

Clinical Study Data Report

Study Attributes :

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Study : 123-456-789

Study Name : CDISC Connect-A-Thon Test Study III

Study Description : This file contains test data for the CDISC Connect-A-Thon event scheduled for the DIA 38th annual meeting in Chicago.

Protocol Name : CDISC-123-456-789

Basic Definitions : Units of Measure

Name	ID	Language	Symbol
Kilogram	MU.KG	en	English: Kilogram
		fr	French: Kilogram
Pound	MU.LB	en	English: Pound
		fr	French: Pound
dilberts/ml	MU.DPML	en	dilberts/ml
filberts/ml	MU.FPML	en	filberts/ml

Study : 123-456-789

Metadata Version : Version 1.1.0

Include Prior MetaData Version : There are no prior metadata versions defined

Protocol Study Events :

Study Event ID	Order Number	Mandatory ?
SE.VISIT0	1	Yes
SE.VISIT1	2	Yes

Study Event Definitions :

Name	ID	Repeating ?	Type	Category
Pre-treatment	SE.VISIT0	No	Scheduled	PreTreatment
Post-treatment	SE.VISIT1	No	Scheduled	PostTreatment

Form Definitions :

Name	ID	Repeating ?
Adverse Events	FORM.AE	No
Concom Meds	FORM.CONMED	No
Demography	FORM.DEMOG	No
Treatment Assignment	FORM.DRUGPHRM	No
Pharmacokinetics	FORM.PHARMVIT	No
Physical Exam	FORM.VITPHYEX	No

Item Group References for Form : Adverse Events

Item Group Name	Item Group ID	Order Number	Mandatory ?
Adverse Events	IG.AE	1	No

Item Group References for Form : Concom Meds

Item Group Name	Item Group ID	Order Number	Mandatory ?
Concom Meds	IG.CONMED	1	No

Item Group References for Form : Demography

Item Group Name	Item Group ID	Order Number	Mandatory ?
Demography	IG.DEMOG	1	No

Item Group References for Form : Treatment Assignment

Item Group Name	Item Group ID	Order Number	Mandatory ?
Treatment Assignment	IG.DRUG_TRT	1	No

Item Group References for Form : Pharmacokinetics

Item Group Name	Item Group ID	Order Number	Mandatory ?
Pharmacokinetics	IG.PHARMO1	1	No

Item Group References for Form : Physical Exam

Item Group Name	Item Group ID	Order Number	Mandatory ?
Physical Exam	IG.PHYEX	1	No

Item Groups :

Part 1 :

Name	ID	Rep.?	Is Ref. Data ?
Adverse Events	IG.AE	Yes	No
Concom Meds	IG.CONMED	Yes	No
Demography	IG.DEMOG	Yes	No
Treatment Assignment	IG.DRUG_TRT	Yes	No
Pharmacokinetics	IG.PHARMO1	Yes	No
Physical Exam	IG.PHYEX	Yes	No
Sample Reference Data	IG.REFSAMP	Yes	Yes

Part 2 :

Name	SAS Dataset	Domain	Origin	Role	Comment
Adverse Events	AE	AE Domain	AE Origin	AE Role	AE Comment
Concom Meds	CONMED	Conmed Domain	Conmed Origin	Conmed Role	Conmed Comment
Demography	DEMOG	Demog Domain	Demog Origin	Demog Role	Demog Comment
Treatment Assignment	DRUG_TRT	Treatment Domain	Treatment Origin	Treatment Role	Treatment Comment
Pharmacokinetics	PHARMO1	PK Domain	PK Origin	PK Role	PK Comment
Physical Exam	PHYEX	PE Domain	PE Origin	PE Role	PE Comment
Sample Reference Data	REFSAMP				

Items for Item Group : Adverse Events

Item Name	Item ID	Order Number	Mandatory ?
Therapeutic Area	IT.TAREA	1	No
Protocol Number	IT.PNO	2	No
Country	IT.SCTRY	3	No
Record status, 5 levels, internal use	IT.F_STATUS	4	No
Line Number	IT.LINE_NO	5	No
Conmed Indication	IT.AETERM	6	No
Start Month - Enter Two Digits 01-12	IT.AESTMON	7	No
Start Day - Enter Two Digits 01-31	IT.AESTDAY	8	No
Start Year - Enter Four Digit Year	IT.AESTYR	9	No
Derived Start Date	IT.AESTDT	10	No
Stop Month - Enter Two Digits 01-12	IT.AEENMON	11	No
Stop Day - Enter Two Digits 01-31	IT.AEENDAY	12	No
Stop Year - Enter Four Digit Year	IT.AEENYR	13	No
Derived Stop Date	IT.AEENDT	14	No
Severity	IT.AESEV	15	No
Relationship to study drug	IT.AEREL	16	No
Outcome	IT.AEOUT	17	No

Item Name	Item ID	Order Number	Mandatory ?
Actions taken re study drug	IT.AEACTTRT	18	No
Actions taken, other	IT.AECONTRT	19	No

Items for Item Group : Concom Meds

Item Name	Item ID	Order Number	Mandatory ?
Compound	IT.R_DRUG	1	No
Therapeutic Area	IT.TAREA	2	No
Protocol Number	IT.PNO	3	No
Country	IT.SCTRY	4	No
Record status, 5 levels, internal use	IT.F_STATUS	5	No
Line Number	IT.LINE_NO	6	No
Medication For Conmed	IT.MEDIC	7	No
Start Month - Enter Two Digits 01-12	IT.STRTMON	8	No
Start Day - Enter Two Digits 01-31	IT.STRTDAY	9	No
Start Year - Enter Four Digit Year	IT.STRTYR	10	No
Derived Start Date	IT.STRT_DT	11	No
Check if Ongoing	IT.ONGOING	12	No
Stop Month - Enter Two Digits 01-12	IT.STOPMON	13	No
Stop Day - Enter Two Digits 01-31	IT.STOPDAY	14	No
Stop Year - Enter Four Digit Year	IT.STOPYR	15	No
Derived Stop Date	IT.STOP_DT	16	No
Dose and Unit	IT.DOSEUNIT	17	No
Conmed Route	IT.ROUTE	18	No
Conmed Regimen	IT.REGIMEN	19	No
Conmed Indication	IT.INDIC	20	No
Check If Taken for AE	IT.AE_RELAT	21	No

Items for Item Group : Demography

Item Name	Item ID	Order Number	Mandatory ?
Compound	IT.R_DRUG	1	No
Therapeutic Area	IT.TAREA	2	No
Protocol Number	IT.PNO	3	No

Item Name	Item ID	Order Number	Mandatory ?
Country	IT.SCTRY	4	No
Record status, 5 levels, internal use	IT.F_STATUS	5	No
Height	IT.HT	6	No
Weight	IT.WT	7	No
Gender	IT.SEX	8	No
Date of Birth	IT.DOB	9	No
Ethnic Group	IT.RACE	10	No
Height Units	IT.HTUNITS	11	No
Weight Units	IT.WTUNITS	12	No

Items for Item Group : Treatment Assignment

Item Name	Item ID	Order Number	Mandatory ?
Compound	IT.R_DRUG	1	No
Therapeutic Area	IT.TAREA	2	No
Protocol Number	IT.PNO	3	No
Country	IT.SCTRY	4	No
Record status, 5 levels, internal use	IT.F_STATUS	5	No
Assigned Study Drug Treatment	IT.DRUG_TRT	6	No

