

DATA TRANSFER GUIDELINES

for Celgene Corporation CC-5013-PC-002

Author:



Quintiles Project Code:

YKA46505

Project Database ID:

YKA46505

AUTHORIZATION

The signatures on this page indicate review and approval of this document.

Programmer:

(Sig.) _____ Date: _____

Name: 

Data Operations Coordinator:

(Sig.) _____ Date: _____

Name: 

Lead Biostatistician:

(Sig.) _____ Date: _____

Name: 

Sponsor Representative:

(Sig.) _____ Date: _____

Name: 

Data Team Lead:

(Sig.) _____ Date: _____

Name: 

Distribution List for this Document

Name	Title	Office/Sponsor
██████████	Lead Biostatistician	Celgene Corporation
██████████████████	Sponsor Representative	Celgene Corporation
██████████	Clinical Programmer	Celgene Corporation
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Document Version History

Version	Version Date	Significant changes
V01	18 March 2010	N/A First Authorized Version
V02	02 September 2010	<ul style="list-style-type: none">Quintiles programmer name updated to ██████████ in distribution list.Updated Celgene Lead Biostatistician to ██████████Section 6 updated, ePRO data added, LAB names changed, grammatical errors corrected.
V03	20 June 2011	<ul style="list-style-type: none">Quintiles DOC and DTL names updated to ██████████ and ██████████ respectivelyUpdated Section 3 to reference sftp site and the removal of PGP encryption
V03	26 July 2011	<ul style="list-style-type: none">The addition of the new Trial Continuation dataset in section 6.1

1. PURPOSE

To describe the procedure for handling data transfers, including the generation and use of this project-specific Data Transfer Guidelines document to ensure the accurate and timely transfer of data for this project from Data Management.

2. TRANSFER FORMAT

- ☒ SAS datasets, version: *Version 8.02*
☐ SAS datasets in transport file, version/transport method: *Version 8, CPORT*____
☐ Other: _____

3. TRANSFER MEDIUM

- ☒ FTP ☐ Courier ☐ Secure Quintiles Network Drive ☐ Secure Email ☐ Non-Secure Email
- ☐ CD ☐ Diskette ☐ PGP Encrypted ☐ Zipped ☒ Password-protected

- ☒ Other: The test first transfer containing dummy data will be sent to the sponsor via e-mail, as well as the 1st Live transfer.

4. TRANSFER TYPE

- | | |
|-------------------------------------|-------------|
| <input checked="" type="checkbox"/> | Cumulative |
| <input type="checkbox"/> | Incremental |

5. TRANSFER FREQUENCY

- ☐ Monthly (1st day of the month) ☐ Quarterly
☒ Bi-monthly ☐ Other: _____

One (1) test transfer (containing dummy UAT data) will be performed on a mutually agreed upon date. Thereafter, data transfer will be provided bi-monthly or on an as-needed basis. One (1) final transfer will be performed subsequent to database lock.

6. LIST OF ELECTRONIC FILES TO BE TRANSFERRED

These electronic files are to be sent to:

- ☐ The Quintiles Lead Biostatistician
☒ The Sponsor

The following datasets will be included in the transfer:

File Name	Description of Contents
SCREEN	SCREENING
ENROLL	ENROLLMENT
DOV	DATE OF VISIT
DM	DEMOGRAPHICS
ELIG	ELIGIBILITY
CONDIAG	CONFIRM DIAGNOSIS
MEDHX	MEDICAL HISTORY
PRIORTX	PRIOR THERAPIES FOR THIS DISEASE
PSAT2	PRIOR HORMONAL ANTI-CANCER THERAPIES FOR THIS DISEASE
PSAT3	OTHER PRIOR ANTI-CANCER THERAPIES FOR THIS DISEASE
PCS	PRIOR CANCER SURGERIES FOR THIS DISEASE
PRT	PRIOR RADIATION THERAPIES
VS	VITAL SIGNS
CHEM	CENTRAL LABS CHEMISTRY
HEM	CENTRAL LABS HEMATOLOGY
URIN	URINALYSIS
ECG	ECG
ECOG	ECOG PERFORMANCE STATUS
PROASM2	PATIENT REPORTED OUTCOME2
TARGETQ	TARGETQ
TUMOR_M	TARGET LESIONS
TUMOR_NTB	NON-TARGET LESIONS SCREENING
PKBS	ADDITIONAL PK SUBSTUDY INFORM CONSENT
PISIGN	PRINCIPAL INVESTIGATOR SIGNATURE
GATE	AE, CONMED, CPROC AND HOSP
AE	ADVERSE EVENTS
CMED1	PRIOR/CONCOMITANT MEDICATIONS
CPROC	CONCOMITANT PROCEDURES/SURGERIES
HOSP	HOSPITALIZATION
PROASM1	PATIENT REPORTED OUTCOME1
PKSAMPI	PHARMACOKINETIC PK INTENSIVE SAMPLING
BIOBC	BIOMARKER BLOOD COLLECTION

File Name	Description of Contents
EX2	Study DRUG Record
EX3	STUDY DRUG RECORD-DOCETAXEL
EX4	STUDY DRUG RECORD-PREDNISONE
PKSAMPS	PHARMACOKINETIC PK SPARSE SAMPLING
TUMOR_MP	NON-TARGET LESIONS
TUMOR_MRESP	TUMOR RESPONSE
CYCLE	CYCLE SELECTION
DS	DISCONTINUATION
SURVIVE	SURVIVAL
SURVTH	SURVIVAL INFORMATION
DEATH	DEATH
UNSDOV	UNSCHEDULED ASSESSMENTS
WCFU	WITHDRAW CONSENT FROM FOLLOW-UP
COMMENTS	COMMENTS
LAB	ICON Lab Data
LAB_RAW	ICON Raw data
ASSIGNMT	Assignment
BPI_SF	BPI Short Form
EQ5D	EQ-5D
FACTP	FACT-P
CONT	TRIAL CONTINUATION
FORMAT	Custom Formats File*

*This is for the PHT diary datasets

7. DETAILED FILE SPECIFICATIONS

See Annotated Design for Trial: YKA46505 (Appendix A).

7.1 Basic File Structure

Each dataset will have the following common variables:

STUDY	-	Contains the Study ID (CC-5013-PC-002)
INVSITE	-	Patient's SITEID
PT	-	Patient's ID
	-	Combination of the SITEID and the SUBJID
VISNAME	-	Visit name according to the Time and Events document (Corresponds to the VISITNUM)
VISIT	-	Contains the VISITNUM where the data is entered
VISDT,		
VISDTF	-	Date of visit where the data is entered.

Please note that some datasets do not have the date of visit added to the dataset, as then

there is no specific date of visit (e.g. Study Discontinuation and Death visits).

8. DESCRIPTION OF ANY CALCULATED VARIABLES

8.1 Dates en Times

All Dates and Times which will be derived and displayed with the following fields, Day (01), Month (JAN) and Year (2009) will be character variables and there will be a numeric dat of type date 9 which will display 01Jan2009. For times there will be an hour, minute (indicated by X) and second (which will default to 00 if not used) and a numeric time of type time 8.

8.2 Relationship between the VISIT name and the VISIT number

Below is a table with all the visit names and the corresponding visit numbers:

Visit Name	Visit Number
Screening	1
Cycle 1 Day 1	2
Cycle 1 Day 14	3
Cycle 2 Day 1	4
Cycle 3 Day 1	5
Cycle 4 Day 1	6
Cycle 5 Day 1	7
Cycle 6 Day 1	8
Cycle 7 Day 1	9
Cycle 8 Day 1	10
Cycle 9 Day 1	11
Cycle 10 Day 1	12
Cycle 11 Day 1	13
Cycle 12 Day 1	14
Cycle 13 Day 1	15
Cycle 14 Day 1	16
Cycle 15 Day 1	17
Cycle 16 Day 1	18
Cycle X Day 1 - RV	19
TX Phase Discont	20
Follow-Up Day 28	21
Long-Term Survival - RV	22
Death	23

Visit Name	Visit Number
Study Completion	24
Withdraw Consent From Follow-Up	25
AE/CM/CP/HOSP	26
Unscheduled - RV	99

9. TESTING STRATEGY

9.1. TRANSFER PROGRAM(S) VALIDATION

All SAS datasets will be validated by the Programmer and the DOC before the test transfer is sent.

The Programmer's testing includes: a review of the structure to make sure it is consistent with sponsor specifications; a review of the dataset observation count against the CDMS count; a review of the export log to ensure that it is error free; a review of distinct values (pre and post manipulation) for variables manipulated in the export; a review of the datasets to ensure that they can be successfully opened and a visual check to ensure that the data is correctly represented in the appropriate variables,

The DOC's testing includes: a review of the actual patient data of one full patient (or as many as needed) to make sure the data is correct in every field; a review of all dates to ensure that they are stored accurately; a review to ensure that data are not truncated and that all expected items and files are present in the transfer.

If coding has been initiated, the validation will include a comparison of one coded record in each 'coded' transfer dataset/file against the appropriate thesaurus to confirm that all coding variables are present and correctly populated.

The data transfer programming will be revalidated if there are any changes to the programs from Sponsor feedback or relevant CDMS structural changes.

9.2. TRANSFER QUALITY CONTROL

At each subsequent transfer, the Programmer will review the export program logs to ensure that they are error free and will check that the datasets can successfully be opened.

Additionally the Programmer will check that key fields such as the Sponsor name, protocol number, visit, etc. are accurate and that at database lock (or any other major deliverable), the number of patients is the same in the transfer dataset as in the eDC system or CDMS.

If coding had not been initiated for the export program validation, validation of the first transfer with coding will include a review of one coded record in each 'coded' dataset/file against the appropriate thesaurus to confirm that all coding variables are present and correctly populated.

10. KEY CONTACTS

Name	Title	Associated Company	Phone Number	Fax Number	E-mail
[REDACTED]	Sr Data Manager	Celgene Corporation	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	Statistician	Celgene Corporation	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	Clinical Programmer	Celgene Corporation	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	Data Operations Coordinator	QBLM	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	Programmer	QBLM	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	Data Team Lead	QBLM	[REDACTED]	[REDACTED]	[REDACTED]

Celgene
Annotated Design For Trial: YKA46505

Protocol: CC-5013-PC-002

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Time and Events Schedule For Study: YKA46505																															
	Assessment	CRF	Screening (SCREEN) [S]	AE/CM/CP/HOSP (AE/CM/CP/HOSP) [S]	Study Completion (PISIGN) [S]	Conflict (Conflict) [U/R/D]	Cycle 1 Day 1 (C1D1) [S/D]	Cycle 1 Day 14 (C1D14) [S/D]	Cycle 2 Day 1 (C2D1) [S/D]	Cycle 3 Day 1 (C3D1) [S/D]	Cycle 4 Day 1 (C4D1) [S/D]	Cycle 5 Day 1 (C5D1) [S/D]	Cycle 6 Day 1 (C6D1) [S/D]	Cycle 7 Day 1 (C7D1) [S/D]	Cycle 8 Day 1 (C8D1) [S/D]	Cycle 9 Day 1 (C9D1) [S/D]	Cycle 10 Day 1 (C10D1) [S/D]	Cycle 11 Day 1 (C11D1) [S/D]	Cycle 12 Day 1 (C12D1) [S/D]	Cycle 13 Day 1 (C13D1) [S/D]	Cycle 14 Day 1 (C14D1) [S/D]	Cycle 15 Day 1 (C15D1) [S/D]	Cycle 16 Day 1 (C16D1) [S/D]	Cycle X Day 1 (CXD1) [S/R/D]	TX Phase Discont (DISCON TX) [S/D]	Follow- Up Day 28 (FU1) [S/D]	Long- Term Survival (SURV) [S/R/D]	DEATH (Death) [S/D]	Unscheduled (UNSCH) [U/R/D]	Withdraw Consent From Follow-Up (WCFU) [S/D]	
1	DATE OF VISIT	DOV	1				1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1		1		1	
2	DEMOGRAPHICS	DEMOG	2																												
3	ELIGIBILITY	ELIG	3																												
4	CONFIRM DIAGNOSIS	CONDIAG	4-DF																												
5	MEDICAL HISTORY	MEDHX	5-DF																												
6	PRIOR THERAPIES FOR THIS DISEASE	PRIORTX	6-DF																												
7	PRIOR HORMONAL ANTI-CANCER THERAPIES FOR THIS DISEASE	PRIHRM	7-RF-DF																												
8	OTHER PRIOR ANTI-CANCER THERAPIES FOR THIS DISEASE	PRIOCT	8-RF-DF																												
9	PRIOR CANCER SURGERIES FOR THIS DISEASE	PRISURG	9-RF-DF																												
10	Prior Radiation Therapies	PRIXRT	10-RF-DF																												
11	VITAL SIGNS	VITALS	11-DF																												
12	BLOOD CHEMISTRY	CLABCHEM	12-DF				3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	4-DF	4				4-DF	
13	HEMATOLOGY	CLABHEM	13-DF				4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	5-DF	5				5-DF	
14	URINALYSIS	CLABURI	14-DF				5		5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	6-DF	6				6-DF	
15	ECG Base	ECG	15-DF																												
16	ECOG PERFORMANCE STATUS SCALE BASELINE	ECOG	16-DF																												
17	PATIENT REPORTED OUTCOMES 2	PROASM2	17-DF						7	7		7	7		7	7		7	7		7	7			9-DF						
18	TARGETQ	TARGEQ	18-DF								8			8			8			8			8	10-DF	10					10-DF	
19	TARGET LESIONS	TUMOR_M	19-DF							9-DF			9-DF			9-DF			9-DF			9-DF		9-DF	11-DF	11-DF				11-DF	
20	NON-TARGET LESIONS	TUMOR_NTB	20-DF																												
21	ADDITIONAL PK SUBSTUDY INFORMED CONSENT	PKBS	21-DF																												
22	AE, CONMED, CPROC and HOSP	AE/CM/CP/HOSP		1																											
23	ADVERSE EVENTS > 1 STUDY TREATMENT	AE2		2-RF-DF																											
24	PRIOR/CONCOMITANT MEDICATIONS	CMED1		3-RF-DF																											
25	CONCOMITANT PROCEDURES/SURGERIES	CPROC		4-RF-DF																											
26	HOSPITALIZATION	HOSP		5-RF-DF																											
27	PRINCIPAL INVESTIGATOR'S SIGNATURE	PISIGN			1																										
28	VITAL SIGNS	VITALS					2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	3-DF	3				3-DF	
29	ECOG PERFORMANCE STATUS SCALE	ECOG2					6		6	6	6	6	6	6	6	6	6	6	6	6	6	6	6	6	7-DF	8				8-DF	
30	PATIENT REPORTED OUTCOMES 1	PROASM1					7				7			7			7			7			7	8-DF	9				9-DF		
31	PHARMACOKINETIC (PK) INTENSIVE SAMPLING	PKSAMPI					8-DF																								
32	BIOMARKER BLOOD COLLECTION	BIOBC					9				12			12			12			12			12	14-DF	14						
33	STUDY DRUG RECORD	STDRUG					10-RF		8-RF	8-RF	13-RF	8-RF	8-RF	13-RF	8-RF	8-RF	13-RF	8-RF	8-RF	13-RF	8-RF	8-RF	13-RF	15-RF-DF							
34	STUDY DRUG RECORD - Docetaxel	STDRUG2 - DOCX					11-RF		9-RF	9-RF	14-RF	9-RF	9-RF	14-RF	9-RF	9-RF	14-RF	9-RF	9-RF	14-RF	9-RF	9-RF	14-RF	16-RF-DF							
35	STUDY DRUG RECORD - Prednisone	STDRUG3 - PRED					12-RF		10-RF	10-RF	15-RF	10-RF	10-RF	15-RF	10-RF	10-RF	15-RF	10-RF	10-RF	15-RF	10-RF	10-RF	15-RF	17-RF-DF							
36	PHARMACOKINETIC (PK) SPARSE SAMPLING	PKSAMPS						5-DF																							
37	NON-TARGET LESIONS	TUMOR_NTP									10-RF-DF			10-RF-DF			10-RF-DF			10-RF-DF			10-RF-DF	12-RF-DF	12-RF-DF					12-RF-DF	
38	TUMOR RESPONSE	TUMOR_MRESP									11-DF			11-DF			11-DF			11-DF			11-DF	13-DF	13-DF					13-DF	
39	CYCLE SELECTION	CYCLE																						2							
40	DISCONTINUATION	DISCON TX																							2						
41	ECG	ECG																							7				7-DF		
42	Trial Continuation	CON																							15-DF						
43	DATE OF VISIT	DOV																								1					
44	SURVIVAL	SURVI																									2				
45	SURVIVAL INFORMATION	SRV INFO																									3-DF				
46	DEATH	DEATH																										1			
47	UNSCHEDULED ASSESSMENTS	UNSDOV																											2		

/22/2011

YKA46505 : SYSTEM SCREENING (SCR)		
1.	Subject Initials <i>[read-only]</i>	A3 <i>(Enter a dash if no middle initial)</i> (sdeYKA46505:t_SCREEN.INITIAL1) [INITIALS, CHAR, 3, \$3]
2.	Date Subject Signed Informed Consent <i>[read-only]</i>	Req / Req / Req (2009-2025) (sdeYKA46505:t_SCREEN.INFCDT1)
3.	Date of Birth <i>[read-only]</i>	Req / Req / Req (1900-2025) (sdeYKA46505:t_SCREEN.BRTHDT1)

Item Design Notes:	
Item No.	Design Note
1.	Mapped to Demog eCRF
2.	Mapped to Demog eCRF
3.	Mapped to Demog eCRF

CDD: sdeYKA46505 Table: t_SCREEN Key Type: PATIENTVISIT		
Column Name	Column Data Type	Design Note
INITIAL1	STRING(3) - A3	
INFCDT1	DATE - DDMONYYYY	
BRTHDT1	DATE - DDMONYYYY	

Domain Name: [SCREEN]

Domain Label: [SCREENING]

Additional items:

[STUDY, CHAR, 20, \$20],

[PT, CHAR, 20, \$20],

[INVSITE, CHAR, 20, \$20],

[VISNAME, CHAR, 60, \$60],

[VISIT, NUM, 8],

[VISDT, NUM, 8, DATE9],

YKA46505 : SYSTEM ENROLLMENT (ENR)		
1. Subject ID	A7 (sdeYKA46505:t_ENROLL.SUBJID)	[SUBJID, CHAR, 20, \$20]
REMINDER: Subject ID is a 7-digit number, which is a combination of the 3 digit Site Number, followed by the last 4-digit Subject Screening Number beginning with 1. [read-only]		

Item Design Notes:	
Item No.	Design Note
1.	Mapped from System Enrollment to Demog

CDD: sdeYKA46505 Table: t_ENROLL Key Type: PATIENTVISIT		
Column Name	Column Data Type	Design Note
SUBJID	STRING(7) - A7	

Domain Name: [ENROLL]
Domain Label: [ENROLLMENT]
Additional items:

