
NT10   
NT11   
NT12   
NT13   
NT14   
NT15   
NT16   
NT17   
NT18   
NT19   
NT20   
NT21   
NT22   
NT23   
NT24   
NT25   
NT26   
NT27   
NT28   
NT29   
NT30

TULNKID

TRLNKID

1

**TU = Tumor Identification**

**TR = Tumor Results**

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: Non-Target Lesion Baseline**

**Generated On: 22 Mar 2018 22:20:59**

---

NT31	○
NT32	○
NT33	○
NT34	○
NT35	○
NT36	○
NT37	○
NT38	○
NT39	○
NT40	○
NT41	○
NT42	○
NT43	○
NT44	○
NT45	○
NT46	○
NT47	○
NT48	○
NT49	○
NT50	○
NT51	○
NT52	○
NT53	○
NT54	○
NT55	○
NT56	○
NT57	○
NT58	○
NT59	○
NT60	○

**TU = Tumor Identification**

**TR = Tumor Results**

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: Non-Target Lesion Baseline**

**Generated On: 22 Mar 2018 22:20:59**

---

NT61	<input type="radio"/>
NT62	<input type="radio"/>
NT63	<input type="radio"/>
NT64	<input type="radio"/>
NT65	<input type="radio"/>
NT66	<input type="radio"/>
<b>TULNKID</b>	<input type="radio"/>
<b>TRLNKID</b>	<input type="radio"/>
NT67	<input type="radio"/>
NT68	<input type="radio"/>
NT69	<input type="radio"/>
NT70	<input type="radio"/>
NT71	<input type="radio"/>
NT72	<input type="radio"/>
NT73	<input type="radio"/>
NT74	<input type="radio"/>
NT75	<input type="radio"/>
NT76	<input type="radio"/>
NT77	<input type="radio"/>
NT78	<input type="radio"/>
NT79	<input type="radio"/>
NT80	<input type="radio"/>
NT81	<input type="radio"/>
NT82	<input type="radio"/>
NT83	<input type="radio"/>
NT84	<input type="radio"/>
NT85	<input type="radio"/>
NT86	<input type="radio"/>
NT87	<input type="radio"/>
NT88	<input type="radio"/>
NT89	<input type="radio"/>
NT90	<input type="radio"/>

TU = Tumor Identification

TR = Tumor Results

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: Non-Target Lesion Baseline**

**Generated On: 22 Mar 2018 22:20:59**

---

TULNKID	NT91	<input type="checkbox"/>
TRLNKID	NT92	<input type="checkbox"/>
	NT93	<input type="checkbox"/>
	NT94	<input type="checkbox"/>
	NT95	<input type="checkbox"/>
	NT96	<input type="checkbox"/>
	NT97	<input type="checkbox"/>
	NT98	<input type="checkbox"/>
	NT99	<input type="checkbox"/>

---

Control/Non-Injected Lesion

SUPPTU.QVAL where QNAM = NINJLES

SUPPTR.QVAL where QNAM = NINJLES

(2)

---

Anatomical Site

TULOC	Adrenal Gland	<input type="checkbox"/>
	Bone	<input type="checkbox"/>
	Brain	<input type="checkbox"/>
	Breast	<input type="checkbox"/>
	Chest Wall	<input type="checkbox"/>
	Colon/Large Intestine	<input type="checkbox"/>
	Esophagus/Oesophagus	<input type="checkbox"/>
	Gall bladder/Bile duct	<input type="checkbox"/>
	Head and Neck	<input type="checkbox"/>
	Heart/Pericardium	<input type="checkbox"/>
	Kidney	<input type="checkbox"/>
	Leptomeningeal	<input type="checkbox"/>
	Liver	<input type="checkbox"/>
	Lung - RUL	<input type="checkbox"/>
	Lung - RML	<input type="checkbox"/>
	Lung - RLL	<input type="checkbox"/>
	Lung - LUL	<input type="checkbox"/>
	Lung - LLL	<input type="checkbox"/>

TU = Tumor Identification

TR = Tumor Results

PROD\_22MAR2018\_1.00: UNIQUE

Project Name: NEKNKTR1726201

Form: Non-Target Lesion Baseline

Generated On: 22 Mar 2018 22:20:59

---

<b>TULOC</b>	Lung - Hilum	<input type="checkbox"/>
	Lung - Other	<input type="checkbox"/>
	Lymph Nodes	<input type="checkbox"/>
	Ovary/Fallopian tube	<input type="checkbox"/>
	Pancreas	<input type="checkbox"/>
	Pelvis (non-bone)	<input type="checkbox"/>
	Peritoneum	<input type="checkbox"/>
	Pleura	<input type="checkbox"/>
	Rectum	<input type="checkbox"/>
	Skin - Scalp	<input type="checkbox"/>
	Skin - Trunk	<input type="checkbox"/>
	Skin - Back	<input type="checkbox"/>
	Skin - RU Extremity	<input type="checkbox"/>
	Skin - RL Extremity	<input type="checkbox"/>
	Skin - LU Extremity	<input type="checkbox"/>
	Skin - LL Extremity	<input type="checkbox"/>
	Skin - Other	<input type="checkbox"/>
	Small intestine	<input type="checkbox"/>
	Soft tissue	<input type="checkbox"/>
	Spleen	<input type="checkbox"/>
	Stomach	<input type="checkbox"/>
	Trachea/Bronchi	<input type="checkbox"/>
	Urinary Bladder	<input type="checkbox"/>
	Uterus	<input type="checkbox"/>
	Other	<input type="checkbox"/>

---

If Other, specify

**SUPPTU.QVAL where QNAM = TUATOTH**

**4**

---

Anatomical Description

**SUPPTU.QVAL where QNAM = TUDESC**

**5**

---

---

TU = Tumor Identification

TR = Tumor Results

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: Non-Target Lesion Baseline**

**Generated On: 22 Mar 2018 22:20:59**

Method of Assessment

Conventional CT  ⑥

Spiral CT

MRI

TUMETHOD

PET/CT

TRMETHOD

Bone Scan

X-ray

Digital Photography with

Calipers

Physical Exam

Other

If Other, specify

SUPPTU.QVAL where QNAM = TUMEOTH

⑦

SUPPTR.QVAL where QNAM = TUMEOTH

Date of Assessment (dd-mon-yyyy)

TUDTC TRDTC

⑧

Lesion Status

Present  ⑨

Absent

Unequivocal Progression

TRSTAT = NOT DONE if Not Assessed is checked Not Assessed

TRREASND = NOT ASSESSED if Not Assessed is checked

DERIVED:NOW

NOT SUBMITTED

⑩

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: Non-Target Lesion Baseline**

**Generated On: 22 Mar 2018 22:20:59**

---

Field Name	Data Type	Units	Values	Include Field OID
① NLMID	\$4		NT01 = NT01 NT02 = NT02 NT03 = NT03 NT04 = NT04 NT05 = NT05 NT06 = NT06 NT07 = NT07 NT08 = NT08 NT09 = NT09 NT10 = NT10 NT11 = NT11 NT12 = NT12 NT13 = NT13 NT14 = NT14 NT15 = NT15 NT16 = NT16 NT17 = NT17	NLMID

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: Non-Target Lesion Baseline**

**Generated On: 22 Mar 2018 22:20:59**

---

Field Name	Data Type	Units	Values	Include Field OID
			NT18 =	
			NT18	
			NT19 =	
			NT19	
			NT20 =	
			NT20	
			NT21 =	
			NT21	
			NT22 =	
			NT22	
			NT23 =	
			NT23	
			NT24 =	
			NT24	
			NT25 =	
			NT25	
			NT26 =	
			NT26	
			NT27 =	
			NT27	
			NT28 =	
			NT28	
			NT29 =	
			NT29	
			NT30 =	
			NT30	
			NT31 =	
			NT31	
			NT32 =	
			NT32	
			NT33 =	
			NT33	
			NT34 =	
			NT34	

---

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: Non-Target Lesion Baseline**

**Generated On: 22 Mar 2018 22:20:59**

---

Field Name	Data Type	Units	Values	Include Field OID
			NT35 =	
			NT35	
			NT36 =	
			NT36	
			NT37 =	
			NT37	
			NT38 =	
			NT38	
			NT39 =	
			NT39	
			NT40 =	
			NT40	
			NT41 =	
			NT41	
			NT42 =	
			NT42	
			NT43 =	
			NT43	
			NT44 =	
			NT44	
			NT45 =	
			NT45	
			NT46 =	
			NT46	
			NT47 =	
			NT47	
			NT48 =	
			NT48	
			NT49 =	
			NT49	
			NT50 =	
			NT50	
			NT51 =	
			NT51	

---

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: Non-Target Lesion Baseline**

**Generated On: 22 Mar 2018 22:20:59**

---

Field Name	Data Type	Units	Values	Include Field OID
			NT52 =	
			NT52	
			NT53 =	
			NT53	
			NT54 =	
			NT54	
			NT55 =	
			NT55	
			NT56 =	
			NT56	
			NT57 =	
			NT57	
			NT58 =	
			NT58	
			NT59 =	
			NT59	
			NT60 =	
			NT60	
			NT61 =	
			NT61	
			NT62 =	
			NT62	
			NT63 =	
			NT63	
			NT64 =	
			NT64	
			NT65 =	
			NT65	
			NT66 =	
			NT66	
			NT67 =	
			NT67	
			NT68 =	
			NT68	

---

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: Non-Target Lesion Baseline**

**Generated On: 22 Mar 2018 22:20:59**

---

Field Name	Data Type	Units	Values	Include Field OID
			NT69 =	
			NT69	
			NT70 =	
			NT70	
			NT71 =	
			NT71	
			NT72 =	
			NT72	
			NT73 =	
			NT73	
			NT74 =	
			NT74	
			NT75 =	
			NT75	
			NT76 =	
			NT76	
			NT77 =	
			NT77	
			NT78 =	
			NT78	
			NT79 =	
			NT79	
			NT80 =	
			NT80	
			NT81 =	
			NT81	
			NT82 =	
			NT82	
			NT83 =	
			NT83	
			NT84 =	
			NT84	
			NT85 =	
			NT85	

---

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: Non-Target Lesion Baseline**

**Generated On: 22 Mar 2018 22:20:59**

---

Field Name	Data Type	Units	Values	Include Field OID
			NT86 =	
			NT86	
			NT87 =	
			NT87	
			NT88 =	
			NT88	
			NT89 =	
			NT89	
			NT90 =	
			NT90	
			NT91 =	
			NT91	
			NT92 =	
			NT92	
			NT93 =	
			NT93	
			NT94 =	
			NT94	
			NT95 =	
			NT95	
			NT96 =	
			NT96	
			NT97 =	
			NT97	
			NT98 =	
			NT98	
			NT99 =	
			NT99	

---

② NLMCTRL 1

---

NLMCTRL

---

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: Non-Target Lesion Baseline**

**Generated On: 22 Mar 2018 22:20:59**

---

Field Name	Data Type	Units	Values	Include Field OID
③ NLMSITE	\$22		Adrenal Gland = Adrenal Gland Bone = Bone Brain = Brain Breast = Breast Chest Wall = Chest Wall Colon/Large Intestine = Colon/Large Intestine Esophagus/O esophagus = Esophagus/O esophagus Gall bladder/Bile duct = Gall bladder/Bile duct Head and Neck = Head and Neck Heart/Pericar dium = Heart/Pericar dium	NLMSITE

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: Non-Target Lesion Baseline**

**Generated On: 22 Mar 2018 22:20:59**

---

Field Name	Data Type	Units	Values	Include Field OID
			Kidney = Kidney Leptomening eal = Leptomening eal Liver = Liver Lung - RUL = Lung - RUL Lung - RML = Lung - RML Lung - RLL = Lung - RLL Lung - LUL = Lung - LUL Lung - LLL = Lung - LLL Lung - Hilum = Lung - Hilum Lung - Other = Lung - Other Lymph Nodes = Lymph Nodes	

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name:** NEKNKTR1726201

**Form:** Non-Target Lesion Baseline

**Generated On:** 22 Mar 2018 22:20:59

---

Field Name	Data Type	Units	Values	Include Field OID
			Ovary/Fallopian tube =	
			Ovary/Fallopian tube	
			Pancreas =	
			Pancreas	
			Pelvis	
			(non-bone) =	
			Pelvis	
			(non-bone)	
			Peritoneum =	
			Peritoneum	
			Pleura =	
			Pleura	
			Rectum =	
			Rectum	
			Skin - Scalp	
			= Skin -	
			Scalp	
			Skin - Trunk	
			= Skin -	
			Trunk	
			Skin - Back	
			= Skin -	
			Back	
			Skin - RU	
			Extremity =	
			Skin - RU	
			Extremity	
			Skin - RL	
			Extremity =	
			Skin - RL	
			Extremity	

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name:** NEKNKTR1726201

**Form:** Non-Target Lesion Baseline

**Generated On:** 22 Mar 2018 22:20:59

---

Field Name	Data Type	Units	Values	Include Field OID
			Skin - LU Extremity = Skin - LU Extremity Skin - LL Extremity = Skin - LL Extremity Skin - Other = Skin - Other Small intestine = Small intestine Soft tissue = Soft tissue Spleen = Spleen Stomach = Stomach Trachea/Bro nchi = Trachea/Bro nchi Urinary Bladder = Urinary Bladder Uterus = Uterus Other = Other	

---

---

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name:** NEKNKTR1726201

**Form:** Non-Target Lesion Baseline

**Generated On:** 22 Mar 2018 22:20:59

---

Field Name	Data Type	Units	Values	Include Field OID
④ NLMOTH1	\$200		NLMOTH1	
⑤ NLMDESC	\$200		NLMDESC	
⑥ NLMMETH	\$33		Conventional CT = Conventional CT Spiral CT = Spiral CT MRI = MRI PET/CT = PET/CT Bone Scan = Bone Scan X-ray = X-ray Digital Photography with Calipers = Digital Photography with Calipers Physical Exam = Physical Exam Other = Other	NLMMETH
⑦ NLMOTH2	\$100		NLMOTH2	

---

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: Non-Target Lesion Baseline**

**Generated On: 22 Mar 2018 22:20:59**

---

Field Name	Data Type	Units	Values	Include Field OID
⑧ NLMSCDA	dd MMM T	yyyy		NLMSCDA T
⑨ NLMSTAT	\$23		Present = Present Absent = Absent Uequivocal Progression = Uequivocal Progression Not Assessed = Not Assessed	NLMSTAT
⑩ Z_NOW	dd MMM yyyy HH nn ss			Z_NOW

---

PC = Pharmacokinetic Concentrations

PROD\_22MAR2018\_1.00: UNIQUE

Project Name: NEKNKTR1726201

Form: Urine PK Sample

Generated On: 22 Mar 2018 22:20:59

PCSPEC = URINE

Was a urine PK sample collected?

Yes  ①

No

PCSTAT = NOT DONE if No is checked

Collection Date (dd-mon-yyyy)

\_\_\_\_\_ ②

Collection Time (24-hour clock)

PCDTC

\_\_\_\_\_ ③

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name:** NEKNKTR1726201

**Form:** Urine PK Sample

**Generated On:** 22 Mar 2018 22:20:59

---

	Field Name	Data Type	Units	Values	Include Field OID
①	PKUPERF	\$1		Y = Yes N = No	PKUPERF
②	PKUDAT	dd MMM yyyy			PKUDAT
③	PKUTIM	HH:nn			PKUTIM

---

ZB = Biomarkers

PROD\_22MAR2018\_1.00: UNIQUE

Project Name: NEKNKTR1726201

Form: Biomarker Sample (Day 1)

Generated On: 22 Mar 2018 22:20:59

ZBCAT = BIOMARKER

Biomarker samples collected?

Yes  ①  
No

ZBSTAT where ZBTESTCD = ZBALL

Date of Collection (dd-mon-yyyy)

ZBDTC

②

Planned Timepoint

ZBTPT

Pre-dose ③

Not Done

ZBSTAT

④

Time of Collection (24-hour clock)

ZBDTC

⑤

Planned Timepoint

ZBTPT

6 Hrs Post-dose ③

Not Done

ZBSTAT

④

Time of Collection (24-hour clock)

ZBDTC

⑤

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name:** NEKNKTR1726201

**Form:** Biomarker Sample (Day 1)

**Generated On:** 22 Mar 2018 22:20:59

---

	Field Name	Data Type	Units	Values	Include Field OID
①	PDPERF	\$1		Y = Yes N = No	PDPERF
②	PDDAT	dd MMM yyyy			PDDAT
③	PDTPT	\$45		Pre-dose 6 Hrs Post-dose	PDTPT
④	PDND	1			PDND
⑤	PDTIM	HH:nn			PDTIM

---

**PROD\_22MAR2018\_1.00: UNIQUE****Project Name:** NEKNKTR1726201**Form:** Biomarker Sample (C3D1)**Generated On:** 22 Mar 2018 22:20:59

---

Biomarker samples collected?Yes  ①  
No 

---

Date of Collection (dd-mon-yyyy) \_\_\_\_\_ ②

---

Planned Timepoint

Pre-dose ③

---

Not Done

④

---

Time of Collection (24-hour clock) \_\_\_\_\_ ⑤

---

Planned Timepoint

3 Hrs Post-dose ③

---

Not Done

④

---

Time of Collection (24-hour clock) \_\_\_\_\_ ⑤

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name:** NEKNKTR1726201

**Form:** Biomarker Sample (C3D1)

**Generated On:** 22 Mar 2018 22:20:59

---

	Field Name	Data Type	Units	Values	Include Field OID
①	PDPERF	\$1		Y = Yes N = No	PDPERF
②	PDDAT	dd MMM yyyy			PDDAT
③	PDTPT1	\$20		Pre-dose 3 Hrs Post-dose	PDTPT1
④	PDND	1			PDND
⑤	PDTIM	HH:nn			PDTIM

---

PE = Physical Examination

See CRF Page 101

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: Ophthalmology Exam**

**Generated On: 22 Mar 2018 22:20:59**

---

Exam Date (dd-mon-yyyy)

①

---

Was an eye Exam done?

Yes  ②

No

---

Was fundus photography performed?

Yes  ③

No

---

Were any clinically significant new or worsened abnormalities noted?

Yes  ④

No

**RELREC = Related Records**

If yes, specify clinically significant adverse events below:

---

Adverse Event 1

SUPPPE.QVAL where QNAM = AENO1

⑤

---

Adverse Event 2

SUPPPE.QVAL where QNAM = AENO2

⑥

---

Adverse Event 3

SUPPPE.QVAL where QNAM = AENO3

⑦

Create RELREC records to connect to the following:

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name:** NEKNKTR1726201

**Form:** Ophthalmology Exam

**Generated On:** 22 Mar 2018 22:20:59

---

	Field Name	Data Type	Units	Values	Include Field OID
①	OADAT	dd MMM yyyy			OADAT
②	OPAEYEX	\$1		Y = Yes N = No	OPAEYEX
③	OAFUND	\$1		Y = Yes N = No	OAFUND
④	OAABN	\$1		Y = Yes N = No	OAABN
⑤	OAAE1	\$50			OAAE1
⑥	OAAE2	\$50			OAAE2
⑦	OAAE3	\$50			OAAE3

---

[IS = Immunogenicity Specimen Assessments]

PROD\_22MAR2018\_1.00: UNIQUE

Project Name: NEKNKTR1726201

Form: Immunogenicity Sample Collection NKTR-214

Generated On: 22 Mar 2018 22:20:59

[ISCAT = IMMUNOGENICITY]

[ISSCAT = NKTR-214]

Was the immunogenicity sample collected?

Yes  ①  
No

[ISSTAT = NOT DONE if No is checked]

Date of Collection (dd-mon-yyyy)

②

Time of Collection

[ISDTC]  
Fixed Unit: 24-hour clock ③

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: Immunogenicity Sample Collection NKTR-214**

**Generated On: 22 Mar 2018 22:20:59**

---

	Field Name	Data Type	Units	Values	Include Field OID
①	IMPERF	\$1		Y = Yes N = No	IMPERF
②	IMDAT	dd MMM yyyy			IMDAT
③	IMTIM	HH:nn			IMTIM

---

IS = Immunogenicity Specimen Assessments

PROD\_22MAR2018\_1.00: UNIQUE

Project Name: NEKNKTR1726201

Form: Immunogenicity Sample Collection Nivolumab

Generated On: 22 Mar 2018 22:20:59

[ISCAT = IMMUNOGENICITY]

[ISSCAT = NIVOLUMAB]

Was the immunogenicity sample collected:

Yes  ①

No

[ISSTAT = NOT DONE if No is checked]

Date of Collection (dd-mon-yyyy)

\_\_\_\_\_ ②

[SDTC]

Time of Collection

Fixed Unit: 24-hour clock ③

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: Immunogenicity Sample Collection Nivolumab**

**Generated On: 22 Mar 2018 22:20:59**

---

	Field Name	Data Type	Units	Values	Include Field OID
①	IMPERF	\$1		Y = Yes N = No	IMPERF
②	IMDAT	dd MMM yyyy			IMDAT
③	IMTIM	HH:nn			IMTIM

---

PC = Pharmacokinetic Concentrations

See CRF Page 157

PROD\_22MAR2018\_1.00: UNIQUE

Project Name: NEKNKTR1726201

Form: PK Blood Sample

PCSPEC = PLASMA

Generated On: 22 Mar 2018 22:20:59

---

Was the sample collected?

Yes  ①  
No

Date of Collection (dd-mon-yyyy)

\_\_\_\_\_ ②

Time of Collection

Fixed Unit: 24-hour clock ③

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name:** NEKNKTR1726201

**Form:** PK Blood Sample

**Generated On:** 22 Mar 2018 22:20:59

---

	Field Name	Data Type	Units	Values	Include Field OID
①	PCPERF	\$1		Y = Yes N = No	PCPERF
②	PCDAT	dd MMM yyyy			PCDAT
③	PCTIM_P	HH:nn			PCTIM_P

---

PC = Pharmacokinetic Concentrations

PROD\_22MAR2018\_1.00: UNIQUE

Project Name: NEKNKTR1726201

Form: PK Sample NKTR-262 (Day 1)

Generated On: 22 Mar 2018 22:20:59

Was the sample collected?

Yes  ①

No

PCSTAT where PCTESTCD = PCALL

Planned Timepoint

PCTPT Pre-dose ②

Not Done

PCSTAT ③

Date of Collection (dd-mon-yyyy)

④

Time of Collection (24-hour clock)

PCDTC ⑤

Planned Timepoint

PCTPT 1 Hr Post-dose ②

Not Done

PCSTAT ③

Date of Collection (dd-mon-yyyy)

④

Time of Collection (24-hour clock)

PCDTC ⑤

Planned Timepoint

3 Hrs Post-dose ②

PCTPT

Not Done

PCSTAT ③

PC = Pharmacokinetic Concentrations

PROD\_22MAR2018\_1.00: UNIQUE

Project Name: NEKNKTR1726201

Form: PK Sample NKTR-262 (Day 1)

Generated On: 22 Mar 2018 22:20:59

---

Date of Collection (dd-mon-yyyy) \_\_\_\_\_ ④

Time of Collection (24-hour clock) \_\_\_\_\_ PCDTC ⑤

Planned Timepoint \_\_\_\_\_ PCTPT 6 Hrs Post-dose ②

Not Done \_\_\_\_\_ PCSTAT ③

Date of Collection (dd-mon-yyyy) \_\_\_\_\_ ④

Time of Collection (24-hour clock) \_\_\_\_\_ PCDTC ⑤

---

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: PK Sample NKTR-262 (Day 1)**

**Generated On: 22 Mar 2018 22:20:59**

---

	Field Name	Data Type	Units	Values	Include Field OID
①	PCPERF	\$1		Y = Yes N = No	PCPERF
②	PCTPT1	\$30		Pre-dose 1 Hr Post-dose 3 Hrs Post-dose 6 Hrs Post-dose	PCTPT1
③	PCTPTND	1			PCTPTND
④	PCDAT	dd MMM yyyy			PCDAT
⑤	PCTIM_P	HH:nn			PCTIM_P

---

**PC = Pharmacokinetic Concentrations**

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: PK Sample NKTR-262 (Unscheduled)**

**Generated On: 22 Mar 2018 22:20:59**

**See CRF Page 171**

Was the sample collected?

Yes  ①

**NOT SUBMITTED if No is checked**

No

Planned Timepoint

Pre-dose ②

Not Done

**NOT SUBMITTED if No is checked**

③

Date of Collection (dd-mon-yyyy)

④

Time of Collection (24-hour clock)

⑤

Planned Timepoint

1 Hr Post-dose ②

Not Done

**NOT SUBMITTED if No is checked**

③

Date of Collection (dd-mon-yyyy)

④

Time of Collection (24-hour clock)

⑤

Planned Timepoint

3 Hrs Post-dose ②

Not Done

**NOT SUBMITTED if No is checked**

③

PC = Pharmacokinetic Concentrations

PROD\_22MAR2018\_1.00: UNIQUE

Project Name: NEKNKTR1726201

Form: PK Sample NKTR-262 (Unscheduled)

Generated On: 22 Mar 2018 22:20:59

See CRF Page 172

Date of Collection (dd-mon-yyyy) \_\_\_\_\_ ④

Time of Collection (24-hour clock) \_\_\_\_\_ ⑤

Planned Timepoint 6 Hrs Post-dose ②

Not Done NOT SUBMITTED if No is checked ③

Date of Collection (dd-mon-yyyy) \_\_\_\_\_ ④

Time of Collection (24-hour clock) \_\_\_\_\_ ⑤

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: PK Sample NKTR-262 (Unscheduled)**

**Generated On: 22 Mar 2018 22:20:59**

---

	Field Name	Data Type	Units	Values	Include Field OID
①	PCPERF	\$1		Y = Yes N = No	PCPERF
②	PCTPT1	\$30		Pre-dose 1 Hr Post-dose 3 Hrs Post-dose 6 Hrs Post-dose	PCTPT1
③	PCTPTND	1			PCTPTND
④	PCDAT	dd MMM yyyy			PCDAT
⑤	PCTIM_P	HH:nn			PCTIM_P

---

PC = Pharmacokinetic Concentrations

PROD\_22MAR2018\_1.00: UNIQUE

Project Name: NEKNKTR1726201

Form: PK NKTR-262 (non-dosing day)

Generated On: 22 Mar 2018 22:20:59

---

Was the sample collected?

Yes  ①

No

PCSTAT = NOT DONE if No is checked

Date of Collection (dd-mon-yyyy)

\_\_\_\_\_ ②

PCDTC

Time of Collection (24-hour clock)

\_\_\_\_\_ ③

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name:** NEKNKTR1726201

**Form:** PK NKTR-262 (non-dosing day)

**Generated On:** 22 Mar 2018 22:20:59

---

	Field Name	Data Type	Units	Values	Include Field OID
①	PCPERF	\$1		Y = Yes N = No	PCPERF
②	PCDAT		dd MMM yyyy		PCDAT
③	PCTIM_P		HH:nn		PCTIM_P

---

PC = Pharmacokinetic Concentrations

See CRF Page 171

**PROD\_22MAR2018\_1.00: UNIQUE**  
**Project Name: NEKNKTR1726201**  
**Form: PK Sample NKTR-262 (C3D1)**  
**Generated On: 22 Mar 2018 22:20:59**

Was the sample collected?

Yes  1  
No

Planned Timepoint

Pre-dose 2

Not Done

3

Date of Collection (dd-mon-yyyy)

4

Time of Collection (24-hour clock)

5

Planned Timepoint

1 Hr Post-dose 2

Not Done

3

Date of Collection (dd-mon-yyyy)

4

Time of Collection (24-hour clock)

5

Planned Timepoint

3 Hrs Post-dose 2

Not Done

3

PC = Pharmacokinetic Concentrations

See CRF Page 172

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: PK Sample NKTR-262 (C3D1)**

**Generated On: 22 Mar 2018 22:20:59**

---

Date of Collection (dd-mon-yyyy) \_\_\_\_\_ **(4)**

Time of Collection (24-hour clock) \_\_\_\_\_ **(5)**

---

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: PK Sample NKTR-262 (C3D1)**

**Generated On: 22 Mar 2018 22:20:59**

---

	Field Name	Data Type	Units	Values	Include Field OID
①	PCPERF	\$1		Y = Yes N = No	PCPERF
②	PCTPT3	\$30		Pre-dose 1 Hr Post-dose 3 Hrs Post-dose	PCTPT3
③	PCTPTND	1			PCTPTND
④	PCDAT	dd MMM yyyy			PCDAT
⑤	PCTIM_P	HH:nn			PCTIM_P

---

PC = Pharmacokinetic Concentrations

See CRF Page 171

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: PK Sample NKTR-262**

**Generated On: 22 Mar 2018 22:20:59**

Was the sample collected?

Yes  1  
No

Planned Timepoint

Pre-dose 2

Not Done

3

Date of Collection (dd-mon-yyyy)

4

Time of Collection (24-hour clock)

5

Planned Timepoint

2 Hrs Post-dose 2

Not Done

3

Date of Collection (dd-mon-yyyy)

4

Time of Collection (24-hour clock)

5

Planned Timepoint

3 Hrs Post-dose 2

Not Done

3

PC = Pharmacokinetic Concentrations

See CRF Page 172

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: PK Sample NKTR-262**

**Generated On: 22 Mar 2018 22:20:59**

---

Date of Collection (dd-mon-yyyy) \_\_\_\_\_ **(4)**

Time of Collection (24-hour clock) \_\_\_\_\_ **(5)**

---

---

Planned Timepoint \_\_\_\_\_ 6 Hrs Post-dose **(2)**

---

Not Done \_\_\_\_\_ **(3)**

---

Date of Collection (dd-mon-yyyy) \_\_\_\_\_ **(4)**

---

Time of Collection (24-hour clock) \_\_\_\_\_ **(5)**

---

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: PK Sample NKTR-262**

**Generated On: 22 Mar 2018 22:20:59**

---

	Field Name	Data Type	Units	Values	Include Field OID
①	PCPERF	\$1		Y = Yes N = No	PCPERF
②	PCTPT4	\$30		Pre-dose 2 Hrs Post-dose 3 Hrs Post-dose 6 Hrs Post-dose	PCTPT4
③	PCTPTND	1			PCTPTND
④	PCDAT	dd MMM yyyy			PCDAT
⑤	PCTIM_P	HH:nn			PCTIM_P

---

**PROD\_22MAR2018\_1.00: UNIQUE****Project Name: NEKNKTR1726201****Form: PK Sample NKTR-262 (same day dosing)****Generated On: 22 Mar 2018 22:20:59**

Was the sample collected?

Yes  1  
No 

Planned Timepoint

Pre-dose 2

Not Done

3

Date of Collection (dd-mon-yyyy)

4

Time of Collection (24-hour clock)

5

Planned Timepoint

3 Hrs Post-dose 2

Not Done

3

Date of Collection (dd-mon-yyyy)

4

Time of Collection (24-hour clock)

5

Planned Timepoint

6 Hrs Post-dose 2

Not Done

3

PC = Pharmacokinetic Concentrations

See CRF Page 172

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: PK Sample NKTR-262 (same day dosing)**

**Generated On: 22 Mar 2018 22:20:59**

---

Date of Collection (dd-mon-yyyy) \_\_\_\_\_ **④**

Time of Collection (24-hour clock) \_\_\_\_\_ **⑤**

---

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: PK Sample NKTR-262 (same day dosing)**

**Generated On: 22 Mar 2018 22:20:59**

---

	Field Name	Data Type	Units	Values	Include Field OID
①	PCPERF	\$1		Y = Yes N = No	PCPERF
②	PCTPT5	\$30		Pre-dose 3 Hrs Post-dose 6 Hrs Post-dose	PCTPT5
③	PCTPTND	1			PCTPTND
④	PCDAT	dd MMM yyyy			PCDAT
⑤	PCTIM_P	HH:nn			PCTIM_P

---

PC = Pharmacokinetic Concentrations

See CRF Page 171

PROD\_22MAR2018\_1.00: UNIQUE

Project Name: NEKNKTR1726201

Form: PK Sample NKTR-214 (C2D3)

Generated On: 22 Mar 2018 22:20:59

Was the sample collected?

Yes  1  
No

Planned Timepoint

Pre-dose 2

Not Done

3

Date of Collection (dd-mon-yyyy)

4

Time of Collection (24-hour clock)

5

Planned Timepoint

End of Infusion 2

Not Done

3

Date of Collection (dd-mon-yyyy)

4

Time of Collection (24-hour clock)

5

Planned Timepoint

1 Hr Post-dose 2

Not Done

3

PC = Pharmacokinetic Concentrations

See CRF Page 172

PROD\_22MAR2018\_1.00: UNIQUE

Project Name: NEKNKTR1726201

Form: PK Sample NKTR-214 (C2D3)

Generated On: 22 Mar 2018 22:20:59

---

Date of Collection (dd-mon-yyyy) \_\_\_\_\_ ④

---

Time of Collection (24-hour clock) \_\_\_\_\_ ⑤

---

Planned Timepoint 3 Hrs Post-dose ②

---

Not Done \_\_\_\_\_ ③

---

Date of Collection (dd-mon-yyyy) \_\_\_\_\_ ④

---

Time of Collection (24-hour clock) \_\_\_\_\_ ⑤

---

Planned Timepoint 6 Hrs Post-dose ②

---

Not Done \_\_\_\_\_ ③

---

Date of Collection (dd-mon-yyyy) \_\_\_\_\_ ④

---

Time of Collection (24-hour clock) \_\_\_\_\_ ⑤

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: PK Sample NKTR-214 (C2D3)**

**Generated On: 22 Mar 2018 22:20:59**

---

	Field Name	Data Type	Units	Values	Include Field OID
①	PCPERF	\$1		Y = Yes N = No	PCPERF
②	PCTPT6	\$30		Pre-dose End PCTPT6 of Infusion 1 Hr Post-dose 3 Hrs Post-dose 6 Hrs Post-dose	
③	PCTPTND	1			PCTPTND
④	PCDAT	dd MMM yyyy			PCDAT
⑤	PCTIM_P	HH:nn			PCTIM_P

---

PC = Pharmacokinetic Concentrations

PROD\_22MAR2018\_1.00: UNIQUE

Project Name: NEKNKTR1726201

Form: PK Sample NKTR-214 (Unscheduled)

See CRF Page 171

Generated On: 22 Mar 2018 22:20:59

Was the sample collected?

Yes  ①  
No

NOT SUBMITTED if No is checked

Planned Timepoint

Pre-dose ②

Not Done

NOT SUBMITTED if checked

③

Date of Collection (dd-mon-yyyy)

④

Time of Collection (24-hour clock)

⑤

Planned Timepoint

End of Infusion ②

Not Done

NOT SUBMITTED if checked

③

Date of Collection (dd-mon-yyyy)

④

Time of Collection (24-hour clock)

⑤

Planned Timepoint

1 Hr Post-dose ②

Not Done

NOT SUBMITTED if checked

③

**PC = Pharmacokinetic Concentrations**

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: PK Sample NKTR-214 (Unscheduled)**

**See CRF Page 172**

**Generated On: 22 Mar 2018 22:20:59**

---

Date of Collection (dd-mon-yyyy) \_\_\_\_\_ **(4)**

Time of Collection (24-hour clock) \_\_\_\_\_ **(5)**

Planned Timepoint \_\_\_\_\_ 3 Hrs Post-dose **(2)**

Not Done **NOT SUBMITTED if checked** **(3)**

Date of Collection (dd-mon-yyyy) \_\_\_\_\_ **(4)**

Time of Collection (24-hour clock) \_\_\_\_\_ **(5)**

Planned Timepoint \_\_\_\_\_ 6 Hrs Post-dose **(2)**

Not Done \_\_\_\_\_ **(3)**

Date of Collection (dd-mon-yyyy) \_\_\_\_\_ **(4)**

Time of Collection (24-hour clock) \_\_\_\_\_ **(5)**

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: PK Sample NKTR-214 (Unscheduled)**

**Generated On: 22 Mar 2018 22:20:59**

---

	Field Name	Data Type	Units	Values	Include Field OID
①	PCPERF	\$1		Y = Yes N = No	PCPERF
②	PCTPT6	\$30		Pre-dose End PCTPT6 of Infusion 1 Hr Post-dose 3 Hrs Post-dose 6 Hrs Post-dose	
③	PCTPTND	1			PCTPTND
④	PCDAT	dd MMM yyyy			PCDAT
⑤	PCTIM_P	HH:nn			PCTIM_P

---

PC = Pharmacokinetic Concentrations

CO = Comments

PROD\_22MAR2018\_1.00: UNIQUE

Project Name: NEKNKTR1726201

Form: PK Results Log NKTR-214 (C2D3)

Generated On: 22 Mar 2018 22:20:59

---

Planned Timepoint

PCTPT PCTEST

Pre-dose NKTR-214-RC ①

Not Done

PCSTAT

②

Not Resulted

Below Limit of Quantitation ③

Not reportable

Insufficient sample

PCREASND

Not Tested at this Dose Group

Not Tested - Consent

Withdrawn

Not Tested at this Time Point

Above Limit of Quantitation

Other (specify in comment)

Result

Fixed Unit: (ng/mL) ④

PCORRES PCORRESU

Comment

RDOMAIN = PC

COVAL

⑤

Planned Timepoint

PCTPT PCTEST

Pre-dose NKTR-214-AC ①

Not Done

PCSTAT

②

Not Resulted

Below Limit of Quantitation ③

PCREASND

Not reportable

Insufficient sample

CO = Comments

PROD\_22MAR2018\_1.00: UNIQUE

Project Name: NEKNKTR1726201

Form: PK Results Log NKTR-214 (C2D3)

Generated On: 22 Mar 2018 22:20:59

- 
- Not Tested at this Dose Group   
Not Tested - Consent   
Withdrawn   
Not Tested at this Time Point   
Above Limit of Quantitation   
Other (specify in comment)
- 

Result Fixed Unit: (ng/mL) **(4)**

---

Comment **(5)**

---

Planned Timepoint Pre-dose Unconjugated IL-2 **(1)**

---

Not Done **(2)**

---

Not Resulted Below Limit of Quantitation   
Not reportable   
Insufficient sample   
Not Tested at this Dose Group   
Not Tested - Consent   
Withdrawn   
Not Tested at this Time Point   
Above Limit of Quantitation   
Other (specify in comment)

---

Result Fixed Unit: (ng/mL) **(4)**

---

PC = Pharmacokinetic Concentrations

See CRF Page 194

CO = Comments

PROD\_22MAR2018\_1.00: UNIQUE

Project Name: NEKNKTR1726201

Form: PK Results Log NKTR-214 (C2D3)

Generated On: 22 Mar 2018 22:20:59

---

Comment

---

(5)

Planned Timepoint

Pre-dose sCD25 (1)

Not Done

---

(2)

Not Resulted

Below Limit of Quantitation

(3)

Not reportable

Insufficient sample

Not Tested at this Dose Group

Not Tested - Consent

Withdrawn

Not Tested at this Time Point

Above Limit of Quantitation

Other (specify in comment)

---

Result

---

Fixed Unit: (ng/mL) (4)

---

Comment

---

(5)

---

Planned Timepoint

---

End of infusion NKTR-214-RC (1)

---

Not Done

---

(2)

PC = Pharmacokinetic Concentrations

See CRF Page 194

CO = Comments

PROD\_22MAR2018\_1.00: UNIQUE

Project Name: NEKNKTR1726201

Form: PK Results Log NKTR-214 (C2D3)

Generated On: 22 Mar 2018 22:20:59

---

Not Resulted

Below Limit of Quantitation  ③

Not reportable

Insufficient sample

Not Tested at this Dose Group

Not Tested - Consent

Withdrawn

Not Tested at this Time Point

Above Limit of Quantitation

Other (specify in comment)

---

Result

Fixed Unit: (ng/mL) ④

---

---

Comment

---

---

⑤

---

---

Planned Timepoint

End of Infusion NKTR-214-AC ①

---

Not Done

---

②

---

Not Resulted

Below Limit of Quantitation  ③

Not reportable

Insufficient sample

Not Tested at this Dose Group

Not Tested - Consent

Withdrawn

Not Tested at this Time Point

Above Limit of Quantitation

Other (specify in comment)

---

---

PC = Pharmacokinetic Concentrations

See CRF Page 194

CO = Comments

PROD\_22MAR2018\_1.00: UNIQUE

Project Name: NEKNKTR1726201

Form: PK Results Log NKTR-214 (C2D3)

Generated On: 22 Mar 2018 22:20:59

Result Fixed Unit: (ng/mL) **4**

Comment **5**

Planned Timepoint End of Infusion Unconjugated **1**  
IL-2

Not Done **2**

Not Resulted **3**

Below Limit of Quantitation   
Not reportable   
Insufficient sample   
Not Tested at this Dose Group   
Not Tested - Consent   
Withdrawn   
Not Tested at this Time Point   
Above Limit of Quantitation   
Other (specify in comment)

Result Fixed Unit: (ng/mL) **4**

Comment **5**

Planned Timepoint End of Infusion sCD25 **1**

PC = Pharmacokinetic Concentrations

See CRF Page 194

CO = Comments

PROD\_22MAR2018\_1.00: UNIQUE

Project Name: NEKNKTR1726201

Form: PK Results Log NKTR-214 (C2D3)

Generated On: 22 Mar 2018 22:20:59

---

Not Done

(2)

Not Resulted

Below Limit of Quantitation

(3)

Not reportable

Insufficient sample

Not Tested at this Dose Group

Not Tested - Consent

Withdrawn

Not Tested at this Time Point

Above Limit of Quantitation

Other (specify in comment)

---

Result

Fixed Unit: (ng/mL) (4)

---

Comment

(5)

---

Planned Timepoint

1 Hr Post-dose NKTR-214-RC (1)

---

Not Done

(2)

---

Not Resulted

Below Limit of Quantitation

(3)

Not reportable

Insufficient sample

Not Tested at this Dose Group

Not Tested - Consent

Withdrawn

Not Tested at this Time Point

PC = Pharmacokinetic Concentrations

See CRF Page 194

CO = Comments

PROD\_22MAR2018\_1.00: UNIQUE

Project Name: NEKNKTR1726201

Form: PK Results Log NKTR-214 (C2D3)

Generated On: 22 Mar 2018 22:20:59

---

Above Limit of Quantitation   
Other (specify in comment)

---

Result Fixed Unit: (ng/mL) **(4)**

---

---

Comment **(5)**

---

---

Planned Timepoint Hr Post-dose NKTR-214-AC **(1)**

---

Not Done **(2)**

---

Not Resulted Below Limit of Quantitation  **(3)**  
Not reportable   
Insufficient sample   
Not Tested at this Dose Group   
Not Tested - Consent   
Withdrawn   
Not Tested at this Time Point   
Above Limit of Quantitation   
Other (specify in comment) 

---

Result Fixed Unit: (ng/mL) **(4)**

---

---

Comment **(5)**

---

---

## CO = Comments

PROD\_22MAR2018\_1.00: UNIQUE

Project Name: NEKNKTR1726201

Form: PK Results Log NKTR-214 (C2D3)

Generated On: 22 Mar 2018 22:20:59

---

Planned Timepoint                                  1 Hr Post-dose Unconjugated 1  
    IL-2

---

Not Done   2

---

Not Resulted    Below Limit of Quantitation 3  
    Not reportable ○  
    Insufficient sample ○  
    Not Tested at this Dose Group ○  
    Not Tested - Consent ○  
    Withdrawn ○  
    Not Tested at this Time Point ○  
    Above Limit of Quantitation ○  
    Other (specify in comment) ○

---

Result    Fixed Unit: (ng/mL) 4

---

---

Comment   5

---

---

Planned Timepoint                                  1 Hr Post-dose sCD25 1

---

---

Not Done   2

---

---

Not Resulted    Below Limit of Quantitation 3  
    Not reportable ○  
    Insufficient sample ○

---

PC = Pharmacokinetic Concentrations

See CRF Page 194

CO = Comments

PROD\_22MAR2018\_1.00: UNIQUE

Project Name: NEKNKTR1726201

Form: PK Results Log NKTR-214 (C2D3)

Generated On: 22 Mar 2018 22:20:59

---

Not Tested at this Dose Group

Not Tested - Consent

Withdrawn

Not Tested at this Time Point

Above Limit of Quantitation

Other (specify in comment)

---

Result

Fixed Unit: (ng/mL) **(4)**

---

---

Comment

---

---

**(5)**

---

---

Planned Timepoint

3 Hrs Post-dose NKTR-214-RC **(1)**

---

Not Done

---

**(2)**

---

Not Resulted

Below Limit of Quantitation  **(3)**

Not reportable

Insufficient sample

Not Tested at this Dose Group

Not Tested - Consent

Withdrawn

Not Tested at this Time Point

Above Limit of Quantitation

Other (specify in comment)

---

Result

Fixed Unit: (ng/mL) **(4)**

---

---

PC = Pharmacokinetic Concentrations

See CRF Page 194

CO = Comments

PROD\_22MAR2018\_1.00: UNIQUE

Project Name: NEKNKTR1726201

Form: PK Results Log NKTR-214 (C2D3)

Generated On: 22 Mar 2018 22:20:59

---

Comment

(5)

Planned Timepoint

3 Hrs Post-dose NKTR-214-AC (1)

Not Done

(2)

Not Resulted

Below Limit of Quantitation

(3)

Not reportable

Insufficient sample

Not Tested at this Dose Group

Not Tested - Consent

Withdrawn

Not Tested at this Time Point

Above Limit of Quantitation

Other (specify in comment)

---

Result

Fixed Unit: (ng/mL) (4)

---

Comment

(5)

---

Planned Timepoint

3 Hrs Post-dose Unconjugated (1)

IL-2

---

Not Done

(2)

PC = Pharmacokinetic Concentrations

See CRF Page 194

CO = Comments

PROD\_22MAR2018\_1.00: UNIQUE

Project Name: NEKNKTR1726201

Form: PK Results Log NKTR-214 (C2D3)