Items for Item Group : Pharmacokinetics

Item Name	Item ID	Order Number	Mandatory ?
Compound	IT.R_DRUG	1	No
Therapeutic Area	IT.TAREA	2	No
Protocol Number	IT.PNO	3	No
Country	IT.SCTRY	4	No
Record status, 5 levels, internal use	IT.F_STATUS	5	No
Pretreatment yr	IT.PKYR0	6	No
1-h year	IT.PKYR1	7	No
2-h year	IT.PKYR2	8	No
3-h year	IT.PKYR3	9	No
4-h year	IT.PKYR4	10	No
8-h year	IT.PKYR8	11	No
16-h year	IT.PKYR16	12	No
24-h year	IT.PKYR24	13	No
Meal year	IT.MEALYR	14	No

Item Name	Item ID	Order Number	Mandatory ?
Pretreatment mon	IT.PKMON0	15	No
1-h mon	IT.PKMON1	16	No
2-h mon	IT.PKMON2	17	No
3-h mon	IT.PKMON3	18	No
4-h mon	IT.PKMON4	19	No
8-h mon	IT.PKMON8	20	No
16-h mon	IT.PKMON16	21	No
24-h mon	IT.PKMON24	22	No
Meal mon	IT.MEALMON	23	No
Pretreatment day	IT.PKDAY0	24	No
1-h day	IT.PKDAY1	25	No
2-h day	IT.PKDAY2	26	No
3-h day	IT.PKDAY3	27	No
4-h day	IT.PKDAY4	28	No
8-h day	IT.PKDAY8	29	No
16-h day	IT.PKDAY16	30	No
24-h day	IT.PKDAY24	31	No
Meal day	IT.MEALDAY	32	No
Not done	IT.NOTDONE	33	No
Pretreatment date	IT.PK_DT0	34	No
1-h date	IT.PK_DT1	35	No
2-h date	IT.PK_DT2	36	No
3-h date	IT.PK_DT3	37	No
4-h date	IT.PK_DT4	38	No
8-h date	IT.PK_DT8	39	No
16-h date	IT.PK_DT16	40	No
24-h date	IT.PK_DT24	41	No
Date of last meal	IT.MEAL_DT	42	No
Pretreatment time	IT.PK_TIM0	43	No
1-h time	IT.PK_TIM1	44	No
2-h time	IT.PK_TIM2	45	No
3-h time	IT.PK_TIM3	46	No
4-h time	IT.PK_TIM4	47	No
8-h time	IT.PK_TIM8	48	No
16-h time	IT.PK_TIM16	49	No
24-h time	IT.PK_TIM24	50	No
Time of last meal	IT.MEALTIM	51	No

Items for Item Group : Physical Exam

Item Name	Item ID	Order Number	Mandatory ?
Compound	IT.R_DRUG	1	No
Therapeutic Area	IT.TAREA	2	No
Protocol Number	IT.PNO	3	No
Country	IT.SCTRY	4	No
Record status, 5 levels, internal use	IT.F_STATUS	5	No
Physical Exam Body System	IT.BODY_SYS	6	No
Normal/Abnormal/Not Done	IT.ABNORM	7	No
Comment	IT.COMMT1	8	No

Items for Item Group : Sample Reference Data

Item Name	Item ID	Order Number	Mandatory ?
Record Number	IT.REF1	1	Yes
Text	IT.REF2	2	No

Items :

Items for which additional information is available are in red (and linked)

Part 1 :

Name	ID	Data Type	Length	Signif. Digits
Normal/Abnormal/Not Done	IT.ABNORM	integer	1	
Actions taken re study drug	IT.AEACTTRT	text	1	
Actions taken, other	IT.AECONTRT	text	1	
Stop Day - Enter Two Digits 01-31	IT.AEENDAY	text	2	
Derived Stop Date	IT.AEENDT	text	8	
Stop Month - Enter Two Digits 01-12	IT.AEENMON	text	2	
Stop Year - Enter Four Digit Year	IT.AEENYR	text	4	
Outcome	IT.AEOUT	text	1	
Relationship to study drug	IT.AEREL	text	1	
Severity	IT.AESEV	text	1	
Start Day - Enter Two	IT.AESTDAY	text	2	

Name	ID	Data Type	Length	Signif. Digits
Digits 01-31				
Derived Start Date	IT.AESTDT	text	8	
Start Month - Enter Two Digits 01-12	IT.AESTMON	text	2	
Start Year - Enter Four Digit Year	IT.AESTYR	text	4	
Conmed Indication	IT.AETERM	text	100	
Check If Taken for AE	IT.AE_RELAT	text	1	
Physical Exam Body System	IT.BODY_SYS	integer	2	
Comment	IT.COMMT1	text	200	
Date of Birth	IT.DOB	text	8	
Dose and Unit	IT.DOSEUNIT	text	20	
Assigned Study Drug Treatment	IT.DRUG_TRT	integer	1	
Record status, 5 levels, internal use	IT.F_STATUS	text	1	
Height	IT.HT	float	4	1
Height Units	IT.HTUNITS	text	2	
Conmed Indication	IT.INDIC	text	100	
Line Number	IT.LINE_NO	integer	2	
Meal day	IT.MEALDAY	text	2	
Meal mon	IT.MEALMON	text	2	
Time of last meal	IT.MEALTIM	text	4	
Meal year	IT.MEALYR	text	4	
Date of last meal	IT.MEAL_DT	text	8	
Medication For Conmed	IT.MEDIC	text	200	
Not done	IT.NOTDONE	text	1	
Check if Ongoing	IT.ONGOING	text	1	
Pretreatment day	IT.PKDAY0	text	2	
1-h day	IT.PKDAY1	text	2	
16-h day	IT.PKDAY16	text	2	
2-h day	IT.PKDAY2	text	2	
24-h day	IT.PKDAY24	text	2	
3-h day	IT.PKDAY3	text	2	
4-h day	IT.PKDAY4	text	2	
8-h day	IT.PKDAY8	text	2	
Pretreatment mon	IT.PKMON0	text	2	
1-h mon	IT.PKMON1	text	2	
16-h mon	IT.PKMON16	text	2	
2-h mon	IT.PKMON2	text	2	

Name	ID	Data Type	Length	Signif. Digits
24-h mon	IT.PKMON24	text	2	
3-h mon	IT.PKMON3	text	2	
4-h mon	IT.PKMON4	text	2	
8-h mon	IT.PKMON8	text	2	
Pretreatment yr	IT.PKYR0	text	4	
1-h year	IT.PKYR1	text	4	
16-h year	IT.PKYR16	text	4	
2-h year	IT.PKYR2	text	4	
24-h year	IT.PKYR24	text	4	
3-h year	IT.PKYR3	text	4	
4-h year	IT.PKYR4	text	4	
8-h year	IT.PKYR8	text	4	
Pretreatment date	IT.PK_DT0	text	8	
1-h date	IT.PK_DT1	text	8	
16-h date	IT.PK_DT16	text	8	
2-h date	IT.PK_DT2	text	8	
24-h date	IT.PK_DT24	text	8	
3-h date	IT.PK_DT3	text	8	
4-h date	IT.PK_DT4	text	8	
8-h date	IT.PK_DT8	text	8	
Pretreatment time	IT.PK_TIM0	text	4	
1-h time	IT.PK_TIM1	text	4	
16-h time	IT.PK_TIM16	text	4	
2-h time	IT.PK_TIM2	text	4	
24-h time	IT.PK_TIM24	text	4	
3-h time	IT.PK_TIM3	text	4	
4-h time	IT.PK_TIM4	text	4	
8-h time	IT.PK_TIM8	text	4	
Protocol Number	IT.PNO	text	15	
Ethnic Group	IT.RACE	text	10	
Conmed Regimen	IT.REGIMEN	integer	1	
Conmed Route	IT.ROUTE	integer	2	
Compound	IT.R_DRUG	text	8	
Country	IT.SCTRY	text	4	
Gender	IT.SEX	text	6	
Stop Day - Enter Two Digits 01-31	IT.STOPDAY	text	2	
Stop Month - Enter Two Digits 01-12	IT.STOPMON	text	2	
Stop Year - Enter Four Digit Year	IT.STOPYR	text	4	