[STUDY, CHAR, 20, \$20],
[PT, CHAR, 20, \$20],
[INVSITE, CHAR, 20, \$20],
[VISNAME, CHAR, 60, \$60],
[VISIT, NUM, 8],
[VISDT, NUM, 8, DATE9],

YKA46505 : DATE OF VISIT (DOV)		
Date of Visit		
1.	Date of Visit	Req <input type="checkbox"/> / Req <input type="checkbox"/> / Req <input type="checkbox"/> (2009-2025) (sdeYKA46505:t_DOV.DOV)

CDD: sdeYKA46505 Table: t_DOV Key Type: PATIENTVISIT

Column Name	Column Data Type	Design Note
DOV	DATE - DDMONYYYY	

[DOVDTF, CHAR, 200, \$200],[DOVDT, NUM, 8, DATE9]

Domain Name: [DOV]
Domain Label: [DATE OF VISIT]
Additional items:

[STUDY, CHAR, 20, \$20],
[PT, CHAR, 20, \$20],
[INVSITE, CHAR, 20, \$20],
[VISNAME, CHAR, 60, \$60],
[VISIT, NUM, 8],

YKA46505 : DEMOGRAPHICS (DEMOG)

Demographics

1. Subject ID

REMINDER: Subject ID is a 7-digit number, which is a combination of the 3 digit Site Number, followed by the last 4-digit Subject Screening Number beginning with 1. *[read-only]*

A7

(sdeYKA46505:t_DM.SUBJID)

[SUBJID, CHAR, 20, \$20]

2. Subject Initials *[read-only]*

A3

(Enter a dash if no middle initial) (sdeYKA46505:t_DM.INITIALS)

[INITIALS, CHAR, 3, \$3]

3. Date of Informed Consent *[read-only]*

Req / Req / Req

(2009-2025) (sdeYKA46505:t_DM.INFCDT)

*

4. Date of Birth *[read-only]*

Req / Req / Req

(1900-2025) (sdeYKA46505:t_DM.BRTHDT)

**

5. Sex *[read-only]*

(sdeYKA46505:t_DM.SEXN)

[2] ☐ Female

[1] ☐ Male

[SEXN, NUM,8], [SEX, CHAR, 6, \$6]

6. Ethnicity

(sdeYKA46505:t_DM.ETHNICN)

[1] ☐ Hispanic or Latino

[2] ☐ Not Hispanic or Latino

[ETHNICN, NUM,8], [ETHNIC, CHAR, 50, \$50]

7. Primary Race (select only one)

(sdeYKA46505:t_DM.RACEN)

[1] ☐ American Indian or Alaska Native

[2] ☐ Asian

[3] ☐ Black or African American

[4] ☐ Native Hawaiian or Other Pacific Islanders

[5] ☐ White

Other, specify: (sdeYKA46505:t_DM.RACEOTH)

A200

[RACEOTH, CHAR, 200, \$200]

Item Design Notes:	
Item No.	Design Note
1.	Mapped from System Enrollment to Demog
2.	Subject Initials mapped from System Screening form.
3.	Date of Informed Consent mapped from System Screening form.
4.	Date of Birth mapped from System Screening
5.	Sex = Male

CDD: sdeYKA46505 Table: t_DM Key Type: PATIENTVISIT		
Column Name	Column Data Type	Design Note
SUBJID	STRING(7) - A7	
INITIALS	STRING(3) - A3	
INFCDT	DATE - DDMYYYYY	
BRTHDT	DATE - DDMYYYYY	
SEXN	NUMERIC	
ETHNICN	NUMERIC	
RACEN	NUMERIC	
RACEOTH	STRING(200) - A200	

*[INFCDTF, CHAR, 200, \$200],[INFCDT, NUM, 8, DATE9]
**[BRTHDTF, CHAR, 200, \$200],[BRTHDT, NUM, 8, DATE9]

Domain Name: [DM]
Domain Label: [DEMOGRAPHICS]
Additional items:

[STUDY, CHAR, 20, \$20],
[PT, CHAR, 20, \$20],
[INVSITE, CHAR, 20, \$20],
[VISNAME, CHAR, 60, \$60],
[VISIT, NUM, 8],
[VISDT, NUM, 8, DATE9],

http://usadc-vsi46sp2a.quintiles.net/YKA46505/pfts.dll?S=304d1838&C=TM_169&FMID=0&FMRV=0&ISID=0&ITID=0&VM=2&TN=YKA46505&SP=&AS=2047&CP=65535&FP=0&RSV=0

7/22/2011

YKA46505 : ELIGIBILITY (ELIG)

Eligibility

1.

Did the subject meet all of the criteria for eligibility into the study?

[ELIGYNN , NUM , 8] ,
[ELIGYN , CHAR , 200 , \$200]
[RANDNM , CHAR , 7 , \$7]

(sdeYKA46505:t_ELIG.ELIGYNN)
[1] ☐ Yes, enter (sdeYKA46505:t_ELIG.PT1)
Randomization
Number
A7
[2] ☐ No, enter the Incl/Excl criteria number(s)
for which the subject failed

Please select the Inclusion or Exclusion Criteria number for which the subject failed

2.

Inclusion/Exclusion Criteria Number Entry

2.a

Please select the Inclusion or Exclusion Criteria number for which the subject failed

[INCFAIL , CHAR , 200 , \$200] , [INCFAILN , NUM , 8]
[EXCFAIL , CHAR , 200 , \$200] , [EXCFAILN , NUM , 8]

(sdeYKA46505:t_ELIG.FAILN)
[1] ☐ Inclusion Criteria
Pulldown List 1 (sdeYKA46505:t_ELIG.INCFAIL)
[2] ☐ Exclusion Criteria
Pulldown List 2 (sdeYKA46505:t_ELIG.EXCFAIL)

[FAILN , NUM , 8 , 8] , [FAIL , CHAR , 200 , \$200]

Pulldown List 1:			
RefName	Display Text	Value	Design Note
eintELIGINCNUM1	Inclusion 1	1	
eintELIGINCNUM2	Inclusion 2	2	
eintELIGINCNUM3	Inclusion 3	3	
eintELIGINCNUM4	Inclusion 4	4	
eintELIGINCNUM5	Inclusion 5	5	
eintELIGINCNUM6	Inclusion 6	6	
eintELIGINCNUM7	Inclusion 7	7	
eintELIGINCNUM8	Inclusion 8	8	
eintELIGINCNUM9	Inclusion 9	9	
eintELIGINCNUM10	Inclusion 10	10	

Pulldown List 2:			
RefName	Display Text	Value	Design Note
eintELIGEXCNUM1	Exclusion 1	1	
eintELIGEXCNUM2	Exclusion 2	2	
eintELIGEXCNUM3	Exclusion 3	3	
eintELIGEXCNUM4	Exclusion 4	4	
eintELIGEXCNUM5	Exclusion 5	5	
eintELIGEXCNUM6	Exclusion 6	6	
eintELIGEXCNUM7	Exclusion 7	7	
eintELIGEXCNUM8	Exclusion 8	8	
eintELIGEXCNUM9	Exclusion 9	9	
eintELIGEXCNUM10	Exclusion 10	10	
eintELIGEXCNUM11	Exclusion 11	11	
eintELIGEXCNUM12	Exclusion 12	12	
eintELIGEXCNUM13	Exclusion 13	13	
eintELIGEXCNUM14	Exclusion 14	14	
eintELIGEXCNUM15	Exclusion 15	15	
eintELIGEXCNUM16	Exclusion 16	16	
eintELIGEXCNUM17	Exclusion 17	17	
eintELIGEXCNUM18	Exclusion 18	18	
eintELIGEXCNUM19	Exclusion 19	19	

Domain Name: [ELIG]
Domain Label: [ELIGIBILITY]
Additional items:

[STUDY, CHAR, 20, \$20],
[PT, CHAR, 20, \$20],
[INVSITE, CHAR, 20, \$20],
[VISNAME, CHAR, 60, \$60],
[VISIT, NUM, 8],
[VISDT, NUM, 8, DATE9],

PLEASE NOTE: PLEASE MERGE ELIGYNN AND ELIGYN WITH ALL OTHER
VARIABLES IN ELIGIBILITY.

CDD: sdeYKA46505 Table: t_ELIG Key Type: PATIENTVISIT		
Column Name	Column Data Type	Design Note
ELIGYNN	NUMERIC	
PT1	STRING(7) - A7	
FAILN	NUMERIC	
INCFAIL	STRING(255) - 1, 2, 3, 4, 5, 6, 7, 8, 9, 10	
EXCFAIL	STRING(255) - 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19	

http://usadc-vsi46sp2a.quintiles.net/YKA46505/pfts.dll?S=304d1838&C=TM_169&FMID=0&FMRV=0&ISID=0&ITID=0&VM=2&TN=YKA46505&SP=&AS=2047&CP=65535&FP=0&RSV=0

7/22/2011

YKA46505 : CONFIRM DIAGNOSIS (CONDIAG)			
CONFIRM DIAGNOSIS			
NOTE: If confirmed both rising PSA and radiologic progression, then disease progression is considered "radiologic progression".			
1. Date subject's disease was confirmed hormone refractory:	NReq/Unk <input type="button" value="v"/> / Req <input type="button" value="v"/> / Req <input type="button" value="v"/> (1900-2025) (sdeYKA46505:t_CONF.DTHRD)	*	
2. Date subject's disease was confirmed metastatic:	NReq/Unk <input type="button" value="v"/> / Req <input type="button" value="v"/> / Req <input type="button" value="v"/> (1900-2025) (sdeYKA46505:t_CONF.DTDmet)	**	
3. What is the confirmed type of disease progression?	(sdeYKA46505:t_CONF.PPSAM) [1] <input type="radio"/> Rising PSA only [2] <input type="radio"/> Radiographic Progression		

CDD: sdeYKA46505 Table: t_CONF Key Type: PATIENTVISIT		
Column Name	Column Data Type	Design Note
DTHRD	DATE - DDMYYYYY	
DTDmet	DATE - DDMYYYYY	
PPSAM	NUMERIC	

*[DTHRDTF, CHAR, 200, \$200],[DTHRDT, NUM, 8, DATE9]
**[DTMETDTF, CHAR, 200, \$200],[DTMETDT, NUM, 8, DATE9]

Domain Name: [CONDIAG]
Domain Label: [CONFIRM DIAGNOSIS]
Additional items:

[STUDY, CHAR, 20, \$20],
[PT, CHAR, 20, \$20],
[INVSITE, CHAR, 20, \$20],
[VISNAME, CHAR, 60, \$60],
[VISIT, NUM, 8],
[VISDT, NUM, 8, DATE9],

YKA46505 : MEDICAL HISTORY (MEDHX)

Medical History

1. Is there a relevant medical history?

(sdeYKA46505:t_MEDHX.MHQN)
[2] ☐ No [1] ☐ Yes

Diagnosis

MHDECOD

[hidden]

MHMODIFY

MHBODSYS

LLTCDM

LLTNMM

HLTNMM

HLGTNMM

PTCDM

DICTVER

Date of Diagnosis

Active Diagnosis

2.

Diagnosis Entry

2.a

Diagnosis:

A200

(sdeYKA46505:t_MEDHX.MHTERM)
[MHTERM, CHAR, 200, \$200]

2.b*

MHDECOD [hidden]

A200

(sdeYKA46505:t_MEDHX.MHDECOD)
[MHDECOD, CHAR, 200, \$200]

2.c*

MHMODIFY [hidden]

A200

(sdeYKA46505:t_MEDHX.MHMODIFY)
[MHMODIFY, CHAR, 200, \$200]

2.d*

MHBODSYS [hidden]

A200

(sdeYKA46505:t_MEDHX.MHBODSYS)
[MHBODSYS, CHAR, 200, \$200]

2.e*

LLTCDM [hidden]

A200

(sdeYKA46505:t_MEDHX.LLTCDM)
[LLTCDM, CHAR, 200, \$200]

2.f*

LLTNMM [hidden]

A200

(sdeYKA46505:t_MEDHX.LLTNMM)
[LLTNMM, CHAR, 200, \$200]

2.g*

HLTNMM [hidden]

A200

(sdeYKA46505:t_MEDHX.HLTNMM)
[HLTNMM, CHAR, 200, \$200]

2.h*

HLGTNMM [hidden]

A200

(sdeYKA46505:t_MEDHX.HLGTNMM)
[HLGTNMM, CHAR, 200, \$200]

2.i*

PTCDM [hidden]

A200

(sdeYKA46505:t_MEDHX.PTCDM)
[PTCDM, CHAR, 200, \$200]

2.j*

DICTVER [hidden]

A200

(sdeYKA46505:t_MEDHX.DICTVER)
[DICTVER, CHAR, 200, \$200]

2.k

Date of Diagnosis:

[MHSTDTF, CHAR, 200, \$200],[MHSTDT, NUM, 8, DATE9]

Req/Unk / Req/Unk / Req (1900-2025) (sdeYKA46505:t_MEDHX.MHSTDT)

2.l

Is this Diagnosis Active?

[MHACTDTF, CHAR, 200, \$200],[MHACTDT, NUM, 8, DATE9]

(sdeYKA46505:t_MEDHX.MHACTN) [MHACTN,NUM,8,8], [MHACT, CHAR,200,\$200]
[2] ☐ No
Date of Resolution
Req/Unk / Req/Unk / Req (1900-2025) (sdeYKA46505:t_MEDHX.MHACTDT)
[1] ☐ Yes

* Item is not required

Form Design Note:

Requirements: 1. Diagnosis is coded field. 2. Add-entry form 3. Unknown will be an option in the date pull-down menus

CDD: sdeYKA46505 Table: t_MEDHX Key Type: PATIENTVISIT		
Column Name	Column Data Type	Design Note
MHQN	NUMERIC	
MHTERM	STRING(200) - A200	
MHDECOD	STRING(200) - A200	
MHMODIFY	STRING(200) - A200	
MHBODSYS	STRING(200) - A200	
LLTCDM	STRING(200) - A200	
LLTNMM	STRING(200) - A200	
HLTNMM	STRING(200) - A200	
HLGTNMM	STRING(200) - A200	
PTCDM	STRING(200) - A200	
DICTVER	STRING(200) - A200	
MHSTDT	DATE - DDMONYYYY	
MHACTN	NUMERIC	
MHACTDT	DATE - DDMONYYYY	

Domain Name: [MEDHX]

Domain Label: [MEDICAL HISTORY]

Additional items:

[STUDY, CHAR, 20, \$20],
[PT, CHAR, 20, \$20],
[INVSITE, CHAR, 20, \$20],
[VISNAME, CHAR, 60, \$60],
[VISIT, NUM, 8],
[VISDT, NUM, 8, DATE9],

PLEASE NOTE: PLEASE MERGE MQHNN AND MHQNN WITH ALL OTHER VARIABLES IN MEDICAL HISTORY.

YKA46505 : PRIOR THERAPIES FOR THIS DISEASE (PRIORTX)		
1.	For this disease were there any Prior Radiation Therapies?	(sdeYKA46505:t_PRIORTX.PRTQ) [2] <input type="radio"/> No [1] <input type="radio"/> Yes [PRTQN,NUM,8,8], [PRTQ, CHAR,200,\$200]
2.	For this disease were there any Prior Cancer Surgeries?	(sdeYKA46505:t_PRIORTX.PCSQ) [2] <input type="radio"/> No [1] <input type="radio"/> Yes [PCSQN,NUM,8,8], [PCSQ, CHAR,200,\$200]
3.	For this disease were there any Prior Hormonal Anti-Cancer Therapies?	(sdeYKA46505:t_PRIORTX.PRHACTQ) [2] <input type="radio"/> No [1] <input type="radio"/> Yes [PRHACTQN,NUM,8,8], [PRHACTQ, CHAR,200,\$200]
4.	For this disease were there any Other Prior Anti-Cancer Therapies?	(sdeYKA46505:t_PRIORTX.PROACTQ) [2] <input type="radio"/> No [1] <input type="radio"/> Yes [PROACTQN,NUM,8,8], [PROACTQ, CHAR,200,\$200]

Item Design Notes:	
Item No.	Design Note
1.	If = Yes Dynamically trigger PRIXRT
2.	If = Yes Dynamically trigger PRISURG
3.	If = Yes Dynamically trigger PRIHRM
4.	If = Yes Dynamically trigger PRIOCT

CDD: sdeYKA46505 Table: t_PRIORTX Key Type: PATIENTVISIT		
Column Name	Column Data Type	Design Note
PRTQ	NUMERIC	
PCSQ	NUMERIC	
PRHACTQ	NUMERIC	
PROACTQ	NUMERIC	

Domain Name: [PRIORTX]
Domain Label: [PRIOR THERAPIES FOR THIS DISEASE]
Additional items:

[STUDY, CHAR, 20, \$20],
[PT, CHAR, 20, \$20],
[INVSITE, CHAR, 20, \$20],
[VISNAME, CHAR, 60, \$60],
[VISIT, NUM, 8,8],
[VISDT, NUM, 8, DATE9],

YKA46505 : PRIOR HORMONAL ANTI-CANCER THERAPIES FOR THIS DISEASE (PRIHRM) - Repeating Form

#		Regimen #	Date Started	Date Stopped	
1	<div><div></div></div>				
Treatment Regimen		[PATSEQN,NUM,8,8]			
1.*	Regimen # [read-c	<div><div>xx</div>(sdeYKA46505:t_PSAT2.PATSEQN)</div>			
2.	Date Started	[PATSTDTF, CHAR, 200, \$200],[PATSTDT, NUM, 8, DATE9]		<div><div></div></div>	(1900-2025) (sdeYKA46505:t_PSAT2.PATSTDT)
3.	Date Stopped	[PATENDTF, CHAR, 200, \$200],[PATENDT, NUM, 8, DATE9]		<div><div></div></div>	(1900-2025) (sdeYKA46505:t_PSAT2.PATENDT)
4.	Number of Cycles	[PATYNN,NUM,8,8], [PATYN, CHAR,200,\$200]		<div>(sdeYKA46505:t_PSAT2.PATYNN) [1] <div><div></div></div> xx (1 =< n <= 50) (sdeYKA46505:t_PSAT2.PATCYC) [96] <div><div></div></div> Unknown</div>	
	Drug Name	Drug Name		[PATCYC, NUM, 8, 8]	
5.			[hidden]		[hidden] [hidden] [hidden] [hidden] [hidden] [hidden] [hidden] [hidden] [hidden] [hidden] [hidden] [hidden]

