ClinicalTrial.govID=NCT00081796 Protocol=EFC6089[XRP9881B/3001] uploaded 04/29/2015

LIBNAME	MEMNAME	MEMLABEL	CRDATE	NOBS	NVARS
PDS135	AE	Adverse Events	16APR15	9702	50
PDS135	BATCHNUM	Batch Number	16APR15	2797	12
PDS135	CADIAG	Cancer Diagnosis	16APR15	217	25
PDS135	CARADIO	Radiotherapy for Cancer	16APR15	503	17
PDS135	CASURG	Cancer Surgery	16APR15	1167	13
PDS135	CHEMO	Anti-tumor Chemotherapy	16APR15	1651	24
PDS135	CLINPH	Clinphone IVRS panel	16APR15	217	34
PDS135	CONMEDS	Previous and concomitant meds	16APR15	9892	30
PDS135	CREACLEA	Creatinine Clearance	16APR15	3210	10
PDS135	DEMO	Demography	16APR15	217	12
PDS135	DISPOSIT	Study completion	16APR15	216	11
PDS135	ECG	ECG	16APR15	229	13
PDS135	EMPLSTAT	Employment Status	16APR15	560	10
PDS135	ENROLL	Subject enrollment	16APR15	217	5
PDS135	FERCCP	Fertility and contraception	16APR15	217	13
PDS135	HORMREC	Hormonal Receptor Status	16APR15	1059	13
PDS135	HTWT	Height and weight	16APR15	1720	30
PDS135	INCEXC	Inclusion/exclusion	16APR15	225	12
PDS135	INFCON	Informed consent	16APR15	218	11
PDS135	INVSIG	Investigator signature	16APR15	215	8
PDS135	INVSIGS	Investigator signature/Study End	16APR15	216	8
PDS135	IPOPCARE	In-patient or Out-patient Care	16APR15	2429	35
PDS135	LABS	Lab findings	16APR15	133814	39
PDS135	MEDHIST	Medical History	16APR15	855	15
PDS135	NEUROEXM	Neurological Exam	16APR15	1720	19
PDS135	NORMALS	Normal lab ranges	16APR15	72	19
PDS135	NORMALS2	Normal lab ranges for Data Entry	16APR15	11555	19
PDS135	ONCADMIN	Study Med Admin (Oncology)	16APR15	5144	41
PDS135	ONCDEATH	Death	16APR15	211	9
PDS135	OTHPROC	Other Procedures	16APR15	373	9
PDS135	OVRSP	Overall Response	16APR15	1894	7
PDS135	OVRSPIRC	Overall Response (Radpharm)	16APR15	878	56
PDS135	PAFUSTAT	Patient Follow-up Status	16APR15	466	11
PDS135	PATWKIRC	Patient Work-Up (Radpharm)	16APR15	3233	20
PDS135	PATWORK	Patient Work-Up	16APR15	8031	15
PDS135	PERFSTAT	Performance Status	16APR15	1720	13
PDS135	PREG	Pregnancy	16APR15	217	12
PDS135	QOLEQ5D	EQ5D health questionnaire	16APR15	2391	13
PDS135	QOLGEN	QOL General	16APR15	67990	14
PDS135	QOLQ	Quality of Life Administration	16APR15	3279	10
PDS135	RANDOM	Randomization	16APR15	217	13

PDS135	RESPONSE	Date of response/Disease progres	16APR15	431	9
PDS135	SMW	Study med discont/wdraw	16APR15	215	9
PDS135	SOURCE	Source of death information	16APR15	211	24
PDS135	TIMELOSS	Time Loss	16APR15	560	9
PDS135	TUMASIRC	Tumor Assessment (Radpharm)	16APR15	4293	24
PDS135	TUMASSES	Tumor Assessment	16APR15	7283	19
PDS135	TUMTHER	Tumor Therapy	16APR15	890	23
PDS135	VITAL	Vital signs	16APR15	1720	29
PDS135	VSDT	Visit date	16APR15	2329	7
PDS135	WAIVER	Request for Waiver	16APR15	31	15
PDS135	WAIVSIG	Waiver Signatures	16APR15	31	11
N = 52					

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Library Member Name=AE

LIBNAME	MEMNAME	MEMLABEL	CRDATE	NOBS	VARNUM	NAME	LABEL	TYPE	LENGTH	FORMAT
PDS135	AE	Adverse Events	16APR15	9702	1	AEETM	AE end time (24hr clock)	2	5	$
PDS135	AE	Adverse Events	16APR15	9702	2	AEMODIFY	AE desc (modified reported term)	2	200	$
PDS135	AE	Adverse Events	16APR15	9702	3	AENCICD	NCI code (oncology)	2	16	$
PDS135	AE	Adverse Events	16APR15	9702	4	AENCIMOD	NCI Term (mod rptd term onco)	2	200	$
PDS135	AE	Adverse Events	16APR15	9702	5	AENCISEL	NCI select term (oncology)	2	80	$
PDS135	AE	Adverse Events	16APR15	9702	6	AENCISN	NCI short name (oncology)	2	80	$
PDS135	AE	Adverse Events	16APR15	9702	7	AENCITRM	NCI Term (rptd term onco)	2	200	$
PDS135	AE	Adverse Events	16APR15	9702	8	AENCIWF	NCI workflow item	2	5	$
PDS135	AE	Adverse Events	16APR15	9702	9	AENROTH	Specify if reason is other	2	100	$
PDS135	AE	Adverse Events	16APR15	9702	10	AENUM	AE number	2	10	$
PDS135	AE	Adverse Events	16APR15	9702	11	AEONCMOD	AE desc (onco term derived)	2	200	$
PDS135	AE	Adverse Events	16APR15	9702	12	AESTM	AE start time (24hr clock)	2	5	$
PDS135	AE	Adverse Events	16APR15	9702	13	AETERM	AE desc (reported term)	2	200	$
PDS135	AE	Adverse Events	16APR15	9702	14	AEWF	AE coding workflow item	2	5	$
PDS135	AE	Adverse Events	16APR15	9702	15	CYCLE	Treatment cycle	1	8	
PDS135	AE	Adverse Events	16APR15	9702	16	LLT_CODE	Meddra LLT code	2	38	$
PDS135	AE	Adverse Events	16APR15	9702	17	PAGENUM	Page number	2	4	$
PDS135	AE	Adverse Events	16APR15	9702	18	PROJCD	Project code	2	10	$
PDS135	AE	Adverse Events	16APR15	9702	19	PT_SOC_C	Meddra PT and SOC code	2	38	$
PDS135	AE	Adverse Events	16APR15	9702	20	SBKEY	Subset key	2	2	$
PDS135	AE	Adverse Events	16APR15	9702	21	SEQNUM	Sequence number	1	8	
PDS135	AE	Adverse Events	16APR15	9702	22	AEEDY	AE end day	1	8	
PDS135	AE	Adverse Events	16APR15	9702	23	AESDY	AE start day	1	8	
PDS135	AE	Adverse Events	16APR15	9702	24	AEACTOTH	Other significant intervention	2	20	
PDS135	AE	Adverse	16APR15	9702	25	AEACTTRT	Action taken with study tx	2	40	

		Events								
PDS135	AE	Adverse Events	16APR15	9702	26	AECAUSAL	AE relationship to study tx	2	20	
PDS135	AE	Adverse Events	16APR15	9702	27	AECONT	AE previously reported	2	20	
PDS135	AE	Adverse Events	16APR15	9702	28	AECONTRT	Additional treatment given	2	20	
PDS135	AE	Adverse Events	16APR15	9702	29	AEGRADE	AE grade (oncology)	2	20	
PDS135	AE	Adverse Events	16APR15	9702	30	AENOTREL	Reason not related to study tx	2	40	
PDS135	AE	Adverse Events	16APR15	9702	31	AEOCCUR	Mark if no AE occurred	2	20	
PDS135	AE	Adverse Events	16APR15	9702	32	AEOUT	AE outcome	2	30	
PDS135	AE	Adverse Events	16APR15	9702	33	AESER	AE serious	2	20	
PDS135	AE	Adverse Events	16APR15	9702	34	AESEV	AE intensity	2	20	
PDS135	AE	Adverse Events	16APR15	9702	35	AESTAT	AE status (oncology)	2	30	
PDS135	AE	Adverse Events	16APR15	9702	36	ALERT	AE is an alert term	2	20	
PDS135	AE	Adverse Events	16APR15	9702	37	CAUS	Most likely cause (oncology)	2	30	
PDS135	AE	Adverse Events	16APR15	9702	38	EVALND	Evaluation not done	2	20	
PDS135	AE	Adverse Events	16APR15	9702	39	LBRESYN	AE represents a lab result	2	20	
PDS135	AE	Adverse Events	16APR15	9702	40	PSID	Treatment phase	2	20	
PDS135	AE	Adverse Events	16APR15	9702	41	SAETYP1	Resulted in death	2	20	
PDS135	AE	Adverse Events	16APR15	9702	42	SAETYP2	Life-threatening	2	20	
PDS135	AE	Adverse Events	16APR15	9702	43	SAETYP3	Persis/signif/disable/incapacity	2	20	
PDS135	AE	Adverse Events	16APR15	9702	44	SAETYP4	Require/prolong hospitalization	2	20	
PDS135	AE	Adverse Events	16APR15	9702	45	SAETYP5	Congenital anomaly/birth defect	2	20	
PDS135	AE	Adverse Events	16APR15	9702	46	SAETYP6	Other medically important	2	20	
PDS135	AE	Adverse Events	16APR15	9702	47	RSUBJID	De-identified Subject ID for Study	2	9	
PDS135	AE	Adverse Events	16APR15	9702	48	RUSUBJID	De-identified Unique Subj. ID for Study	2	18	
PDS135	AE	Adverse Events	16APR15	9702	49	AESWK	Study Week of Start of Adverse Event for Deaths	1	8	
PDS135	AE	Adverse Events	16APR15	9702	50	AEEWK	Study Week of End of Adverse Event for Deaths	1	8	

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Library Member Name=BATCHNUM

LIBNAME	MEMNAME	MEMLABEL	CRDATE	NOBS	VARNUM	NAME	LABEL	TYPE	LENGTH	FORMAT
PDS135	BATCHNUM	Batch Number	16APR15	2797	1	BNCYCLE	Cycle day	1	8	
PDS135	BATCHNUM	Batch Number	16APR15	2797	2	BNDR	Batch drug	2	35	$
PDS135	BATCHNUM	Batch Number	16APR15	2797	3	BNIT	Batch interval	2	10	$
PDS135	BATCHNUM	Batch Number	16APR15	2797	4	BNTYP	Type of Number	2	80	$
PDS135	BATCHNUM	Batch Number	16APR15	2797	5	CYCLE	Treatment cycle	1	8	
PDS135	BATCHNUM	Batch Number	16APR15	2797	6	PAGENUM	Page number	2	4	$
PDS135	BATCHNUM	Batch Number	16APR15	2797	7	PROJCD	Project code	2	10	$
PDS135	BATCHNUM	Batch Number	16APR15	2797	8	SEQNUM	Sequence number	1	8	
PDS135	BATCHNUM	Batch Number	16APR15	2797	9	TRTARM	Treatment arm	2	2	$
PDS135	BATCHNUM	Batch Number	16APR15	2797	10	EVALND	Evaluation not done	2	20	
PDS135	BATCHNUM	Batch Number	16APR15	2797	11	RSUBJID	De-identified Subject ID for Study	2	9	
PDS135	BATCHNUM	Batch Number	16APR15	2797	12	RUSUBJID	De-identified Unique Subj. ID for Study	2	18	

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Library Member Name=CADIAG

LIBNAME	MEMNAME	MEMLABEL	CRDATE	NOBS	VARNUM	NAME	LABEL	TYPE	LENGTH	FORMAT
PDS135	CADIAG	Cancer Diagnosis	16APR15	217	1	CDHISTTX	Histological type (text)	2	80	$
PDS135	CADIAG	Cancer Diagnosis	16APR15	217	2	CDHSTLTX	Result other - specify	2	80	$
PDS135	CADIAG	Cancer Diagnosis	16APR15	217	3	CDLN	TNM Lymph nodes	2	3	$
PDS135	CADIAG	Cancer Diagnosis	16APR15	217	4	CDMET	TNM Metastasis	2	3	$
PDS135	CADIAG	Cancer Diagnosis	16APR15	217	5	CDRFPMM	Obsolete:First R/P date - month	2	3	$
PDS135	CADIAG	Cancer Diagnosis	16APR15	217	6	CDSTAGE	TNM Stage	2	4	$
PDS135	CADIAG	Cancer Diagnosis	16APR15	217	7	CDSUBSIT	Primary tumor subsite	2	80	$
PDS135	CADIAG	Cancer Diagnosis	16APR15	217	8	CDTUM	TNM Tumor size	2	3	$
PDS135	CADIAG	Cancer Diagnosis	16APR15	217	9	CYCLE	Treatment cycle	1	8	
PDS135	CADIAG	Cancer Diagnosis	16APR15	217	10	PAGENUM	Page number	2	4	$
PDS135	CADIAG	Cancer Diagnosis	16APR15	217	11	PROJCD	Project code	2	10	$
PDS135	CADIAG	Cancer Diagnosis	16APR15	217	12	SEQNUM	Sequence number	1	8	
PDS135	CADIAG	Cancer Diagnosis	16APR15	217	13	CDDY	Diagnosis day - from date derived	1	8	
PDS135	CADIAG	Cancer Diagnosis	16APR15	217	14	CDFRPDY	First Relapse/Prog day	1	8	
PDS135	CADIAG	Cancer Diagnosis	16APR15	217	15	CDRELDY	Relapse day - from date derived	1	8	
PDS135	CADIAG	Cancer Diagnosis	16APR15	217	16	CDHISTCD	Histological type result	2	40	
PDS135	CADIAG	Cancer Diagnosis	16APR15	217	17	CDHISTGR	Histopathological grade	2	40	
PDS135	CADIAG	Cancer Diagnosis	16APR15	217	18	CDMTH	Cancer diagnosis method	2	20	
PDS135	CADIAG	Cancer Diagnosis	16APR15	217	19	CDOPDIS	Operable disease	2	20	
PDS135	CADIAG	Cancer Diagnosis	16APR15	217	20	CDPTMET	Metastasis primary tumor (yes/no)	2	20	
PDS135	CADIAG	Cancer Diagnosis	16APR15	217	21	CDSITECD	Primary tumor site code	2	30	
PDS135	CADIAG	Cancer Diagnosis	16APR15	217	22	EVALND	Evaluation not done	2	20	
PDS135	CADIAG	Cancer Diagnosis	16APR15	217	23	EXTDIS	Disease extent at study entry	2	30	
PDS135	CADIAG	Cancer Diagnosis	16APR15	217	24	RSUBJID	De-identified Subject ID for Study	2	9	
PDS135	CADIAG	Cancer	16APR15	217	25	RUSUBJID	De-identified Unique Subj.	2	18	

		Diagnosis				ID for Study			

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Library Member Name=CARADIO

LIBNAME	MEMNAME	MEMLABEL	CRDATE	NOBS	VARNUM	NAME	LABEL	TYPE	LENGTH	FORMAT
PDS135	CARADIO	Radiotherapy for Cancer	16APR15	503	1	CRDO	Cumulative dose	1	8	
PDS135	CARADIO	Radiotherapy for Cancer	16APR15	503	2	CRSITE	Prior radiotherapy site	2	80	$
PDS135	CARADIO	Radiotherapy for Cancer	16APR15	503	3	CRSUBSIT	Prior radiotherapy subsite	2	40	$
PDS135	CARADIO	Radiotherapy for Cancer	16APR15	503	4	CYCLE	Treatment cycle	1	8	
PDS135	CARADIO	Radiotherapy for Cancer	16APR15	503	5	PAGENUM	Page number	2	4	$
PDS135	CARADIO	Radiotherapy for Cancer	16APR15	503	6	PROJCD	Project code	2	10	$
PDS135	CARADIO	Radiotherapy for Cancer	16APR15	503	7	SEQNUM	Sequence number	1	8	
PDS135	CARADIO	Radiotherapy for Cancer	16APR15	503	8	CREDY	Dose end day - from date derived	1	8	
PDS135	CARADIO	Radiotherapy for Cancer	16APR15	503	9	CRSDY	Dose start day - from date derived	1	8	
PDS135	CARADIO	Radiotherapy for Cancer	16APR15	503	10	CROCCUR	Mark if no prior radiotherapy	2	20	
PDS135	CARADIO	Radiotherapy for Cancer	16APR15	503	11	CRRSP	Response of Prior Radiotherapy	2	20	
PDS135	CARADIO	Radiotherapy for Cancer	16APR15	503	12	CRSITECD	Prior radiotherapy site code	2	30	
PDS135	CARADIO	Radiotherapy for Cancer	16APR15	503	13	CRUNIT	Cumulative dose unit	2	20	
PDS135	CARADIO	Radiotherapy for Cancer	16APR15	503	14	EVALND	Evaluation not done	2	20	
PDS135	CARADIO	Radiotherapy for Cancer	16APR15	503	15	INTENT	Intent	2	20	
PDS135	CARADIO	Radiotherapy for Cancer	16APR15	503	16	RSUBJID	De-identified Subject ID for Study	2	9	
PDS135	CARADIO	Radiotherapy for Cancer	16APR15	503	17	RUSUBJID	De-identified Unique Subj. ID for Study	2	18	