Name	ID	Data Type	Length	Signif. Digits
Derived Stop Date	IT.STOP_DT	text	8	
Start Day - Enter Two Digits 01-31	IT.STRTDAY	text	2	
Start Month - Enter Two Digits 01-12	IT.STRTMON	text	2	
Start Year - Enter Four Digit Year	IT.STRTYR	text	4	
Derived Start Date	IT.STRT_DT	text	8	
Therapeutic Area	IT.TAREA	text	4	
Weight	IT.WT	float	4	1
Weight Units	IT.WTUNITS	text	2	
Record Number	IT.REF1	integer	8	
Text	IT.REF2	text	40	

Part 2 :

Name	Code List Ref.	SAS Field Name	SDS Var Name
Normal/Abnormal/Not Done	CL.N_A_ND	ABNORM	ABNORM SDS Variable Name
Actions taken re study drug	CL.AEACTTR	AEACTTRT	
Actions taken, other	CL.AECONTR	AECONTRT	
Stop Day - Enter Two Digits 01-31		AEENDAY	
Derived Stop Date		AEENDT	
Stop Month - Enter Two Digits 01-12		AEENMON	
Stop Year - Enter Four Digit Year		AEENYR	
Outcome	CL.AEOUT	AEOUT	
Relationship to study drug	CL.AEREL	AEREL	
Severity	CL.AESEV	AESEV	
Start Day - Enter Two Digits 01-31		AESTDAY	
Derived Start Date		AESTDT	
Start Month - Enter Two Digits 01-12		AESTMON	
Start Year - Enter Four Digit Year		AESTYR	
Conmed Indication		AETERM	
Check If Taken for AE	CL.AEREL	AE_RELAT	
Physical Exam Body	CL.PE_TEST	BODY_SYS	

Name	Code List Ref.	SAS Field Name	SDS Var Name
System			
Comment		COMMT1	
Date of Birth		DOB	
Dose and Unit		DOSEUNIT	
Assigned Study Drug Treatment	CL.DRUGTRTF	DRUG_TRT	
Record status, 5 levels, internal use	CL.F_STATU	F_STATUS	
Height		HT	
Height Units		HTUNITS	
Conmed Indication		INDIC	
Line Number		LINE_NO	
Meal day		MEALDAY	
Meal mon		MEALMON	
Time of last meal		MEALTIM	
Meal year		MEALYR	
Date of last meal		MEAL_DT	
Medication For Conmed		MEDIC	
Not done		NOTDONE	
Check if Ongoing		ONGOING	
Pretreatment day		PKDAY0	
1-h day		PKDAY1	
16-h day		PKDAY16	
2-h day		PKDAY2	
24-h day		PKDAY24	
3-h day		PKDAY3	
4-h day		PKDAY4	
8-h day		PKDAY8	
Pretreatment mon		PKMON0	
1-h mon		PKMON1	
16-h mon		PKMON16	
2-h mon		PKMON2	
24-h mon		PKMON24	
3-h mon		PKMON3	
4-h mon		PKMON4	
8-h mon		PKMON8	
Pretreatment yr		PKYR0	
1-h year		PKYR1	
16-h year		PKYR16	
2-h year		PKYR2	
24-h year		PKYR24	
3-h year		PKYR3	

Name	Code List Ref.	SAS Field Name	SDS Var Name
4-h year		PKYR4	
8-h year		PKYR8	
Pretreatment date		PK_DT0	
1-h date		PK_DT1	
16-h date		PK_DT16	
2-h date		PK_DT2	
24-h date		PK_DT24	
3-h date		PK_DT3	
4-h date		PK_DT4	
8-h date		PK_DT8	
Pretreatment time		PK_TIM0	
1-h time		PK_TIM1	
16-h time		PK_TIM16	
2-h time		PK_TIM2	
24-h time		PK_TIM24	
3-h time		PK_TIM3	
4-h time		PK_TIM4	
8-h time		PK_TIM8	
Protocol Number		PNO	
Ethnic Group		RACE	
Conmed Regimen	CL.REGF	REGIMEN	
Conmed Route	CL.ROUTEF	ROUTE	
Compound		R_DRUG	
Country	CL.SCTRYF	SCTRY	
Gender	CL.SEXF	SEX	
Stop Day - Enter Two Digits 01-31		STOPDAY	
Stop Month - Enter Two Digits 01-12		STOPMON	
Stop Year - Enter Four Digit Year		STOPYR	
Derived Stop Date		STOP_DT	
Start Day - Enter Two Digits 01-31		STRTDAY	
Start Month - Enter Two Digits 01-12		STRTMON	
Start Year - Enter Four Digit Year		STRTYR	
Derived Start Date		STRT_DT	
Therapeutic Area	CL.TAREAF	TAREA	
Weight		WT	
Weight Units		WTUNITS	

Name	Code List Ref.	SAS Field Name	SDS Var Name
Record Number		REF1	
Text		REF2	

Part 3 :

Name	Origin	Role	Comment
Normal/Abnormal/Not Done	ABNORM Origin	ABNORM Role	ABNORM Comment
Actions taken re study drug			
Actions taken, other			
Stop Day - Enter Two Digits 01-31			
Derived Stop Date			
Stop Month - Enter Two Digits 01-12			
Stop Year - Enter Four Digit Year			
Outcome			
Relationship to study drug			
Severity			
Start Day - Enter Two Digits 01-31			
Derived Start Date			
Start Month - Enter Two Digits 01-12			
Start Year - Enter Four Digit Year			
Conmed Indication			
Check If Taken for AE			
Physical Exam Body System			
Comment			
Date of Birth			
Dose and Unit			
Assigned Study Drug Treatment			
Record status, 5 levels, internal use			
Height			
Height Units			
Conmed Indication			
Line Number			

Name	Origin	Role	Comment
Meal day			
Meal mon			
Time of last meal			
Meal year			
Date of last meal			
Medication For Conmed			
Not done			
Check if Ongoing			
Pretreatment day			
1-h day			
16-h day			
2-h day			
24-h day			
3-h day			
4-h day			
8-h day			
Pretreatment mon			
1-h mon			
16-h mon			
2-h mon			
24-h mon			
3-h mon			
4-h mon			
8-h mon			
Pretreatment yr			
1-h year			
16-h year			
2-h year			
24-h year			
3-h year			
4-h year			
8-h year			
Pretreatment date			
1-h date			
16-h date			
2-h date			
24-h date			
3-h date			
4-h date			
8-h date			
Pretreatment time			
1-h time			