ANTI-CANCER THERAPIES Entry

5.a	Drug Name	[PATDRUG, CHAR, 200, \$200]	[CMDECOD, CHAR, 200, \$200]	A200	(sdeYKA46505:t_PSAT2.PATDRUG)									
5.b*	Drug Name [hidden]	[PATDRUG2, CHAR, 200, \$200]		A200	(sdeYKA46505:t_PSAT2.PATDRUG2)									
5.c*	ATC1 [hidden]	[ATC1, CHAR, 200, \$200]		A200	(sdeYKA46505:t_PSAT2.ATC1)									
5.d*	ATC2 [hidden]	[ATC2, CHAR, 200, \$200]		A200	(sdeYKA46505:t_PSAT2.ATC2)									
5.e*	ATC3 [hidden]	[ATC3, CHAR, 200, \$200]		A200	(sdeYKA46505:t_PSAT2.ATC3)									
5.f*	ATC3_CODE [hidden]	[ATC3CODE, CHAR, 200, \$200]		A200	(sdeYKA46505:t_PSAT2.ATC3_CODE)									
5.g*	ATC4 [hidden]	[ATC4, CHAR, 200, \$200]		A200	(sdeYKA46505:t_PSAT2.ATC4)									
5.h*	ATC4_CODE [hidden]	[ATC4CODE, CHAR, 200, \$200]		A200	(sdeYKA46505:t_PSAT2.ATC4_CODE)									
5.i*	SYN [hidden]	[SYN, CHAR, 200, \$200]		A200	(sdeYKA46505:t_PSAT2.SYN)									
5.j*	SYN_CODE [hidden]	[SYNCODE, CHAR, 200, \$200]		A200	(sdeYKA46505:t_PSAT2.SYN_CODE)									
5.k*	GENERICNM [hidden]	[GENRICNM, CHAR, 200, \$200]		A200	(sdeYKA46505:t_PSAT2.GENERICNM)									
5.l*	DICTVER [hidden]	[DICTVER, CHAR, 200, \$200]		A200	(sdeYKA46505:t_PSAT2.DICTVER)									
5.m*	ATC1_CODE [hidden]	[ATC1CODE, CHAR, 200, \$200]		A200	(sdeYKA46505:t_PSAT2.ATC1_CODE)									
5.n*	ATC2_CODE [hidden]	[ATC2CODE, CHAR, 200, \$200]		A200	(sdeYKA46505:t_PSAT2.ATC2_CODE)									
5.o*	PN_CODE [hidden]	[PN_CODE, CHAR, 200, \$200]		A200	(sdeYKA46505:t_PSAT2.PN_CODE)									

* Item is not required

PLEASE NOTE: PLEASE MERGE TREATMENT REGIMEN AND ANTI-CANCER THERAPIES FOR EVERY SUBJECT

Column Name	Column Data Type	Design Note
PATSEQN	NUMERIC - N2	
PATSTDT	DATE - DDMONYYYY	
PATENDT	DATE - DDMONYYYY	
PATYNN	NUMERIC	
PATCYC	NUMERIC - N2	
PATDRUG	STRING(200) - A200	
PATDRUG2	STRING(200) - A200	
ATC1	STRING(200) - A200	
ATC2	STRING(200) - A200	
ATC3	STRING(200) - A200	
ATC3_CODE	STRING(200) - A200	
ATC4	STRING(200) - A200	
ATC4_CODE	STRING(200) - A200	
SYN	STRING(200) - A200	
SYN_CODE	STRING(200) - A200	
GENERICNM	STRING(200) - A200	
DICTVER	STRING(200) - A200	
ATC1_CODE	STRING(200) - A200	
ATC2_CODE	STRING(200) - A200	
PN_CODE	STRING(200) - A200	

YKA46505 : OTHER PRIOR ANTI-CANCER THERAPIES FOR THIS DISEASE (PRIOCT) - Repeating Form						
#		Sequence #	Treatment	Date Started	Date Stopped	Best Response
1	<div></div>					
Treatment Regimen						
1. *	Sequence # [read-only]			<div>xx</div> (sdeYKA46505:t_PSAT3.PSAT3SEQN) [PATSEQN,NUM,8,8]		
2.	Treatment			<div>A200</div> (sdeYKA46505:t_PSAT3.PATDRUG) [PATDRUG,CHAR,200,\$200]		
3.	Date Started			[PATSTDTF,CHAR,200,\$200],[PATSTD,NUM,8,DATE9] <div>Req/Unk / Req/Unk / Req (1950-2025) (sdeYKA46505:t_PSAT3.PATSTD)</div>		
4.	Date Stopped			[PATENDTF,CHAR,200,\$200],[PATENDT,NUM,8,DATE9] <div>Req/Unk / Req/Unk / Req (1950-2025) (sdeYKA46505:t_PSAT3.PATENDT)</div>		
5.	Best Response			<div>(sdeYKA46505:t_PSAT3.PATRSPN) [1] Complete Response [2] Partial Response [4] Stable Disease [3] Progressive Disease [96] Unknown [5] Adjuvant</div> [PATRSPNN,NUM,8,8], [PATRSPN,CHAR,200,\$200]		
* Item is not required						

CDD: sdeYKA46505 Table: t_PSAT3 Key Type: PATIENTVISIT		
Column Name	Column Data Type	Design Note
PSAT3SEQN	NUMERIC - N2	
PATDRUG	STRING(200) - A200	
PATSTD	DATE - DDMONYYYY	
PATENDT	DATE - DDMONYYYY	
PATRSPN	NUMERIC	

Domain Name: [PSAT3]
Domain Label: [OTHER PRIOR ANTI-CANCER THERAPIES FOR THIS DISEASE]
Additional items:

[STUDY,CHAR,20,\$20],
[PT,CHAR,20,\$20],
[INVSITE,CHAR,20,\$20],
[VISNAME,CHAR,60,\$60],
[VISIT,NUM,8,8],
[VISDT,NUM,8,DATE9],

YKA46505 : PRIOR CANCER SURGERIES FOR THIS DISEASE (PRISURG) - Repeating Form

#	Sequence #	Surgery Date	Surgical Procedure
1			

Prior Cancer Surgeries For This Disease

1.*	Sequence # <i>[read-only]</i>	xx (sdeYKA46505:t_PCS.PCSSEQN)	[PCSSQN, NUM, 8, 8]
2.	Surgery Date	[PCSDTF, CHAR, 200, \$200],[PCSDT, NUM, 8, DATE9]	Req/Unk / Req/Unk / Req (1900-2025) (sdeYKA46505:t_PCS.PCSDT)
3.	Surgical Procedure	A200	(sdeYKA46505:t_PCS.PCSPROC) [PCSPROC, CHAR, 200, \$200]
4.*	SURGCODE <i>[hidden]</i>	A200	(sdeYKA46505:t_PCS.PCDECODE) [PCDECODE, CHAR, 200, \$200]
5.*	LLTCDPC <i>[hidden]</i>	A200	(sdeYKA46505:t_PCS.LLTCDPC) [LLTCDPC, CHAR, 200, \$200]
6.*	LLTNMPC <i>[hidden]</i>	A200	(sdeYKA46505:t_PCS.LLTNMPC) LLTNMPC, CHAR, 200, \$200]
7.*	SURGCODE <i>[hidden]</i>	A200	(sdeYKA46505:t_PCS.HLTNMPC) [HLTNMPC, CHAR, 200, \$200]
8.*	HLGTNMPC <i>[hidden]</i>	A200	(sdeYKA46505:t_PCS.HLGTNMPC) [HLGTNMPC, CHAR, 200, \$200]
9.*	PTCDPC <i>[hidden]</i>	A200	(sdeYKA46505:t_PCS.PTCDPC) [PTCDPC, CHAR, 200, \$200]
10.*	DICTVER <i>[hidden]</i>	A200	(sdeYKA46505:t_PCS.DICTVER) [DICTVER, CHAR, 200, \$200]
11.*	PCBODSYS <i>[hidden]</i>	A200	(sdeYKA46505:t_PCS.PCBODSYS) [PCBODSYS, CHAR, 200, \$200]

* Item is not required

CDD: sdeYKA46505 Table: t_PCS Key Type: PATIENTVISIT		
Column Name	Column Data Type	Design Note
LLTCDPC	STRING(200) - A200	
LLTNMPC	STRING(200) - A200	
HLTNMPC	STRING(200) - A200	
HLGTNMPC	STRING(200) - A200	
PTCDPC	STRING(200) - A200	
DICTVER	STRING(200) - A200	
PCBODSYS	STRING(200) - A200	
PCSDT	DATE - DDMONYYYY	
PCSPROC	STRING(200) - A200	
PCDECODE	STRING(200) - A200	
PCSSEQN	NUMERIC - N2	

Domain Name: [PCS]

Domain Label: [PRIOR CANCER SURGERIES FOR THIS DISEASE]

Additional items:

[STUDY, CHAR, 20, \$20],

[PT, CHAR, 20, \$20],

[INVSITE, CHAR, 20, \$20],

[VISNAME, CHAR, 60, \$60],

[VISIT, NUM, 8,8],

[VISDT, NUM, 8, DATE9],

YKA46505 : Prior Radiation Therapies (PRIXRT) - Repeating Form

#	Sequence #	Treatment Site	Type of Radiation Therapy	Date Started	Date Stopped	Dose	Number of Fractions	Intent	Settings	
1	<div><div></div><div></div><div></div></div>									
1. * Sequence # <i>[read-only]</i>				<div><div>xx</div><div>(sdeYKA46505:t_PRT.PRIXRSEQ)</div><div>[PRIXRSEQ,NUM,8,8]</div></div>						
2. Treatment Site				<div><div>A200</div><div>(sdeYKA46505:t_PRT.PRTSITE)</div><div>[PRTSITE,CHAR,200,\$200]</div></div>						
3. Type of Radiation Therapy <div>[PRTTYPEN,NUM,8,8],[PRTTYPE,CHAR,200,\$200]</div> <div>[PRTBEAMN,NUM,8,8],[PRTBEAM,CHAR,200,\$200]</div>				<div>(sdeYKA46505:t_PRT.PRTTYPEN)</div> <div>[1]<div><div></div></div>(sdeYKA46505:t_PRT.PRTBEAMN)</div> <div>External Beam</div> <div>[1]<div><div></div></div>Total Brain Irradiation (TBI)</div> <div>[2]<div><div></div></div>Whole Body Irradiation</div> <div>[2]<div><div></div></div>Radio-Immuno Therapy</div> <div>[3]<div><div></div></div>Brachytherapy</div> <div>[99]<div><div></div></div>Other, Specify<div>A200</div><div>(sdeYKA46505:t_PRT.PRTSPE)</div><div>[PRTSPE,CHAR,200,\$200]</div></div>						

4. Date Started [PRTSTDTF,CHAR,200,\$200],[PRTSTDT,NUM,8,DATE9]				Req/Unk /Req/Unk /Req (1900-2025)(sdeYKA46505:t_PRT.PRTSTDT)						
5. Date Stopped [PRTENDTF,CHAR,200,\$200],[PRTENDT,NUM,8,DATE9]				Req/Unk /Req/Unk /Req (1900-2025)(sdeYKA46505:t_PRT.PRTENDT)						
6. Dose [PRTDOSEN,NUM,8,8],[PRTDOSE,CHAR,200,\$200]				(sdeYKA46505:t_PRT.PRTDOSEN) [1] xx(Gy)(sdeYKA46505:t_PRT.PRTDOSE1) [2] xxxx(cGY)(sdeYKA46505:t_PRT.PRTDOSE2) [96] Unknown [PRTDOSE1,NUM,8,8] [PRTDOSE2,NUM,8,8]						
7. Number of Fractions [PRTYNN,NUM,8,8],[PRTYN,CHAR,200,\$200]				(sdeYKA46505:t_PRT.PRTYNN) [1] xxxFractions(sdeYKA46505:t_PRT.PRTFRACT) [96] Unknown [PRTFRACT,NUM,8,8]						
8. Intent				(sdeYKA46505:t_PRT.PRTINTN) [1] Adjuvant [2] Curative [3] Palliative [96] Unknown [PRTINTN,NUM,8,8],[PRTINT,CHAR,200,\$200]						
9. Settings [PRTSETTN,NUM,8,8],[PRTSETT,CHAR,200,\$200]				(sdeYKA46505:t_PRT.PRTSETTN) [1] Stand Alone Radiation Therapy [2] Concurrent with other Anti-Cancer Therapy [3] Sequential to other Anti-Cancer Therapy						
* Item is not required										

Form Design Note:

1.Repeating form, for each treatment site
2. Day is not required (allow unk as an option) *month is not required except within the year that the study starts, year is required * Edit check

CDD: sdeYKA46505 Table: t_PRT Key Type: PATIENTVISIT		
Column Name	Column Data Type	Design Note
PRIXRSEQ	NUMERIC - N2	
PRTSITE	STRING(200) - A200	
PRTTYPEN	NUMERIC	
PRTBEAMN	NUMERIC	
PRTSPE	STRING(200) - A200	
PRTSTDT	DATE - DDMONYYYY	
PRTENDT	DATE - DDMONYYYY	
PRTDOSEN	NUMERIC	
PRTDOSE1	NUMERIC - N2	
PRTDOSE2	NUMERIC - N4	
PRTYNN	NUMERIC	
PRTFRACT	NUMERIC - N3	
PRTINTN	NUMERIC	
PRTSETTN	NUMERIC	

Domain Name: [PRT]
Domain Label: [PRIOR RADIATION THERAPIES]
Additional items:

[STUDY,CHAR,20,\$20],
[PT,CHAR,20,\$20],
[INVSITE,CHAR,20,\$20],
[VISNAME,CHAR,60,\$60],
[VISIT,NUM,8,8],
[VISDT,NUM,8,DATE9],

YKA46505 : VITAL SIGNS (VITALS)			
Vital Signs			
1.	Date Vital Signs Taken	Req / Req / Req (2009-2025) (sdeYKA46505:t_VITALS1.VTDT)	
2.	Height	xxx.x in cm (sdeYKA46505:t_VITALS1.HEIGHT)	[HEIGHT, NUM,8.1] [HEIGHTU,CHAR,10,\$10]
3.	Weight	xxx.x lbs kg (sdeYKA46505:t_VITALS1.WEIGHT)	[WEIGHT, NUM,8.1] [WEIGHTU,CHAR,10,\$10]
4.	BMI [read-only]	xxx.x (sdeYKA46505:t_VITALS1.BMI)	[BMI, NUM,8.1]
5.	Temperature	xxx.x °F °C (sdeYKA46505:t_VITALS1.TEMP)	[TEMP, NUM,8.1] [TEMPU,CHAR,10,\$10]
6.	Blood Pressure	xxx / (sdeYKA46505:t_VITALS1.SYBP) xxx mmHg (sdeYKA46505:t_VITALS1.DIABP) Systolic Diastolic	[DIABP, NUM,8] [DIABPU,CHAR,10,\$10]
7.	Pulse	xxx bpm (sdeYKA46505:t_VITALS1.PULSE)	[PULSE, NUM,8, 8.1] [PULSEU,CHAR,10,\$10]

Form Design Note:
Screening/Baseline Vital Signs

Item Design Notes:	
Item No.	Design Note
2.	HEIGHT_UNIT - This column will contain the unit as selected in InForm. HEIGHT_NORM - This column will contain the normalized value of the number.
3.	WEIGHT_UNIT - This column will contain the unit as selected in InForm. WEIGHT_NORM - This column will contain the normalized value of the number.
5.	TEMP_UNIT - This column will contain the unit as selected in InForm. TEMP_NORM - This column will contain the normalized value of the number.

CDD: sdeYKA46505 Table: t_VITALS1 Key Type: PATIENTVISIT		
Column Name	Column Data Type	Design Note
VTDT	DATE - DDMONYYYY	
HEIGHT	FLOAT - F5.1	
WEIGHT	FLOAT - F5.1	
BMI	FLOAT - F5.1	
TEMP	FLOAT - F5.1	
SYSBP	NUMERIC - N3	
DIABP	NUMERIC - N3	
PULSE	NUMERIC - N3	

Domain Name: [VS]
Domain Label: [VITAL SIGNS]
Additional items:

[STUDY, CHAR, 20, \$20],
[PT, CHAR, 20, \$20],
[INVSITE, CHAR, 20, \$20],
[VISNAME, CHAR, 60, \$60],
[VISIT, NUM, 8],
[VISDT, NUM, 8, DATE9],

PLEASE NOTE: PLEASE
APPEND ALL VITAL SIGNS
DATASETS

YKA46505 : BLOOD CHEMISTRY (CLABCHEM)		
Blood Chemistry		
1. Was a Blood Chemistry sample collected?	[LBYNN, NUM,8], [LBYN, CHAR, 200, \$200]	(sdeYKA46505:t_CLAB2.LBYN) [2] <input type="radio"/> No [1] <input type="radio"/> Yes Date of sample collection: Req <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (2009-2025) (sdeYKA46505:t_CLAB2.LBDT) Accession number: (sdeYKA46505:t_CLAB2.ACCNUM) A20 [ACCNUM, CHAR, 20, \$20] [LBDTF, CHAR, 200, \$200],[LBDT, NUM, 8, DATE9]

CDD: sdeYKA46505 Table: t_CLAB2 Key Type: PATIENTVISIT		
Column Name	Column Data Type	Design Note
LBYN	NUMERIC	
LBDT	DATE - DDMONYYYY	
ACCNUM	STRING(20) - A20	

Domain Name: [CHEM]
Domain Label: [CENTRAL LABS CHEMISTRY]
Additional items:

[STUDY, CHAR, 20, \$20],
[PT, CHAR, 20, \$20],
[INVSITE, CHAR, 20, \$20],
[VISNAME, CHAR, 60, \$60],
[VISIT, NUM, 8],
[VISDT, NUM, 8, DATE9],

YKA46505 : HEMATOLOGY (CLABHEM)		
Hematology		
1. Was a Hematology sample collected?	<div>[LBYNN, NUM,8], [LBYN, CHAR, 200, \$200]</div>	<div>(sdeYKA46505:t_CLAB1.LBYN) [2] <input type="radio"/> No [1] <input type="radio"/> Yes Date of sample collection: Req <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (2009-2025) (sdeYKA46505:t_CLAB1.LBDT) Accession number: (sdeYKA46505:t_CLAB1.ACCNUM) A20 <div>[LBDTF, CHAR, 200, \$200],[LBDT, NUM, 8, DATE9]</div><div>[ACCNUM, CHAR, 20, \$20]</div></div>

CDD: sdeYKA46505 Table: t_CLAB1 Key Type: PATIENTVISIT		
Column Name	Column Data Type	Design Note
LBYN	NUMERIC	
LBDT	DATE - DDMONYYYY	
ACCNUM	STRING(20) - A20	

Domain Name: [HEM]
Domain Label: [CENTRAL LABS HEMATOLOGY]
Additional items:

[STUDY, CHAR, 20, \$20],
[PT, CHAR, 20, \$20],
[INVSITE, CHAR, 20, \$20],
[VISNAME, CHAR, 60, \$60],
[VISIT, NUM, 8],
[VISDT, NUM, 8, DATE9],

YKA46505 : URINALYSIS (CLABURI)

Urinalysis

1. Was a Urinalysis sample collected?

[LBYNN, NUM,8],[LBYN, CHAR, 200,\$200]

[LBDTF, CHAR, 200, \$200],[LBDT, NUM, 8, DATE9]