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Library Member Name=CASURG

LIBNAME	MEMNAME	MEMLABEL	CRDATE	NOBS	VARNUM	NAME	LABEL	TYPE	LENGTH	FORMAT
PDS135	CASURG	Cancer Surgery	16APR15	1167	1	CSTERM	Cancer surgery verbatim term	2	200	$
PDS135	CASURG	Cancer Surgery	16APR15	1167	2	CYCLE	Treatment cycle	1	8	
PDS135	CASURG	Cancer Surgery	16APR15	1167	3	PAGENUM	Page number	2	4	$
PDS135	CASURG	Cancer Surgery	16APR15	1167	4	PROJCD	Project code	2	10	$
PDS135	CASURG	Cancer Surgery	16APR15	1167	5	SEQNUM	Sequence number	1	8	
PDS135	CASURG	Cancer Surgery	16APR15	1167	6	CSEDY	CS end day - from date derived	1	8	
PDS135	CASURG	Cancer Surgery	16APR15	1167	7	CSND	Cancer surgery not done	2	20	
PDS135	CASURG	Cancer Surgery	16APR15	1167	8	CSOCCUR	Mark if no cancer surgery	2	20	
PDS135	CASURG	Cancer Surgery	16APR15	1167	9	CSSITE	Cancer surgery site	2	30	
PDS135	CASURG	Cancer Surgery	16APR15	1167	10	CSSITECD	Cancer surgery site code	2	30	
PDS135	CASURG	Cancer Surgery	16APR15	1167	11	EVALND	Evaluation not done	2	20	
PDS135	CASURG	Cancer Surgery	16APR15	1167	12	RSUBJID	De-identified Subject ID for Study	2	9	
PDS135	CASURG	Cancer Surgery	16APR15	1167	13	RUSUBJID	De-identified Unique Subj. ID for Study	2	18	

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Library Member Name=CHEMO

LIBNAME	MEMNAME	MEMLABEL	CRDATE	NOBS	VARNUM	NAME	LABEL	TYPE	LENGTH	FORMAT
PDS135	CHEMO	Anti-tumor Chemotherapy	16APR15	1651	1	CTCYCLE	Number of cycles	1	8	
PDS135	CHEMO	Anti-tumor Chemotherapy	16APR15	1651	2	CTDO	Chemo dose	1	8	
PDS135	CHEMO	Anti-tumor Chemotherapy	16APR15	1651	3	CTDRLCD	Chemo who-drl code	2	11	$
PDS135	CHEMO	Anti-tumor Chemotherapy	16APR15	1651	4	CTMODIFY	CT modify term (entry field)	2	200	$
PDS135	CHEMO	Anti-tumor Chemotherapy	16APR15	1651	5	CTTERM	CT term as reported (derived)	2	200	$
PDS135	CHEMO	Anti-tumor Chemotherapy	16APR15	1651	6	CTUNIT	Chemo unit	2	20	$
PDS135	CHEMO	Anti-tumor Chemotherapy	16APR15	1651	7	CTWF	Chemo work flow item	2	5	$
PDS135	CHEMO	Anti-tumor Chemotherapy	16APR15	1651	8	CYCLE	Treatment cycle	1	8	
PDS135	CHEMO	Anti-tumor Chemotherapy	16APR15	1651	9	PAGENUM	Page number	2	4	$
PDS135	CHEMO	Anti-tumor Chemotherapy	16APR15	1651	10	PROJCD	Project code	2	10	$
PDS135	CHEMO	Anti-tumor Chemotherapy	16APR15	1651	11	REGNUM	Regimen number	1	8	
PDS135	CHEMO	Anti-tumor Chemotherapy	16APR15	1651	12	SEQNUM	Sequence number	1	8	
PDS135	CHEMO	Anti-tumor Chemotherapy	16APR15	1651	13	CTEDY	Chemo end day - from date derived	1	8	
PDS135	CHEMO	Anti-tumor Chemotherapy	16APR15	1651	14	CTRELDY	Relapse/Prog day - from date derived	1	8	
PDS135	CHEMO	Anti-tumor Chemotherapy	16APR15	1651	15	CTSDY	Chemo start day - from date derived	1	8	
PDS135	CHEMO	Anti-tumor Chemotherapy	16APR15	1651	16	CTCONT	Chemo previously reported	2	20	
PDS135	CHEMO	Anti-tumor Chemotherapy	16APR15	1651	17	CTOCCUR	Mark if no chemo therapy	2	20	
PDS135	CHEMO	Anti-tumor Chemotherapy	16APR15	1651	18	CTON	Chemo ongoing	2	20	
PDS135	CHEMO	Anti-tumor Chemotherapy	16APR15	1651	19	CTREADIS	Reason for Chemotherapy Discont	2	40	
PDS135	CHEMO	Anti-tumor Chemotherapy	16APR15	1651	20	CTRSP	Chemo best response per regimen	2	40	
PDS135	CHEMO	Anti-tumor Chemotherapy	16APR15	1651	21	EVALND	Evaluation not done	2	20	
PDS135	CHEMO	Anti-tumor Chemotherapy	16APR15	1651	22	INTENT	Intent	2	20	
PDS135	CHEMO	Anti-tumor Chemotherapy	16APR15	1651	23	RSUBJID	De-identified Subject ID for Study	2	9	
PDS135	CHEMO	Anti-tumor Chemotherapy	16APR15	1651	24	RUSUBJID	De-identified Unique Subj. ID for Study	2	18	

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Library Member Name=CLINPH

LIBNAME	MEMNAME	MEMLABEL	CRDATE	NOBS	VARNUM	NAME	LABEL	TYPE	LENGTH	FORMAT
PDS135	CLINPH	Clinphone IVRS panel	16APR15	217	1	AGEREC	Recorded age	1	8	
PDS135	CLINPH	Clinphone IVRS panel	16APR15	217	2	CALLTM	Call time	2	5	$
PDS135	CLINPH	Clinphone IVRS panel	16APR15	217	3	CYCLE	Treatment cycle	1	8	
PDS135	CLINPH	Clinphone IVRS panel	16APR15	217	4	KITCD	Kit code	2	8	$
PDS135	CLINPH	Clinphone IVRS panel	16APR15	217	5	KITLBL	Kit label	2	80	$
PDS135	CLINPH	Clinphone IVRS panel	16APR15	217	6	KITNUM	Assigned kit number	2	8	$
PDS135	CLINPH	Clinphone IVRS panel	16APR15	217	7	KITNUMCO	Obsolete: Corrected kit number	2	8	$
PDS135	CLINPH	Clinphone IVRS panel	16APR15	217	8	KITRPTD	Kit number reported by site	2	8	$
PDS135	CLINPH	Clinphone IVRS panel	16APR15	217	9	PAGENUM	Page number	2	4	$
PDS135	CLINPH	Clinphone IVRS panel	16APR15	217	10	PROJCD	Project code	2	10	$
PDS135	CLINPH	Clinphone IVRS panel	16APR15	217	11	RNNUM	Randomization number	2	8	$
PDS135	CLINPH	Clinphone IVRS panel	16APR15	217	12	SEQNUM	Sequence number	1	8	
PDS135	CLINPH	Clinphone IVRS panel	16APR15	217	13	STRATLBL	Stratification label	2	80	$
PDS135	CLINPH	Clinphone IVRS panel	16APR15	217	14	STRATNUM	Stratification number	1	8	
PDS135	CLINPH	Clinphone IVRS panel	16APR15	217	15	STRATX	Stratification criteria X	2	50	$
PDS135	CLINPH	Clinphone IVRS panel	16APR15	217	16	STRATY	Stratification criteria Y	2	50	$
PDS135	CLINPH	Clinphone IVRS panel	16APR15	217	17	STRATZ	Stratification criteria Z	2	50	$
PDS135	CLINPH	Clinphone IVRS panel	16APR15	217	18	STRAXLBL	Stratification X label	2	50	$
PDS135	CLINPH	Clinphone IVRS panel	16APR15	217	19	STRAYLBL	Stratification Y label	2	50	$
PDS135	CLINPH	Clinphone IVRS panel	16APR15	217	20	STRAZLBL	Stratification Z label	2	50	$
PDS135	CLINPH	Clinphone IVRS panel	16APR15	217	21	TRTCD	Treatment group code	1	8	
PDS135	CLINPH	Clinphone IVRS panel	16APR15	217	22	TRTKIT	Treatment group code for kit	2	2	$
PDS135	CLINPH	Clinphone IVRS panel	16APR15	217	23	TRTKITLB	Treatment group label for kit	2	80	$
PDS135	CLINPH	Clinphone IVRS panel	16APR15	217	24	TRTLBL	Treatment group label	2	80	$
PDS135	CLINPH	Clinphone IVRS	16APR15	217	25	TRTRND	Treatment group code for	2	2	$

		panel						RandNo			
PDS135	CLINPH	Clinphone IVRS panel	16APR15	217	26	TRTRNDLB	Treatment group label for RandNo	2	80	$
PDS135	CLINPH	Clinphone IVRS panel	16APR15	217	27	CALLDY	Call day	1	8	
PDS135	CLINPH	Clinphone IVRS panel	16APR15	217	28	KITCHGDY	Kit change day	1	8	
PDS135	CLINPH	Clinphone IVRS panel	16APR15	217	29	AGEUNIT	Age unit	2	20	
PDS135	CLINPH	Clinphone IVRS panel	16APR15	217	30	CALLTYP	Call type	2	20	
PDS135	CLINPH	Clinphone IVRS panel	16APR15	217	31	RNFORCED	Forced randomization	2	20	
PDS135	CLINPH	Clinphone IVRS panel	16APR15	217	32	SEX	Sex	2	10	
PDS135	CLINPH	Clinphone IVRS panel	16APR15	217	33	RSUBJID	De-identified Subject ID for Study	2	9	
PDS135	CLINPH	Clinphone IVRS panel	16APR15	217	34	RUSUBJID	De-identified Unique Subj. ID for Study	2	18	

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Library Member Name=CONMEDS

LIBNAME	MEMNAME	MEMLABEL	CRDATE	NOBS	VARNUM	NAME	LABEL	TYPE	LENGTH	FORMAT
PDS135	CONMEDS	Previous and concomitant meds	16APR15	9892	1	CMDO	Med dose	2	20	$
PDS135	CONMEDS	Previous and concomitant meds	16APR15	9892	2	CMDOTX	Med dose-unit-frequency-route	2	80	$
PDS135	CONMEDS	Previous and concomitant meds	16APR15	9892	3	CMDRLCD	Who-drl code	2	11	$
PDS135	CONMEDS	Previous and concomitant meds	16APR15	9892	4	CMFQ	Med frequency	2	20	$
PDS135	CONMEDS	Previous and concomitant meds	16APR15	9892	5	CMMODIFY	Med modify term (entry field)	2	200	$
PDS135	CONMEDS	Previous and concomitant meds	16APR15	9892	6	CMPTMLBL	Planned time crf label	2	100	$
PDS135	CONMEDS	Previous and concomitant meds	16APR15	9892	7	CMRO	Med route	2	20	$
PDS135	CONMEDS	Previous and concomitant meds	16APR15	9892	8	CMTERM	Med term as reported (derived)	2	200	$
PDS135	CONMEDS	Previous and concomitant meds	16APR15	9892	9	CMUNIT	Med dose unit	2	20	$
PDS135	CONMEDS	Previous and concomitant meds	16APR15	9892	10	CMWF	Med coding workflow item	2	5	$
PDS135	CONMEDS	Previous and concomitant meds	16APR15	9892	11	CYCLE	Treatment cycle	1	8	
PDS135	CONMEDS	Previous and concomitant meds	16APR15	9892	12	PAGENUM	Page number	2	4	$
PDS135	CONMEDS	Previous and concomitant meds	16APR15	9892	13	PROJCD	Project code	2	10	$
PDS135	CONMEDS	Previous and concomitant meds	16APR15	9892	14	REGNUM	Regimen number	1	8	
PDS135	CONMEDS	Previous and concomitant meds	16APR15	9892	15	SEQNUM	Sequence number	1	8	
PDS135	CONMEDS	Previous and concomitant meds	16APR15	9892	16	CMEDY	Med end day	1	8	
PDS135	CONMEDS	Previous and concomitant meds	16APR15	9892	17	CMSDY	Med start day	1	8	
PDS135	CONMEDS	Previous and concomitant meds	16APR15	9892	18	CMCONT	Conmed previously reported	2	20	
PDS135	CONMEDS	Previous and concomitant meds	16APR15	9892	19	CMOCCUR	Mark if no med present	2	20	
PDS135	CONMEDS	Previous and concomitant meds	16APR15	9892	20	CMON	Conmed ongoing	2	20	
PDS135	CONMEDS	Previous and concomitant meds	16APR15	9892	21	CMPE	Conmed period of use (1)	2	20	
PDS135	CONMEDS	Previous and concomitant meds	16APR15	9892	22	CMPE2	Conmed period of use (2)	2	20	
PDS135	CONMEDS	Previous and concomitant meds	16APR15	9892	23	CMPE3	Conmed period of use (3)	2	20	
PDS135	CONMEDS	Previous and concomitant meds	16APR15	9892	24	CMPE4	Conmed period of use (4)	2	20	
PDS135	CONMEDS	Previous and	16APR15	9892	25	CMPE5	Conmed period of use	2	20	

		concomitant meds						(5)		
PDS135	CONMEDS	Previous and concomitant meds	16APR15	9892	26	CMREAS	Reason/indication for med	2	40	
PDS135	CONMEDS	Previous and concomitant meds	16APR15	9892	27	CMSTAT	Ongoing from previous collection	2	40	
PDS135	CONMEDS	Previous and concomitant meds	16APR15	9892	28	EVALND	Evaluation not done	2	20	
PDS135	CONMEDS	Previous and concomitant meds	16APR15	9892	29	RSUBJID	De-identified Subject ID for Study	2	9	
PDS135	CONMEDS	Previous and concomitant meds	16APR15	9892	30	RUSUBJID	De-identified Unique Subj. ID for Study	2	18	

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Library Member Name=CREACLEA

LIBNAME	MEMNAME	MEMLABEL	CRDATE	NOBS	VARNUM	NAME	LABEL	TYPE	LENGTH	FORMAT
PDS135	CREACLEA	Creatinine Clearance	16APR15	3210	1	CALCRES	Calculated result	2	20	$
PDS135	CREACLEA	Creatinine Clearance	16APR15	3210	2	CYCLE	Treatment cycle	1	8	
PDS135	CREACLEA	Creatinine Clearance	16APR15	3210	3	ORGRES	Result in original units	2	20	$
PDS135	CREACLEA	Creatinine Clearance	16APR15	3210	4	PAGENUM	Page number	2	4	$
PDS135	CREACLEA	Creatinine Clearance	16APR15	3210	5	PROJCD	Project code	2	10	$
PDS135	CREACLEA	Creatinine Clearance	16APR15	3210	6	CCNR	If creatinine is abnormal	2	20	
PDS135	CREACLEA	Creatinine Clearance	16APR15	3210	7	EVALND	Evaluation not done	2	20	
PDS135	CREACLEA	Creatinine Clearance	16APR15	3210	8	LBOCCUR	Laboratory test not applicable	2	20	
PDS135	CREACLEA	Creatinine Clearance	16APR15	3210	9	RSUBJID	De-identified Subject ID for Study	2	9	
PDS135	CREACLEA	Creatinine Clearance	16APR15	3210	10	RUSUBJID	De-identified Unique Subj. ID for Study	2	18	