Generated On: 22 Mar 2018 22:20:59

---

Not Resulted

Below Limit of Quantitation  ③

Not reportable

Insufficient sample

Not Tested at this Dose Group

Not Tested - Consent

Withdrawn

Not Tested at this Time Point

Above Limit of Quantitation

Other (specify in comment)

---

Result

Fixed Unit: (ng/mL) ④

---

---

Comment

---

---

⑤

---

---

Planned Timepoint

3 Hrs Post-dose sCD25 ①

---

Not Done

---

②

---

Not Resulted

Below Limit of Quantitation  ③

Not reportable

Insufficient sample

Not Tested at this Dose Group

Not Tested - Consent

Withdrawn

Not Tested at this Time Point

Above Limit of Quantitation

Other (specify in comment)

---

---

PC = Pharmacokinetic Concentrations

See CRF Page 194

CO = Comments

PROD\_22MAR2018\_1.00: UNIQUE

Project Name: NEKNKTR1726201

Form: PK Results Log NKTR-214 (C2D3)

Generated On: 22 Mar 2018 22:20:59

---

Result

Fixed Unit: (ng/mL) **(4)**

---

---

Comment

---

---

**(5)**

Planned Timepoint

6 Hrs Post-dose NKTR-214-RC **(1)**

---

Not Done

---

**(2)**

Not Resulted

Below Limit of Quantitation  **(3)**

Not reportable

Insufficient sample

Not Tested at this Dose Group

Not Tested - Consent

Withdrawn

Not Tested at this Time Point

Above Limit of Quantitation

Other (specify in comment)

---

Result

Fixed Unit: (ng/mL) **(4)**

---

---

Comment

---

---

**(5)**

Planned Timepoint

6 Hrs Post-dose NKTR-214-AC **(1)**

---

---

PC = Pharmacokinetic Concentrations

See CRF Page 194

CO = Comments

PROD\_22MAR2018\_1.00: UNIQUE

Project Name: NEKNKTR1726201

Form: PK Results Log NKTR-214 (C2D3)

Generated On: 22 Mar 2018 22:20:59

---

Not Done

(2)

Not Resulted

Below Limit of Quantitation

(3)

Not reportable

Insufficient sample

Not Tested at this Dose Group

Not Tested - Consent

Withdrawn

Not Tested at this Time Point

Above Limit of Quantitation

Other (specify in comment)

---

Result

Fixed Unit: (ng/mL) (4)

---

Comment

(5)

---

Planned Timepoint

6 Hrs Post-dose Unconjugated (1)  
IL-2

---

Not Done

(2)

---

Not Resulted

Below Limit of Quantitation

(3)

Not reportable

Insufficient sample

Not Tested at this Dose Group

Not Tested - Consent

Withdrawn

CO = Comments

PROD\_22MAR2018\_1.00: UNIQUE

Project Name: NEKNKTR1726201

Form: PK Results Log NKTR-214 (C2D3)

Generated On: 22 Mar 2018 22:20:59

- 
- Not Tested at this Time Point   
Above Limit of Quantitation   
Other (specify in comment)
- 

Result Fixed Unit: (ng/mL) **(4)**

---

Comment **(5)**

---

Planned Timepoint 6 Hrs Post-dose sCD25 **(1)**

---

Not Done **(2)**

---

Not Resulted Below Limit of Quantitation   
Not reportable   
Insufficient sample   
Not Tested at this Dose Group   
Not Tested - Consent   
Withdrawn   
Not Tested at this Time Point   
Above Limit of Quantitation   
Other (specify in comment)

---

Result Fixed Unit: (ng/mL) **(4)**

---

Comment **(5)**

---

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: PK Results Log NKTR-214 (C2D3)**

**Generated On: 22 Mar 2018 22:20:59**

---

Field Name	Data Type	Units	Values	Include Field OID

---

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: PK Results Log NKTR-214 (C2D3)**

**Generated On: 22 Mar 2018 22:20:59**

---

Field Name	Data Type	Units	Values	Include Field OID
① PCTPTL6	\$40		Planned	PCTPTL6

---

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: PK Results Log NKTR-214 (C2D3)**

**Generated On: 22 Mar 2018 22:20:59**

---

Field Name	Data Type	Units	Values	Include Field OID
② PCTPTND	1		PCTPTND	
③ PCPERF6	\$30		Below Limit of Quantitation = Below Limit of Quantitation Not reportable = Not reportable Insufficient sample = Insufficient sample Not Tested at this Dose Group = Not Tested at this Dose Group Not Tested - Consent Withdrawn = Not Tested - Consent Withdrawn Not Tested at this Time Point = Not Tested at this Time Point	

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name:** NEKNKTR1726201

**Form:** PK Results Log NKTR-214 (C2D3)

**Generated On:** 22 Mar 2018 22:20:59

---

Field Name	Data Type	Units	Values	Include Field OID
			Above Limit of Quantitation = Above Limit of Quantitation Other (specify in comment) = Other (specify in comment)	
④ PCORRES6	8.3			PCORRES6
⑤ PCCCOMM	\$200			PCCCOMM

---

PC = Pharmacokinetic Concentrations

CO = Comments

PROD\_22MAR2018\_1.00: UNIQUE

Project Name: NEKNKTR1726201

See CRF Page 194

Form: PK Results Log NKTR-214 (Unscheduled)

Generated On: 22 Mar 2018 22:20:59

---

---

Planned Timepoint

Pre-dose NKTR-214-RC 1

Not Done

NOT SUBMITTED if checked 2

---

Not Resulted

Below Limit of Quantitation 3

Not reportable 4

Insufficient sample 5

Not Tested at this Dose Group 6

Not Tested - Consent 7

Withdrawn 8

Not Tested at this Time Point 9

Above Limit of Quantitation 10

Other (specify in comment) 11

---

Result

Fixed Unit: (ng/mL) 4

---

Comment

---

---

5

Planned Timepoint

Pre-dose NKTR-214-AC 1

Not Done

NOT SUBMITTED if checked 2

---

Not Resulted

Below Limit of Quantitation 3

Not reportable 4

Insufficient sample 5

---

PC = Pharmacokinetic Concentrations

CO = Comments

PROD\_22MAR2018\_1.00: UNIQUE

Project Name: NEKNKTR1726201

See CRF Page 194

Form: PK Results Log NKTR-214 (Unscheduled)

Generated On: 22 Mar 2018 22:20:59

- 
- Not Tested at this Dose Group   
Not Tested - Consent   
Withdrawn   
Not Tested at this Time Point   
Above Limit of Quantitation   
Other (specify in comment)
- 

Result Fixed Unit: (ng/mL) **(4)**

Comment **(5)**

Planned Timepoint Pre-dose Unconjugated IL-2 **(1)**

Not Done **NOT SUBMITTED if checked (2)**

Not Resulted Below Limit of Quantitation   
Not reportable   
Insufficient sample   
Not Tested at this Dose Group   
Not Tested - Consent   
Withdrawn   
Not Tested at this Time Point   
Above Limit of Quantitation   
Other (specify in comment)

---

Result Fixed Unit: (ng/mL) **(4)**

PC = Pharmacokinetic Concentrations

CO = Comments

PROD\_22MAR2018\_1.00: UNIQUE

Project Name: NEKNKTR1726201

Form: PK Results Log NKTR-214 (Unscheduled)

See CRF Page 194

Generated On: 22 Mar 2018 22:20:59

Comment

(5)

Planned Timepoint

Pre-dose sCD25 (1)

Not Done

NOT SUBMITTED if checked

(2)

Not Resulted

Below Limit of Quantitation

(3)

Not reportable

Insufficient sample

Not Tested at this Dose Group

Not Tested - Consent

Withdrawn

Not Tested at this Time Point

Above Limit of Quantitation

Other (specify in comment)

Result

Fixed Unit: (ng/mL) (4)

Comment

(5)

Planned Timepoint

End of infusion NKTR-214-RC (1)

Not Done

NOT SUBMITTED if checked

(2)

CO = Comments

PC = Pharmacokinetic Concentrations

PROD\_22MAR2018\_1.00: UNIQUE

Project Name: NEKNKTR1726201

See CRF Page 194

Form: PK Results Log NKTR-214 (Unscheduled)

Generated On: 22 Mar 2018 22:20:59

Not Resulted

Below Limit of Quantitation  ③

Not reportable

Insufficient sample

Not Tested at this Dose Group

Not Tested - Consent

Withdrawn

Not Tested at this Time Point

Above Limit of Quantitation

Other (specify in comment)

Result

Fixed Unit: (ng/mL) ④

Comment

⑤

Planned Timepoint

End of Infusion NKTR-214-AC ①

Not Done

NOT SUBMITTED if checked ②

Not Resulted

Below Limit of Quantitation  ③

Not reportable

Insufficient sample

Not Tested at this Dose Group

Not Tested - Consent

Withdrawn

Not Tested at this Time Point

Above Limit of Quantitation

Other (specify in comment)

PC = Pharmacokinetic Concentrations

CO = Comments

PROD\_22MAR2018\_1.00: UNIQUE

Project Name: NEKNKTR1726201

Form: PK Results Log NKTR-214 (Unscheduled)

See CRF Page 194

Generated On: 22 Mar 2018 22:20:59

Result

Fixed Unit: (ng/mL) **④**

Comment

**⑤**

Planned Timepoint

End of Infusion Unconjugated **①**  
IL-2

Not Done

**NOT SUBMITTED if checked** **②**

Not Resulted

Below Limit of Quantitation **③**

Not reportable

Insufficient sample

Not Tested at this Dose Group

Not Tested - Consent

Withdrawn

Not Tested at this Time Point

Above Limit of Quantitation

Other (specify in comment)

Result

Fixed Unit: (ng/mL) **④**

Comment

**⑤**

Planned Timepoint

End of Infusion sCD25 **①**

PC = Pharmacokinetic Concentrations

CO = Comments

PROD\_22MAR2018\_1.00: UNIQUE

Project Name: NEKNKTR1726201

Form: PK Results Log NKTR-214 (Unscheduled)

See CRF Page 194

Generated On: 22 Mar 2018 22:20:59

Not Done

NOT SUBMITTED if checked

(2)

Not Resulted

Below Limit of Quantitation

Not Tested at this Dose Group

Not Tested - Consent

Withdrawn

Not Tested at this Time Point

Above Limit of Quantitation

Other (specify in comment)

Result

Fixed Unit: (ng/mL) (4)

Comment

(5)

Planned Timepoint

1 Hr Post-dose NKTR-214-RC (1)

Not Done

NOT SUBMITTED if checked

(2)

Not Resulted

Below Limit of Quantitation

Not Tested at this Dose Group

Not Tested - Consent

Not Tested at this Time Point

CO = Comments

PC = Pharmacokinetic Concentrations

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name:** NEKNKTR1726201

See CRF Page 194

**Form:** PK Results Log NKTR-214 (Unscheduled)

**Generated On:** 22 Mar 2018 22:20:59

---

Above Limit of Quantitation   
Other (specify in comment)

---

**Result** Fixed Unit: (ng/mL) **4**

---

**Comment** **5**

---

---

**Planned Timepoint** Hr Post-dose NKTR-214-AC **1**

---

**Not Done** **2**

---

**Not Resulted**

Below Limit of Quantitation  **3**  
Not reportable   
Insufficient sample   
Not Tested at this Dose Group   
Not Tested - Consent   
Withdrawn   
Not Tested at this Time Point   
Above Limit of Quantitation   
Other (specify in comment)

---

**Result** Fixed Unit: (ng/mL) **4**

---

**Comment** **5**

---

---

## CO = Comments

**PC = Pharmacokinetic Concentrations**

PROD 22MAR2018 1.00: UNIQUE

**Project Name:** NEKNKTR1726201

Form: PK Results Log NKTR-214 (Unscheduled)

See CRF Page 194

Generated On: 22 Mar 2018 22:20:59

## Planned Timepoint

## 1 Hr Post-dose Unconjugated **1** IL-2

Not Done

**NOT SUBMITTED if checked**

Not Resulted

Below Limit of Quantitation

Not reportable

Insufficient sample

Not Tested at this Dose Group

Not Tested - Consent

Withdrawn

Not Tested at this Time Point

## Above Limit of Quantitation

Other (specify in comment)

## Result

Fixed Unit: (ng/mL) **4**

## Comment

-5

## Planned Timepoint

## 1 Hr Post-dose sCD25

Not Done

-2

Not Resulted

Below Limit of Quantitation  (3)  
Not reportable   
Insufficient sample

PC = Pharmacokinetic Concentrations

CO = Comments

PROD\_22MAR2018\_1.00: UNIQUE

Project Name: NEKNKTR1726201

See CRF Page 194

Form: PK Results Log NKTR-214 (Unscheduled)

Generated On: 22 Mar 2018 22:20:59

- 
- Not Tested at this Dose Group   
Not Tested - Consent   
Withdrawn   
Not Tested at this Time Point   
Above Limit of Quantitation   
Other (specify in comment)
- 

Result Fixed Unit: (ng/mL) **(4)**

Comment **(5)**

Planned Timepoint 3 Hrs Post-dose NKTR-214-RC **(1)**

Not Done **NOT SUBMITTED if checked (2)**

Not Resulted Below Limit of Quantitation   
Not reportable   
Insufficient sample   
Not Tested at this Dose Group   
Not Tested - Consent   
Withdrawn   
Not Tested at this Time Point   
Above Limit of Quantitation   
Other (specify in comment)

---

Result Fixed Unit: (ng/mL) **(4)**

PC = Pharmacokinetic Concentrations

CO = Comments

PROD\_22MAR2018\_1.00: UNIQUE

Project Name: NEKNKTR1726201

See CRF Page 194

Form: PK Results Log NKTR-214 (Unscheduled)

Generated On: 22 Mar 2018 22:20:59

Comment

(5)

Planned Timepoint

3 Hrs Post-dose NKTR-214-AC (1)

Not Done

NOT SUBMITTED if checked (2)

Not Resulted

Below Limit of Quantitation

(3)

Not reportable

Insufficient sample

Not Tested at this Dose Group

Not Tested - Consent

Withdrawn

Not Tested at this Time Point

Above Limit of Quantitation

Other (specify in comment)

Result

Fixed Unit: (ng/mL) (4)

Comment

(5)

Planned Timepoint

3 Hrs Post-dose Unconjugated (1)

IL-2

Not Done

(2)

PC = Pharmacokinetic Concentrations

CO = Comments

PROD\_22MAR2018\_1.00: UNIQUE

Project Name: NEKNKTR1726201

See CRF Page 194

Form: PK Results Log NKTR-214 (Unscheduled)

Generated On: 22 Mar 2018 22:20:59

Not Resulted

Below Limit of Quantitation  ③

Not reportable

Insufficient sample

Not Tested at this Dose Group

Not Tested - Consent

Withdrawn

Not Tested at this Time Point

Above Limit of Quantitation

Other (specify in comment)

Result

Fixed Unit: (ng/mL) ④

Comment

⑤

Planned Timepoint

3 Hrs Post-dose sCD25 ①

Not Done

NOT SUBMITTED if checked ②

Not Resulted

Below Limit of Quantitation  ③

Not reportable

Insufficient sample

Not Tested at this Dose Group

Not Tested - Consent

Withdrawn

Not Tested at this Time Point

Above Limit of Quantitation

Other (specify in comment)

CO = Comments

PC = Pharmacokinetic Concentrations

PROD\_22MAR2018\_1.00: UNIQUE

Project Name: NEKNKTR1726201

See CRF Page 194

Form: PK Results Log NKTR-214 (Unscheduled)

Generated On: 22 Mar 2018 22:20:59

Result Fixed Unit: (ng/mL) **④**

---

---

Comment **⑤**

---

---

Planned Timepoint 6 Hrs Post-dose NKTR-214-RC **①**

---

Not Done NOT SUBMITTED if checked **②**

---

Not Resulted Below Limit of Quantitation  **③**

Not reportable

Insufficient sample

Not Tested at this Dose Group

Not Tested - Consent

Withdrawn

Not Tested at this Time Point

Above Limit of Quantitation

Other (specify in comment)

---

Result Fixed Unit: (ng/mL) **④**

---

---

Comment **⑤**

---

---

Planned Timepoint 6 Hrs Post-dose NKTR-214-AC **①**

---

---

PC = Pharmacokinetic Concentrations

CO = Comments

PROD\_22MAR2018\_1.00: UNIQUE

Project Name: NEKNKTR1726201

See CRF Page 194

Form: PK Results Log NKTR-214 (Unscheduled)

Generated On: 22 Mar 2018 22:20:59

Not Done

NOT SUBMITTED if checked

(2)

Not Resulted

Below Limit of Quantitation

Not reportable

Insufficient sample

Not Tested at this Dose Group

Not Tested - Consent

Withdrawn

Not Tested at this Time Point

Above Limit of Quantitation

Other (specify in comment)

Result

Fixed Unit: (ng/mL)

(4)

Comment

(5)

Planned Timepoint

6 Hrs Post-dose Unconjugated

IL-2

Not Done

(2)

Not Resulted

Below Limit of Quantitation

Not reportable

Insufficient sample

Not Tested at this Dose Group

Not Tested - Consent

Withdrawn

CO = Comments

PC = Pharmacokinetic Concentrations

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name:** NEKNKTR1726201

See CRF Page 194

**Form:** PK Results Log NKTR-214 (Unscheduled)

**Generated On:** 22 Mar 2018 22:20:59

- 
- Not Tested at this Time Point   
Above Limit of Quantitation   
Other (specify in comment)
- 

**Result** Fixed Unit: (ng/mL) **(4)**

---

---

**Comment** **(5)**

---

---

**Planned Timepoint** 6 Hrs Post-dose sCD25 **(1)**

---

**Not Done** **NOT SUBMITTED if checked** **(2)**

---

**Not Resulted** Below Limit of Quantitation   
Not reportable   
Insufficient sample   
Not Tested at this Dose Group   
Not Tested - Consent   
Withdrawn   
Not Tested at this Time Point   
Above Limit of Quantitation   
Other (specify in comment)

---

**Result** Fixed Unit: (ng/mL) **(4)**

---

---

**Comment** **(5)**

---

---

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: PK Results Log NKTR-214 (Unscheduled)**

**Generated On: 22 Mar 2018 22:20:59**

---

Field Name	Data Type	Units	Values	Include Field OID

---

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: PK Results Log NKTR-214 (Unscheduled)**

**Generated On: 22 Mar 2018 22:20:59**

---

Field Name	Data Type	Units	Values	Include Field OID
① PCTPTL6	\$40		Planned	PCTPTL6

---

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: PK Results Log NKTR-214 (Unscheduled)**

**Generated On: 22 Mar 2018 22:20:59**

---

Field Name	Data Type	Units	Values	Include Field OID
② PCTPTND	1		PCTPTND	
③ PCPERF6	\$30		Below Limit of Quantitation = Below Limit of Quantitation Not reportable = Not reportable Insufficient sample = Insufficient sample Not Tested at this Dose Group = Not Tested at this Dose Group Not Tested - Consent Withdrawn = Not Tested - Consent Withdrawn Not Tested at this Time Point = Not Tested at this Time Point	

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name:** NEKNKTR1726201

**Form:** PK Results Log NKTR-214 (Unscheduled)

**Generated On:** 22 Mar 2018 22:20:59

---

Field Name	Data Type	Units	Values	Include Field OID
			Above Limit of Quantitation = Above Limit of Quantitation Other (specify in comment) = Other (specify in comment)	
④ PCORRES6	8.3		PCORRES6	
⑤ PCCOMM	\$200		PCCOMM	

---

PC = Pharmacokinetic Concentrations

PROD\_22MAR2018\_1.00: UNIQUE

Project Name: NEKNKTR1726201

Form: PK Sample NKTR-214 (C3D3)

Generated On: 22 Mar 2018 22:20:59

See CRF Page 171

Was the sample collected?

Yes  1  
No

Planned Timepoint

Pre-dose 2

Not Done

3

Date of Collection (dd-mon-yyyy)

4

Time of Collection (24-hour clock)

5

Planned Timepoint

End of Infusion 2

Not Done

3

Date of Collection (dd-mon-yyyy)

4

Time of Collection (24-hour clock)

5

Planned Timepoint

1 Hr Post-dose 2

Not Done

3

PC = Pharmacokinetic Concentrations

PROD\_22MAR2018\_1.00: UNIQUE

Project Name: NEKNKTR1726201

See CRF Page 172

Form: PK Sample NKTR-214 (C3D3)

Generated On: 22 Mar 2018 22:20:59

---

Date of Collection (dd-mon-yyyy) \_\_\_\_\_ ④

---

Time of Collection (24-hour clock) \_\_\_\_\_ ⑤

---

Planned Timepoint \_\_\_\_\_ 3 Hrs Post-dose ②

---

Not Done \_\_\_\_\_ ③

---

Date of Collection (dd-mon-yyyy) \_\_\_\_\_ ④

---

Time of Collection (24-hour clock) \_\_\_\_\_ ⑤

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: PK Sample NKTR-214 (C3D3)**

**Generated On: 22 Mar 2018 22:20:59**

---

	Field Name	Data Type	Units	Values	Include Field OID
①	PCPERF	\$1		Y = Yes N = No	PCPERF
②	PCTPT7	\$30		Pre-dose End PCTPT7 of Infusion 1 Hr Post-dose 3 Hrs Post-dose	
③	PCTPTND	1			PCTPTND
④	PCDAT	dd MMM yyyy			PCDAT
⑤	PCTIM_P	HH:nn			PCTIM_P

---

PC = Pharmacokinetic Concentrations

See CRF Page 194

CO = Comments

PROD\_22MAR2018\_1.00: UNIQUE

Project Name: NEKNKTR1726201

Form: PK Results Log NKTR-214 (C3D3)

Generated On: 22 Mar 2018 22:20:59

---

---

Planned Timepoint

Pre-dose NKTR-214-RC **(1)**

Not Done

**(2)**

Not Resulted

Below Limit of Quantitation **(3)**

Not reportable

Insufficient sample

Not Tested at this Dose Group

Not Tested - Consent

Withdrawn

Not Tested at this Time Point

Above Limit of Quantitation

Other (specify in comment)

---

Result

Fixed Unit: (ng/mL) **(4)**

---

Comment

**(5)**

---

---

Planned Timepoint

Pre-dose NKTR-214-AC **(1)**

Not Done

**(2)**

---

Not Resulted

Below Limit of Quantitation **(3)**

Not reportable

Insufficient sample

---

PC = Pharmacokinetic Concentrations

See CRF Page 194

CO = Comments

PROD\_22MAR2018\_1.00: UNIQUE

Project Name: NEKNKTR1726201

Form: PK Results Log NKTR-214 (C3D3)

Generated On: 22 Mar 2018 22:20:59

---

Not Tested at this Dose Group

Not Tested - Consent

Withdrawn

Not Tested at this Time Point

Above Limit of Quantitation

Other (specify in comment)

---

Result

Fixed Unit: (ng/mL) **(4)**

---

---

Comment

---

---

**(5)**

---

---

Planned Timepoint

Pre-dose Unconjugated IL-2 **(1)**

---

Not Done

**(2)**

---

---

Not Resulted

Below Limit of Quantitation  **(3)**

Not reportable

Insufficient sample

Not Tested at this Dose Group

Not Tested - Consent

Withdrawn

Not Tested at this Time Point

Above Limit of Quantitation

Other (specify in comment)

---

Result

Fixed Unit: (ng/mL) **(4)**

---

---

PC = Pharmacokinetic Concentrations

See CRF Page 194

CO = Comments

PROD\_22MAR2018\_1.00: UNIQUE

Project Name: NEKNKTR1726201

Form: PK Results Log NKTR-214 (C3D3)

Generated On: 22 Mar 2018 22:20:59

---

Comment

(5)

Planned Timepoint

Pre-dose sCD25 (1)

Not Done

(2)

Not Resulted

Below Limit of Quantitation (3)

Not reportable

Insufficient sample

Not Tested at this Dose Group

Not Tested - Consent

Withdrawn

Not Tested at this Time Point

Above Limit of Quantitation

Other (specify in comment)

---

Result

Fixed Unit: (ng/mL) (4)

---

Comment

(5)

---

Planned Timepoint

End of infusion NKTR-214-RC (1)

---

Not Done

(2)

PC = Pharmacokinetic Concentrations

See CRF Page 194

CO = Comments

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: PK Results Log NKTR-214 (C3D3)**

**Generated On: 22 Mar 2018 22:20:59**

---

Not Resulted

Below Limit of Quantitation  ③

Not reportable

Insufficient sample

Not Tested at this Dose Group

Not Tested - Consent

Withdrawn

Not Tested at this Time Point

Above Limit of Quantitation

Other (specify in comment)

---

Result

Fixed Unit: (ng/mL) ④

---

---

Comment

---

---

⑤

---

---

Planned Timepoint

End of Infusion NKTR-214-AC ①

---

Not Done

---

②

---

Not Resulted

Below Limit of Quantitation  ③

Not reportable

Insufficient sample

Not Tested at this Dose Group

Not Tested - Consent

Withdrawn

Not Tested at this Time Point

Above Limit of Quantitation

Other (specify in comment)

---

---

PC = Pharmacokinetic Concentrations

CO = Comments

See CRF Page 194

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: PK Results Log NKTR-214 (C3D3)**

**Generated On: 22 Mar 2018 22:20:59**

---

Result

Fixed Unit: (ng/mL) **④**

---

---

---

Comment

---

---

**⑤**

---

Planned Timepoint

End of Infusion Unconjugated **①**  
IL-2

---

---

Not Done

---

**②**

---

Not Resulted

Below Limit of Quantitation  **③**  
Not reportable   
Insufficient sample   
Not Tested at this Dose Group   
Not Tested - Consent   
Withdrawn   
Not Tested at this Time Point   
Above Limit of Quantitation   
Other (specify in comment)

---

---

Result

Fixed Unit: (ng/mL) **④**

---

---

---

Comment

---

---

**⑤**

---

Planned Timepoint

End of Infusion sCD25 **①**

---

PC = Pharmacokinetic Concentrations

See CRF Page 194

CO = Comments

PROD\_22MAR2018\_1.00: UNIQUE

Project Name: NEKNKTR1726201

Form: PK Results Log NKTR-214 (C3D3)

Generated On: 22 Mar 2018 22:20:59

---

Not Done

(2)

Not Resulted

Below Limit of Quantitation

(3)

Not reportable

Insufficient sample

Not Tested at this Dose Group

Not Tested - Consent

Withdrawn

Not Tested at this Time Point

Above Limit of Quantitation

Other (specify in comment)

---

Result

Fixed Unit: (ng/mL) (4)

---

Comment

(5)

---

Planned Timepoint

1 Hr Post-dose NKTR-214-RC (1)

---

Not Done

(2)

---

Not Resulted

Below Limit of Quantitation

(3)

Not reportable

Insufficient sample

Not Tested at this Dose Group

Not Tested - Consent

Withdrawn

Not Tested at this Time Point

PC = Pharmacokinetic Concentrations

CO = Comments

See CRF Page 194

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name:** NEKNKTR1726201

**Form:** PK Results Log NKTR-214 (C3D3)

**Generated On:** 22 Mar 2018 22:20:59

---

Above Limit of Quantitation   
Other (specify in comment)

---

**Result** Fixed Unit: (ng/mL) **4**

---

**Comment** **5**

---

---

**Planned Timepoint** Hr Post-dose NKTR-214-AC **1**

---

**Not Done** **2**

---

**Not Resulted** Below Limit of Quantitation  **3**  
Not reportable   
Insufficient sample   
Not Tested at this Dose Group   
Not Tested - Consent   
Withdrawn   
Not Tested at this Time Point   
Above Limit of Quantitation   
Other (specify in comment)

---

**Result** Fixed Unit: (ng/mL) **4**

---

**Comment** **5**

---

---

PC = Pharmacokinetic Concentrations

CO = Comments

See CRF Page 194

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: PK Results Log NKTR-214 (C3D3)**

**Generated On: 22 Mar 2018 22:20:59**

---

Planned Timepoint                            1 Hr Post-dose Unconjugated **1**  
    IL-2

---

Not Done                                      **2**

---

Not Resulted                                Below Limit of Quantitation **3**  
    Not reportable   
    Insufficient sample   
    Not Tested at this Dose Group   
    Not Tested - Consent   
    Withdrawn   
    Not Tested at this Time Point   
    Above Limit of Quantitation   
    Other (specify in comment)

---

Result                                        Fixed Unit: (ng/mL) **4**  

---

---

Comment                                     **5**  

---

---

Planned Timepoint                        1 Hr Post-dose sCD25 **1**  

---

Not Done                                    **2**  

---

Not Resulted                                Below Limit of Quantitation **3**  
    Not reportable   
    Insufficient sample

---

PC = Pharmacokinetic Concentrations

CO = Comments

See CRF Page 194

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name:** NEKNKTR1726201

**Form:** PK Results Log NKTR-214 (C3D3)

**Generated On:** 22 Mar 2018 22:20:59

Not Tested at this Dose Group

Not Tested - Consent

Withdrawn

Not Tested at this Time Point

Above Limit of Quantitation

Other (specify in comment)

**Result**

Fixed Unit: (ng/mL) **(4)**

**Comment**

**(5)**

**Planned Timepoint**

3 Hrs Post-dose NKTR-214-RC **(1)**

**Not Done**

**(2)**

**Not Resulted**

Below Limit of Quantitation  **(3)**

Not reportable

Insufficient sample

Not Tested at this Dose Group

Not Tested - Consent

Withdrawn

Not Tested at this Time Point

Above Limit of Quantitation

Other (specify in comment)

**Result**

Fixed Unit: (ng/mL) **(4)**

PC = Pharmacokinetic Concentrations

CO = Comments

See CRF Page 194

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name:** NEKNKTR1726201

**Form:** PK Results Log NKTR-214 (C3D3)

**Generated On:** 22 Mar 2018 22:20:59

---

Comment

---

(5)

Planned Timepoint

3 Hrs Post-dose NKTR-214-AC (1)

Not Done

---

(2)

Not Resulted

Below Limit of Quantitation (3)

Not reportable

Insufficient sample

Not Tested at this Dose Group

Not Tested - Consent

Withdrawn

Not Tested at this Time Point

Above Limit of Quantitation

Other (specify in comment)

---

Result

Fixed Unit: (ng/mL) (4)

---

---

Comment

---

(5)

Planned Timepoint

3 Hrs Post-dose Unconjugated IL-2 (1)

Not Done

---

(2)

PC = Pharmacokinetic Concentrations

CO = Comments

See CRF Page 194

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: PK Results Log NKTR-214 (C3D3)**

**Generated On: 22 Mar 2018 22:20:59**

---

Not Resulted

Below Limit of Quantitation  ③

Not reportable

Insufficient sample

Not Tested at this Dose Group

Not Tested - Consent

Withdrawn

Not Tested at this Time Point

Above Limit of Quantitation

Other (specify in comment)

---

Result

Fixed Unit: (ng/mL) ④

---

---

Comment

---

---

⑤

---

---

Planned Timepoint

3 Hrs Post-dose sCD25 ①

---

Not Done

---

②

---

Not Resulted

Below Limit of Quantitation  ③

Not reportable

Insufficient sample

Not Tested at this Dose Group

Not Tested - Consent

Withdrawn

Not Tested at this Time Point

Above Limit of Quantitation

Other (specify in comment) 

---

---

PC = Pharmacokinetic Concentrations

CO = Comments

See CRF Page 194

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name:** NEKNKTR1726201

**Form:** PK Results Log NKTR-214 (C3D3)

**Generated On:** 22 Mar 2018 22:20:59

---

Result

Fixed Unit: (ng/mL) **④**

---

---

Comment

**⑤**

---

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: PK Results Log NKTR-214 (C3D3)**

**Generated On: 22 Mar 2018 22:20:59**

---

Field Name	Data Type	Units	Values	Include Field OID

---

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: PK Results Log NKTR-214 (C3D3)**

**Generated On: 22 Mar 2018 22:20:59**

---

Field Name	Data Type	Units	Values	Include Field OID
① PCTPTL7	\$40		Planned	PCTPTL7

---

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: PK Results Log NKTR-214 (C3D3)**

**Generated On: 22 Mar 2018 22:20:59**

---

Field Name	Data Type	Units	Values	Include Field OID
② PCTPTND	1		PCTPTND	
③ PCPERF6	\$30		Below Limit of Quantitation = Below Limit of Quantitation Not reportable = Not reportable Insufficient sample = Insufficient sample Not Tested at this Dose Group = Not Tested at this Dose Group Not Tested - Consent Withdrawn = Not Tested - Consent Withdrawn Not Tested at this Time Point = Not Tested at this Time Point	

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name:** NEKNKTR1726201

**Form:** PK Results Log NKTR-214 (C3D3)

**Generated On:** 22 Mar 2018 22:20:59

---

Field Name	Data Type	Units	Values	Include Field OID
			Above Limit of Quantitation = Above Limit of Quantitation Other (specify in comment) = Other (specify in comment)	
④ PCORRES6	8.3		PCORRES6	
⑤ PCCOMM	\$200		PCCOMM	

---

PC = Pharmacokinetic Concentrations

See CRF Page 177

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: PK Sample NKTR-214 (non-dosing day)**

**Generated On: 22 Mar 2018 22:20:59**

---

Was the sample collected?

Yes  ①  
No

Date of Collection (dd-mon-yyyy)

②

Time of Collection (24-hour clock)

③

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: PK Sample NKTR-214 (non-dosing day)**

**Generated On: 22 Mar 2018 22:20:59**

---

	Field Name	Data Type	Units	Values	Include Field OID
①	PCPERF	\$1		Y = Yes N = No	PCPERF
②	PCDAT	dd MMM yyyy			PCDAT
③	PCTIM_P	HH:nn			PCTIM_P

---

CO = Comments

PROD\_22MAR2018\_1.00: UNIQUE

Project Name: NEKNKTR1726201

Form: PK Results Log NKTR-214 (non-dosing day)

Generated On: 22 Mar 2018 22:20:59

---

---

Planned TimepointNKTR-214-RC **(1)**

---

Not Done**(2)**

---

Not ResultedBelow Limit of Quantitation  **(3)**Not reportable Insufficient sample Not Tested at this Dose Group Not Tested - Consent 

Withdrawn

Not Tested at this Time Point Above Limit of Quantitation Other (specify in comment) 

---

ResultFixed Unit: ng/mL **(4)**

---

Comment**(5)**

---

Planned TimepointNKTR-214-AC **(1)**

---

Not Done**(2)**

---

Not ResultedBelow Limit of Quantitation  **(3)**Not reportable Insufficient sample

PC = Pharmacokinetic Concentrations

CO = Comments

See CRF Page 194

PROD\_22MAR2018\_1.00: UNIQUE

Project Name: NEKNKTR1726201

Form: PK Results Log NKTR-214 (non-dosing day)

Generated On: 22 Mar 2018 22:20:59

---

Not Tested at this Dose Group

Not Tested - Consent

Withdrawn

Not Tested at this Time Point

Above Limit of Quantitation

Other (specify in comment)

---

Result

Fixed Unit: ng/mL **(4)**

---

---

Comment

---

---

**(5)**

---

---

Planned Timepoint

Unconjugated IL-2 **(1)**

---

Not Done

**(2)**

---

---

Not Resulted

Below Limit of Quantitation  **(3)**

Not reportable

Insufficient sample

Not Tested at this Dose Group

Not Tested - Consent

Withdrawn

Not Tested at this Time Point

Above Limit of Quantitation

Other (specify in comment)

---

Result

Fixed Unit: ng/mL **(4)**

---

---

PC = Pharmacokinetic Concentrations

CO = Comments

See CRF Page 194

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: PK Results Log NKTR-214 (non-dosing day)**

**Generated On: 22 Mar 2018 22:20:59**

---

Comment

(5)

Planned Timepoint

sCD25 (1)

Not Done

(2)

Not Resulted

Below Limit of Quantitation

(3)

Not reportable

Insufficient sample

Not Tested at this Dose Group

Not Tested - Consent

Withdrawn

Not Tested at this Time Point

Above Limit of Quantitation

Other (specify in comment)

---

Result

Fixed Unit: ng/mL (4)

---

Comment

(5)

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: PK Results Log NKTR-214 (non-dosing day)**

**Generated On: 22 Mar 2018 22:20:59**

---

Field Name	Data Type	Units	Values	Include Field OID
① PCTPT8	\$30		NKTR-214- PCTPT8 RC NKTR-2 14-AC Unco njugated IL-2 sCD25	
② PCTPTND	1		PCTPTND	
③ PCPERF6	\$30		Below Limit PCPERF6 of Quantitation = Below Limit of Quantitation Not reportable = Not reportable Insufficient sample = Insufficient sample Not Tested at this Dose Group = Not Tested at this Dose Group	

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name:** NEKNKTR1726201

**Form:** PK Results Log NKTR-214 (non-dosing day)

**Generated On:** 22 Mar 2018 22:20:59

---

Field Name	Data Type	Units	Values	Include Field OID
			Not Tested - Consent Withdrawn = Not Tested - Consent Withdrawn Not Tested at this Time Point = Not Tested at this Time Point Above Limit of Quantitation = Above Limit of Quantitation Other (specify in comment) = Other (specify in comment)	
④	PCORRES6	8.3		PCORRES6
⑤	PCCOMM	\$200		PCCOMM

---

PC = Pharmacokinetic Concentrations

See CRF Page 171

**PROD\_22MAR2018\_1.00: UNIQUE**  
**Project Name: NEKNKTR1726201**  
**Form: PK Sample NKTR-214 (Cycle 4)**  
**Generated On: 22 Mar 2018 22:20:59**

Was the sample collected?

Yes  1  
No

Planned Timepoint

Pre-dose 2

Not Done

3

Date of Collection (dd-mon-yyyy)

4

Time of Collection (24-hour clock)

5

Planned Timepoint

1 Hr Post-dose 2

Not Done

3

Date of Collection (dd-mon-yyyy)

4

Time of Collection (24-hour clock)

5

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: PK Sample NKTR-214 (Cycle 4)**

**Generated On: 22 Mar 2018 22:20:59**

---

	Field Name	Data Type	Units	Values	Include Field OID
①	PCPERF	\$1		Y = Yes N = No	PCPERF
②	PCTPT9	\$30		Pre-dose 1 Hr Post-dose	PCTPT9
③	PCTPTND	1			PCTPTND
④	PCDAT	dd MMM yyyy			PCDAT
⑤	PCTIM_P	HH:nn			PCTIM_P

---

PC = Pharmacokinetic Concentrations

CO = Comments

PROD\_22MAR2018\_1.00: UNIQUE

See CRF Page 194

Project Name: NEKNKTR1726201

Form: PK Results Log NKTR-214 (Cycle 4)

Generated On: 22 Mar 2018 22:20:59

---

---

Planned Timepoint

Pre-dose NKTR-214-RC **(1)**

Not Done

**(2)**

---

Not Resulted

Below Limit of Quantitation **(3)**

Not reportable

Insufficient sample

Not Tested at this Dose Group

Not Tested - Consent   
Withdrawn

Not Tested at this Time Point

Above Limit of Quantitation

Other (specify in comment)

---

Result

Fixed Unit: (ng/mL) **(4)**

---

Comment

**(5)**

---

---

Planned Timepoint

Pre-dose NKTR-214-AC **(1)**

Not Done

**(2)**

---

Not Resulted

Below Limit of Quantitation **(3)**

Not reportable

Insufficient sample

---

PC = Pharmacokinetic Concentrations

CO = Comments

See CRF Page 194

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: PK Results Log NKTR-214 (Cycle 4)**

**Generated On: 22 Mar 2018 22:20:59**

---

Not Tested at this Dose Group

Not Tested - Consent

Withdrawn

Not Tested at this Time Point

Above Limit of Quantitation

Other (specify in comment)

---

**Result**

Fixed Unit: (ng/mL) **(4)**

---

---

**Comment**

---

---

**(5)**

---

---

**Planned Timepoint**

Pre-dose Unconjugated IL-2 **(1)**

---

**Not Done**

---

**(2)**

---

**Not Resulted**

Below Limit of Quantitation  **(3)**

Not reportable

Insufficient sample

Not Tested at this Dose Group

Not Tested - Consent

Withdrawn

Not Tested at this Time Point

Above Limit of Quantitation

Other (specify in comment)

---

**Result**

Fixed Unit: (ng/mL) **(4)**

---

---

PC = Pharmacokinetic Concentrations

CO = Comments

See CRF Page 194

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: PK Results Log NKTR-214 (Cycle 4)**

**Generated On: 22 Mar 2018 22:20:59**

---

Comment

(5)

---

Planned Timepoint

Pre-dose sCD25 (1)

---

Not Done

(2)

---

Not Resulted

Below Limit of Quantitation (3)

Not reportable

Insufficient sample

Not Tested at this Dose Group

Not Tested - Consent

Withdrawn

Not Tested at this Time Point

Above Limit of Quantitation

Other (specify in comment)

---

Result

Fixed Unit: (ng/mL) (4)

---

Comment

(5)

---

Planned Timepoint

1 Hr Post-dose NKTR-214-RC (1)

---

Not Done

(2)

PC = Pharmacokinetic Concentrations

CO = Comments

See CRF Page 194

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: PK Results Log NKTR-214 (Cycle 4)**

**Generated On: 22 Mar 2018 22:20:59**

---

Not Resulted

Below Limit of Quantitation  ③

Not reportable

Insufficient sample

Not Tested at this Dose Group

Not Tested - Consent

Withdrawn

Not Tested at this Time Point

Above Limit of Quantitation

Other (specify in comment)

---

Result

Fixed Unit: (ng/mL) ④

---

---

Comment

---

---

⑤

---

---

Planned Timepoint

1 Hr Post-dose NKTR-214-AC ①

---

Not Done

---

②

---

Not Resulted

Below Limit of Quantitation  ③

Not reportable

Insufficient sample

Not Tested at this Dose Group

Not Tested - Consent

Withdrawn

Not Tested at this Time Point

Above Limit of Quantitation

Other (specify in comment)

---

---

PC = Pharmacokinetic Concentrations

CO = Comments

See CRF Page 194

PROD\_22MAR2018\_1.00: UNIQUE

Project Name: NEKNKTR1726201

Form: PK Results Log NKTR-214 (Cycle 4)

Generated On: 22 Mar 2018 22:20:59

Result

Fixed Unit: (ng/mL) **④**

Comment

**⑤**

Planned Timepoint

1 Hr Post-dose Unconjugated **①**  
IL-2

Not Done

**②**

Not Resulted

Below Limit of Quantitation  **③**  
Not reportable   
Insufficient sample   
Not Tested at this Dose Group   
Not Tested - Consent   
Withdrawn   
Not Tested at this Time Point   
Above Limit of Quantitation   
Other (specify in comment)

Result

Fixed Unit: (ng/mL) **④**

Comment

**⑤**

Planned Timepoint

1 Hr Post-dose sCD25 **①**

PC = Pharmacokinetic Concentrations

CO = Comments

See CRF Page 194

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: PK Results Log NKTR-214 (Cycle 4)**

**Generated On: 22 Mar 2018 22:20:59**

---

Not Done

(2)

Not Resulted

Below Limit of Quantitation

Not reportable

Insufficient sample

Not Tested at this Dose Group

Not Tested - Consent

Withdrawn

Not Tested at this Time Point

Above Limit of Quantitation

Other (specify in comment)

---

Result

Fixed Unit: (ng/mL) (4)

---

---

Comment

---

(5)

---

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: PK Results Log NKTR-214 (Cycle 4)**

**Generated On: 22 Mar 2018 22:20:59**

---

Field Name	Data Type	Units	Values	Include Field OID
① PCTPTL9	\$40		Pre-dose NKTR-214- RC Pre-dose NKTR-214- AC Pre-dose Unconjugate d IL-2  Pre-dose sCD25 1 Hr Post-dose NKTR-214- RC 1 Hr Post-dose NKTR-214- AC 1 Hr Post-dose Unconjugate d IL-2 1 Hr Post-dose sCD25	PCTPTL9
② PCTPTND	1			PCTPTND
③ PCPERF6	\$30		Below Limit of Quantitation = Below Limit of Quantitation	PCPERF6

**PROD\_22MAR2018\_1.00: UNIQUE****Project Name:** NEKNKTR1726201**Form:** PK Results Log NKTR-214 (Cycle 4)**Generated On:** 22 Mar 2018 22:20:59

---

Field Name	Data Type	Units	Values	Include Field OID
			Not reportable = Not reportable Insufficient sample = Insufficient sample Not Tested at this Dose Group = Not Tested at this Dose Group Not Tested - Consent Withdrawn = Not Tested - Consent Withdrawn Not Tested at this Time Point = Not Tested at this Time Point Above Limit of Quantitation = Above Limit of Quantitation	

---

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name:** NEKNKTR1726201

**Form:** PK Results Log NKTR-214 (Cycle 4)

**Generated On:** 22 Mar 2018 22:20:59

---

Field Name	Data Type	Units	Values	Include Field OID
			Other (specify in comment) = Other (specify in comment)	
<b>④</b> PCORRES6	8.3			PCORRES6
<b>⑤</b> PCCOMM	\$200			PCCOMM

---

**PROD\_22MAR2018\_1.00: UNIQUE****Project Name: NEKNKTR1726201****Form: PK Sample NKTR-214 (same day dosing)****Generated On: 22 Mar 2018 22:20:59**

Was the sample collected?