(sdeYKA46505:t_CLAB4.LBYN)
[2] ☐ No
[1] ☐ (sdeYKA46505:t_CLAB4.DIPSTK)
Yes
Was Urine dipstick:
[1] ☐ Normal [DIPSTKN, NUM,8],[DIPSTK, CHAR, 200,\$200]
[2] ☐ (sdeYKA46505:t_CLAB4.ABNORM1)
Abnormal
If Abnormal, was sample sent to central lab?
[1] ☐ Yes [ABNORM1N, NUM,8],[ABNORM1, CHAR, 200,\$200]
Date of sample collection:
Req / Req / Req (2009-2025) (sdeYKA46505:t_CLAB4.LBDT)
Accession number: (sdeYKA46505:t_CLAB4.ACCNUM)
A20 [ACCNUM, CHAR, 20, \$20]
[2] ☐ No

CDD: sdeYKA46505 Table: t_CLAB4 Key Type: PATIENTVISIT		
Column Name	Column Data Type	Design Note
LBYN	NUMERIC	
DIPSTK	NUMERIC	
ABNORM1	NUMERIC	
LBDT	DATE - DDMONYYYY	
ACCNUM	STRING(20) - A20	

Domain Name: [URIN]
Domain Label: [URINALYSIS]
Additional items:

[STUDY, CHAR, 20, \$20],
[PT, CHAR, 20, \$20],
[INVSITE, CHAR, 20, \$20],
[VISNAME, CHAR, 60, \$60],
[VISIT, NUM, 8],
[VISDT, NUM, 8, DATE9],

YKA46505 : ECG Base (ECG)		
ECG Base		
1.	Date of ECG	[ECGDTF, CHAR, 200, \$200],[ECGDT, NUM, 8, DATE9]
2.	Overall Interpretation of ECG *Please record abnormal/clinically significant ECG findings on Relevant Medical History form	(sdeYKA46505:t_EG2BASE.EGINTPN) [1] <input type="radio"/> Normal [2] <input type="radio"/> Abnormal, Not Clinically Significant [3] <input type="radio"/> Abnormal, Clinically Significant* [EGINTPN, NUM,8],[EGINTP, CHAR, 200, \$200]

Form Design Note:

Edit Check to verify Med Hx form complete

Item Design Notes:	
Item No.	Design Note
2.	Edit Check to verify Med Hx form complete

CDD: sdeYKA46505 Table: t_EG2BASE Key Type: PATIENTVISIT		
Column Name	Column Data Type	Design Note
EGDT	DATE - DDMONYYYY	
EGINTPN	NUMERIC	

Domain Name: [ECG]
Domain Label: [ECG]
Additional items:

[STUDY, CHAR, 20, \$20],
[PT, CHAR, 20, \$20],
[INVSITE, CHAR, 20, \$20],
[VISNAME, CHAR, 60, \$60],
[VISIT, NUM, 8],
[VISDT, NUM, 8, DATE9],

PLEASE NOTE: APPEND ALL ECG DATASETS

YKA46505 : ECOG PERFORMANCE STATUS SCALE BASELINE (ECOG)		
ECOG PERFORMANCE STATUS SCALE BASELINE		
1.	Grade	(sdeYKA46505:t_ECOG1.ciGRADE) [0] <input type="radio"/> 0 [1] <input type="radio"/> 1 [2] <input type="radio"/> 2 [ECOGGRN, NUM, 8], [ECOGGR, CHAR, 200, \$200]

CDD: sdeYKA46505 Table: t_ECOG1 Key Type: PATIENTVISIT		
Column Name	Column Data Type	Design Note
ciGRADE	NUMERIC	

Domain Name: [ECOG]
Domain Label: [ECOG PERFORMANCE STATUS]
Additional items:

[STUDY, CHAR, 20, \$20],
[PT, CHAR, 20, \$20],
[INVSITE, CHAR, 20, \$20],
[VISNAME, CHAR, 60, \$60],
[VISIT, NUM, 8],
[VISDT, NUM, 8, DATE9],

PLEASE NOTE: APPEND ALL ECOG DATASETS

YKA46505 : PATIENT REPORTED OUTCOMES 2 (PROASM2)		
PATIENT REPORTED OUTCOMES 2		
1.	Did the subject complete the PRO Assessment?	<div>(sdeYKA46505:t_PROASM2.PROASM2) [1] <input type="radio"/> BPI-SF [PROASM2N, NUM, 8], [PROASM2, CHAR, 200, \$200]</div> <div>[95] <input type="radio"/> (sdeYKA46505:t_PROASM2.PROBPI) Not done [1] <input type="radio"/> Health Reasons [PROBPIN, NUM, 8], [PROBPI, CHAR, 200, \$200] [2] <input type="radio"/> Non-Health Reasons</div>

CDD: sdeYKA46505	Table: t_PROASM2	Key Type: PATIENTVISIT
Column Name	Column Data Type	Design Note
PROASM2	NUMERIC	
PROBPI	NUMERIC	

Domain Name: [PROASM2]
Domain Label: [PATIENT REPORTED OUTCOME2]
Additional items:

[STUDY, CHAR, 20, \$20],
[PT, CHAR, 20, \$20],
[INVSITE, CHAR, 20, \$20],
[VISNAME, CHAR, 60, \$60],
[VISIT, NUM, 8],
[VISDT, NUM, 8, DATE9],

YKA46505 : TARGETQ (TARGEQ)		
TARGETQ		
1.	Were there any Target Lesions identified?	(sdeYKA46505:t_TARGEQ.TARGETQ) [1] <input type="radio"/> Yes [2] <input type="radio"/> No [TARGETQN, NUM, 8], [TARGETQ, CHAR, 200, \$200]
2.	Were there any Non-Target Lesions identified?	(sdeYKA46505:t_TARGEQ.NONTARQ) [1] <input type="radio"/> Yes [2] <input type="radio"/> No [NONTARQN, NUM, 8], [NONTARQ, CHAR, 200, \$200]

CDD: sdeYKA46505 Table: t_TARGEQ Key Type: PATIENTVISIT		
Column Name	Column Data Type	Design Note
TARGETQ	NUMERIC	
NONTARQ	NUMERIC	

Domain Name: [TARGETQ]
Domain Label: [TARGETQ]
Additional items:

[STUDY, CHAR, 20, \$20],
[PT, CHAR, 20, \$20],
[INVSITE, CHAR, 20, \$20],
[VISNAME, CHAR, 60, \$60],
[VISIT, NUM, 8],
[VISDT, NUM, 8, DATE9],

YKA46505 : TARGET LESIONS (TUMOR_M)

	Lesion Number	Location	Date of Assessment	Method of Assessment	Length:
1.					
Measurable/Target Lesion Entry					
1.a	Lesion Number:	x (sdeYKA46505:t_TUMOR_M.LESNO) [LESNO, NUM,8]			
1.b	Location:	<div>(sdeYKA46505:t_TUMOR_M.LOCGRP1_1)</div> <div>[1] <input type="radio"/> Organ or soft tissue (longest axis)</div> <div>Pulldown List 1 (sdeYKA46505:t_TUMOR_M.LOCNUM1_1)</div> <div>[2] <input type="radio"/> Lymph nodes (shortest axis)</div> <div>Pulldown List 2 (sdeYKA46505:t_TUMOR_M.LOCNUMN2)</div> <div>[97] <input type="radio"/> Other Soft Tissue (longest axis), Specify:</div> <div>A200 (sdeYKA46505:t_TUMOR_M.SPECST_1)</div> <div>[SPECST, CHAR, 200, \$200]</div> <div>[98] <input type="radio"/> Other Organ (longest axis), Specify:</div> <div>A200 (sdeYKA46505:t_TUMOR_M.SPECOR_1)</div> <div>[SPECOR, CHAR, 200, \$200]</div>			
1.c	Date of Assessment:	Req / Req / Req (2009-2025) (sdeYKA46505:t_TUMOR_M.ASSED1)			
1.d	Method of Assessment:	<div>(sdeYKA46505:t_TUMOR_M.METHOTH1)</div> <div>[1] <input type="radio"/> Pulldown List 3 (sdeYKA46505:t_TUMOR_M.METHODN1)</div> <div>[99] <input type="radio"/> Other, specify: (sdeYKA46505:t_TUMOR_M.OTHSPEC)</div> <div>A200 [OTHSPEC, CHAR, 200, \$200]</div>			
1.e*	Length:	xxx mm (sdeYKA46505:t_TUMOR_M.LENGTH) [LENGTH, NUM,8]			
Total Length, All Target Lesions					
2.*	Total Length (all target lesions):	xxx mm (sdeYKA46505:t_TUMOR_M.TAREAC) [TAREAC, NUM,8]			
* Item is not required					

Form Design Note:

This is an Add Entry form.

Item Design Notes:	
Item No.	Design Note
1.b	Location will be mapped to next visit.

Pulldown List 1:			
RefName	Display Text	Value	Design Note
ABDOMINAL	Abdominal	9	
ADRENAL	Adrenal	10	
BONE	Bone	6	
BRAIN	Brain	5	
BREAST	Breast	11	
COLON	Colon	8	
LIVER	Liver	2	
LUNG	Lung	1	
OVARY	Ovary	12	
PROSTATE	Prostate	7	
SKIN	Skin	4	
SPLEEN	Spleen	13	

Pulldown List 2:			
RefName	Display Text	Value	Design Note
WALRING	Waldeyer ring	1	
CERVSUP	Cervical - Supraclavicular	2	
CERVOCC	Cervical - Occipital	3	
CERVPREAU	Cervical - Pre-auricular	4	
INF	Infraclavicular	5	
AXPEC	Axillary and pectoral	6	
MED	Mediastinal	7	
HIL	Hilar	8	
EPBR	Epitrochlear and brachial	9	
SP	Spleen	10	
PAR	Paraaortic	11	

Domain Name: [TUMOR_M]

Domain Label: [TARGET LESIONS]

Additional items:

[STUDY, CHAR, 20, \$20],
[PT, CHAR, 20, \$20],
[INVSITE, CHAR, 20, \$20],
[VISNAME, CHAR, 60, \$60],
[VISIT, NUM, 8],
[VISDT, NUM, 8, DATE9],

PLEASE NOTE: MERGE TAREAC (TOTAL LENGTH) WITH THE REST OF THE VARIABLE IN TUMOR_M

MES	Mesenteric	12	
ILL	Illiatic	13	
INGFEM	Inguinal and femoral	14	
POP	Popliteal	15	

Pulldown List 3:			
RefName	Display Text	Value	Design Note
BONESCAN	Bone scan	1	
PETCT	PET/CT	11	
PET	PET	2	
RADIONUCLIDE	Radionuclide	3	
CT	CT	4	
SPIRALCT	Spiral CT	5	
MRI	MRI	6	
XRAY	X-Ray	7	
PHOTOMEASURE	Photo measurement	8	
CLINASSESS	Clinical Assessment	9	
LESNOTASSESS	Lesion not assessed	10	
CALIPER	Caliper	14	

CDD: sdeYKA46505 Table: t_TUMOR_M Key Type: PATIENTVISIT		
Column Name	Column Data Type	Design Note
LOCGRPN1_1	NUMERIC	
LOCNUMN1_1	STRING(255) - 9, 10, 6, 5, 11, 8, 2, 1, 12, 7, 4, 13	
LOCNUMN2	STRING(255) - 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15	
SPECST_1	STRING(200) - A200	
SPECOR_1	STRING(200) - A200	
ASSEDIT	DATE - DDMYYYYY	
METHOTHN1	NUMERIC	
METHODN1	STRING(255) - 1, 11, 2, 3, 4, 5, 6, 7, 8, 9, 10, 14	
OTHSPEC	STRING(200) - A200	
LENGTH	NUMERIC - N3	
TAREAC	NUMERIC - N3	
LESNO	NUMERIC - N1	

YKA46505 : NON-TARGET LESIONS (TUMOR_NTB)				
Non-Target Lesion				
1. Were any Non-Target Lesions identified?		(sdeYKA46505:t_TUMOR_NTB.LESIOYNN) [1] <input type="radio"/> Yes [2] <input type="radio"/> No		[LESIOYNN, NUM,8],[LESIOYNC, CHAR, 200,\$200]
Lesion Number		Location		Date of Assessment Method of Assessment
2.				
Lesion Details Entry				
2.a Lesion Number:		xx (sdeYKA46505:t_TUMOR_NTB.LESNO) [LESNO, NUM,8]		
2.b Location:		(sdeYKA46505:t_TUMOR_NTB.LOCGRP2) [1] <input type="radio"/> Organ or soft tissue Pull down List 1 (sdeYKA46505:t_TUMOR_NTB.LOCNUM4) [2] <input type="radio"/> Lymph nodes Pull down List 2 (sdeYKA46505:t_TUMOR_NTB.LOCNUM2) [3] <input type="radio"/> Other non-measureable disease Pull down List 3 (sdeYKA46505:t_TUMOR_NTB.LOCNUM3) [4] <input type="radio"/> Abnormal tumor marker, Specify: (sdeYKA46505:t_TUMOR_NTB.SPECTM) A200 [SPECTM, CHAR, 200, \$200] [97] <input type="radio"/> Other Soft Tissue, Specify: (sdeYKA46505:t_TUMOR_NTB.SPECST) A200 [SPECST, CHAR, 200, \$200] [98] <input type="radio"/> Other Organ, Specify: (sdeYKA46505:t_TUMOR_NTB.SPECOR) A200 [SPECOR, CHAR, 200, \$200]		
2.c Date of Assessment:		Req / Req / Req (2009-2025) (sdeYKA46505:t_TUMOR_NTB.ASSED)		
2.d Method of Assessment:		(sdeYKA46505:t_TUMOR_NTB.METHOTHN) [1] <input type="radio"/> Pull down List 4 (sdeYKA46505:t_TUMOR_NTB.METHODN) [99] <input type="radio"/> Other, specify: (sdeYKA46505:t_TUMOR_NTB.OTHSPEC) A200 [OTHSPEC, CHAR, 200, \$200]		

Form Design Note:

This is an Add Entry form.

Item Design Notes:	
Item No.	Design Note
2.b	Location will be mapped to TUMOR_NTP at next visit.

Pull down List 1:			
RefName	Display Text	Value	Design Note
ABDOMINAL	Abdominal	9	
ADRENAL	Adrenal	10	
BONE	Bone	6	
BRAIN	Brain	5	
BREAST	Breast	11	
COLON	Colon	8	
LIVER	Liver	2	
LUNG	Lung	1	
OVARY	Ovary	12	
PROSTATE	Prostate	7	
SKIN	Skin	4	
SPLEEN	Spleen	13	
BIOMARKER	Biomarker	14	

Pull down List 2:			
RefName	Display Text	Value	Design Note
WALRING	Waldeyer ring	1	
CERVSUP	Cervical - Supraclavicular	2	
CERVOCC	Cervical - Occipital	3	
CERVPREAU	Cervical - Pre-auricular	4	
INF	Infraclavicular	5	
AXPEC	Axillary and pectoral	6	

Domain Name: [TUMOR_NTB]
Domain Label: [NON-TARGET LESIONS]
Additional items:

[STUDY, CHAR, 20, \$20],
[PT, CHAR, 20, \$20],
[INVSITE, CHAR, 20, \$20],
[VISNAME, CHAR, 60, \$60],
[VISIT, NUM, 8],
[VISDT, NUM, 8, DATE9],

PLEASE NOTE: PLEASE MERGE LESIOYNN AND LESIOYNC WITH THE REST OF THE VARIABLES IN TUMOR_NTB

MED	Mediastinal	7	
HIL	Hilar	8	
EPBR	Epitrochlear and brachial	9	
SP	Spleen	10	
PAR	Paraaortic	11	
MES	Mesenteric	12	
ILL	Illiatic	13	
INGFEM	Inguinal and femoral	14	
POP	Popliteal	15	

Pulldown List 3:			
RefName	Display Text	Value	Design Note
PLEFF	Pericardial Effusion	1	
PEEFF	Pleural Effusion	2	
ASCITES	Ascites	3	
BONEL	Bone Lesions	4	
LDISEA	Leptomeningeal Disease	5	
IBDISEA	Inflammatory Breast Disease	6	
LYMPHCP	Lymphangitis Cutis / Pulmonis	7	
ABMASS	Abdominal masses that are not confirmed by imaging	8	
CYSTICL	Cystic Lesions	9	
TUMORL	Tumor Lesions in a previously irradiated area	10	

Pulldown List 4:			
RefName	Display Text	Value	Design Note
BONESCAN	Bone scan	1	
PETCT	PET/CT	11	
PET	PET	2	
RADIONUCLIDE	Radionuclide	3	
CT	CT	4	
SPIRALCT	Spiral CT	5	
MRI	MRI	6	
XRAY	X-Ray	7	
PHOTOMEASURE	Photo measurement	8	
CLINASSESS	Clinical Assessment	9	
CALIPER	Caliper	14	
NOTASS	Not Assessed	95	

CDD: sdeYKA46505 Table: t_TUMOR_NTB Key Type: PATIENTVISIT		
Column Name	Column Data Type	Design Note
LESIOYNN	NUMERIC	
LESNO	NUMERIC - N2	
LOCGRPN2	NUMERIC	
LOCNUMN4	STRING(255) - 9, 10, 6, 5, 11, 8, 2, 1, 12, 7, 4, 13, 14	
LOCNUMN2	STRING(255) - 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15	
LOCNUMN3	STRING(255) - 1, 2, 3, 4, 5, 6, 7, 8, 9, 10	
SPECTM	STRING(200) - A200	
SPECST	STRING(200) - A200	
SPECOR	STRING(200) - A200	
ASSED	DATE - DDMONYYYY	
METHOTHN	NUMERIC	
METHODN	STRING(255) - 1, 11, 2, 3, 4, 5, 6, 7, 8, 9, 14, 95	
OTHSPEC	STRING(200) - A200	

YKA46505 : ADDITIONAL PK SUBSTUDY INFORMED CONSENT (PKBS)		
ADDITIONAL PK SUBSTUDY INFORMED CONSENT		
1.	Date Pharmacokinetic (PK) substudy Informed Consent Signed: [PKSAMPN, NUM,8],[PKSAMP, CHAR, 200,\$200]	(sdeYKA46505:t_PKSSIC.PKSAMPN) [1] <input type="radio"/> Date Req <input checked="" type="checkbox"/> / Req <input checked="" type="checkbox"/> / Req <input checked="" type="checkbox"/> (2009-2025) (sdeYKA46505:t_PKSSIC.PKDATE) [94] <input type="radio"/> Not Applicable
2.*	Indicate which PK the subject will enter into:	(sdeYKA46505:t_PKSSIC.TYPEPK) [1] <input type="radio"/> Sparse [2] <input type="radio"/> Intensive [TYPEPKN, NUM,8],[TYPEPK, CHAR, 200,\$200]
* Item is not required		

Item Design Notes:	
Item No.	Design Note
2.	If = Sparse, PKSAMPS form will appear dynamically at C1D14 If = Intensive, PKSAMPI form will appear dynamically at C1D1

CDD: sdeYKA46505 Table: t_PKSSIC Key Type: PATIENTVISIT		
Column Name	Column Data Type	Design Note
PKSAMPN	NUMERIC	
PKDATE	DATE - DDMONYYYY	
TYPEPK	NUMERIC	