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Library Member Name=DEMO

LIBNAME	MEMNAME	MEMLABEL	CRDATE	NOBS	VARNUM	NAME	LABEL	TYPE	LENGTH	FORMAT
PDS135	DEMO	Demography	16APR15	217	1	AGE	Calculated age	1	8	
PDS135	DEMO	Demography	16APR15	217	2	AGEREC	Recorded age	1	8	
PDS135	DEMO	Demography	16APR15	217	3	CYCLE	Treatment cycle	1	8	
PDS135	DEMO	Demography	16APR15	217	4	PAGENUM	Page number	2	4	$
PDS135	DEMO	Demography	16APR15	217	5	PROJCD	Project code	2	10	$
PDS135	DEMO	Demography	16APR15	217	6	AGEUNIT	Age unit	2	20	
PDS135	DEMO	Demography	16APR15	217	7	EVALND	Evaluation not done	2	20	
PDS135	DEMO	Demography	16APR15	217	8	RACE	Race	2	20	
PDS135	DEMO	Demography	16APR15	217	9	SEX	Sex	2	10	
PDS135	DEMO	Demography	16APR15	217	10	RSUBJID	De-identified Subject ID for Study	2	9	
PDS135	DEMO	Demography	16APR15	217	11	RUSUBJID	De-identified Unique Subj. ID for Study	2	18	
PDS135	DEMO	Demography	16APR15	217	12	REGION	Region of the world	2	25	

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Library Member Name=DISPOSIT

LIBNAME	MEMNAME	MEMLABEL	CRDATE	NOBS	VARNUM	NAME	LABEL	TYPE	LENGTH	FORMAT
PDS135	DISPOSIT	Study completion	16APR15	216	1	CYCLE	Treatment cycle	1	8	
PDS135	DISPOSIT	Study completion	16APR15	216	2	PAGENUM	Page number	2	4	$
PDS135	DISPOSIT	Study completion	16APR15	216	3	PROJCD	Project code	2	10	$
PDS135	DISPOSIT	Study completion	16APR15	216	4	DSDY	Study comp/disc day	1	8	
PDS135	DISPOSIT	Study completion	16APR15	216	5	WDDY	Last dose day	1	8	
PDS135	DISPOSIT	Study completion	16APR15	216	6	DSREAS	Primary reason for study discont	2	40	
PDS135	DISPOSIT	Study completion	16APR15	216	7	DSSTAT	Subject completed the study	2	20	
PDS135	DISPOSIT	Study completion	16APR15	216	8	EVALND	Evaluation not done	2	20	
PDS135	DISPOSIT	Study completion	16APR15	216	9	RSUBJID	De-identified Subject ID for Study	2	9	
PDS135	DISPOSIT	Study completion	16APR15	216	10	RUSUBJID	De-identified Unique Subj. ID for Study	2	18	
PDS135	DISPOSIT	Study completion	16APR15	216	11	DSWK	Study comp/disc week, for Death	1	8	

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Library Member Name=ECG

LIBNAME	MEMNAME	MEMLABEL	CRDATE	NOBS	VARNUM	NAME	LABEL	TYPE	LENGTH	FORMAT
PDS135	ECG	ECG	16APR15	229	1	CYCLE	Treatment cycle	1	8	
PDS135	ECG	ECG	16APR15	229	2	EGACTTM	ECG actual time-24hr clock	2	5	$
PDS135	ECG	ECG	16APR15	229	3	EGFIND	ECG finding	1	8	
PDS135	ECG	ECG	16APR15	229	4	EGHR	ECG heart rate	1	8	
PDS135	ECG	ECG	16APR15	229	5	PAGENUM	Page number	2	4	$
PDS135	ECG	ECG	16APR15	229	6	PROJCD	Project code	2	10	$
PDS135	ECG	ECG	16APR15	229	7	SEQNUM	Sequence number	1	8	
PDS135	ECG	ECG	16APR15	229	8	EGDY	ECG day	1	8	
PDS135	ECG	ECG	16APR15	229	9	EGINTP	Interpretation clin signif abn	2	40	
PDS135	ECG	ECG	16APR15	229	10	EVALND	Evaluation not done	2	20	
PDS135	ECG	ECG	16APR15	229	11	SAMEDATE	Same as visit date indicator	2	20	
PDS135	ECG	ECG	16APR15	229	12	RSUBJID	De-identified Subject ID for Study	2	9	
PDS135	ECG	ECG	16APR15	229	13	RUSUBJID	De-identified Unique Subj. ID for Study	2	18	

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Library Member Name=EMPLSTAT

LIBNAME	MEMNAME	MEMLABEL	CRDATE	NOBS	VARNUM	NAME	LABEL	TYPE	LENGTH	FORMAT
PDS135	EMPLSTAT	Employment Status	16APR15	560	1	CYCLE	Treatment cycle	1	8	
PDS135	EMPLSTAT	Employment Status	16APR15	560	2	PAGENUM	Page number	2	4	$
PDS135	EMPLSTAT	Employment Status	16APR15	560	3	PROJCD	Project code	2	10	$
PDS135	EMPLSTAT	Employment Status	16APR15	560	4	SEQNUM	Sequence number	1	8	
PDS135	EMPLSTAT	Employment Status	16APR15	560	5	EMDIS	Patient on disability	2	20	
PDS135	EMPLSTAT	Employment Status	16APR15	560	6	EMDISTYP	Disability type	2	20	
PDS135	EMPLSTAT	Employment Status	16APR15	560	7	EMSTAT	Employment status	2	20	
PDS135	EMPLSTAT	Employment Status	16APR15	560	8	EVALND	Evaluation not done	2	20	
PDS135	EMPLSTAT	Employment Status	16APR15	560	9	RSUBJID	De-identified Subject ID for Study	2	9	
PDS135	EMPLSTAT	Employment Status	16APR15	560	10	RUSUBJID	De-identified Unique Subj. ID for Study	2	18	

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Library Member Name=ENROLL

LIBNAME	MEMNAME	MEMLABEL	CRDATE	NOBS	VARNUM	NAME	LABEL	TYPE	LENGTH	FORMAT
PDS135	ENROLL	Subject enrollment	16APR15	217	1	CYCLE	Treatment cycle	1	8	
PDS135	ENROLL	Subject enrollment	16APR15	217	2	PAGENUM	Page number	2	4	$
PDS135	ENROLL	Subject enrollment	16APR15	217	3	PROJCD	Project code	2	10	$
PDS135	ENROLL	Subject enrollment	16APR15	217	4	RSUBJID	De-identified Subject ID for Study	2	9	
PDS135	ENROLL	Subject enrollment	16APR15	217	5	RUSUBJID	De-identified Unique Subj. ID for Study	2	18	

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Library Member Name=FERCCP

LIBNAME	MEMNAME	MEMLABEL	CRDATE	NOBS	VARNUM	NAME	LABEL	TYPE	LENGTH	FORMAT
PDS135	FERCCP	Fertility and contraception	16APR15	217	1	CYCLE	Treatment cycle	1	8	
PDS135	FERCCP	Fertility and contraception	16APR15	217	2	PAGENUM	Page number	2	4	$
PDS135	FERCCP	Fertility and contraception	16APR15	217	3	PROJCD	Project code	2	10	$
PDS135	FERCCP	Fertility and contraception	16APR15	217	4	SBKEY	Subset key	2	2	$
PDS135	FERCCP	Fertility and contraception	16APR15	217	5	SEQNUM	Sequence number	1	8	
PDS135	FERCCP	Fertility and contraception	16APR15	217	6	LSMENDY	Last menses day	1	8	
PDS135	FERCCP	Fertility and contraception	16APR15	217	7	SURGDY	Sterilization day	1	8	
PDS135	FERCCP	Fertility and contraception	16APR15	217	8	CBPO	Childbearing potential	2	20	
PDS135	FERCCP	Fertility and contraception	16APR15	217	9	EVALND	Evaluation not done	2	20	
PDS135	FERCCP	Fertility and contraception	16APR15	217	10	MTHCCP	Method of contraception	2	40	
PDS135	FERCCP	Fertility and contraception	16APR15	217	11	NCBSTAT	Reason no childbearing potential	2	30	
PDS135	FERCCP	Fertility and contraception	16APR15	217	12	RSUBJID	De-identified Subject ID for Study	2	9	
PDS135	FERCCP	Fertility and contraception	16APR15	217	13	RUSUBJID	De-identified Unique Subj. ID for Study	2	18	

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Library Member Name=HORMREC

LIBNAME	MEMNAME	MEMLABEL	CRDATE	NOBS	VARNUM	NAME	LABEL	TYPE	LENGTH	FORMAT
PDS135	HORMREC	Hormonal Receptor Status	16APR15	1059	1	CYCLE	Treatment cycle	1	8	
PDS135	HORMREC	Hormonal Receptor Status	16APR15	1059	2	HER2POS	HER-2 Receptors Positive Value	1	8	
PDS135	HORMREC	Hormonal Receptor Status	16APR15	1059	3	HRRECTYP	Hormonal Receptor Type	2	80	$
PDS135	HORMREC	Hormonal Receptor Status	16APR15	1059	4	PAGENUM	Page number	2	4	$
PDS135	HORMREC	Hormonal Receptor Status	16APR15	1059	5	PROJCD	Project code	2	10	$
PDS135	HORMREC	Hormonal Receptor Status	16APR15	1059	6	SEQNUM	Sequence number	1	8	
PDS135	HORMREC	Hormonal Receptor Status	16APR15	1059	7	HRDY	Horm recept day - from date derived	1	8	
PDS135	HORMREC	Hormonal Receptor Status	16APR15	1059	8	EVALND	Evaluation not done	2	20	
PDS135	HORMREC	Hormonal Receptor Status	16APR15	1059	9	HRESTREC	Estrogen receptors	2	20	
PDS135	HORMREC	Hormonal Receptor Status	16APR15	1059	10	HRPROREC	Progesterone receptors	2	20	
PDS135	HORMREC	Hormonal Receptor Status	16APR15	1059	11	HRRECSTA	Hormonal Receptor Status	2	20	
PDS135	HORMREC	Hormonal Receptor Status	16APR15	1059	12	RSUBJID	De-identified Subject ID for Study	2	9	
PDS135	HORMREC	Hormonal Receptor Status	16APR15	1059	13	RUSUBJID	De-identified Unique Subj. ID for Study	2	18	

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Library Member Name=HTWT

LIBNAME	MEMNAME	MEMLABEL	CRDATE	NOBS	VARNUM	NAME	LABEL	TYPE	LENGTH	FORMAT
PDS135	HTWT	Height and weight	16APR15	1720	1	BMI	Body mass index (reported)	1	8	
PDS135	HTWT	Height and weight	16APR15	1720	2	BMIDV	Body mass index (derived)	1	8	
PDS135	HTWT	Height and weight	16APR15	1720	3	BSA	Body surface area (reported)	1	8	
PDS135	HTWT	Height and weight	16APR15	1720	4	BSADV	Body surface area sq meter (drv)	1	8	
PDS135	HTWT	Height and weight	16APR15	1720	5	CYCLE	Treatment cycle	1	8	
PDS135	HTWT	Height and weight	16APR15	1720	6	HT	Height (reported)	1	8	
PDS135	HTWT	Height and weight	16APR15	1720	7	HTDV	Height in centimeters (derived)	1	8	
PDS135	HTWT	Height and weight	16APR15	1720	8	HTWTTM	Actual time (24hr clock)	2	5	$
PDS135	HTWT	Height and weight	16APR15	1720	9	HWPRFDO	Planned dose reference	2	10	$
PDS135	HTWT	Height and weight	16APR15	1720	10	HWPTM	Planned start time (elapsed)	2	10	$
PDS135	HTWT	Height and weight	16APR15	1720	11	HWPTME	Planned end time (elapsed)	2	10	$
PDS135	HTWT	Height and weight	16APR15	1720	12	HWPTMLBL	Planned time crf label	2	100	$
PDS135	HTWT	Height and weight	16APR15	1720	13	PAGENUM	Page number	2	4	$
PDS135	HTWT	Height and weight	16APR15	1720	14	PROJCD	Project code	2	10	$
PDS135	HTWT	Height and weight	16APR15	1720	15	SBKEY	Subset key	2	2	$
PDS135	HTWT	Height and weight	16APR15	1720	16	SEQNUM	Sequence number	1	8	
PDS135	HTWT	Height and weight	16APR15	1720	17	WT	Weight (reported)	1	8	
PDS135	HTWT	Height and weight	16APR15	1720	18	WTDV	Weight in kilograms (derived)	1	8	
PDS135	HTWT	Height and weight	16APR15	1720	19	WTEST	Weight estimated	1	8	
PDS135	HTWT	Height and weight	16APR15	1720	20	HTWTDY	Evaluation day	1	8	
PDS135	HTWT	Height and weight	16APR15	1720	21	BSAUNIT	Body surface area units	2	20	
PDS135	HTWT	Height and weight	16APR15	1720	22	EVALND	Evaluation not done	2	20	
PDS135	HTWT	Height and weight	16APR15	1720	23	FRAME	Frame	2	20	
PDS135	HTWT	Height and weight	16APR15	1720	24	HTUNIT	Height unit	2	20	
PDS135	HTWT	Height and	16APR15	1720	25	HWPRFEQ	Planned ref event qualifier	2	20	

		weight								
PDS135	HTWT	Height and weight	16APR15	1720	26	HWPRFET	Planned reference event	2	40	
PDS135	HTWT	Height and weight	16APR15	1720	27	SAMEDATE	Same as visit date indicator	2	20	
PDS135	HTWT	Height and weight	16APR15	1720	28	WTUNIT	Weight unit	2	20	
PDS135	HTWT	Height and weight	16APR15	1720	29	RSUBJID	De-identified Subject ID for Study	2	9	
PDS135	HTWT	Height and weight	16APR15	1720	30	RUSUBJID	De-identified Unique Subj. ID for Study	2	18	

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Library Member Name=INCEXC

LIBNAME	MEMNAME	MEMLABEL	CRDATE	NOBS	VARNUM	NAME	LABEL	TYPE	LENGTH	FORMAT
PDS135	INCEXC	Inclusion/exclusion	16APR15	225	1	CRNUM	Criterion number per protocol	2	3	$
PDS135	INCEXC	Inclusion/exclusion	16APR15	225	2	CYCLE	Treatment cycle	1	8	
PDS135	INCEXC	Inclusion/exclusion	16APR15	225	3	PAGENUM	Page number	2	4	$
PDS135	INCEXC	Inclusion/exclusion	16APR15	225	4	PROJCD	Project code	2	10	$
PDS135	INCEXC	Inclusion/exclusion	16APR15	225	5	SBKEY	Subset key	2	2	$
PDS135	INCEXC	Inclusion/exclusion	16APR15	225	6	SEQNUM	Sequence number	1	8	
PDS135	INCEXC	Inclusion/exclusion	16APR15	225	7	WAIVERDY	Waiver day	1	8	
PDS135	INCEXC	Inclusion/exclusion	16APR15	225	8	EVALND	Evaluation not done	2	20	
PDS135	INCEXC	Inclusion/exclusion	16APR15	225	9	INEX	Subj meet all incl/excl criteria	2	20	
PDS135	INCEXC	Inclusion/exclusion	16APR15	225	10	WAIVER	Waiver obtained	2	20	
PDS135	INCEXC	Inclusion/exclusion	16APR15	225	11	RSUBJID	De-identified Subject ID for Study	2	9	
PDS135	INCEXC	Inclusion/exclusion	16APR15	225	12	RUSUBJID	De-identified Unique Subj. ID for Study	2	18	

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Library Member Name=INFCON

LIBNAME	MEMNAME	MEMLABEL	CRDATE	NOBS	VARNUM	NAME	LABEL	TYPE	LENGTH	FORMAT
PDS135	INFCON	Informed consent	16APR15	218	1	CYCLE	Treatment cycle	1	8	
PDS135	INFCON	Informed consent	16APR15	218	2	IFCNTM	Time consent obtain (24hr clock)	2	5	$
PDS135	INFCON	Informed consent	16APR15	218	3	PAGENUM	Page number	2	4	$
PDS135	INFCON	Informed consent	16APR15	218	4	PROJCD	Project code	2	10	$
PDS135	INFCON	Informed consent	16APR15	218	5	SBKEY	Subset key	2	2	$
PDS135	INFCON	Informed consent	16APR15	218	6	SEQNUM	Sequence number	1	8	
PDS135	INFCON	Informed consent	16APR15	218	7	IFCNDY	Day consent obtained	1	8	
PDS135	INFCON	Informed consent	16APR15	218	8	CNOTH	Consent obtained from	2	30	
PDS135	INFCON	Informed consent	16APR15	218	9	EVALND	Evaluation not done	2	20	
PDS135	INFCON	Informed consent	16APR15	218	10	RSUBJID	De-identified Subject ID for Study	2	9	
PDS135	INFCON	Informed consent	16APR15	218	11	RUSUBJID	De-identified Unique Subj. ID for Study	2	18	