Yes  1  
No 

Planned Timepoint

Pre-dose 2

Not Done

3

Date of Collection (dd-mon-yyyy)

4

Time of Collection (24-hour clock)

5

Planned Timepoint

End of Infusion 2

Not Done

3

Date of Collection (dd-mon-yyyy)

4

Time of Collection (24-hour clock)

5

Planned Timepoint

3 Hrs Post-dose 2

Not Done

3

PC = Pharmacokinetic Concentrations

See CRF Page 172

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: PK Sample NKTR-214 (same day dosing)**

**Generated On: 22 Mar 2018 22:20:59**

---

Date of Collection (dd-mon-yyyy) \_\_\_\_\_ **(4)**

Time of Collection (24-hour clock) \_\_\_\_\_ **(5)**

---

---

Planned Timepoint \_\_\_\_\_ 6 Hrs Post-dose **(2)**

---

Not Done \_\_\_\_\_ **(3)**

---

Date of Collection (dd-mon-yyyy) \_\_\_\_\_ **(4)**

---

Time of Collection (24-hour clock) \_\_\_\_\_ **(5)**

---

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: PK Sample NKTR-214 (same day dosing)**

**Generated On: 22 Mar 2018 22:20:59**

---

	Field Name	Data Type	Units	Values	Include Field OID
①	PCPERF	\$1		Y = Yes N = No	PCPERF
②	PCTPT10	\$30		Pre-dose End PCTPT10 of Infusion 3 Hrs Post-dose 6 Hrs Post-dose	
③	PCTPTND	1			PCTPTND
④	PCDAT	dd MMM yyyy			PCDAT
⑤	PCTIM_P	HH:nn			PCTIM_P

---

PC = Pharmacokinetic Concentrations

CO = Comments

See CRF Page 194

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name:** NEKNKTR1726201

**Form:** PK Results Log NKTR-214 (same day dosing)

**Generated On:** 22 Mar 2018 22:20:59

---

---

Planned Timepoint

Pre-dose NKTR-214-RC **(1)**

Not Done

**(2)**

---

Not Resulted

Below Limit of Quantitation **(3)**

Not reportable

Insufficient sample

Not Tested at this Dose Group

Not Tested - Consent

Withdrawn

Not Tested at this Time Point

Above Limit of Quantitation

Other (specify in comment)

---

Result

Fixed Unit: (ng/mL) **(4)**

---

Comment

**(5)**

---

---

Planned Timepoint

Pre-dose NKTR-214-AC **(1)**

Not Done

**(2)**

---

Not Resulted

Below Limit of Quantitation **(3)**

Not reportable

Insufficient sample

---

PC = Pharmacokinetic Concentrations

CO = Comments

See CRF Page 194

PROD\_22MAR2018\_1.00: UNIQUE

Project Name: NEKNKTR1726201

Form: PK Results Log NKTR-214 (same day dosing)

Generated On: 22 Mar 2018 22:20:59

---

Not Tested at this Dose Group

Not Tested - Consent

Withdrawn

Not Tested at this Time Point

Above Limit of Quantitation

Other (specify in comment)

---

Result

Fixed Unit: (ng/mL) **(4)**

---

---

Comment

---

---

**(5)**

---

---

Planned Timepoint

Pre-dose Unconjugated IL-2 **(1)**

---

Not Done

---

**(2)**

---

Not Resulted

Below Limit of Quantitation  **(3)**

Not reportable

Insufficient sample

Not Tested at this Dose Group

Not Tested - Consent

Withdrawn

Not Tested at this Time Point

Above Limit of Quantitation

Other (specify in comment)

---

Result

Fixed Unit: (ng/mL) **(4)**

---

---

PC = Pharmacokinetic Concentrations

CO = Comments

See CRF Page 194

PROD\_22MAR2018\_1.00: UNIQUE

Project Name: NEKNKTR1726201

Form: PK Results Log NKTR-214 (same day dosing)

Generated On: 22 Mar 2018 22:20:59

---

Comment

---

(5)

Planned Timepoint

Pre-dose sCD25 (1)

Not Done

---

(2)

Not Resulted

Below Limit of Quantitation (3)

Not reportable

Insufficient sample

Not Tested at this Dose Group

Not Tested - Consent

Withdrawn

Not Tested at this Time Point

Above Limit of Quantitation

Other (specify in comment)

---

Result

Fixed Unit: (ng/mL) (4)

---

Comment

---

(5)

Planned Timepoint

End of Infusion NKTR-214-RC (1)

Not Done

---

(2)

PC = Pharmacokinetic Concentrations

CO = Comments

See CRF Page 194

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: PK Results Log NKTR-214 (same day dosing)**

**Generated On: 22 Mar 2018 22:20:59**

---

Not Resulted

Below Limit of Quantitation  ③

Not reportable

Insufficient sample

Not Tested at this Dose Group

Not Tested - Consent

Withdrawn

Not Tested at this Time Point

Above Limit of Quantitation

Other (specify in comment)

---

Result

Fixed Unit: (ng/mL) ④

---

---

Comment

---

---

⑤

---

---

Planned Timepoint

End of Infusion NKTR-214-AC ①

---

Not Done

---

②

---

Not Resulted

Below Limit of Quantitation  ③

Not reportable

Insufficient sample

Not Tested at this Dose Group

Not Tested - Consent

Withdrawn

Not Tested at this Time Point

Above Limit of Quantitation

Other (specify in comment) 

---

---

PC = Pharmacokinetic Concentrations

CO = Comments

See CRF Page 194

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name:** NEKNKTR1726201

**Form:** PK Results Log NKTR-214 (same day dosing)

**Generated On:** 22 Mar 2018 22:20:59

---

Result Fixed Unit: (ng/mL) **(4)**

Comment **(5)**

Planned Timepoint End of Infusion Unconjugated **(1)**  
IL-2

Not Done **(2)**

Not Resulted Below Limit of Quantitation **(3)**  
Not reportable  
Insufficient sample  
Not Tested at this Dose Group  
Not Tested - Consent  
Withdrawn  
Not Tested at this Time Point  
Above Limit of Quantitation  
Other (specify in comment)

---

Result Fixed Unit: (ng/mL) **(4)**

Comment **(5)**

Planned Timepoint End of Infusion sCD25 **(1)**

PC = Pharmacokinetic Concentrations

CO = Comments

See CRF Page 194

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: PK Results Log NKTR-214 (same day dosing)**

**Generated On: 22 Mar 2018 22:20:59**

---

Not Done

(2)

Not Resulted

Below Limit of Quantitation

(3)

Not reportable

Insufficient sample

Not Tested at this Dose Group

Not Tested - Consent

Withdrawn

Not Tested at this Time Point

Above Limit of Quantitation

Other (specify in comment)

---

Result

Fixed Unit: (ng/mL) (4)

---

Comment

(5)

---

Planned Timepoint

3 Hrs Post-dose NKTR-214-RC (1)

---

Not Done

(2)

---

Not Resulted

Below Limit of Quantitation

(3)

Not reportable

Insufficient sample

Not Tested at this Dose Group

Not Tested - Consent

Withdrawn

Not Tested at this Time Point

PC = Pharmacokinetic Concentrations

CO = Comments

See CRF Page 194

PROD\_22MAR2018\_1.00: UNIQUE

Project Name: NEKNKTR1726201

Form: PK Results Log NKTR-214 (same day dosing)

Generated On: 22 Mar 2018 22:20:59

---

Above Limit of Quantitation   
Other (specify in comment)

---

Result Fixed Unit: (ng/mL) **(4)**  

---

Comment **(5)**  

---

---

Planned Timepoint 3 Hrs Post-dose NKTR-214-AC **(1)**  

---

Not Done **(2)**  

---

Not Resulted Below Limit of Quantitation  **(3)**  
Not reportable   
Insufficient sample   
Not Tested at this Dose Group   
Not Tested - Consent   
Withdrawn   
Not Tested at this Time Point   
Above Limit of Quantitation   
Other (specify in comment)   

---

Result Fixed Unit: (ng/mL) **(4)**  

---

Comment **(5)**  

---

---



PC = Pharmacokinetic Concentrations

CO = Comments

See CRF Page 194

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: PK Results Log NKTR-214 (same day dosing)**

**Generated On: 22 Mar 2018 22:20:59**

---

Not Tested at this Dose Group

Not Tested - Consent

Withdrawn

Not Tested at this Time Point

Above Limit of Quantitation

Other (specify in comment)

---

**Result**

Fixed Unit: (ng/mL) **(4)**

---

---

**Comment**

---

---

**(5)**

---

---

**Planned Timepoint**

6 Hrs Post-dose NKTR-214-RC **(1)**

---

**Not Done**

---

**(2)**

---

**Not Resulted**

Below Limit of Quantitation  **(3)**

Not reportable

Insufficient sample

Not Tested at this Dose Group

Not Tested - Consent

Withdrawn

Not Tested at this Time Point

Above Limit of Quantitation

Other (specify in comment)

---

**Result**

Fixed Unit: (ng/mL) **(4)**

---

---

PC = Pharmacokinetic Concentrations

CO = Comments

See CRF Page 194

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name:** NEKNKTR1726201

**Form:** PK Results Log NKTR-214 (same day dosing)

**Generated On:** 22 Mar 2018 22:20:59

---

Comment

---

(5)

Planned Timepoint

6 Hrs Post-dose NKTR-214-AC (1)

Not Done

---

(2)

Not Resulted

Below Limit of Quantitation (3)

Not reportable

Insufficient sample

Not Tested at this Dose Group

Not Tested - Consent

Withdrawn

Not Tested at this Time Point

Above Limit of Quantitation

Other (specify in comment)

---

Result

Fixed Unit: (ng/mL) (4)

---

Comment

---

(5)

Planned Timepoint

6 Hrs Post-dose Unconjugated IL-2 (1)

Not Done

---

(2)

PC = Pharmacokinetic Concentrations

CO = Comments

See CRF Page 194

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: PK Results Log NKTR-214 (same day dosing)**

**Generated On: 22 Mar 2018 22:20:59**

---

Not Resulted

Below Limit of Quantitation  ③

Not reportable

Insufficient sample

Not Tested at this Dose Group

Not Tested - Consent

Withdrawn

Not Tested at this Time Point

Above Limit of Quantitation

Other (specify in comment)

---

Result

Fixed Unit: (ng/mL) ④

---

---

Comment

---

---

⑤

---

---

Planned Timepoint

6 Hrs Post-dose sCD25 ①

---

Not Done

---

②

---

Not Resulted

Below Limit of Quantitation  ③

Not reportable

Insufficient sample

Not Tested at this Dose Group

Not Tested - Consent

Withdrawn

Not Tested at this Time Point

Above Limit of Quantitation

Other (specify in comment) 

---

---

PC = Pharmacokinetic Concentrations

CO = Comments

See CRF Page 194

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: PK Results Log NKTR-214 (same day dosing)**

**Generated On: 22 Mar 2018 22:20:59**

---

Result

Fixed Unit: (ng/mL) **④**

---

---

Comment

**⑤**

---

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: PK Results Log NKTR-214 (same day dosing)**

**Generated On: 22 Mar 2018 22:20:59**

---

Field Name	Data Type	Units	Values	Include Field OID

---

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: PK Results Log NKTR-214 (same day dosing)**

**Generated On: 22 Mar 2018 22:20:59**

---

Field Name	Data Type	Units	Values	Include Field OID
① PCTPTL10	\$40		Planned	PCTPTL10

---

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: PK Results Log NKTR-214 (same day dosing)**

**Generated On: 22 Mar 2018 22:20:59**

---

Field Name	Data Type	Units	Values	Include Field OID
② PCTPTND	1		PCTPTND	
③ PCPERF6	\$30		Below Limit of Quantitation = Below Limit of Quantitation Not reportable = Not reportable Insufficient sample = Insufficient sample Not Tested at this Dose Group = Not Tested at this Dose Group Not Tested - Consent Withdrawn = Not Tested - Consent Withdrawn Not Tested at this Time Point = Not Tested at this Time Point	

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: PK Results Log NKTR-214 (same day dosing)**

**Generated On: 22 Mar 2018 22:20:59**

---

Field Name	Data Type	Units	Values	Include Field OID
			Above Limit of Quantitation = Above Limit of Quantitation Other (specify in comment) = Other (specify in comment)	
④ PCORRES6	8.3		PCORRES6	
⑤ PCCOMM	\$200		PCCOMM	

---

**PROD\_22MAR2018\_1.00: UNIQUE****Project Name: NEKNKTR1726201****Form: PK Sample NKTR-214 (C2D1)****Generated On: 22 Mar 2018 22:20:59**

Was the sample collected?

Yes  1  
No 

Planned Timepoint

Pre-dose 2

Not Done

3

Date of Collection (dd-mon-yyyy)

4

Time of Collection (24-hour clock)

5

Planned Timepoint

End of Infusion 2

Not Done

3

Date of Collection (dd-mon-yyyy)

4

Time of Collection (24-hour clock)

5

Planned Timepoint

3 Hrs Post-dose 2

Not Done

3

PC = Pharmacokinetic Concentrations

See CRF Page 172

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: PK Sample NKTR-214 (C2D1)**

**Generated On: 22 Mar 2018 22:20:59**

---

Date of Collection (dd-mon-yyyy) \_\_\_\_\_ **(4)**

Time of Collection (24-hour clock) \_\_\_\_\_ **(5)**

---

---

Planned Timepoint \_\_\_\_\_ 6 Hrs Post-dose **(2)**

---

Not Done \_\_\_\_\_ **(3)**

---

Date of Collection (dd-mon-yyyy) \_\_\_\_\_ **(4)**

---

Time of Collection (24-hour clock) \_\_\_\_\_ **(5)**

---

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: PK Sample NKTR-214 (C2D1)**

**Generated On: 22 Mar 2018 22:20:59**

---

	Field Name	Data Type	Units	Values	Include Field OID
①	PCPERF	\$1		Y = Yes N = No	PCPERF
②	PCTPT11	\$30		Pre-dose End PCTPT11 of Infusion 3 Hrs Post-dose 6 Hrs Post-dose	
③	PCTPTND	1			PCTPTND
④	PCDAT	dd MMM yyyy			PCDAT
⑤	PCTIM_P	HH:nn			PCTIM_P

---

PC = Pharmacokinetic Concentrations

CO = Comments

See CRF Page 194

PROD\_22MAR2018\_1.00: UNIQUE

Project Name: NEKNKTR1726201

Form: PK Results Log NKTR-214 (C2D1)

Generated On: 22 Mar 2018 22:20:59

---

---

Planned Timepoint

Pre-dose NKTR-214-RC **(1)**

Not Done

**(2)**

Not Resulted

Below Limit of Quantitation **(3)**

Not reportable

Insufficient sample

Not Tested at this Dose Group

Not Tested - Consent

Withdrawn

Not Tested at this Time Point

Above Limit of Quantitation

Other (specify in comment)

---

Result

Fixed Unit: (ng/mL) **(4)**

---

Comment

**(5)**

---

Planned Timepoint

Pre-dose NKTR-214-AC **(1)**

Not Done

**(2)**

---

Not Resulted

Below Limit of Quantitation **(3)**

Not reportable

Insufficient sample

---

PC = Pharmacokinetic Concentrations

CO = Comments

See CRF Page 194

PROD\_22MAR2018\_1.00: UNIQUE

Project Name: NEKNKTR1726201

Form: PK Results Log NKTR-214 (C2D1)

Generated On: 22 Mar 2018 22:20:59

---

Not Tested at this Dose Group

Not Tested - Consent

Withdrawn

Not Tested at this Time Point

Above Limit of Quantitation

Other (specify in comment)

---

Result

Fixed Unit: (ng/mL) **(4)**

---

---

Comment

---

---

**(5)**

---

---

Planned Timepoint

Pre-dose Unconjugated IL-2 **(1)**

---

Not Done

---

**(2)**

---

Not Resulted

Below Limit of Quantitation  **(3)**

Not reportable

Insufficient sample

Not Tested at this Dose Group

Not Tested - Consent

Withdrawn

Not Tested at this Time Point

Above Limit of Quantitation

Other (specify in comment)

---

Result

Fixed Unit: (ng/mL) **(4)**

---

---

PC = Pharmacokinetic Concentrations

CO = Comments

See CRF Page 194

PROD\_22MAR2018\_1.00: UNIQUE

Project Name: NEKNKTR1726201

Form: PK Results Log NKTR-214 (C2D1)

Generated On: 22 Mar 2018 22:20:59

---

Comment

---

(5)

Planned Timepoint

---

Pre-dose sCD25 (1)

Not Done

---

(2)

Not Resulted

Below Limit of Quantitation (3)

Not reportable

Insufficient sample

Not Tested at this Dose Group

Not Tested - Consent

Withdrawn

Not Tested at this Time Point

Above Limit of Quantitation

Other (specify in comment)

---

Result

---

Fixed Unit: (ng/mL) (4)

(4)

Comment

---

(5)

Planned Timepoint

---

End of Infusion NKTR-214-RC (1)

(1)

Not Done

---

(2)

PC = Pharmacokinetic Concentrations

CO = Comments

See CRF Page 194

PROD\_22MAR2018\_1.00: UNIQUE

Project Name: NEKNKTR1726201

Form: PK Results Log NKTR-214 (C2D1)

Generated On: 22 Mar 2018 22:20:59

---

Not Resulted

Below Limit of Quantitation  3

Not reportable

Insufficient sample

Not Tested at this Dose Group

Not Tested - Consent

Withdrawn

Not Tested at this Time Point

Above Limit of Quantitation

Other (specify in comment)

---

Result

Fixed Unit: (ng/mL) 4

---

---

Comment

---

---

5

Planned Timepoint

End of Infusion NKTR-214-AC 1

---

Not Done

---

2

Not Resulted

Below Limit of Quantitation  3

Not reportable

Insufficient sample

Not Tested at this Dose Group

Not Tested - Consent

Withdrawn

Not Tested at this Time Point

Above Limit of Quantitation

Other (specify in comment) 

---

---

PC = Pharmacokinetic Concentrations

CO = Comments

See CRF Page 194

PROD\_22MAR2018\_1.00: UNIQUE

Project Name: NEKNKTR1726201

Form: PK Results Log NKTR-214 (C2D1)

Generated On: 22 Mar 2018 22:20:59

Result

Fixed Unit: (ng/mL) **④**

Comment

**⑤**

Planned Timepoint

End of Infusion Unconjugated **①**  
IL-2

Not Done

**②**

Not Resulted

Below Limit of Quantitation **③**  
Not reportable   
Insufficient sample   
Not Tested at this Dose Group   
Not Tested - Consent   
Withdrawn   
Not Tested at this Time Point   
Above Limit of Quantitation   
Other (specify in comment)

Result

Fixed Unit: (ng/mL) **④**

Comment

**⑤**

Planned Timepoint

End of Infusion sCD25 **①**

PC = Pharmacokinetic Concentrations

CO = Comments

See CRF Page 194

PROD\_22MAR2018\_1.00: UNIQUE

Project Name: NEKNKTR1726201

Form: PK Results Log NKTR-214 (C2D1)

Generated On: 22 Mar 2018 22:20:59

---

Not Done

(2)

Not Resulted

Below Limit of Quantitation

(3)

Not reportable

Insufficient sample

Not Tested at this Dose Group

Not Tested - Consent

Withdrawn

Not Tested at this Time Point

Above Limit of Quantitation

Other (specify in comment)

---

Result

Fixed Unit: (ng/mL) (4)

---

Comment

(5)

---

Planned Timepoint

3 Hrs Post-dose NKTR-214-RC (1)

---

Not Done

(2)

---

Not Resulted

Below Limit of Quantitation

(3)

Not reportable

Insufficient sample

Not Tested at this Dose Group

Not Tested - Consent

Withdrawn

Not Tested at this Time Point

PC = Pharmacokinetic Concentrations

CO = Comments

See CRF Page 194

PROD\_22MAR2018\_1.00: UNIQUE

Project Name: NEKNKTR1726201

Form: PK Results Log NKTR-214 (C2D1)

Generated On: 22 Mar 2018 22:20:59

---

Above Limit of Quantitation   
Other (specify in comment)

---

Result Fixed Unit: (ng/mL) **(4)**

---

---

Comment **(5)**

---

---

Planned Timepoint 3 Hrs Post-dose NKTR-214-AC **(1)**

---

Not Done **(2)**

---

Not Resulted Below Limit of Quantitation  **(3)**  
Not reportable   
Insufficient sample   
Not Tested at this Dose Group   
Not Tested - Consent   
Withdrawn   
Not Tested at this Time Point   
Above Limit of Quantitation   
Other (specify in comment) 

---

Result Fixed Unit: (ng/mL) **(4)**

---

---

Comment **(5)**

---

---



PC = Pharmacokinetic Concentrations

CO = Comments

See CRF Page 194

PROD\_22MAR2018\_1.00: UNIQUE

Project Name: NEKNKTR1726201

Form: PK Results Log NKTR-214 (C2D1)

Generated On: 22 Mar 2018 22:20:59

---

Not Tested at this Dose Group

Not Tested - Consent

Withdrawn

Not Tested at this Time Point

Above Limit of Quantitation

Other (specify in comment)

---

Result

Fixed Unit: (ng/mL) **(4)**

---

---

Comment

---

---

**(5)**

---

---

Planned Timepoint

6 Hrs NKTR-214-RC **(1)**

---

Not Done

---

**(2)**

---

Not Resulted

Below Limit of Quantitation  **(3)**

Not reportable

Insufficient sample

Not Tested at this Dose Group

Not Tested - Consent

Withdrawn

Not Tested at this Time Point

Above Limit of Quantitation

Other (specify in comment)

---

Result

Fixed Unit: (ng/mL) **(4)**

---

---

PC = Pharmacokinetic Concentrations

CO = Comments

See CRF Page 194

PROD\_22MAR2018\_1.00: UNIQUE

Project Name: NEKNKTR1726201

Form: PK Results Log NKTR-214 (C2D1)

Generated On: 22 Mar 2018 22:20:59

---

Comment

---

(5)

Planned Timepoint

6 Hrs NKTR-214-AC (1)

Not Done

---

(2)

Not Resulted

Below Limit of Quantitation

(3)

Not reportable

Insufficient sample

Not Tested at this Dose Group

Not Tested - Consent

Withdrawn

Not Tested at this Time Point

Above Limit of Quantitation

Other (specify in comment)

---

Result

---

Fixed Unit: (ng/mL) (4)

---

Comment

---

(5)

---

Planned Timepoint

---

6 Hrs Unconjugated IL-2 (1)

---

Not Done

---

(2)

PC = Pharmacokinetic Concentrations

CO = Comments

See CRF Page 194

PROD\_22MAR2018\_1.00: UNIQUE

Project Name: NEKNKTR1726201

Form: PK Results Log NKTR-214 (C2D1)

Generated On: 22 Mar 2018 22:20:59

---

Not Resulted

Below Limit of Quantitation  ③

Not reportable

Insufficient sample

Not Tested at this Dose Group

Not Tested - Consent

Withdrawn

Not Tested at this Time Point

Above Limit of Quantitation

Other (specify in comment)

---

Result

Fixed Unit: (ng/mL) ④

---

---

Comment

---

---

⑤

---

---

Planned Timepoint

6 Hrs sCD25 ①

---

Not Done

---

②

---

Not Resulted

Below Limit of Quantitation  ③

Not reportable

Insufficient sample

Not Tested at this Dose Group

Not Tested - Consent

Withdrawn

Not Tested at this Time Point

Above Limit of Quantitation

Other (specify in comment)

---

---

PC = Pharmacokinetic Concentrations

CO = Comments

See CRF Page 194

PROD\_22MAR2018\_1.00: UNIQUE

Project Name: NEKNKTR1726201

Form: PK Results Log NKTR-214 (C2D1)

Generated On: 22 Mar 2018 22:20:59

---

Result

Fixed Unit: (ng/mL) **④**

---

---

Comment

**⑤**

---

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: PK Results Log NKTR-214 (C2D1)**

**Generated On: 22 Mar 2018 22:20:59**

---

Field Name	Data Type	Units	Values	Include Field OID

---

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name:** NEKNKTR1726201

**Form:** PK Results Log NKTR-214 (C2D1)

**Generated On:** 22 Mar 2018 22:20:59

---

Field Name	Data Type	Units	Values	Include Field OID
① PCTPTL11	\$40		Planned	PCTPTL11

---

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: PK Results Log NKTR-214 (C2D1)**

**Generated On: 22 Mar 2018 22:20:59**

---

Field Name	Data Type	Units	Values	Include Field OID
② PCTPTND	1		PCTPTND	
③ PCPERF6	\$30		Below Limit of Quantitation = Below Limit of Quantitation Not reportable = Not reportable Insufficient sample = Insufficient sample Not Tested at this Dose Group = Not Tested at this Dose Group Not Tested - Consent Withdrawn = Not Tested - Consent Withdrawn Not Tested at this Time Point = Not Tested at this Time Point	

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name:** NEKNKTR1726201

**Form:** PK Results Log NKTR-214 (C2D1)

**Generated On:** 22 Mar 2018 22:20:59

---

Field Name	Data Type	Units	Values	Include Field OID
			Above Limit of Quantitation = Above Limit of Quantitation Other (specify in comment) = Other (specify in comment)	
④ PCORRES6	8.3		PCORRES6	
⑤ PCCOMM	\$200		PCCOMM	

---

**PROD\_22MAR2018\_1.00: UNIQUE****Project Name: NEKNKTR1726201****Form: PK Sample NKTR-214 (Cycle Day 1)****Generated On: 22 Mar 2018 22:20:59**

Was the sample collected?

Yes  1  
No 

Planned Timepoint

End of Infusion 2

Not Done

3

Date of Collection (dd-mon-yyyy)

4

Time of Collection (24-hour clock)

5

Planned Timepoint

2 Hrs Post-dose 2

Not Done

3

Date of Collection (dd-mon-yyyy)

4

Time of Collection (24-hour clock)

5

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: PK Sample NKTR-214 (Cycle Day 1)**

**Generated On: 22 Mar 2018 22:20:59**

---

	Field Name	Data Type	Units	Values	Include Field OID
①	PCPERF	\$1		Y = Yes N = No	PCPERF
②	PCTPT12	\$30		End of Infusion 2 Hrs Post-dose	PCTPT12
③	PCTPTND	1			PCTPTND
④	PCDAT	dd MMM yyyy			PCDAT
⑤	PCTIM_P	HH:nn			PCTIM_P

---

PC = Pharmacokinetic Concentrations

CO = Comments

See CRF Page 194

PROD\_22MAR2018\_1.00: UNIQUE

Project Name: NEKNKTR1726201

Form: PK Results Log NKTR-214 (Cycle Day 1)

Generated On: 22 Mar 2018 22:20:59

---

---

Planned Timepoint

End of Infusion NKTR-214-RC **(1)**

Not Done

**(2)**

Not Resulted

Below Limit of Quantitation **(3)**

Not reportable

Insufficient sample

Not Tested at this Dose Group

Not Tested - Consent

Withdrawn

Not Tested at this Time Point

Above Limit of Quantitation

Other (specify in comment)

---

Result

Fixed Unit: (ng/mL) **(4)**

---

Comment

**(5)**

---

---

Planned Timepoint

End of Infusion NKTR-214-AC **(1)**

Not Done

**(2)**

---

Not Resulted

Below Limit of Quantitation **(3)**

Not reportable

Insufficient sample

---

PC = Pharmacokinetic Concentrations

CO = Comments

See CRF Page 194

PROD\_22MAR2018\_1.00: UNIQUE

Project Name: NEKNKTR1726201

Form: PK Results Log NKTR-214 (Cycle Day 1)

Generated On: 22 Mar 2018 22:20:59

---

Not Tested at this Dose Group

Not Tested - Consent

Withdrawn

Not Tested at this Time Point

Above Limit of Quantitation

Other (specify in comment)

---

Result

Fixed Unit: (ng/mL) **(4)**

---

---

Comment

---

---

**(5)**

---

---

Planned Timepoint

End of Infusion Unconjugated **(1)**  
IL-2

---

---

Not Done

---

---

**(2)**

---

---

Not Resulted

Below Limit of Quantitation  **(3)**

Not reportable

Insufficient sample

Not Tested at this Dose Group

Not Tested - Consent

Withdrawn

Not Tested at this Time Point

Above Limit of Quantitation

Other (specify in comment)

---

Result

Fixed Unit: (ng/mL) **(4)**

---

---

PC = Pharmacokinetic Concentrations

CO = Comments

See CRF Page 194

PROD\_22MAR2018\_1.00: UNIQUE

Project Name: NEKNKTR1726201

Form: PK Results Log NKTR-214 (Cycle Day 1)

Generated On: 22 Mar 2018 22:20:59

---

Comment

(5)

Planned Timepoint

End of Infusion sCD25 (1)

Not Done

(2)

Not Resulted

Below Limit of Quantitation (3)

Not reportable

Insufficient sample

Not Tested at this Dose Group

Not Tested - Consent

Withdrawn

Not Tested at this Time Point

Above Limit of Quantitation

Other (specify in comment)

Result

Fixed Unit: (ng/mL) (4)

Comment

(5)

Planned Timepoint

2 Hrs Post-dose NKTR-214-RC (1)

Not Done

(2)

PC = Pharmacokinetic Concentrations

CO = Comments

See CRF Page 194

PROD\_22MAR2018\_1.00: UNIQUE

Project Name: NEKNKTR1726201

Form: PK Results Log NKTR-214 (Cycle Day 1)

Generated On: 22 Mar 2018 22:20:59

---

Not Resulted

Below Limit of Quantitation  ③

Not reportable

Insufficient sample

Not Tested at this Dose Group

Not Tested - Consent

Withdrawn

Not Tested at this Time Point

Above Limit of Quantitation

Other (specify in comment)

---

Result

Fixed Unit: (ng/mL) ④

---

---

Comment

---

---

⑤

---

---

Planned Timepoint

2 Hrs Post-dose NKTR-214-AC ①

---

Not Done

---

②

---

Not Resulted

Below Limit of Quantitation  ③

Not reportable

Insufficient sample

Not Tested at this Dose Group

Not Tested - Consent

Withdrawn

Not Tested at this Time Point

Above Limit of Quantitation

Other (specify in comment)

---

---

PC = Pharmacokinetic Concentrations

CO = Comments

See CRF Page 194

PROD\_22MAR2018\_1.00: UNIQUE

Project Name: NEKNKTR1726201

Form: PK Results Log NKTR-214 (Cycle Day 1)

Generated On: 22 Mar 2018 22:20:59

---

Result

Fixed Unit: (ng/mL) **(4)**

---

---

---

Comment

---

---

**(5)**

---

Planned Timepoint

2 Hrs Post-dose Unconjugated **(1)**  
IL-2

---

Not Done

---

**(2)**

---

Not Resulted

Below Limit of Quantitation  **(3)**  
Not reportable   
Insufficient sample   
Not Tested at this Dose Group   
Not Tested - Consent   
Withdrawn   
Not Tested at this Time Point   
Above Limit of Quantitation   
Other (specify in comment)

---

---

Result

Fixed Unit: (ng/mL) **(4)**

---

---

---

Comment

---

---

**(5)**

---

Planned Timepoint

2 Hrs Post-dose sCD25 **(1)**

---

PC = Pharmacokinetic Concentrations

CO = Comments

See CRF Page 194

PROD\_22MAR2018\_1.00: UNIQUE

Project Name: NEKNKTR1726201

Form: PK Results Log NKTR-214 (Cycle Day 1)

Generated On: 22 Mar 2018 22:20:59

---

Not Done

(2)

Not Resulted

Below Limit of Quantitation

Not reportable

Insufficient sample

Not Tested at this Dose Group

Not Tested - Consent

Withdrawn

Not Tested at this Time Point

Above Limit of Quantitation

Other (specify in comment)

---

Result

Fixed Unit: (ng/mL) (4)

---

---

---

Comment

---

(5)

---

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: PK Results Log NKTR-214 (Cycle Day 1)**

**Generated On: 22 Mar 2018 22:20:59**

---

Field Name	Data Type	Units	Values	Include Field OID
① PCTPTL12	\$40		End of Infusion NKTR-214- RC End of Infusion NKTR-214- AC End of Infusion Unconjugate d IL-2 End of Infusion scD25 2 Hrs Post-dose NKTR-214- RC 2 Hrs Post-dose NKTR-214- AC 2 Hrs Post-dose Unconjugate d IL-2 2 Hrs Post-dose scD25	PCTPTL12
② PCTPTND	1			PCTPTND
③ PCPERF6	\$30		Below Limit of Quantitation = Below Limit of Quantitation	PCPERF6

---

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name:** NEKNKTR1726201

**Form:** PK Results Log NKTR-214 (Cycle Day 1)

**Generated On:** 22 Mar 2018 22:20:59

---

Field Name	Data Type	Units	Values	Include Field OID
			Not reportable = Not reportable Insufficient sample = Insufficient sample Not Tested at this Dose Group = Not Tested at this Dose Group Not Tested - Consent Withdrawn = Not Tested - Consent Withdrawn Not Tested at this Time Point = Not Tested at this Time Point Above Limit of Quantitation = Above Limit of Quantitation	

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name:** NEKNKTR1726201

**Form:** PK Results Log NKTR-214 (Cycle Day 1)

**Generated On:** 22 Mar 2018 22:20:59

---

Field Name	Data Type	Units	Values	Include Field OID
			Other (specify in comment)= Other (specify in comment)	
<b>④</b> PCORRES6	8.3			PCORRES6
<b>⑤</b> PCCOMM	\$200			PCCOMM

---

**PROD\_22MAR2018\_1.00: UNIQUE**  
**Project Name: NEKNKTR1726201**  
**Form: PK Sample Nivolumab**  
**Generated On: 22 Mar 2018 22:20:59**

---

Was the sample collected?

Yes  **1**  
No

---

Date of Collection (dd-mon-yyyy)

---

**2**

Time of Collection (24-hour clock)

---

**3**

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name:** NEKNKTR1726201

**Form:** PK Sample Nivolumab

**Generated On:** 22 Mar 2018 22:20:59

---

	Field Name	Data Type	Units	Values	Include Field OID
①	PCPERF	\$1		Y = Yes N = No	PCPERF
②	PCDAT	dd MMM yyyy			PCDAT
③	PCTIM_P	HH:nn			PCTIM_P

---

PC = Pharmacokinetic Concentrations

See CRF Page 171

**PROD\_22MAR2018\_1.00: UNIQUE**  
**Project Name: NEKNKTR1726201**  
**Form: PK Sample NKTR-262 (C2D1)**  
**Generated On: 22 Mar 2018 22:20:59**

Was the sample collected?

Yes  1  
No

Planned Timepoint

Pre-dose 2

Not Done

3

Date of Collection (dd-mon-yyyy)

4

Time of Collection (24-hour clock)

5

Planned Timepoint

3 Hrs Post-dose 2

Not Done

3

Date of Collection (dd-mon-yyyy)

4

Time of Collection (24-hour clock)

5

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: PK Sample NKTR-262 (C2D1)**

**Generated On: 22 Mar 2018 22:20:59**

---

	Field Name	Data Type	Units	Values	Include Field OID
①	PCPERF	\$1		Y = Yes N = No	PCPERF
②	PCTPT14	\$30		Pre-dose 3 Hrs Post-dose	PCTPT14
③	PCTPTND	1			PCTPTND
④	PCDAT	dd MMM yyyy			PCDAT
⑤	PCTIM_P	HH:nn			PCTIM_P

---

PC = Pharmacokinetic Concentrations

PROD\_22MAR2018\_1.00: UNIQUE

Project Name: NEKNKTR1726201

Form: PK Sample NKTR-214 (C3D1)

Generated On: 22 Mar 2018 22:20:59

See CRF Page 171

Was the sample collected?

Yes  1  
No

Planned Timepoint

Pre-dose 2

Not Done

3

Date of Collection (dd-mon-yyyy)

4

Time of Collection (24-hour clock)

5

Planned Timepoint

End of Infusion 2

Not Done

3

Date of Collection (dd-mon-yyyy)

4

Time of Collection (24-hour clock)

5

Planned Timepoint

3 Hrs Post-dose 2

Not Done

3

PC = Pharmacokinetic Concentrations

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: PK Sample NKTR-214 (C3D1)**

**Generated On: 22 Mar 2018 22:20:59**

See CRF Page 171

---

Date of Collection (dd-mon-yyyy) \_\_\_\_\_ **(4)**

---

Time of Collection (24-hour clock) \_\_\_\_\_ **(5)**

---

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: PK Sample NKTR-214 (C3D1)**

**Generated On: 22 Mar 2018 22:20:59**

---

	Field Name	Data Type	Units	Values	Include Field OID
①	PCPERF	\$1		Y = Yes N = No	PCPERF
②	PCTPT7	\$30		Pre-dose End PCTPT7 of Infusion 3 Hrs Post-dose	
③	PCTPTND	1			PCTPTND
④	PCDAT	dd MMM yyyy			PCDAT
⑤	PCTIM_P	HH:nn			PCTIM_P

---

PC = Pharmacokinetic Concentrations

PROD\_22MAR2018\_1.00: UNIQUE

Project Name: NEKNKTR1726201

Form: PK Sample NKTR-214 (D1)

Generated On: 22 Mar 2018 22:20:59

See CRF Page 171

Was the sample collected?

Yes  1  
No

Planned Timepoint

Pre-dose 2

Not Done

3

Date of Collection (dd-mon-yyyy)

4

Time of Collection (24-hour clock)

5

Planned Timepoint

End of Infusion 2

Not Done

3

Date of Collection (dd-mon-yyyy)

4

Time of Collection (24-hour clock)

5

Planned Timepoint

2 Hrs Post-dose 2

Not Done

3

PC = Pharmacokinetic Concentrations

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name:** NEKNKTR1726201

**Form:** PK Sample NKTR-214 (D1)

**Generated On:** 22 Mar 2018 22:20:59

See CRF Page 171

---

Date of Collection (dd-mon-yyyy) \_\_\_\_\_ **(4)**

---

Time of Collection (24-hour clock) \_\_\_\_\_ **(5)**

---

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: PK Sample NKTR-214 (D1)**

**Generated On: 22 Mar 2018 22:20:59**

---

	Field Name	Data Type	Units	Values	Include Field OID
①	PCPERF	\$1		Y = Yes N = No	PCPERF
②	PCTPT7	\$30		Pre-dose End PCTPT7 of Infusion 2 Hrs Post-dose	
③	PCTPTND	1			PCTPTND
④	PCDAT	dd MMM yyyy			PCDAT
⑤	PCTIM_P	HH:nn			PCTIM_P

---

PC = Pharmacokinetic Concentrations

PROD\_22MAR2018\_1.00: UNIQUE

Project Name: NEKNKTR1726201

Form: PK Sample NKTR-262 (C3)

Generated On: 22 Mar 2018 22:20:59

See CRF Page 171

Was the sample collected?

Yes  1  
No

Planned Timepoint

Pre-dose 2

Not Done

3

Date of Collection (dd-mon-yyyy)

4

Time of Collection (24-hour clock)

5

Planned Timepoint

End of Infusion 2

Not Done

3

Date of Collection (dd-mon-yyyy)

4

Time of Collection (24-hour clock)

5

Planned Timepoint

3 Hrs Post-dose 2

Not Done

3

PC = Pharmacokinetic Concentrations

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name:** NEKNKTR1726201

**Form:** PK Sample NKTR-262 (C3)

**Generated On:** 22 Mar 2018 22:20:59

See CRF Page 171

---

Date of Collection (dd-mon-yyyy) \_\_\_\_\_ **(4)**

---

Time of Collection (24-hour clock) \_\_\_\_\_ **(5)**

---

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: PK Sample NKTR-262 (C3)**

**Generated On: 22 Mar 2018 22:20:59**

---

	Field Name	Data Type	Units	Values	Include Field OID
①	PCPERF	\$1		Y = Yes N = No	PCPERF
②	PCTPT14	\$30		Pre-dose End PCTPT14 of Infusion 3 Hrs Post-dose	
③	PCTPTND	1			PCTPTND
④	PCDAT	dd MMM yyyy			PCDAT
⑤	PCTIM_P	HH:nn			PCTIM_P

---

VS = Vital Signs

PROD\_22MAR2018\_1.00: UNIQUE

See CRF Page 97

Project Name: NEKNKTR1726201

Form: Vital Signs

Generated On: 22 Mar 2018 22:20:59

Were vital signs collected?

Yes  1  
No

Date of Assessment (dd-mon-yyyy)

2

Weight

3

Weight Unit

Kilogram  4  
Pound

Temperature

5

Temperature Unit

C  6  
F

Respiratory Rate (breaths/min)

7

Heart Rate (beats/min)

8

Supine Systolic BP (mmHg)

VSORRES where VSTESTCD = SYSBP

9

VSORRESU

Supine Diastolic BP (mmHg)

VSORRES where VSTESTCD = DIABP

10

VSORRESU

**PROD\_22MAR2018\_1.00: UNIQUE****Project Name:** NEKNKTR1726201**Form:** Vital Signs**Generated On:** 22 Mar 2018 22:20:59

	Field Name	Data Type	Units	Values	Include Field OID
①	VSPERF1	\$1		Y = Yes N = No	VSPERF1
②	VSDAT	dd MMM yyyy			VSDAT
③	WEIGHT	4.1			WEIGHT
④	WEIGHTU	\$2		kg = Kilogram LB = Pound	WEIGHTU
⑤	TEMP	4.1			TEMP
⑥	TEMPU	\$1		C = C F = F	TEMPU
⑦	RESP	8			RESP
⑧	HR	8			HR
⑨	SYSBP1	8			SYSBP1
⑩	DIABP1	8			DIABP1

ZB = Biomarkers

PROD\_22MAR2018\_1.00: UNIQUE

Project Name: NEKNKTR1726201

Form: MOA Sample

ZBCAT = MOA

Generated On: 22 Mar 2018 22:20:59

---

Was the sample collected?

ZBSTAT

Yes  ①  
No

---

Date of Collection (dd-mon-yyyy)

②

---

Time of Collection (24-hour clock)

ZBDTC

③

---

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name:** NEKNKTR1726201

**Form:** MOA Sample

**Generated On:** 22 Mar 2018 22:20:59

---

	Field Name	Data Type	Units	Values	Include Field OID
①	LPPERF	\$1		Y = Yes N = No	LPPERF
②	LBDAT	dd MMM yyyy			LBDAT
③	LBTIM	HH:nn			LBTIM

---

ZB = Biomarkers

PROD\_22MAR2018\_1.00: UNIQUE

Project Name: NEKNKTR1726201

Form: MOA Sample (Day 1)

ZBCAT = MOA

Generated On: 22 Mar 2018 22:20:59

Was the sample collected?

Yes  ①  
No

ZBSTAT where ZBTESTCD = ZBALL

Date of Collection (dd-mon-yyyy)

ZBDTC

②

Planned Timepoint

ZBTPT Pre-dose ③

Not Done

ZBSTAT

④

Time of Collection (24-hour clock)

ZBDTC

⑤

Planned Timepoint

ZBTPT 3 Hrs Post-dose ③

Not Done

ZBSTAT

④

Time of Collection (24-hour clock)

ZBDTC

⑤

Planned Timepoint

ZBTPT 6 Hrs Post-dose ③

Not Done

ZBSTAT

④

Time of Collection (24-hour clock)

ZBDTC

⑤

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name:** NEKNKTR1726201

**Form:** MOA Sample (Day 1)

**Generated On:** 22 Mar 2018 22:20:59

---

	Field Name	Data Type	Units	Values	Include Field OID
①	LPPERF	\$1		Y = Yes N = No	LPPERF
②	LBDAT	dd MMM yyyy			LBDAT
③	LBTPPT	\$20		Pre-dose 3 Hrs Post-dose 6 Hrs Post-dose	LBTPPT
④	LBTPND	1			LBTPND
⑤	LBTIM	HH:nn			LBTIM

---

**PROD\_22MAR2018\_1.00: UNIQUE****Project Name: NEKNKTR1726201****Form: MOA Sample (C3D1)****Generated On: 22 Mar 2018 22:20:59**

Was the sample collected?

Yes  ①  
No 

Date of Collection (dd-mon-yyyy)

②

Planned Timepoint

Pre-dose ③

Not Done

④

Time of Collection (24-hour clock)

⑤

Planned Timepoint

3 Hrs Post-dose ③

Not Done

④

Time of Collection (24-hour clock)

⑤

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name:** NEKNKTR1726201

**Form:** MOA Sample (C3D1)

**Generated On:** 22 Mar 2018 22:20:59

---

	Field Name	Data Type	Units	Values	Include Field OID
①	LPPERF	\$1		Y = Yes N = No	LPPERF
②	LBDAT	dd MMM yyyy			LBDAT
③	LBTPT1	\$20		Pre-dose 3 Hrs Post-dose	LBTPT1
④	LBTPND	1			LBTPND
⑤	LBTIM	HH:nn			LBTIM

---

VS = Vital Signs

PROD\_22MAR2018\_1.00: UNIQUE

Project Name: NEKNKTR1726201

Form: Vital Signs C1D1

Generated On: 22 Mar 2018 22:20:59

Were vital signs collected?