Domain Name: [PKBS]
Domain Label: [ADDITIONAL PK SUBSTUDY INFORM CONSENT]
Additional items:
[STUDY, CHAR, 20, \$20],
[PT, CHAR, 20, \$20],
[INVSITE, CHAR, 20, \$20],
[VISNAME, CHAR, 60, \$60],
[VISIT, NUM, 8],
[VISDT, NUM, 8, DATE9],

YKA46505 : AE, CONMED, CPROC and HOSP (AE/CM/CP/HOSP)		
1.	Are there any Concomitant Procedures/Surgeries? [CPQN, NUM,8],[CPQ, CHAR, 200,\$200]	(sdeYKA46505:t_GATE.CPQN) [2] <input type="radio"/> No [1] <input type="radio"/> Yes
2.	Were any Prior/Concomitant Medications taken? [CMQN, NUM,8],[CMQ, CHAR, 200,\$200]	(sdeYKA46505:t_GATE.CMQN) [2] <input type="radio"/> No [1] <input type="radio"/> Yes
3.	Were there any Adverse Events? [AEQN, NUM,8],[AEQ, CHAR, 200,\$200]	(sdeYKA46505:t_GATE.AEQN) [2] <input type="radio"/> No [1] <input type="radio"/> Yes
4.	Were there any Hospitalizations? [HPQN, NUM,8],[HPQ, CHAR, 200,\$200]	(sdeYKA46505:t_GATE.HPQN) [2] <input type="radio"/> No [1] <input type="radio"/> Yes

Form Design Note:

1. If any of these are checked 'Yes', a corresponding page is dynamically created
Each dynamically created ONLY once

CDD: sdeYKA46505 Table: t_GATE Key Type: PATIENTVISIT		
Column Name	Column Data Type	Design Note
CPQN	NUMERIC	
CMQN	NUMERIC	
AEQN	NUMERIC	
HPQN	NUMERIC	

Domain Name: [GATE]
Domain Label: [AE,CONMED,CPROC AND HOSP]
Additional items:

[STUDY, CHAR, 20, \$20],
[PT, CHAR, 20, \$20],
[INVSITE, CHAR, 20, \$20],
[VISNAME, CHAR, 60, \$60],
[VISIT, NUM, 8],
[VISDT, NUM, 8, DATE9],

YKA46505 : ADVERSE EVENTS >1 STUDY TREATMENT (AE2) - Repeating Form

#	Sequence #	Adverse Event	Start Date	End Date	Severity	Relationship to Celgene Study Drug	Relationship to Other Study Treatment(s)	Action taken with respect to Celgene Study Drug
1								

Adverse Events

1.*	Sequence # <i>[read-only]</i>	[AESEQN, NUM,8]	xxx (sdeYKA46505:t_AE2.AESEQN)					
2.	Adverse Event	[AETERM, CHAR, 200, \$200]	A200 (sdeYKA46505:t_AE2.AETERM)					
3.*	AEDECOD <i>[hidden]</i>	[AEDECOD, CHAR, 200, \$200]	A200 (sdeYKA46505:t_AE2.AEDECOD)					
4.*	LLTCD <i>[hidden]</i>	[LLTCD, CHAR, 200, \$200]	A200 (sdeYKA46505:t_AE2.LLTCD)					
5.*	LLTNM <i>[hidden]</i>	LLTNM, CHAR, 200, \$200]	A200 (sdeYKA46505:t_AE2.LLTNM)					
6.*	HLTNM <i>[hidden]</i>	[HLTNM, CHAR, 200, \$200]	A200 (sdeYKA46505:t_AE2.HLTNM)					
7.*	HLGTNM <i>[hidden]</i>	[HLGTNM, CHAR, 200, \$200]	A200 (sdeYKA46505:t_AE2.HLGTNM)					
8.*	PTCD <i>[hidden]</i>	[PTCD, CHAR, 200, \$200]	A200 (sdeYKA46505:t_AE2.PTCD)					
9.*	DICTVER <i>[hidden]</i>	[DICTVER, CHAR, 200, \$200]	A200 (sdeYKA46505:t_AE2.DICTVER)					
10.	Start Date	[AESTDTF, CHAR, 200, \$200],[AESTDT, NUM, 8, DATE9]	Req/Unk / Req/Unk / Req (2009-2025) (sdeYKA46505:t_AE2.AESTDT)					
11.	End Date	[AEENDTF, CHAR, 200, \$200],[AEENDT, NUM, 8, DATE9]	(sdeYKA46505:t_AE2.AEONGON) [2] Req/Unk / Req/Unk / Req (2009-2025) (sdeYKA46505:t_AE2.AEENDT) [1] Ongoing [AEONGO, NUM,8],[AEONGO, CHAR, 200, \$200]					
12.	Severity	[AESEVNN, NUM,8], [AESEVN, CHAR, 200, \$200]	(sdeYKA46505:t_AE2.AESEVN) [1] Mild/Grade 1 [2] Moderate/Grade 2 [3] Severe/Grade 3 [4] Life-threatening/Grade 4 [5] Death/Grade 5					
13.	Relationship to Celgene Study Drug	[AERELNN, NUM,8], [AERELN, CHAR, 200, \$200]	(sdeYKA46505:t_AE2.AERELN) [1] Not suspected [2] Suspected					
14.	Relationship to Other Study Treatment(s)		(sdeYKA46505:t_AE2.AERELOTN) [1] Not suspected [AERELOTN, NUM,8], [2] Suspected [AERELOTH, CHAR, 200, \$200]					
15.	Action taken with respect to Celgene Study Drug	[AEACNN, NUM,8], [AEACN, CHAR, 200, \$200]	(sdeYKA46505:t_AE2.AEACN) [1] Dose not changed [2] Dose reduced [4] Dose interrupted [5] Dose interrupted and reduced [6] Drug withdrawn permanently [94] Not Applicable					
16.	Action Taken with respect to Other Study Treatment(s)	[AEACNOTN, NUM,8], [AEACNOTH, CHAR, 200, \$200]	(sdeYKA46505:t_AE2.AEACNOTN) [1] Dose not changed [2] Dose reduced [4] Dose interrupted [5] Dose interrupted and reduced [6] Drug withdrawn permanently [94] Not Applicable					
17.	Were concomitant and/or additional treatments given?		(sdeYKA46505:t_AE2.AECONTRN) [2] No [AECONTRN, NUM,8], [1] Yes [AECONTR, CHAR, 200, \$200]					
18.	Is this a Serious Adverse Event? Note: Serious Adverse Events are those that: • Result in death • Are immediately life-threatening • Require or prolong in-patient hospitalization • Result in persistent or significant disability or incapacity • Result in a congenital anomaly/birth defect	[AESERNN, NUM,8], [AESERN, CHAR, 200, \$200]	(sdeYKA46505:t_AE2.AESERN) [2] No [1] Yes					

Domain Name: [AE]

Domain Label: [Adverse Events]

Additional items:

[STUDY, CHAR, 20, \$20],
[PT, CHAR, 20, \$20],
[INVSITE, CHAR, 20, \$20],
[VISNAME, CHAR, 60, \$60],
[VISIT, NUM, 8],
[VISDT, NUM, 8, DATE9],

http://usadc-vsi46sp2a.quintiles.net/YKA46505/pfts.dll?S=304d1838&C=TM_169&FMID=0&FMRV=0&ISID=0&ITID=0&VM=2&TN=YKA46505&SP=&AS=2047&CP=65535&FP=0&RSV=0

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• Are other important medical events		
Serious Adverse Events must be reported within 24 hrs to Celgene Corporation.		
19.*	AEMODIFY [hidden] <div>[AEMODIFY, CHAR, 200, \$200]</div>	<div>A200</div> <div>(sdeYKA46505:t_AE2.AEMODIFY)</div>
20.*	AEBODSYS [hidden] <div>[AEBODSYS, CHAR, 200, \$200]</div>	<div>A200</div> <div>(sdeYKA46505:t_AE2.AEBODSYS)</div>
21.*	AETRTEM [hidden] <div>[AETRTEM, CHAR, 200, \$200]</div>	<div>A200</div> <div>(sdeYKA46505:t_AE2.AETRTEM)</div>
* Item is not required		

Form Design Note:
AE2 to be associated with CMED1

CDD: sdeYKA46505 Table: t_AE2 Key Type: PATIENTVISIT		
Column Name	Column Data Type	Design Note
AESEQN	NUMERIC - N3	
AETERM	STRING(200) - A200	
AEDECOD	STRING(200) - A200	
LLTCD	STRING(200) - A200	
LLTNM	STRING(200) - A200	
HLTNM	STRING(200) - A200	
HLGTNM	STRING(200) - A200	
PTCD	STRING(200) - A200	
DICTVER	STRING(200) - A200	
AESTDT	DATE - DDMONYYYY	
AEENDT	DATE - DDMONYYYY	
AESEVN	NUMERIC	
AERELN	NUMERIC	
AERELOTN	NUMERIC	
AEACN	NUMERIC	
AEACNOTN	NUMERIC	
AECONTRN	NUMERIC	
AESERN	NUMERIC	
AEMODIFY	STRING(200) - A200	
AEONGON	NUMERIC	
AEBODSYS	STRING(200) - A200	
AETRTEM	STRING(200) - A200	

/22/2011

22.	Frequency	<div>[CMFQ, NUM, 8] [CMFQU, CHAR, 200, \$200]</div>	<div>(sdeYKA46505:t_CM1.CMFQ) [1] <input type="radio"/> Pulldown List 2 <input checked="" type="checkbox"/> (sdeYKA46505:t_CM1.CMDOSFQN) [99] <input type="radio"/> Other, specify: <div>A200</div> (sdeYKA46505:t_CM1.CMFQOTH) <div>[CMDOSFQN, NUM, 8] [CMDOSFQ, CHAR, 200, \$200]</div></div>
23.	Route	<div>[CMROUTE, CHAR, 200, \$200]</div>	<div>Pulldown List 3 <input checked="" type="checkbox"/> (sdeYKA46505:t_CM1.CMROUTEN)</div>
24.*	CMCLAS <i>[hidden]</i>	<div>[CMROUTEN, NUM, 8] [CMCLAS, CHAR, 200, \$200]</div>	<div>A200 (sdeYKA46505:t_CM1.CMCLAS) <div>[CMFQOTH, CHAR, 200, \$200]</div></div>
25.*	CMCLASCD <i>[hidden]</i>		<div>A200 (sdeYKA46505:t_CM1.CMCLASCD) <div>[CMCLASCD, CHAR, 200, \$200]</div></div>
26.*	CMMODIFY <i>[hidden]</i>		<div>A200 (sdeYKA46505:t_CM1.CMMODIFY) <div>[CMMODIFY, CHAR, 200, \$200]</div></div>
* Item is not required			

Form Design Note:

CMED1 to be associated with AE2

Pulldown List 1:			
RefName	Display Text	Value	Design Note
eintCMFreqmg	milligrams (mg)	1	
eintCMFreqGm	grams (Gm)	2	
eintCMFreqIU	international units (IU)	3	
eintCMFreqml	milliliters (ml)	4	
eintCMUnitoz	ounce (oz)	5	

Pulldown List 2:			
RefName	Display Text	Value	Design Note
eintCMFreqQD	Once daily (OD)	1	
eintCMFreqBID	Twice daily (BID)	2	
eintCMFreqTID	Three times daily (TID)	3	
eintCMFreqQID	Four times daily (QID)	4	
eintCMFreqQOD	Every other day (QOD)	5	
eintCMFreqQW	Once weekly (QW)	6	
eintCMFreqQAM	In morning (QAM)	7	
eintCMFreqQHS	At night (QHS)	8	
eintCMFreqPRN	As needed (PRN)	9	

Pulldown List 3:			
RefName	Display Text	Value	Design Note
mintRouteBUC	Buccal Mucosa (BUC)	1	
mintRouteCAUD	Caudal (CAUD)	2	
mintRouteAU	Ear, both (AU)	3	
mintRouteAD	Ear, right (AU)	4	
mintRouteAS	Ear, left (AS)	5	
mintRouteAN	Ear, unspecified (AN)	6	
mintRouteEPI	Epidural (EPI)	7	
mintRouteON	Eye, unspecified (Intraocular) (ON)	8	
mintRouteOS	Eye, left (OS)	9	
mintRouteOD	Eye, right (OD)	10	
mintRouteOU	Eye, both (OU)	11	
mintRouteMP	Implant (MP)	12	
mintRouteIHNB	Inhalation, Nasal, both (IHNB)	13	
mintRouteIHNL	Inhalation, Nasal, left (IHNL)	14	
mintRouteIHNR	Inhalation, Nasal, right (IHNR)	15	
mintRouteIHO	Inhalation, Oral (IHO)	16	
mintRouteIH	Inhalation, unspecified (IH)	17	
mintRouteINJ	Injection, unspecified (INJ)	18	
mintRoutePROX	Interproximal (between teeth) (PROX)	19	
mintRouteIA	Intraarterial (IA)	20	
mintRouteIR	Intraarticular (IR)	21	
mintRouteIC	Intracardiac(IC)	22	
mintRouteID	Intradermal (ID)	23	

mintRouteIG	Intragastric (IG)	24	
mintRouteIJ	Intrajejunal (IJ)	25	
mintRouteIM	Intramuscular (IM)	26	
mintRouteIN	Intranasal (IN)	27	
mintRouteIO	Intraoral (IO)	28	
mintRouteIP	Intraperitoneal (IP)	29	
mintRouteIL	Intrapleural (IL)	30	
mintRouteISP	Intraspinal (ISP)	31	
mintRouteIT	Intrathecal (IT)	32	
mintRouteTR	Intratracheal (TR)	33	
mintRouteIU	Intrauterine (IU)	34	
mintRouteIV	Intravenous (IV)	35	
mintRouteIVEN	Intraventricular (IVEN)	36	
mintRouteIRG	Irrigation (IRG)	37	
mintRouteLING	Lingual Mucosa (LING)	38	
mintRouteNG	Nasogastric (NG)	39	
mintRoutePO	Oral (PO)	40	
mintRouteOSTY	Ostomy (any) (OSTY)	41	
mintRoutePA	Palatal (PA)	42	
mintRoutePR	Per Rectal (PR)	43	
mintRoutePJ	Periarticular (PJ)	44	
mintRouteRAD	Radiation Therapy by any route (RAD)	45	
mintRouteSC	Subcutaneous (SC)	46	
mintRouteSG	Subgingival (SG)	47	
mintRouteSL	Sublingual (SL)	48	
mintRouteTO	Topical (TO)	49	
mintRouteTD	Transdermal (TD)	50	
mintRouteUR	Urethral (UR)	51	
mintRouteVA	Vaginal (VA)	52	

CDD: sdeYKA46505 Table: t_CM1 Key Type: PATIENTVISIT		
Column Name	Column Data Type	Design Note
CMSEQN	NUMERIC - N2	
CMTRT	STRING(200) - A200	
CMDECOD	STRING(200) - A200	
ATC1	STRING(200) - A200	
ATC1_CODE	STRING(200) - A200	
ATC2	STRING(200) - A200	
ATC2_CODE	STRING(200) - A200	
ATC3	STRING(200) - A200	
ATC3_CODE	STRING(200) - A200	
ATC4	STRING(200) - A200	
ATC4_CODE	STRING(200) - A200	
PN_CODE	STRING(200) - A200	
SYN	STRING(200) - A200	
SYN_CODE	STRING(200) - A200	
GENERICNM	STRING(200) - A200	
DICTVER	STRING(200) - A200	
CMREAS	STRING(200) - A200	
CMDOSE	STRING(50) - A50	
CMDSOTHN	NUMERIC	
CMDOSUN	STRING(255) - 1, 2, 3, 4, 5	
CMDSPOTH	STRING(200) - A200	
CMFQ	NUMERIC	
CMDOSFQN	STRING(255) - 1, 2, 3, 4, 5, 6, 7, 8, 9	
CMFQOTH	STRING(200) - A200	
CMROUTEN	STRING(255) - 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23, 24, 25, 26, 27, 28, 29, 30, 31, 32, 33, 34, 35, 36, 37, 38, 39, 40, 41, 42, 43, 44, 45, 46, 47, 48, 49, 50, 51, 52	
CMCLAS	STRING(200) - A200	
CMCLASCD	STRING(200) - A200	
CMMODIFY	STRING(200) - A200	
CMSTDT	DATE - DDMYYYYY	
CMONGON	NUMERIC	
CMENDT	DATE - DDMYYYYY	

YKA46505 : CONCOMITANT PROCEDURES/SURGERIES (CPROC) - Repeating Form

#		Procedure/Surgery	Indication	Date of Procedure/Surgery	Elective Procedure/Surgery
1	<div><div></div></div>				

Concomitant Procedures

1.*	Sequence # [hidden]		xx (sdeYKA46505:t_CPRO.CPSEQN)	[CPSEQN, NUM, 8]
2.	Procedure/Surgery	[CPTERM, CHAR, 200, \$200]	A200 (sdeYKA46505:t_CPRO.CPTERM)	
3.*	Coded Term [hidden]	[CPDECOD, CHAR, 200, \$200]	A200 (sdeYKA46505:t_CPRO.CPDECOD)	
4.	Indication	[CPINDI, CHAR, 200, \$200]	A200 (sdeYKA46505:t_CPRO.CPINDI)	
5.*	CPMODIFY [hidden]	[CPMODIFY, CHAR, 200, \$200]	A200 (sdeYKA46505:t_CPRO.CPMODIFY)	
6.*	CPBODSYS [hidden]	[CPBODSYS, CHAR, 200, \$200]	A200 (sdeYKA46505:t_CPRO.CPBODSYS)	
7.*	LLTCDP [hidden]	[LLTCDP, CHAR, 200, \$200]	A200 (sdeYKA46505:t_CPRO.LLTCDP)	
8.*	LLTNMP [hidden]	[LLTNMP, CHAR, 200, \$200]	A200 (sdeYKA46505:t_CPRO.LLTNMP)	
9.*	HLTNMP [hidden]	[HLTNMP, CHAR, 200, \$200]	A200 (sdeYKA46505:t_CPRO.HLTNMP)	
10.*	HLGTNMP [hidden]	[HLGTNMP, CHAR, 200, \$200]	A200 (sdeYKA46505:t_CPRO.HLGTNMP)	
11.*	PTCDP [hidden]	[PTCDP, CHAR, 200, \$200]	A200 (sdeYKA46505:t_CPRO.PTCDP)	
12.*	DICTVER [hidden]	[DICTVER, CHAR, 200, \$200]	A200 (sdeYKA46505:t_CPRO.DICTVER)	
13.	Date of Procedure/Surgery		Req / Req / Req (2009-2025) (sdeYKA46505:t_CPRO.CPDT)	[CPDTF, CHAR, 200, \$200],[CPDT, NUM, 8, DATE9]
14.	Was the Procedure/Surgery elective?	[CPELCTNN, NUM, 8], [CPELECTN, CHAR, 200, \$200]	(sdeYKA46505:t_CPRO.CPELECTN) [2] No [1] Yes	