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Library Member Name=INVSIG

LIBNAME	MEMNAME	MEMLABEL	CRDATE	NOBS	VARNUM	NAME	LABEL	TYPE	LENGTH	FORMAT
PDS135	INVSIG	Investigator signature	16APR15	215	1	CYCLE	Treatment cycle	1	8	
PDS135	INVSIG	Investigator signature	16APR15	215	2	PAGENUM	Page number	2	4	$
PDS135	INVSIG	Investigator signature	16APR15	215	3	PROJCD	Project code	2	10	$
PDS135	INVSIG	Investigator signature	16APR15	215	4	INVSIGDY	Signature day	1	8	
PDS135	INVSIG	Investigator signature	16APR15	215	5	EVALND	Evaluation not done	2	20	
PDS135	INVSIG	Investigator signature	16APR15	215	6	INVSIG	Investigator signature indicator	2	20	
PDS135	INVSIG	Investigator signature	16APR15	215	7	RSUBJID	De-identified Subject ID for Study	2	9	
PDS135	INVSIG	Investigator signature	16APR15	215	8	RUSUBJID	De-identified Unique Subj. ID for Study	2	18	

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Library Member Name=INVSIGS

LIBNAME	MEMNAME	MEMLABEL	CRDATE	NOBS	VARNUM	NAME	LABEL	TYPE	LENGTH	FORMAT
PDS135	INVSIGS	Investigator signature/Study End	16APR15	216	1	CYCLE	Treatment cycle	1	8	
PDS135	INVSIGS	Investigator signature/Study End	16APR15	216	2	PAGENUM	Page number	2	4	$
PDS135	INVSIGS	Investigator signature/Study End	16APR15	216	3	PROJCD	Project code	2	10	$
PDS135	INVSIGS	Investigator signature/Study End	16APR15	216	4	INVSIGDY	Signature day	1	8	
PDS135	INVSIGS	Investigator signature/Study End	16APR15	216	5	EVALND	Evaluation not done	2	20	
PDS135	INVSIGS	Investigator signature/Study End	16APR15	216	6	INVSIG	Investigator signature indicator	2	20	
PDS135	INVSIGS	Investigator signature/Study End	16APR15	216	7	RSUBJID	De-identified Subject ID for Study	2	9	
PDS135	INVSIGS	Investigator signature/Study End	16APR15	216	8	RUSUBJID	De-identified Unique Subj. ID for Study	2	18	

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Library Member Name=IPOPCARE

LIBNAME	MEMNAME	MEMLABEL	CRDATE	NOBS	VARNUM	NAME	LABEL	TYPE	LENGTH	FORMAT
PDS135	IPOPCARE	In-patient or Out-patient Care	16APR15	2429	1	CYCLE	Treatment cycle	1	8	
PDS135	IPOPCARE	In-patient or Out-patient Care	16APR15	2429	2	ERVSNUM	Number of Emergency Room visits	1	8	
PDS135	IPOPCARE	In-patient or Out-patient Care	16APR15	2429	3	GPVSNUM	Number of Gen Practitioner visit	1	8	
PDS135	IPOPCARE	In-patient or Out-patient Care	16APR15	2429	4	NURVSNUM	Number of Nurse visits	1	8	
PDS135	IPOPCARE	In-patient or Out-patient Care	16APR15	2429	5	ODRVSNUM	Number of Other Physician visits	1	8	
PDS135	IPOPCARE	In-patient or Out-patient Care	16APR15	2429	6	OHPVSNUM	Number of Oth health prof visits	1	8	
PDS135	IPOPCARE	In-patient or Out-patient Care	16APR15	2429	7	OIVSNUM	Number of Onco/Internist visits	1	8	
PDS135	IPOPCARE	In-patient or Out-patient Care	16APR15	2429	8	PAGENUM	Page number	2	4	$
PDS135	IPOPCARE	In-patient or Out-patient Care	16APR15	2429	9	PROJCD	Project code	2	10	$
PDS135	IPOPCARE	In-patient or Out-patient Care	16APR15	2429	10	PTXVSNUM	Number of Physiotherapy visits	1	8	
PDS135	IPOPCARE	In-patient or Out-patient Care	16APR15	2429	11	RHBVSNUM	Number of Rehabilitation visits	1	8	
PDS135	IPOPCARE	In-patient or Out-patient Care	16APR15	2429	12	SEQNUM	Sequence number	1	8	
PDS135	IPOPCARE	In-patient or Out-patient Care	16APR15	2429	13	IPAODY	Admission/Transfer - day	1	8	
PDS135	IPOPCARE	In-patient or Out-patient Care	16APR15	2429	14	IPDCDY	Discharge/Transfer - day	1	8	
PDS135	IPOPCARE	In-patient or Out-patient Care	16APR15	2429	15	DROCCUR	Physician visits not applicable	2	20	
PDS135	IPOPCARE	In-patient or Out-patient Care	16APR15	2429	16	EROCCUR	Emerg room visits not applicable	2	20	
PDS135	IPOPCARE	In-patient or Out-patient Care	16APR15	2429	17	EVALND	Evaluation not done	2	20	
PDS135	IPOPCARE	In-patient or Out-patient Care	16APR15	2429	18	GPVS	Seen by General Practioner?	2	20	
PDS135	IPOPCARE	In-patient or Out-patient Care	16APR15	2429	19	IPAOON	Admission/Transfer - ongoing	2	20	
PDS135	IPOPCARE	In-patient or Out-patient Care	16APR15	2429	20	IPAOREAS	Reason for Admission	2	40	
PDS135	IPOPCARE	In-patient or Out-patient Care	16APR15	2429	21	IPAOU	Admission Unit	2	20	
PDS135	IPOPCARE	In-patient or Out-patient Care	16APR15	2429	22	IPDCON	Discharge/Transfer - ongoing	2	20	
PDS135	IPOPCARE	In-patient or Out-patient Care	16APR15	2429	23	IPHOAO	Patient admitted to hospital?	2	20	
PDS135	IPOPCARE	In-patient or Out-patient Care	16APR15	2429	24	IPHOPROC	Any major procedures performed?	2	20	
PDS135	IPOPCARE	In-patient or Out-	16APR15	2429	25	NURVS	Seen by Nurse?	2	20	

		patient Care								
PDS135	IPOPCARE	In-patient or Out-patient Care	16APR15	2429	26	ODRVS	Seen by Other Physician?	2	20	
PDS135	IPOPCARE	In-patient or Out-patient Care	16APR15	2429	27	OHPOCCUR	Other health prof not applicable	2	20	
PDS135	IPOPCARE	In-patient or Out-patient Care	16APR15	2429	28	OHPVS	Seen by Other health prof?	2	20	
PDS135	IPOPCARE	In-patient or Out-patient Care	16APR15	2429	29	OIVS	Seen by Oncologist/Internist?	2	20	
PDS135	IPOPCARE	In-patient or Out-patient Care	16APR15	2429	30	OPVS	Were there Out-patient visits?	2	20	
PDS135	IPOPCARE	In-patient or Out-patient Care	16APR15	2429	31	PROCPERF	Any major procedures performed?	2	20	
PDS135	IPOPCARE	In-patient or Out-patient Care	16APR15	2429	32	PTXVS	Seen by Physiotherapy prof?	2	20	
PDS135	IPOPCARE	In-patient or Out-patient Care	16APR15	2429	33	RHBVS	Seen by Rehabilitation prof?	2	20	
PDS135	IPOPCARE	In-patient or Out-patient Care	16APR15	2429	34	RSUBJID	De-identified Subject ID for Study	2	9	
PDS135	IPOPCARE	In-patient or Out-patient Care	16APR15	2429	35	RUSUBJID	De-identified Unique Subj. ID for Study	2	18	

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Library Member Name=LABS

LIBNAME	MEMNAME	MEMLABEL	CRDATE	NOBS	VARNUM	NAME	LABEL	TYPE	LENGTH	FORMAT
PDS135	LABS	Lab findings	16APR15	133814	1	CYCLE	Treatment cycle	1	8	
PDS135	LABS	Lab findings	16APR15	133814	2	LBACTTM	Specimen collect time 24hr clock	2	5	$
PDS135	LABS	Lab findings	16APR15	133814	3	LBDFID	Data file identification	2	20	$
PDS135	LABS	Lab findings	16APR15	133814	4	LBPRFDO	Planned dose reference	2	10	$
PDS135	LABS	Lab findings	16APR15	133814	5	LBPTM	Planned start time (elapsed)	2	10	$
PDS135	LABS	Lab findings	16APR15	133814	6	LBPTME	Planned end time (elapsed)	2	10	$
PDS135	LABS	Lab findings	16APR15	133814	7	LBPTMLBL	Planned time crf label	2	100	$
PDS135	LABS	Lab findings	16APR15	133814	8	LBSMNUM	Lab sample id/accession id	2	20	$
PDS135	LABS	Lab findings	16APR15	133814	9	LBSMTX	Lab sample comment	2	200	$
PDS135	LABS	Lab findings	16APR15	133814	10	ORGRES	Result in original units	2	20	$
PDS135	LABS	Lab findings	16APR15	133814	11	PAGENUM	Page number	2	4	$
PDS135	LABS	Lab findings	16APR15	133814	12	PROJCD	Project code	2	10	$
PDS135	LABS	Lab findings	16APR15	133814	13	SBKEY	Subset key	2	2	$
PDS135	LABS	Lab findings	16APR15	133814	14	SEQNUM	Sequence number	1	8	
PDS135	LABS	Lab findings	16APR15	133814	15	STDNRC	Norm Rng char result std unit	2	80	$
PDS135	LABS	Lab findings	16APR15	133814	16	STDNRHI	Norm Rng upper limit std unit SI	1	8	
PDS135	LABS	Lab findings	16APR15	133814	17	STDNRLO	Norm Rng lower limit std unit SI	1	8	
PDS135	LABS	Lab findings	16APR15	133814	18	STDRESC	Analysis char result std unit	2	80	$
PDS135	LABS	Lab findings	16APR15	133814	19	STDRESN	Analysis numeric result std unit	1	8	
PDS135	LABS	Lab findings	16APR15	133814	20	ORGNRC	Norm Rng char result orig unit	2	80	$
PDS135	LABS	Lab findings	16APR15	133814	21	ORGNRHI	Norm Rng upper limit orig unit	1	8	
PDS135	LABS	Lab findings	16APR15	133814	22	ORGNRLO	Norm Rng lower limit orig unit	1	8	
PDS135	LABS	Lab findings	16APR15	133814	23	NRIND	Normal range indicator	2	1	
PDS135	LABS	Lab findings	16APR15	133814	24	LBDY	Specimen collect day	1	8	
PDS135	LABS	Lab findings	16APR15	133814	25	LBRPTDY	Day results reported by lab	1	8	
PDS135	LABS	Lab findings	16APR15	133814	26	EVALND	Evaluation not done	2	20	
PDS135	LABS	Lab findings	16APR15	133814	27	LBFAST	Sample taken fasting	2	20	
PDS135	LABS	Lab findings	16APR15	133814	28	LBPRFEQ	Planned ref event qualifier	2	20	
PDS135	LABS	Lab findings	16APR15	133814	29	LBPRFET	Planned reference event	2	40	
PDS135	LABS	Lab findings	16APR15	133814	30	LBRETFL	Retransmission flag	2	40	
PDS135	LABS	Lab findings	16APR15	133814	31	LBTEST	Lab test name	2	70	
PDS135	LABS	Lab findings	16APR15	133814	32	LBTSMT	Test methodology	2	40	
PDS135	LABS	Lab findings	16APR15	133814	33	LBTSPA	Test panel	2	40	
PDS135	LABS	Lab findings	16APR15	133814	34	ORGUNIT	Original unit	2	20	
PDS135	LABS	Lab findings	16APR15	133814	35	SAMELAB	Same as previous lab indicator	2	20	
PDS135	LABS	Lab findings	16APR15	133814	36	STDUNIT	Standard unit (SI)	2	20	
PDS135	LABS	Lab findings	16APR15	133814	37	RSUBJID	De-identified Subject ID for	2	9	

							Study			
PDS135	LABS	Lab findings	16APR15	133814	38	RUSUBJID	De-identified Unique Subj. ID for Study	2	18	
PDS135	LABS	Lab findings	16APR15	133814	39	RANDLBID	De-identified lab id	1	8	

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Library Member Name=MEDHIST

LIBNAME	MEMNAME	MEMLABEL	CRDATE	NOBS	VARNUM	NAME	LABEL	TYPE	LENGTH	FORMAT
PDS135	MEDHIST	Medical History	16APR15	855	1	CYCLE	Treatment cycle	1	8	
PDS135	MEDHIST	Medical History	16APR15	855	2	MHTERM	Medical/surg hx (reported term)	2	80	$
PDS135	MEDHIST	Medical History	16APR15	855	3	PAGENUM	Page number	2	4	$
PDS135	MEDHIST	Medical History	16APR15	855	4	PROJCD	Project code	2	10	$
PDS135	MEDHIST	Medical History	16APR15	855	5	SBKEY	Subset key	2	2	$
PDS135	MEDHIST	Medical History	16APR15	855	6	SEQNUM	Sequence number	1	8	
PDS135	MEDHIST	Medical History	16APR15	855	7	MHSDTIMP	Level of imputation, Medhist start date	2	20	
PDS135	MEDHIST	Medical History	16APR15	855	8	MHEDTIMP	Level of imputation, Medhist end date	2	20	
PDS135	MEDHIST	Medical History	16APR15	855	9	MHEDY	Med/sur hx end day	1	8	
PDS135	MEDHIST	Medical History	16APR15	855	10	MHSDY	Medical hx start day	1	8	
PDS135	MEDHIST	Medical History	16APR15	855	11	EVALND	Evaluation not done	2	20	
PDS135	MEDHIST	Medical History	16APR15	855	12	MHOCCUR	Mark if no relevant med/surg hx	2	20	
PDS135	MEDHIST	Medical History	16APR15	855	13	MHSTAT	Medical history status	2	20	
PDS135	MEDHIST	Medical History	16APR15	855	14	RSUBJID	De-identified Subject ID for Study	2	9	
PDS135	MEDHIST	Medical History	16APR15	855	15	RUSUBJID	De-identified Unique Subj. ID for Study	2	18	

ClinicalTrial.govID=NCT00081796 Protocol=EFC6089[XRP9881B/3001] uploaded 04/29/2015

Library Member Name=NEUROEXM

LIBNAME	MEMNAME	MEMLABEL	CRDATE	NOBS	VARNUM	NAME	LABEL	TYPE	LENGTH	FORMAT
PDS135	NEUROEXM	Neurological Exam	16APR15	1720	1	CYCLE	Treatment cycle	1	8	
PDS135	NEUROEXM	Neurological Exam	16APR15	1720	2	NEEXAM	Neurological exam type	2	35	$
PDS135	NEUROEXM	Neurological Exam	16APR15	1720	3	NEPRFDO	Planned dose reference	2	10	$
PDS135	NEUROEXM	Neurological Exam	16APR15	1720	4	NEPRFEQ	Planned ref event qualifier	1	8	
PDS135	NEUROEXM	Neurological Exam	16APR15	1720	5	NEPRFET	Planned reference event	1	8	
PDS135	NEUROEXM	Neurological Exam	16APR15	1720	6	NEPTM	Planned start time (elapsed)	2	10	$
PDS135	NEUROEXM	Neurological Exam	16APR15	1720	7	NEPTME	Planned end time (elapsed)	2	10	$
PDS135	NEUROEXM	Neurological Exam	16APR15	1720	8	NEPTMLBL	Planned time crf label	2	100	$
PDS135	NEUROEXM	Neurological Exam	16APR15	1720	9	NETX	Other NE exam - specify	2	60	$
PDS135	NEUROEXM	Neurological Exam	16APR15	1720	10	PAGENUM	Page number	2	4	$
PDS135	NEUROEXM	Neurological Exam	16APR15	1720	11	PROJCD	Project code	2	10	$
PDS135	NEUROEXM	Neurological Exam	16APR15	1720	12	SEQNUM	Sequence number	1	8	
PDS135	NEUROEXM	Neurological Exam	16APR15	1720	13	NEDY	Day neuro exam - from date derived	1	8	
PDS135	NEUROEXM	Neurological Exam	16APR15	1720	14	EVALND	Evaluation not done	2	20	
PDS135	NEUROEXM	Neurological Exam	16APR15	1720	15	NERESULT	Neurological exam result	2	40	
PDS135	NEUROEXM	Neurological Exam	16APR15	1720	16	NESYMPYN	Sensory symptom response	2	20	
PDS135	NEUROEXM	Neurological Exam	16APR15	1720	17	SAMEDATE	Same as visit date indicator	2	20	
PDS135	NEUROEXM	Neurological Exam	16APR15	1720	18	RSUBJID	De-identified Subject ID for Study	2	9	
PDS135	NEUROEXM	Neurological Exam	16APR15	1720	19	RUSUBJID	De-identified Unique Subj. ID for Study	2	18	