Yes  1  
No

VSSTAT where VSTESTCD = VSALL

Date of Assessment (dd-mon-yyyy)

VSDTC

2

Weight

VSORRES where VSTESTCD = WEIGHT

3

Weight Unit

Kilogram  4  
VSORRESU  
Pound

Planned Time Point

VSTPT Pre-dose 5

Not Done

VSSTAT

6

Time (24-hour clock)

VSDTC

7

Temperature

VSORRES where VSTESTCD = TEMP

8

Temperature Unit

VSORRESU  
C   
F  9

Respiratory Rate (breaths/min)

VSORRESU

VSORRES where VSTESTCD = RESP

10

Heart Rate (beats/min)

VSORRESU

VSORRES where VSTESTCD = HR

11

Oxygen Saturation (%)

VSORRESU

VSORRES where VSTESTCD = OXYSAT

12

**VS = Vital Signs**

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: Vital Signs C1D1**

**Generated On: 22 Mar 2018 22:20:59**

---

Supine Systolic BP (mmHg) VSORRES where VSTESTCD = SYSBP **(13)**  
\_\_\_\_\_ VSORRESU

---

Supine Diastolic BP (mmHg) VSORRES where VSTESTCD = DIABP **(14)**  
\_\_\_\_\_ VSORRESU

---

Planned Time Point VSTPT 1 Hr Post-dose **(5)**

---

Not Done VSSTAT **(6)**

---

Time (24-hour clock) VSDTC **(7)**

---

Temperature VSORRES where VSTESTCD = TEMP **(8)**

---

Temperature Unit VSORRESU **(9)**  
C   
F

---

Respiratory Rate (breaths/min) VSORRES where VSTESTCD = RESP **(10)**  
\_\_\_\_\_ VSORRESU

---

Heart Rate (beats/min) VSORRES where VSTESTCD = HR **(11)**  
\_\_\_\_\_ VSORRESU

---

Oxygen Saturation (%) VSORRES where VSTESTCD = OXYSAT **(12)**  
\_\_\_\_\_ VSORRESU

---

Supine Systolic BP (mmHg) VSORRES where VSTESTCD = SYSBP **(13)**  
\_\_\_\_\_ VSORRESU

---

Supine Diastolic BP (mmHg) VSORRES where VSTESTCD = DIABP **(14)**  
\_\_\_\_\_ VSORRESU

VS = Vital Signs

See CRF Page 337

PROD\_22MAR2018\_1.00: UNIQUE

Project Name: NEKNKTR1726201

Form: Vital Signs C1D1

Generated On: 22 Mar 2018 22:20:59

Planned Time Point 2 Hrs Post-dose **(5)**

Not Done \_\_\_\_\_ **(6)**

Time (24-hour clock) \_\_\_\_\_ **(7)**

Temperature \_\_\_\_\_ **(8)**

Temperature Unit C  **(9)**  
F

Respiratory Rate (breaths/min) \_\_\_\_\_ **(10)**

Heart Rate (beats/min) \_\_\_\_\_ **(11)**

Oxygen Saturation (%) \_\_\_\_\_ **(12)**

Supine Systolic BP (mmHg) \_\_\_\_\_ **(13)**

Supine Diastolic BP (mmHg) \_\_\_\_\_ **(14)**

Planned Time Point 3 Hrs Post-dose **(5)**

Not Done \_\_\_\_\_ **(6)**

Time (24-hour clock) \_\_\_\_\_ **(7)**

VS = Vital Signs

PROD\_22MAR2018\_1.00: UNIQUE

See CRF Page 337

Project Name: NEKNKTR1726201

Form: Vital Signs C1D1

Generated On: 22 Mar 2018 22:20:59

---

Temperature

⑧

---

Temperature Unit

C  ⑨  
F

---

Respiratory Rate (breaths/min)

⑩

---

Heart Rate (beats/min)

⑪

---

Oxygen Saturation (%)

⑫

---

Supine Systolic BP (mmHg)

⑬

---

Supine Diastolic BP (mmHg)

⑭

**PROD\_22MAR2018\_1.00: UNIQUE****Project Name:** NEKNKTR1726201**Form:** Vital Signs C1D1**Generated On:** 22 Mar 2018 22:20:59

	Field Name	Data Type	Units	Values	Include Field OID
①	VSPERF1	\$1		Y = Yes N = No	VSPERF1
②	VSDAT	dd MMM yyyy			VSDAT
③	WEIGHT	4.1			WEIGHT
④	WEIGHTU	\$2		kg = Kilogram LB = Pound	WEIGHTU
⑤	VSTPT3	\$20		Pre-dose 1 Hr Post-dose 2 Hrs Post-dose 3 Hrs Post-dose	VSTPT3
⑥	VSPERF2	1			VSPERF2
⑦	VSTIM	HH:nn			VSTIM
⑧	TEMP	4.1			TEMP
⑨	TEMPU	\$1		C = C F = F	TEMPU

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name:** NEKNKTR1726201

**Form:** Vital Signs C1D1

**Generated On:** 22 Mar 2018 22:20:59

---

	Field Name	Data Type	Units	Values	Include Field OID
⑩	RESP	8			RESP
⑪	HR	8			HR
⑫	OXYSAT	8			OXYSAT
⑬	SYSBP1	8			SYSBP1
⑭	DIABP1	8			DIABP1

---

VS = Vital Signs

PROD\_22MAR2018\_1.00: UNIQUE

See CRF Page 337

Project Name: NEKNKTR1726201

Form: Vital Signs (C4D1)

Generated On: 22 Mar 2018 22:20:59

Were vital signs collected?

Yes  1  
No

Date of Assessment (dd-mon-yyyy)

2

Weight

3

Weight Unit

Kilogram  4  
Pound

Planned Time Point

Pre-dose 5

Not Done

6

Time (24-hour clock)

7

Temperature

8

Temperature Unit

C  9  
F

Respiratory Rate (breaths/min)

10

Heart Rate (beats/min)

11

Oxygen Saturation (%)

12

**VS = Vital Signs**

**See CRF Page 337**

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: Vital Signs (C4D1)**

**Generated On: 22 Mar 2018 22:20:59**

Supine Systolic BP (mmHg) \_\_\_\_\_ **(13)**

Supine Diastolic BP (mmHg) \_\_\_\_\_ **(14)**

Planned Time Point 1 Hr Post-dose **(5)**

Not Done \_\_\_\_\_ **(6)**

Time (24-hour clock) \_\_\_\_\_ **(7)**

Temperature \_\_\_\_\_ **(8)**

Temperature Unit C  **(9)**  
F

Respiratory Rate (breaths/min) \_\_\_\_\_ **(10)**

Heart Rate (beats/min) \_\_\_\_\_ **(11)**

Oxygen Saturation (%) \_\_\_\_\_ **(12)**

Supine Systolic BP (mmHg) \_\_\_\_\_ **(13)**

Supine Diastolic BP (mmHg) \_\_\_\_\_ **(14)**

**PROD\_22MAR2018\_1.00: UNIQUE****Project Name: NEKNKTR1726201****Form: Vital Signs (C4D1)****Generated On: 22 Mar 2018 22:20:59**

	Field Name	Data Type	Units	Values	Include Field OID
①	VSPERF1	\$1		Y = Yes N = No	VSPERF1
②	VSDAT	dd MMM yyyy			VSDAT
③	WEIGHT	4.1			WEIGHT
④	WEIGHTU	\$2		kg = Kilogram LB = Pound	WEIGHTU
⑤	VSTPT4	\$30		Pre-dose 1 Hr Post-dose	VSTPT4
⑥	VSPERF2	1			VSPERF2
⑦	VSTIM	HH:nn			VSTIM
⑧	TEMP	4.1			TEMP
⑨	TEMPU	\$1		C = C F = F	TEMPU
⑩	RESP	8			RESP

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name:** NEKNKTR1726201

**Form:** Vital Signs (C4D1)

**Generated On:** 22 Mar 2018 22:20:59

---

Field Name	Data Type	Units	Values	Include Field OID
⑪ HR	8			HR
⑫ OXYSAT	8			OXYSAT
⑬ SYSBP1	8			SYSBP1
⑭ DIABP1	8			DIABP1

---

**VS = Vital Signs**

**PROD\_22MAR2018\_1.00: UNIQUE**

**See CRF Page 337**

**Project Name: NEKNKTR1726201**

**Form: Vital Signs (Day 3)**

**Generated On: 22 Mar 2018 22:20:59**

Were vital signs collected?

Yes  1  
No

Date of Assessment (dd-mon-yyyy)

2

Weight

3

Weight Unit

Kilogram  4  
Pound

Planned Time Point

Pre-dose 5

Not Done

6

Date of Assessment (dd-mon-yyyy)

7

Time (24-hour clock)

8

Temperature

9

Temperature Unit

C  10  
F

Respiratory Rate (breaths/min)

11

Heart Rate (beats/min)

12

**VS = Vital Signs**

**PROD\_22MAR2018\_1.00: UNIQUE**

**See CRF Page 337**

**Project Name: NEKNKTR1726201**

**Form: Vital Signs (Day 3)**

**Generated On: 22 Mar 2018 22:20:59**

Oxygen Saturation (%) \_\_\_\_\_ **(13)**

Supine Systolic BP (mmHg) \_\_\_\_\_ **(14)**

Supine Diastolic BP (mmHg) \_\_\_\_\_ **(15)**

Planned Time Point \_\_\_\_\_ End of Infusion **(5)**

Not Done \_\_\_\_\_ **(6)**

Date of Assessment (dd-mon-yyyy) \_\_\_\_\_ **(7)**

Time (24-hour clock) \_\_\_\_\_ **(8)**

Temperature \_\_\_\_\_ **(9)**

Temperature Unit C  **(10)**  
F

Respiratory Rate (breaths/min) \_\_\_\_\_ **(11)**

Heart Rate (beats/min) \_\_\_\_\_ **(12)**

Oxygen Saturation (%) \_\_\_\_\_ **(13)**

Supine Systolic BP (mmHg) \_\_\_\_\_ **(14)**

**VS = Vital Signs**

**See CRF Page 337**

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: Vital Signs (Day 3)**

**Generated On: 22 Mar 2018 22:20:59**

Supine Diastolic BP (mmHg)

**(15)**

Planned Time Point

1 Hr Post-dose **(5)**

Not Done

**(6)**

Date of Assessment (dd-mon-yyyy)

**(7)**

Time (24-hour clock)

**(8)**

Temperature

**(9)**

Temperature Unit

C  **(10)**

F

Respiratory Rate (breaths/min)

**(11)**

Heart Rate (beats/min)

**(12)**

Oxygen Saturation (%)

**(13)**

Supine Systolic BP (mmHg)

**(14)**

Supine Diastolic BP (mmHg)

**(15)**

VS = Vital Signs

See CRF Page 337

PROD\_22MAR2018\_1.00: UNIQUE

Project Name: NEKNKTR1726201

Form: Vital Signs (Day 3)

Generated On: 22 Mar 2018 22:20:59

Planned Time Point 2 Hrs Post-dose **(5)**

Not Done \_\_\_\_\_ **(6)**

Date of Assessment (dd-mon-yyyy) \_\_\_\_\_ **(7)**

Time (24-hour clock) \_\_\_\_\_ **(8)**

Temperature \_\_\_\_\_ **(9)**

Temperature Unit C  **(10)**  
F

Respiratory Rate (breaths/min) \_\_\_\_\_ **(11)**

Heart Rate (beats/min) \_\_\_\_\_ **(12)**

Oxygen Saturation (%) \_\_\_\_\_ **(13)**

Supine Systolic BP (mmHg) \_\_\_\_\_ **(14)**

Supine Diastolic BP (mmHg) \_\_\_\_\_ **(15)**

Planned Time Point 3 Hrs Post-dose **(5)**

Not Done \_\_\_\_\_ **(6)**

VS = Vital Signs

PROD\_22MAR2018\_1.00: UNIQUE

See CRF Page 337

Project Name: NEKNKTR1726201

Form: Vital Signs (Day 3)

Generated On: 22 Mar 2018 22:20:59

---

Date of Assessment (dd-mon-yyyy) \_\_\_\_\_ 7

---

Time (24-hour clock) \_\_\_\_\_ 8

---

Temperature \_\_\_\_\_ 9

---

Temperature Unit C  10  
F

---

Respiratory Rate (breaths/min) \_\_\_\_\_ 11

---

Heart Rate (beats/min) \_\_\_\_\_ 12

---

Oxygen Saturation (%) \_\_\_\_\_ 13

---

Supine Systolic BP (mmHg) \_\_\_\_\_ 14

---

Supine Diastolic BP (mmHg) \_\_\_\_\_ 15

**PROD\_22MAR2018\_1.00: UNIQUE****Project Name: NEKNKTR1726201****Form: Vital Signs (Day 3)****Generated On: 22 Mar 2018 22:20:59**

	Field Name	Data Type	Units	Values	Include Field OID
①	VSPERF1	\$1		Y = Yes N = No	VSPERF1
②	VSDAT	dd MMM yyyy			VSDAT
③	WEIGHT	4.1			WEIGHT
④	WEIGHTU	\$2		kg = Kilogram LB = Pound	WEIGHTU
⑤	VSTPT5	\$25		Pre-dose End VSTPT5 of Infusion 1 Hr Post-dose 2 Hrs Post-dose 3 Hrs Post-dose	
⑥	VSPERF2	1			VSPERF2
⑦	VSDAT2	dd MMM yyyy			VSDAT2
⑧	VSTIM	HH:nn			VSTIM

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name:** NEKNKTR1726201

**Form:** Vital Signs (Day 3)

**Generated On:** 22 Mar 2018 22:20:59

---

	Field Name	Data Type	Units	Values	Include Field OID
⑨	TEMP	4.1			TEMP
⑩	TEMPU	\$1		C = C F = F	TEMPU
⑪	RESP	8			RESP
⑫	HR	8			HR
⑬	OXYSAT	8			OXYSAT
⑭	SYSBP1	8			SYSBP1
⑮	DIABP1	8			DIABP1

---

VS = Vital Signs

PROD\_22MAR2018\_1.00: UNIQUE

See CRF Page 337

Project Name: NEKNKTR1726201

Form: Vital Signs (Day 1)

Generated On: 22 Mar 2018 22:20:59

Were vital signs collected?

Yes  1  
No

Date of Assessment (dd-mon-yyyy)

2

Weight

3

Weight Unit

Kilogram  4  
Pound

Planned Timepoint

Pre-dose 5

Not Done

6

Time (24-hour clock)

7

Temperature

8

Temperature Unit

C  9  
F

Respiratory Rate (breaths/min)

10

Heart Rate (beats/min)

11

Oxygen Saturation (%)

12

VS = Vital Signs

See CRF Page 337

PROD\_22MAR2018\_1.00: UNIQUE

Project Name: NEKNKTR1726201

Form: Vital Signs (Day 1)

Generated On: 22 Mar 2018 22:20:59

Supine Systolic BP (mmHg) \_\_\_\_\_ (13)

Supine Diastolic BP (mmHg) \_\_\_\_\_ (14)

Planned Timepoint \_\_\_\_\_ 2 Hrs Post-dose (5)

Not Done \_\_\_\_\_ (6)

Time (24-hour clock) \_\_\_\_\_ (7)

Temperature \_\_\_\_\_ (8)

Temperature Unit C  (9)  
F

Respiratory Rate (breaths/min) \_\_\_\_\_ (10)

Heart Rate (beats/min) \_\_\_\_\_ (11)

Oxygen Saturation (%) \_\_\_\_\_ (12)

Supine Systolic BP (mmHg) \_\_\_\_\_ (13)

Supine Diastolic BP (mmHg) \_\_\_\_\_ (14)

VS = Vital Signs

See CRF Page 337

PROD\_22MAR2018\_1.00: UNIQUE

Project Name: NEKNKTR1726201

Form: Vital Signs (Day 1)

Generated On: 22 Mar 2018 22:20:59

---

Planned Timepoint	3 Hrs Post-dose	(5)
Not Done		(6)
Time (24-hour clock)		(7)
Temperature		(8)
Temperature Unit	C <input type="checkbox"/> (9) F <input type="checkbox"/>	
Respiratory Rate (breaths/min)		(10)
Heart Rate (beats/min)		(11)
Oxygen Saturation (%)		(12)
Supine Systolic BP (mmHg)		(13)
Supine Diastolic BP (mmHg)		(14)

---

**PROD\_22MAR2018\_1.00: UNIQUE****Project Name: NEKNKTR1726201****Form: Vital Signs (Day 1)****Generated On: 22 Mar 2018 22:20:59**

	Field Name	Data Type	Units	Values	Include Field OID
①	VSPERF1	\$1		Y = Yes N = No	VSPERF1
②	VSDAT	dd MMM yyyy			VSDAT
③	WEIGHT	4.1			WEIGHT
④	WEIGHTU	\$2		kg = Kilogram LB = Pound	WEIGHTU
⑤	VSDTPT6	\$25		Pre-dose 2 Hrs Post-dose 3 Hrs Post-dose	VSDTPT6
⑥	VSND	1			VSND
⑦	VSTIM	HH:nn			VSTIM
⑧	TEMP	4.1			TEMP
⑨	TEMPU	\$1		C = C F = F	TEMPU

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name:** NEKNKTR1726201

**Form:** Vital Signs (Day 1)

**Generated On:** 22 Mar 2018 22:20:59

---

	Field Name	Data Type	Units	Values	Include Field OID
⑩	RESP	8			RESP
⑪	HR	8			HR
⑫	OXYSAT	8			OXYSAT
⑬	SYSBP1	8			SYSBP1
⑭	DIABP1	8			DIABP1

---

**VS = Vital Signs**

**See CRF Page 337**

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: Vital Signs (same day dosing)**

**Generated On: 22 Mar 2018 22:20:59**

Were vital signs collected?

Yes  1  
No

Date of Assessment (dd-mon-yyyy)

2

Weight

3

Weight Unit

Kilogram  4  
Pound

Planned Timepoint

Pre-dose 5

Not Done

6

Time (24-hour clock)

7

Temperature

8

Temperature Unit

C  9  
F

Respiratory Rate (breaths/min)

10

Heart Rate (beats/min)

11

Oxygen Saturation (%)

12

VS = Vital Signs

See CRF Page 337

PROD\_22MAR2018\_1.00: UNIQUE

Project Name: NEKNKTR1726201

Form: Vital Signs (same day dosing)

Generated On: 22 Mar 2018 22:20:59

Supine Systolic BP (mmHg)

13

Supine Diastolic BP (mmHg)

Fixed Unit: (mmHg) 14

Planned Timepoint

End of Infusion 5

Not Done

6

Time (24-hour clock)

7

Temperature

8

Temperature Unit

C  9  
F

Respiratory Rate (breaths/min)

10

Heart Rate (beats/min)

11

Oxygen Saturation (%)

12

Supine Systolic BP (mmHg)

13

Supine Diastolic BP (mmHg)

Fixed Unit: (mmHg) 14

VS = Vital Signs

See CRF Page 337

PROD\_22MAR2018\_1.00: UNIQUE

Project Name: NEKNKTR1726201

Form: Vital Signs (same day dosing)

Generated On: 22 Mar 2018 22:20:59

Planned Timepoint 2 Hrs Post-dose **(5)**

Not Done \_\_\_\_\_ **(6)**

Time (24-hour clock) \_\_\_\_\_ **(7)**

Temperature \_\_\_\_\_ **(8)**

Temperature Unit C  **(9)**  
F

Respiratory Rate (breaths/min) \_\_\_\_\_ **(10)**

Heart Rate (beats/min) \_\_\_\_\_ **(11)**

Oxygen Saturation (%) \_\_\_\_\_ **(12)**

Supine Systolic BP (mmHg) \_\_\_\_\_ **(13)**

Supine Diastolic BP (mmHg) Fixed Unit: (mmHg) **(14)**

Planned Timepoint 3 Hrs Post-dose **(5)**

Not Done \_\_\_\_\_ **(6)**

VS = Vital Signs

PROD\_22MAR2018\_1.00: UNIQUE

See CRF Page 337

Project Name: NEKNKTR1726201

Form: Vital Signs (same day dosing)

Generated On: 22 Mar 2018 22:20:59

---

Time (24-hour clock) \_\_\_\_\_ ⑦

---

Temperature \_\_\_\_\_ ⑧

---

Temperature Unit C  ⑨  
F

---

Respiratory Rate (breaths/min) \_\_\_\_\_ ⑩

---

Heart Rate (beats/min) \_\_\_\_\_ ⑪

---

Oxygen Saturation (%) \_\_\_\_\_ ⑫

---

Supine Systolic BP (mmHg) \_\_\_\_\_ ⑬

---

Supine Diastolic BP (mmHg) \_\_\_\_\_ Fixed Unit: (mmHg) ⑭

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name:** NEKNKTR1726201

**Form:** Vital Signs (same day dosing)

**Generated On:** 22 Mar 2018 22:20:59

---

	Field Name	Data Type	Units	Values	Include Field OID
①	VSPERF1	\$1		Y = Yes N = No	VSPERF1
②	VSDAT	dd MMM yyyy			VSDAT
③	WEIGHT	4.1			WEIGHT
④	WEIGHTU	\$2		kg = Kilogram LB = Pound	WEIGHTU
⑤	VSDTPT7	\$35		Pre-dose End of Infusion 2 Hrs Post-dose 3 Hrs Post-dose	VSDTPT7
⑥	VSND	1			VSND
⑦	VSTIM	HH:nn			VSTIM
⑧	TEMP	4.1			TEMP
⑨	TEMPU	\$1		C = C F = F	TEMPU

---

---

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name:** NEKNKTR1726201

**Form:** Vital Signs (same day dosing)

**Generated On:** 22 Mar 2018 22:20:59

---

Field Name	Data Type	Units	Values	Include Field OID
⑩ RESP	8			RESP
⑪ HR	8			HR
⑫ OXYSAT	8			OXYSAT
⑬ SYSBP1	8			SYSBP1
⑭ DIABP1	8			DIABP1

---

VS = Vital Signs

PROD\_22MAR2018\_1.00: UNIQUE

Project Name: NEKNKTR1726201

Form: Vitals Signs (Cycle 4)

Generated On: 22 Mar 2018 22:20:59

See CRF Page 337

Were vital signs collected?

Yes  1  
No

Date of Assessment (dd-mon-yyyy)

2

Weight

3

Weight Unit

Kilogram  4  
Pound

Planned Timepoint

End of Infusion 5

Not Done

6

Time (24-hour clock)

7

Temperature

8

Temperature Unit

C  9  
F

Respiratory Rate (breaths/min)

10

Heart Rate (beats/min)

11

Oxygen Saturation (%)

12

VS = Vital Signs

See CRF Page 337

PROD\_22MAR2018\_1.00: UNIQUE

Project Name: NEKNKTR1726201

Form: Vitals Signs (Cycle 4)

Generated On: 22 Mar 2018 22:20:59

Supine Systolic BP (mmHg) \_\_\_\_\_ ⑬

Supine Diastolic BP (mmHg) \_\_\_\_\_ ⑭

Planned Timepoint 2 Hrs Post-dose ⑮

Not Done \_\_\_\_\_ ⑯

Time (24-hour clock) \_\_\_\_\_ ⑰

Temperature \_\_\_\_\_ ⑱

Temperature Unit C  ⑲  
F

Respiratory Rate (breaths/min) \_\_\_\_\_ ⑳

Heart Rate (beats/min) \_\_\_\_\_ ㉑

Oxygen Saturation (%) \_\_\_\_\_ ㉒

Supine Systolic BP (mmHg) \_\_\_\_\_ ㉓

Supine Diastolic BP (mmHg) \_\_\_\_\_ ㉔

**PROD\_22MAR2018\_1.00: UNIQUE****Project Name: NEKNKTR1726201****Form: Vitals Signs (Cycle 4)****Generated On: 22 Mar 2018 22:20:59**

	Field Name	Data Type	Units	Values	Include Field OID
①	VSPERF1	\$1		Y = Yes N = No	VSPERF1
②	VSDAT	dd MMM yyyy			VSDAT
③	WEIGHT	4.1			WEIGHT
④	WEIGHTU	\$2		kg = Kilogram LB = Pound	WEIGHTU
⑤	VSDTPT8	\$35		End of Infusion 2 Hrs Post-dose	VSDTPT8
⑥	VSND	1			VSND
⑦	VSTIM	HH:nn			VSTIM
⑧	TEMP	4.1			TEMP
⑨	TEMPU	\$1		C = C F = F	TEMPU
⑩	RESP	8			RESP

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name:** NEKNKTR1726201

**Form:** Vitals Signs (Cycle 4)

**Generated On:** 22 Mar 2018 22:20:59

---

Field Name	Data Type	Units	Values	Include Field OID
⑪ HR	8			HR
⑫ OXYSAT	8			OXYSAT
⑬ SYSBP1	8			SYSBP1
⑭ DIABP1	8			DIABP1

---

VS = Vital Signs

See CRF Page 337

PROD\_22MAR2018\_1.00: UNIQUE

Project Name: NEKNKTR1726201

Form: Vital Signs (q1h x 4)

Generated On: 22 Mar 2018 22:20:59

Were vital signs collected?

Yes  1  
No

Date of Assessment (dd-mon-yyyy)

2

Weight

3

Weight Unit

Kilogram  4  
Pound

Planned Time Point

VSSPID = 1

24 Hrs Post-dose 5

Not Done

6

Time (24-hour clock)

7

Temperature

8

Temperature Unit

C  9  
F

Respiratory Rate (breaths/min)

10

Heart Rate (beats/min)

11

Supine Systolic BP (mmHg)

12

VS = Vital Signs

See CRF Page 337

PROD\_22MAR2018\_1.00: UNIQUE

Project Name: NEKNKTR1726201

Form: Vital Signs (q1h x 4)

Generated On: 22 Mar 2018 22:20:59

Supine Diastolic BP (mmHg)

(13)

Planned Time Point

VSSPID = 2

2nd Vitals Collection (5)

Not Done

(6)

Time (24-hour clock)

(7)

Temperature

(8)

Temperature Unit

C  (9)  
F

Respiratory Rate (breaths/min)

(10)

Heart Rate (beats/min)

(11)

Supine Systolic BP (mmHg)

(12)

Supine Diastolic BP (mmHg)

(13)

Planned Time Point

VSSPID = 3

3rd Vitals Collection (5)

Not Done

(6)

**VS = Vital Signs**

**PROD\_22MAR2018\_1.00: UNIQUE**

**See CRF Page 337**

**Project Name: NEKNKTR1726201**

**Form: Vital Signs (q1h x 4)**

**Generated On: 22 Mar 2018 22:20:59**

Time (24-hour clock) \_\_\_\_\_ **(7)**

Temperature \_\_\_\_\_ **(8)**

Temperature Unit C  **(9)**  
F

Respiratory Rate (breaths/min) \_\_\_\_\_ **(10)**

Heart Rate (beats/min) \_\_\_\_\_ **(11)**

Supine Systolic BP (mmHg) \_\_\_\_\_ **(12)**

Supine Diastolic BP (mmHg) \_\_\_\_\_ **(13)**

Planned Time Point \_\_\_\_\_ **VSSPID = 4** **(5)**  
4th Vitals Collection

Not Done \_\_\_\_\_ **(6)**

Time (24-hour clock) \_\_\_\_\_ **(7)**

Temperature \_\_\_\_\_ **(8)**

Temperature Unit C  **(9)**  
F

VS = Vital Signs

PROD\_22MAR2018\_1.00: UNIQUE

See CRF Page 337

Project Name: NEKNKTR1726201

Form: Vital Signs (q1h x 4)

Generated On: 22 Mar 2018 22:20:59

---

Respiratory Rate (breaths/min) \_\_\_\_\_ ⑩

Heart Rate (beats/min) \_\_\_\_\_ ⑪

Supine Systolic BP (mmHg) \_\_\_\_\_ ⑫

Supine Diastolic BP (mmHg) \_\_\_\_\_ ⑬

---

**PROD\_22MAR2018\_1.00: UNIQUE****Project Name: NEKNKTR1726201****Form: Vital Signs (q1h x 4)****Generated On: 22 Mar 2018 22:20:59**

	Field Name	Data Type	Units	Values	Include Field OID
①	VSPERF1	\$1		Y = Yes N = No	VSPERF1
②	VSDAT	dd MMM yyyy			VSDAT
③	WEIGHT	4.1			WEIGHT
④	WEIGHTU	\$2		kg = Kilogram LB = Pound	WEIGHTU
⑤	VSTPT9	\$66		24 Hrs Post-dose 2n d Vitals Collection 3r d Vitals Collection 4t h Vitals Collection	VSTPT9
⑥	VSND	1			VSND
⑦	VSTIM	HH:nn			VSTIM
⑧	TEMP	4.1			TEMP
⑨	TEMPU	\$1		C = C	TEMPU

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: Vital Signs (q1h x 4)**

**Generated On: 22 Mar 2018 22:20:59**

---

Field Name	Data Type	Units	Values	Include Field OID
<hr/>				
			F = F	
<b>⑩</b> RESP	8		RESP	
<b>⑪</b> HR	8		HR	
<b>⑫</b> SYSBP1	8		SYSBP1	
<b>⑬</b> DIABP1	8		DIABP1	
<hr/>				

VS = Vital Signs

See CRF Page 337

PROD\_22MAR2018\_1.00: UNIQUE

Project Name: NEKNKTR1726201

Form: Vital Signs (q1h x 2)

Generated On: 22 Mar 2018 22:20:59

Were vital signs collected?

Yes  1  
No

Date of Assessment (dd-mon-yyyy)

2

Weight

3

Weight Unit

Kilogram  4  
Pound

Planned Time Point

VSSPID = 1 48 Hrs Post-Dose 5

Not Done

6

Time (24-hour clock)

7

Temperature

8

Temperature Unit

C  9  
F

Respiratory Rate (breaths/min)

10

Heart Rate (beats/min)

11

Supine Systolic BP (mmHg)

12

VS = Vital Signs

See CRF Page 337

PROD\_22MAR2018\_1.00: UNIQUE

Project Name: NEKNKTR1726201

Form: Vital Signs (q1h x 2)

Generated On: 22 Mar 2018 22:20:59

Supine Diastolic BP (mmHg)

(13)

Planned Time Point

VSSPID = 2

2nd Vitals Collection (5)

Not Done

(6)

Time (24-hour clock)

(7)

Temperature

(8)

Temperature Unit

C  (9)

F

Respiratory Rate (breaths/min)

(10)

Heart Rate (beats/min)

(11)

Supine Systolic BP (mmHg)

(12)

Supine Diastolic BP (mmHg)

(13)

**PROD\_22MAR2018\_1.00: UNIQUE****Project Name: NEKNKTR1726201****Form: Vital Signs (q1h x 2)****Generated On: 22 Mar 2018 22:20:59**

	Field Name	Data Type	Units	Values	Include Field OID
①	VSPERF1	\$1		Y = Yes N = No	VSPERF1
②	VSDAT	dd MMM yyyy			VSDAT
③	WEIGHT	4.1			WEIGHT
④	WEIGHTU	\$2		kg = Kilogram LB = Pound	WEIGHTU
⑤	VSTPT10	\$30		48 Hrs Post-Dose 2n d Vitals Collection	VSTPT10
⑥	VSND	1			VSND
⑦	VSTIM	HH:nn			VSTIM
⑧	TEMP	4.1			TEMP
⑨	TEMPU	\$1		C = C F = F	TEMPU
⑩	RESP	8			RESP

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name:** NEKNKTR1726201

**Form:** Vital Signs (q1h x 2)

**Generated On:** 22 Mar 2018 22:20:59

---

Field Name	Data Type	Units	Values	Include Field OID
⑪ HR	8			HR
⑫ SYSBP1	8			SYSBP1
⑬ DIABP1	8			DIABP1

---

VS = Vital Signs

PROD\_22MAR2018\_1.00: UNIQUE

See CRF Page 337

Project Name: NEKNKTR1726201

Form: Vital Signs (q1h x 3)

Generated On: 22 Mar 2018 22:20:59

Were vital signs collected?

Yes  1  
No

Date of Assessment (dd-mon-yyyy)

2

Weight

3

Weight Unit

Kilogram  4  
Pound

VSSPID = 1

Planned Time Point

24 Hrs Post-dose 5

Not Done

6

Time (24-hour clock)

7

Temperature

8

Temperature Unit

C  9  
F

Respiratory Rate (breaths/min)

10

Heart Rate (beats/min)

11

Oxygen Saturation (%)

12

VS = Vital Signs

See CRF Page 337

PROD\_22MAR2018\_1.00: UNIQUE

Project Name: NEKNKTR1726201

Form: Vital Signs (q1h x 3)

Generated On: 22 Mar 2018 22:20:59

Supine Systolic BP (mmHg) \_\_\_\_\_ (13)

Supine Diastolic BP (mmHg) \_\_\_\_\_ (14)

VSSPID = 2

Planned Time Point \_\_\_\_\_ 2nd Vitals Collection (5)

Not Done \_\_\_\_\_ (6)

Time (24-hour clock) \_\_\_\_\_ (7)

Temperature \_\_\_\_\_ (8)

Temperature Unit C  (9)  
F

Respiratory Rate (breaths/min) \_\_\_\_\_ (10)

Heart Rate (beats/min) \_\_\_\_\_ (11)

Oxygen Saturation (%) \_\_\_\_\_ (12)

Supine Systolic BP (mmHg) \_\_\_\_\_ (13)

Supine Diastolic BP (mmHg) \_\_\_\_\_ (14)

VS = Vital Signs

See CRF Page 337

PROD\_22MAR2018\_1.00: UNIQUE

Project Name: NEKNKTR1726201

Form: Vital Signs (q1h x 3)

Generated On: 22 Mar 2018 22:20:59

VSSPID = 3

Planned Time Point

3rd Vitals Collection **(5)**

Not Done

**(6)**

Time (24-hour clock)

**(7)**

Temperature

**(8)**

Temperature Unit

C  **(9)**  
F

Respiratory Rate (breaths/min)

**(10)**

Heart Rate (beats/min)

**(11)**

Oxygen Saturation (%)

**(12)**

Supine Systolic BP (mmHg)

**(13)**

Supine Diastolic BP (mmHg)

**(14)**

**PROD\_22MAR2018\_1.00: UNIQUE****Project Name: NEKNKTR1726201****Form: Vital Signs (q1h x 3)****Generated On: 22 Mar 2018 22:20:59**

	Field Name	Data Type	Units	Values	Include Field OID
①	VSPERF1	\$1		Y = Yes N = No	VSPERF1
②	VSDAT	dd MMM yyyy			VSDAT
③	WEIGHT	4.1			WEIGHT
④	WEIGHTU	\$2		kg = Kilogram LB = Pound	WEIGHTU
⑤	VSTPT12	\$30		24 Hrs Post-dose 2n d Vitals Collection 3r d Vitals Collection	VSTPT12
⑥	VSPERF2	1			VSPERF2
⑦	VSTIM	HH:nn			VSTIM
⑧	TEMP	4.1			TEMP
⑨	TEMPU	\$1		C = C F = F	TEMPU

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: Vital Signs (q1h x 3)**

**Generated On: 22 Mar 2018 22:20:59**

---

	Field Name	Data Type	Units	Values	Include Field OID
⑩	RESP	8			RESP
⑪	HR	8			HR
⑫	OXYSAT	8			OXYSAT
⑬	SYSBP1	8			SYSBP1
⑭	DIABP1	8			DIABP1

---

VS = Vital Signs

See CRF Page 337

PROD\_22MAR2018\_1.00: UNIQUE

Project Name: NEKNKTR1726201

Form: Vital Signs (non-dosing day)

Generated On: 22 Mar 2018 22:20:59

Were vital signs collected?

Yes  1  
No

Date of Assessment (dd-mon-yyyy)

2

Time (24-hour clock)

3

Temperature

4

Temperature Unit

C  5  
F

Respiratory Rate (breaths/min)

6

Heart Rate (beats/min)

7

Supine Systolic BP (mmHg)

8

Supine Diastolic BP mmHg

9

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name:** NEKNKTR1726201

**Form:** Vital Signs (non-dosing day)

**Generated On:** 22 Mar 2018 22:20:59

---

	Field Name	Data Type	Units	Values	Include Field OID
①	VSPERF1	\$1		Y = Yes N = No	VSPERF1
②	VSDAT		dd MMM yyyy		VSDAT
③	VSTIM		HH:nn		VSTIM
④	TEMP		4.1		TEMP
⑤	TEMPU	\$1		C = C F = F	TEMPU
⑥	RESP		8		RESP
⑦	HR		8		HR
⑧	SYSBP1		8		SYSBP1
⑨	DIABP1		8		DIABP1

---

TU = Tumor Identification

TR = Tumor Results

See CRF Page 130

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: Target Lesion Measurement**

**Generated On: 22 Mar 2018 22:20:59**

---

Were Target Lesions Assessed at this visit?

Yes  ①  
No

Lesion (Derived from Screening)

T01  ②  
T02   
T03   
T04   
T05

Anatomical Site (Derived from Screening)

Adrenal Gland  ③  
Bone   
Brain   
Breast   
Chest Wall   
Colon/Large Intestine   
Esophagus/Oesophagus   
Gall bladder/Bile duct   
Head and Neck   
Heart/Pericardium   
Kidney   
Leptomeningeal   
Liver   
Lung - RUL   
Lung - RML   
Lung - RLL   
Lung - LUL   
Lung - LLL   
Lung - Hilum   
Lung - Other   
Lymph Nodes

TU = Tumor Identification

TR = Tumor Results

See CRF Page 131

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name:** NEKNKTR1726201

**Form:** Target Lesion Measurement

**Generated On:** 22 Mar 2018 22:20:59

---

Ovary/Fallopian tube   
Pancreas   
Pelvis (non-bone)   
Peritoneum   
Pleura   
Rectum   
Skin - Scalp   
Skin - Trunk   
Skin - Back   
Skin - RU Extremity   
Skin - RL Extremity   
Skin - LU Extremity   
Skin - LL Extremity   
Skin - Other   
Small intestine   
Soft tissue   
Spleen   
Stomach   
Trachea/Bronchi   
Urinary Bladder   
Uterus   
Other

---

If Other, specify (Derived from Screening) \_\_\_\_\_ ④

---

Anatomical Description (Derived from Screening) \_\_\_\_\_ ⑤

---

Not Assessed \_\_\_\_\_ **TRSTAT** \_\_\_\_\_ ⑥  
**TRREASND**

TU = Tumor Identification

TR = Tumor Results

See CRF Page 132

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name:** NEKNKTR1726201

**Form:** Target Lesion Measurement

**Generated On:** 22 Mar 2018 22:20:59

---

Method of Assessment

Conventional CT  7  
Spiral CT   
MRI   
PET/CT   
X-ray   
Digital Photography with   
Calipers

---

Date of Assessment (dd-mon-yyyy)

8

Lymph Node Short Axis (mm)

9

Longest Measurement (mm)

10

Was this lesion irradiated, resected, or injected since previous  
assessment?

SUPPTR.QVAL where QNAM = IRRS

Yes  11  
No

---

**PROD\_22MAR2018\_1.00: UNIQUE****Project Name:** NEKNKTR1726201**Form:** Target Lesion Measurement**Generated On:** 22 Mar 2018 22:20:59

Field Name	Data Type	Units	Values	Include Field OID
① LM1YN	\$1		Y = Yes N = No	LM1YN
② LMID_1	\$3		T01 = T01 T02 = T02 T03 = T03 T04 = T04 T05 = T05	LMID_1
③ LMSITE_1	\$22		Adrenal Gland = Adrenal Gland Bone = Bone Brain = Brain Breast = Breast Chest Wall = Chest Wall Colon/Large Intestine = Colon/Large Intestine Esophagus/O esophagus = Esophagus/O esophagus	LMSITE_1

**PROD\_22MAR2018\_1.00: UNIQUE****Project Name: NEKNKTR1726201****Form: Target Lesion Measurement****Generated On: 22 Mar 2018 22:20:59**

Field Name	Data Type	Units	Values	Include Field OID
			Gall bladder/Bile duct = Gall bladder/Bile duct Head and Neck = Head and Neck Heart/Pericar dium = Heart/Pericar dium Kidney = Kidney Leptomening eal = Leptomening eal Liver = Liver Lung - RUL = Lung - RUL Lung - RML = Lung - RML Lung - RLL = Lung - RLL Lung - LUL = Lung - LUL Lung - LLL = Lung - LLL	

**PROD\_22MAR2018\_1.00: UNIQUE****Project Name:** NEKNKTR1726201**Form:** Target Lesion Measurement**Generated On:** 22 Mar 2018 22:20:59

Field Name	Data Type	Units	Values	Include Field OID
			Lung - Hilum = Lung - Hilum Lung - Other = Lung - Other Lymph Nodes = Lymph Nodes Ovary/Fallop ian tube = Ovary/Fallop ian tube Pancreas = Pancreas Pelvis (non-bone) = Pelvis (non-bone) Peritoneum = Peritoneum Pleura = Pleura Rectum = Rectum Skin - Scalp = Skin - Scalp Skin - Trunk = Skin - Trunk	

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name:** NEKNKTR1726201

**Form:** Target Lesion Measurement

**Generated On:** 22 Mar 2018 22:20:59

---

Field Name	Data Type	Units	Values	Include Field OID
			Skin - Back	
			= Skin -	
			Back	
			Skin - RU	
			Extremity =	
			Skin - RU	
			Extremity	
			Skin - RL	
			Extremity =	
			Skin - RL	
			Extremity	
			Skin - LU	
			Extremity =	
			Skin - LU	
			Extremity	
			Skin - LL	
			Extremity =	
			Skin - LL	
			Extremity	
			Skin - Other	
			= Skin -	
			Other	
			Small	
			intestine =	
			Small	
			intestine	
			Soft tissue =	
			Soft tissue	
			Spleen =	
			Spleen	
			Stomach =	
			Stomach	

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: Target Lesion Measurement**

**Generated On: 22 Mar 2018 22:20:59**

---

Field Name	Data Type	Units	Values	Include Field OID
			Trachea/Bro nchi = Trachea/Bro nchi Urinary Bladder = Urinary Bladder Uterus = Uterus Other = Other	
④ LMOTH1_1	\$200			LMOTH1_1
⑤ LMDESC_1	\$200			LMDESC_1
⑥ LMND	1			LMND
⑦ LMMETHO	\$33	D	Conventional CT = D Conventional CT Spiral CT = Spiral CT MRI = MRI PET/CT = PET/CT X-ray = X-ray	LMMETHO

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name:** NEKNKTR1726201

**Form:** Target Lesion Measurement

**Generated On:** 22 Mar 2018 22:20:59

---

Field Name	Data Type	Units	Values	Include Field OID
			Digital Photography with Calipers = Digital Photography with Calipers	
⑧ LMSCDAT	dd MMM yyyy			LMSCDAT
⑨ LMSD	8			LMSD
⑩ LMBIDI	8			LMBIDI
⑪ LMIRRS	\$1		Y = Yes N = No	LMIRRS

---

TU = Tumor Identification

TR = Tumor Results

See CRF Page 139

PROD\_22MAR2018\_1.00: UNIQUE

Project Name: NEKNKTR1726201

Form: Non-Target Lesion

Generated On: 22 Mar 2018 22:20:59

---

Were Non-Target Lesions Assessed at this visit?