* Item is not required

CDD: sdeYKA46505 Table: t_CPRO Key Type: PATIENTVISIT		
Column Name	Column Data Type	Design Note
CPTERM	STRING(200) - A200	
CPDECOD	STRING(200) - A200	
CPINDI	STRING(200) - A200	
CPMODIFY	STRING(200) - A200	
CPBODSYS	STRING(200) - A200	
LLTCDP	STRING(200) - A200	
LLTNMP	STRING(200) - A200	
HLTNMP	STRING(200) - A200	
HLGTNMP	STRING(200) - A200	
PTCDP	STRING(200) - A200	
DICTVER	STRING(200) - A200	
CPDT	DATE - DDMYYYYY	
CPELECTN	NUMERIC	
CPSEQN	NUMERIC - N2	

Domain Name: [CPROC]
Domain Label: [CONCOMITANT PROCEDURES/SURGERIES]
Additional items:

[STUDY, CHAR, 20, \$20],
[PT, CHAR, 20, \$20],
[INVSITE, CHAR, 20, \$20],
[VISNAME, CHAR, 60, \$60],
[VISIT, NUM, 8],
[VISDT, NUM, 8, DATE9],

YKA46505 : HOSPITALIZATION (HOSP) - Repeating Form

#		For which AE number was the subject hospitalized?	Date admitted to the hospital:	Date discharged from the hospital:	Provide number of days spent in Special Care Units and/or Standard Care Units:
1	<div><div></div><div></div><div></div></div>				

HOSPITALIZATION

1. For which AE number was the subject hospitalized?

xxx (sdeYKA46505:t_HOSP.SEQNUM) [SEQNUM, NUM, 8]

2. Date admitted to the hospital:

[DTADMDTF, CHAR, 200, \$200],[DTADMDT, NUM, 8, DATE9]

Req / Req / Req (2009-2025) (sdeYKA46505:t_HOSP.DTADM)

3. Date discharged from the hospital:

[DTDISDTF, CHAR, 200, \$200],[DTDISDT, NUM, 8, DATE9]

Req / Req / Req (2009-2025) (sdeYKA46505:t_HOSP.DTDIS)

4. Provide number of days spent in Special Care Units and/or Standard Care Units:

[CBSDAYN, NUM, 8],
[CBSDAY, CHAR, 200, \$200]

[CBCN, NUM, 8],
[CBC, CHAR, 200, \$200]

(sdeYKA46505:t_HOSP.cbSDAY1)
[1] ☐ Special Care Units xxx.xx (sdeYKA46505:t_HOSP.SDAY1) [SDAY1, NUM, 8, 3.2]
(sdeYKA46505:t_HOSP.CHECK2_CBC)
[2] ☐ Standard Care Units xxx.xx (sdeYKA46505:t_HOSP.SDAY2) [SDAY2, NUM, 8, 3.2]

CDD: sdeYKA46505 Table: t_HOSP Key Type: PATIENTVISIT

Column Name	Column Data Type	Design Note
SEQNUM	NUMERIC - N3	
DTADM	DATE - DDMONYYYY	
DTDIS	DATE - DDMONYYYY	
cbSDAY1	STRING(255)	
SDAY1	FLOAT - F6.2	
CHECK2_CBC	STRING(255)	
SDAY2	FLOAT - F6.2	

Domain Name: [HOSP]
Domain Label: [HOSPITALIZATION]
Additional items:

[STUDY, CHAR, 20, \$20],
[PT, CHAR, 20, \$20],
[INVSITE, CHAR, 20, \$20],
[VISNAME, CHAR, 60, \$60],
[VISIT, NUM, 8],
[VISDT, NUM, 8, DATE9],

YKA46505 : PRINCIPAL INVESTIGATOR'S SIGNATURE (PISIGN)		
PRINCIPAL INVESTIGATOR'S SIGNATURE		
1. Is the case book ready to be signed?	(sdeYKA46505:t_PISIGN.SGBOOKN) [1] <input type="radio"/> Yes [2] <input type="radio"/> No	[SGBOOKN, NUM, 8],[SGBOOK, CHAR, 200,\$200]

CDD: sdeYKA46505 Table: t_PISIGN Key Type: PATIENTVISIT		
Column Name	Column Data Type	Design Note
SGBOOKN	NUMERIC	

Domain Name: [PISIGN]
Domain Label: [PRINCIPAL INVESTIGATOR'S SIGNATURE]
Additional items:

[STUDY, CHAR, 20, \$20],
[PT, CHAR, 20, \$20],
[INVSITE, CHAR, 20, \$20],
[VISNAME, CHAR, 60, \$60],
[VISIT, NUM, 8],
[VISDT, NUM, 8, DATE9],

YKA46505 : VITAL SIGNS (VITALS)									
Vital Signs									
1.	Weight	[WEIGHT, NUM, 8.1]			xxx.x	<input type="radio"/> lbs <input type="radio"/> kg (sdeYKA46505:t_VITALS4.WEIGHT)	[WEIGHTU, CHAR, 10, \$10]		
2.	Temperature	[TEMP, NUM, 8.1]			xxx.x	<input type="radio"/> °F <input type="radio"/> °C (sdeYKA46505:t_VITALS4.TEMP)	[TEMPU, CHAR, 10, \$10]		
3.	Blood Pressure	[SYSBP, NUM, 8]			xxx / (sdeYKA46505:t_VITALS4.SYSBP)	xxx mmHg (sdeYKA46505:t_VITALS4.DIABP)	[DIABP, NUM, 8]		
					Systolic	Diastolic	[DIABPU, CHAR, 10, \$10]		
4.	Pulse	[PULSE, NUM, 8, 8.1]			xxx	bpm (sdeYKA46505:t_VITALS4.PULSE)	[PULSEU, CHAR, 10, \$10]		

Item Design Notes:	
Item No.	Design Note
1.	WEIGHT_UNIT - This column will contain the unit as selected in InForm. WEIGHT_NORM - This column will contain the normalized value of the number.
2.	TEMP_UNIT - This column will contain the unit as selected in InForm. TEMP_NORM - This column will contain the normalized value of the number.

Domain Name: [VS]
Domain Label: [VITAL SIGNS]
Additional items:

[STUDY, CHAR, 20, \$20],
[PT, CHAR, 20, \$20],
[INVSITE, CHAR, 20, \$20],
[VISNAME, CHAR, 60, \$60],
[VISIT, NUM, 8],
[VISDT, NUM, 8, DATE9],

CDD: sdeYKA46505 Table: t_VITALS4 Key Type: PATIENTVISIT		
Column Name	Column Data Type	Design Note
WEIGHT	FLOAT - F5.1	
TEMP	FLOAT - F5.1	
SYSBP	NUMERIC - N3	
DIABP	NUMERIC - N3	
PULSE	NUMERIC - N3	

YKA46505 : ECOG PERFORMANCE STATUS SCALE (ECOG2)		
ECOG PERFORMANCE STATUS SCALE (ECOG2)		
1.	Grade	<div><div>[ECOGGRN, NUM, 8], [ECOGGR, CHAR, 200, \$200]</div><div>(sdeYKA46505:t_ECOG2.grade) [0] 0 [1] 1 [2] 2 [3] 3 [4] 4 [5] 5</div></div>

CDD: sdeYKA46505 Table: t_ECOG2 Key Type: PATIENTVISIT		
Column Name	Column Data Type	Design Note
grade	NUMERIC	

Domain Name: [ECOG]

Domain Label: [ECOG PERFORMANCE STATUS]

Additional items:

[STUDY, CHAR, 20, \$20],

[PT, CHAR, 20, \$20],

[INVSITE, CHAR, 20, \$20],

[VISNAME, CHAR, 60, \$60],

[VISIT, NUM, 8],

[VISDT, NUM, 8, DATE9],

YKA46505 : PATIENT REPORTED OUTCOMES 1 (PROASM1)		
PATIENT REPORTED OUTCOMES 1		
1.	Did the subject complete the BPI-SF PRO Assessment? <div><div>[BPIPron, NUM, 8], [BPIPRO, CHAR, 200, \$200]</div><div>[PRONO2N, NUM, 8], [PRONO2, CHAR, 200, \$200]</div></div>	(sdeYKA46505:t_PROASM1.BPIPRO) [1] <input type="radio"/> Yes [95] <input type="radio"/> (sdeYKA46505:t_PROASM1.PRONO2) Not done [1] <input type="radio"/> Health Reasons [2] <input type="radio"/> Non-Health Reasons
2.	Did the subject complete the FACT-P PRO Assessment? <div><div>[PROFACTN, NUM, 8], [PROFACT, CHAR, 200, \$200]</div><div>[PRONON, NUM, 8], [PRONO, CHAR, 200, \$200]</div></div>	(sdeYKA46505:t_PROASM1.PROFACT) [1] <input type="radio"/> Yes [95] <input type="radio"/> (sdeYKA46505:t_PROASM1.PRONO) Not done [1] <input type="radio"/> Health Reasons [2] <input type="radio"/> Non-Health Reasons
3.	Did the subject complete the EQ-5D PRO Assessment? <div><div>[PROASMN, NUM, 8], [PROASM, CHAR, 200, \$200]</div><div>[PRONDN, NUM, 8], [PROND, CHAR, 200, \$200]</div></div>	(sdeYKA46505:t_PROASM1.PROASM) [1] <input type="radio"/> Yes [95] <input type="radio"/> (sdeYKA46505:t_PROASM1.PROND) Not done [1] <input type="radio"/> Health Reasons [2] <input type="radio"/> Non-Health Reasons

CDD: sdeYKA46505 Table: t_PROASM1 Key Type: PATIENTVISIT		
Column Name	Column Data Type	Design Note
BPIPRO	NUMERIC	
PRONO2	NUMERIC	
PROFACT	NUMERIC	
PRONO	NUMERIC	
PROASM	NUMERIC	
PROND	NUMERIC	

Domain Name: [PROASM1]

Domain Label: [PATIENT REPORTED OUTCOME1]

Additional items:

[STUDY, CHAR, 20, \$20],
[PT, CHAR, 20, \$20],
[INVSITE, CHAR, 20, \$20],
[VISNAME, CHAR, 60, \$60],
[VISIT, NUM, 8],
[VISDT, NUM, 8, DATE9],

YKA46505 : PHARMACOKINETIC (PK) INTENSIVE SAMPLING (PKSAMPI)			
PHARMACOKINETIC (PK) INTENSIVE SAMPLING			
1.	Lenalidomide dose administered	[DOSEN, NUM, 8], [DOSE, CHAR, 200, \$200]	Pulldown List 1 (sdeYKA46505:t_PKSAMPI.DOSE)
2.	Actual date for administration of Lenalidomide/placebo:	[ADMLDTF, CHAR, 200, \$200], [ADMLDT, NUM, 8, DATE9]	Req / Req / Req (2009-2025) (sdeYKA46505:t_PKSAMPI.ADMLDT)
3.	Actual time for administration of Lenalidomide/placebo:	[ADMLTMF, CHAR, 200, \$200], [ADMLTM, NUM, 8, TIME5]	Req : Req 24-hour clock (sdeYKA46505:t_PKSAMPI.ADMLTM)
4.	Actual date of last meal prior to administration of Len:	[MLADMDTF, CHAR, 200, \$200], [MLADMDT, NUM, 8, DATE9]	Req / Req / Req (2009-2025) (sdeYKA46505:t_PKSAMPI.MLADMDT)
5.	Actual time of last meal prior to administration of Le	[MLADMTMF, CHAR, 200, \$200], [MLADMTM, NUM, 8, TIME5]	Req : Req 24-hour clock (sdeYKA46505:t_PKSAMPI.MLADMTM)
6.	Actual time for the start of doxetaxel infusion:	[DOCTMF, CHAR, 200, \$200], [DOCTM, NUM, 8, TIME5]	Req : Req 24-hour clock (sdeYKA46505:t_PKSAMPI.DOCTM)
7.	Actual time for any meal eaten within 4 hours followi	[INTPKTMF, CHAR, 200, \$200], [INTPKTM, NUM, 8, TIME5]	Req : Req 24-hour clock (sdeYKA46505:t_PKSAMPI.INTPKTM)
8.	Actual time of 1 Hour (post Lenalidomide dose) PK s	[PD1TMF, CHAR, 200, \$200], [PD1TM, NUM, 8, TIME5]	Req : Req 24-hour clock (sdeYKA46505:t_PKSAMPI.PD1TM)
9.	Actual time of 1.5 Hour (post Lenalidomide dose) PK	[PD15TMF, CHAR, 200, \$200], [PD15TM, NUM, 8, TIME5]	Req : Req 24-hour clock (sdeYKA46505:t_PKSAMPI.PD15TM)
10.	Actual time of 2 Hour (post Lenalidomide do	[PD2TMF, CHAR, 200, \$200], [PD2TM, NUM, 8, TIME5]	Req : Req 24-hour clock (sdeYKA46505:t_PKSAMPI.PD2TM)
11.	Actual time of 3 Hour (post Lenalidomide dos	[PD3TMF, CHAR, 200, \$200], [PD3TM, NUM, 8, TIME5]	Req : Req 24-hour clock (sdeYKA46505:t_PKSAMPI.PD3TM)
12.	Actual time of 4 Hour (post Lenalidomide dose)	[PD4TMF, CHAR, 200, \$200], [PD4TM, NUM, 8, TIME5]	Req : Req 24-hour clock (sdeYKA46505:t_PKSAMPI.PD4TM)
13.	Actual time of 6-8 Hour (post Lenalidomide dose) PK	[PD68TMF, CHAR, 200, \$200], [PD68TM, NUM, 8, TIME5]	Req : Req 24-hour clock (sdeYKA46505:t_PKSAMPI.PD68TM)

Pulldown List 1:			
RefName	Display Text	Value	Design Note
DOSEA	25 mg QD	1	
DOSEB	20 mg QD	2	
DOSEC	15 mg QD	3	
DOSED	10 mg QD	4	
DOSEE	0 mg QD	5	

CDD: sdeYKA46505 Table: t_PKSAMPI Key Type: PATIENTVISIT		
Column Name	Column Data Type	Design Note
MLADMDT	DATE - DDMYYYYY	
MLADMTM	DATE - HHMM	
DOCTM	DATE - HHMM	
INTPKTM	DATE - HHMM	
PD1TM	DATE - HHMM	
PD15TM	DATE - HHMM	
PD2TM	DATE - HHMM	
PD3TM	DATE - HHMM	
PD4TM	DATE - HHMM	
PD68TM	DATE - HHMM	
DOSE	STRING(255) - 1, 2, 3, 4, 5	
ADMLDT	DATE - DDMYYYYY	
ADMLTM	DATE - HHMM	

Domain Name: [PKSAMPI]
Domain Label: [PHARMACOKINETIC (PK) INTENSIVE SAMPLING]
Additional items:

[STUDY, CHAR, 20, \$20],
[PT, CHAR, 20, \$20],
[INVSITE, CHAR, 20, \$20],
[VISNAME, CHAR, 60, \$60],
[VISIT, NUM, 8],
[VISDT, NUM, 8, DATE9],

YKA46505 : BIOMARKER BLOOD COLLECTION (BIOBC)		
BIOMARKER BLOOD COLLECTION		
1.	Was a Biomarker sample collected? <div>[LBYNN, NUM, 8], [LBYN, CHAR, 200, \$200]</div>	(sdeYKA46505:t_BIOBC.LBYNNb) [2] <input type="radio"/> No [1] <input type="radio"/> Yes [94] <input type="radio"/> Not Applicable
2. *	Collection Date <div>[LBDTF, CHAR, 200, \$200],[LBDT, NUM, 8, DATE9]</div>	Req <input type="checkbox"/> / Req <input type="checkbox"/> / Req <input type="checkbox"/> (2009-2025) (sdeYKA46505:t_BIOBC.LBDT5)
3. *	Accession number	A20 (sdeYKA46505:t_BIOBC.ACCNUM) <div>[ACCNUM, CHAR, 20, \$20]</div>
* Item is not required		

CDD: sdeYKA46505 Table: t_BIOBC Key Type: PATIENTVISIT		
Column Name	Column Data Type	Design Note
LBYNNb	NUMERIC	
LBDT5	DATE - DDMONYYYY	
ACCNUM	STRING(20) - A20	

Domain Name: [BIOBC]
Domain Label: [BIOMARKER BLOOD COLLECTION]
Additional items:

[STUDY, CHAR, 20, \$20],
[PT, CHAR, 20, \$20],
[INVSITE, CHAR, 20, \$20],
[VISNAME, CHAR, 60, \$60],
[VISIT, NUM, 8],
[VISDT, NUM, 8, DATE9],

YKA46505 : STUDY DRUG RECORD (STDRUG) - Repeating Form

#		Dose Start Date	Dose Stop Date	Dose Assigned	Reason for Dose Assignment
1	<div></div>				

Study Drug Record

1. Dose Start Date

[EXSTDTF, CHAR, 200, \$200],[EXSTD, NUM, 8, DATE9]

2. Dose Stop Date

[EXENDTF, CHAR, 200, \$200],[EXENDT, NUM, 8, DATE9]

3. Dose Assigned

(sdeYKA46505:t_EX2.EXDOSEN)
Dose Assigned:
[1] 25 mg QD
[2] 20 mg QD
[3] 15 mg QD
[4] 10 mg QD
[5] 0 mg QD
[6] Permanently Discontinued

[EXDOSENN, NUM,8],
[EXDOSEN, CHAR, 200, \$200]

4. Reason for Dose Assignment

[EXREASN, NUM,8],
[EXREASN2, CHAR, 200, \$200]

(sdeYKA46505:t_EX2.EXREASN2)
[1] Adverse Event, specify AE Sequence # | xxx | (sdeYKA46505:t_EX2.DSAENUM) [DSAENUM, NUM,8]
[7] Per protocol
[99] Other, specify A200 (sdeYKA46505:t_EX2.EXOTH)
[EXOTH, CHAR, 200, \$200]

Form Design Note:

The team recommends that a statement about reconciliation between dose changes due to Adverse Event and the Adverse Events page is added to the study Monitoring Plan.