Name	Origin	Role	Comment
16-h time			
2-h time			
24-h time			
3-h time			
4-h time			
8-h time			
Protocol Number			
Ethnic Group			
Conmed Regimen			
Conmed Route			
Compound			
Country			
Gender			
Stop Day - Enter Two Digits 01-31			
Stop Month - Enter Two Digits 01-12			
Stop Year - Enter Four Digit Year			
Derived Stop Date			
Start Day - Enter Two Digits 01-31			
Start Month - Enter Two Digits 01-12			
Start Year - Enter Four Digit Year			
Derived Start Date			
Therapeutic Area			
Weight			
Weight Units			
Record Number			
Text			

Additional information for Items :

Additional information for item : Normal/Abnormal/Not Done

Question :

Translated Text	Language
English: Normal/Abnormal/Not Done?	en
French: Normal/Abnormal/Not Done?	fr

External Question :

Dictionary	Version	Code
Websters	2001 Unabridged	NormAbnormNotDone

Checks :

Compa-rator	Soft/ Hard	Check Value	Measurement Unit Name	Error Message	Language
LT	Hard	1	dilberts/ml	English: The value must be between 1 and 3.	en
				French: The value must be between 1 and 3.	fr
				Spanish: The value must be between 1 and 3.	es
GT	Hard	3	dilberts/ml	The value must be between 1 and 3.	en
EQ	Soft	2	dilberts/ml	English: Is the value really abnormal?	en
				Spanish: ¿Is the value really abnormal?	es

Additional information for item : Actions taken re study drug

Question :

Translated Text	Language
Actions taken re study drug?	en

Code Lists :

CodeLists for which additional information is available are in red (and linked)

Name	ID	Data Type	SAS Format Name
AE Action Taken, Study Drug	CL.AEACTTR	text	AEACTTR
AE Action Taken, Other	CL.AECONTR	text	AECONTR
AE Outcome	CL.AEOUT	text	AEOUT
AE Relationship to Study Drug	CL.AEREL	text	AEREL
AE Severity	CL.AESEV	text	AESEV

Name	ID	Data Type	SAS Format Name
Assigned Study Drug	CL.DRUGTRTF	integer	DRUGTRTF
Record Status, Internal	CL.F_STATU	text	F_STATU
Normal/Abnormal/Not Done	CL.N_A_ND	integer	N_A_ND
PE Body System	CL.PE_TEST	integer	PE_TEST
Conmed Regimen	CL.REGF	integer	REGF
Conmed Route	CL.ROUTEF	integer	ROUTEF
Country	CL.SCTRYF	text	SCTRYF
Gender	CL.SEXF	text	SEXF
Therapeutic Area	CL.TAREAF	text	TAREAF
LOINC Version 2.0	LOINC	text	LOINC

Additional information for CodeList : AE Action Taken, Study Drug

Coded Value	Decoded Value	Language
0	None	en
	French: None	fr
	Spanish: None	es
1	Discontinued permanently	en
2	Reduced	en
3	Interrupted	en

Additional information for CodeList : AE Action Taken, Other

Coded Value	Decoded Value	Language
0	None	en
1	Medication required	en
2	Hospitalization required or prolonged	en
3	Other	en

Additional information for CodeList : AE Outcome

Coded Value	Decoded Value	Language
1	Resolved, no residual effects	en
2	Continuing	en
3	Resolved, residual effects	en
4	Death	en

Additional information for CodeList : AE Relationship to Study Drug

Coded Value	Decoded Value	Language
0	None	en
1	Unlikely	en
2	Possible	en

Coded Value	Decoded Value	Language
3	Probable	en

Additional information for CodeList : AE Severity

Coded Value	Decoded Value	Language
1	Mild	en
2	Moderate	en
3	Severe	en
4	Life Threatening	en

Additional information for CodeList : Assigned Study Drug

Coded Value	Decoded Value	Language
1	Treatment A	en
2	Treatment B	en
3	Treatment C	en

Additional information for CodeList : Record Status, Internal

Coded Value	Decoded Value	Language
S	Source verified, not queried	en
V	Source verified, queried	en

Additional information for CodeList : Normal/Abnormal/Not Done

Coded Value	Decoded Value	Language
1	Normal	en
2	Abnormal	en
3	Not Done	en

Additional information for CodeList : PE Body System

Coded Value	Decoded Value	Language
1	Head, Neck and Thyroid	en
2	Eyes, Ears, Nose and Throat	en
3	Chest	en
4	Lungs	en
5	Heart	en
6	Lymph Nodes	en
7	Abdomen	en
8	Anorectal	en
9	Genitalia	en
10	Skin	en

Coded Value	Decoded Value	Language
11	Musculoskeletal	en
12	Neurological	en
13	Other	en

Additional information for CodeList : Conmed Regimen

Coded Value	Decoded Value	Language
1	q.d.	en
2	b.i.d.	en
3	t.i.d.	en
4	q.i.d.	en
5	q.o.d.	en
6	q.h.s.	en
7	cont. IV	en
8	prn	en
9	If not in list, record as Other	en

Additional information for CodeList : Conmed Route

Coded Value	Decoded Value	Language
1	IV	en
2	IM	en
3	PO	en
4	SC	en
5	PV	en
6	PR	en
7	Sublingual	en
8	Inhaled	en
9	Topical	en
10	If not in list	en

Additional information for CodeList : Country

Coded Value	Decoded Value	Language
USA	United States	en

Additional information for CodeList : Gender

Coded Value	Decoded Value	Language
F	Female	en
M	Male	en

Additional information for CodeList : Therapeutic Area

Coded Value	Decoded Value	Language
ONC	Oncology	en

Additional information for CodeList : LOINC Version 2.0

This is an external CodeList

Dictionary	Version
LOINC	2.0

Presentations :

Presentation	ID	Language
English	PRS.EN	en
French	PRS.FR	fr
Spanish	PRS.ES	es

Administration Data :

Study = 123-456-789

User : ID = USR.cdisc001

User Type = Other

Full Name : Shirley Williams

First Name : Shirley

Last Name : Williams

Organization: CDISC

Location Reference : CDISC Headquarters

User : ID = USR.inv001

User Type = Investigator

Full Name : John Smith, M.D.

First Name : John

Last Name : Smith

Organization: Roswell Park

Location Reference : Roswell Park

User : ID = USR.inv002

User Type = Investigator

Full Name : Jane Doe, M.D.