NOT SUBMITTED

Yes  ①  
No

---

Lesion (Derived from Screening)

NT01  ②  
NT02   
NT03   
NT04   
NT05   
NT06   
NT07   
NT08   
NT09   
NT10   
NT11   
NT12   
NT13   
NT14   
NT15   
NT16   
NT17   
NT18   
NT19   
NT20   
NT21   
NT22   
NT23   
NT24   
NT25   
NT26   
NT27

---

TU = Tumor Identification

TR = Tumor Results

See CRF Page 140

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: Non-Target Lesion**

**Generated On: 22 Mar 2018 22:20:59**

---

NT28	<input type="radio"/>
NT29	<input type="radio"/>
NT30	<input type="radio"/>
NT31	<input type="radio"/>
NT32	<input type="radio"/>
NT33	<input type="radio"/>
NT34	<input type="radio"/>
NT35	<input type="radio"/>
NT36	<input type="radio"/>
NT37	<input type="radio"/>
NT38	<input type="radio"/>
NT39	<input type="radio"/>
NT40	<input type="radio"/>
NT41	<input type="radio"/>
NT42	<input type="radio"/>
NT43	<input type="radio"/>
NT44	<input type="radio"/>
NT45	<input type="radio"/>
NT46	<input type="radio"/>
NT47	<input type="radio"/>
NT48	<input type="radio"/>
NT49	<input type="radio"/>
NT50	<input type="radio"/>
NT51	<input type="radio"/>
NT52	<input type="radio"/>
NT53	<input type="radio"/>
NT54	<input type="radio"/>
NT55	<input type="radio"/>
NT56	<input type="radio"/>
NT57	<input type="radio"/>

TU = Tumor Identification

TR = Tumor Results

PROD\_22MAR2018\_1.00: UNIQUE

See CRF Page 141

Project Name: NEKNKTR1726201

Form: Non-Target Lesion

Generated On: 22 Mar 2018 22:20:59

---

NT58   
NT59   
NT60   
NT61   
NT62   
NT63   
NT64   
NT65   
NT66   
NT67   
NT68   
NT69   
NT70   
NT71   
NT72   
NT73   
NT74   
NT75   
NT76   
NT77   
NT78   
NT79   
NT80   
NT81   
NT82   
NT83   
NT84   
NT85   
NT86   
NT87

TU = Tumor Identification

TR = Tumor Results

PROD\_22MAR2018\_1.00: UNIQUE

See CRF Page 142

Project Name: NEKNKTR1726201

Form: Non-Target Lesion

Generated On: 22 Mar 2018 22:20:59

---

NT88  
NT89  
NT90  
NT91  
NT92  
NT93  
NT94  
NT95  
NT96  
NT97  
NT98  
NT99

---

Anatomical Site (Derived from Screening)

Adrenal Gland  (3)  
Bone   
Brain   
Breast   
Chest Wall   
Colon/Large Intestine   
Esophagus/Oesophagus   
Gall bladder/Bile duct   
Head and Neck   
Heart/Pericardium   
Kidney   
Leptomeningeal   
Liver   
Lung - RUL   
Lung - RML   
Lung - RLL   
Lung - LUL

---

TU = Tumor Identification

TR = Tumor Results

See CRF Page 143

PROD\_22MAR2018\_1.00: UNIQUE

Project Name: NEKNKTR1726201

Form: Non-Target Lesion

Generated On: 22 Mar 2018 22:20:59

---

- |                      |                          |
|----------------------|--------------------------|
| Lung - LLL           | <input type="checkbox"/> |
| Lung - Hilum         | <input type="checkbox"/> |
| Lung - Other         | <input type="checkbox"/> |
| Lymph Nodes          | <input type="checkbox"/> |
| Ovary/Fallopian tube | <input type="checkbox"/> |
| Pancreas             | <input type="checkbox"/> |
| Pelvis (non-bone)    | <input type="checkbox"/> |
| Peritoneum           | <input type="checkbox"/> |
| Pleura               | <input type="checkbox"/> |
| Rectum               | <input type="checkbox"/> |
| Skin - Scalp         | <input type="checkbox"/> |
| Skin - Trunk         | <input type="checkbox"/> |
| Skin - Back          | <input type="checkbox"/> |
| Skin - RU Extremity  | <input type="checkbox"/> |
| Skin - RL Extremity  | <input type="checkbox"/> |
| Skin - LU Extremity  | <input type="checkbox"/> |
| Skin - LL Extremity  | <input type="checkbox"/> |
| Skin - Other         | <input type="checkbox"/> |
| Small intestine      | <input type="checkbox"/> |
| Soft tissue          | <input type="checkbox"/> |
| Spleen               | <input type="checkbox"/> |
| Stomach              | <input type="checkbox"/> |
| Trachea/Bronchi      | <input type="checkbox"/> |
| Urinary Bladder      | <input type="checkbox"/> |
| Uterus               | <input type="checkbox"/> |
| Other                | <input type="checkbox"/> |

---

If Other, specify (Derived from Screening) \_\_\_\_\_

④

---

Anatomical Description (Derived from Screening) \_\_\_\_\_

⑤

TU = Tumor Identification

TR = Tumor Results

See CRF Page 144

PROD\_22MAR2018\_1.00: UNIQUE

Project Name: NEKNKTR1726201

Form: Non-Target Lesion

Generated On: 22 Mar 2018 22:20:59

---

Method of Assessment

- Conventional CT  ⑥  
Spiral CT   
MRI   
PET/CT   
Bone Scan   
X-ray   
Digital Photography with   
Calipers   
Physical Exam   
Other
- 

If Other, specify

⑦

Date of Assessment (dd-mon-yyyy)

⑧

Lesion Status

- Present  ⑨  
Absent   
Unequivocal Progression   
Not Assessed
-

**PROD\_22MAR2018\_1.00: UNIQUE****Project Name: NEKNKTR1726201****Form: Non-Target Lesion****Generated On: 22 Mar 2018 22:20:59**

---

Field Name	Data Type	Units	Values	Include Field OID
① NLM1YN	\$1		Y = Yes N = No	NLM1YN
② NLMID_1	\$4		NT01 = NT01 NT02 = NT02 NT03 = NT03 NT04 = NT04 NT05 = NT05 NT06 = NT06 NT07 = NT07 NT08 = NT08 NT09 = NT09 NT10 = NT10 NT11 = NT11 NT12 = NT12 NT13 = NT13 NT14 = NT14 NT15 = NT15	NLMID_1

---

**PROD\_22MAR2018\_1.00: UNIQUE****Project Name: NEKNKTR1726201****Form: Non-Target Lesion****Generated On: 22 Mar 2018 22:20:59**

---

Field Name	Data Type	Units	Values	Include Field OID
			NT16 =	
			NT16	
			NT17 =	
			NT17	
			NT18 =	
			NT18	
			NT19 =	
			NT19	
			NT20 =	
			NT20	
			NT21 =	
			NT21	
			NT22 =	
			NT22	
			NT23 =	
			NT23	
			NT24 =	
			NT24	
			NT25 =	
			NT25	
			NT26 =	
			NT26	
			NT27 =	
			NT27	
			NT28 =	
			NT28	
			NT29 =	
			NT29	
			NT30 =	
			NT30	
			NT31 =	
			NT31	
			NT32 =	
			NT32	

---

**PROD\_22MAR2018\_1.00: UNIQUE****Project Name: NEKNKTR1726201****Form: Non-Target Lesion****Generated On: 22 Mar 2018 22:20:59**

---

Field Name	Data Type	Units	Values	Include Field OID
			NT33 =	
			NT33	
			NT34 =	
			NT34	
			NT35 =	
			NT35	
			NT36 =	
			NT36	
			NT37 =	
			NT37	
			NT38 =	
			NT38	
			NT39 =	
			NT39	
			NT40 =	
			NT40	
			NT41 =	
			NT41	
			NT42 =	
			NT42	
			NT43 =	
			NT43	
			NT44 =	
			NT44	
			NT45 =	
			NT45	
			NT46 =	
			NT46	
			NT47 =	
			NT47	
			NT48 =	
			NT48	
			NT49 =	
			NT49	

---

**PROD\_22MAR2018\_1.00: UNIQUE****Project Name: NEKNKTR1726201****Form: Non-Target Lesion****Generated On: 22 Mar 2018 22:20:59**

---

Field Name	Data Type	Units	Values	Include Field OID
			NT50 =	
			NT50	
			NT51 =	
			NT51	
			NT52 =	
			NT52	
			NT53 =	
			NT53	
			NT54 =	
			NT54	
			NT55 =	
			NT55	
			NT56 =	
			NT56	
			NT57 =	
			NT57	
			NT58 =	
			NT58	
			NT59 =	
			NT59	
			NT60 =	
			NT60	
			NT61 =	
			NT61	
			NT62 =	
			NT62	
			NT63 =	
			NT63	
			NT64 =	
			NT64	
			NT65 =	
			NT65	
			NT66 =	
			NT66	

---

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name:** NEKNKTR1726201

**Form:** Non-Target Lesion

**Generated On:** 22 Mar 2018 22:20:59

---

Field Name	Data Type	Units	Values	Include Field OID
			NT67 =	
			NT67	
			NT68 =	
			NT68	
			NT69 =	
			NT69	
			NT70 =	
			NT70	
			NT71 =	
			NT71	
			NT72 =	
			NT72	
			NT73 =	
			NT73	
			NT74 =	
			NT74	
			NT75 =	
			NT75	
			NT76 =	
			NT76	
			NT77 =	
			NT77	
			NT78 =	
			NT78	
			NT79 =	
			NT79	
			NT80 =	
			NT80	
			NT81 =	
			NT81	
			NT82 =	
			NT82	
			NT83 =	
			NT83	

---

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name:** NEKNKTR1726201

**Form:** Non-Target Lesion

**Generated On:** 22 Mar 2018 22:20:59

---

Field Name	Data Type	Units	Values	Include Field OID
			NT84 =	
			NT84	
			NT85 =	
			NT85	
			NT86 =	
			NT86	
			NT87 =	
			NT87	
			NT88 =	
			NT88	
			NT89 =	
			NT89	
			NT90 =	
			NT90	
			NT91 =	
			NT91	
			NT92 =	
			NT92	
			NT93 =	
			NT93	
			NT94 =	
			NT94	
			NT95 =	
			NT95	
			NT96 =	
			NT96	
			NT97 =	
			NT97	
			NT98 =	
			NT98	
			NT99 =	
			NT99	

---

---

**PROD\_22MAR2018\_1.00: UNIQUE****Project Name: NEKNKTR1726201****Form: Non-Target Lesion****Generated On: 22 Mar 2018 22:20:59**

---

Field Name	Data Type	Units	Values	Include Field OID
③ NLMSITE_1 \$22			Adrenal Gland = Adrenal Gland Bone = Bone Brain = Brain Breast = Breast Chest Wall = Chest Wall Colon/Large Intestine = Colon/Large Intestine Esophagus/O esophagus = Esophagus/O esophagus Gall bladder/Bile duct = Gall bladder/Bile duct Head and Neck = Head and Neck Heart/Pericar dium = Heart/Pericar dium	NLMSITE_1

---

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name:** NEKNKTR1726201

**Form:** Non-Target Lesion

**Generated On:** 22 Mar 2018 22:20:59

---

Field Name	Data Type	Units	Values	Include Field OID
			Kidney = Kidney Leptomening eal = Leptomening eal Liver = Liver Lung - RUL = Lung - RUL Lung - RML = Lung - RML Lung - RLL = Lung - RLL Lung - LUL = Lung - LUL Lung - LLL = Lung - LLL Lung - Hilum = Lung - Hilum Lung - Other = Lung - Other Lymph Nodes = Lymph Nodes	

**PROD\_22MAR2018\_1.00: UNIQUE****Project Name: NEKNKTR1726201****Form: Non-Target Lesion****Generated On: 22 Mar 2018 22:20:59**

---

Field Name	Data Type	Units	Values	Include Field OID
			Ovary/Fallopian tube =	
			Ovary/Fallopian tube	
			Pancreas =	
			Pancreas	
			Pelvis	
			(non-bone) =	
			Pelvis	
			(non-bone)	
			Peritoneum =	
			Peritoneum	
			Pleura =	
			Pleura	
			Rectum =	
			Rectum	
			Skin - Scalp	
			= Skin -	
			Scalp	
			Skin - Trunk	
			= Skin -	
			Trunk	
			Skin - Back	
			= Skin -	
			Back	
			Skin - RU	
			Extremity =	
			Skin - RU	
			Extremity	
			Skin - RL	
			Extremity =	
			Skin - RL	
			Extremity	

---

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name:** NEKNKTR1726201

**Form:** Non-Target Lesion

**Generated On:** 22 Mar 2018 22:20:59

---

Field Name	Data Type	Units	Values	Include Field OID
			Skin - LU Extremity = Skin - LU Extremity Skin - LL Extremity = Skin - LL Extremity Skin - Other = Skin - Other Small intestine = Small intestine Soft tissue = Soft tissue Spleen = Spleen Stomach = Stomach Trachea/Bro nchi = Trachea/Bro nchi Urinary Bladder = Urinary Bladder Uterus = Uterus Other = Other	

---

---

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name:** NEKNKTR1726201

**Form:** Non-Target Lesion

**Generated On:** 22 Mar 2018 22:20:59

---

Field Name	Data Type	Units	Values	Include Field OID
④ NLMOTH1_ \$200			NLMOTH1_ 1	
⑤ NLMDESC_ \$200			NLMDESC_ 1	
⑥ NLMMETH \$33			Conventional CT = Conventional CT Spiral CT = Spiral CT MRI = MRI PET/CT = PET/CT Bone Scan = Bone Scan X-ray = X-ray Digital Photography with Calipers = Digital Photography with Calipers Physical Exam = Physical Exam	NLMMETH

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name:** NEKNKTR1726201

**Form:** Non-Target Lesion

**Generated On:** 22 Mar 2018 22:20:59

---

Field Name	Data Type	Units	Values	Include Field OID
			Other = Other	
<b>⑦</b> NLMOTH2	\$100			NLMOTH2
<b>⑧</b> NLMSFDA	dd MMM			NLMSFDA
	T	yyyy		T
<b>⑨</b> NLMSTAT	\$23		Present = Present Absent = Absent Uequivocal Progression = Uequivocal Progression Not Assessed = Not Assessed	NLMSTAT

---

TU = Tumor Identification

TR = Tumor Results

PROD\_22MAR2018\_1.00: UNIQUE

Project Name: NEKNKTR1726201

Form: New Lesion Measurement

Generated On: 22 Mar 2018 22:20:59

TUORRES = NEW

TUTESTCD = TUMIDENT

TUTEST = Tumor Identification

Lesion

TULNKID  
TRLNKID

①

Anatomical Site

TULOC

Adrenal Gland

Bone

Brain

Breast

Chest Wall

Colon/Large Intestine

Esophagus/Oesophagus

Gall bladder/Bile duct

Head and Neck

Heart/Pericardium

Kidney

Leptomeningeal

Liver

Lung - RUL

Lung - RML

Lung - RLL

Lung - LUL

Lung - LLL

Lung - Hilum

Lung - Other

Lymph Nodes

Ovary/Fallopian tube

Pancreas

Pelvis (non-bone)

Peritoneum

Pleura

Rectum

Skin - Scalp

**TU = Tumor Identification**

**TR = Tumor Results**

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: New Lesion Measurement**

**Generated On: 22 Mar 2018 22:20:59**

---

- Skin - Trunk
- Skin - Back
- Skin - RU Extremity
- Skin - RL Extremity
- Skin - LU Extremity
- Skin - LL Extremity
- Skin - Other
- Small intestine
- Soft tissue
- Spleen
- Stomach
- Trachea/Bronchi
- Urinary Bladder
- Uterus
- Other

---

If Other, specify

**SUPPTU.QVAL where QNAM = TUATOTH**

**3**

---

Anatomical Description

**SUPPTU.QVAL where QNAM = TUDESC**

**4**

---

Date of Assessment (dd-mon-yyyy)

**TUDTC** **TRDTC**

**5**

---

Method of Assessment

- Conventional CT
- Spiral CT
- MRI
- PET/CT
- X-ray
- Digital Photography with
- Calipers
- Other

**TUMETHOD**

**TRMETHOD**

TU = Tumor Identification

TR = Tumor Results

PROD\_22MAR2018\_1.00: UNIQUE

Project Name: NEKNKTR1726201

Form: New Lesion Measurement

Generated On: 22 Mar 2018 22:20:59

If Other, specify	SUPPTU.QVAL where QNAM = TUMEOTH SUPPTR.QVAL where QNAM = TUMEOTH	(7)
Lymph Node Short Axis (mm)	TRORRES where TRTESTCD = SAXIS TRORRESU	(8)
Longest Measurement (mm)	TRORRES where TRTESTCD = LDIAM TRORRESU	(9)
Not Measurable	TRSTAT	(10)
DERIVED: [Lesion No. 'n'] to add to form name	NOT SUBMITTED	(11)

**PROD\_22MAR2018\_1.00: UNIQUE****Project Name:** NEKNKTR1726201**Form:** New Lesion Measurement**Generated On:** 22 Mar 2018 22:20:59

---

Field Name	Data Type	Units	Values	Include Field OID
① NLID	3			NLID
② NLSITE	\$22		Adrenal Gland = Adrenal Gland Bone = Bone Brain = Brain Breast = Breast Chest Wall = Chest Wall Colon/Large Intestine = Colon/Large Intestine Esophagus/O esophagus = Esophagus/O esophagus Gall bladder/Bile duct = Gall bladder/Bile duct Head and Neck = Head and Neck Heart/Pericar dium = Heart/Pericar dium	NLSITE

---

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name:** NEKNKTR1726201

**Form:** New Lesion Measurement

**Generated On:** 22 Mar 2018 22:20:59

---

Field Name	Data Type	Units	Values	Include Field OID
			Kidney = Kidney Leptomening eal = Leptomening eal Liver = Liver Lung - RUL = Lung - RUL Lung - RML = Lung - RML Lung - RLL = Lung - RLL Lung - LUL = Lung - LUL Lung - LLL = Lung - LLL Lung - Hilum = Lung - Hilum Lung - Other = Lung - Other Lymph Nodes = Lymph Nodes	

**PROD\_22MAR2018\_1.00: UNIQUE****Project Name:** NEKNKTR1726201**Form:** New Lesion Measurement**Generated On:** 22 Mar 2018 22:20:59

---

Field Name	Data Type	Units	Values	Include Field OID
			Ovary/Fallopian tube =	
			Ovary/Fallopian tube	
			Pancreas =	
			Pancreas	
			Pelvis	
			(non-bone) =	
			Pelvis	
			(non-bone)	
			Peritoneum =	
			Peritoneum	
			Pleura =	
			Pleura	
			Rectum =	
			Rectum	
			Skin - Scalp	
			= Skin -	
			Scalp	
			Skin - Trunk	
			= Skin -	
			Trunk	
			Skin - Back	
			= Skin -	
			Back	
			Skin - RU	
			Extremity =	
			Skin - RU	
			Extremity	
			Skin - RL	
			Extremity =	
			Skin - RL	
			Extremity	

---

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name:** NEKNKTR1726201

**Form:** New Lesion Measurement

**Generated On:** 22 Mar 2018 22:20:59

---

Field Name	Data Type	Units	Values	Include Field OID
			Skin - LU Extremity = Skin - LU Extremity Skin - LL Extremity = Skin - LL Extremity Skin - Other = Skin - Other Small intestine = Small intestine Soft tissue = Soft tissue Spleen = Spleen Stomach = Stomach Trachea/Bro nchi = Trachea/Bro nchi Urinary Bladder = Urinary Bladder Uterus = Uterus Other = Other	

---

---

**PROD\_22MAR2018\_1.00: UNIQUE****Project Name:** NEKNKTR1726201**Form:** New Lesion Measurement**Generated On:** 22 Mar 2018 22:20:59

Field Name	Data Type	Units	Values	Include Field OID
③ NLSPEC	\$100			NLSPEC
④ NLDESC	\$200			NLDESC
⑤ NLDAT	dd MMM yyyy			NLDAT
⑥ NLMETHO	\$33 D		Conventional CT = D Conventional CT Spiral CT = Spiral CT MRI = MRI PET/CT = PET/CT X-ray = X-ray Digital Photography with Calipers = Digital Photography with Calipers Other = Other	NLMETHO
⑦ NLSPEC2	\$50			NLSPEC2
⑧ NLSD	8			NLSD

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name:** NEKNKTR1726201

**Form:** New Lesion Measurement

**Generated On:** 22 Mar 2018 22:20:59

---

Field Name	Data Type	Units	Values	Include Field OID
⑨ NLBIDI	8			NLBIDI
⑩ NLNM	1			NLNM
⑪ Z_FORMNA\$40 ME				Z_FORMNA ME

---

RS = Disease Response

PROD\_22MAR2018\_1.00: UNIQUE

Project Name: NEKNKTR1726201

Form: Response

Generated On: 22 Mar 2018 22:20:59

---

Date of Evaluation (dd-mon-yyyy)

RSDTC

①

Evaluation of Target Lesion

RSORRES

Complete Response

Partial Response

Stable Disease

Progressive Disease

Not Evaluable

Evaluation of Non-Target Lesion

RSORRES

Complete Response

Non Complete Response/Non

Progressive Disease

Progressive Disease

Not Evaluable

Not Applicable

---

Were there any new lesions?

Yes

④

No

---

RECIST 1.1 Overall Response

RSORRES

Complete Response

Partial Response

Stable Disease

Progressive Disease

Not Evaluable

**PROD\_22MAR2018\_1.00: UNIQUE****Project Name:** NEKNKTR1726201**Form:** Response**Generated On:** 22 Mar 2018 22:20:59

	Field Name	Data Type	Units	Values	Include Field OID
①	RSSTDAT	dd MMM yyyy			RSSTDAT
②	RSSTRESP	\$2		CR = Complete Response PR = Partial Response SD = Stable Disease PD = Progressive Disease NE = Not Evaluable	RSSTRESP
③	RSSTRES	\$13		CR = Complete Response Non-CR/Non -PD = Non Complete Response/No n Progressive Disease PD = Progressive Disease NE = Not Evaluable NA = Not Applicable	RSSTRES

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name:** NEKNKTR1726201

**Form:** Response

**Generated On:** 22 Mar 2018 22:20:59

---

Field Name	Data Type	Units	Values	Include Field OID
④ IRNEWLSN	\$1		Y = Yes N = No	IRNEWLSN
⑤ RSSTRESO	\$2		CR = Complete Response PR = Partial Response SD = Stable Disease PD = Progressive Disease NE = Not Evaluable	RSSTRESO

---

**EX = Exposure**

**EC = Exposure as Collected**

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: NKTR-262 Administration**

**Generated On: 22 Mar 2018 22:20:59**

**EXTRT = NKTR-262**

**ECTRT = NKTR-262**

**ECPRESP = Y**

Was NKTR-262 administered?

**ECMOOD = PERFORMED**

**ECOCCUR**

Yes  ①  
No

Date NKTR-262 Administered (dd-mon-yyyy)

**EXSTDTC**

**ECSTDTC**

②

Planned NKTR-262 Dose

**ECDOSE** Fixed Unit: mg

**ECDOSU**

**EXDOSE**

**ECMOOD = SCHEDULED**

Planned NKTR-262 Volume

Fixed Unit: mL

**SUPPEX.QVAL where QNAM = PL262VOL**

Injected Lesion Number, Location and Description **SUPPEX.QVAL where QNAM = EXLNLD**

⑤

Measurement of Injected Lesion

Fixed Unit: mm

**SUPPEX.QVAL where QNAM = EXLMEAS**

⑥

Was a Target Lesion used for injection?

**SUPPEX.QVAL where QNAM = EXTLYN**

Yes  ⑦  
No

If Yes, complete the following:

Injected Target Number, Location and Description **SUPPEX.QVAL where QNAM = EXTLNLD**

⑧

Measurement of Injected Target Lesion

Fixed Unit: mm

**SUPPEX.QVAL where QNAM = EXMITL**

⑨

Was Interventional Radiology guidance required for  
NKTR-262 administration?

**SUPPEX.QVAL where QNAM = EXIRREQ**

Yes  ⑩  
No

**EX = Exposure**

**EC = Exposure as Collected**

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name:** NEKNKTR1726201

**Form:** NKTR-262 Administration

**Generated On:** 22 Mar 2018 22:20:59

---

If Yes, specify method used

**SUPPEX.QVAL where QNAM = EXIRSPC**

CT  11

PET/CT

Ultrasound

Other

---

If Other, Specify method

**SUPPEX.QVAL where QNAM = EXMSROT**

12

---

Injection Start Time

**ECMOOD = PERFORMED**

Fixed Unit: 24-hour clock 13

**EXSTDTC** **ECSTDTC**

---

Total Volume Injected per lesion

Fixed Unit: mL 14

**Used to derive EXDOSE and ECDOSE**

**SUPPEX.QVAL where QNAM = AC262VOL**

**SUPPEC.QVAL where QNAM = AC262VOL**

---

Was dose interrupted?

**SUPPEX.QVAL where QNAM = EXINT**

Yes  15

No

---

If Yes, Reason interrupted

**SUPPEX.QVAL where QNAM = EXRSNINT**

Adverse Event  16

Other

---

If Other, specify reason interrupted

**SUPPEX.QVAL where QNAM = EXINTSP**

17

---

Primary AE Number and Term

**SUPPEX.QVAL where QNAM = EXINTAE**

18

---

Was dose delayed?

**SUPPEX.QVAL where QNAM = EXDEL**

Yes  19

No

---

If Yes, Reason delayed

Adverse Event  20

**SUPPEX.QVAL where QNAM = EXRSNDEL**

**EX = Exposure**

**PROD\_22MAR2018\_1.00: UNIQUE**  
**Project Name: NEKNKTR1726201**  
**Form: NKTR-262 Administration**  
**Generated On: 22 Mar 2018 22:20:59**

---

Other

---

If Other, specify reason delayed

**SUPPEX.QVAL where QNAM = EXDELSP**

**(21)**

---

**PROD\_22MAR2018\_1.00: UNIQUE****Project Name:** NEKNKTR1726201**Form:** NKTR-262 Administration**Generated On:** 22 Mar 2018 22:20:59

	Field Name	Data Type	Units	Values	Include Field OID
①	EXPOCCUR\$1			Y = Yes N = No	EXPOCCUR
②	EXSTDAT	dd MMM yyyy			EXSTDAT
③	EXPDOSE	4.2			EXPDOSE
④	EXPVOL	3.2			EXPVOL
⑤	EXLNLD	\$50			EXLNLD
⑥	EXLMEAS	2			EXLMEAS
⑦	EXTLYN	\$1		Y = Yes N = No	EXTLYN
⑧	EXTLNLD	\$50			EXTLNLD
⑨	EXMITL	8			EXMITL
⑩	EXIRREQ	\$1		Y = Yes N = No	EXIRREQ
⑪	EXIRSPC	\$10		CT = CT	EXIRSPC

**PROD\_22MAR2018\_1.00: UNIQUE****Project Name:** NEKNKTR1726201**Form:** NKTR-262 Administration**Generated On:** 22 Mar 2018 22:20:59

Field Name	Data Type	Units	Values	Include Field OID
			PET/CT = PET/CT Ultrasound = Ultrasound Other = Other	
<b>⑫ EXMSROT</b>	\$100			EXMSROT
<b>⑬ EXSTTIM</b>	HH:nn			EXSTTIM
<b>⑭ EXTVAMT</b>	3.2			EXTVAMT
<b>⑮ EXINTRP</b>	\$1		Y = Yes N = No	EXINTRP
<b>⑯ EXINTRS</b>	\$17		AE = Adverse Event OTHER = Other	EXINTRS
<b>⑰ EXINTSP</b>	\$200			EXINTSP
<b>⑱ EXAEN262</b>	\$100			EXAEN262
<b>⑲ EXDEL</b>	\$1		Y = Yes N = No	EXDEL

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name:** NEKNKTR1726201

**Form:** NKTR-262 Administration

**Generated On:** 22 Mar 2018 22:20:59

---

Field Name	Data Type	Units	Values	Include Field OID
②⓪ EXDELRS	\$17		AE = Adverse Event OTHER = Other	EXDELRS
②① EXDELSP	\$200			EXDELSP

---

EX = Exposure

EC = Exposure as Collected

PROD\_22MAR2018\_1.00: UNIQUE

Project Name: NEKNKTR1726201

Form: NKTR-214 Administration

Generated On: 22 Mar 2018 22:20:59

EXTRT = NKTR-214

ECTRT = NKTR-214

Was the NKTR-214 dose administered?

ECPRESP = Y

Yes  1  
No

ECMOOD = PERFORMED

ECOCCUR

Administration Date (dd-mon-yyyy)

EXSTDTC ECSTDTC

2

Administration Start Time

Fixed Unit: 24-hour clock 3

EXSTDTC ECSTDTC

Administration End Time

Fixed Unit: 24-hour clock 4

EXENDTC ECENDTC

Planned Dose

Fixed Unit: mg/kg 5

ECMOOD = SCHEDULED

ECDOSE

ECDOSU

Total Dose

Fixed Unit: mg 6

EXDOSU

ECDOSU

ECMOOD = PERFORMED

ECDOSE

EXDOSE

Total Volume Administered

Fixed Unit: mL 7

SUPPEX.QVAL where QNAM = EXTVAMT

Was dose reduced from previous dose?

SUPPEX.QVAL where QNAM = EXRED

Yes  8  
No

If dose was reduced, enter new planned dose SUPPEX.QVAL where QNAM = EXPDOSE2 9

Specify Reason

EXADJ

Adverse Event  10

ECADJ

Other

**EX = Exposure**

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name:** NEKNKTR1726201

**Form:** NKTR-214 Administration

**Generated On:** 22 Mar 2018 22:20:59

---

If Other Reason for Reduction, specify

**SUPPEX.QVAL where QNAM = EXREDSP**

**(11)**

---

Primary AE Number and Term

**SUPPEX.QVAL where QNAM = EXREDAE**

**(12)**

---

Was the dose delayed?

**SUPPEX.QVAL where QNAM = EXDEL**

Yes  **(13)**  
No

---

Specify Reason

Adverse Event  **(14)**

**SUPPEX.QVAL where QNAM = EXRSNDEL**

Other

---

If Other Reason for Delay, specify

**SUPPEX.QVAL where QNAM = EXDELSP**

**(15)**

---

Primary AE Number and Term

**SUPPEX.QVAL where QNAM = EXDELAE**

**(16)**

---

Was the NKTR-214 dose interrupted?

**SUPPEX.QVAL where QNAM = EXINT**

Yes  **(17)**  
No

---

Date of interruption (dd-mon-yyyy)

**SUPPEX.QVAL where QNAM = EXINTDTC**

**(18)**

---

Time of interruption (24-hour clock)

**SUPPEX.QVAL where QNAM = EXINTDTC**

**(19)**

---

Was the administration restarted?

**SUPPEX.QVAL where QNAM = EXREYN**

Yes  **(20)**  
No

---

Restart date (dd-mon-yyyy)

**SUPPEX.QVAL where QNAM = EXREDTC**

**(21)**

---

Restart time (24-hour clock)

**SUPPEX.QVAL where QNAM = EXREDTC**

**(22)**

**EX = Exposure**

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: NKTR-214 Administration**

**Generated On: 22 Mar 2018 22:20:59**

---

Reason for interruption

Adverse Event  **23**

**SUPPEX.QVAL where QNAM = EXRSNINT**

Other

---

If Other, specify reason interrupted

**SUPPEX.QVAL where QNAM = EXINTSP**

**24**

Primary AE Number and Term

**SUPPEX.QVAL where QNAM = EXINTAE**

**25**

**PROD\_22MAR2018\_1.00: UNIQUE****Project Name:** NEKNKTR1726201**Form:** NKTR-214 Administration**Generated On:** 22 Mar 2018 22:20:59

	Field Name	Data Type	Units	Values	Include Field OID
①	EXPOCCUR\$1			Y = Yes N = No	EXPOCCUR
②	EXSTDAT	dd MMM yyyy			EXSTDAT
③	EXSTTIM	HH:nn			EXSTTIM
④	EXENTIM	HH:nn			EXENTIM
⑤	EXPDOSE	4.2			EXPDOSE
⑥	EXDOSE	4.3			EXDOSE
⑦	EXTVAMT	3.2			EXTVAMT
⑧	EXRED	\$1		Y = Yes N = No	EXRED
⑨	EXPDOSE2	8.4			EXPDOSE2
⑩	EXRSN2	\$13		Adverse Event = Adverse Event	EXRSN2

**PROD\_22MAR2018\_1.00: UNIQUE****Project Name: NEKNKTR1726201****Form: NKTR-214 Administration****Generated On: 22 Mar 2018 22:20:59**

Field Name	Data Type	Units	Values	Include Field OID
			Other = Other	
<b>(11)</b> EXRSN2SP	\$100			EXRSN2SP
<b>(12)</b> EXAENO2	\$100			EXAENO2
<b>(13)</b> EXDEL	\$1		Y = Yes N = No	EXDEL
<b>(14)</b> EXRSN3	\$13		Adverse Event = Adverse Event Other = Other	EXRSN3
<b>(15)</b> EXRSN3SP	\$100			EXRSN3SP
<b>(16)</b> EXAENO3	\$100			EXAENO3
<b>(17)</b> EXINTRP	\$1		Y = Yes N = No	EXINTRP
<b>(18)</b> EXINDAT	dd MMM yyyy			EXINDAT

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: NKTR-214 Administration**

**Generated On: 22 Mar 2018 22:20:59**

---

Field Name	Data Type	Units	Values	Include Field OID
⑯ EXINTIM	HH:nn			EXINTIM
㉐ EXRSYN	\$1		Y = Yes N = No	EXRSYN
㉑ EXRSTDAT	dd MMM yyyy			EXRSTDAT
㉒ EXRSTIM	HH:nn			EXRSTIM
㉓ EXINTRS	\$17		AE = Adverse Event OTHER = Other	EXINTRS
㉔ EXINTSP	\$200			EXINTSP
㉕ EXAENO4	\$100			EXAENO4

---

EX = Exposure

EC = Exposure as Collected

PROD\_22MAR2018\_1.00: UNIQUE

Project Name: NEKNKTR1726201

Form: Nivolumab Administration

Generated On: 22 Mar 2018 22:20:59

EXTRT = NIVOLUMAB

ECTRT = NIVOLUMAB

ECPRESP = Y

Was the Nivolumab dose administered?

ECMOOD = PERFORMED

ECOCCUR

Yes

1

No

Administration Start Date (dd-mon-yyyy)

EXSTDTC

ECSTDTC

2

Administration Start Time

Fixed Unit: 24-hour clock

EXSTDTC

ECSTDTC

3

Administration End Time

Fixed Unit: 24-hour clock

EXENDTC

ECENDTC

4

Actual Dose Administered

Fixed Unit: mg

EXDOSE

EXDOSU

ECDOSE

ECADOSU

5

Was the dose delayed?

SUPPEX.QVAL where QNAM = EXDEL

Yes

6

No

Was the Nivolumab dose interrupted?

SUPPEX.QVAL where QNAM = EXINT

Yes

7

No

Time of Interruption (24-hour clock)

SUPPEX.QVAL where QNAM = EXINTDTC

8

Was the administration re-started?

SUPPEX.QVAL where QNAM = EXREYN

Yes

9

No

Restart Time (24-hour clock)

SUPPEX.QVAL where QNAM = EXREDTC

10

**EX = Exposure**

## EC = Exposure as Collected

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name:** NEKNKTR1726201

## **Form: Nivolumab Administration**

**Generated On: 22 Mar 2018 22:20:59**

## Reason For Interruption

SUPPEX.QVAL where QNAM = EXRSNINT

## Adverse Event

11

Other

If Other Reason for Interruption, specify

SUPPEX.QVAL where QNAM = EXINTSP

12

### Primary AE Number and Term

SUPPEX.QVAL where QNAM = EXINTAE

## Primary AE Number and Term

Primary AE Number and Term SUPPEX.QVAL where QNAM = EXINTAE 13

**IDVAR = AESPID**

## SUPPEX.QVAL where QNAM = EXINTAE

**IDVAR = AESPID**

**PROD\_22MAR2018\_1.00: UNIQUE****Project Name:** NEKNKTR1726201**Form:** Nivolumab Administration**Generated On:** 22 Mar 2018 22:20:59

	Field Name	Data Type	Units	Values	Include Field OID
①	EXPOCCUR\$1			Y = Yes N = No	EXPOCCUR
②	EXSTDAT	dd MMM yyyy			EXSTDAT
③	EXSTTIM	HH:nn			EXSTTIM
④	EXENTIM	HH:nn			EXENTIM
⑤	EXDOSE	4.3			EXDOSE
⑥	EXDEL	\$1		Y = Yes N = No	EXDEL
⑦	EXINTRP	\$1		Y = Yes N = No	EXINTRP
⑧	EXINTIM	HH:nn			EXINTIM
⑨	EXREYN	\$1		Y = Yes N = No	EXREYN
⑩	EXRETIM	HH:nn			EXRETIM

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name:** NEKNKTR1726201

**Form:** Nivolumab Administration

**Generated On:** 22 Mar 2018 22:20:59

---

Field Name	Data Type	Units	Values	Include Field OID
<b>(11)</b> EXINTREA	\$13		Adverse Event = Adverse Event Other = Other	EXINTREA
<b>(12)</b> EXINTSPE	\$100			EXINTSPE
<b>(13)</b> EXAENO	\$200			EXAENO

---

**EX = Exposure**

**EC = Exposure as Collected**

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: IV Hydration**

**Generated On: 22 Mar 2018 22:20:59**

**EXTRT = HYDRATION**

**ECTRT = HYDRATION**

**ECPRESP = Y**

Was IV hydration administered for NKTR-214?

**ECMOOD = PERFORMED**

**ECOCCUR**

Yes  ①  
No

Date (dd-mon-yyyy)

**EXSTDTC**

②

Time

**EXENDTC**

**ECSTDTC**

**ECENDTC**

Fixed Unit: 24-hour clock ③

Volume

**EXDOSE**

**ECDOSE**

④

Unit

**EXDOSU**

**ECDOSU**

Liter  ⑤  
mL

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name:** NEKNKTR1726201

**Form:** IV Hydration

**Generated On:** 22 Mar 2018 22:20:59

---

	Field Name	Data Type	Units	Values	Include Field OID
①	HYADYN	\$1		Y = Yes N = No	HYADYN
②	HYDAT		dd MMM yyyy		HYDAT
③	HYTIM		HH:nn		HYTIM
④	HYVOL	\$10			HYVOL
⑤	HYVOLU	\$5		Liter = Liter mL = mL	HYVOLU

---

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name:** NEKNKTR1726201

**Form:** Status

**Generated On:** 22 Mar 2018 22:20:59

---

Did the subject continue to the next cycle?

NOT SUBMITTED

Yes  1  
No

---

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name:** NEKNKTR1726201

**Form:** Status

**Generated On:** 22 Mar 2018 22:20:59

---

Field Name	Data Type	Units	Values	Include Field OID
① STATUS	\$1		Y = Yes N = No	STATUS

---

DS = Disposition

DM = Demographics

PROD\_22MAR2018\_1.00: UNIQUE

Project Name: NEKNKTR1726201

Form: End of Treatment (NKTR-262)

Generated On: 22 Mar 2018 22:20:59

DSCAT = DISPOSITION EVENT

DSSCAT = END OF NKTR-262 TREATMENT

Date decision was made to discontinue NKTR-262  
(dd-mon-yyyy)

DSSTDTC

①

Primary Reason for Discontinuing Treatment

Progressive Disease By

②

DTERM where DSDECOD = PROGRESSIVE DISEASE RECIST

DTERM where DSDECOD = PROGRESSIVE DISEASE Progressive Disease Clinical

Progression

DTERM where DSDECOD = ADVERSE EVENT Adverse Event

DTERM where DSDECOD = DEATH Death

DTHFL

DTERM where DSDECOD = PHYSICIAN DECISION Physician's Decision

DTERM where DSDECOD = WITHDRAWAL BY SUBJECT Withdrawal by Patient

DTERM where DSDECOD = OTHER Noncompliance of the Patient

DTERM where DSDECOD = SYMPTOMATIC DE Symptomatic deterioration

Achievement of Maximal

DTERM where DSDECOD = ACHIEVEMENT Response

Pregnancy

DTERM where DSDECOD = PREGNANCY

DTERM where DSDECOD = LOST TO FOLLOW-UP Lost to Follow-Up

DTERM where DSDECOD = STUDY TERMINATED BY SPONSOR Sponsor Decision

DTERM where DSDECOD = LACK OF EFFICACY Lack of accessible/eligible  
lesion for injection

If Physician Decision, specify

SUPPDS.QVAL where QNAM = DSPHYS

③

If Withdrawal by Patient, specify

SUPPDS.QVAL where QNAM = DSWC

④

If Adverse Event, specify

SUPPDS.QVAL where QNAM = DSAETERM

⑤

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: End of Treatment (NKTR-262)**

**Generated On: 22 Mar 2018 22:20:59**

---

Field Name	Data Type	Units	Values	Include Field OID
① DSSTDAT4 dd MMM yyyy				DSSTDAT4
② DSDECOD4 \$48			PROGRESSIDSDECOD4 VE DISEASE BY RECIST = Progressive Disease By RECIST PROGRESSI VE DISEASE CLINICAL PROGRESSI ON = Progressive Disease Clinical Progression ADVERSE EVENT = Adverse Event DEATH = Death PHYSICIAN DECISION = Physician's Decision	

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: End of Treatment (NKTR-262)**

**Generated On: 22 Mar 2018 22:20:59**

---

Field Name	Data Type	Units	Values	Include Field OID
			WITHDRA WAL BY SUBJECT = Withdrawal by Patient NON-COMP LIANCE WITH STUDY DRUG = Noncomplian ce of the Patient SYMPTOM ATIC DETERIOR ATION = Symptomatic deterioration ACHIEVEM ENT OF MAXIMAL RESPONSE = Achievement of Maximal Response	

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: End of Treatment (NKTR-262)**

**Generated On: 22 Mar 2018 22:20:59**

---

Field Name	Data Type	Units	Values	Include Field OID
			PREGNANC Y = Pregnancy LOST TO FOLLOW-U P = Lost to Follow-Up SPONSOR DECISION = Sponsor Decision LACK OF ACCESSIBL E/ELIGIBLE LESION FOR INJECTION = Lack of accessible/eli gible lesion for injection	
③	DSPHYS4	\$200		DSPHYS4
④	DSWC4	\$200		DSWC4
⑤	DSAETERM	\$200 4		DSAETERM 4

---

**DS = Disposition**

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: End of Treatment (NKTR-214)**

**Generated On: 22 Mar 2018 22:20:59**

**See CRF Page 445**

**DSCAT = DISPOSITION EVENT**

**DSSCAT = END OF NKTR-214 TREATMENT**

Date decision was made to discontinue NKTR-214  
(dd-mon-yyyy)

**①**

Primary Reason for Discontinuing Treatment

Progressive Disease By RECIST

Progressive Disease Clinical Progression

Adverse Event

Physician's Decision

Withdrawal by Patient

Noncompliance of the Patient

Symptomatic deterioration

Achievement of Maximal Response

Pregnancy

Lost to Follow-Up

Sponsor Decision

Death

If Physician Decision, specify

**③**

If Withdrawal by Patient, specify

**④**

If Adverse Event, specify

**⑤**

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: End of Treatment (NKTR-214)**

**Generated On: 22 Mar 2018 22:20:59**

---

Field Name	Data Type	Units	Values	Include Field OID
① DSSTDAT	dd MMM yyyy			DSSTDAT
② DSDECOD	\$48		PROGRESS IDSDECOD VE DISEASE BY RECIST = Progressive Disease By RECIST PROGRESSI VE DISEASE CLINICAL PROGRESSI ON = Progressive Disease Clinical Progression ADVERSE EVENT = Adverse Event PHYSICIAN DECISION = Physician's Decision	

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: End of Treatment (NKTR-214)**

**Generated On: 22 Mar 2018 22:20:59**

---

Field Name	Data Type	Units	Values	Include Field OID
			WITHDRA WAL BY SUBJECT = Withdrawal by Patient NON-COMP LIANCE WITH STUDY DRUG = Noncomplian ce of the Patient SYMPTOM ATIC DETERIOR ATION = Symptomatic deterioration ACHIEVEM ENT OF MAXIMAL RESPONSE = Achievement of Maximal Response	

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: End of Treatment (NKTR-214)**

**Generated On: 22 Mar 2018 22:20:59**

---

Field Name	Data Type	Units	Values	Include Field OID
			PREGNANC Y = Pregnancy LOST TO FOLLOW-U P = Lost to Follow-Up SPONSOR DECISION = Sponsor Decision DEATH = Death	
③	DSPHYS	\$200		DSPHYS
④	DSWC	\$200		DSWC
⑤	DSAETERM	\$200		DSAETERM

---

**DS = Disposition**

**PROD\_22MAR2018\_1.00: UNIQUE**

**See CRF Page 445**

**Project Name: NEKNKTR1726201**

**Form: End of Treatment (Nivolumab)**

**Generated On: 22 Mar 2018 22:20:59**

**DSCAT = DISPOSITION EVENT**

**DSSCAT = END OF NIVOLUMAB TREATMENT**

---

Date decision was made to discontinue Nivolumab  
(dd-mon-yyyy) \_\_\_\_\_

**①**

Primary Reason for Discontinuing Treatment

Progressive Disease By  **②**

RECIST

Progressive Disease Clinical

Progression

Adverse Event

Physician's Decision

Withdrawal by Patient

Noncompliance of the Patient

Symptomatic deterioration

Achievement of Maximal

Response

Pregnancy

Lost to Follow-Up

Sponsor Decision

Death

---

If Physician Decision, specify \_\_\_\_\_

**③**

---

If Withdrawal by Patient, specify \_\_\_\_\_

**④**

---

If Adverse Event, specify \_\_\_\_\_

**⑤**

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: End of Treatment (Nivolumab)**

**Generated On: 22 Mar 2018 22:20:59**

---

Field Name	Data Type	Units	Values	Include Field OID
① DSSTDAT3	dd MMM yyyy			DSSTDAT3
② DSDECOD3	\$48		PROGRESSIDSDECOD3 VE DISEASE BY RECIST = Progressive Disease By RECIST PROGRESSI VE DISEASE CLINICAL PROGRESSI ON = Progressive Disease Clinical Progression ADVERSE EVENT = Adverse Event PHYSICIAN DECISION = Physician's Decision	

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: End of Treatment (Nivolumab)**

**Generated On: 22 Mar 2018 22:20:59**

---

Field Name	Data Type	Units	Values	Include Field OID
			WITHDRA WAL BY SUBJECT = Withdrawal by Patient NON-COMP LIANCE WITH STUDY DRUG = Noncomplian ce of the Patient SYMPTOM ATIC DETERIOR ATION = Symptomatic deterioration ACHIEVEM ENT OF MAXIMAL RESPONSE = Achievement of Maximal Response	

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: End of Treatment (Nivolumab)**

**Generated On: 22 Mar 2018 22:20:59**

---

Field Name	Data Type	Units	Values	Include Field OID
			PREGNANC Y = Pregnancy LOST TO FOLLOW-U P = Lost to Follow-Up SPONSOR DECISION = Sponsor Decision DEATH = Death	
③	DSPHYS3	\$200		DSPHYS3
④	DSWC	\$200		DSWC
⑤	DSAETERM\$200 3			DSAETERM 3

---

**DS = Disposition**

**DM = Demographics**

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: End of Study**

**DSCAT = DISPOSITION EVENT**

**Generated On: 22 Mar 2018 22:20:59**

**DSSCAT = END OF STUDY**

---

Date of End of Study (dd-mon-yyyy)

**DSSTDTC**

**RFENDTC**

**①**

**DSTERM where DSDECOD = LOST TO FOLLOW-UP**

Lost to Follow-Up

**②**

Primary Reason for End of Study

**DSTERM where DSDECOD = WITHDRAWAL BY SUBJECT**

Withdrawal by Patient

**③**

**DSTERM where DSDECOD = DEATH**

Death

**DTHFL**

**DSTERM where DSDECOD = STUDY TERMINATED BY SPONSOR**

Sponsor's Decision

**④**

---

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name:** NEKNKTR1726201

**Form:** End of Study

**Generated On:** 22 Mar 2018 22:20:59

---

Field Name	Data Type	Units	Values	Include Field OID
① DSSTDAT2	dd MMM yyyy			DSSTDAT2
② DSDECOD2	\$27		LOST TO FOLLOW-U P = Lost to Follow-Up WITHDRA WAL BY SUBJECT = Withdrawal by Patient DEATH = Death SPONSOR DECISION = Sponsor's Decision	DSDECOD2

---

**PROD\_22MAR2018\_1.00: UNIQUE**  
**Project Name: NEKNKTR1726201**  
**Form: Adverse Events YN**  
**Generated On: 22 Mar 2018 22:20:59**

---

Were any Adverse Events experienced?

NOT SUBMITTED

Yes  1  
No

---

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name:** NEKNKTR1726201

**Form:** Adverse Events YN

**Generated On:** 22 Mar 2018 22:20:59

---

Field Name	Data Type	Units	Values	Include Field OID
① AEYN	\$1		Y = Yes N = No	AEYN

---

AE = Adverse Events

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: Adverse Events**

**Generated On: 22 Mar 2018 22:20:59**

---

Adverse Event

AETERM

1

---

Start Date (dd-mon-yyyy)

AESTDTC

2

---

Start Time (24-hour clock)

AEENDTC

3

---

Ongoing

AEENRF

4

---

End Date (dd-mon-yyyy)

AEENDTC

5

---

End Time (24-hour clock)

AETOXGR

6

---

Grade

Grade 1  7

Grade 2

Grade 3

Grade 4

Grade 5

---

Serious Event

AE SER

Yes  8

No

All SAEs must be reported by fax to Nektar Therapeutics

Drug Safety within 1 business day of discovery: Drug

Safety

Fax No: (855) 482-7233 or (415) 482-5410

---

Is AE related to study procedure?