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Library Member Name=NORMALS

LIBNAME	MEMNAME	MEMLABEL	CRDATE	NOBS	VARNUM	NAME	LABEL	TYPE	LENGTH	FORMAT
PDS135	NORMALS	Normal lab ranges	16APR15	72	1	AGEMAX	Upper limit of age range	1	8	
PDS135	NORMALS	Normal lab ranges	16APR15	72	2	AGEMN	Lower limit of age range	1	8	
PDS135	NORMALS	Normal lab ranges	16APR15	72	3	ORGNRC	Norm Rng char result orig unit	2	80	$
PDS135	NORMALS	Normal lab ranges	16APR15	72	4	ORGNRHI	Norm Rng upper limit orig unit	1	8	
PDS135	NORMALS	Normal lab ranges	16APR15	72	5	ORGNRLO	Norm Rng lower limit orig unit	1	8	
PDS135	NORMALS	Normal lab ranges	16APR15	72	6	SEQNUM	Sequence number	1	8	
PDS135	NORMALS	Normal lab ranges	16APR15	72	7	STDNRC	Norm Rng char result std unit	2	80	$
PDS135	NORMALS	Normal lab ranges	16APR15	72	8	STDNRHI	Norm Rng upper limit std unit SI	1	8	
PDS135	NORMALS	Normal lab ranges	16APR15	72	9	STDNRLO	Norm Rng lower limit std unit SI	1	8	
PDS135	NORMALS	Normal lab ranges	16APR15	72	10	AGEUNIT	Age unit	2	20	
PDS135	NORMALS	Normal lab ranges	16APR15	72	11	LBTEST	Lab test name	2	70	
PDS135	NORMALS	Normal lab ranges	16APR15	72	12	LBTSMT	Test methodology	2	40	
PDS135	NORMALS	Normal lab ranges	16APR15	72	13	LBTSPA	Test panel	2	40	
PDS135	NORMALS	Normal lab ranges	16APR15	72	14	ORGUNIT	Original unit	2	20	
PDS135	NORMALS	Normal lab ranges	16APR15	72	15	POTERMCD	Population (code)	2	40	
PDS135	NORMALS	Normal lab ranges	16APR15	72	16	SEX	Sex	2	10	
PDS135	NORMALS	Normal lab ranges	16APR15	72	17	STAGE	Stage of life	2	20	
PDS135	NORMALS	Normal lab ranges	16APR15	72	18	STDUNIT	Standard unit (SI)	2	20	
PDS135	NORMALS	Normal lab ranges	16APR15	72	19	RANDLBID	De-identified lab id	1	8	

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Library Member Name=NORMALS2

LIBNAME	MEMNAME	MEMLABEL	CRDATE	NOBS	VARNUM	NAME	LABEL	TYPE	LENGTH	FORMAT
PDS135	NORMALS2	Normal lab ranges for Data Entry	16APR15	11555	1	AGEMAX	Upper limit of age range	1	8	
PDS135	NORMALS2	Normal lab ranges for Data Entry	16APR15	11555	2	AGEMN	Lower limit of age range	1	8	
PDS135	NORMALS2	Normal lab ranges for Data Entry	16APR15	11555	3	ORGNRC	Norm Rng char result orig unit	2	80	$
PDS135	NORMALS2	Normal lab ranges for Data Entry	16APR15	11555	4	ORGNRHI	Norm Rng upper limit orig unit	1	8	
PDS135	NORMALS2	Normal lab ranges for Data Entry	16APR15	11555	5	ORGNRLO	Norm Rng lower limit orig unit	1	8	
PDS135	NORMALS2	Normal lab ranges for Data Entry	16APR15	11555	6	SEQNUM	Sequence number	1	8	
PDS135	NORMALS2	Normal lab ranges for Data Entry	16APR15	11555	7	STDNRC	Norm Rng char result std unit	2	80	$
PDS135	NORMALS2	Normal lab ranges for Data Entry	16APR15	11555	8	STDNRHI	Norm Rng upper limit std unit SI	1	8	
PDS135	NORMALS2	Normal lab ranges for Data Entry	16APR15	11555	9	STDNRLO	Norm Rng lower limit std unit SI	1	8	
PDS135	NORMALS2	Normal lab ranges for Data Entry	16APR15	11555	10	AGEUNIT	Age unit	2	20	
PDS135	NORMALS2	Normal lab ranges for Data Entry	16APR15	11555	11	LBTEST	Lab test name	2	70	
PDS135	NORMALS2	Normal lab ranges for Data Entry	16APR15	11555	12	LBTSMT	Test methodology	2	40	
PDS135	NORMALS2	Normal lab ranges for Data Entry	16APR15	11555	13	LBTSPA	Test panel	2	40	
PDS135	NORMALS2	Normal lab ranges for Data Entry	16APR15	11555	14	ORGUNIT	Original unit	2	20	
PDS135	NORMALS2	Normal lab ranges for Data Entry	16APR15	11555	15	POTERMCD	Population (code)	2	40	
PDS135	NORMALS2	Normal lab ranges for Data Entry	16APR15	11555	16	SEX	Sex	2	10	
PDS135	NORMALS2	Normal lab ranges for Data Entry	16APR15	11555	17	STAGE	Stage of life	2	20	
PDS135	NORMALS2	Normal lab ranges for Data Entry	16APR15	11555	18	STDUNIT	Standard unit (SI)	2	20	
PDS135	NORMALS2	Normal lab ranges for Data Entry	16APR15	11555	19	RANDLBID	De-identified lab id	1	8	

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Library Member Name=ONCADMIN

LIBNAME	MEMNAME	MEMLABEL	CRDATE	NOBS	VARNUM	NAME	LABEL	TYPE	LENGTH	FORMAT
PDS135	ONCADMIN	Study Med Admin (Oncology)	16APR15	5144	1	CYCLE	Treatment cycle	1	8	
PDS135	ONCADMIN	Study Med Admin (Oncology)	16APR15	5144	2	OADILSOL	Diluting solution	2	60	$
PDS135	ONCADMIN	Study Med Admin (Oncology)	16APR15	5144	3	OADOSE	Dose given per administration	1	8	
PDS135	ONCADMIN	Study Med Admin (Oncology)	16APR15	5144	4	OADOSFRQ	Frequency of dosing	2	80	$
PDS135	ONCADMIN	Study Med Admin (Oncology)	16APR15	5144	5	OADOSINT	Intended Dose	1	8	
PDS135	ONCADMIN	Study Med Admin (Oncology)	16APR15	5144	6	OADOSTOT	Total daily dose given	1	8	
PDS135	ONCADMIN	Study Med Admin (Oncology)	16APR15	5144	7	OADOUNIT	Dose unit	2	80	$
PDS135	ONCADMIN	Study Med Admin (Oncology)	16APR15	5144	8	OAETM	End time of dose - 24 hr clock	2	5	$
PDS135	ONCADMIN	Study Med Admin (Oncology)	16APR15	5144	9	OAFORM	Dosage form at this exposure	2	80	$
PDS135	ONCADMIN	Study Med Admin (Oncology)	16APR15	5144	10	OAPTMLBL	Planned time crf label	2	100	$
PDS135	ONCADMIN	Study Med Admin (Oncology)	16APR15	5144	11	OAROUTE	Route of admin at this exposure	2	80	$
PDS135	ONCADMIN	Study Med Admin (Oncology)	16APR15	5144	12	OASTM	Start time of dose - 24 hr clock	2	5	$
PDS135	ONCADMIN	Study Med Admin (Oncology)	16APR15	5144	13	OATABMN	Nb of Tablets taken-lower dose	1	8	
PDS135	ONCADMIN	Study Med Admin (Oncology)	16APR15	5144	14	OATABMX	Nb of Tablets taken-higher dose	1	8	
PDS135	ONCADMIN	Study Med Admin (Oncology)	16APR15	5144	15	OATDOSUN	Total Dose unit	2	80	$
PDS135	ONCADMIN	Study Med Admin (Oncology)	16APR15	5144	16	OATRTCD	Numeric assignment from random	1	8	
PDS135	ONCADMIN	Study Med Admin (Oncology)	16APR15	5144	17	OATRTGRP	Sequence of treatment identifier	2	80	$
PDS135	ONCADMIN	Study Med Admin (Oncology)	16APR15	5144	18	OATRTNM	Active treatment received	2	80	$
PDS135	ONCADMIN	Study Med Admin (Oncology)	16APR15	5144	19	PAGENUM	Page number	2	4	$
PDS135	ONCADMIN	Study Med Admin (Oncology)	16APR15	5144	20	PROJCD	Project code	2	10	$
PDS135	ONCADMIN	Study Med Admin (Oncology)	16APR15	5144	21	SBKEY	Subset key	2	2	$
PDS135	ONCADMIN	Study Med Admin (Oncology)	16APR15	5144	22	SEQNUM	Sequence number	1	8	
PDS135	ONCADMIN	Study Med Admin (Oncology)	16APR15	5144	23	OAEDY	Act end dose day - from date derived	1	8	
PDS135	ONCADMIN	Study Med Admin (Oncology)	16APR15	5144	24	OASDY	Act start day - from date derived	1	8	
PDS135	ONCADMIN	Study Med Admin	16APR15	5144	25	EVALND	Evaluation not done	2	20	

PDS135	ONCADMIN	Study Med Admin (Oncology)									
PDS135	ONCADMIN	Study Med Admin (Oncology)	16APR15	5144	26	OADELAY	Treatment delayed	2	20	
PDS135	ONCADMIN	Study Med Admin (Oncology)	16APR15	5144	27	OADEREAS	Reason treatment delayed	2	40	
PDS135	ONCADMIN	Study Med Admin (Oncology)	16APR15	5144	28	OAINCP	Infusion completed per schedule	2	20	
PDS135	ONCADMIN	Study Med Admin (Oncology)	16APR15	5144	29	OAINCR	Dose increased?	2	20	
PDS135	ONCADMIN	Study Med Admin (Oncology)	16APR15	5144	30	OAINCREA	Reason for dose increased	2	40	
PDS135	ONCADMIN	Study Med Admin (Oncology)	16APR15	5144	31	OAINREAS	Reason infusion not per schedule	2	40	
PDS135	ONCADMIN	Study Med Admin (Oncology)	16APR15	5144	32	OAINTER	Dose interrupted	2	20	
PDS135	ONCADMIN	Study Med Admin (Oncology)	16APR15	5144	33	OAITREAS	Reason dose interrupted	2	40	
PDS135	ONCADMIN	Study Med Admin (Oncology)	16APR15	5144	34	OANA	Not applicable	2	20	
PDS135	ONCADMIN	Study Med Admin (Oncology)	16APR15	5144	35	OAOMIT	Dose omitted	2	20	
PDS135	ONCADMIN	Study Med Admin (Oncology)	16APR15	5144	36	OAOMREAS	Reason for dose omission	2	40	
PDS135	ONCADMIN	Study Med Admin (Oncology)	16APR15	5144	37	OAREDUCE	Dose reduced yes/no	2	20	
PDS135	ONCADMIN	Study Med Admin (Oncology)	16APR15	5144	38	OAREREAS	Reason dose reduced	2	40	
PDS135	ONCADMIN	Study Med Admin (Oncology)	16APR15	5144	39	OASITE	Administration site	2	20	
PDS135	ONCADMIN	Study Med Admin (Oncology)	16APR15	5144	40	RSUBJID	De-identified Subject ID for Study	2	9	
PDS135	ONCADMIN	Study Med Admin (Oncology)	16APR15	5144	41	RUSUBJID	De-identified Unique Subj. ID for Study	2	18	

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Library Member Name=ONCDEATH

LIBNAME	MEMNAME	MEMLABEL	CRDATE	NOBS	VARNUM	NAME	LABEL	TYPE	LENGTH	FORMAT
PDS135	ONCDEATH	Death	16APR15	211	1	CYCLE	Treatment cycle	1	8	
PDS135	ONCDEATH	Death	16APR15	211	2	PAGENUM	Page number	2	4	$
PDS135	ONCDEATH	Death	16APR15	211	3	PROJCD	Project code	2	10	$
PDS135	ONCDEATH	Death	16APR15	211	4	DECAUSCD	Cause of death code	2	40	
PDS135	ONCDEATH	Death	16APR15	211	5	DEOCCUR	Death not applicable	2	20	
PDS135	ONCDEATH	Death	16APR15	211	6	EVALND	Evaluation not done	2	20	
PDS135	ONCDEATH	Death	16APR15	211	7	RSUBJID	De-identified Subject ID for Study	2	9	
PDS135	ONCDEATH	Death	16APR15	211	8	RUSUBJID	De-identified Unique Subj. ID for Study	2	18	
PDS135	ONCDEATH	Death	16APR15	211	9	DEATHWK	Study Week of Death	1	8	

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Library Member Name=OTHPROC

LIBNAME	MEMNAME	MEMLABEL	CRDATE	NOBS	VARNUM	NAME	LABEL	TYPE	LENGTH	FORMAT
PDS135	OTHPROC	Other Procedures	16APR15	373	1	CYCLE	Treatment cycle	1	8	
PDS135	OTHPROC	Other Procedures	16APR15	373	2	PAGENUM	Page number	2	4	$
PDS135	OTHPROC	Other Procedures	16APR15	373	3	PROJCD	Project code	2	10	$
PDS135	OTHPROC	Other Procedures	16APR15	373	4	SEQNUM	Sequence number	1	8	
PDS135	OTHPROC	Other Procedures	16APR15	373	5	OPDY	Day assessed - from date derived	1	8	
PDS135	OTHPROC	Other Procedures	16APR15	373	6	EVALND	Evaluation not done	2	20	
PDS135	OTHPROC	Other Procedures	16APR15	373	7	OPTYP	Type of procedure	2	40	
PDS135	OTHPROC	Other Procedures	16APR15	373	8	RSUBJID	De-identified Subject ID for Study	2	9	
PDS135	OTHPROC	Other Procedures	16APR15	373	9	RUSUBJID	De-identified Unique Subj. ID for Study	2	18	

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Library Member Name=OVRSP

LIBNAME	MEMNAME	MEMLABEL	CRDATE	NOBS	VARNUM	NAME	LABEL	TYPE	LENGTH	FORMAT
PDS135	OVRSP	Overall Response	16APR15	1894	1	CYCLE	Treatment cycle	1	8	
PDS135	OVRSP	Overall Response	16APR15	1894	2	PAGENUM	Page number	2	4	$
PDS135	OVRSP	Overall Response	16APR15	1894	3	PROJCD	Project code	2	10	$
PDS135	OVRSP	Overall Response	16APR15	1894	4	EVALND	Evaluation not done	2	20	
PDS135	OVRSP	Overall Response	16APR15	1894	5	OVRSP	Overall response	2	40	
PDS135	OVRSP	Overall Response	16APR15	1894	6	RSUBJID	De-identified Subject ID for Study	2	9	
PDS135	OVRSP	Overall Response	16APR15	1894	7	RUSUBJID	De-identified Unique Subj. ID for Study	2	18	

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Library Member Name=OVRSPIRC