CDD: sdeYKA46505 Table: t_EX2 Key Type: PATIENTVISIT		
Column Name	Column Data Type	Design Note
EXSTD	DATE - DDMONYYYY	
EXEND	DATE - DDMONYYYY	
EXDOSEN	NUMERIC	
EXREASN2	NUMERIC	
DSAENUM	NUMERIC - N3	
EXOTH	STRING(200) - A200	

Domain Name: [EX2]
Domain Label: [STUDY DRUG RECORD]
Additional items:

[STUDY, CHAR, 20, \$20],
[PT, CHAR, 20, \$20],
[INVSITE, CHAR, 20, \$20],
[VISNAME, CHAR, 60, \$60],
[VISIT, NUM, 8],
[VISDT, NUM, 8, DATE9],

http://usadc-vsi46sp2a.quintiles.net/YKA46505/pfts.dll?S=304d1838&C=TM_169&FMID=0&FMRV=0&ISID=0&ITID=0&VM=2&TN=YKA46505&SP=&AS=2047&CP=65535&FP=0&RSV=0

7/22/2011

YKA46505 : STUDY DRUG RECORD - Docetaxel (STDRUG2 - DOCX) - Repeating Form

#		Dose Start Date	Dose Stop Date	Dose Assigned	Actual dose per administration	Reason for Dose Assignment	
1	<div></div>						

Study Drug Record

1. Dose Start Date	[EXSTDTF, CHAR, 200, \$200],[EXSTDT, NUM, 8, DATE9]	Req <div></div> / Req <div></div> / Req <div></div> (2009-2025) (sdeYKA46505:t_EX3.EXSTDT)
2. Dose Stop Date [editable]	[EXENDTF, CHAR, 200, \$200],[EXENDT, NUM, 8, DATE9]	Req <div></div> / Req <div></div> / Req <div></div> (2009-2025) (sdeYKA46505:t_EX3.EXENDT)
3. Dose Assigned	(sdeYKA46505:t_EX3.EXDOSEN2) Dose Assigned: [1] <div></div> 75 mg/m2 [EXDOSE2N, NUM, 8], [2] <div></div> 60 mg/m2 [EXDOSE2, CHAR, 200, \$200] [3] <div></div> 0 mg/m2 [4] <div></div> Permanently Discontinued	
4. Actual dose per administration	[DSADMN, NUM, 8]	xxx mg (sdeYKA46505:t_EX3.DSADMN) [DSADMNU, CHAR, 200, \$200]
5. Reason for Dose Assignment	(sdeYKA46505:t_EX3.EXREASN2) [1] <div></div> Adverse Event, specify AE Sequence # xxx (sdeYKA46505:t_EX3.DSAENUM) [DSAENUM, NUM, 8] [7] <div></div> Per protocol [99] <div></div> Other, specify A200 (sdeYKA46505:t_EX3.EXOTH) [EXOTH, CHAR, 200, \$200] <div></div>	

Form Design Note:

The team recommends that a statement about reconciliation between dose changes due to Adverse Event and the Adverse Events page is added to the study Monitoring Plan.

CDD: sdeYKA46505 Table: t_EX3 Key Type: PATIENTVISIT		
Column Name	Column Data Type	Design Note
EXSTDT	DATE - DDMONYYYY	
EXENDT	DATE - DDMONYYYY	
EXDOSEN2	NUMERIC	
DSADMN	NUMERIC - N4	
EXREASN2	NUMERIC	
DSAENUM	NUMERIC - N3	
EXOTH	STRING(200) - A200	

Domain Name: [EX3]
Domain Label: [STUDY DRUG RECORD-DOCETAXEL]
Additional items:

[STUDY, CHAR, 20, \$20],
[PT, CHAR, 20, \$20],
[INVSITE, CHAR, 20, \$20],
[VISNAME, CHAR, 60, \$60],
[VISIT, NUM, 8],
[VISDT, NUM, 8, DATE9],

YKA46505 : STUDY DRUG RECORD - Prednisone (STDRUG3 - PRED) - Repeating Form

#		Dose Start Date	Dose Stop Date	Dose Assigned	Reason for Dose Assignment
1	<div><div></div><div></div><div></div></div>				

Study Drug Record - Prednisone

1. Dose Start Date	[EXSTDTF, CHAR, 200, \$200],[EXSTD, NUM, 8, DATE9]	Req <div></div> / Req <div></div> / Req <div></div> (2009-2025) (sdeYKA46505:t_EX4.EXSTD)
2. Dose Stop Date	[EXENDTF, CHAR, 200, \$200],[EXENDT, NUM, 8, DATE9]	Req <div></div> / Req <div></div> / Req <div></div> (2009-2025) (sdeYKA46505:t_EX4.EXENDT)
3. Dose Assigned		(sdeYKA46505:t_EX4.EXDOSEN3) Dose Assigned: [1] <div></div> 5 mg BID [2] <div></div> 0 mg BID [3] <div></div> Permanently Discontinued [EXDOSE3N, NUM,8], [EXDOSE3, CHAR, 200, \$200]
4. Reason for Dose Assignment	[EXREASN, NUM,8], [EXREASN2, CHAR, 200, \$200]	(sdeYKA46505:t_EX4.EXREASN2) [1] <div></div> Adverse Event, specify AE Sequence # xxx (sdeYKA46505:t_EX4.DSAENUM) [DSAENUM, NUM,8] [7] <div></div> Per protocol [99] <div></div> Other, specify A200 (sdeYKA46505:t_EX4.EXOTH) [EXOTH, CHAR, 200, \$200]

Form Design Note:

The team recommends that a statement about reconciliation between dose changes due to Adverse Event and the Adverse Events page is added to the study Monitoring Plan.

CDD: sdeYKA46505 Table: t_EX4 Key Type: PATIENTVISIT		
Column Name	Column Data Type	Design Note
EXSTD	DATE - DDMONYYYY	
EXEND	DATE - DDMONYYYY	
EXDOSEN3	NUMERIC	
EXREASN2	NUMERIC	
DSAENUM	NUMERIC - N3	
EXOTH	STRING(200) - A200	

Domain Name: [EX4]

Domain Label: [STUDY DRUG RECORD-PREDNISONE]

Additional items:

[STUDY, CHAR, 20, \$20],

[PT, CHAR,20, \$20],

[INVSITE, CHAR, 20, \$20],

[VISNAME, CHAR, 60, \$60],

[VISIT, NUM, 8],

[VISDT, NUM, 8, DATE9],

YKA46505 : PHARMACOKINETIC (PK) SPARSE SAMPLING (PKSAMPS)			
PHARMACOKINETIC (PK) SPARSE SAMPLING			
1.	Lenalidomide dose administered (Day before PK visit):	[DOSELVN, NUM,8],[DOSELV, CHAR, 200, \$200]	Pulldown List 1 (sdeYKA46505:t_PKSAMPS.DOSELV)
2.	Actual date for administration of Lenalidomide/placebo	[INTPKDTF, CHAR, 200, \$200],[INTPKDT, NUM, 8, DATE9]	Req / Req / Req (2009-2025) (sdeYKA46505:t_PKSAMPS.INTPKDT)
3.	Actual time for administration of Lenali	[INTPKTMF, CHAR, 200, \$200],[INTPKDTM, NUM, 8, TIME5]	Req : Req 24-hour clock (sdeYKA46505:t_PKSAMPS.INPKDTM)
4.	Lenalidomide dose administered (Day of PK sampling):	[DOSELV2N, NUM,8],[DOSELV2, CHAR, 200, \$200]	Pulldown List 2 (sdeYKA46505:t_PKSAMPS.DOSELV2)
5.	Actual date for administration of Lenalidomide/place	[LNPKDTF, CHAR, 200, \$200],[LNPKDT, NUM, 8, DATE9]	Req / Req / Req (2009-2025) (sdeYKA46505:t_PKSAMPS.LNPKDT)
6.	Actual time for administration of Lenalidomide/plac	[LNPKTMF, CHAR, 200, \$200],[LNPKTM, NUM, 8, TIME5]	Req : Req 24-hour clock (sdeYKA46505:t_PKSAMPS.LNPKTM)
7.	Actual date of last meal prior to administration of Ler	[INPKDDTF, CHAR, 200, \$200],[INPKDDT, NUM, 8, DATE9]	Req / Req / Req (2009-2025) (sdeYKA46505:t_PKSAMPS.INPKDDT)
8.	Actual time of last meal prior to administration of Le	[INPKLTMF, CHAR, 200, \$200],[INPKLTM, NUM, 8, TIME5]	Req : Req 24-hour clock (sdeYKA46505:t_PKSAMPS.INPKLDTM)
9.	Actual time of meal eaten within 4 hours following ad	[PLENTMF, CHAR, 200, \$200],[PLENTM, NUM, 8, TIME5]	Req : Req 24-hour clock (sdeYKA46505:t_PKSAMPS.PLENTM)
10.	Actual time of PK sample 1 (approximate)	[PKSMPTMF, CHAR, 200, \$200],[PKSMPTM, NUM, 8, TIME5]	Req : Req 24-hour clock (sdeYKA46505:t_PKSAMPS.PKSMPTM)
11.	Actual time of PK sample 2 (greater than 1 Hour post	[PKSP2TMF, CHAR, 200, \$200],[PKSP2TM, NUM, 8, TIME5]	Req : Req 24-hour clock (sdeYKA46505:t_PKSAMPS.PKSMP2TM)

Pulldown List 1:			
RefName	Display Text	Value	Design Note
DOSEA	25 mg QD	1	
DOSEB	20 mg QD	2	
DOSEC	15 mg QD	3	
DOSED	10 mg QD	4	
DOSEE	0 mg QD	5	

Pulldown List 2:			
RefName	Display Text	Value	Design Note
DOSEA	25 mg QD	1	
DOSEB	20 mg QD	2	
DOSEC	15 mg QD	3	
DOSED	10 mg QD	4	
DOSEE	0 mg QD	5	

CDD: sdeYKA46505 Table: t_PKSAMPS Key Type: PATIENTVISIT		
Column Name	Column Data Type	Design Note
DOSELV	STRING(255) - 1, 2, 3, 4, 5	
INTPKDT	DATE - DDMYYYYY	
INPKDTM	DATE - HHMM	
DOSELV2	STRING(255) - 1, 2, 3, 4, 5	
LNPKDT	DATE - DDMYYYYY	
LNPKTM	DATE - HHMM	
INPKDDT	DATE - DDMYYYYY	
INPKLDTM	DATE - HHMM	
PLENTM	DATE - HHMM	
PKSMPTM	DATE - HHMM	
PKSMP2TM	DATE - HHMM	

Domain Name: [PKSAMPS]
Domain Label: [PHARMACOKINETIC (PK) SPARSE SAMPLING]
Additional items:

[STUDY, CHAR, 20, \$20],
[PT, CHAR, 20, \$20],
[INVSITE, CHAR, 20, \$20],
[VISNAME, CHAR, 60, \$60],
[VISIT, NUM, 8],
[VISDT, NUM, 8, DATE9],

YKA46505 : NON-TARGET LESIONS (TUMOR_NTP) - Repeating Form

#	Lesion Number	Location	Date of Assessment	Current Status	Method of Assessment
1					

Lesion Details

1. Lesion Number:

[LESNO, NUM, 8]

2. Location:

[LOCGRP2N, NUM, 8], [LOCGRP2C, CHAR, 200, \$200]

[LOCNUM4N, NUM, 8], [LOCNUMN4, CHAR, 200, \$200]

[LOCNUM2N, NUM, 8], [LOCNUMN2, CHAR, 200, \$200]

[LOCNUM3N, NUM, 8], [LOCNUMN3, CHAR, 200, \$200]

3. Date of Assessment:

[ASSETDF, CHAR, 200, \$200], [ASSETD, NUM, 8, DATE9]

4. Current Status

[CURSTATN, NUM, 8], [CURSTAT, CHAR, 200, \$200]

5. * Method of Assessment:

[METHODN, NUM, 8], [METHODC, CHAR, 200, \$200]

xx (sdeYKA46505:t_TUMOR_MP.LESNO)

(sdeYKA46505:t_TUMOR_MP.LOCGRP2N)
[1] ☐ Organ or soft tissue
Pulldown List 1 (sdeYKA46505:t_TUMOR_MP.LOCNUMN4)
[2] ☐ Lymph nodes
Pulldown List 2 (sdeYKA46505:t_TUMOR_MP.LOCNUMN2)
[3] ☐ Other non-measureable disease
Pulldown List 3 (sdeYKA46505:t_TUMOR_MP.LOCNUMN3)
[4] ☐ Abnormal tumor marker, Specify: (sdeYKA46505:t_TUMOR_MP.SPECTM)
A200 [SPECTM, CHAR, 200, \$200]
[97] ☐ Other Soft Tissue, Specify: (sdeYKA46505:t_TUMOR_MP.SPECST)
A200 [SPECST, CHAR, 200, \$200]
[98] ☐ Other Organ, Specify: (sdeYKA46505:t_TUMOR_MP.SPECOR)
A200 [SPECOR, CHAR, 200, \$200]

Req / Req / Req (2009-2025) (sdeYKA46505:t_TUMOR_MP.ASSETD)

(sdeYKA46505:t_TUMOR_MP.CURSTATN)
[1] ☐ Absent/Normal
[2] ☐ Present/Stable
[3] ☐ Progressed
[95] ☐ Not assessed

(sdeYKA46505:t_TUMOR_MP.METHOTHN)
[1] ☐ Pulldown List 4 (sdeYKA46505:t_TUMOR_MP.METHODN) [METHOTHN, NUM, 8], [METHOTHC, CHAR, 200, \$200]
[99] ☐ Other, specify: (sdeYKA46505:t_TUMOR_MP.OTHSPEC)
A200 [OTHSPEC, CHAR, 200, \$200]

* Item is not required

Form Design Note:

This is a Repeating form.

Item Design Notes:	
Item No.	Design Note
2.	Location will be mapped to TUMOR_NTP at next visit.

Pulldown List 1:			
RefName	Display Text	Value	Design Note
ABDOMINAL	Abdominal	9	
ADRENAL	Adrenal	10	
BONE	Bone	6	
BRAIN	Brain	5	
BREAST	Breast	11	
COLON	Colon	8	
LIVER	Liver	2	
LUNG	Lung	1	
OVARY	Ovary	12	
PROSTATE	Prostate	7	
SKIN	Skin	4	
SPLEEN	Spleen	13	
BIOMARKER	Biomarker	14	

Domain Name: [TUMOR_MP]
Domain Label: [NON-TARGET LESIONS]
Additional items:

[STUDY, CHAR, 20, \$20],
[PT, CHAR, 20, \$20],
[INVSITE, CHAR, 20, \$20],
[VISNAME, CHAR, 60, \$60],
[VISIT, NUM, 8],
[VISDT, NUM, 8, DATE9],

Pulldown List 2:			
RefName	Display Text	Value	Design Note
WALRING	Waldeyer ring	1	
CERVSUP	Cervical - Supraclavicular	2	
CERVOCC	Cervical - Occipital	3	

http://usadc-vsi46sp2a.quintiles.net/YKA46505/pfts.dll?S=304d1838&C=TM_169&FMID=0&FMRV=0&ISID=0&ITID=0&VM=2&TN=YKA46505&SP=-&AS=2047&CP=65535&FP=0&RSV=0

7/22/2011

CERVPREAU	Cervical - Pre-auricular	4	
INF	Infraclavicular	5	
AXPEC	Axillary and pectoral	6	
MED	Mediastinal	7	
HIL	Hilar	8	
EPBR	Epitrochlear and brachial	9	
SP	Spleen	10	
PAR	Paraaortic	11	
MES	Mesenteric	12	
ILL	Illiic	13	
INGFEM	Inguinal and femoral	14	
POP	Popliteal	15	

Pulldown List 3:			
RefName	Display Text	Value	Design Note
PLEFF	Pericardial Effusion	1	
PEEFF	Pleural Effusion	2	
ASCITES	Ascites	3	
BONEL	Bone Lesions	4	
LDISEA	Leptomeningeal Disease	5	
IBDISEA	Inflammatory Breast Disease	6	
LYMPHCP	Lymphangitis Cutis / Pulmonis	7	
ABMASS	Abdominal masses that are not confirmed by imaging	8	
CYSTICL	Cystic Lesions	9	
TUMORL	Tumor Lesions in a previously irradiated area	10	

Pulldown List 4:			
RefName	Display Text	Value	Design Note
BONESCAN	Bone scan	1	
PETCT	PET/CT	11	
PET	PET	2	
RADIONUCLIDE	Radionuclide	3	
CT	CT	4	
SPIRALCT	Spiral CT	5	
MRI	MRI	6	
XRAY	X-Ray	7	
PHOTOMEASURE	Photo measurement	8	
CLINASSESS	Clinical Assessment	9	
CALIPER	Caliper	14	
NOTASS	Not Assessed	95	

CDD: sdeYKA46505 Table: t_TUMOR_MP Key Type: PATIENTVISIT		
Column Name	Column Data Type	Design Note
LESNO	NUMERIC - N2	
LOCGRPN2	NUMERIC	
LOCNUMN4	STRING(255) - 9, 10, 6, 5, 11, 8, 2, 1, 12, 7, 4, 13, 14	
LOCNUMN2	STRING(255) - 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15	
LOCNUMN3	STRING(255) - 1, 2, 3, 4, 5, 6, 7, 8, 9, 10	
SPECTM	STRING(200) - A200	
SPECST	STRING(200) - A200	
SPECOR	STRING(200) - A200	
ASSED	DATE - DDMYYYYY	
CURSTATN	NUMERIC	
METHOTHN	NUMERIC	
METHODN	STRING(255) - 1, 11, 2, 3, 4, 5, 6, 7, 8, 9, 14, 95	
OTHSPEC	STRING(200) - A200	

YKA46505 : TUMOR RESPONSE (TUMOR_MRESP)		
Tumor Response		
1.	Investigator Assessment of Best Overall Response	<div>(sdeYKA46505:t_TUMOR_MRESP.BOVRN)</div> <div>[1] <input type="radio"/> Complete Response</div> <div>[2] <input type="radio"/> Partial Response</div> <div>[4] <input type="radio"/> Stable Disease</div> <div>[3] <input type="radio"/> Progressive Disease</div> <div>[19] <input type="radio"/> Inevaluable for Response</div> <div>[95] <input type="radio"/> Not Done</div> <div>[BOVRN, NUM,8],[BOVRC, CHAR, 200,\$200]</div>
2.	Was symptomatic deterioration noted?	<div>(sdeYKA46505:t_TUMOR_MRESP.DETRIORN)</div> <div>[2] <input type="radio"/> No</div> <div>[1] <input type="radio"/> Yes</div> <div>[DETRIORN, NUM,8],[DETRIORC, CHAR, 200,\$200]</div>

CDD: sdeYKA46505 Table: t_TUMOR_MRESP Key Type: PATIENTVISIT		
Column Name	Column Data Type	Design Note
BOVRN	NUMERIC	
DETRIORN	NUMERIC	

Domain Name: [TUMOR_MRESP]
Domain Label: [TUMOR RESPONSE]
Additional items:

[STUDY, CHAR, 20, \$20],
[PT, CHAR, 20, \$20],
[INVSITE, CHAR, 20, \$20],
[VISNAME, CHAR, 60, \$60],
[VISIT, NUM, 8],
[VISDT, NUM, 8, DATE9],

YKA46505 : CYCLE SELECTION (CYCLE)		
Cycle Selection		
1.	Please indicate what cycle number this is:	Pulldown List 1 (sdeYKA46505:t_CYCLE.pdCYCLEY) [CYCLEN, NUM,8], [CYCLE, CHAR, 200,\$200]