AERELNST

Yes  9

No

---

Relationship to NKTR-262

AEREL

Not Related  10

**AE = Adverse Events**

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: Adverse Events**

**Generated On: 22 Mar 2018 22:20:59**

---

Related

Relationship to NKTR-214

**SUPPAE.QVAL where QNAM = AEREL2**

Not Related  **(11)**

Related

Relationship to Nivolumab

**SUPPAE.QVAL where QNAM = AEACN3**

Not Related  **(12)**

Related

Action Taken with NKTR-262

**AEACN**

Dose Not Changed  **(13)**

Dose Delayed

Dose Interrupted

Drug Discontinued

Dose Reduced

Not Applicable

Action Taken with NKTR-214

**SUPPAE.QVAL where QNAM = AEACN2**

Dose Not Changed  **(14)**

Dose Delayed

Dose Reduced

Drug Interrupted

Drug Discontinued

Not Applicable

Action Taken with Nivolumab

**SUPPAE.QVAL where QNAM = AEACN3**

Dose Not Changed  **(15)**

Dose Delayed

Drug Interrupted

Drug Discontinued

Not Applicable

**AE = Adverse Events**

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: Adverse Events**

**Generated On: 22 Mar 2018 22:20:59**

---

Other Action Taken

None  **16**

**AECONTRT** Concomitant Medication

Non-Drug Therapy

**AEACNOTH**

**AESHOSP** Hospitalization

Other

If Non-drug Therapy or Other, specify

**SUPPAE.QVAL where QNAM = ACNOTH** **17**

Outcome

Recovered/Resolved  **18**

Recovered/Resolved with

Sequelae

**AEOUT**

Recovering/Resolving

Not Recovered/Not Resolved

**AESDTH** Fatal

Unknown

DERIVED:NOW

**19**

**PROD\_22MAR2018\_1.00: UNIQUE****Project Name: NEKNKTR1726201****Form: Adverse Events****Generated On: 22 Mar 2018 22:20:59**

	Field Name	Data Type	Units	Values	Include Field OID
①	AETERM	\$200			AETERM
②	AESTDAT	dd MMM yyyy			AESTDAT
③	AESTTIM	HH:nn			AESTTIM
④	AEONGO	1			AEONGO
⑤	AEENDAT	dd MMM yyyy			AEENDAT
⑥	AEENTIM	HH:nn			AEENTIM
⑦	AESEV	1		1 = Grade 1 2 = Grade 2 3 = Grade 3 4 = Grade 4 5 = Grade 5	AESEV
⑧	AESER	\$1		Y = Yes N = No	AESER
⑨	AEREL2	\$1		Y = Yes N = No	AEREL2

**PROD\_22MAR2018\_1.00: UNIQUE****Project Name: NEKNKTR1726201****Form: Adverse Events****Generated On: 22 Mar 2018 22:20:59**

	Field Name	Data Type	Units	Values	Include Field OID
⑩	AEREL3	\$16		NOT RELATED = Not Related RELATED = Related	AEREL3
⑪	AEREL	\$16		NOT RELATED = Not Related RELATED = Related	AEREL
⑫	AEREL4	\$16		NOT RELATED = Not Related RELATED = Related	AEREL4
⑬	AEACN1	\$16		DOSE NOT CHANGED = Dose Not Changed DOSE DELAYED = Dose Delayed DOSE INTERRUP TED = Dose Interrupted	AEACN1

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: Adverse Events**

**Generated On: 22 Mar 2018 22:20:59**

---

Field Name	Data Type	Units	Values	Include Field OID
			DRUG WITHDRA WN = Drug Discontinued DOSE REDUCED = Dose Reduced NOT APPLICABL E = Not Applicable	
<b>(14)</b> AEACN	\$16		DOSE NOT CHANGED = Dose Not Changed DOSE DELAYED = Dose Delayed DOSE REDUCED = Dose Reduced DRUG INTERRUP TED = Drug Interrupted DRUG WITHDRA WN = Drug Discontinued	AEACN

---

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: Adverse Events**

**Generated On: 22 Mar 2018 22:20:59**

---

Field Name	Data Type	Units	Values	Include Field OID
			NOT APPLICABL E = Not Applicable	
<b>⑯ AEACN2</b>	\$16		DOSE NOT CHANGED = Dose Not Changed DOSE DELAYED = Dose Delayed DRUG INTERRUP TED = Drug Interrupted DRUG WITHDRA WN = Drug Discontinued NOT APPLICABL E = Not Applicable	AEACN2
<b>⑯ AEACNOT</b>	\$22	H	NONE = None	AEACNOT H

---

**PROD\_22MAR2018\_1.00: UNIQUE****Project Name: NEKNKTR1726201****Form: Adverse Events****Generated On: 22 Mar 2018 22:20:59**

Field Name	Data Type	Units	Values	Include Field OID
			CONCOMIT ANT MEDICATI ON = Concomitant Medication NON-DRUG THERAPY = Non-Drug Therapy HOSPITALI ZATION = Hospitalizati on OTHER = Other	
⑯ ACNOTH	\$50		ACNOTH	
⑰ AEOUT	\$32		RECOVERE AEOUT D/RESOLV ED = Recovered/R esolved RECOVERE D/RESOLV ED WITH SEQUELAE = Recovered/R esolved with Sequelae	

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: Adverse Events**

**Generated On: 22 Mar 2018 22:20:59**

---

Field Name	Data Type	Units	Values	Include Field OID
			RECOVERI NG/RESOL VING = Recovering/ Resolving NOT RECOVERE D/NOT RESOLVED = Not Recovered/N ot Resolved FATAL = Fatal U = Unknown	
<b>(19)</b>	<b>Z_NOW</b>	dd MMM yyyy HH nn ss		<b>Z_NOW</b>

---

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: Prior and Concomitant Medications YN**

**Generated On: 22 Mar 2018 22:20:59**

---

Were any medications taken?

**NOT SUBMITTED**

Yes  **1**  
No

---

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: Prior and Concomitant Medications YN**

**Generated On: 22 Mar 2018 22:20:59**

---

Field Name	Data Type	Units	Values	Include Field OID
① CMYN	\$1		Y = Yes N = No	CMYN

---

CM = Concomitant Medications

RELREC = Related Records

PROD\_22MAR2018\_1.00: UNIQUE

Project Name: NEKNKTR1726201

Form: Prior and Concomitant Medication

Generated On: 22 Mar 2018 22:20:59

Medication / Therapy Name \_\_\_\_\_ CMTRT ①

If Indication is an AE, give Primary AE Number and Term \_\_\_\_\_ CMINDC ②  
IDVARVAL IDVAR = AESPID

If Indication is an AE, give Secondary (if applicable) AE Number and Term \_\_\_\_\_ CMINDC ③  
IDVARVAL IDVAR = AESPID

If Indication is MH, give Primary MH Number and Term \_\_\_\_\_ CMINDC ④  
IDVARVAL IDVAR = MHSPID

Other Indication \_\_\_\_\_ CMINDC ⑤  
CMINDC = concatenate CMAENO, CMAENO2, CMN

Dose \_\_\_\_\_ CMDOSE ⑥

Unit \_\_\_\_\_ Gram ⑦  
Milligram  
Microgram  
Milliliter  
Capsule Dosing Unit  
Tablet Dosing Unit  
Other  
CMDOSU

If Other Unit, specify \_\_\_\_\_ Percentage ⑧  
Percent Inhibition  
Percent Volume per Volume; vol%  
Percent Weight per Volume  
Percent Weight per Weight  
Percent per Minute  
per 100 High Powered Fields  
CMDOSU

**CM = Concomitant Medications**

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: Prior and Concomitant Medication**

**Generated On: 22 Mar 2018 22:20:59**

---

Per 100 White Blood Cells   
/10<sup>3</sup> cells   
Daily; Per Day   
Per Deciliter   
Per Hour   
per High Powered Field   
Per Kilogram   
Per Liter   
per Low Powered Field   
Per Milliliter   
Every Month; Per Month   
Per Nanoliter   
Per Picoliter   
/mm<sup>3</sup>; Per Microliter   
per Visual Field   
Every week; Per Week; QS   
100 International units/Milliliter   
10<sup>4</sup>/mm<sup>3</sup>; 10<sup>4</sup>/uL;   
10<sup>7</sup>/mL   
10<sup>5</sup>/mm<sup>3</sup>; 10<sup>5</sup>/uL;   
10<sup>8</sup>/mL   
TIU/L; Tera International Unit   
per Liter   
10<sup>6</sup>/mm<sup>3</sup>; 10<sup>6</sup>/uL; T/L;   
TI/L; Tera/L   
Thousand CFU; Thousand   
Colony Forming Units   
Thousand CFU/g; Thousand   
Colony Forming Units per   
Gram   
Thousand CFU/mL; Thousand   
Colony Forming Units per   
Milliliter

**CMDOSU**

CM = Concomitant Medications

PROD\_22MAR2018\_1.00: UNIQUE

Project Name: NEKNKTR1726201

Form: Prior and Concomitant Medication

Generated On: 22 Mar 2018 22:20:59

---

<input type="checkbox"/>	10^3 copies/mL
<input type="checkbox"/>	10^3 DNA copies/mL
<input type="checkbox"/>	Thousand Organisms
<input type="checkbox"/>	Thousand Organisms per
<input type="checkbox"/>	Gram; Thousand Organisms/g
<input type="checkbox"/>	Thousand Organisms per
<input type="checkbox"/>	Milliliter; Thousand
<input type="checkbox"/>	Organisms/mL
<input type="checkbox"/>	10^3 RNA copies/mL
<input type="checkbox"/>	10^3/hpf
<input type="checkbox"/>	10^3/L
<input type="checkbox"/>	10^4/hpf
<input type="checkbox"/>	10^4/L
<input type="checkbox"/>	10^5/hpf
<input type="checkbox"/>	10^2/mL
<input type="checkbox"/>	Million CFU; Million Colony
<input type="checkbox"/>	Forming Units
<input type="checkbox"/>	Million CFU/g; Million
<input type="checkbox"/>	Colony Forming Units per
<input type="checkbox"/>	Gram
<input type="checkbox"/>	Million CFU/mL; Million
<input type="checkbox"/>	Colony Forming Units per
<input type="checkbox"/>	Milliliter
<input type="checkbox"/>	10^6 copies/mL
<input type="checkbox"/>	10^6 DNA copies/mL
<input type="checkbox"/>	Million IU; Million
<input type="checkbox"/>	International Units
<input type="checkbox"/>	10^6 IU/mL
<input type="checkbox"/>	Million Organisms
<input type="checkbox"/>	Million Organisms per Gram;
<input type="checkbox"/>	Million Organisms/g
<input type="checkbox"/>	Million Organisms per
<input type="checkbox"/>	Milligram; Million
<input type="checkbox"/>	Organisms/mg

CM = Concomitant Medications

PROD\_22MAR2018\_1.00: UNIQUE

Project Name: NEKNKTR1726201

Form: Prior and Concomitant Medication

Generated On: 22 Mar 2018 22:20:59

---

<b>CMDOSU</b>	Million Organisms per <input type="checkbox"/> Milliliter; Million Organisms/mL
	$10^6$ RNA copies/mL <input type="checkbox"/> $10^6$ /g <input type="checkbox"/>
	$10^6$ /hpf <input type="checkbox"/> $10^3$ /mL; M/L; Mega/L <input type="checkbox"/>
	$10^6$ /dL <input type="checkbox"/> $10^2$ /mm <sup>3</sup> ; $10^2$ /uL; <input type="checkbox"/> $10^5$ /mL <input type="checkbox"/>
	Billion CFU; Billion Colony <input type="checkbox"/> Forming Units
	Billion CFU/g; Billion Colony <input type="checkbox"/> Forming Units per Gram
	Billion CFU/mL; Billion <input type="checkbox"/> Colony Forming Units per Milliliter
	Billion Organisms <input type="checkbox"/> Billion Organisms per Gram; <input type="checkbox"/> Billion Organisms/g
	Billion Organisms per <input type="checkbox"/> Milligram; Billion Organisms/mg
	Billion Organisms per <input type="checkbox"/> Milliliter; Billion Organisms/mL
	$10^3$ /mm <sup>3</sup> ; $10^3$ /uL; <input type="checkbox"/> $10^6$ /mL; G/L; GI/L; Giga per Liter
	Arbitrary Fluorescence Unit <input type="checkbox"/> Attogram <input type="checkbox"/>
	Antigen Unit per Milliliter <input type="checkbox"/> Attomole <input type="checkbox"/>
	Ampere <input type="checkbox"/>
	Ampule Dosing Unit <input type="checkbox"/>

CM = Concomitant Medications

PROD\_22MAR2018\_1.00: UNIQUE

Project Name: NEKNKTR1726201

Form: Prior and Concomitant Medication

Generated On: 22 Mar 2018 22:20:59

---

Atomic Mass Unit	<input type="checkbox"/>
Anti-Xa Activity International Unit	<input type="checkbox"/>
Anti-Xa Activity International Unit per Milliliter	<input type="checkbox"/>
Antibody Unit	<input type="checkbox"/>
Immunoglobulin A Phospholipid Units per Milliliter	<input type="checkbox"/>
Application Dosing Unit	<input type="checkbox"/>
Atmosphere	<input type="checkbox"/>
Absorbance Unit	<input type="checkbox"/>
Absorbance Unit per Minute	<input type="checkbox"/>
Allergy Unit per Milliliter	<input type="checkbox"/>
<b>CMDOSU</b>	<input type="checkbox"/>
Bag Dosing Unit	<input type="checkbox"/>
Bar Dosing Unit	<input type="checkbox"/>
Bioequivalent Allergy Unit	<input type="checkbox"/>
Bioequivalent Allergy Unit per Milliliter	<input type="checkbox"/>
Biological Unit per Milliliter	<input type="checkbox"/>
Beats per Minute	<input type="checkbox"/>
Bel	<input type="checkbox"/>
Biscuit	<input type="checkbox"/>
Blocks	<input type="checkbox"/>
Bolus Dosing Unit	<input type="checkbox"/>
Bottle Dosing Unit	<input type="checkbox"/>
Box Dosing Unit	<input type="checkbox"/>
Becquerel	<input type="checkbox"/>
Becquerel per Gram	<input type="checkbox"/>
Becquerel per Kilogram	<input type="checkbox"/>
Becquerel per Liter	<input type="checkbox"/>

**CM = Concomitant Medications**

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: Prior and Concomitant Medication**

**Generated On: 22 Mar 2018 22:20:59**

---

Becquerel per Milligram;  Kilobecquerel per Gram;

kBq/g

Becquerel per Milliliter;

Kilobecquerel per Liter;

kBq/L

Becquerel per Microgram;

Bq/mcg; Kilobecquerel per

Milligram; MBq/g;

Megabecquerel per Gram;

kBq/mg

Becquerel per Microliter;

Kilobecquerel per Milliliter;

MBq/L; Megabecquerel per

Liter; kBq/mL

Breaths per Minute

Bethesda Unit

Bethesda Unit per Milliliter

Degree Celsius

Calorie

Can Dosing Unit

Capful Dosing Unit

Caplet Dosing Unit

Capsule Dosing Unit; cap

Cartridge Dosing Unit

50 Percent Cell Culture

Infective Dose per Dose

50 Percent Cell Culture

Infective Dose per Milliliter

Candela

Colony Forming Unit per

Gram

Colony Forming Unit per

Milliliter

Centigram

**CMDOSU**

**CM = Concomitant Medications**

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: Prior and Concomitant Medication**

**Generated On: 22 Mar 2018 22:20:59**

---

Centigray	<input type="checkbox"/>
Curie	<input type="checkbox"/>
Curie per Gram; Microcurie per Microgram; Millicurie per Milligram; mCi/mg; uCi/ug	<input type="checkbox"/>
Curie per Kilogram;	<input type="checkbox"/>
Microcurie per Milligram; Millicurie per Gram; mCi/g; uCi/mg	<input type="checkbox"/>
Curie per Liter; Microcurie per Microliter; uCi/uL	<input type="checkbox"/>
Curie per Milligram;	<input type="checkbox"/>
Millicurie per Microgram; mCi/ug	<input type="checkbox"/>
Curie per Milliliter	<input type="checkbox"/>
Ci/mcg; Curie per Microgram	<input type="checkbox"/>
Ci/mcL; Curie per Microliter	<input type="checkbox"/>
<b>CMDOSU</b>	
Cigar Dosing Unit	<input type="checkbox"/>
Cigarette Dosing Unit	<input type="checkbox"/>
Centiliter	<input type="checkbox"/>
Centimeter	<input type="checkbox"/>
cm H2O	<input type="checkbox"/>
Centimeters per Minute	<input type="checkbox"/>
cm/sec	<input type="checkbox"/>
Square Centimeter	<input type="checkbox"/>
Centimole	<input type="checkbox"/>
Millimoles per Deciliter; mmol/dL	<input type="checkbox"/>
Coat Dosing Unit	<input type="checkbox"/>
Container Dosing Unit	<input type="checkbox"/>
copies/mL	<input type="checkbox"/>
copies/uL	<input type="checkbox"/>
Coulomb	<input type="checkbox"/>

**CM = Concomitant Medications**

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: Prior and Concomitant Medication**

**Generated On: 22 Mar 2018 22:20:59**

---

Counts per Minute	<input type="checkbox"/>
$10^{-2}$ sec; Centisecond; csec	<input type="checkbox"/>
Cup Dosing Unit	<input type="checkbox"/>
Grating Cycles per Centimeter; cpcm	<input type="checkbox"/>
Cycle per Minute	<input type="checkbox"/>
Cycle per Second	<input type="checkbox"/>
Cylinder Dosing Unit	<input type="checkbox"/>
D Antigen Unit	<input type="checkbox"/>
D Antigen Unit per Milliliter	<input type="checkbox"/>
Decamole per Liter; Moles per Deciliter; mol/dL	<input type="checkbox"/>
Day	<input type="checkbox"/>
Decibel	<input type="checkbox"/>
Degree Unit of Plane Angle	<input type="checkbox"/>
<b>CMDOSU</b>	<b>Diopter</b>
Disk Dosing Unit	<input type="checkbox"/>
Deciliter	<input type="checkbox"/>
Decimole	<input type="checkbox"/>
DNA Copies per Milliliter	<input type="checkbox"/>
Disintegrations per Minute	<input type="checkbox"/>
Disintegrations per Minute per 0.5 Milliliter	<input type="checkbox"/>
Disintegrations per Minute per 100 milligrams; dpm/cg	<input type="checkbox"/>
Disintegrations per Minute per Milligram	<input type="checkbox"/>
Disintegrations per Minute per Milliliter	<input type="checkbox"/>
Dram	<input type="checkbox"/>
Drum Dosing Unit	<input type="checkbox"/>
Dyne	<input type="checkbox"/>

**CM = Concomitant Medications**

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: Prior and Concomitant Medication**

**Generated On: 22 Mar 2018 22:20:59**

---

50 Percent Embryo Infective   
Dose per Dose   
50 Percent Embryo Infective   
Dose per Milliliter   
Enzyme-Linked   
Immunosorbent Assay Unit   
Enzyme-Linked   
Immunosorbent Assay Unit   
per Dose   
Enzyme-Linked   
Immunosorbent Assay Unit   
per Milliliter   
Enzyme Unit   
Equivalent Weight   
EU/dL; Ehrlich Units   
Degree Fahrenheit   
Farad   
Fibrinogen Equivalent Units   
Femtogram   
Fingertip Unit   
Cubic Micrometer; Cubic   
Micron; Femtoliter; um3   
Femtomole   
Femtomole per Gram   
Femtomole per Liter   
Fluid Ounce Imperial   
Fluid Ounce US   
Fraction of 1   
F/s; FPS; Frames per Second;   
Frames/sec   
Foot   
Square Foot   
Standard Cubic Foot

**CM = Concomitant Medications**

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: Prior and Concomitant Medication**

**Generated On: 22 Mar 2018 22:20:59**

---

Gram	<input type="checkbox"/>
Gram per Animal	<input type="checkbox"/>
Gram per Animal per Day	<input type="checkbox"/>
Gram per Animal per Week	<input type="checkbox"/>
Gram per Cage	<input type="checkbox"/>
Gram per Cage per Day	<input type="checkbox"/>
Gram per Cage per Week	<input type="checkbox"/>
Gram per Square Centimeter	<input type="checkbox"/>
Gram per Day; g/24h; g/d; gram/24 Hours; gram/day	<input type="checkbox"/>
Gram per Deciliter; g%	<input type="checkbox"/>
Gram per Gram	<input type="checkbox"/>
Gram per Gram per Day	<input type="checkbox"/>
<b>CMDOSU</b>	<b>Gram per Kilogram;</b>
Milligram per Gram; mg/g	<input type="checkbox"/>
Gram per Kilogram per Day;	<input type="checkbox"/>
Milligram per Gram per Day; mg/g/day	<input type="checkbox"/>
Gram per Liter; Kilogram per Cubic Meter; Microgram per	<input type="checkbox"/>
Microliter; Milligram per Milliliter; g/L; kg/m3; mg/mL; ug/uL	<input type="checkbox"/>
Gram per Square Meter	<input type="checkbox"/>
Gram per Square Meter per Day	<input type="checkbox"/>
Gram per Mole	<input type="checkbox"/>
Gauss	<input type="checkbox"/>
Gigabecquerel	<input type="checkbox"/>
Gigabecquerel per Gram; Kilobecquerel per Microgram; kBq/ug	<input type="checkbox"/>

**CM = Concomitant Medications**

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: Prior and Concomitant Medication**

**Generated On: 22 Mar 2018 22:20:59**

---

**CMDOSU**

Gigabecquerel per Milligram;   
MBq/mcg; MBq/ug;  
Megabecquerel per  
Microgram  
GBq/mcg; Gigabecquerel per   
Microgram; MBq/ng;  
Megabecquerel per nanogram  
Immunoglobulin G   
Phospholipid Units per  
Milliliter  
Grain   
Drop   
Gray   
Henry   
Histamine Equivalent Prick   
Unit  
Homeopathic Dilution Unit   
HU   
Hour; hr   
Hectopascal   
High Power Field   
Hertz   
Implant Dosing Unit   
Inch   
Square Inch   
Inhalation Dosing Unit   
IE; International Unit   
IU/dL   
International Unit per Gram   
International Unit per  
Kilogram   
International units per   
Kilogram per Hour

**CM = Concomitant Medications**

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: Prior and Concomitant Medication**

**Generated On: 22 Mar 2018 22:20:59**

---

IE/L; IU/L; International Unit per Liter; mIU/mL	<input type="checkbox"/>
International Unit per Milligram	<input type="checkbox"/>
IE/mL; International Unit per Milliliter; Kilo International Unit per Liter; kIU/L	<input type="checkbox"/>
Jar Dosing Unit	<input type="checkbox"/>
Joule	<input type="checkbox"/>
Kallikrein Inhibitor Unit	<input type="checkbox"/>
Katal	<input type="checkbox"/>
Kilobecquerel	<input type="checkbox"/>
GBq/L; Gigabecquerel per Liter; Kilobecquerel per Microliter; MBq/mL;	<input type="checkbox"/>
Megabecquerel per Milliliter	<input type="checkbox"/>
Kilogram-Calorie	<input type="checkbox"/>
Kilodalton; Kilounified	<input type="checkbox"/>
Atomic Mass Unit; ku	<input type="checkbox"/>
Kilogram	<input type="checkbox"/>
Kilogram per Centimeter	<input type="checkbox"/>
Kilogram per Square Centimeter	<input type="checkbox"/>
Gram per Milliliter; Kilogram per Liter; g/mL; gram/mL; kg/L; mg/uL	<input type="checkbox"/>
Kilogram per Square Meter	<input type="checkbox"/>
kilohertz	<input type="checkbox"/>
Kit Dosing Unit	<input type="checkbox"/>
Kilo International Unit	<input type="checkbox"/>
Kilometer	<input type="checkbox"/>
Kilometer Per Hour	<input type="checkbox"/>
Kilonewton per Centimeter Squared; kdyn/cm2	<input type="checkbox"/>

**CM = Concomitant Medications**

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: Prior and Concomitant Medication**

**Generated On: 22 Mar 2018 22:20:59**

---

Kilopascal	<input type="checkbox"/>
Pa/mL/sec	<input type="checkbox"/>
$10^3$ sec; Kilosecond; ksec	<input type="checkbox"/>
Kilo United States Pharmacopoeia Unit	<input type="checkbox"/>
Liter	<input type="checkbox"/>
L/h	<input type="checkbox"/>
Liters per Hour per Square Meter	<input type="checkbox"/>
Liter per Kilogram	<input type="checkbox"/>
Liter per Liter; dL/dL; mL/mL; uL/uL	<input type="checkbox"/>
Liters per Minute	<input type="checkbox"/>
Liters per Minute per Square Meter	<input type="checkbox"/>
L/sec	<input type="checkbox"/>
Pound	<input type="checkbox"/>
Lumen	<input type="checkbox"/>
Log10 50 Percent Embryo	<input type="checkbox"/>
Infective Dose per Dose	<input type="checkbox"/>
Log10 50 Percent Cell Culture	<input type="checkbox"/>
Infective Dose per Dose	<input type="checkbox"/>
log10 CFU/g	<input type="checkbox"/>
log10 CFU/mL	<input type="checkbox"/>
log10 copies/mL	<input type="checkbox"/>
Log10 Enzyme-Linked Immunosorbent Assay Unit	<input type="checkbox"/>
Log10 Enzyme-Linked Immunosorbent Assay Unit	<input type="checkbox"/>
per Dose	<input type="checkbox"/>
log10 IU/mL	<input type="checkbox"/>
Log10 50 Percent Tissue	<input type="checkbox"/>
Culture Infective Dose per Dose	<input type="checkbox"/>

**CM = Concomitant Medications**

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: Prior and Concomitant Medication**

**Generated On: 22 Mar 2018 22:20:59**

---

Lozenge Dosing Unit	<input type="checkbox"/>
Low Power Field	<input type="checkbox"/>
Lux	<input type="checkbox"/>
Meter	<input type="checkbox"/>
Meter Per Second	<input type="checkbox"/>
m/sec2	<input type="checkbox"/>
Square Meter	<input type="checkbox"/>
Cubic Meter	<input type="checkbox"/>
Megabecquerel	<input type="checkbox"/>
GBq/mL; Gigabecquerel per Milliliter; Megabecquerel per	<input type="checkbox"/>
Microliter	<input type="checkbox"/>
Millicurie	<input type="checkbox"/>
Microcurie per Gram; uCi/g	<input type="checkbox"/>
Millicurie per Kilogram; uCi/g	<input type="checkbox"/>
Microcurie per Milliliter; uCi/mL	<input type="checkbox"/>
Millicurie per Liter; uCi/mL	<input type="checkbox"/>
Milliequivalent	<input type="checkbox"/>
Milliequivalents per Day	<input type="checkbox"/>
Milliequivalent per Deciliter	<input type="checkbox"/>
Milliequivalent Per Gram	<input type="checkbox"/>
Milliequivalent Per Kilogram	<input type="checkbox"/>
Milliequivalent Per Liter; mEq/L	<input type="checkbox"/>
Millivalent per Liter; mval/L	<input type="checkbox"/>
Milliequivalent per Milliliter	<input type="checkbox"/>
Milliequivalent per Millimole	<input type="checkbox"/>
Milliequivalent Per Microgram; mEq/mcg	<input type="checkbox"/>
Milliequivalent Per Microliter	<input type="checkbox"/>
Molecules of Equivalent Soluble Fluorochromes	<input type="checkbox"/>

**CM = Concomitant Medications**

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: Prior and Concomitant Medication**

**Generated On: 22 Mar 2018 22:20:59**

---

**CMDOSU**

- Median Fluorescence
- Intensity
- Milligram
- Milligram per Animal
- Milligram per Day
- Milligram per Deciliter; mg%
- Milligram per Gram per Hour
- Milligram per Gram per Minute
- Milligram per Hour
- Milligram per Kilogram; ug/g
- Milligram per Kilogram per Day
- Milligram per Kilogram per Hour
- Milligram per Kilogram per Minute
- Gram per Cubic Meter;
- Microgram per Milliliter;
- Milligram per Liter; g/m3;
- mcg/mL; mg/L; ng/uL; ug/mL
- Milligram per Square Meter
- Milligram per Square Meter per Day
- Milligram per Square Meter per Hour
- Milligram per Square Meter per Minute
- Milligram per Minute
- Milligram per Milliliter per Minute
- ug/mmol
- Megahertz
- International Mile
- Minute Unit of Time

**CM = Concomitant Medications**

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: Prior and Concomitant Medication**

**Generated On: 22 Mar 2018 22:20:59**

---

Micro-International Unit per   
milliliter; mIE/L; miU/L;  
mcIU/mL; uIU/mL  
  
mJoule/cm<sup>2</sup>   
  
Millikatal   
Milliliter; cm<sup>3</sup>   
Milliliter per Animal   
Milliliter per Animal per Day   
Milliliter per Animal per Week   
Milliliter per Breath   
Milliliter per Cage   
**CMDOSU** Milliliter per Cage per Day   
Milliliter per Cage per Week   
Milliliter per Centimeter;   
dL/m   
mL/cm H<sub>2</sub>O   
Milliliter per Day   
Milliliters per Deciliter   
Milliliter per Gram   
L/day/kg; L/kg/d; Milliliter   
per Gram per Day; mL/day/g;  
mL/g/day; uL/day/mg;  
uL/mg/day  
Milliliter per Gram per Hour   
Milliliter per Gram per Minute   
Milliliters per Hour   
Milliliter per Kilogram   
Milliliter per Kilogram per Day   
Milliliter per Kilogram per Hour

**CM = Concomitant Medications**

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: Prior and Concomitant Medication**

**Generated On: 22 Mar 2018 22:20:59**

---

Milliliter per Kilogram per   
Minute; mL/kg/min;  
mL/min/kg; uL/g/min;  
uL/min/g  
Milliliter per Square Meter   
Milliliter per Square Meter   
per Day  
Milliliter per Square Meter   
per Hour  
Milliliter per Square Meter   
per Minute  
Milliliters per Minute   
mL/min/1.73m<sup>2</sup>   
Milliliter per Minute per Torr   
Milliliters per Millimeter of   
Mercury   
mL/mmHg/min/L   
mL/sec   
mL/sec/1.73m<sup>2</sup>   
Millimeter   
Millimeters per Two Hours   
Millimeter per Hour   
Millimeters per Minute   
Millimeters per Second   
Square Millimeter   
Millimeter of Mercury   
Millimeter Mercury Per Liter   
Per Minute  
Millimeter of Mercury per   
Second   
Millimole   
Millimole per 24 Hours   
Millimole per Gram

**CMDOSU**

**CM = Concomitant Medications**

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: Prior and Concomitant Medication**

**Generated On: 22 Mar 2018 22:20:59**

---

Millimole per Kilogram	<input type="checkbox"/>
Micromole per Milliliter;	<input type="checkbox"/>
Millimole per Liter; Mole per	<input type="checkbox"/>
Cubic Meter; mcmol/mL;	<input type="checkbox"/>
mmol/L; mol/m <sup>3</sup> ; nmol/uL;	<input type="checkbox"/>
umol/mL	<input type="checkbox"/>
mmol/min/kPa	<input type="checkbox"/>
mmol/min/kPa/L	<input type="checkbox"/>
mmol/mol	<input type="checkbox"/>
Mole	<input type="checkbox"/>
Mole per Gram	<input type="checkbox"/>
Mole per Liter; mmol/mL;	<input type="checkbox"/>
mol/L	<input type="checkbox"/>
Mole per Milligram	<input type="checkbox"/>
Mole per Milliliter	<input type="checkbox"/>
Mole per Mol; mmol/mmol	<input type="checkbox"/>
Month	<input type="checkbox"/>
Milliosmole	<input type="checkbox"/>
Milliosmole per Kilogram	<input type="checkbox"/>
Millipascal	<input type="checkbox"/>
Miles per Hour	<input type="checkbox"/>
Immunoglobulin M	<input type="checkbox"/>
Phospholipid Units per	<input type="checkbox"/>
Milliliter	<input type="checkbox"/>
Millisecond	<input type="checkbox"/>
mU/L	<input type="checkbox"/>
Millivolt	<input type="checkbox"/>
Millivolt * Minutes	<input type="checkbox"/>
Millivolt Squared per Hertz;	<input type="checkbox"/>
Millivolt <sup>2</sup> /Hertz	<input type="checkbox"/>
Nanocurie	<input type="checkbox"/>
Nebule	<input type="checkbox"/>
Needle Gauge	<input type="checkbox"/>

**CM = Concomitant Medications**

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: Prior and Concomitant Medication**

**Generated On: 22 Mar 2018 22:20:59**

---

Newton	<input type="checkbox"/>
Nanogram	<input type="checkbox"/>
Nanogram per Deciliter	<input type="checkbox"/>
Microgram per Cubic Meter; ng/L; pg/mL; ug/m3	<input type="checkbox"/>
Normalized Fluorescence	<input type="checkbox"/>
Intensity Unit; Normalized Intensity Unit; Relative Fluorescence Intensity Unit;	<input type="checkbox"/>
Relative Intensity Unit	<input type="checkbox"/>
Nanokatal	<input type="checkbox"/>
Nanokatal per Liter	<input type="checkbox"/>
Nanoliter	<input type="checkbox"/>
Nanometer	<input type="checkbox"/>
Nanomole	<input type="checkbox"/>
Nanomoles Bone Collagen Equivalents per Liter	<input type="checkbox"/>
Nanomoles Bone Collagen Equivalents per Millimole	<input type="checkbox"/>
Nanomole per Liter	<input type="checkbox"/>
Nanomole per Milliliter per Minute	<input type="checkbox"/>
Nanosecond	<input type="checkbox"/>
Nanounit per Centiliter	<input type="checkbox"/>
Ohm	<input type="checkbox"/>
Osmole	<input type="checkbox"/>
Ounce	<input type="checkbox"/>
/Year; Every Year; Per Annum; Per Year	<input type="checkbox"/>
Pascal	<input type="checkbox"/>
Pack	<input type="checkbox"/>
Pack Year	<input type="checkbox"/>
Pack Dosing Unit; Package Dosing Unit	<input type="checkbox"/>

**CM = Concomitant Medications**

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: Prior and Concomitant Medication**

**Generated On: 22 Mar 2018 22:20:59**

---

Packet Dosing Unit	<input type="checkbox"/>
Patch Dosing Unit	<input type="checkbox"/>
Pellet Dosing Unit	<input type="checkbox"/>
Per Minute	<input type="checkbox"/>
Per Second	<input type="checkbox"/>
Plaque Forming Unit	<input type="checkbox"/>
Plaque Forming Unit per Dose	<input type="checkbox"/>
Plaque Forming Unit per Milliliter	<input type="checkbox"/>
Picogram	<input type="checkbox"/>
Picogram per Deciliter	<input type="checkbox"/>
fg/mL; pg/L	<input type="checkbox"/>
Pipe Dosing Unit	<input type="checkbox"/>
Pixel	<input type="checkbox"/>
PPCM; Pixels per Centimeter	<input type="checkbox"/>
CMDOSU	<input type="checkbox"/>
PPI; Pixels per Inch	<input type="checkbox"/>
Picokatal	<input type="checkbox"/>
Picoliter	<input type="checkbox"/>
Picometer	<input type="checkbox"/>
Picomole	<input type="checkbox"/>
Femtomole per Milliliter;	<input type="checkbox"/>
Picomole per Liter; fmol/mL	<input type="checkbox"/>
Protein Nitrogen Unit per Milliliter	<input type="checkbox"/>
Point	<input type="checkbox"/>
Pouch Dosing Unit	<input type="checkbox"/>
Part per Billion	<input type="checkbox"/>
Part per Million	<input type="checkbox"/>
Part per Thousand	<input type="checkbox"/>
Parts per Trillion	<input type="checkbox"/>
Pressor Unit	<input type="checkbox"/>
Picosecond	<input type="checkbox"/>

**CM = Concomitant Medications**

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: Prior and Concomitant Medication**

**Generated On: 22 Mar 2018 22:20:59**

---

Pounds per Square Inch	<input type="checkbox"/>
British Pint; Imperial Pint	<input type="checkbox"/>
US Pint	<input type="checkbox"/>
Puff	<input type="checkbox"/>
Quantity Sufficient	<input type="checkbox"/>
Rad	<input type="checkbox"/>
Ratio	<input type="checkbox"/>
Ring Dosing Unit	<input type="checkbox"/>
RNA Copies per Milliliter	<input type="checkbox"/>
Roentgen	<input type="checkbox"/>
Revolution per Minute	<input type="checkbox"/>
Sachet dosing unit	<input type="checkbox"/>
Standardized Biological Unit per Milliliter	<input type="checkbox"/>
Standard Cubic Meter	<input type="checkbox"/>
<b>CMDOSU</b>	<b>██████████</b>
Scoopful Dosing Unit	<input type="checkbox"/>
Second	<input type="checkbox"/>
SFU/10 <sup>6</sup> PBMC; Spots/10 <sup>6</sup> PBMC	<input type="checkbox"/>
Shock Wave	<input type="checkbox"/>
Siemens	<input type="checkbox"/>
Spray Dosing Unit	<input type="checkbox"/>
Standardized Quality Unit per Milliliter	<input type="checkbox"/>
Steps	<input type="checkbox"/>
Strip Dosing Unit	<input type="checkbox"/>
Suppository Dosing Unit	<input type="checkbox"/>
Sievert	<input type="checkbox"/>
Syringe Dosing Unit	<input type="checkbox"/>
Tablet Dosing Unit; tab	<input type="checkbox"/>
Tampon Dosing Unit	<input type="checkbox"/>
Tablespoon Dosing Unit	<input type="checkbox"/>

CM = Concomitant Medications

PROD\_22MAR2018\_1.00: UNIQUE

Project Name: NEKNKTR1726201

Form: Prior and Concomitant Medication

Generated On: 22 Mar 2018 22:20:59

---

50 Percent Tissue Culture   
Infective Dose per Dose   
Tesla   
Titer   
Torr   
Trace Dosing Unit   
Troche Dosing Unit   
Teaspoon Dosing Unit   
Tube Dosing Unit   
Tuberculin Unit   
Tuberculin Unit per Milliliter   
Unit   
CARR U; Carratelli Unit   
Unit per Animal   
Unit per Centiliter   
Unit per Deciliter   
Unit per Gram   
Unit per Gram per Day   
Unit per Gram per Hour   
Unit per Gram per Minute   
Unit per Kilogram   
Unit per kilogram per Day   
Unit per Kilogram per Hour   
Unit per Kilogram per Minute   
Unit per Liter; mU/mL   
Unit per Square Meter   
Unit per Square Meter per Day   
Unit per Square Meter per Hour   
Unit per Square Meter per Minute

**CM = Concomitant Medications**

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: Prior and Concomitant Medication**

**Generated On: 22 Mar 2018 22:20:59**

---

Unit per Milligram   
Unit per Milliliter   
Unit per Millimole   
Microcurie; mcCi   
Microcurie per Kilogram; mcCi/kg   
Microcurie per Liter; mcCi/L   
Microequivalent   
Microequivalent per Liter;   
Nanoequivalent per Milliliter; nEq/mL   
Microgram; mcg   
Microgram per Animal   
Microgram per Day; mcg/day   
Microgram per Deciliter   
**CMDOSU** Microgram per Gram per Day   
Microgram per Gram per Hour   
Microgram per Gram per Minute   
Micrograms per Hour; mcg/h   
Microgram per Kilogram; mcg/kg; ng/g; ug/kg   
Microgram per Kilogram per Day   
Microgram per Kilogram per Hour   
Gamma per Kilogram per Minute; Microgram per Kilogram per Minute;   
gamma/kg/min; mcg/kg/min   
Microgram per Liter;   
Milligram per Cubic Meter; Nanogram per Milliliter; mcg/L; mg/m<sup>3</sup>; ng/mL; ug/L

**CM = Concomitant Medications**

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: Prior and Concomitant Medication**

**Generated On: 22 Mar 2018 22:20:59**

---

Microgram per Square Meter	<input type="checkbox"/>
Microgram per Square Meter	<input type="checkbox"/>
per Day	<input type="checkbox"/>
Microgram per Square Meter	<input type="checkbox"/>
per Hour	<input type="checkbox"/>
Microgram per Square Meter	<input type="checkbox"/>
per Minute	<input type="checkbox"/>
Micrograms per Minute;	<input type="checkbox"/>
mcg/min	<input type="checkbox"/>
Microgram per Milliliter per	<input type="checkbox"/>
Hour	<input type="checkbox"/>
Microgram Equivalent	<input type="checkbox"/>
Microkatal; mckat	<input type="checkbox"/>
Microkatal per Liter; mckat/L	<input type="checkbox"/>
Microliter; mcL; mm3	<input type="checkbox"/>
Microliter per Milliliter;	<input type="checkbox"/>
mcL/mL	<input type="checkbox"/>
Micron; mcm	<input type="checkbox"/>
MicroSquare Meter	<input type="checkbox"/>
Micromole; mcmol	<input type="checkbox"/>
Micromoles per Day;	<input type="checkbox"/>
mcmol/day	<input type="checkbox"/>
Micromole per Liter	<input type="checkbox"/>
Micromole per Liter per	<input type="checkbox"/>
Minute	<input type="checkbox"/>
Micromoles per Liter per	<input type="checkbox"/>
Second	<input type="checkbox"/>
Micromole per Milligram per	<input type="checkbox"/>
Minute	<input type="checkbox"/>
mcmol/min; umol/min	<input type="checkbox"/>
Microosmole	<input type="checkbox"/>
Microsecond	<input type="checkbox"/>
Microvolt; mcV	<input type="checkbox"/>
Microvolt * Seconds	<input type="checkbox"/>

**CM = Concomitant Medications**

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: Prior and Concomitant Medication**

**Generated On: 22 Mar 2018 22:20:59**

---

- Volt   
V/s; Volt per Second   
volume fraction   
Vial Dosing Unit   
**CMDOSU** Virtual Pixel   
Wafer Dosing Unit   
Watt   
V\*sec; Volt Second;   
Volt-second; Weber   
Week   
Yard   
Year
- 

Frequency

- Daily (QD)  ⑨  
Twice per day (BID)   
3 Times per day (TID)   
4 Times per day (QID)   
**CMDOSFRQ** Every Other Day   
As needed (PRN)   
Once   
QM   
QS   
Other
- 

If Other Frequency, specify

- One Time Per Week  ⑩  
BIS; Twice per week   
**CMDOSFRQ** 2 Times Per Year   
3 Times Per Month   
TIS; Three times a week   
3 Times Per Year
-

**CM = Concomitant Medications**

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: Prior and Concomitant Medication**

**Generated On: 22 Mar 2018 22:20:59**

---

4 Times Per Month	<input type="checkbox"/>
4 times per week; QIS	<input type="checkbox"/>
4 Times Per Year	<input type="checkbox"/>
5 Times Daily	<input type="checkbox"/>
5 Times Per Month	<input type="checkbox"/>
5 Times Per Week	<input type="checkbox"/>
5 Times Per Year	<input type="checkbox"/>
6 Times Daily	<input type="checkbox"/>
6 Times Per Month	<input type="checkbox"/>
6 Times Per Week	<input type="checkbox"/>
6 Times Per Year	<input type="checkbox"/>
7 Times Per Week	<input type="checkbox"/>
<b>CMDOSFRQ</b>	
Ad Libitum	<input type="checkbox"/>
BD; Twice per day	<input type="checkbox"/>
Twice per month	<input type="checkbox"/>
Continuous	<input type="checkbox"/>
Every 2 weeks; Q2S	<input type="checkbox"/>
Every 3 weeks; Q3S	<input type="checkbox"/>
Every 4 weeks; Q4S	<input type="checkbox"/>
Every 5 weeks; Q5S	<input type="checkbox"/>
Every 6 Weeks; Q6S	<input type="checkbox"/>
Every 7 weeks; Q7S	<input type="checkbox"/>
Every 8 weeks; Q8S	<input type="checkbox"/>
Every week; Per Week; QS	<input type="checkbox"/>
Intermittent	<input type="checkbox"/>
Occasional	<input type="checkbox"/>
Once	<input type="checkbox"/>
/Year; Every Year; Per	<input type="checkbox"/>
Annum; Per Year	<input type="checkbox"/>
As needed	<input type="checkbox"/>
Every 10 hours	<input type="checkbox"/>

CM = Concomitant Medications

PROD\_22MAR2018\_1.00: UNIQUE

Project Name: NEKNKTR1726201

Form: Prior and Concomitant Medication

Generated On: 22 Mar 2018 22:20:59

---

Every 11 hours	<input type="radio"/>
Every 12 hours	<input type="radio"/>
Every 13 hours	<input type="radio"/>
Every 14 hours	<input type="radio"/>
Every 15 hours	<input type="radio"/>
Every 16 hours	<input type="radio"/>
Every 17 hours	<input type="radio"/>
Every 18 hours	<input type="radio"/>
Every 19 hours	<input type="radio"/>
Every 20 hours	<input type="radio"/>
Every 21 hours	<input type="radio"/>
Every 22 hours	<input type="radio"/>
Every 23 hours	<input type="radio"/>
Every 24 hours	<input type="radio"/>
Every 2 hours	<input type="radio"/>
Every two months	<input type="radio"/>
Every 3 days	<input type="radio"/>
Every 3 hours	<input type="radio"/>
Every 3 months	<input type="radio"/>
Every 4 days	<input type="radio"/>
Every 4 hours	<input type="radio"/>
Every 4 months	<input type="radio"/>
Every 5 days	<input type="radio"/>
Every 5 hours	<input type="radio"/>
Every 6 hours	<input type="radio"/>
Every 6 Months	<input type="radio"/>
Every 7 hours	<input type="radio"/>
Every 8 hours	<input type="radio"/>
Every 9 hours	<input type="radio"/>
Daily; Per Day	<input type="radio"/>

CMDOSFRQ

**CM = Concomitant Medications**

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: Prior and Concomitant Medication**