First Name : Jane

Last Name : Doe

Organization: Fred Hutchinson

Location Reference : Fred Hutchinson

Location : ID = LOC.CDISCHome

Location Name : CDISC Headquarters

Location Type : Other

Metadata Version Reference :

Study ID : 123-456-789

Metadata Version ID : v1.1.0

Effective Date : 20011019T10:45:57-05:00

Location : ID = LOC.site001

Location Name : Fred Hutchinson

Location Type : Site

Metadata Version Reference :

Study ID : 123-456-789

Metadata Version ID : v1.1.0

Effective Date : 20011019T10:45:57-05:00

Location : ID = LOC.site002

Location Name : Roswell Park

Location Type : Site

Metadata Version Reference :

Study ID : 123-456-789

Metadata Version ID : v1.1.0

Effective Date : 20011019T10:45:57-05:00

Signature Definition : ID = SD.cdisc001-es

Methodology : Electronic

Signature Meaning : Signature Meaning

Legal Reason : Legal Reason

Reference Data: Study = 123-456-789

Item Group : Sample Reference Data

Items for which additional information is available are in red (and linked)

Repeat key: 1

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Record Number	1		
Text	Sample reference data line 1		

Audit Record for this Item Group :

User : Shirley Williams

Location : CDISC Headquarters

Date- and Timestamp : 2002-04-23T08:15:47-06:00

Item Group : Sample Reference Data

Items for which additional information is available are in red (and linked)

Repeat key: 2

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Record Number	2		
Text	Sample reference data line 2		

Audit Record for this Item Group :

User : Shirley Williams

Location : CDISC Headquarters

Date- and Timestamp : 2002-04-23T08:15:47-06:00

Clinical Data: Study = 123-456-789

MetaDataVersion ID = v1.1.0

Subject Data:

Subject Key = 001

Investigator for this subject : John Smith, M.D.

Last Name : Smith

First Name : John

Location : Roswell Park

Site for this subject: Roswell Park

Study Event Data:

Study Event = Pre-treatment

Form Data:

ID = Demography

Item Group : Demography

Repeat key: 1

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	V		
Height	73		
Weight	204		
Gender	M		
Date of Birth	19600403		
Ethnic Group	Caucasian		
Height Units	in		
Weight Units	lb		

[Audit Record for this Item Group :](#)

[User :](#) John Smith

[Location :](#) Roswell Park

[Date- and Timestamp :](#) 2002-02-04T14:01:32-05:00

[Source ID :](#) 46902604

Form Data:

ID = Treatment Assignment

[Item Group :](#) Treatment Assignment

[Repeat key:](#) 1

[Transaction type:](#) Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		

Item	Value	is Null?	Trans.Type
Record status, 5 levels, internal use	V		
Assigned Study Drug Treatment	1		

Audit Record for this Item Group :

User : John Smith

Location : Roswell Park

Date- and Timestamp : 2002-02-04T14:06:32-05:00

Source ID : 46878904

Form Data:

ID = Pharmacokinetics

Item Group : Pharmacokinetics

Repeat key: 1

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	V		
Pretreatment yr	1999		
1-h year	1999		
2-h year	1999		
3-h year	1999		
4-h year	1999		
8-h year	1999		
16-h year	1999		

Item	Value	is Null?	Trans.Type
24-h year	1999		
Meal year	1999		
Pretreatment mon	06		
1-h mon	06		
2-h mon	06		
3-h mon	06		
4-h mon	06		
8-h mon	06		
16-h mon	06		
24-h mon	06		
Meal mon	06		
Pretreatment day	20		
1-h day	20		
2-h day	20		
3-h day	20		
4-h day	20		
8-h day	20		
16-h day	20		
24-h day	21		
Meal day	20		
Pretreatment date	19990620		
1-h date	19990620		
2-h date	19990620		
3-h date	19990620		
4-h date	19990620		
8-h date	19990620		
16-h date	19990620		
24-h date	19990621		
Date of last meal	19990620		
Pretreatment time	0600		
1-h time	0700		
2-h time	0800		
3-h time	0900		
4-h time	1000		
8-h time	1400		
16-h time	1800		
24-h time	0600		
Time of last meal	0500		

Audit Record for this Item Group :

User : John Smith

Location : Roswell Park

Date- and Timestamp : 2002-02-04T14:11:32-05:00

Source ID : 46881304

Form Data:

ID = Physical Exam

Item Group : Physical Exam

Repeat key: 1

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	V		
Physical Exam Body System	1		
Normal/Abnormal/Not Done	1		

Audit Record for this Item Group :

User : John Smith

Location : Roswell Park

Date- and Timestamp : 2002-02-04T14:16:32-05:00

Source ID : 46869304

Item Group : Physical Exam

Repeat key: 2

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	V		
Physical Exam Body System	2		
Normal/Abnormal/Not Done	1		

Audit Record for this Item Group :

User : John Smith

Location : Roswell Park

Date- and Timestamp : 2002-02-04T14:16:32-05:00

Source ID : 46869504

Item Group : Physical Exam

Repeat key: 3

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	V		
Physical Exam Body System	3		

Item	Value	is Null?	Trans.Type
Normal/Abnormal/Not Done	1		

Audit Record for this Item Group :

User : John Smith

Location : Roswell Park

Date- and Timestamp : 2002-02-04T14:16:32-05:00

Source ID : 46869604

Item Group : Physical Exam

Repeat key: 4

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	V		
Physical Exam Body System	4		
Normal/Abnormal/Not Done	2		
Comment	MILD WHEEZING		

Audit Record for this Item Group :

User : John Smith

Location : Roswell Park

Date- and Timestamp : 2002-02-04T14:16:32-05:00

Source ID : 46869804

Item Group : Physical Exam

Repeat key: 5

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	V		
Physical Exam Body System	5		
Normal/Abnormal/Not Done	2		
Comment	TACHYCARDIA		

Audit Record for this Item Group :

User : John Smith

Location : Roswell Park

Date- and Timestamp : 2002-02-04T14:16:32-05:00

Source ID : 46869904

Item Group : Physical Exam

Repeat key: 6

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels,	V		

Item	Value	is Null?	Trans.Type
internal use			
Physical Exam Body System	6		
Normal/Abnormal/Not Done	2		
Comment	SLIGHTLY ENLARGED-NCS		

Audit Record for this Item Group :

User : John Smith

Location : Roswell Park

Date- and Timestamp : 2002-02-04T14:16:32-05:00

Source ID : 46870604

Item Group : Physical Exam

Repeat key: 7

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	V		
Physical Exam Body System	7		
Normal/Abnormal/Not Done	1		

Audit Record for this Item Group :

User : John Smith

Location : Roswell Park

Date- and Timestamp : 2002-02-04T14:16:32-05:00

Source ID : 46870904

Item Group : Physical Exam

Repeat key: 8

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	V		
Physical Exam Body System	8		
Normal/Abnormal/Not Done	3		

Audit Record for this Item Group :

User : John Smith

Location : Roswell Park

Date- and Timestamp : 2002-02-04T14:16:32-05:00

Source ID : 46871004

Item Group : Physical Exam

Repeat key: 9

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		

Item	Value	is Null?	Trans.Type
Country	USA		
Record status, 5 levels, internal use	V		
Physical Exam Body System	9		
Normal/Abnormal/Not Done	1		

Audit Record for this Item Group :

User : John Smith

Location : Roswell Park

Date- and Timestamp : 2002-02-04T14:16:32-05:00

Source ID : 46871204

Item Group : Physical Exam

Repeat key: 10

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	V		
Physical Exam Body System	10		
Normal/Abnormal/Not Done	2		
Comment	PET		

Audit Record for this Item Group :

User : John Smith

Location : Roswell Park

Date- and Timestamp : 2002-02-04T14:16:32-05:00

Source ID : 46871504

Item Group : Physical Exam

Repeat key: 11

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	V		
Physical Exam Body System	11		
Normal/Abnormal/Not Done	1		

Audit Record for this Item Group :