LIBNAME	MEMNAME	MEMLABEL	CRDATE	NOBS	VARNUM	NAME	LABEL	TYPE	LENGTH	FORMAT
PDS135	OVRSPIRC	Overall Response (Radpharm)	16APR15	878	1	B_PCBSLD	Percent Change from Base-Bone	2	10	$
PDS135	OVRSPIRC	Overall Response (Radpharm)	16APR15	878	2	B_PCNSLD	Percent Change from Nadir-Bone	2	10	$
PDS135	OVRSPIRC	Overall Response (Radpharm)	16APR15	878	3	B_SLD	Sum of the longest diameter-Bone	2	10	$
PDS135	OVRSPIRC	Overall Response (Radpharm)	16APR15	878	4	CYCLE	Treatment cycle	1	8	
PDS135	OVRSPIRC	Overall Response (Radpharm)	16APR15	878	5	GCOM5	Comment 5	2	200	$
PDS135	OVRSPIRC	Overall Response (Radpharm)	16APR15	878	6	NB_PCBSL	Percent Change from Base-NBone	2	10	$
PDS135	OVRSPIRC	Overall Response (Radpharm)	16APR15	878	7	NB_PCNSL	Percent Change from Nadir-NBone	2	10	$
PDS135	OVRSPIRC	Overall Response (Radpharm)	16APR15	878	8	NB_SLD	Sum of the longest diamet-NBone	2	10	$
PDS135	OVRSPIRC	Overall Response (Radpharm)	16APR15	878	9	NEWLES	New lesions	2	1	$
PDS135	OVRSPIRC	Overall Response (Radpharm)	16APR15	878	10	ORTX	Overall response - specify	2	80	$
PDS135	OVRSPIRC	Overall Response (Radpharm)	16APR15	878	11	OVRSCRIT	Overall Response Criteria	1	8	
PDS135	OVRSPIRC	Overall Response (Radpharm)	16APR15	878	12	PAGENUM	Page number	2	4	$
PDS135	OVRSPIRC	Overall Response (Radpharm)	16APR15	878	13	PCBSLD	Percent Change from Baseline	2	10	$
PDS135	OVRSPIRC	Overall Response (Radpharm)	16APR15	878	14	PCNSLD	Percent Change from Nadir	2	10	$
PDS135	OVRSPIRC	Overall Response (Radpharm)	16APR15	878	15	PROJCD	Project code	2	10	$
PDS135	OVRSPIRC	Overall Response (Radpharm)	16APR15	878	16	REVTYPE	Type of person	2	40	$
PDS135	OVRSPIRC	Overall Response (Radpharm)	16APR15	878	17	RPFRE	First response	1	8	
PDS135	OVRSPIRC	Overall Response (Radpharm)	16APR15	878	18	SLD	Sum of the longest diameters	2	10	$
PDS135	OVRSPIRC	Overall Response (Radpharm)	16APR15	878	19	VISIT	Planned clinical encounter	2	40	$
PDS135	OVRSPIRC	Overall Response (Radpharm)	16APR15	878	20	B_INTRS1_DY	Day of Integrated Resp-Bone	1	8	
PDS135	OVRSPIRC	Overall Response (Radpharm)	16APR15	878	21	B_OVRSP1_DY	Day of Best Overall Resp-Bone	1	8	
PDS135	OVRSPIRC	Overall Response (Radpharm)	16APR15	878	22	B_OVRSPD_DY	Day of Overall Response-Bone	1	8	
PDS135	OVRSPIRC	Overall Response (Radpharm)	16APR15	878	23	B_RPDPDT_DY	Day of Disease Progression-Bone	1	8	
PDS135	OVRSPIRC	Overall Response (Radpharm)	16APR15	878	24	B_RPFRED_DY	Day of First Response-Bone	1	8	
PDS135	OVRSPIRC	Overall Response	16APR15	878	25	INTRSPDT_DY	Day of Integrated	1	8	

							Response			
PDS135	OVRSPIRC	Overall Response (Radpharm)	16APR15	878	26	NB_INTR1_DY	Day of Integrated Resp-NBone	1	8	
PDS135	OVRSPIRC	Overall Response (Radpharm)	16APR15	878	27	NB_OVRS2_DY	Day of Best Overall Resp-NBone	1	8	
PDS135	OVRSPIRC	Overall Response (Radpharm)	16APR15	878	28	NB_OVRS3_DY	Day of Overall Response-NBone	1	8	
PDS135	OVRSPIRC	Overall Response (Radpharm)	16APR15	878	29	NB_RPDPD_DY	Day of Disease Progress-NBone	1	8	
PDS135	OVRSPIRC	Overall Response (Radpharm)	16APR15	878	30	NB_RPFRE_DY	Day of First Response-NBone	1	8	
PDS135	OVRSPIRC	Overall Response (Radpharm)	16APR15	878	31	OVRSPDT_DY	Day of Overall Response	1	8	
PDS135	OVRSPIRC	Overall Response (Radpharm)	16APR15	878	32	OVRSPBDT_DY	Day of Best Overall Response	1	8	
PDS135	OVRSPIRC	Overall Response (Radpharm)	16APR15	878	33	RPDPDT_DY	Day of Disease Progression	1	8	
PDS135	OVRSPIRC	Overall Response (Radpharm)	16APR15	878	34	RPFREDT_DY	Day of First Response	1	8	
PDS135	OVRSPIRC	Overall Response (Radpharm)	16APR15	878	35	B_INTRSP	Integrated Response-Bone	2	40	
PDS135	OVRSPIRC	Overall Response (Radpharm)	16APR15	878	36	B_ORNTL	Over NonTarget lesion resp-Bone	2	40	
PDS135	OVRSPIRC	Overall Response (Radpharm)	16APR15	878	37	B_ORTL	Overall Target lesion resp-Bone	2	40	
PDS135	OVRSPIRC	Overall Response (Radpharm)	16APR15	878	38	B_OVRSP	Overall Response-Bone	2	40	
PDS135	OVRSPIRC	Overall Response (Radpharm)	16APR15	878	39	B_OVRSPB	Best Overall Response-Bone	2	40	
PDS135	OVRSPIRC	Overall Response (Radpharm)	16APR15	878	40	B_RPDP	Disease Progression-Bone	2	20	
PDS135	OVRSPIRC	Overall Response (Radpharm)	16APR15	878	41	EVALND	Evaluation not done	2	20	
PDS135	OVRSPIRC	Overall Response (Radpharm)	16APR15	878	42	INTRSP	Integrated Response	2	40	
PDS135	OVRSPIRC	Overall Response (Radpharm)	16APR15	878	43	NB_INTRS	Integrated Response-NBone	2	40	
PDS135	OVRSPIRC	Overall Response (Radpharm)	16APR15	878	44	NB_ORNTL	Over NonTarget lesion resp-NBone	2	40	
PDS135	OVRSPIRC	Overall Response (Radpharm)	16APR15	878	45	NB_ORTL	Overall Target lesion resp-NBone	2	40	
PDS135	OVRSPIRC	Overall Response (Radpharm)	16APR15	878	46	NB_OVRS1	Best Overall Response-NBone	2	40	
PDS135	OVRSPIRC	Overall Response (Radpharm)	16APR15	878	47	NB_OVRSP	Overall Response-NBone	2	40	
PDS135	OVRSPIRC	Overall Response (Radpharm)	16APR15	878	48	NB_RPDP	Disease Progression-NBone	2	20	
PDS135	OVRSPIRC	Overall Response (Radpharm)	16APR15	878	49	ORNTL	Overall resp non-target lesion	2	40	
PDS135	OVRSPIRC	Overall Response (Radpharm)	16APR15	878	50	ORREADR	Film reader	2	30	
PDS135	OVRSPIRC	Overall Response (Radpharm)	16APR15	878	51	ORTL	Response of target lesion	2	40	
PDS135	OVRSPIRC	Overall Response (Radpharm)	16APR15	878	52	OVRSP	Overall response	2	40	

PDS135	OVRSPIRC	Overall Response (Radpharm)	16APR15	878	53	OVRSPB	Best Overall Response	2	40	
PDS135	OVRSPIRC	Overall Response (Radpharm)	16APR15	878	54	RPDP	Disease Progression	2	20	
PDS135	OVRSPIRC	Overall Response (Radpharm)	16APR15	878	55	RSUBJID	De-identified Subject ID for Study	2	9	
PDS135	OVRSPIRC	Overall Response (Radpharm)	16APR15	878	56	RUSUBJID	De-identified Unique Subj. ID for Study	2	18	

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Library Member Name=PAFUSTAT

LIBNAME	MEMNAME	MEMLABEL	CRDATE	NOBS	VARNUM	NAME	LABEL	TYPE	LENGTH	FORMAT
PDS135	PAFUSTAT	Patient Follow-up Status	16APR15	466	1	CYCLE	Treatment cycle	1	8	
PDS135	PAFUSTAT	Patient Follow-up Status	16APR15	466	2	PAGENUM	Page number	2	4	$
PDS135	PAFUSTAT	Patient Follow-up Status	16APR15	466	3	PROJCD	Project code	2	10	$
PDS135	PAFUSTAT	Patient Follow-up Status	16APR15	466	4	SEQNUM	Sequence number	1	8	
PDS135	PAFUSTAT	Patient Follow-up Status	16APR15	466	5	PFDY	Last contact day - from date derived	1	8	
PDS135	PAFUSTAT	Patient Follow-up Status	16APR15	466	6	EVALND	Evaluation not done	2	20	
PDS135	PAFUSTAT	Patient Follow-up Status	16APR15	466	7	PFPTSTAT	Patient status	2	20	
PDS135	PAFUSTAT	Patient Follow-up Status	16APR15	466	8	PFSOURCE	Source of patient status inform	2	30	
PDS135	PAFUSTAT	Patient Follow-up Status	16APR15	466	9	RSUBJID	De-identified Subject ID for Study	2	9	
PDS135	PAFUSTAT	Patient Follow-up Status	16APR15	466	10	RUSUBJID	De-identified Unique Subj. ID for Study	2	18	
PDS135	PAFUSTAT	Patient Follow-up Status	16APR15	466	11	PFWK	Stdy week Last contact,when status Dead	1	8	

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Library Member Name=PATWKIRC

LIBNAME	MEMNAME	MEMLABEL	CRDATE	NOBS	VARNUM	NAME	LABEL	TYPE	LENGTH	FORMAT
PDS135	PATWKIRC	Patient Work-Up (Radpharm)	16APR15	3233	1	CYCLE	Treatment cycle	1	8	
PDS135	PATWKIRC	Patient Work-Up (Radpharm)	16APR15	3233	2	PAGENUM	Page number	2	4	$
PDS135	PATWKIRC	Patient Work-Up (Radpharm)	16APR15	3233	3	PROJCD	Project code	2	10	$
PDS135	PATWKIRC	Patient Work-Up (Radpharm)	16APR15	3233	4	PWEVTYP	Type of evaluation	2	40	$
PDS135	PATWKIRC	Patient Work-Up (Radpharm)	16APR15	3233	5	PWMTHLB	Label of Method of evaluation	2	50	$
PDS135	PATWKIRC	Patient Work-Up (Radpharm)	16APR15	3233	6	PWMTHSP	Other method of eval - specify	2	60	$
PDS135	PATWKIRC	Patient Work-Up (Radpharm)	16APR15	3233	7	PWSITE	Site Assessed	2	35	$
PDS135	PATWKIRC	Patient Work-Up (Radpharm)	16APR15	3233	8	PWTX	Evaluation comment	2	60	$
PDS135	PATWKIRC	Patient Work-Up (Radpharm)	16APR15	3233	9	REVTYPE	Type of person	2	40	$
PDS135	PATWKIRC	Patient Work-Up (Radpharm)	16APR15	3233	10	RI	Reconstruction interval	2	10	$
PDS135	PATWKIRC	Patient Work-Up (Radpharm)	16APR15	3233	11	SEQNUC	Sequence number char	2	10	$
PDS135	PATWKIRC	Patient Work-Up (Radpharm)	16APR15	3233	12	SEQNUM	Sequence number	1	8	
PDS135	PATWKIRC	Patient Work-Up (Radpharm)	16APR15	3233	13	VISIT	Planned clinical encounter	2	40	$
PDS135	PATWKIRC	Patient Work-Up (Radpharm)	16APR15	3233	14	PWDY	Day assessed - from date derived	1	8	
PDS135	PATWKIRC	Patient Work-Up (Radpharm)	16APR15	3233	15	EVALND	Evaluation not done	2	20	
PDS135	PATWKIRC	Patient Work-Up (Radpharm)	16APR15	3233	16	PWMTH	Method of evaluation	2	40	
PDS135	PATWKIRC	Patient Work-Up (Radpharm)	16APR15	3233	17	PWND	Patient workup eval not done	2	20	
PDS135	PATWKIRC	Patient Work-Up (Radpharm)	16APR15	3233	18	PWTUMINV	Tumor involvement yes/no	2	20	
PDS135	PATWKIRC	Patient Work-Up (Radpharm)	16APR15	3233	19	RSUBJID	De-identified Subject ID for Study	2	9	
PDS135	PATWKIRC	Patient Work-Up (Radpharm)	16APR15	3233	20	RUSUBJID	De-identified Unique Subj. ID for Study	2	18	

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Library Member Name=PATWORK

LIBNAME	MEMNAME	MEMLABEL	CRDATE	NOBS	VARNUM	NAME	LABEL	TYPE	LENGTH	FORMAT
PDS135	PATWORK	Patient Work-Up	16APR15	8031	1	CYCLE	Treatment cycle	1	8	
PDS135	PATWORK	Patient Work-Up	16APR15	8031	2	PAGENUM	Page number	2	4	$
PDS135	PATWORK	Patient Work-Up	16APR15	8031	3	PROJCD	Project code	2	10	$
PDS135	PATWORK	Patient Work-Up	16APR15	8031	4	PWEVTYP	Type of evaluation	2	40	$
PDS135	PATWORK	Patient Work-Up	16APR15	8031	5	PWMTHTX	Other method of eval - specify	2	60	$
PDS135	PATWORK	Patient Work-Up	16APR15	8031	6	PWSITE	Site Assessed	2	35	$
PDS135	PATWORK	Patient Work-Up	16APR15	8031	7	PWTX	Evaluation comment	2	60	$
PDS135	PATWORK	Patient Work-Up	16APR15	8031	8	SEQNUM	Sequence number	1	8	
PDS135	PATWORK	Patient Work-Up	16APR15	8031	9	PWDY	Day assessed - from date derived	1	8	
PDS135	PATWORK	Patient Work-Up	16APR15	8031	10	EVALND	Evaluation not done	2	20	
PDS135	PATWORK	Patient Work-Up	16APR15	8031	11	PWMTH	Method of evaluation	2	40	
PDS135	PATWORK	Patient Work-Up	16APR15	8031	12	PWND	Patient workup eval not done	2	20	
PDS135	PATWORK	Patient Work-Up	16APR15	8031	13	PWTUMINV	Tumor involvement yes/no	2	20	
PDS135	PATWORK	Patient Work-Up	16APR15	8031	14	RSUBJID	De-identified Subject ID for Study	2	9	
PDS135	PATWORK	Patient Work-Up	16APR15	8031	15	RUSUBJID	De-identified Unique Subj. ID for Study	2	18	

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Library Member Name=PERFSTAT

LIBNAME	MEMNAME	MEMLABEL	CRDATE	NOBS	VARNUM	NAME	LABEL	TYPE	LENGTH	FORMAT
PDS135	PERFSTAT	Performance Status	16APR15	1720	1	CYCLE	Treatment cycle	1	8	
PDS135	PERFSTAT	Performance Status	16APR15	1720	2	PAGENUM	Page number	2	4	$
PDS135	PERFSTAT	Performance Status	16APR15	1720	3	PROJCD	Project code	2	10	$
PDS135	PERFSTAT	Performance Status	16APR15	1720	4	PSSTAT	Performance status	1	8	
PDS135	PERFSTAT	Performance Status	16APR15	1720	5	PSWHOST	WHO Performance status	1	8	
PDS135	PERFSTAT	Performance Status	16APR15	1720	6	SBKEY	Subset key	2	2	$
PDS135	PERFSTAT	Performance Status	16APR15	1720	7	SEQNUM	Sequence number	1	8	
PDS135	PERFSTAT	Performance Status	16APR15	1720	8	PSDY	Day performed - from date derived	1	8	
PDS135	PERFSTAT	Performance Status	16APR15	1720	9	EVALND	Evaluation not done	2	20	
PDS135	PERFSTAT	Performance Status	16APR15	1720	10	PSNA	Performance status not applic	2	20	
PDS135	PERFSTAT	Performance Status	16APR15	1720	11	SAMEDATE	Same as visit date indicator	2	20	
PDS135	PERFSTAT	Performance Status	16APR15	1720	12	RSUBJID	De-identified Subject ID for Study	2	9	
PDS135	PERFSTAT	Performance Status	16APR15	1720	13	RUSUBJID	De-identified Unique Subj. ID for Study	2	18	