**Generated On: 22 Mar 2018 22:20:59**

---

- CMDOSFRQ**
- |                        |                          |
|------------------------|--------------------------|
| Every hour             | <input type="checkbox"/> |
| 4 times per day        | <input type="checkbox"/> |
| Every Month; Per Month | <input type="checkbox"/> |
| Every other day        | <input type="checkbox"/> |
| 3 times per day        | <input type="checkbox"/> |
| Unknown                | <input type="checkbox"/> |
- 

- Route
- CMROUTE**
- |                          |                          |
|--------------------------|--------------------------|
| Oral                     | <input type="checkbox"/> |
| Intravenous              | <input type="checkbox"/> |
| Conjunctival             | <input type="checkbox"/> |
| Intramuscular            | <input type="checkbox"/> |
| Rectal                   | <input type="checkbox"/> |
| Nasal                    | <input type="checkbox"/> |
| Subcutaneous             | <input type="checkbox"/> |
| Sublingual               | <input type="checkbox"/> |
| Topical                  | <input type="checkbox"/> |
| Respiratory (inhalation) | <input type="checkbox"/> |
| Vaginal                  | <input type="checkbox"/> |
| Other                    | <input type="checkbox"/> |
- 

- If Other Route, specify
- CMROUTE**
- |                  |                          |
|------------------|--------------------------|
| Auricular (Otic) | <input type="checkbox"/> |
| Buccal           | <input type="checkbox"/> |
| Conjunctival     | <input type="checkbox"/> |
| Cutaneous        | <input type="checkbox"/> |
| Dental           | <input type="checkbox"/> |
| Dietary          | <input type="checkbox"/> |
| Electro-Osmosis  | <input type="checkbox"/> |
| Endocervical     | <input type="checkbox"/> |
| Endosinusial     | <input type="checkbox"/> |
| Endotracheal     | <input type="checkbox"/> |
-

**CM = Concomitant Medications**

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: Prior and Concomitant Medication**

**Generated On: 22 Mar 2018 22:20:59**

---

Enteral	<input type="checkbox"/>
Epidural	<input type="checkbox"/>
Extra-Amniotic	<input type="checkbox"/>
Extracorporeal	<input type="checkbox"/>
Hemodialysis	<input type="checkbox"/>
Infiltration	<input type="checkbox"/>
Interstitial	<input type="checkbox"/>
Intra-Abdominal	<input type="checkbox"/>
Intra-Amniotic	<input type="checkbox"/>
Intra-Arterial	<input type="checkbox"/>
Intra-Articular	<input type="checkbox"/>
Intrabiliary	<input type="checkbox"/>
Intrabronchial	<input type="checkbox"/>
Intrabursal	<input type="checkbox"/>
Intracameral	<input type="checkbox"/>
Intracardiac	<input type="checkbox"/>
Intracartilaginous	<input type="checkbox"/>
Intracaudal	<input type="checkbox"/>
Intracavernous	<input type="checkbox"/>
Intracavitory	<input type="checkbox"/>
Intracerebral	<input type="checkbox"/>
Intracisternal	<input type="checkbox"/>
Intracorneal	<input type="checkbox"/>
Intracoronal, Dental	<input type="checkbox"/>
Intracoronal	<input type="checkbox"/>
Intracorporus Cavernosum	<input type="checkbox"/>
Intradermal	<input type="checkbox"/>
Intradiscal	<input type="checkbox"/>
Intraductal	<input type="checkbox"/>
Intraduodenal	<input type="checkbox"/>

**CMROUTE**

**CM = Concomitant Medications**

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: Prior and Concomitant Medication**

**Generated On: 22 Mar 2018 22:20:59**

---

Intradural	<input type="checkbox"/>
Intraepidermal	<input type="checkbox"/>
Intraesophageal	<input type="checkbox"/>
Intragastric	<input type="checkbox"/>
Intragingival	<input type="checkbox"/>
Intrahepatic	<input type="checkbox"/>
Intraileal	<input type="checkbox"/>
Intrajejunal	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraluminal	<input type="checkbox"/>
Intralymphatic	<input type="checkbox"/>
Intramedullary	<input type="checkbox"/>
Intrameningeal	<input type="checkbox"/>
Intramuscular	<input type="checkbox"/>
Intraocular	<input type="checkbox"/>
Intraovarian	<input type="checkbox"/>
Intrapalatal	<input type="checkbox"/>
Intraparenchymal	<input type="checkbox"/>
Intrapericardial	<input type="checkbox"/>
Intrapерitoneal	<input type="checkbox"/>
Intrapleural	<input type="checkbox"/>
Intraprostatic	<input type="checkbox"/>
Intrapulmonary	<input type="checkbox"/>
Intrasinal	<input type="checkbox"/>
Intraspinal	<input type="checkbox"/>
Intrastomal	<input type="checkbox"/>
Intrasynovial	<input type="checkbox"/>
Intratendinous	<input type="checkbox"/>
Intratesticular	<input type="checkbox"/>
Intrathecal	<input type="checkbox"/>

**CMROUTE**

**CM = Concomitant Medications**

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: Prior and Concomitant Medication**

**Generated On: 22 Mar 2018 22:20:59**

---

Intrathoracic	<input type="checkbox"/>
Intratubular	<input type="checkbox"/>
Intratumor	<input type="checkbox"/>
Intr tympanic	<input type="checkbox"/>
Intrauterine	<input type="checkbox"/>
Intravascular	<input type="checkbox"/>
Intravenous	<input type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Intraventricular	<input type="checkbox"/>
Intravesical	<input type="checkbox"/>
Intravitreal	<input type="checkbox"/>
Iontophoresis	<input type="checkbox"/>
Irrigation	<input type="checkbox"/>
Laryngeal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Nasogastric	<input type="checkbox"/>
Not Applicable	<input type="checkbox"/>
Occlusive Dressing Technique	<input type="checkbox"/>
Ophthalmic	<input type="checkbox"/>
Oral	<input type="checkbox"/>
Oral Gavage	<input type="checkbox"/>
Oromucosal	<input type="checkbox"/>
Oropharyngeal	<input type="checkbox"/>
Parenteral	<input type="checkbox"/>
Percutaneous	<input type="checkbox"/>
Periarticular	<input type="checkbox"/>
Peridural	<input type="checkbox"/>
Perineural	<input type="checkbox"/>
Periodontal	<input type="checkbox"/>

**CMROUTE**

**CM = Concomitant Medications**

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: Prior and Concomitant Medication**

**Generated On: 22 Mar 2018 22:20:59**

---

<b>CMROUTE</b>	<input type="checkbox"/> Perivenous
	<input type="checkbox"/> Rectal
	<input type="checkbox"/> Respiratory (Inhalation)
	<input type="checkbox"/> Retrobulbar
	<input type="checkbox"/> Soft Tissue
	<input type="checkbox"/> Subarachnoid
	<input type="checkbox"/> Subconjunctival
	<input type="checkbox"/> Subcutaneous
	<input type="checkbox"/> Sublingual
	<input type="checkbox"/> Submucosal
	<input type="checkbox"/> Subtenon
	<input type="checkbox"/> Topical
	<input type="checkbox"/> Transdermal
	<input type="checkbox"/> Transmammary
	<input type="checkbox"/> Transmucosal
	<input type="checkbox"/> Transplacental
	<input type="checkbox"/> Transtracheal
	<input type="checkbox"/> Transtympanic
	<input type="checkbox"/> Unassigned
	<input type="checkbox"/> Unknown
	<input type="checkbox"/> Ureteral
	<input type="checkbox"/> Urethral
	<input type="checkbox"/> Vaginal

---

Started prior to first dose of study drug

**CMSTRF**

Yes  **13**  
No

---

Start Date (dd-mon-yyyy)

**CMSTDTC**

**14**

---

CM = Concomitant Medications

PROD\_22MAR2018\_1.00: UNIQUE

Project Name: NEKNKTR1726201

Form: Prior and Concomitant Medication

Generated On: 22 Mar 2018 22:20:59

---

Ongoing

CMENRF

15

End Date (dd-mon-yyyy)

CMENDTC

16

---

**PROD\_22MAR2018\_1.00: UNIQUE****Project Name: NEKNKTR1726201****Form: Prior and Concomitant Medication****Generated On: 22 Mar 2018 22:20:59**

	Field Name	Data Type	Units	Values	Include Field OID
①	CMTRT	\$100			CMTRT
②	CMAENO	\$105			CMAENO
③	CMAENO2	\$105			CMAENO2
④	CMMHNO	\$105			CMMHNO
⑤	CMINDC	\$100			CMINDC
⑥	CMDSTXT	8.2			CMDSTXT
⑦	CMDOSU	\$7		g = Gram mg = Milligram ug = Microgram mL = Milliliter CAPSULE = Capsule Dosing Unit TABLET = Tablet Dosing Unit OTHER = Other	CMDOSU

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: Prior and Concomitant Medication**

**Generated On: 22 Mar 2018 22:20:59**

---

Field Name	Data Type	Units	Values	Include Field OID
⑧ OTHSPEC2	\$25		% = Percentage % INHIBITIO N = Percent Inhibition %(v/v) = Percent Volume per Volume; vol% %(w/v) = Percent Weight per Volume %(w/w) = Percent Weight per Weight %/min = Percent per Minute /100 HPFs = per 100 High Powered Fields /100 WBC = Per 100 White Blood Cells /10^3 cells = /10^3 cells /day = Daily; Per Day	OTHSPEC2

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: Prior and Concomitant Medication**

**Generated On: 22 Mar 2018 22:20:59**

---

Field Name	Data Type	Units	Values	Include Field OID
			/dL = Per Deciliter /h = Per Hour /HPF = per High Powered Field /kg = Per Kilogram /L = Per Liter /LPF = per Low Powered Field /mL = Per Milliliter /month = Every Month; Per Month /nL = Per Nanoliter /pL = Per Picoliter /uL = /mm <sup>3</sup> ; Per Microliter /WF = per Visual Field /wk = Every week; Per Week; QS	

**PROD\_22MAR2018\_1.00: UNIQUE****Project Name: NEKNKTR1726201****Form: Prior and Concomitant Medication****Generated On: 22 Mar 2018 22:20:59**

Field Name	Data Type	Units	Values	Include Field OID
			100 IU/mL = 100 International units/Millilit er $10^{10}/\text{L}$ = $10^4/\text{mm}^3$ ; $10^4/\mu\text{L}$ ; $10^7/\text{mL}$ $10^{11}/\text{L}$ = $10^5/\text{mm}^3$ ; $10^5/\mu\text{L}$ ; $10^8/\text{mL}$ $10^{12} \text{ IU/L}$ = TIU/L; Tera International Unit per Liter $10^{12}/\text{L}$ = $10^6/\text{mm}^3$ ; $10^6/\mu\text{L}$ ; T/L; TI/L; Tera/L $10^3 \text{ CFU}$ = Thousand CFU; Thousand Colony Forming Units	

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name:** NEKNKTR1726201

**Form:** Prior and Concomitant Medication

**Generated On:** 22 Mar 2018 22:20:59

---

Field Name	Data Type	Units	Values	Include Field OID
			10^3 CFU/g = Thousand CFU/g; Thousand Colony Forming Units per Gram 10^3 CFU/mL = Thousand CFU/mL; Thousand Colony Forming Units per Milliliter 10^3 copies/mL = 10^3 copies/mL 10^3 DNA copies/mL = 10^3 DNA copies/mL 10^3 organisms = Thousand Organisms	

**PROD\_22MAR2018\_1.00: UNIQU**

**Project Name:** NEKNKTR1726201

#### **Form: Prior and Concomitant Medication**

**Generated On: 22 Mar 2018 22:20:59**

Field Name	Data Type	Units	Values	Include Field OID
			10^3	
			organisms/g	
			= Thousand	
			Organisms	
			per Gram;	
			Thousand	
			Organisms/g	
			10^3	
			organisms/m	
			L =	
			Thousand	
			Organisms	
			per Milliliter;	
			Thousand	
			Organisms/m	
			L	
			10^3 RNA	
			copies/mL =	
			10^3 RNA	
			copies/mL	
			10^3/hpf =	
			10^3/hpf	
			10^3/L =	
			10^3/L	
			10^4/hpf =	
			10^4/hpf	
			10^4/L =	
			10^4/L	
			10^5/hpf =	
			10^5/hpf	
			10^5/L =	
			10^2/mL	

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name:** NEKNKTR1726201

**Form:** Prior and Concomitant Medication

**Generated On:** 22 Mar 2018 22:20:59

---

Field Name	Data Type	Units	Values	Include Field OID
			$10^6$ CFU = Million CFU; Million Colony Forming Units $10^6$ CFU/g = Million CFU/g; Million Colony Forming Units per Gram $10^6$ CFU/mL = Million CFU/mL; Million Colony Forming Units per Milliliter $10^6$ copies/mL = $10^6$ copies/mL $10^6$ DNA copies/mL = $10^6$ DNA copies/mL	

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name:** NEKNKTR1726201

**Form:** Prior and Concomitant Medication

**Generated On:** 22 Mar 2018 22:20:59

---

Field Name	Data Type	Units	Values	Include Field OID
			10^6 IU = Million IU; Million International Units 10^6 IU/mL = 10^6 IU/mL 10^6 organisms = Million Organisms 10^6 organisms/g = Million Organisms per Gram; Million Organisms/g 10^6 organisms/m g = Million Organisms per Milligram; Million Organisms/m g	

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: Prior and Concomitant Medication**

**Generated On: 22 Mar 2018 22:20:59**

---

Field Name	Data Type	Units	Values	Include Field OID
			$10^6$ organisms/m L = Million Organisms per Milliliter; Million Organisms/m L $10^6$ RNA copies/mL = $10^6$ RNA copies/mL $10^6/g$ = $10^6/g$ $10^6/hpf$ = $10^6/hpf$ $10^6/L$ = $10^3/mL$ ; M/L; Mega/L $10^7/L$ = $10^6/dL$ $10^8/L$ = $10^2/mm^3$ ; $10^2/uL$ ; $10^5/mL$ $10^9$ CFU = Billion CFU; Billion Colony Forming Units	

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name:** NEKNKTR1726201

**Form:** Prior and Concomitant Medication

**Generated On:** 22 Mar 2018 22:20:59

---

Field Name	Data Type	Units	Values	Include Field OID
			$10^9$ CFU/g = Billion CFU/g; Billion Colony Forming Units per Gram $10^9$ CFU/mL = Billion CFU/mL; Billion Colony Forming Units per Milliliter $10^9$ organisms = Billion Organisms $10^9$ organisms/g = Billion Organisms per Gram; Billion Organisms/g	

**PROD\_22MAR2018\_1.00: UNIQUE****Project Name: NEKNKTR1726201****Form: Prior and Concomitant Medication****Generated On: 22 Mar 2018 22:20:59**

Field Name	Data Type	Units	Values	Include Field OID
			10^9 organisms/m g = Billion Organisms per Milligram; Billion Organisms/m g 10^9 organisms/m L = Billion Organisms per Milliliter; Billion Organisms/m L 10^9/L = 10^3/mm3; 10^3/uL; 10^6/mL; G/L; GI/L; Giga per Liter AFU = Arbitrary Fluorescence Unit ag = Attogram AgU/mL = Antigen Unit per Milliliter	

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: Prior and Concomitant Medication**

**Generated On: 22 Mar 2018 22:20:59**

---

Field Name	Data Type	Units	Values	Include Field OID
			amol = Attomole	
			amp = Ampere	
			AMPULE = Ampule	
			Dosing Unit	
			amu = Atomic Mass	
			Unit	
			anti-Xa IU = Anti-Xa	
			Activity	
			International	
			Unit	
			anti-Xa	
			IU/mL = Anti-Xa	
			Activity	
			International	
			Unit per	
			Milliliter	
			Antibody	
			Unit =	
			Antibody	
			Unit	
			APL U/mL = Immunoglobi	
			n A	
			Phospholipid	
			Units per	
			Milliliter	

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: Prior and Concomitant Medication**

**Generated On: 22 Mar 2018 22:20:59**

---

Field Name	Data Type	Units	Values	Include Field OID
			APPLICATI ON = Application Dosing Unit atm = Atmosphere AU = Absorbance Unit AU/min = Absorbance Unit per Minute AU/mL = Allergy Unit per Milliliter BAG = Bag Dosing Unit BAR = Bar Dosing Unit BAU = Bioequivalen t Allergy Unit BAU/mL = Bioequivalen t Allergy Unit per Milliliter BE/mL = Biological Unit per Milliliter	

**PROD\_22MAR2018\_1.00: UNIQUE****Project Name: NEKNKTR1726201****Form: Prior and Concomitant Medication****Generated On: 22 Mar 2018 22:20:59**

---

Field Name	Data Type	Units	Values	Include Field OID
			BEATS/MIN = Beats per Minute bel = Bel BISCUIT = Biscuit BLOCKS = Blocks BOLUS = Bolus Dosing Unit BOTTLE = Bottle Dosing Unit BOX = Box Dosing Unit Bq = Becquerel Bq/g = Becquerel per Gram Bq/kg = Becquerel per Kilogram Bq/L = Becquerel per Liter Bq/mg = Becquerel per Milligram; Kilobecquere l per Gram; kBq/g	

---

**PROD\_22MAR2018\_1.00: UNIQUE****Project Name: NEKNKTR1726201****Form: Prior and Concomitant Medication****Generated On: 22 Mar 2018 22:20:59**

Field Name	Data Type	Units	Values	Include Field OID
			Bq/mL = Becquerel per Milliliter; Kilobecquere l per Liter; kBq/L Bq/ug = Becquerel per Microgram; Bq/mcg; Kilobecquere l per Milligram; MBq/g; Megabecquer el per Gram; kBq/mg Bq/uL = Becquerel per Microliter; Kilobecquere l per Milliliter; MBq/L; Megabecquer el per Liter; kBq/mL	

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: Prior and Concomitant Medication**

**Generated On: 22 Mar 2018 22:20:59**

---

Field Name	Data Type	Units	Values	Include Field OID
			BREATHS/ MIN = Breaths per Minute BU = Bethesda Unit BU/mL = Bethesda Unit per Milliliter C = Degree Celsius cal = Calorie CAN = Can Dosing Unit CAPFUL = Capful Dosing Unit CAPLET = Caplet Dosing Unit CAPSULE = Capsule Dosing Unit; cap CARTRIDG E = Cartridge Dosing Unit	

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: Prior and Concomitant Medication**

**Generated On: 22 Mar 2018 22:20:59**

---

Field Name	Data Type	Units	Values	Include Field OID
			CCID	
			50/dose = 50	
			Percent Cell	
			Culture	
			Infective	
			Dose per	
			Dose	
			CCID 50/mL	
			= 50 Percent	
			Cell Culture	
			Infective	
			Dose per	
			Milliliter	
			cd = Candela	
			CFU/g =	
			Colony	
			Forming	
			Unit per	
			Gram	
			CFU/mL =	
			Colony	
			Forming	
			Unit per	
			Milliliter	
			cg =	
			Centigram	
			cGy =	
			Centigray	
			Ci = Curie	

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name:** NEKNKTR1726201

**Form:** Prior and Concomitant Medication

**Generated On:** 22 Mar 2018 22:20:59

---

Field Name	Data Type	Units	Values	Include Field OID
			Ci/g = Curie per Gram; Microcurie per Microgram; Millicurie per Milligram; mCi/mg; uCi/ug Ci/kg = Curie per Kilogram; Microcurie per Milligram; Millicurie per Gram; mCi/g; uCi/mg Ci/L = Curie per Liter; Microcurie per Microliter; uCi/uL Ci/mg = Curie per Milligram; Millicurie per Microgram; mCi/ug	

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: Prior and Concomitant Medication**

**Generated On: 22 Mar 2018 22:20:59**

---

Field Name	Data Type	Units	Values	Include Field OID
			Ci/mL = Curie per Milliliter	
			Ci/ug = Ci/mcg; Curie per Microgram	
			Ci/uL = Ci/mcL; Curie per Microliter	
			CIGAR = Cigar Dosing Unit	
			CIGARETT	
			E = Cigarette Dosing Unit	
			cL = Centiliter	
			cm = Centimeter	
			cm H2O = cm H2O	
			cm/min = Centimeters per Minute	
			cm/s = cm/sec	
			cm2 = Square Centimeter	
			cmol = Centimole	

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: Prior and Concomitant Medication**

**Generated On: 22 Mar 2018 22:20:59**

---

Field Name	Data Type	Units	Values	Include Field OID
			cmol/L = Millimoles per Deciliter; mmol/dL COAT = Coat Dosing Unit CONTAINE R = Container Dosing Unit copies/mL = copies/mL copies/uL = copies/uL Coulomb = Coulomb cpm = Counts per Minute cs = 10^-2 sec; Centisecond; csec CUP = Cup Dosing Unit cy/cm = Grating Cycles per Centimeter; cpcm	

**PROD\_22MAR2018\_1.00: UNIQUE****Project Name: NEKNKTR1726201****Form: Prior and Concomitant Medication****Generated On: 22 Mar 2018 22:20:59**

---

Field Name	Data Type	Units	Values	Include Field OID
			cycle/min = Cycle per Minute	
			cycle/sec = Cycle per Second	
			CYLINDER = Cylinder	
			Dosing Unit	
			DAgU = D Antigen Unit	
			DAgU/mL = D Antigen	
			Unit per Milliliter	
			damol/L = Decamole	
			per Liter; Moles per Deciliter;	
			mol/dL	
			DAYs = Day	
			dB = Decibel	
			deg = Degree	
			Unit of Plane Angle	
			DIOPTER = Diopter	
			DISK = Disk Dosing Unit	
			dL = Deciliter	
			dmol = Decimole	

---

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: Prior and Concomitant Medication**

**Generated On: 22 Mar 2018 22:20:59**

---

Field Name	Data Type	Units	Values	Include Field OID
			DNA copies/mL = DNA Copies per Milliliter DPM = Disintegratio ns per Minute dpm/0.5 mL = Disintegratio ns per Minute per 0.5 Milliliter dpm/100mg = Disintegratio ns per Minute per 100 milligrams; dpm/cg dpm/mg = Disintegratio ns per Minute per Milligram dpm/mL = Disintegratio ns per Minute per Milliliter	

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: Prior and Concomitant Medication**

**Generated On: 22 Mar 2018 22:20:59**

---

Field Name	Data Type	Units	Values	Include Field OID
			dram = Dram DRUM = Drum Dosing Unit dyn = Dyne EID 50/dose = 50 Percent Embryo Infective Dose per Dose EID 50/mL = 50 Percent Embryo Infective Dose per Milliliter ELISA unit = Enzyme-Lin ked Immunosorb ent Assay Unit ELISA unit/dose = Enzyme-Lin ked Immunosorb ent Assay Unit per Dose	

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name:** NEKNKTR1726201

**Form:** Prior and Concomitant Medication

**Generated On:** 22 Mar 2018 22:20:59

---

Field Name	Data Type	Units	Values	Include Field OID
			ELISA unit/mL = Enzyme-Lin ked Immunosorb ent Assay Unit per Milliliter Enzyme U = Enzyme Unit eq = Equivalent Weight EU = EU/dL; Ehrlich Units F = Degree Fahrenheit Farad = Farad FEU = Fibrinogen Equivalent Units fg = Femtogram FINGERTIP UNIT = Fingertip Unit	

**PROD\_22MAR2018\_1.00: UNIQUE****Project Name: NEKNKTR1726201****Form: Prior and Concomitant Medication****Generated On: 22 Mar 2018 22:20:59**

---

Field Name	Data Type	Units	Values	Include Field OID
			fL = Cubic Micrometer; Cubic Micron; Femtoliter; um3 fmol = Femtomole fmol/g = Femtomole per Gram fmol/L = Femtomole per Liter foz_br = Fluid Ounce Imperial foz_us = Fluid Ounce US fraction of 1 = Fraction of 1 Frames/s = F/s; FPS; Frames per Second; Frames/sec ft = Foot ft2 = Square Foot ft3 = Standard Cubic Foot	

---

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name:** NEKNKTR1726201

**Form:** Prior and Concomitant Medication

**Generated On:** 22 Mar 2018 22:20:59

---

Field Name	Data Type	Units	Values	Include Field OID
			g = Gram g/animal = Gram per Animal g/animal/day = = Gram per Animal per Day g/animal/wk = = Gram per Animal per Week g/cage = Gram per Cage g/cage/day = Gram per Cage per Day g/cage/wk = Gram per Cage per Week g/cm2 = Gram per Square Centimeter g/day = Gram per Day; g/24h; g/d; gram/24 Hours; gram/day	

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: Prior and Concomitant Medication**

**Generated On: 22 Mar 2018 22:20:59**

---

Field Name	Data Type	Units	Values	Include Field OID
			g/dL = Gram per Deciliter; g% g/g = Gram per Gram g/g/day = Gram per Gram per Day g/kg = Gram per Kilogram; Milligram per Gram; mg/g g/kg/day = Gram per Kilogram per Day; Milligram per Gram per Day; mg/g/day	

**PROD\_22MAR2018\_1.00: UNIQUE****Project Name: NEKNKTR1726201****Form: Prior and Concomitant Medication****Generated On: 22 Mar 2018 22:20:59**

Field Name	Data Type	Units	Values	Include Field OID
			g/L = Gram per Liter; Kilogram per Cubic Meter; Microgram per Microliter; Milligram per Milliliter; g/L; kg/m3; mg/mL; ug/uL g/m2 = Gram per Square Meter g/m2/day = Gram per Square Meter per Day g/mol = Gram per Mole Gauss = Gauss GBq = Gigabecquerel GBq/g = Gigabecquerel per Gram; Kilobecquerel per Microgram; kBq/ug	

**PROD\_22MAR2018\_1.00: UNIQUE****Project Name: NEKNKTR1726201****Form: Prior and Concomitant Medication****Generated On: 22 Mar 2018 22:20:59**

---

Field Name	Data Type	Units	Values	Include Field OID
			GBq/mg = Gigabecquer el per Milligram; MBq/mcg; MBq/ug; Megabecquer el per Microgram GBq/ug = GBq/mcg; Gigabecquer el per Microgram; MBq/ng; Megabecquer el per nanogram GPL U/mL = Immunoglobi n G Phospholipid Units per Milliliter grain = Grain gtt = Drop Gy = Gray Henry = Henry HEP = Histamine Equivalent Prick Unit	

---

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: Prior and Concomitant Medication**

**Generated On: 22 Mar 2018 22:20:59**

---

Field Name	Data Type	Units	Values	Include Field OID
			HOMEOPA THIC DILUTION = Homeopathic Dilution Unit Hounsfield Unit = HU HOURS = Hour; hr hPa = Hectopascal HPF = High Power Field Hz = Hertz IMPLANT = Implant Dosing Unit in = Inch in2 = Square Inch INHALATI ON = Inhalation Dosing Unit IU = IE; International Unit IU/dL = IU/dL IU/g = International Unit per Gram	

---

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name:** NEKNKTR1726201

**Form:** Prior and Concomitant Medication

**Generated On:** 22 Mar 2018 22:20:59

---

Field Name	Data Type	Units	Values	Include Field OID
			IU/kg = International Unit per Kilogram IU/kg/h = International units per Kilogram per Hour IU/L = IE/L; IU/L; International Unit per Liter; mIU/mL IU/mg = International Unit per Milligram IU/mL = IE/mL; International Unit per Milliliter; Kilo International Unit per Liter; kIU/L	

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name:** NEKNKTR1726201

**Form:** Prior and Concomitant Medication

**Generated On:** 22 Mar 2018 22:20:59

---

Field Name	Data Type	Units	Values	Include Field OID
			JAR = Jar Dosing Unit Joule = Joule KALLIKREI N INHIBITOR UNIT = Kallikrein Inhibitor Unit kat = Katal kBq = Kilobecquere l kBq/uL = GBq/L; Gigabecquer el per Liter; Kilobecquere l per Microliter; MBq/mL; Megabecquer el per Milliliter	

**PROD\_22MAR2018\_1.00: UNIQUE****Project Name: NEKNKTR1726201****Form: Prior and Concomitant Medication****Generated On: 22 Mar 2018 22:20:59**

---

Field Name	Data Type	Units	Values	Include Field OID
			kcal = Kilogram-Ca lorie kDa = Kilodalton; Kilounified Atomic Mass Unit; ku kg = Kilogram kg/cm = Kilogram per Centimeter kg/cm <sup>2</sup> = Kilogram per Square Centimeter kg/L = Gram per Milliliter; Kilogram per Liter; g/mL; gram/mL; kg/L; mg/uL kg/m <sup>2</sup> = Kilogram per Square Meter kHz = kilohertz KIT = Kit Dosing Unit kIU = Kilo International Unit	

---

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: Prior and Concomitant Medication**

**Generated On: 22 Mar 2018 22:20:59**

---

Field Name	Data Type	Units	Values	Include Field OID
			km =	
			Kilometer	
			km/h =	
			Kilometer	
			Per Hour	
			kN/cm <sup>2</sup> =	
			Kilonewton	
			per	
			Centimeter	
			Squared;	
			kdyn/cm <sup>2</sup>	
			kPa =	
			Kilopascal	
			kPa/L/sec =	
			Pa/mL/sec	
			ks = 10 <sup>3</sup>	
			sec;	
			Kilosecond;	
			ksec	
			kUSP = Kilo	
			United States	
			Pharmacopoe	
			ia Unit	
			L = Liter	
			L/h = L/h	
			L/h/m <sup>2</sup> =	
			Liters per	
			Hour per	
			Square Meter	
			L/kg = Liter	
			per Kilogram	

---

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: Prior and Concomitant Medication**

**Generated On: 22 Mar 2018 22:20:59**

---

Field Name	Data Type	Units	Values	Include Field OID
			L/L = Liter per Liter; dL/dL; mL/mL; uL/uL L/min = Liters per Minute L/min/m2 = Liters per Minute per Square Meter L/s = L/sec LB = Pound lm = Lumen log EID 50/dose = Log10 50 Percent Embryo Infective Dose per Dose log10 CCID 50/dose = Log10 50 Percent Cell Culture Infective Dose per Dose	

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name:** NEKNKTR1726201

**Form:** Prior and Concomitant Medication

**Generated On:** 22 Mar 2018 22:20:59

---

Field Name	Data Type	Units	Values	Include Field OID
			log10 CFU/g = log10 CFU/g log10 CFU/mL = log10 CFU/mL log10 copies/mL = log10 copies/mL Log10 ELISA unit = Log10 Enzyme-Lin ked Immunosorb ent Assay Unit Log10 ELISA unit/dose = Log10 Enzyme-Lin ked Immunosorb ent Assay Unit per Dose	

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: Prior and Concomitant Medication**

**Generated On: 22 Mar 2018 22:20:59**

---

Field Name	Data Type	Units	Values	Include Field OID
			log10 IU/mL	
			= log10	
			IU/mL	
			log10 TCID	
			50/dose =	
			Log10 50	
			Percent	
			Tissue	
			Culture	
			Infective	
			Dose per	
			Dose	
			LOZENGE =	
			Lozenge	
			Dosing Unit	
			LPF = Low	
			Power Field	
			lx = Lux	
			m = Meter	
			m/sec =	
			Meter Per	
			Second	
			m/sec2 =	
			m/sec2	
			m2 = Square	
			Meter	
			m3 = Cubic	
			Meter	
			MBq =	
			Megabecquer	
			el	

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: Prior and Concomitant Medication**

**Generated On: 22 Mar 2018 22:20:59**

---

Field Name	Data Type	Units	Values	Include Field OID
			MBq/uL = GBq/mL; Gigabecquerel per Milliliter; Megabecquerel per Microliter mCi = Millicurie mCi/kg = Microcurie per Gram; Millicurie per Kilogram; uCi/g mCi/L = Microcurie per Milliliter; Millicurie per Liter; uCi/mL mEq = Milliequivale nt mEq/day = Milliequivale nts per Day mEq/dL = Milliequivale nt per Deciliter	

**PROD\_22MAR2018\_1.00: UNIQUE****Project Name: NEKNKTR1726201****Form: Prior and Concomitant Medication****Generated On: 22 Mar 2018 22:20:59**

---

Field Name	Data Type	Units	Values	Include Field OID
			mEq/g = Milliequivale nt Per Gram mEq/kg = Milliequivale nt Per Kilogram mEq/L = Milliequivale nt Per Liter; Millivalent per Liter; mval/L = Milliequivale nt per Milliliter mEq/mmol = Milliequivale nt per Millimole mEq/ug = Milliequivale nt Per Microgram; mEq/mcg mEq/uL = Milliequivale nt Per Microliter	

---

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: Prior and Concomitant Medication**

**Generated On: 22 Mar 2018 22:20:59**

---

Field Name	Data Type	Units	Values	Include Field OID
			MESF = Molecules of Equivalent Soluble Fluorochrom es MFI = Median Fluorescence Intensity mg = Milligram mg/animal = Milligram per Animal mg/day = Milligram per Day mg/dL = Milligram per Deciliter; mg% mg/g/h = Milligram per Gram per Hour mg/g/min = Milligram per Gram per Minute mg/h = Milligram per Hour	

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name:** NEKNKTR1726201

**Form:** Prior and Concomitant Medication

**Generated On:** 22 Mar 2018 22:20:59

---

Field Name	Data Type	Units	Values	Include Field OID
			mg/kg = Milligram per Kilogram; ug/g mg/kg/day = Milligram per Kilogram per Day mg/kg/h = Milligram per Kilogram per Hour mg/kg/min = Milligram per Kilogram per Minute mg/L = Gram per Cubic Meter; Microgram per Milliliter; Milligram per Liter; g/m3; mcg/mL; mg/L; ng/uL; ug/mL	

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name:** NEKNKTR1726201

**Form:** Prior and Concomitant Medication

**Generated On:** 22 Mar 2018 22:20:59

---

Field Name	Data Type	Units	Values	Include Field OID
			mg/m <sup>2</sup> = Milligram per Square Meter mg/m <sup>2</sup> /day = Milligram per Square Meter per Day mg/m <sup>2</sup> /h = Milligram per Square Meter per Hour mg/m <sup>2</sup> /min = Milligram per Square Meter per Minute mg/min = Milligram per Minute mg/mL/min = Milligram per Milliliter per Minute mg/mol = ug/mmol MHz = Megahertz Mile = International Mile	

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name:** NEKNKTR1726201

**Form:** Prior and Concomitant Medication

**Generated On:** 22 Mar 2018 22:20:59

---

Field Name	Data Type	Units	Values	Include Field OID
			min = Minute Unit of Time mIU/L = Micro-Intern ational Unit per milliliter; mIE/L; mIU/L; mcIU/mL; uIU/mL mJoule/cm2 = mJoule/cm2 mkat = Millikatal mL = Milliliter; cm3 mL/animal = Milliliter per Animal mL/animal/d ay = Milliliter per Animal per Day mL/animal/w k = Milliliter per Animal per Week	

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name:** NEKNKTR1726201

**Form:** Prior and Concomitant Medication

**Generated On:** 22 Mar 2018 22:20:59

---

Field Name	Data Type	Units	Values	Include Field OID
			mL/breath = Milliliter per Breath mL/cage = Milliliter per Cage mL/cage/day = Milliliter per Cage per Day mL/cage/wk = Milliliter per Cage per Week mL/cm = Milliliter per Centimeter; dL/m mL/cm H <sub>2</sub> O = mL/cm H <sub>2</sub> O mL/day = Milliliter per Day mL/dL = Milliliters per Deciliter mL/g = Milliliter per Gram	

**PROD\_22MAR2018\_1.00: UNIQUE****Project Name: NEKNKTR1726201****Form: Prior and Concomitant Medication****Generated On: 22 Mar 2018 22:20:59**

Field Name	Data Type	Units	Values	Include Field OID
			mL/g/day = L/day/kg; L/kg/d; Milliliter per Gram per Day; mL/day/g; mL/g/day; uL/day/mg; uL/mg/day mL/g/h = Milliliter per Gram per Hour mL/g/min = Milliliter per Gram per Minute mL/h = Milliliters per Hour mL/kg = Milliliter per Kilogram mL/kg/day = Milliliter per Kilogram per Day mL/kg/h = Milliliter per Kilogram per Hour	

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: Prior and Concomitant Medication**

**Generated On: 22 Mar 2018 22:20:59**

---

Field Name	Data Type	Units	Values	Include Field OID
			mL/kg/min = Milliliter per Kilogram per Minute; mL/kg/min; mL/min/kg; uL/g/min; uL/min/g mL/m <sup>2</sup> = Milliliter per Square Meter mL/m <sup>2</sup> /day = Milliliter per Square Meter per Day mL/m <sup>2</sup> /h = Milliliter per Square Meter per Hour mL/m <sup>2</sup> /min = Milliliter per Square Meter per Minute mL/min = Milliliters per Minute mL/min/1.73 m <sup>2</sup> = mL/min/1.73 m <sup>2</sup>	

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name:** NEKNKTR1726201

**Form:** Prior and Concomitant Medication

**Generated On:** 22 Mar 2018 22:20:59

---

Field Name	Data Type	Units	Values	Include Field OID
			mL/min/mm	
			Hg =	
			Milliliter per	
			Minute per	
			Torr	
			mL/mmHg =	
			Milliliters	
			per	
			Millimeter of	
			Mercury	
			mL/mmHg/	
			min/L =	
			mL/mmHg/	
			min/L	
			mL/s =	
			mL/sec	
			mL/sec/1.73	
			m2 =	
			mL/sec/1.73	
			m2	
			mm =	
			Millimeter	
			mm/2h =	
			Millimeters	
			per Two	
			Hours	
			mm/h =	
			Millimeter	
			per Hour	
			mm/min =	
			Millimeters	
			per Minute	

**PROD\_22MAR2018\_1.00: UNIQUE****Project Name: NEKNKTR1726201****Form: Prior and Concomitant Medication****Generated On: 22 Mar 2018 22:20:59**

---

Field Name	Data Type	Units	Values	Include Field OID
			mm/sec = Millimeters per Second	
			mm2 = Square Millimeter	
			mmHg = Millimeter of Mercury	
			mmHg/L/mi	
			n = Millimeter Mercury Per Liter Per Minute	
			mmHg/sec = Millimeter of Mercury per Second	
			mmol = Millimole	
			mmol/day = Millimole per 24 Hours	
			mmol/g = Millimole per Gram	
			mmol/kg = Millimole per Kilogram	

---

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: Prior and Concomitant Medication**

**Generated On: 22 Mar 2018 22:20:59**

---

Field Name	Data Type	Units	Values	Include Field OID
			mmol/L = Micromole per Milliliter; Millimole per Liter; Mole per Cubic Meter; mcmol/mL; mmol/L; mol/m3; nmol/uL; umol/mL mmol/min/k Pa = mmol/min/k Pa mmol/min/k Pa/L = mmol/min/k Pa/L mmol/mol = mmol/mol mol = Mole mol/g = Mole per Gram mol/L = Mole per Liter; mmol/mL; mol/L	

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: Prior and Concomitant Medication**

**Generated On: 22 Mar 2018 22:20:59**

---

Field Name	Data Type	Units	Values	Include Field OID
			mol/mg =	
			Mole per	
			Milligram	
			mol/mL =	
			Mole per	
			Milliliter	
			mol/mol =	
			Mole per	
			Mole;	
			mmol/mmol	
			MONTHS =	
			Month	
			mOsm =	
			Milliosmole	
			mOsm/kg =	
			Milliosmole	
			per Kilogram	
			mPa =	
			Millipascal	
			mph = Miles	
			per Hour	
			MPL U/mL	
			=	
			Immunoglobi	
			n M	
			Phospholipid	
			Units per	
			Milliliter	

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: Prior and Concomitant Medication**

**Generated On: 22 Mar 2018 22:20:59**

---

Field Name	Data Type	Units	Values	Include Field OID
			msec =	
			Millisecond	
			mU/L =	
			mU/L	
			mV =	
			Millivolt	
			mV*min =	
			Millivolt *	
			Minutes	
			mV2/Hz =	
			Millivolt	
			Squared per	
			Hertz;	
			Millivolt^2/	
			Hertz	
			nCi =	
			Nanocurie	
			NEBULE =	
			Nebule	
			NEEDLE	
			GAUGE =	
			Needle	
			Gauge	
			Newton =	
			Newton	
			ng =	
			Nanogram	
			ng/dL =	
			Nanogram	
			per Deciliter	

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name:** NEKNKTR1726201

**Form:** Prior and Concomitant Medication

**Generated On:** 22 Mar 2018 22:20:59

---

Field Name	Data Type	Units	Values	Include Field OID
			ng/L = Microgram per Cubic Meter; ng/L; pg/mL; ug/m3 NIU = Normalized Fluorescence Intensity Unit; Normalized Intensity Unit; Relative Fluorescence Intensity Unit; Relative Intensity Unit	

**PROD\_22MAR2018\_1.00: UNIQUE****Project Name: NEKNKTR1726201****Form: Prior and Concomitant Medication****Generated On: 22 Mar 2018 22:20:59**

---

Field Name	Data Type	Units	Values	Include Field OID
			nkat = Nanokatal nkat/L = Nanokatal per Liter nL = Nanoliter nm = Nanometer nmol = Nanomole nmol BCE/L = Nanomoles Bone Collagen Equivalents per Liter nmol BCE/mmol = Nanomoles Bone Collagen Equivalents per Millimole nmol/L = Nanomole per Liter nmol/mL/mi n = Nanomole per Milliliter per Minute	

---

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: Prior and Concomitant Medication**

**Generated On: 22 Mar 2018 22:20:59**

---

Field Name	Data Type	Units	Values	Include Field OID
			nsec = Nanosecond	
			nU/cL = Nanounit per Centiliter	
			ohm = Ohm	
			osm = Osmole	
			oz = Ounce	
			PA = /Year; Every Year; Per Annum; Per Year	
			Pascal = Pascal	
			PACK = Pack	
			Pack Year = Pack Year	
			PACKAGE = Pack	
			Dosing Unit; Package	
			Dosing Unit	
			PACKET = Packet	
			Dosing Unit	
			PATCH = Patch Dosing	
			Unit	
			PELLET = Pellet Dosing	
			Unit	

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: Prior and Concomitant Medication**

**Generated On: 22 Mar 2018 22:20:59**

---

Field Name	Data Type	Units	Values	Include Field OID
			per min = Per Minute	
			per sec = Per Second	
			PFU = Plaque	
			Forming	
			Unit	
			PFU/dose = Plaque	
			Forming	
			Unit per	
			Dose	
			PFU/mL = Plaque	
			Forming	
			Unit per	
			Milliliter	
			pg = Picogram	
			pg/dL = Picogram per	
			Deciliter	
			pg/L = fg/mL; pg/L	
			PIPE = Pipe	
			Dosing Unit	
			PIXEL = Pixel	
			PIXELS/cm	
			= PPCM; Pixels per	
			Centimeter	

**PROD\_22MAR2018\_1.00: UNIQUE****Project Name: NEKNKTR1726201****Form: Prior and Concomitant Medication****Generated On: 22 Mar 2018 22:20:59**

---

Field Name	Data Type	Units	Values	Include Field OID
			PIXELS/in = PPI; Pixels per Inch pkat = Picokatal pL = Picoliter pm = Picometer pmol = Picomole pmol/L = Femtomole per Milliliter; Picomole per Liter; fmol/mL PNU/mL = Protein Nitrogen Unit per Milliliter POINT = Point POUCH = Pouch Dosing Unit ppb = Part per Billion ppm = Part per Million ppth = Part per Thousand	

---

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: Prior and Concomitant Medication**

**Generated On: 22 Mar 2018 22:20:59**

---

Field Name	Data Type	Units	Values	Include Field OID
			pptr = Parts per Trillion PRESSOR UNITS = Pressor Unit psec = Picosecond psi = Pounds per Square Inch pt_br = British Pint; Imperial Pint pt_us = US Pint PUFF = Puff QUANTITY SUFFICIEN T = Quantity Sufficient Rad = Rad RATIO = Ratio RING = Ring Dosing Unit RNA copies/mL = RNA Copies per Milliliter Roentgen = Roentgen rpm = Revolution per Minute	

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: Prior and Concomitant Medication**

**Generated On: 22 Mar 2018 22:20:59**

---

Field Name	Data Type	Units	Values	Include Field OID
			SACHET = Sachet dosing unit SBE/mL = Standardized Biological Unit per Milliliter scm = Standard Cubic Meter SCOOPFUL = Scoopful Dosing Unit sec = Second SFC/10^6 PBMC = SFU/10^6 PBMC; Spots/10^6 PBMC Shock Wave = Shock Wave Siemens = Siemens SPRAY = Spray Dosing Unit SQU/mL = Standardized Quality Unit per Milliliter	

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: Prior and Concomitant Medication**

**Generated On: 22 Mar 2018 22:20:59**

---

Field Name	Data Type	Units	Values	Include Field OID
			STEPS = Steps STRIP = Strip Dosing Unit SUPPOSITO RY = Suppository Dosing Unit Sv = Sievert SYRINGE = Syringe Dosing Unit TABLET = Tablet Dosing Unit; tab TAMPON = Tampon Dosing Unit Tbsp = Tablespoon Dosing Unit TCID 50/dose = 50 Percent Tissue Culture Infective Dose per Dose	

**PROD\_22MAR2018\_1.00: UNIQUE****Project Name: NEKNKTR1726201****Form: Prior and Concomitant Medication****Generated On: 22 Mar 2018 22:20:59**

---

Field Name	Data Type	Units	Values	Include Field OID
			Tesla = Tesla titer = Titer Torr = Torr TRACE = Trace Dosing Unit TROCHE = Troche Dosing Unit tsp = Teaspoon Dosing Unit TUBE = Tube Dosing Unit tuberculin unit = Tuberculin Unit tuberculin unit/mL = Tuberculin Unit per Milliliter U = Unit U.CARR = CARR U; Carratelli Unit U/animal = Unit per Animal	

---

**PROD\_22MAR2018\_1.00: UNIQUE****Project Name: NEKNKTR1726201****Form: Prior and Concomitant Medication****Generated On: 22 Mar 2018 22:20:59**