User : John Smith

Location : Roswell Park

Date- and Timestamp : 2002-02-04T14:16:32-05:00

Source ID : 46871704

Item Group : Physical Exam

Repeat key: 12

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		

Item	Value	is Null?	Trans.Type
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	V		
Physical Exam Body System	12		
Normal/Abnormal/Not Done	1		

[Audit Record for this Item Group :](#)

[User :](#) John Smith

[Location :](#) Roswell Park

[Date- and Timestamp :](#) 2002-02-04T14:16:32-05:00

[Source ID :](#) 46872504

[Item Group :](#) Physical Exam

[Repeat key:](#) 13

[Transaction type:](#) Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	V		
Physical Exam Body System	13		
Normal/Abnormal/Not Done	1		

[Audit Record for this Item Group :](#)

[User :](#) John Smith

[Location :](#) Roswell Park

Date- and Timestamp : 2002-02-04T14:16:32-05:00

Source ID : 46873104

Study Event Data:

Study Event = Post-treatment

Form Data:

ID = Adverse Events

Item Group : Adverse Events

Repeat key: 1

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	V		
Line Number	1		
Conmed Indication	HEADACHE		
Start Month - Enter Two Digits 01-12	06		
Start Day - Enter Two Digits 01-31	10		
Start Year - Enter Four Digit Year	1999		
Derived Start Date	19990610		
Stop Month - Enter Two Digits 01-12	06		
Stop Day - Enter Two Digits 01-31	14		

Item	Value	is Null?	Trans.Type
Stop Year - Enter Four Digit Year	1999		
Derived Stop Date	19990614		
Severity	1		
Relationship to study drug	0		
Outcome	1		
Actions taken re study drug	0		
Actions taken, other	1		

Audit Record for this Item Group :

User : John Smith

Location : Roswell Park

Date- and Timestamp : 2002-02-04T14:21:32-05:00

Source ID : 46898304

Item Group : Adverse Events

Repeat key: 2

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	V		
Line Number	2		
Conmed Indication	CONGESTION		
Start Month - Enter Two Digits 01-12	06		
Start Day - Enter Two Digits 01-31	11		
Start Year - Enter Four Digit Year	1999		
Derived Start Date	19990611		

Item	Value	is Null?	Trans.Type
Severity	1		
Relationship to study drug	0		
Outcome	2		
Actions taken re study drug	0		
Actions taken, other	1		

[Audit Record for this Item Group :](#)

[User :](#) John Smith

[Location :](#) Roswell Park

[Date- and Timestamp :](#) 2002-02-04T14:21:32-05:00

[Source ID :](#) 46903404

Form Data:

ID = Concom Meds

[Item Group :](#) Concom Meds

[Repeat key:](#) 1

[Transaction type:](#) Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	V		
Line Number	1		
Medication For Conmed	TYLENOL		
Start Month - Enter Two Digits 01-12	06		

Item	Value	is Null?	Trans.Type
Start Day - Enter Two Digits 01-31	10		
Start Year - Enter Four Digit Year	1999		
Derived Start Date	19990610		
Stop Month - Enter Two Digits 01-12	06		
Stop Day - Enter Two Digits 01-31	14		
Stop Year - Enter Four Digit Year	1999		
Derived Stop Date	19990614		
Dose and Unit	325/MG		
Conmed Route	3		
Conmed Regimen	8		
Conmed Indication	HEADACHE		
Check If Taken for AE	0		

Audit Record for this Item Group :

User : John Smith

Location : Roswell Park

Date- and Timestamp : 2002-02-04T14:26:32-05:00

Source ID : 46896304

Item Group : Concom Meds

Repeat key: 2

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	V		
Line Number	2		

Item	Value	is Null?	Trans.Type
Medication For Conmed	SUDAFED		
Start Month - Enter Two Digits 01-12	06		
Start Day - Enter Two Digits 01-31	11		
Start Year - Enter Four Digit Year	1999		
Derived Start Date	19990611		
Check if Ongoing	X		
Dose and Unit	30/MG		
Conmed Route	3		
Conmed Regimen	8		
Conmed Indication	CONGESTION		
Check If Taken for AE	0		

[Audit Record for this Item Group :](#)

[User :](#) John Smith

[Location :](#) Roswell Park

[Date- and Timestamp :](#) 2002-02-04T14:26:32-05:00

[Source ID :](#) 46901404

Subject Data:

Subject Key = 002

Investigator for this subject : John Smith, M.D.

Last Name : Smith

First Name : John

Location : Roswell Park

Site for this subject: Roswell Park

Study Event Data:

Study Event = Pre-treatment

Form Data:

ID = Demography

Item Group : Demography

Repeat key: 1

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Height	64		
Weight	153		
Gender	F		
Date of Birth	19470214		
Ethnic Group	Black		
Height Units	in		
Weight Units	lb		

[Audit Record for this Item Group :](#)

[User :](#) John Smith

[Location :](#) Roswell Park

[Date- and Timestamp :](#) 2002-02-04T14:31:32-05:00

[Source ID :](#) 46851404

Form Data:

ID = Treatment Assignment

[Item Group :](#) Treatment Assignment

[Repeat key:](#) 1

[Transaction type:](#) Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		

Item	Value	is Null?	Trans.Type
Record status, 5 levels, internal use	S		
Assigned Study Drug Treatment	1		

Audit Record for this Item Group :

User : John Smith

Location : Roswell Park

Date- and Timestamp : 2002-02-04T14:36:32-05:00

Source ID : 46918304

Form Data:

ID = Pharmacokinetics

Item Group : Pharmacokinetics

Repeat key: 1

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	V		
Pretreatment yr	1999		
1-h year	1999		
2-h year	1999		
3-h year	1999		
4-h year	1999		
8-h year	1999		
16-h year	1999		

Item	Value	is Null?	Trans.Type
24-h year	1999		
Meal year	1999		
Pretreatment mon	06		
1-h mon	06		
2-h mon	06		
3-h mon	06		
4-h mon	06		
8-h mon	06		
16-h mon	06		
24-h mon	06		
Meal mon	06		
Pretreatment day	20		
1-h day	20		
2-h day	20		
3-h day	20		
4-h day	20		
8-h day	20		
16-h day	20		
24-h day	21		
Meal day	20		
Pretreatment date	19990620		
1-h date	19990620		
2-h date	19990620		
3-h date	19990620		
4-h date	19990620		
8-h date	19990620		
16-h date	19990620		
24-h date	19990621		
Date of last meal	19990620		
Pretreatment time	0600		
1-h time	0700		
2-h time	0800		
3-h time	0900		
4-h time	1000		
8-h time	1400		
16-h time	1800		
24-h time	0600		
Time of last meal	0500		

Audit Record for this Item Group :

User : John Smith

Location : Roswell Park

Date- and Timestamp : 2002-02-04T14:41:32-05:00

Source ID : 46921804

Form Data:

ID = Physical Exam

Item Group : Physical Exam

Repeat key: 1

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Physical Exam Body System	1		
Normal/Abnormal/Not Done	1		

Audit Record for this Item Group :

User : John Smith

Location : Roswell Park

Date- and Timestamp : 2002-02-04T14:46:32-05:00

Source ID : 46903804

Item Group : Physical Exam

Repeat key: 2

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Physical Exam Body System	2		
Normal/Abnormal/Not Done	1		

Audit Record for this Item Group :