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Library Member Name=PREG

LIBNAME	MEMNAME	MEMLABEL	CRDATE	NOBS	VARNUM	NAME	LABEL	TYPE	LENGTH	FORMAT
PDS135	PREG	Pregnancy	16APR15	217	1	CYCLE	Treatment cycle	1	8	
PDS135	PREG	Pregnancy	16APR15	217	2	PAGENUM	Page number	2	4	$
PDS135	PREG	Pregnancy	16APR15	217	3	PROJCD	Project code	2	10	$
PDS135	PREG	Pregnancy	16APR15	217	4	SBKEY	Subset key	2	2	$
PDS135	PREG	Pregnancy	16APR15	217	5	SEQNUM	Sequence number	1	8	
PDS135	PREG	Pregnancy	16APR15	217	6	PGSMDY	Specimen collect day	1	8	
PDS135	PREG	Pregnancy	16APR15	217	7	EVALND	Evaluation not done	2	20	
PDS135	PREG	Pregnancy	16APR15	217	8	PGRES	Pregnancy test result	2	20	
PDS135	PREG	Pregnancy	16APR15	217	9	PGTSTYP	Pregnancy test type	2	20	
PDS135	PREG	Pregnancy	16APR15	217	10	SAMEDATE	Same as visit date indicator	2	20	
PDS135	PREG	Pregnancy	16APR15	217	11	RSUBJID	De-identified Subject ID for Study	2	9	
PDS135	PREG	Pregnancy	16APR15	217	12	RUSUBJID	De-identified Unique Subj. ID for Study	2	18	

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Library Member Name=QOLEQ5D

LIBNAME	MEMNAME	MEMLABEL	CRDATE	NOBS	VARNUM	NAME	LABEL	TYPE	LENGTH	FORMAT
PDS135	QOLEQ5D	EQ5D health questionnaire	16APR15	2391	1	CYCLE	Treatment cycle	1	8	
PDS135	QOLEQ5D	EQ5D health questionnaire	16APR15	2391	2	EYLHEALR	EQ5D linear health scale result	1	8	
PDS135	QOLEQ5D	EQ5D health questionnaire	16APR15	2391	3	PAGENUM	Page number	2	4	$
PDS135	QOLEQ5D	EQ5D health questionnaire	16APR15	2391	4	PROJCD	Project code	2	10	$
PDS135	QOLEQ5D	EQ5D health questionnaire	16APR15	2391	5	EYDY	Assessment day	1	8	
PDS135	QOLEQ5D	EQ5D health questionnaire	16APR15	2391	6	EVALND	Evaluation not done	2	20	
PDS135	QOLEQ5D	EQ5D health questionnaire	16APR15	2391	7	EYANXR	EQ5D anxiety depression result	2	40	
PDS135	QOLEQ5D	EQ5D health questionnaire	16APR15	2391	8	EYMOBR	EQ5D mobility result	2	40	
PDS135	QOLEQ5D	EQ5D health questionnaire	16APR15	2391	9	EYPAINR	EQ5D pain result	2	40	
PDS135	QOLEQ5D	EQ5D health questionnaire	16APR15	2391	10	EYSELFR	EQ5D self care result	2	40	
PDS135	QOLEQ5D	EQ5D health questionnaire	16APR15	2391	11	EYUSACTR	EQ5D usual activities result	2	40	
PDS135	QOLEQ5D	EQ5D health questionnaire	16APR15	2391	12	RSUBJID	De-identified Subject ID for Study	2	9	
PDS135	QOLEQ5D	EQ5D health questionnaire	16APR15	2391	13	RUSUBJID	De-identified Unique Subj. ID for Study	2	18	

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Library Member Name=QOLGEN

LIBNAME	MEMNAME	MEMLABEL	CRDATE	NOBS	VARNUM	NAME	LABEL	TYPE	LENGTH	FORMAT
PDS135	QOLGEN	QOL General	16APR15	67990	1	CYCLE	Treatment cycle	1	8	
PDS135	QOLGEN	QOL General	16APR15	67990	2	PAGENUM	Page number	2	4	$
PDS135	QOLGEN	QOL General	16APR15	67990	3	PROJCD	Project code	2	10	$
PDS135	QOLGEN	QOL General	16APR15	67990	4	QCDDESC	QOL question description	2	200	$
PDS135	QOLGEN	QOL General	16APR15	67990	5	QCOVER	QOL numeric overall result	1	8	
PDS135	QOLGEN	QOL General	16APR15	67990	6	QCQGRP	QOL question group	2	200	$
PDS135	QOLGEN	QOL General	16APR15	67990	7	QCQID	QOL question identifier	2	10	$
PDS135	QOLGEN	QOL General	16APR15	67990	8	SBKEY	Subset key	2	2	$
PDS135	QOLGEN	QOL General	16APR15	67990	9	SEQNUM	Sequence number	1	8	
PDS135	QOLGEN	QOL General	16APR15	67990	10	QCDY	QOL day	1	8	
PDS135	QOLGEN	QOL General	16APR15	67990	11	EVALND	Evaluation not done	2	20	
PDS135	QOLGEN	QOL General	16APR15	67990	12	QCRESN	QOL numeric result	2	20	
PDS135	QOLGEN	QOL General	16APR15	67990	13	RSUBJID	De-identified Subject ID for Study	2	9	
PDS135	QOLGEN	QOL General	16APR15	67990	14	RUSUBJID	De-identified Unique Subj. ID for Study	2	18	

ClinicalTrial.govID=NCT00081796 Protocol=EFC6089[XRP9881B/3001] uploaded 04/29/2015

Library Member Name=QOLQ

LIBNAME	MEMNAME	MEMLABEL	CRDATE	NOBS	VARNUM	NAME	LABEL	TYPE	LENGTH	FORMAT
PDS135	QOLQ	Quality of Life Administration	16APR15	3279	1	CYCLE	Treatment cycle	1	8	
PDS135	QOLQ	Quality of Life Administration	16APR15	3279	2	PAGENUM	Page number	2	4	$
PDS135	QOLQ	Quality of Life Administration	16APR15	3279	3	PROJCD	Project code	2	10	$
PDS135	QOLQ	Quality of Life Administration	16APR15	3279	4	SEQNUM	Sequence number	1	8	
PDS135	QOLQ	Quality of Life Administration	16APR15	3279	5	QOLDY	QOL completion day	1	8	
PDS135	QOLQ	Quality of Life Administration	16APR15	3279	6	EVALND	Evaluation not done	2	20	
PDS135	QOLQ	Quality of Life Administration	16APR15	3279	7	QOLCP	Questionnaire Completed?	2	20	
PDS135	QOLQ	Quality of Life Administration	16APR15	3279	8	QOLREAS	Primary reason not completed	2	40	
PDS135	QOLQ	Quality of Life Administration	16APR15	3279	9	RSUBJID	De-identified Subject ID for Study	2	9	
PDS135	QOLQ	Quality of Life Administration	16APR15	3279	10	RUSUBJID	De-identified Unique Subj. ID for Study	2	18	

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Library Member Name=RANDOM

LIBNAME	MEMNAME	MEMLABEL	CRDATE	NOBS	VARNUM	NAME	LABEL	TYPE	LENGTH	FORMAT
PDS135	RANDOM	Randomization	16APR15	217	1	CYCLE	Treatment cycle	1	8	
PDS135	RANDOM	Randomization	16APR15	217	2	KITNUM	Kit number	2	8	$
PDS135	RANDOM	Randomization	16APR15	217	3	OLBLTRT	Open label treatment arm	2	2	$
PDS135	RANDOM	Randomization	16APR15	217	4	PAGENUM	Page number	2	4	$
PDS135	RANDOM	Randomization	16APR15	217	5	PROJCD	Project code	2	10	$
PDS135	RANDOM	Randomization	16APR15	217	6	RNNUM	Randomization number	2	8	$
PDS135	RANDOM	Randomization	16APR15	217	7	RNTM	Randomization time	2	5	$
PDS135	RANDOM	Randomization	16APR15	217	8	SBKEY	Subset key	2	2	$
PDS135	RANDOM	Randomization	16APR15	217	9	SEQNUM	Sequence number	1	8	
PDS135	RANDOM	Randomization	16APR15	217	10	RNDY	Randomization day	1	8	
PDS135	RANDOM	Randomization	16APR15	217	11	EVALND	Evaluation not done	2	20	
PDS135	RANDOM	Randomization	16APR15	217	12	RSUBJID	De-identified Subject ID for Study	2	9	
PDS135	RANDOM	Randomization	16APR15	217	13	RUSUBJID	De-identified Unique Subj. ID for Study	2	18	

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Library Member Name=RESPONSE

LIBNAME	MEMNAME	MEMLABEL	CRDATE	NOBS	VARNUM	NAME	LABEL	TYPE	LENGTH	FORMAT
PDS135	RESPONSE	Date of response/Disease progres	16APR15	431	1	CYCLE	Treatment cycle	1	8	
PDS135	RESPONSE	Date of response/Disease progres	16APR15	431	2	PAGENUM	Page number	2	4	$
PDS135	RESPONSE	Date of response/Disease progres	16APR15	431	3	PROJCD	Project code	2	10	$
PDS135	RESPONSE	Date of response/Disease progres	16APR15	431	4	RPDPDY	Disease Progression day	1	8	
PDS135	RESPONSE	Date of response/Disease progres	16APR15	431	5	RPFREDY	First Response day	1	8	
PDS135	RESPONSE	Date of response/Disease progres	16APR15	431	6	EVALND	Evaluation not done	2	20	
PDS135	RESPONSE	Date of response/Disease progres	16APR15	431	7	RPOCCUR	Mark if not applicable	2	20	
PDS135	RESPONSE	Date of response/Disease progres	16APR15	431	8	RSUBJID	De-identified Subject ID for Study	2	9	
PDS135	RESPONSE	Date of response/Disease progres	16APR15	431	9	RUSUBJID	De-identified Unique Subj. ID for Study	2	18	

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Library Member Name=SMW

LIBNAME	MEMNAME	MEMLABEL	CRDATE	NOBS	VARNUM	NAME	LABEL	TYPE	LENGTH	FORMAT
PDS135	SMW	Study med discont/wdraw	16APR15	215	1	CYCLE	Treatment cycle	1	8	
PDS135	SMW	Study med discont/wdraw	16APR15	215	2	PAGENUM	Page number	2	4	$
PDS135	SMW	Study med discont/wdraw	16APR15	215	3	PROJCD	Project code	2	10	$
PDS135	SMW	Study med discont/wdraw	16APR15	215	4	WDDY	Last dose day	1	8	
PDS135	SMW	Study med discont/wdraw	16APR15	215	5	EVALND	Evaluation not done	2	20	
PDS135	SMW	Study med discont/wdraw	16APR15	215	6	REASWD	Primary reason tx discontinued	2	40	
PDS135	SMW	Study med discont/wdraw	16APR15	215	7	WDYN	Subject completed all study tx	2	20	
PDS135	SMW	Study med discont/wdraw	16APR15	215	8	RSUBJID	De-identified Subject ID for Study	2	9	
PDS135	SMW	Study med discont/wdraw	16APR15	215	9	RUSUBJID	De-identified Unique Subj. ID for Study	2	18	

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Library Member Name=SOURCE

LIBNAME	MEMNAME	MEMLABEL	CRDATE	NOBS	VARNUM	NAME	LABEL	TYPE	LENGTH	FORMAT
PDS135	SOURCE	Source of death information	16APR15	211	1	CYCLE	Treatment cycle	1	8	
PDS135	SOURCE	Source of death information	16APR15	211	2	DSSITETX	Disease site other - specify	2	80	$
PDS135	SOURCE	Source of death information	16APR15	211	3	ODSITETX	Site of death - specify	2	80	$
PDS135	SOURCE	Source of death information	16APR15	211	4	PAGENUM	Page number	2	4	$
PDS135	SOURCE	Source of death information	16APR15	211	5	PROJCD	Project code	2	10	$
PDS135	SOURCE	Source of death information	16APR15	211	6	AUTOPSY	Autopsy performed no/yes	2	20	
PDS135	SOURCE	Source of death information	16APR15	211	7	DRTOX	Drug treatment toxicity	2	20	
PDS135	SOURCE	Source of death information	16APR15	211	8	DSSITE1	Disease site at autopsy 1	2	30	
PDS135	SOURCE	Source of death information	16APR15	211	9	DSSITE2	Disease site at autopsy 2	2	30	
PDS135	SOURCE	Source of death information	16APR15	211	10	DSSITE3	Disease site at autopsy 3	2	30	
PDS135	SOURCE	Source of death information	16APR15	211	11	DSSITE4	Disease site at autopsy 4	2	30	
PDS135	SOURCE	Source of death information	16APR15	211	12	DSSITE5	Disease site at autopsy 5	2	30	
PDS135	SOURCE	Source of death information	16APR15	211	13	DSSITE6	Disease site at autopsy 6	2	30	
PDS135	SOURCE	Source of death information	16APR15	211	14	DSSITE7	Disease site at autopsy 7	2	30	
PDS135	SOURCE	Source of death information	16APR15	211	15	EVALND	Evaluation not done	2	20	
PDS135	SOURCE	Source of death information	16APR15	211	16	ODLOC	Site of death (location)	2	20	
PDS135	SOURCE	Source of death information	16APR15	211	17	SOURCE1	Source of info 1	2	30	
PDS135	SOURCE	Source of death information	16APR15	211	18	SOURCE2	Source of info 2	2	30	
PDS135	SOURCE	Source of death information	16APR15	211	19	SOURCE3	Source of info 3	2	30	
PDS135	SOURCE	Source of death information	16APR15	211	20	SOURCE4	Source of info 4	2	30	
PDS135	SOURCE	Source of death information	16APR15	211	21	SOURCE5	Source of info 5	2	30	
PDS135	SOURCE	Source of death information	16APR15	211	22	SOURCE6	Source of info 6	2	30	
PDS135	SOURCE	Source of death information	16APR15	211	23	RSUBJID	De-identified Subject ID for Study	2	9	
PDS135	SOURCE	Source of death information	16APR15	211	24	RUSUBJID	De-identified Unique Subj. ID for Study	2	18	

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Library Member Name=TIMELOSS

LIBNAME	MEMNAME	MEMLABEL	CRDATE	NOBS	VARNUM	NAME	LABEL	TYPE	LENGTH	FORMAT
PDS135	TIMELOSS	Time Loss	16APR15	560	1	CYCLE	Treatment cycle	1	8	
PDS135	TIMELOSS	Time Loss	16APR15	560	2	DDLOSOTH	Nb of days patient missed usual	1	8	
PDS135	TIMELOSS	Time Loss	16APR15	560	3	DDLOSWRK	Nb of days patient missed work	1	8	
PDS135	TIMELOSS	Time Loss	16APR15	560	4	PAGENUM	Page number	2	4	$
PDS135	TIMELOSS	Time Loss	16APR15	560	5	PROJCD	Project code	2	10	$
PDS135	TIMELOSS	Time Loss	16APR15	560	6	EVALND	Evaluation not done	2	20	
PDS135	TIMELOSS	Time Loss	16APR15	560	7	LOSOCCUR	No loss of days of work occured	2	20	
PDS135	TIMELOSS	Time Loss	16APR15	560	8	RSUBJID	De-identified Subject ID for Study	2	9	
PDS135	TIMELOSS	Time Loss	16APR15	560	9	RUSUBJID	De-identified Unique Subj. ID for Study	2	18	

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Library Member Name=TUMASIRC