Pulldown List 1:			
RefName	Display Text	Value	Design Note
eiCYCLE17	Cycle 17	17	
eiCYCLE18	Cycle 18	18	
eiCYCLE19	Cycle 19	19	
eiCYCLE20	Cycle 20	20	
eiCYCLE21	Cycle 21	21	
eiCYCLE22	Cycle 22	22	
eiCYCLE23	Cycle 23	23	
eiCYCLE24	Cycle 24	24	
eiCYCLE25	Cycle 25	25	
eiCYCLE26	Cycle 26	26	
eiCYCLE27	Cycle 27	27	
eiCYCLE28	Cycle 28	28	
eiCYCLE29	Cycle 29	29	
eiCYCLE30	Cycle 30	30	
eiCYCLE31	Cycle 31	31	
eiCYCLE32	Cycle 32	32	
eiCYCLE33	Cycle 33	33	
eiCYCLE34	Cycle 34	34	
eiCYCLE35	Cycle 35	35	
eiCYCLE36	Cycle 36	36	
eiCYCLE37	Cycle 37	37	
eiCYCLE38	Cycle 38	38	
eiCYCLE39	Cycle 39	39	
eiCYCLE40	Cycle 40	40	
eiCYCLE41	Cycle 41	41	
eiCYCLE42	Cycle 42	42	
eiCYCLE43	Cycle 43	43	
eiCYCLE44	Cycle 44	44	
eiCYCLE45	Cycle 45	45	
eiCYCLE46	Cycle 46	46	
eiCYCLE47	Cycle 47	47	
eiCYCLE48	Cycle 48	48	
eiCYCLE49	Cycle 49	49	
eiCYCLE50	Cycle 50	50	

Domain Name: [CYCLE]
Domain Label: [CYCLE SELECTION]
Additional items:

[STUDY, CHAR, 20, \$20],
[PT, CHAR, 20, \$20],
[INVSITE, CHAR, 20, \$20],
[VISNAME, CHAR, 60, \$60],
[VISIT, NUM, 8],
[VISDT, NUM, 8, DATE9],

CDD: sdeYKA46505 Table: t_CYCLE Key Type: PATIENTVISIT		
Column Name	Column Data Type	Design Note
pdCYCLEY	STRING(255) - 17, 18, 19, 20, 21, 22, 23, 24, 25, 26, 27, 28, 29, 30, 31, 32, 33, 34, 35, 36, 37, 38, 39, 40, 41, 42, 43, 44, 45, 46, 47, 48, 49, 50	

YKA46505 : DISCONTINUATION (DISCON TX)		
Discontinuation		
1.	Date of Discontinuation	Req <input type="checkbox"/> / Req <input type="checkbox"/> / Req <input type="checkbox"/> (2009-2025) (sdeYKA46505:t_DS4.DSDT) [DSDTF, CHAR, 200, \$200],[DSDT, NUM, 8, DATE9]
2.	Check ONE primary reason for Discontinuation below	(sdeYKA46505:t_DS4.DSTERMN2) [1] <input type="radio"/> Adverse Event, specify AE Sequence # xxx (n > 0) (sdeYKA46505:t_DS4.DSAENUM) [DSAENUM, NUM,8] [2] <input type="radio"/> Disease Progression [3] <input type="radio"/> Withdrew consent [4] <input type="radio"/> Death [5] <input type="radio"/> Lost to follow up [6] <input type="radio"/> Protocol violation, specify A200 (sdeYKA46505:t_DS4.DSREAS2) [DSREAS2, CHAR, 200, \$200] [99] <input type="radio"/> Other, specify A200 (sdeYKA46505:t_DS4.DSRSOOTH) [DSRSOTH, CHAR, 200, \$200]

Item Design Notes:	
Item No.	Design Note
2.	Dynamically create Death page if Death is checked

CDD: sdeYKA46505 Table: t_DS4 Key Type: PATIENTVISIT		
Column Name	Column Data Type	Design Note
DSDT	DATE - DDMONYYYY	
DSTERMN2	NUMERIC	
DSAENUM	NUMERIC - N3	
DSREAS2	STRING(200) - A200	
DSRSOTH	STRING(200) - A200	

Domain Name: [DS]
Domain Label: [DISCONTINUATION]
Additional items:

[STUDY, CHAR, 20, \$20],
[PT, CHAR, 20, \$20],
[INVSITE, CHAR, 20, \$20],
[VISNAME, CHAR, 60, \$60],
[VISIT, NUM, 8],
[VISDT, NUM, 8, DATE9],

YKA46505 : ECG (ECG)		
ECG		
1.	Date of ECG	[ECGDTF, CHAR, 200, \$200],[ECGDT, NUM, 8, DATE9]Req / Req / Req (2009-2025) (sdeYKA46505:t_EG2POSTBASE.EGDT)
2.	Overall Interpretation of ECG *Please record abnormal/clinically significant ECG findings on the Adverse Events form	(sdeYKA46505:t_EG2POSTBASE.EGINTPN) [1] Normal [2] Abnormal, Not Clinically Significant [3] Abnormal, Clinically Significant* [EGINTPN, NUM,8],[EGINTP, CHAR, 200, \$200]

Item Design Notes:	
Item No.	Design Note
2.	Edit Check to verify AE form complete

CDD: sdeYKA46505 Table: t_EG2POSTBASE Key Type: PATIENTVISIT		
Column Name	Column Data Type	Design Note
EGDT	DATE - DDMONYYYY	
EGINTPN	NUMERIC	

Domain Name: [ECG]
Domain Label: [ECG]
Additional items:

[STUDY, CHAR, 20, \$20],
[PT, CHAR, 20, \$20],
[INVSITE, CHAR, 20, \$20],
[VISNAME, CHAR, 60, \$60],
[VISIT, NUM, 8],
[VISDT, NUM, 8, DATE9],

YKA46505 : Trial Continuation (CON)		
Trial Continuation		
1.	Patient is willing and consents to remain in the trial for survival follow-up only?	<div>(sdeYKA46505:t_fmCON.rdCON) [1] <input type="radio"/> Yes [2] <input type="radio"/> No</div> <div>[CONREMN, NUM, 8, 8] [CONREM, CHAR, 10, \$10]</div>

Form Design Note:
Form is shown dynamically when Withdrew Consent is selected on DISCON TX

CDD: sdeYKA46505 Table: t_fmCON Key Type: PATIENTVISIT		
Column Name	Column Data Type	Design Note
rdCON	NUMERIC	

Domain Name: [CONT]
Domain Label: [TRIAL CONTINUATION]
Additional items:

[STUDY, CHAR, 20, \$20],
[PT, CHAR, 20, \$20],
[INVSITE, CHAR, 20, \$20],
[VISNAME, CHAR, 60, \$60],
[VISIT, NUM, 8],
[VISDT, NUM, 8, DATE9],
[VISDTF, CHAR, 200, \$200]

YKA46505 : DATE OF VISIT (DOV)		
Date of Visit		
1.	Date of Visit	[DOVDTF, CHAR, 200, \$200],[DOVDT, NUM, 8, DATE9]Req / Req / Req (2009-2025) (sdeYKA46505:t_DOV_FU.DOV)
2.	* Instructions for completing Follow-Up Visit	Please record all adverse events, concomitant therapies (including analgesics), concomitant procedures which have occurred or resolved during the 28 day (+/- 7 days) follow up period on the AE/CM/CP/HOSP visit
* Item is not required		

CDD: sdeYKA46505 Table: t_DOV_FU Key Type: PATIENTVISIT		
Column Name	Column Data Type	Design Note
DOV	DATE - DDMONYYYY	

Domain Name: [DOV]
Domain Label: [DATE OF VISIT]
Additional items:

[STUDY, CHAR, 20, \$20],
[PT, CHAR, 20, \$20],
[INVSITE, CHAR, 20, \$20],
[VISNAME, CHAR, 60, \$60],
[VISIT, NUM, 8],
[VISDT, NUM, 8, DATE9],

YKA46505 : SURVIVAL (SURVI)		
Survival		
1.	Date of Contact	Req <input type="checkbox"/> / Req <input type="checkbox"/> / Req <input type="checkbox"/> (2009-2025) (sdeYKA46505:t_SURVIVE1.CONTDT) [CONTDTF, CHAR, 200, \$200],[CONDTDT, NUM, 8, DATE9]
2.	Survival Status	(sdeYKA46505:t_SURVIVE1.STATUSN) [1] <input type="radio"/> Alive [STATUSN, NUM,8],[STATUS, CHAR, 200, \$200] [2] <input type="radio"/> Lost to follow-up Date last known alive: Req <input type="checkbox"/> / Req <input type="checkbox"/> / Req <input type="checkbox"/> (2009-2025) (sdeYKA46505:t_SURVIVE1.LKADT) [3] <input type="radio"/> Dead [LKDTF, CHAR, 200, \$200],[LKDTDT, NUM, 8, DATE9]

Item Design Notes:	
Item No.	Design Note
2.	If = Alive, Dynamically generates the Survival Information page If = Dead, Dynamically generates the Death form

CDD: sdeYKA46505 Table: t_SURVIVE1 Key Type: PATIENTVISIT		
Column Name	Column Data Type	Design Note
CONDTDT	DATE - DDMONYYYY	
STATUSN	NUMERIC	
LKADT	DATE - DDMONYYYY	

Domain Name: [SURVIVE]
Domain Label: [SURVIVAL]
Additional items:

[STUDY, CHAR, 20, \$20],
[PT, CHAR, 20, \$20],
[INVSITE, CHAR, 20, \$20],
[VISNAME, CHAR, 60, \$60],
[VISIT, NUM, 8],
[VISDT, NUM, 8, DATE9],

YKA46505 : SURVIVAL INFORMATION (SRV INFO)			
Survival Information		[STNONEN, NUM,8],	
1.	Were any therapies/drugs used to treat the condition being studied?	[STNONE, CHAR, 200, \$200]	
		(sdeYKA46505:t_SURVTH.STNONEN) [2] <input type="radio"/> No [1] <input type="radio"/> Yes	
Drug Name		Start Date	Stop Date
2.			
2.a	Drug Name	[STTERM, CHAR, 200, \$200]	
		A200 (sdeYKA46505:t_SURVTH.STTERM)	
2.b	Start Date	[STSTDTF, CHAR, 200, \$200],[STSTDT, NUM, 8, DATE9]	
		(sdeYKA46505:t_SURVTH.STSTOGN) [0] <input type="radio"/> Req <input type="button" value="v"/> / Req <input type="button" value="v"/> / Req <input type="button" value="v"/> (2009-2025) (sdeYKA46505:t_SURVTH.STSTDT) [1] <input type="radio"/> Ongoing from previous visit	
		[STSTOGN, NUM,8], [STSTOG, CHAR, 200, \$200]	
2.c	Stop Date	[STENDTF, CHAR, 200, \$200],[STENDT, NUM, 8, DATE9]	
		(sdeYKA46505:t_SURVTH.STENOGN) [2] <input type="radio"/> Req <input type="button" value="v"/> / Req <input type="button" value="v"/> / Req <input type="button" value="v"/> (2009-2025) (sdeYKA46505:t_SURVTH.STENDT) [1] <input type="radio"/> Ongoing	
		[STENOGN, NUM,8], [STENOG, CHAR, 200, \$200]	

CDD: sdeYKA46505 Table: t_SURVTH Key Type: PATIENTVISIT		
Column Name	Column Data Type	Design Note
STNONEN	NUMERIC	
STTERM	STRING(200) - A200	
STSTOGN	NUMERIC	
STSTDT	DATE - DDMONYYYY	
STENOGN	NUMERIC	
STENDT	DATE - DDMONYYYY	

Domain Name: [SURVTH]

Domain Label: [SURVIVAL INFORMATION]

Additional items:

[STUDY, CHAR, 20, \$20],
[PT, CHAR, 20, \$20],
[INVSITE, CHAR, 20, \$20],
[VISNAME, CHAR, 60, \$60],
[VISIT, NUM, 8],
[VISDT, NUM, 8, DATE9],

PLEASE NOTE: PLEASE MERGE STNONEN AND STNONE WITH ALL OTHER VARIABLES IN SURVTH.

YKA46505 : DEATH (DEATH)

Death

1.	Date of Death	[DSDTF, CHAR, 200, \$200],[DSDT, NUM, 8, DATE9]	Req / Req / Req (2009-2025) (sdeYKA46505:t_DS1.DSDT)
2.	Cause of Death	[DSCAUSEN, NUM,8], [DSCAUSE, CHAR, 200, \$200]	Pulldown List 1 (sdeYKA46505:t_DS1.DSCAUSEN) Specify cause of death: A200 (sdeYKA46505:t_DS1.DSREAS) [DSREAS, CHAR, 200, \$200]
3.*	DSDECOD [hidden]	[DSDECOD, CHAR, 200, \$200]	A200 (sdeYKA46505:t_DS1.DSDECOD)
4.*	DSBODSYS [hidden]	[DSBODSYS, CHAR, 200, \$200]	A200 (sdeYKA46505:t_DS1.DSBODSYS)
5.*	DSMODIFY [hidden]	[DSMODIFY, CHAR, 200, \$200]	A200 (sdeYKA46505:t_DS1.DSMODIFY)
6.*	LLTCDD [hidden]	[LLTCD, CHAR, 200, \$200]	A200 (sdeYKA46505:t_DS1.LLTCDD)
7.*	LLTNMD [hidden]	LLTNMD, CHAR, 200, \$200]	A200 (sdeYKA46505:t_DS1.LLTNMD)
8.*	HLTNMD [hidden]	[HLTNMD, CHAR, 200, \$200]	A200 (sdeYKA46505:t_DS1.HLTNMD)
9.*	HLGTNMD [hidden]	[HLGTNMD, CHAR, 200, \$200]	A200 (sdeYKA46505:t_DS1.HLGTNMD)
10.*	PTCDD [hidden]	[PTCDD, CHAR, 200, \$200]	A200 (sdeYKA46505:t_DS1.PTCDD)
11.*	DICTVERD [hidden]	[DICTVER, CHAR, 200, \$200]	A200 (sdeYKA46505:t_DS1.DICTVERD)

* Item is not required

Item Design Notes:	
Item No.	Design Note
1.	Investigator Signature on this form.

Pulldown List 1:			
RefName	Display Text	Value	Design Note
DSMALIG	Early death from malignant disease	1	
DSTOXIC	Early death from toxicity	2	
DSOTHER	Early death because of other cause	99	
DSUNK	Unknown (not assessable or insufficient data)	96	

CDD: sdeYKA46505 Table: t_DS1 Key Type: PATIENTVISIT		
Column Name	Column Data Type	Design Note
DSDT	DATE - DDMONYYYY	
DSCAUSEN	STRING(255) - 1, 2, 99, 96	
DSREAS	STRING(200) - A200	
DSDECOD	STRING(200) - A200	
DSBODSYS	STRING(200) - A200	
DSMODIFY	STRING(200) - A200	
LLTCDD	STRING(200) - A200	
LLTNMD	STRING(200) - A200	
HLTNMD	STRING(200) - A200	
HLGTNMD	STRING(200) - A200	
PTCDD	STRING(200) - A200	
DICTVERD	STRING(200) - A200	

Domain Name: [DEATH]
Domain Label: [DEATH]
Additional items:

[STUDY, CHAR, 20, \$20],
[PT, CHAR, 20, \$20],
[INVSITE, CHAR, 20, \$20],
[VISNAME, CHAR, 60, \$60],
[VISIT, NUM, 8],
[VISDT, NUM, 8, DATE9],

YKA46505 : UNSCHEDULED ASSESSMENTS (UNSDOV)		
UNSCHEDULED ASSESSMENTS		
1. Unscheduled Visit Forms	<div>[VITALS, CHAR, 200, \$200]</div> <div>[ECG, CHAR, 200, \$200]</div> <div>[ECOG2, CHAR, 200, \$200]</div> <div>[CLABHEM, CHAR, 200, \$200]</div> <div>[CLABCHEM, CHAR, 200, \$200]</div> <div>[CLABURI, CHAR, 200, \$200]</div> <div>[TUMOR, CHAR, 200, \$200]</div> <div>[PROASM1, CHAR, 200, \$200]</div>	<div>(sdeYKA46505:t_UNSDOV.CBUNSVS4)</div> <div>[VITALS] <input type="checkbox"/> Vital Signs</div> <div>(sdeYKA46505:t_UNSDOV.cbUNSEGPOSTBASE)</div> <div>[ECG] <input type="checkbox"/> ECG</div> <div>(sdeYKA46505:t_UNSDOV.cbUNSECOG2)</div> <div>[ECOG2] <input type="checkbox"/> ECOG</div> <div>(sdeYKA46505:t_UNSDOV.cbUNSCLAB1)</div> <div>[CLABHEM] <input type="checkbox"/> Hematology</div> <div>(sdeYKA46505:t_UNSDOV.cbUNSCLAB2)</div> <div>[CLABCHEM] <input type="checkbox"/> Blood Chemistry</div> <div>(sdeYKA46505:t_UNSDOV.cbUNSCLAB4)</div> <div>[CLABURI] <input type="checkbox"/> Urinalysis</div> <div>(sdeYKA46505:t_UNSDOV.cbUNSTUMOR)</div> <div>[TUMOR] <input type="checkbox"/> Tumor Assessments</div> <div>(sdeYKA46505:t_UNSDOV.cbUNSPROASM1)</div> <div>[PROASM1] <input type="checkbox"/> Patient Reported Outcomes (PROASM1)</div>

CDD: sdeYKA46505 Table: t_UNSDOV Key Type: PATIENTVISIT		
Column Name	Column Data Type	Design Note
CBUNSVS4	STRING(255)	
cbUNSEGPOSTBASE	STRING(255)	
cbUNSECOG2	STRING(255)	
cbUNSCLAB1	STRING(255)	
cbUNSCLAB2	STRING(255)	
cbUNSCLAB4	STRING(255)	
cbUNSTUMOR	STRING(255)	
cbUNSPROASM1	STRING(255)	

Domain Name: [UNSDOV]

Domain Label: [UNSCHEDULED ASSESSMENT]

Additional items:

[STUDY, CHAR, 20, \$20],

[PT, CHAR, 20, \$20],

[INVSITE, CHAR, 20, \$20],

[VISNAME, CHAR, 60, \$60],

[VISIT, NUM, 8],

[VISDT, NUM, 8, DATE9],

YKA46505 : WITHDRAW CONSENT FROM FOLLOW-UP (WCFU)		
Withdraw Consent From Follow-Up		
1.	Date patient withdrew consent	Req <input type="checkbox"/> / Req <input type="checkbox"/> / Req <input type="checkbox"/> (2009-2025) (sdeYKA46505:t_WCFU.WCFU)

CDD: sdeYKA46505 Table: t_WCFU Key Type: PATIENTVISIT

Column Name	Column Data Type	Design Note
WCFU	DATE - DDMONYYYY	

[WCFUDTF, CHAR, 200, \$200],[WCFUDT, NUM, 8, DATE9]

Domain Name: [WCFU]
Domain Label: [WITHDRAW CONSENT FROM FOLLOW-UP]
Additional items:

[STUDY, CHAR, 20, \$20],
[PT, CHAR, 20, \$20],
[INVSITE, CHAR, 20, \$20],
[VISNAME, CHAR, 60, \$60],
[VISIT, NUM, 8],
[VISDT, NUM, 8, DATE9],

CRB Electronic Signature Affidavit
By my dated signature below, I, [First Name] [Last Name] , verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this patient.
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 marked Submit below.

CRF Electronic Signature Affidavit
By my dated signature below, I, [First Name] [Last Name] , verify that this case report form accurately displays the results of the examinations, tests, evaluations and treatments noted within.
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 marked Submit below.