User : John Smith

Location : Roswell Park

Date- and Timestamp : 2002-02-04T14:46:32-05:00

Source ID : 46903904

Item Group : Physical Exam

Repeat key: 3

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Physical Exam Body System	3		

Item	Value	is Null?	Trans.Type
Normal/Abnormal/Not Done	1		

Audit Record for this Item Group :

User : John Smith

Location : Roswell Park

Date- and Timestamp : 2002-02-04T14:46:32-05:00

Source ID : 46904004

Item Group : Physical Exam

Repeat key: 4

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Physical Exam Body System	4		
Normal/Abnormal/Not Done	2		
Comment	MILD WHEEZING		

Audit Record for this Item Group :

User : John Smith

Location : Roswell Park

Date- and Timestamp : 2002-02-04T14:46:32-05:00

Source ID : 46905504

Item Group : Physical Exam

Repeat key: 5

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Physical Exam Body System	5		
Normal/Abnormal/Not Done	2		
Comment	TACHYCARDIA		

Audit Record for this Item Group :

User : John Smith

Location : Roswell Park

Date- and Timestamp : 2002-02-04T14:46:32-05:00

Source ID : 46906204

Item Group : Physical Exam

Repeat key: 6

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels,	S		

Item	Value	is Null?	Trans.Type
internal use			
Physical Exam Body System	6		
Normal/Abnormal/Not Done	2		
Comment	SLIGHTLY ENLARGED - NCS		

Audit Record for this Item Group :

User : John Smith

Location : Roswell Park

Date- and Timestamp : 2002-02-04T14:46:32-05:00

Source ID : 46907204

Item Group : Physical Exam

Repeat key: 7

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Physical Exam Body System	7		
Normal/Abnormal/Not Done	1		

Audit Record for this Item Group :

User : John Smith

Location : Roswell Park

Date- and Timestamp : 2002-02-04T14:46:32-05:00

Source ID : 46907404

Item Group : Physical Exam

Repeat key: 8

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Physical Exam Body System	8		
Normal/Abnormal/Not Done	3		

Audit Record for this Item Group :

User : John Smith

Location : Roswell Park

Date- and Timestamp : 2002-02-04T14:46:32-05:00

Source ID : 46907804

Item Group : Physical Exam

Repeat key: 9

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		

Item	Value	is Null?	Trans.Type
Country	USA		
Record status, 5 levels, internal use	S		
Physical Exam Body System	9		
Normal/Abnormal/Not Done	1		

Audit Record for this Item Group :

User : John Smith

Location : Roswell Park

Date- and Timestamp : 2002-02-04T14:46:32-05:00

Source ID : 46907904

Item Group : Physical Exam

Repeat key: 10

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Physical Exam Body System	10		
Normal/Abnormal/Not Done	2		
Comment	PETECHIA		

Audit Record for this Item Group :

User : John Smith

Location : Roswell Park

Date- and Timestamp : 2002-02-04T14:46:32-05:00

Source ID : 46908204

Item Group : Physical Exam

Repeat key: 11

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Physical Exam Body System	11		
Normal/Abnormal/Not Done	1		

Audit Record for this Item Group :

User : John Smith

Location : Roswell Park

Date- and Timestamp : 2002-02-04T14:46:32-05:00

Source ID : 46908304

Item Group : Physical Exam

Repeat key: 12

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		

Item	Value	is Null?	Trans.Type
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Physical Exam Body System	12		
Normal/Abnormal/Not Done	1		

[Audit Record for this Item Group :](#)

[User :](#) John Smith

[Location :](#) Roswell Park

[Date- and Timestamp :](#) 2002-02-04T14:46:32-05:00

[Source ID :](#) 46909704

[Item Group :](#) Physical Exam

[Repeat key:](#) 13

[Transaction type:](#) Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Physical Exam Body System	13		
Normal/Abnormal/Not Done	1		

[Audit Record for this Item Group :](#)

[User :](#) John Smith

[Location :](#) Roswell Park

Date- and Timestamp : 2002-02-04T14:46:32-05:00

Source ID : 46909804

Study Event Data:

Study Event = Post-treatment

Form Data:

ID = Concom Meds

Item Group : Concom Meds

Repeat key: 1

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Line Number	1		
Medication For Conmed	TYLENOL		
Start Month - Enter Two Digits 01-12	06		
Start Day - Enter Two Digits 01-31	10		
Start Year - Enter Four Digit Year	1999		
Derived Start Date	19990610		
Stop Month - Enter Two Digits 01-12	06		
Stop Day - Enter Two	14		

Item	Value	is Null?	Trans.Type
Digits 01-31			
Stop Year - Enter Four Digit Year	1999		
Derived Stop Date	19990614		
Dose and Unit	325MG		
Conmed Route	3		
Conmed Regimen	8		
Conmed Indication	HEADACHE		
Check If Taken for AE	0		

Audit Record for this Item Group :

User : John Smith

Location : Roswell Park

Date- and Timestamp : 2002-02-04T14:51:32-05:00

Source ID : 46935504

Subject Data:

Subject Key = 003

Investigator for this subject : John Smith, M.D.

Last Name : Smith

First Name : John

Location : Roswell Park

Site for this subject: Roswell Park

Study Event Data:

Study Event = Pre-treatment

Form Data:

ID = Demography

Item Group : Demography

Repeat key: 1

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Height	65		
Weight	122		
Gender	F		
Date of Birth	19721201		
Ethnic Group	Asian		
Height Units	in		
Weight Units	lb		

[Audit Record for this Item Group :](#)

[User :](#) John Smith

[Location :](#) Roswell Park

[Date- and Timestamp :](#) 2002-02-04T14:56:32-05:00

[Source ID :](#) 46841804

Form Data:

ID = Treatment Assignment

[Item Group :](#) Treatment Assignment

[Repeat key:](#) 1

[Transaction type:](#) Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		

Item	Value	is Null?	Trans.Type
Record status, 5 levels, internal use	S		
Assigned Study Drug Treatment	2		

Audit Record for this Item Group :

User : John Smith

Location : Roswell Park

Date- and Timestamp : 2002-02-04T15:01:32-05:00

Source ID : 46880504

Form Data:

ID = Pharmacokinetics

Item Group : Pharmacokinetics

Repeat key: 1

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	V		
Pretreatment yr	1999		
1-h year	1999		
2-h year	1999		
3-h year	1999		
4-h year	1999		
8-h year	1999		
16-h year	1999		

Item	Value	is Null?	Trans.Type
24-h year	1999		
Meal year	1999		
Pretreatment mon	06		
1-h mon	06		
2-h mon	06		
3-h mon	06		
4-h mon	06		
8-h mon	06		
16-h mon	06		
24-h mon	06		
Meal mon	06		
Pretreatment day	20		
1-h day	20		
2-h day	20		
3-h day	20		
4-h day	20		
8-h day	20		
16-h day	20		
24-h day	21		
Meal day	20		
Pretreatment date	19990620		
1-h date	19990620		
2-h date	19990620		
3-h date	19990620		
4-h date	19990620		
8-h date	19990620		
16-h date	19990620		
24-h date	19990621		
Date of last meal	19990620		
Pretreatment time	0600		
1-h time	0700		
2-h time	0800		
3-h time	0900		
4-h time	1000		
8-h time	1400		
16-h time	1800		
24-h time	0600		
Time of last meal	0500		

Audit Record for this Item Group :