LIBNAME	MEMNAME	MEMLABEL	CRDATE	NOBS	VARNUM	NAME	LABEL	TYPE	LENGTH	FORMAT
PDS135	TUMASIRC	Tumor Assessment (Radpharm)	16APR15	4293	1	CYCLE	Treatment cycle	1	8	
PDS135	TUMASIRC	Tumor Assessment (Radpharm)	16APR15	4293	2	IMAGENO	Image Number	2	10	$
PDS135	TUMASIRC	Tumor Assessment (Radpharm)	16APR15	4293	3	PAGENUM	Page number	2	4	$
PDS135	TUMASIRC	Tumor Assessment (Radpharm)	16APR15	4293	4	PROJCD	Project code	2	10	$
PDS135	TUMASIRC	Tumor Assessment (Radpharm)	16APR15	4293	5	REVTYPE	Type of person	2	50	$
PDS135	TUMASIRC	Tumor Assessment (Radpharm)	16APR15	4293	6	SEQNUC	Sequence number char	2	10	$
PDS135	TUMASIRC	Tumor Assessment (Radpharm)	16APR15	4293	7	SEQNUM	Sequence number	1	8	
PDS135	TUMASIRC	Tumor Assessment (Radpharm)	16APR15	4293	8	TALESMES	Measurement of target lesion	1	8	
PDS135	TUMASIRC	Tumor Assessment (Radpharm)	16APR15	4293	9	TALESNUM	Lesion number	1	8	
PDS135	TUMASIRC	Tumor Assessment (Radpharm)	16APR15	4293	10	TAMEAS	Lesion Measurement	2	5	$
PDS135	TUMASIRC	Tumor Assessment (Radpharm)	16APR15	4293	11	TAMTHTX	Measurement other - specify	2	40	$
PDS135	TUMASIRC	Tumor Assessment (Radpharm)	16APR15	4293	12	TANUM	Lesion number	2	10	$
PDS135	TUMASIRC	Tumor Assessment (Radpharm)	16APR15	4293	13	TASITELB	Label of the lesion site code	2	50	$
PDS135	TUMASIRC	Tumor Assessment (Radpharm)	16APR15	4293	14	TASUBSIT	Description of subsite	2	100	$
PDS135	TUMASIRC	Tumor Assessment (Radpharm)	16APR15	4293	15	VISIT	Planned clinical encounter	2	40	$
PDS135	TUMASIRC	Tumor Assessment (Radpharm)	16APR15	4293	16	TADY	Assessment day - from date derived	1	8	
PDS135	TUMASIRC	Tumor Assessment (Radpharm)	16APR15	4293	17	EVALND	Evaluation not done	2	20	
PDS135	TUMASIRC	Tumor Assessment (Radpharm)	16APR15	4293	18	TAMTH	Measurement method	2	40	
PDS135	TUMASIRC	Tumor Assessment (Radpharm)	16APR15	4293	19	TAND	Tumor assessment not done	2	20	
PDS135	TUMASIRC	Tumor Assessment (Radpharm)	16APR15	4293	20	TAREMES	Measureability recist criteria	2	40	
PDS135	TUMASIRC	Tumor Assessment (Radpharm)	16APR15	4293	21	TARSP	Response non-target lesion	2	40	
PDS135	TUMASIRC	Tumor Assessment (Radpharm)	16APR15	4293	22	TASITECD	Location of lesions code	2	30	
PDS135	TUMASIRC	Tumor Assessment (Radpharm)	16APR15	4293	23	RSUBJID	De-identified Subject ID for Study	2	9	
PDS135	TUMASIRC	Tumor Assessment (Radpharm)	16APR15	4293	24	RUSUBJID	De-identified Unique Subj. ID for Study	2	18	

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Library Member Name=TUMASSES

LIBNAME	MEMNAME	MEMLABEL	CRDATE	NOBS	VARNUM	NAME	LABEL	TYPE	LENGTH	FORMAT
PDS135	TUMASSES	Tumor Assessment	16APR15	7283	1	CYCLE	Treatment cycle	1	8	
PDS135	TUMASSES	Tumor Assessment	16APR15	7283	2	PAGENUM	Page number	2	4	$
PDS135	TUMASSES	Tumor Assessment	16APR15	7283	3	PROJCD	Project code	2	10	$
PDS135	TUMASSES	Tumor Assessment	16APR15	7283	4	SEQNUM	Sequence number	1	8	
PDS135	TUMASSES	Tumor Assessment	16APR15	7283	5	TALESMES	Measurement of target lesion	1	8	
PDS135	TUMASSES	Tumor Assessment	16APR15	7283	6	TALESNUM	Lesion number	1	8	
PDS135	TUMASSES	Tumor Assessment	16APR15	7283	7	TAMEAS	Measurement of target lesion	2	5	$
PDS135	TUMASSES	Tumor Assessment	16APR15	7283	8	TAMTHTX	Measurement other - specify	2	40	$
PDS135	TUMASSES	Tumor Assessment	16APR15	7283	9	TANUM	Lesion number	2	10	$
PDS135	TUMASSES	Tumor Assessment	16APR15	7283	10	TADY	Assessment day - from date derived	1	8	
PDS135	TUMASSES	Tumor Assessment	16APR15	7283	11	EVALND	Evaluation not done	2	20	
PDS135	TUMASSES	Tumor Assessment	16APR15	7283	12	TAMTH	Measurement method	2	40	
PDS135	TUMASSES	Tumor Assessment	16APR15	7283	13	TAND	Tumor assessment not done	2	20	
PDS135	TUMASSES	Tumor Assessment	16APR15	7283	14	TAOCCUR	Patient did not have non target	2	20	
PDS135	TUMASSES	Tumor Assessment	16APR15	7283	15	TAREMES	Measureability recist criteria	2	40	
PDS135	TUMASSES	Tumor Assessment	16APR15	7283	16	TARSP	Response non-target lesion	2	40	
PDS135	TUMASSES	Tumor Assessment	16APR15	7283	17	TASITECD	Location of lesions code	2	30	
PDS135	TUMASSES	Tumor Assessment	16APR15	7283	18	RSUBJID	De-identified Subject ID for Study	2	9	
PDS135	TUMASSES	Tumor Assessment	16APR15	7283	19	RUSUBJID	De-identified Unique Subj. ID for Study	2	18	

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Library Member Name=TUMTHER

LIBNAME	MEMNAME	MEMLABEL	CRDATE	NOBS	VARNUM	NAME	LABEL	TYPE	LENGTH	FORMAT
PDS135	TUMTHER	Tumor Therapy	16APR15	890	1	CYCLE	Treatment cycle	1	8	
PDS135	TUMTHER	Tumor Therapy	16APR15	890	2	PAGENUM	Page number	2	4	$
PDS135	TUMTHER	Tumor Therapy	16APR15	890	3	PROJCD	Project code	2	10	$
PDS135	TUMTHER	Tumor Therapy	16APR15	890	4	REGNUM	Regimen number	1	8	
PDS135	TUMTHER	Tumor Therapy	16APR15	890	5	SEQNUM	Sequence number	1	8	
PDS135	TUMTHER	Tumor Therapy	16APR15	890	6	TTDRLCD	Who-drl code	2	11	$
PDS135	TUMTHER	Tumor Therapy	16APR15	890	7	TTMODIFY	Med modify term (entry field)	2	200	$
PDS135	TUMTHER	Tumor Therapy	16APR15	890	8	TTREGDR	Med term as reported (derived)	2	200	$
PDS135	TUMTHER	Tumor Therapy	16APR15	890	9	TTSITE	Site/procedure	2	80	$
PDS135	TUMTHER	Tumor Therapy	16APR15	890	10	TTWF	Med coding workflow item	2	5	$
PDS135	TUMTHER	Tumor Therapy	16APR15	890	11	TTEDY	Therapy end day - from date derived	1	8	
PDS135	TUMTHER	Tumor Therapy	16APR15	890	12	TTRELDY	Relapse/Progression Day	1	8	
PDS135	TUMTHER	Tumor Therapy	16APR15	890	13	TTSDY	Therapy start day - from date derived	1	8	
PDS135	TUMTHER	Tumor Therapy	16APR15	890	14	EVALND	Evaluation not done	2	20	
PDS135	TUMTHER	Tumor Therapy	16APR15	890	15	INTENT	Intent	2	20	
PDS135	TUMTHER	Tumor Therapy	16APR15	890	16	TTCONT	Previously reported	2	20	
PDS135	TUMTHER	Tumor Therapy	16APR15	890	17	TTOCCUR	Further therapy occurred	2	20	
PDS135	TUMTHER	Tumor Therapy	16APR15	890	18	TTON	Ongoing	2	20	
PDS135	TUMTHER	Tumor Therapy	16APR15	890	19	TTREADIS	Reason for Anti-Tumor Discont	2	40	
PDS135	TUMTHER	Tumor Therapy	16APR15	890	20	TTRSP	Best response	2	40	
PDS135	TUMTHER	Tumor Therapy	16APR15	890	21	TTTYP	Therapy type	2	20	
PDS135	TUMTHER	Tumor Therapy	16APR15	890	22	RSUBJID	De-identified Subject ID for Study	2	9	
PDS135	TUMTHER	Tumor Therapy	16APR15	890	23	RUSUBJID	De-identified Unique Subj. ID for Study	2	18	

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Library Member Name=VITAL

LIBNAME	MEMNAME	MEMLABEL	CRDATE	NOBS	VARNUM	NAME	LABEL	TYPE	LENGTH	FORMAT
PDS135	VITAL	Vital signs	16APR15	1720	1	CYCLE	Treatment cycle	1	8	
PDS135	VITAL	Vital signs	16APR15	1720	2	DIABP	Diastolic blood pressure	1	8	
PDS135	VITAL	Vital signs	16APR15	1720	3	HR	Heart rate	1	8	
PDS135	VITAL	Vital signs	16APR15	1720	4	PAGENUM	Page number	2	4	$
PDS135	VITAL	Vital signs	16APR15	1720	5	PR	Pulse rate	1	8	
PDS135	VITAL	Vital signs	16APR15	1720	6	PROJCD	Project code	2	10	$
PDS135	VITAL	Vital signs	16APR15	1720	7	RESP	Respiratory rate	1	8	
PDS135	VITAL	Vital signs	16APR15	1720	8	SEQNUM	Sequence number	1	8	
PDS135	VITAL	Vital signs	16APR15	1720	9	SYSBP	Systolic blood pressure	1	8	
PDS135	VITAL	Vital signs	16APR15	1720	10	TEMP	Temperature	1	8	
PDS135	VITAL	Vital signs	16APR15	1720	11	TEMPDV	Temperature in celsius (derived)	1	8	
PDS135	VITAL	Vital signs	16APR15	1720	12	VSATMCL	Clock time of vital signs exam	2	5	$
PDS135	VITAL	Vital signs	16APR15	1720	13	VSPRFDO	Planned dose reference	2	10	$
PDS135	VITAL	Vital signs	16APR15	1720	14	VSPRFEQ	Planned ref event qualifier	1	8	
PDS135	VITAL	Vital signs	16APR15	1720	15	VSPRFET	Planned reference event	1	8	
PDS135	VITAL	Vital signs	16APR15	1720	16	VSPTM	Planned start time (elapsed)	2	10	$
PDS135	VITAL	Vital signs	16APR15	1720	17	VSPTME	Planned end time (elapsed)	2	10	$
PDS135	VITAL	Vital signs	16APR15	1720	18	VSPTMLBL	Planned time crf label	2	100	$
PDS135	VITAL	Vital signs	16APR15	1720	19	VSDY	Vital signs day	1	8	
PDS135	VITAL	Vital signs	16APR15	1720	20	BPPOS	Blood pressure position	2	40	
PDS135	VITAL	Vital signs	16APR15	1720	21	EVALND	Evaluation not done	2	20	
PDS135	VITAL	Vital signs	16APR15	1720	22	HRMTH	Heart rate method	2	40	
PDS135	VITAL	Vital signs	16APR15	1720	23	RESPUNIT	Respiration rate unit	2	20	
PDS135	VITAL	Vital signs	16APR15	1720	24	SAMEDATE	Same as visit date indicator	2	20	
PDS135	VITAL	Vital signs	16APR15	1720	25	TEMPSO	Temperature source	2	20	
PDS135	VITAL	Vital signs	16APR15	1720	26	TEMPUNIT	Temperature unit	2	20	
PDS135	VITAL	Vital signs	16APR15	1720	27	VSPOS	Position measurement taken	2	20	
PDS135	VITAL	Vital signs	16APR15	1720	28	RSUBJID	De-identified Subject ID for Study	2	9	
PDS135	VITAL	Vital signs	16APR15	1720	29	RUSUBJID	De-identified Unique Subj. ID for Study	2	18	

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Library Member Name=VSDT

LIBNAME	MEMNAME	MEMLABEL	CRDATE	NOBS	VARNUM	NAME	LABEL	TYPE	LENGTH	FORMAT
PDS135	VSDT	Visit date	16APR15	2329	1	CYCLE	Treatment cycle	1	8	
PDS135	VSDT	Visit date	16APR15	2329	2	PAGENUM	Page number	2	4	$
PDS135	VSDT	Visit date	16APR15	2329	3	PROJCD	Project code	2	10	$
PDS135	VSDT	Visit date	16APR15	2329	4	VISDY	Visit day	1	8	
PDS135	VSDT	Visit date	16APR15	2329	5	EVALND	Evaluation not done	2	20	
PDS135	VSDT	Visit date	16APR15	2329	6	RSUBJID	De-identified Subject ID for Study	2	9	
PDS135	VSDT	Visit date	16APR15	2329	7	RUSUBJID	De-identified Unique Subj. ID for Study	2	18	

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Library Member Name=WAIVER

LIBNAME	MEMNAME	MEMLABEL	CRDATE	NOBS	VARNUM	NAME	LABEL	TYPE	LENGTH	FORMAT
PDS135	WAIVER	Request for Waiver	16APR15	31	1	CYCLE	Treatment cycle	1	8	
PDS135	WAIVER	Request for Waiver	16APR15	31	2	PAGENUM	Page number	2	4	$
PDS135	WAIVER	Request for Waiver	16APR15	31	3	PROJCD	Project code	2	10	$
PDS135	WAIVER	Request for Waiver	16APR15	31	4	SBKEY	Subset key	2	2	$
PDS135	WAIVER	Request for Waiver	16APR15	31	5	WACRNUM1	Waiver criterion number 1	2	3	$
PDS135	WAIVER	Request for Waiver	16APR15	31	6	WACRNUM2	Waiver Criterion Number 2	2	3	$
PDS135	WAIVER	Request for Waiver	16APR15	31	7	WACRNUM3	Waiver Criterion Number 3	2	3	$
PDS135	WAIVER	Request for Waiver	16APR15	31	8	WACRNUM4	Waiver Criterion Number 4	2	3	$
PDS135	WAIVER	Request for Waiver	16APR15	31	9	WAREQDY	Waiver Request Day	1	8	
PDS135	WAIVER	Request for Waiver	16APR15	31	10	EVALND	Evaluation not done	2	20	
PDS135	WAIVER	Request for Waiver	16APR15	31	11	WAANALY	Analysis Interference	2	20	
PDS135	WAIVER	Request for Waiver	16APR15	31	12	WARATIO	Benefit Risk Impact	2	20	
PDS135	WAIVER	Request for Waiver	16APR15	31	13	WASUBMIT	Waiver Submission Required	2	20	
PDS135	WAIVER	Request for Waiver	16APR15	31	14	RSUBJID	De-identified Subject ID for Study	2	9	
PDS135	WAIVER	Request for Waiver	16APR15	31	15	RUSUBJID	De-identified Unique Subj. ID for Study	2	18	

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Library Member Name=WAIVSIG

LIBNAME	MEMNAME	MEMLABEL	CRDATE	NOBS	VARNUM	NAME	LABEL	TYPE	LENGTH	FORMAT
PDS135	WAIVSIG	Waiver Signatures	16APR15	31	1	CYCLE	Treatment cycle	1	8	
PDS135	WAIVSIG	Waiver Signatures	16APR15	31	2	PAGENUM	Page number	2	4	$
PDS135	WAIVSIG	Waiver Signatures	16APR15	31	3	PROJCD	Project code	2	10	$
PDS135	WAIVSIG	Waiver Signatures	16APR15	31	4	WSINVDY	Invest Waiver Sign Day	1	8	
PDS135	WAIVSIG	Waiver Signatures	16APR15	31	5	WSMEDDY	Med Exp Waiver Sign day	1	8	
PDS135	WAIVSIG	Waiver Signatures	16APR15	31	6	EVALND	Evaluation not done	2	20	
PDS135	WAIVSIG	Waiver Signatures	16APR15	31	7	WSGRANT	Waiver Granted Y/N	2	20	
PDS135	WAIVSIG	Waiver Signatures	16APR15	31	8	WSINVSIG	Invest Waiver Sign Y/N	2	20	
PDS135	WAIVSIG	Waiver Signatures	16APR15	31	9	WSMEDSIG	Med Expert Waiver Sign Y/N	2	20	
PDS135	WAIVSIG	Waiver Signatures	16APR15	31	10	RSUBJID	De-identified Subject ID for Study	2	9	
PDS135	WAIVSIG	Waiver Signatures	16APR15	31	11	RUSUBJID	De-identified Unique Subj. ID for Study	2	18	