---

Field Name	Data Type	Units	Values	Include Field OID
			U/cL = Unit per Centiliter U/dL = Unit per Deciliter U/g = Unit per Gram U/g/day = Unit per Gram per Day U/g/h = Unit per Gram per Hour U/g/min = Unit per Gram per Minute U/kg = Unit per Kilogram U/kg/day = Unit per kilogram per Day U/kg/h = Unit per Kilogram per Hour U/kg/min = Unit per Kilogram per Minute	

---

**PROD\_22MAR2018\_1.00: UNIQUE****Project Name: NEKNKTR1726201****Form: Prior and Concomitant Medication****Generated On: 22 Mar 2018 22:20:59**

---

Field Name	Data Type	Units	Values	Include Field OID
			U/L = Unit per Liter; mU/mL U/m <sup>2</sup> = Unit per Square Meter U/m <sup>2</sup> /day = Unit per Square Meter per Day U/m <sup>2</sup> /h = Unit per Square Meter per Hour U/m <sup>2</sup> /min = Unit per Square Meter per Minute U/mg = Unit per Milligram U/mL = Unit per Milliliter U/mmol = Unit per Millimole uCi = Microcurie; mcCi uCi/kg = Microcurie per Kilogram; mcCi/kg	

---

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name:** NEKNKTR1726201

**Form:** Prior and Concomitant Medication

**Generated On:** 22 Mar 2018 22:20:59

---

Field Name	Data Type	Units	Values	Include Field OID
			uCi/L = Microcurie per Liter; mcCi/L uEq = Microequival ent uEq/L = Microequival ent per Liter; Nanoequival ent per Milliliter; nEq/mL ug = Microgram; mcg ug/animal = Microgram per Animal ug/day = Microgram per Day; mcg/day ug/dL = Microgram per Deciliter ug/g/day = Microgram per Gram per Day	

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name:** NEKNKTR1726201

**Form:** Prior and Concomitant Medication

**Generated On:** 22 Mar 2018 22:20:59

---

Field Name	Data Type	Units	Values	Include Field OID
			ug/g/h = Microgram per Gram per Hour ug/g/min = Microgram per Gram per Minute ug/h = Micrograms per Hour; mcg/h ug/kg = Microgram per Kilogram; mcg/kg; ng/g; ug/kg ug/kg/day = Microgram per Kilogram per Day ug/kg/h = Microgram per Kilogram per Hour	

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name:** NEKNKTR1726201

**Form:** Prior and Concomitant Medication

**Generated On:** 22 Mar 2018 22:20:59

---

Field Name	Data Type	Units	Values	Include Field OID
			ug/kg/min = Gamma per Kilogram per Minute; Microgram per Kilogram per Minute; gamma/kg/m in; mcg/kg/min ug/L = Microgram per Liter; Milligram per Cubic Meter; Nanogram per Milliliter; mcg/L; mg/m3; ng/mL; ug/L ug/m2 = Microgram per Square Meter ug/m2/day = Microgram per Square Meter per Day	

**PROD\_22MAR2018\_1.00: UNIQUE****Project Name: NEKNKTR1726201****Form: Prior and Concomitant Medication****Generated On: 22 Mar 2018 22:20:59**

---

Field Name	Data Type	Units	Values	Include Field OID
			ug/m <sup>2</sup> /h = Microgram per Square Meter per Hour ug/m <sup>2</sup> /min = Microgram per Square Meter per Minute ug/min = Micrograms per Minute; mcg/min ug/mL/h = Microgram per Milliliter per Hour ugEq = Microgram Equivalent ukat = Microkatal; mckat ukat/L = Microkatal per Liter; mckat/L uL = Microliter; mcL; mm <sup>3</sup>	

---

**PROD\_22MAR2018\_1.00: UNIQUE****Project Name: NEKNKTR1726201****Form: Prior and Concomitant Medication****Generated On: 22 Mar 2018 22:20:59**

---

Field Name	Data Type	Units	Values	Include Field OID
			uL/mL = Microliter per Milliliter; mcL/mL um = Micron; mcm um2 = MicroSquare Meter umol = Micromole; mcmol umol/day = Micromoles per Day; mcmol/day umol/L = Micromole per Liter umol/L/min = Micromole per Liter per Minute umol/L/sec = Micromoles per Liter per Second umol/mg/min = Micromole per Milligram per Minute	

---

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: Prior and Concomitant Medication**

**Generated On: 22 Mar 2018 22:20:59**

---

Field Name	Data Type	Units	Values	Include Field OID
			umol/min = mcmol/min; umol/min uOsM = Microosmole usec = Microsecond uV = Microvolt; mcV uV*sec = Microvolt * Seconds V = Volt V/sec = V/s; Volt per Second v/v = volume fraction VIAL = Vial Dosing Unit VIRTUAL PIXEL = Virtual Pixel WAFER = Wafer Dosing Unit Watt = Watt Weber = V*sec; Volt Second; Volt-second; Weber	

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name:** NEKNKTR1726201

**Form:** Prior and Concomitant Medication

**Generated On:** 22 Mar 2018 22:20:59

---

Field Name	Data Type	Units	Values	Include Field OID
			WEEKS = Week yd = Yard YEARS = Year	
⑨	CMDOSFR	\$5	QD = Daily (QD) Q BID = Twice per day (BID) TID = 3 Times per day (TID) QID = 4 Times per day (QID) QOD = Every Other Day PRN = As needed (PRN) ONCE = Once QM = QM QS = QS OTHER = Other	CMDOSFR

---

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: Prior and Concomitant Medication**

**Generated On: 22 Mar 2018 22:20:59**

---

Field Name	Data Type	Units	Values	Include Field OID
(10) OTHSPEC3	\$17		1 TIME PER OTHSPEC3 WEEK = One Time Per Week 2 TIMES PER WEEK = BIS; Twice per week 2 TIMES PER YEAR = 2 Times Per Year 3 TIMES PER MONTH = 3 Times Per Month 3 TIMES PER WEEK = TIS; Three times a week 3 TIMES PER YEAR = 3 Times Per Year 4 TIMES PER MONTH = 4 Times Per Month	

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: Prior and Concomitant Medication**

**Generated On: 22 Mar 2018 22:20:59**

---

Field Name	Data Type	Units	Values	Include Field OID
			4 TIMES PER WEEK = 4 times per week; QIS	
			4 TIMES PER YEAR = 4 Times Per Year	
			5 TIMES PER DAY = 5 Times Daily	
			5 TIMES PER MONTH = 5 Times Per Month	
			5 TIMES PER WEEK = 5 Times Per Week	
			5 TIMES PER YEAR = 5 Times Per Year	
			6 TIMES PER DAY = 6 Times Daily	
			6 TIMES PER MONTH = 6 Times Per Month	

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: Prior and Concomitant Medication**

**Generated On: 22 Mar 2018 22:20:59**

---

Field Name	Data Type	Units	Values	Include Field OID
			6 TIMES PER WEEK = 6 Times Per Week	
			6 TIMES PER YEAR = 6 Times Per Year	
			7 TIMES PER WEEK = 7 Times Per Week	
			AD LIBITUM = Ad Libitum	
			BID = BD; Twice per day	
			BIM = Twice per month	
			CONTINUO US = Continuous	
			EVERY 2 WEEKS = Every 2 weeks; Q2S	
			EVERY 3 WEEKS = Every 3 weeks; Q3S	

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: Prior and Concomitant Medication**

**Generated On: 22 Mar 2018 22:20:59**

---

Field Name	Data Type	Units	Values	Include Field OID
			EVERY 4 WEEKS = Every 4 weeks; Q4S	
			EVERY 5 WEEKS = Every 5 weeks; Q5S	
			EVERY 6 WEEKS = Every 6 Weeks; Q6S	
			EVERY 7 WEEKS = Every 7 weeks; Q7S	
			EVERY 8 WEEKS = Every 8 weeks; Q8S	
			EVERY WEEK = Every week; Per Week; QS	
			INTERMITT ENT = Intermittent	
			OCCASION	
			AL = Occasional	
			ONCE = Once	

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: Prior and Concomitant Medication**

**Generated On: 22 Mar 2018 22:20:59**

---

Field Name	Data Type	Units	Values	Include Field OID
			PA = /Year; Every Year; Per Annum; Per Year PRN = As needed Q10H = Every 10 hours Q11H = Every 11 hours Q12H = Every 12 hours Q13H = Every 13 hours Q14H = Every 14 hours Q15H = Every 15 hours Q16H = Every 16 hours Q17H = Every 17 hours Q18H = Every 18 hours	

**PROD\_22MAR2018\_1.00: UNIQUE****Project Name: NEKNKTR1726201****Form: Prior and Concomitant Medication****Generated On: 22 Mar 2018 22:20:59**

---

Field Name	Data Type	Units	Values	Include Field OID
			Q19H = Every 19 hours Q20H = Every 20 hours Q21H = Every 21 hours Q22H = Every 22 hours Q23H = Every 23 hours Q24H = Every 24 hours Q2H = Every 2 hours Q2M = Every two months Q3D = Every 3 days Q3H = Every 3 hours Q3M = Every 3 months Q4D = Every 4 days Q4H = Every 4 hours	

---

**PROD\_22MAR2018\_1.00: UNIQUE****Project Name: NEKNKTR1726201****Form: Prior and Concomitant Medication****Generated On: 22 Mar 2018 22:20:59**

Field Name	Data Type	Units	Values	Include Field OID
			Q4M = Every 4 months Q5D = Every 5 days Q5H = Every 5 hours Q6H = Every 6 hours Q6M = Every 6 Months Q7H = Every 7 hours Q8H = Every 8 hours Q9H = Every 9 hours QD = Daily; Per Day QH = Every hour QID = 4 times per day QM = Every Month; Per Month QOD = Every other day TID = 3 times per day U = Unknown	

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: Prior and Concomitant Medication**

**Generated On: 22 Mar 2018 22:20:59**

---

Field Name	Data Type	Units	Values	Include Field OID
(11) CMROUTE	\$24		ORAL = CMROUTE Oral INTRAVEN OUS = Intravenous CONJUNCT IVAL = Conjunctival INTRAMUS CULAR = Intramuscula r RECTAL = Rectal NASAL = Nasal SUBCUTAN EOUS = Subcutaneou s SUBLINGU AL = Sublingual TOPICAL = Topical RESPIRATO RY (INHALATI ON) = Respiratory (inhalation)	

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: Prior and Concomitant Medication**

**Generated On: 22 Mar 2018 22:20:59**

---

Field Name	Data Type	Units	Values	Include Field OID
			VAGINAL = Vaginal OTHER = Other	
<b>(12)</b>	<b>OTHSPEC4</b>	<b>\$28</b>	AURICULA OTHSPEC4 R (OTIC) = Auricular (Otic) BUCCAL = Buccal CONJUNCT IVAL = Conjunctival CUTANEO US = Cutaneous DENTAL = Dental DIETARY = Dietary ELECTRO- OSMOSIS = Electro-Osm osis ENDOCERV ICAL = Endocervical ENDOSINU SIAL = Endosinusial	

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: Prior and Concomitant Medication**

**Generated On: 22 Mar 2018 22:20:59**

---

Field Name	Data Type	Units	Values	Include Field OID
			ENDOTRAC HEAL = Endotracheal ENTERAL = Enteral EPIDURAL = Epidural EXTRA-AM NIOTIC = Extra-Amnio tic EXTRACOR POREAL = Extracorpore al HEMODIAL YSIS = Hemodialysi s INFILTRAT ION = Infiltration INTERSTITI AL = Interstitial INTRA-AB DOMINAL = Intra-Abdom inal	

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: Prior and Concomitant Medication**

**Generated On: 22 Mar 2018 22:20:59**

---

Field Name	Data Type	Units	Values	Include Field OID
			INTRA-AM	
			NIOTIC =	
			Intra-Amniotic	
			INTRAL =	
			Intra-Arterial	
			INTRAL =	
			Intra-Articular	
			INTRABILIARY =	
			Intrabiliary	
			INTRABRO =	
			Intrabronchial	
			INTRABURSAL =	
			Intrabursal	
			INTRACAMERAL =	
			Intracameral	
			INTRACARTILAGINOUS =	
			Intracartilaginous	

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: Prior and Concomitant Medication**

**Generated On: 22 Mar 2018 22:20:59**

---

Field Name	Data Type	Units	Values	Include Field OID
			INTRACAU	
			DAL =	
			Intracaudal	
			INTRACAV	
			ERNOUS =	
			Intracaverno	
			us	
			INTRACAV	
			ITARY =	
			Intracavitory	
			INTRACER	
			EBRAL =	
			Intracerebral	
			INTRACIST	
			ERNAL =	
			Intracisternal	
			INTRACOR	
			NEAL =	
			Intracorneal	
			INTRACOR	
			ONAL	
			DENTAL =	
			Intracoronal,	
			Dental	
			INTRACOR	
			ONARY =	
			Intracoronary	
			INTRACOR	
			PORUS	
			CAVERNOS	
			UM =	
			Intracorporus	
			Cavernosum	

---

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: Prior and Concomitant Medication**

**Generated On: 22 Mar 2018 22:20:59**

---

Field Name	Data Type	Units	Values	Include Field OID
			INTRADER MAL = Intradermal INTRADISC AL = Intradiscal INTRADUC TAL = Intraductal INTRADUO DENAL = Intraduodenal INTRADUR AL = Intradural INTRAEPID ERMAL = Intraepidermal INTRAESO PHAGEAL = Intraesophageal INTRAGAS TRIC = Intragastric INTRAGIN GIVAL = Intralingingival INTRAHEP ATIC = Intrahepatic	

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: Prior and Concomitant Medication**

**Generated On: 22 Mar 2018 22:20:59**

---

Field Name	Data Type	Units	Values	Include Field OID
			INTRAILYM PHATIC = Intralymphati c INTRAMED ULLARY = Intramedullar y INTRAMEN INGEAL = Intrameninge al INTRAMUS CULAR = Intramuscula r INTRAOCU LAR = Intraocular INTRAHOVA RIAN = Intraovarian	

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: Prior and Concomitant Medication**

**Generated On: 22 Mar 2018 22:20:59**

---

Field Name	Data Type	Units	Values	Include Field OID
			INTRAPAL ATAL = Intrapalatal INTRAPAR ENCHYMA L = Intraparenchymal INTRAPERI CARDIAL = Intrapericardial INTRAPERI TONEAL = Intraperitoneal INTRAPLE URAL = Intrapleural INTRAPRO STATIC = Intraprostatic INTRAPUL MONARY = Intrapulmonary INTRASINA L = Intrasinal INTRASPIN AL = Intraspinal INTRASTO MAL = Intrastomal	

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: Prior and Concomitant Medication**

**Generated On: 22 Mar 2018 22:20:59**

---

Field Name	Data Type	Units	Values	Include Field OID
			INTRASYN	
			OVIAL =	
			Intrasynovial	
			INTRATEN	
			DINOUS =	
			Intratendinou s	
			INTRATEST	
			ICULAR =	
			Intratesticula r	
			INTRATHE	
			CAL =	
			Intrathecal	
			INTRATHO	
			RACIC =	
			Intrathoracic	
			INTRATUB	
			ULAR =	
			Intratubular	
			INTRATUM	
			OR =	
			Intratumor	
			INTRATYM	
			PANIC =	
			Intratympani c	
			INTRAUTE	
			RINE =	
			Intrauterine	
			INTRAVAS	
			CULAR =	
			Intravascular	

---

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: Prior and Concomitant Medication**

**Generated On: 22 Mar 2018 22:20:59**

---

Field Name	Data Type	Units	Values	Include Field OID
			INTRAVEN OUS = Intravenous INTRAVEN OUS BOLUS = Intravenous Bolus INTRAVEN OUS DRIP = Intravenous Drip INTRAVEN TRICULAR = Intraventricul ar INTRAVESI CAL = Intravesical INTRAVITR EAL = Intravitreal IONTOPHO RESIS = Iontophoresis IRRIGATIO N = Irrigation LARYNGE AL = Laryngeal	

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: Prior and Concomitant Medication**

**Generated On: 22 Mar 2018 22:20:59**

---

Field Name	Data Type	Units	Values	Include Field OID
			NASAL =	
			Nasal	
			NASOGAST	
			RIC =	
			Nasogastric	
			NOT	
			APPLICABL	
			E = Not	
			Applicable	
			OCCLUSIV	
			E	
			DRESSING	
			TECHNIQU	
			E =	
			Occlusive	
			Dressing	
			Technique	
			OPHTHAL	
			MIC =	
			Ophthalmic	
			ORAL =	
			Oral	
			ORAL	
			GAVAGE =	
			Oral Gavage	
			OROMUCO	
			SAL =	
			Oromucosal	
			OROPHAR	
			YNGEAL =	
			Oropharynge	
			al	

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: Prior and Concomitant Medication**

**Generated On: 22 Mar 2018 22:20:59**

---

Field Name	Data Type	Units	Values	Include Field OID
			PARENTER AL = Parenteral PERCUTAN EOUS = Percutaneous PERIARTIC ULAR = Periarticular PERIDURA L = Peridural PERINEUR AL = Perineural PERIODON TAL = Periodontal PERIVENO US = Perivenous RECTAL = Rectal RESPIRATO RY (INHALATI ON) = Respiratory (Inhalation) RETROBUL BAR = Retrobulbar SOFT TISSUE = Soft Tissue	

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: Prior and Concomitant Medication**

**Generated On: 22 Mar 2018 22:20:59**

---

Field Name	Data Type	Units	Values	Include Field OID
			SUBARACH NOID = Subarachnoi d SUBCONJU NCTIVAL = Subconjuncti val SUBCUTAN EOUS = Subcutaneou s SUBLINGU AL = Sublingual SUBMUCO SAL = Submucosal SUBTENON = Subtenon TOPICAL = Topical TRANSDER MAL = Transdermal TRANSMA MMARY = Transmamm ary TRANSMU COSAL = Transmucosa l	

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: Prior and Concomitant Medication**

**Generated On: 22 Mar 2018 22:20:59**

---

Field Name	Data Type	Units	Values	Include Field OID
			TRANSPLA CENTAL = Transplacent al	
			TRANSTRA CHEAL = Transtracheal	
			TRANSTY MPANIC = Transtympan ic	
			UNASSIGN ED = Unassigned	
			U = Unknown	
			URETERAL = Ureteral	
			URETHRAL = Urethral	
			VAGINAL = Vaginal	
<b>⑬</b>	CMPRIOR	\$1	Y = Yes N = No	CMPRIOR
<b>⑭</b>	CMSTDAT	dd- MMM- yyyy		CMSTDAT
<b>⑮</b>	CMONGO	1		CMONGO

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: Prior and Concomitant Medication**

**Generated On: 22 Mar 2018 22:20:59**

---

Field Name	Data Type	Units	Values	Include Field OID
<b>(16)</b> CMENDAT	dd- MMM- yyyy		CMENDAT	

---

**PR = Procedures**

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: Prior, Concomitant, and Follow-up Radiotherapy Y/N**

**Generated On: 22 Mar 2018 22:20:59**

**PRCAT = PRIOR, CONCOMITANT, AND FOLLOW-UP RADIOTHERAPY**

Did the patient receive cancer-related radiotherapy prior to or  
during the study?

**PRPRESP = Y**

Yes  **1**  
No

**PROCCUR where PRTRT = RADIOGRAPHY**

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: Prior, Concomitant, and Follow-up Radiotherapy Y/N**

**Generated On: 22 Mar 2018 22:20:59**

---

Field Name	Data Type	Units	Values	Include Field OID
① PRYN	\$1		Y = Yes N = No	PRYN

---

**PR = Procedures**

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: Prior, Concomitant, and Follow-up Radiotherapy**

**Generated On: 22 Mar 2018 22:20:59**

**PRCAT = PRIOR, CONCOMITANT, AND FOLLOW-UP RADIOTHERAPY**

---

Radiotherapy Site

- Axilla  ①  
Bladder   
Bone   
Brain   
Breast   
Colorectal   
Esophagus   
Head and Neck   
**PRLOC**   
Kidney   
Liver   
Lung   
Lymphatic System   
Ovary   
Pancreas   
Skin   
Other

---

If Other Site, specify

**SUPPPR.QVAL where QNAM = PRLOCSP**

②

---

Type of Radiotherapy

- External Beam Radiation  ③  
Therapy  
Stereotactic Radiation   
Therapy  
3D Conformal Radiation   
Therapy  
**PRTRT**   
Intensity-Modulated   
Radiation Therapy  
Volumetric Arc Therapy   
Teletherapy   
Brachytherapy   
Other
- 
-

**PR = Procedures**

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: Prior, Concomitant, and Follow-up Radiotherapy**

**Generated On: 22 Mar 2018 22:20:59**

---

If Other Type, specify

**PRTRT**

**④**

Intent of Radiotherapy

Adjuvant

Curative

Palliative

Total Dose

**PRDOSE**

**⑥**

Units

**PRDOSU**

Gray

Rad

Centigray

Sievert

Start Date (dd-mon-yyyy)

**PRSTDTC**

**⑧**

Stop Date (dd-mon-yyyy)

**PRENDTC**

**⑨**

Best Response

Complete Response (CR)

Partial Response (PR)

Stable Disease (SD)

Disease Progression (PD)

Not Applicable

Unknown

**SUPPPR.QVAL where QNAM = PRRESP**

---

**PROD\_22MAR2018\_1.00: UNIQUE****Project Name: NEKNKTR1726201****Form: Prior, Concomitant, and Follow-up Radiotherapy****Generated On: 22 Mar 2018 22:20:59**

Field Name	Data Type	Units	Values	Include Field OID
① PRLOC	\$16		Axilla = Axilla Bladder = Bladder Bone = Bone Brain = Brain Breast = Breast Colorectal = Colorectal Esophagus = Esophagus Head and Neck = Head and Neck Kidney = Kidney Liver = Liver Lung = Lung Lymphatic System = Lymphatic System Ovary = Ovary Pancreas = Pancreas Skin = Skin Other = Other	PRLOC
② PRSPEC	\$100			PRSPEC

**PROD\_22MAR2018\_1.00: UNIQUE****Project Name: NEKNKTR1726201****Form: Prior, Concomitant, and Follow-up Radiotherapy****Generated On: 22 Mar 2018 22:20:59**

Field Name	Data Type	Units	Values	Include Field OID
③ PRRDTYP	\$3		1 = External Beam Radiation Therapy 2 = Stereotactic Radiation Therapy 3 = 3D Conformal Radiation Therapy 4 = Intensity-Mo dulated Radiation Therapy 5 = Volumetric Arc Therapy 6 = Teletherapy 7 = Brachytherap y 8 = Other	PRRDTYP
④ PRRDOTH	\$200			PRRDOTH
⑤ PRRDINT	\$10		Adjuvant = PRRDINT Adjuvant	

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: Prior, Concomitant, and Follow-up Radiotherapy**

**Generated On: 22 Mar 2018 22:20:59**

---

Field Name	Data Type	Units	Values	Include Field OID
			Curative = Curative Palliative = Palliative	
<b>⑥ PRDOSE</b>	8			PRDOSE
<b>⑦ PRDOSU</b>	\$3		Gy = Gray Rad = Rad cGy = Centigray Sv = Sievert	PRDOSU
<b>⑧ PRSTDAT</b>	dd- MMM- yyyy			PRSTDAT
<b>⑨ PRENDAT</b>	dd- MMM- yyyy			PRENDAT
<b>⑩ PRRESP</b>	\$24		COMPLETE PRRESP RESPONSE (CR) = Complete Response (CR)	

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: Prior, Concomitant, and Follow-up Radiotherapy**

**Generated On: 22 Mar 2018 22:20:59**

---

Field Name	Data Type	Units	Values	Include Field OID
			PARTIAL RESPONSE (PR) = Partial Response (PR) STABLE DISEASE (SD) = Stable Disease (SD) DISEASE PROGRESSI ON (PD) = Disease Progression (PD) NOT APPLICABL E = Not Applicable UNKNOWN = Unknown	

---

**PROD\_22MAR2018\_1.00: UNIQUE**  
**Project Name:** NEKNKTR1726201  
**Form:** Concomitant Procedures YN  
**Generated On:** 22 Mar 2018 22:20:59

---

Were any procedures performed?

NOT SUBMITTED

Yes  1  
No

---

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name:** NEKNKTR1726201

**Form:** Concomitant Procedures YN

**Generated On:** 22 Mar 2018 22:20:59

---

Field Name	Data Type	Units	Values	Include Field OID
① CPYN	\$1		Y = Yes N = No	CPYN

---

**PR = Procedures**

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: Concomitant Procedure**

**Generated On: 22 Mar 2018 22:20:59**

**PRCAT = CONCOMITANT PROCEDURES**

---

Procedure Name

**PRTRT**

**①**

---

Indication

**PRINDC**

**②**

---

Date of Procedure (dd-mon-yyyy)

**PRSTDTC**

**③**

---

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name:** NEKNKTR1726201

**Form:** Concomitant Procedure

**Generated On:** 22 Mar 2018 22:20:59

---

	Field Name	Data Type	Units	Values	Include Field OID
①	CPTERM	\$200			CPTERM
②	CPINDC	\$100			CPINDC
③	CPSTDAT	dd MMM yyyy			CPSTDAT

DV = Protocol Deviations

PROD\_22MAR2018\_1.00: UNIQUE

Project Name: NEKNKTR1726201

Form: Protocol Deviations

Generated On: 22 Mar 2018 22:20:59

---

Subject ID \_\_\_\_\_ ①

Site Protocol Deviation \_\_\_\_\_ Used to generate USUBJID ②

Visit \_\_\_\_\_

Screening  ③

Cycle

Tumor Assessment

End of Treatment

Follow-up

Unscheduled Visit

Not Applicable

`SUPPDV.QVAL where QNAM = DVVISIT`

Cycle \_\_\_\_\_ `SUPPDV.QVAL where QNAM = DVCYNUM` ④

Date of Deviation (dd-mon-yyyy) \_\_\_\_\_ DVSTDTC ⑤

N/A \_\_\_\_\_ NOT SUBMITTED ⑥

Date Deviation Identified (dd-mon-yyyy) \_\_\_\_\_ `SUPPDV.QVAL where QNAM = DVIDDAT` ⑦

Category \_\_\_\_\_

Informed Consent (IC)  ⑧

Eligibility Criteria (EC)

Study Conduct/Procedures (SC)

Efficacy Assessments (EA)

Laboratory (LB)

Safety (SA)

Investigational Product (IP)

Other (OT)

`DVSCAT`

DV = Protocol Deviations

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: Protocol Deviations**

**Generated On: 22 Mar 2018 22:20:59**

---

Sub-Category	(IC) Version	<input type="checkbox"/>	⑨
	(IC) Process	<input type="checkbox"/>	
	(IC) Signature/Date	<input type="checkbox"/>	
	(IC) Failure to Obtain Consent	<input type="checkbox"/>	
	(EC) Inclusion/Exclusion Criteria	<input type="checkbox"/>	
	(SC) Screening/Randomization	<input type="checkbox"/>	
	(SC) Study Assessments	<input type="checkbox"/>	
	(SC) Withdrawal Criteria	<input type="checkbox"/>	
	(SC) Concomitant Medications/Concomitant Therapy/Prohibited Medications	<input type="checkbox"/>	
<b>DVDECOD</b>	(EA) Primary Efficacy Assessment	<input type="checkbox"/>	
	(EA) Secondary Efficacy Assessment	<input type="checkbox"/>	
	(LB) Sample Collection	<input type="checkbox"/>	
	(LB) Sample Processing	<input type="checkbox"/>	
	(LB) Sample Storage	<input type="checkbox"/>	
	(LB) Sample Shipping	<input type="checkbox"/>	
	(SA) SAE Reporting	<input type="checkbox"/>	
	(SA) SUSAR Reporting	<input type="checkbox"/>	
	(SA) AE of Special Interest	<input type="checkbox"/>	
	(IP) Supply	<input type="checkbox"/>	
	(IP) Dispensing/Administration	<input type="checkbox"/>	
	(IP) Handling/Storage/Retention/Accountability	<input type="checkbox"/>	
	Other	<input type="checkbox"/>	

---

---

DV = Protocol Deviations

PROD\_22MAR2018\_1.00: UNIQUE

Project Name: NEKNKTR1726201

Form: Protocol Deviations

Generated On: 22 Mar 2018 22:20:59

---

Protocol Deviation Details

DVTERM

10

---

Severity

DVCAT

Major   
Minor   
Critical

11

---

If Protocol Deviation is Major, please check the box if it  
qualifies as Urgent

SUPPDV.QVAL where QNAM = DVURGENT

12

---

Review Status

Reviewed with action

13

Reviewed with no further  
action

SUPPDV.QVAL where QNAM = DVRSTAT

---

Action Taken

SUPPDV.QVAL where QNAM = ACTION

14

---

Was this Protocol Deviation reported to EC/IRB?

Yes   
No

15

Not Reportable

SUPPDV.QVAL where QNAM = DVECRB

**PROD\_22MAR2018\_1.00: UNIQUE****Project Name: NEKNKTR1726201****Form: Protocol Deviations****Generated On: 22 Mar 2018 22:20:59**

Field Name	Data Type	Units	Values	Include Field OID
① SUBJID_1	\$9		SUBJID_1	
② SITEPD	1		SITEPD	
③ DVVISIT	\$25		Screening = DVVISIT Screening Cycle = Cycle Tumor Assessment = Tumor Assessment End of Treatment = End of Treatment Follow-up = Follow-up Unscheduled Visit = Unscheduled Visit Not Applicable = Not Applicable	
④ DVCWNUM2			DVCWNUM	
⑤ DVDAT	dd MMM yyyy		DVDAT	

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: Protocol Deviations**

**Generated On: 22 Mar 2018 22:20:59**

---

Field Name	Data Type	Units	Values	Include Field OID
⑥ DVDATNA	1		DVDATNA	
⑦ DVIDDAT	dd MMM yyyy		DVIDDAT	
⑧ DVCAT	\$20		IC = Informed Consent (IC) EC = Eligibility Criteria (EC) SC = Study Conduct/Procedures (SC) EA = Efficacy Assessments (EA) LB = Laboratory (LB) SA = Safety (SA) IP = Investigation al Product (IP) OT = Other (OT)	DVCAT

---

**PROD\_22MAR2018\_1.00: UNIQUE****Project Name:** NEKNKTR1726201**Form:** Protocol Deviations**Generated On:** 22 Mar 2018 22:20:59

Field Name	Data Type	Units	Values	Include Field OID
⑨ DVSCAT	\$100		Version = DVSCAT (IC) Version Process = (IC) Process Signature/Da te = (IC) Signature/Da te Failure to Obtain Consent = (IC) Failure to Obtain Consent Inclusion/Ex clusion Criteria = (EC) Inclusion/Ex clusion Criteria Screening/Ra ndomization = (SC) Screening/Ra ndomization Study Assessments = (SC) Study Assessments	

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name:** NEKNKTR1726201

**Form:** Protocol Deviations

**Generated On:** 22 Mar 2018 22:20:59

---

Field Name	Data Type	Units	Values	Include Field OID
			Withdrawal Criteria = (SC) Withdrawal Criteria Concomitant Medications/ Concomitant Therapy/Pro hibited Medications = (SC) Concomitant Medications/ Concomitant Therapy/Pro hibited Medications Primary Efficacy Assessment = (EA) Primary Efficacy Assessment Secondary Efficacy Assessment = (EA) Secondary Efficacy Assessment	

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name:** NEKNKTR1726201

**Form:** Protocol Deviations

**Generated On:** 22 Mar 2018 22:20:59

---

Field Name	Data Type	Units	Values	Include Field OID
			Sample Collection = (LB) Sample Collection Sample Processing = (LB) Sample Processing Sample Storage = (LB) Sample Storage Sample Shipping = (LB) Sample Shipping SAE Reporting = (SA) SAE Reporting SUSAR Reporting = (SA) SUSAR Reporting AE of Special Interest = (SA) AE of Special Interest	

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name:** NEKNKTR1726201

**Form:** Protocol Deviations

**Generated On:** 22 Mar 2018 22:20:59

---

Field Name	Data Type	Units	Values	Include Field OID
			Supply = (IP) Supply Dispensing/ Administrati on = (IP) Dispensing/ Administrati on Handling/Sto rage/Retentio n/Accountabi lity = (IP) Handling/Sto rage/Retentio n/Accountabi lity Other = Other	
<b>⑩</b>	DVTERM	\$200		DVTERM
<b>⑪</b>	DVSEV	\$8	Major = Major Minor = Minor Critical = Critical	DVSEV
<b>⑫</b>	DVURG	1		DVURG

---

---

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name:** NEKNKTR1726201

**Form:** Protocol Deviations

**Generated On:** 22 Mar 2018 22:20:59

---

Field Name	Data Type	Units	Values	Include Field OID
⑬ DVSTAT	\$40		Reviewed with action = Reviewed with action Reviewed with no further action = Reviewed with no further action	DVSTAT
⑭ DVACN	\$200			DVACN
⑮ DVECRB	\$14		Yes = Yes No = No Not Reportable = Not Reportable	DVECRB

---

DD = Death Details

RELREC = Related Records

DM = Demographics

PROD\_22MAR2018\_1.00: UNIQUE

Project Name: NEKNKTR1726201

Form: Death

Generated On: 22 Mar 2018 22:20:59

---

Date of Death (dd-mon-yyyy)

DDDT<sub>C</sub> DTHDTC 1

Primary Cause of Death

Progressive Disease  2

DDORRES Non- PD AE   
Other

AE Number and Term

SUPPDD.QVAL where QNAM = DDAENO 3

IDVAR = AESPID

IDVARVAL

If Other Cause, specify

SUPPDD.QVAL where QNAM = DDCAUOTH 4

---

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name:** NEKNKTR1726201

**Form:** Death

**Generated On:** 22 Mar 2018 22:20:59

---

	Field Name	Data Type	Units	Values	Include Field OID
①	DTHDAT	dd MMM yyyy			DTHDAT
②	DDTEST	\$19		Progressive Disease = Progressive Disease Non- PD AE = Non- PD AE Other = Other	DDTEST
③	DDAENO	\$200			DDAENO
④	DDORRES	\$200			DDORRES

---

SS = Subject Status

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: Survival Follow-up**

**Generated On: 22 Mar 2018 22:20:59**

---

Date of Contact (dd-mon-yyyy)

SSDTC

①

---

Patient Status

Alive

②

Dead

Contact Attempted -

Unknown Status

SSORRES where STESTCD = SURVSTAT

---

Has the patient received any new therapy for cancer since the last dose, visit or contact?

Yes

③

No

Unknown

If Yes, proceed to fill out the Follow-up Anti-Cancer Therapy CRF.

---

**If no new therapies**

---

Has the patient had any scans since last visit or contact?

Yes

⑤

No

SUPPSS.QVAL where QNAM = SCANYN

---

Date of Scan (dd-mon-yyyy)

SUPPSS.QVAL where QNAM = SCANDAT

⑥

What was the Response?

Complete Response

⑦

Partial Response

Stable Disease

Progressive Disease

Not Evaluable

SUPPSS.QVAL where QNAM = FUSTRESO

---

Scan sent to central imaging?

Yes

⑧

No

SUPPSS.QVAL where QNAM = SCNCIYN

---

**PROD\_22MAR2018\_1.00: UNIQUE****Project Name: NEKNKTR1726201****Form: Survival Follow-up****Generated On: 22 Mar 2018 22:20:59**

	Field Name	Data Type	Units	Values	Include Field OID
①	CONTDAT	dd MMM yyyy			CONTDAT
②	PSORRES	\$5		ALIVE = Alive DEAD = Dead UNK = Contact Attempted - Unknown Status	PSORRES
③	PSTHYN	\$1		Y = Yes N = No U = Unknown	PSTHYN
⑤	SCANYN	\$1		Y = Yes N = No	SCANYN
⑥	SCANDAT	dd MMM yyyy			SCANDAT
⑦	FUSTRESO	\$2		CR = Complete Response PR = Partial Response	FUSTRESO

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name:** NEKNKTR1726201

**Form:** Survival Follow-up

**Generated On:** 22 Mar 2018 22:20:59

---

Field Name	Data Type	Units	Values	Include Field OID
<hr/>				
			SD = Stable Disease PD = Progressive Disease NE = Not Evaluable	
⑧	SCNCIYN	\$1	Y = Yes N = No	SCNCIYN
<hr/>				

CM = Concomitant Medications

PROD\_22MAR2018\_1.00: UNIQUE

Project Name: NEKNKTR1726201

Form: Follow-up Anti-Cancer Therapy

Generated On: 22 Mar 2018 22:20:59

CMCAT = FOLLOW-UP ANTI-CANCER THERAPY

Agent Name

CMTRT

①

Start Date (dd-mon-yyyy)

CMSTDTC

②

Ongoing

CMENRF

③

Stop Date (dd-mon-yyyy)

CMENDTC

④

Did patient respond to therapy?

Yes

⑤

No

Unknown

SUPPCM.QVAL where QNAM = PTHER

What was the response?

Complete Response (CR)

⑥

Partial Response (PR)

Stable Disease (SD)

Disease Progression (PD)

Unknown

SUPPCM.QVAL where QNAM = PTRESP

Date of Clinical Progression, if any (dd-mon-yyyy)

⑦

SUPPCM.QVAL where QNAM = PTCPDAT

Date of Progressive Disease per RECIST 1.1 (dd-mon-yyyy)

⑧

SUPPCM.QVAL where QNAM = PTPDDAT

**PROD\_22MAR2018\_1.00: UNIQUE****Project Name:** NEKNKTR1726201**Form:** Follow-up Anti-Cancer Therapy**Generated On:** 22 Mar 2018 22:20:59

Field Name	Data Type	Units	Values	Include Field OID
① DS2TRT	\$50			DS2TRT
② DS2STDAT	dd- MMM- yyyy			DS2STDAT
③ DS2ONGO	1			DS2ONGO
④ DS2STOP	dd- MMM- yyyy			DS2STOP
⑤ DS2THER	\$1		Y = Yes N = No U = Unknown	DS2THER
⑥ DS2RESP	\$20		CR = Complete Response (CR) PR = Partial Response (PR) SD = Stable Disease (SD) PD = Disease Progression (PD) U = Unknown	DS2RESP

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name:** NEKNKTR1726201

**Form:** Follow-up Anti-Cancer Therapy

**Generated On:** 22 Mar 2018 22:20:59

---

Field Name	Data Type	Units	Values	Include Field OID
⑦ DS2DAT1	dd- MMM- yyyy			DS2DAT1
⑧ DS2DAT2	dd- MMM- yyyy			DS2DAT2

---

PC = Pharmacokinetic Concentrations

PROD\_22MAR2018\_1.00: UNIQUE

Project Name: NEKNKTR1726201

Form: Urine PK Pooled Collection

PCSPEC = URINE

Generated On: 22 Mar 2018 22:20:59

Urine PK samples collected?

Yes  ①  
No

PCSTAT where PCTESTCD = PCALL

Collection Period

PCTPT Pre-dose ②

Not Done

PCSTAT ③

Collection Start Date (dd-mon-yyyy)

④

Collection Start Time

PCDTCT

Fixed Unit: 24-hour clock ⑤

Collection End Date (dd-mon-yyyy)

⑥

Collection End Time

PCENDTC

Fixed Unit: 24-hour clock ⑦

Volume Collected

Fixed Unit: mL ⑧

PCORRES

PCORRESU

Collection Period

PCTPT 0-12 Hrs after start of NKTR-262 ⑨

Not Done

PCSTAT

⑩

**PROD\_22MAR2018\_1.00: UNIQUE****Project Name: NEKNKTR1726201****Form: Urine PK Pooled Collection****Generated On: 22 Mar 2018 22:20:59**

Collection Start Date (dd-mon-yyyy)

④

Collection Start Time

Fixed Unit: 24-hour clock ⑤

Collection End Date (dd-mon-yyyy)

⑥

Collection End Time

Fixed Unit: 24-hour clock ⑦

Volume Collected

Fixed Unit: mL ⑧

Collection Period

12-24 Hrs after start of ②  
NKTR-262

Not Done

③

Collection Start Date (dd-mon-yyyy)

④

Collection Start Time

Fixed Unit: 24-hour clock ⑤

Collection End Date (dd-mon-yyyy)

⑥

Collection End Time

Fixed Unit: 24-hour clock ⑦

PC = Pharmacokinetic Concentrations

See CRF Page 626

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name:** NEKNKTR1726201

**Form:** Urine PK Pooled Collection

**Generated On:** 22 Mar 2018 22:20:59

Volume Collected

Fixed Unit: mL **(8)**

Collection Period

24-48 Hrs after start of **(2)**  
NKTR-262

Not Done

**(3)**

Collection Start Date (dd-mon-yyyy)

**(4)**

Collection Start Time

Fixed Unit: 24-hour clock **(5)**

Collection End Date (dd-mon-yyyy)

**(6)**

Collection End Time

Fixed Unit: 24-hour clock **(7)**

Volume Collected

Fixed Unit: mL **(8)**

Collection Period

48-72 Hrs after start of **(2)**  
NKTR-262

Not Done

**(3)**

PC = Pharmacokinetic Concentrations

See CRF Page 626

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: Urine PK Pooled Collection**

**Generated On: 22 Mar 2018 22:20:59**

Collection Start Date (dd-mon-yyyy)

④

Collection Start Time

Fixed Unit: 24-hour clock ⑤

Collection End Date (dd-mon-yyyy)

⑥

Collection End Time

Fixed Unit: 24-hour clock ⑦

Volume Collected

Fixed Unit: mL ⑧

Collection Period

72-96 Hrs after start of ②  
NKTR-262

Not Done

③

Collection Start Date (dd-mon-yyyy)

④

Collection Start Time

Fixed Unit: 24-hour clock ⑤

Collection End Date (dd-mon-yyyy)

⑥

Collection End Time

Fixed Unit: 24-hour clock ⑦

PC = Pharmacokinetic Concentrations

See CRF Page 626

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name:** NEKNKTR1726201

**Form:** Urine PK Pooled Collection

**Generated On:** 22 Mar 2018 22:20:59

Volume Collected

Fixed Unit: mL **(8)**

Collection Period

96-120 Hrs after start of **(2)**  
NKTR-262

Not Done

**(3)**

Collection Start Date (dd-mon-yyyy)

**(4)**

Collection Start Time

Fixed Unit: 24-hour clock **(5)**

Collection End Date (dd-mon-yyyy)

**(6)**

Collection End Time

Fixed Unit: 24-hour clock **(7)**

Volume Collected

Fixed Unit: mL **(8)**

Collection Period

120-144 Hrs after start of **(2)**  
NKTR-262

Not Done

**(3)**

**PROD\_22MAR2018\_1.00: UNIQUE****Project Name: NEKNKTR1726201****Form: Urine PK Pooled Collection****Generated On: 22 Mar 2018 22:20:59**

Collection Start Date (dd-mon-yyyy)

④

Collection Start Time

Fixed Unit: 24-hour clock ⑤

Collection End Date (dd-mon-yyyy)

⑥

Collection End Time

Fixed Unit: 24-hour clock ⑦

Volume Collected

Fixed Unit: mL ⑧

Collection Period

144-168 Hrs after start of ②  
NKTR-262

Not Done

③

Collection Start Date (dd-mon-yyyy)

④

Collection Start Time

Fixed Unit: 24-hour clock ⑤

Collection End Date (dd-mon-yyyy)

⑥

Collection End Time

Fixed Unit: 24-hour clock ⑦

PC = Pharmacokinetic Concentrations

See CRF Page 626

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: Urine PK Pooled Collection**

**Generated On: 22 Mar 2018 22:20:59**

---

Volume Collected

Fixed Unit: mL **(8)**

---

---

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: Urine PK Pooled Collection**

**Generated On: 22 Mar 2018 22:20:59**

---

Field Name	Data Type	Units	Values	Include Field OID
① PKUPERF	\$1		Y = Yes N = No	PKUPERF
② PKUTPT	\$40		Pre-dose 0-1 2 Hrs after start of NKTR-262 1 2-24 Hrs after start of NKTR-262 2 4-48 Hrs after start of NKTR-262 4 8-72 Hrs after start of NKTR-262 7 2-96 Hrs after start of NKTR-262 9 6-120 Hrs after start of NKTR-262 1 20-144 Hrs after start of NKTR-262 1 44-168 Hrs after start of NKTR-262	PKUTPT
③ PKND	1			PKND

---

---

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name:** NEKNKTR1726201

**Form:** Urine PK Pooled Collection

**Generated On:** 22 Mar 2018 22:20:59

---

Field Name	Data Type	Units	Values	Include Field OID
④ PKUSDAT	dd MMM yyyy			PKUSDAT
⑤ PKUSTIM	HH:nn			PKUSTIM
⑥ PKUEDAT	dd MMM yyyy			PKUEDAT
⑦ PKUETIM	HH:nn			PKUETIM
⑧ PKUVOL	5			PKUVOL

---

**PROD\_22MAR2018\_1.00: UNIQUE**  
**Project Name: NEKNKTR1726201**  
**Form: Tumor Assessment Status**  
**Generated On: 22 Mar 2018 22:20:59**

---

Did the subject continue to the next tumor assessment visit?

**NOT SUBMITTED**

Yes  **1**  
No

---

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name:** NEKNKTR1726201

**Form:** Tumor Assessment Status

**Generated On:** 22 Mar 2018 22:20:59

---

Field Name	Data Type	Units	Values	Include Field OID
① STATUS1	\$1		Y = Yes N = No	STATUS1

---

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name: NEKNKTR1726201**

**Form: Follow-up Status**

**Generated On: 22 Mar 2018 22:20:59**

---

Did the subject continue to the next follow-up?

NOT SUBMITTED

Yes  1  
No

---

**PROD\_22MAR2018\_1.00: UNIQUE**

**Project Name:** NEKNKTR1726201

**Form:** Follow-up Status

**Generated On:** 22 Mar 2018 22:20:59

---

Field Name	Data Type	Units	Values	Include Field OID
① STATUS2	\$1		Y = Yes N = No	STATUS2

---