User : John Smith

Location : Roswell Park

Date- and Timestamp : 2002-02-04T15:06:32-05:00

Source ID : 46882404

Form Data:

ID = Physical Exam

Item Group : Physical Exam

Repeat key: 1

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Physical Exam Body System	1		
Normal/Abnormal/Not Done	1		

Audit Record for this Item Group :

User : John Smith

Location : Roswell Park

Date- and Timestamp : 2002-02-04T15:11:32-05:00

Source ID : 46870204

Item Group : Physical Exam

Repeat key: 2

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Physical Exam Body System	2		
Normal/Abnormal/Not Done	1		

Audit Record for this Item Group :

User : John Smith

Location : Roswell Park

Date- and Timestamp : 2002-02-04T15:11:32-05:00

Source ID : 46870404

Item Group : Physical Exam

Repeat key: 3

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Physical Exam Body System	3		

Item	Value	is Null?	Trans.Type
Normal/Abnormal/Not Done	1		

Audit Record for this Item Group :

User : John Smith

Location : Roswell Park

Date- and Timestamp : 2002-02-04T15:11:32-05:00

Source ID : 46870504

Item Group : Physical Exam

Repeat key: 4

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Physical Exam Body System	4		
Normal/Abnormal/Not Done	2		
Comment	MILD WHEEZING		

Audit Record for this Item Group :

User : John Smith

Location : Roswell Park

Date- and Timestamp : 2002-02-04T15:11:32-05:00

Source ID : 46870804

Item Group : Physical Exam

Repeat key: 5

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Physical Exam Body System	5		
Normal/Abnormal/Not Done	2		
Comment	TACHYCARDIA		

Audit Record for this Item Group :

User : John Smith

Location : Roswell Park

Date- and Timestamp : 2002-02-04T15:11:32-05:00

Source ID : 46871304

Item Group : Physical Exam

Repeat key: 6

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels,	S		

Item	Value	is Null?	Trans.Type
internal use			
Physical Exam Body System	6		
Normal/Abnormal/Not Done	2		
Comment	SLIGHTLY ENLARGED - NCS		

Audit Record for this Item Group :

User : John Smith

Location : Roswell Park

Date- and Timestamp : 2002-02-04T15:11:32-05:00

Source ID : 46871904

Item Group : Physical Exam

Repeat key: 7

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Physical Exam Body System	7		
Normal/Abnormal/Not Done	1		

Audit Record for this Item Group :

User : John Smith

Location : Roswell Park

Date- and Timestamp : 2002-02-04T15:11:32-05:00

Source ID : 46872004

Item Group : Physical Exam

Repeat key: 8

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Physical Exam Body System	8		
Normal/Abnormal/Not Done	3		

Audit Record for this Item Group :

User : John Smith

Location : Roswell Park

Date- and Timestamp : 2002-02-04T15:11:32-05:00

Source ID : 46872104

Item Group : Physical Exam

Repeat key: 9

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		

Item	Value	is Null?	Trans.Type
Country	USA		
Record status, 5 levels, internal use	S		
Physical Exam Body System	9		
Normal/Abnormal/Not Done	1		

Audit Record for this Item Group :

User : John Smith

Location : Roswell Park

Date- and Timestamp : 2002-02-04T15:11:32-05:00

Source ID : 46872204

Item Group : Physical Exam

Repeat key: 10

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Physical Exam Body System	10		
Normal/Abnormal/Not Done	2		
Comment	PETECHIA		

Audit Record for this Item Group :

User : John Smith

Location : Roswell Park

Date- and Timestamp : 2002-02-04T15:11:32-05:00

Source ID : 46872704

Item Group : Physical Exam

Repeat key: 11

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Physical Exam Body System	11		
Normal/Abnormal/Not Done	1		

Audit Record for this Item Group :

User : John Smith

Location : Roswell Park

Date- and Timestamp : 2002-02-04T15:11:32-05:00

Source ID : 46872904

Item Group : Physical Exam

Repeat key: 12

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		

Item	Value	is Null?	Trans.Type
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Physical Exam Body System	12		
Normal/Abnormal/Not Done	1		

[Audit Record for this Item Group :](#)

[User :](#) John Smith

[Location :](#) Roswell Park

[Date- and Timestamp :](#) 2002-02-04T15:11:32-05:00

[Source ID :](#) 46873004

[Item Group :](#) Physical Exam

[Repeat key:](#) 13

[Transaction type:](#) Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Physical Exam Body System	13		
Normal/Abnormal/Not Done	1		

[Audit Record for this Item Group :](#)

[User :](#) John Smith

[Location :](#) Roswell Park

Date- and Timestamp : 2002-02-04T15:11:32-05:00

Source ID : 46873604

Study Event Data:

Study Event = Post-treatment

Form Data:

ID = Concom Meds

Item Group : Concom Meds

Repeat key: 1

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Line Number	1		
Medication For Conmed	TYLENOL		
Start Month - Enter Two Digits 01-12	8		
Start Day - Enter Two Digits 01-31	10		
Start Year - Enter Four Digit Year	1999		
Derived Start Date	1999 10		
Conmed Route	3		
Conmed Regimen	8		
Check If Taken for AE	0		

Audit Record for this Item Group :

User : John Smith

Location : Roswell Park

Date- and Timestamp : 2002-02-04T15:16:32-05:00

Source ID : 46741604

Form Data:

ID = Physical Exam

Item Group : Physical Exam

Repeat key: 1

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Physical Exam Body System	1		
Normal/Abnormal/Not Done	1		

Audit Record for this Item Group :

User : John Smith

Location : Roswell Park

Date- and Timestamp : 2002-02-04T15:21:32-05:00

Source ID : 46900504

Item Group : Physical Exam

Repeat key: 2

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Physical Exam Body System	2		
Normal/Abnormal/Not Done	1		

Audit Record for this Item Group :

User : John Smith

Location : Roswell Park

Date- and Timestamp : 2002-02-04T15:21:32-05:00

Source ID : 46900604

Item Group : Physical Exam

Repeat key: 3

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		

Item	Value	is Null?	Trans.Type
Physical Exam Body System	3		
Normal/Abnormal/Not Done	1		

Audit Record for this Item Group :

User : John Smith

Location : Roswell Park

Date- and Timestamp : 2002-02-04T15:21:32-05:00

Source ID : 46900704

Item Group : Physical Exam

Repeat key: 4

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Physical Exam Body System	4		
Normal/Abnormal/Not Done	1		

Audit Record for this Item Group :

User : John Smith

Location : Roswell Park

Date- and Timestamp : 2002-02-04T15:21:32-05:00

Source ID : 46900804

Item Group : Physical Exam

Repeat key: 5

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Physical Exam Body System	5		
Normal/Abnormal/Not Done	1		

Audit Record for this Item Group :

User : John Smith

Location : Roswell Park

Date- and Timestamp : 2002-02-04T15:21:32-05:00

Source ID : 46900904

Item Group : Physical Exam

Repeat key: 6

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		

Item	Value	is Null?	Trans.Type
Physical Exam Body System	6		
Normal/Abnormal/Not Done	1		

Audit Record for this Item Group :

User : John Smith

Location : Roswell Park

Date- and Timestamp : 2002-02-04T15:21:32-05:00

Source ID : 46901004

Item Group : Physical Exam

Repeat key: 7

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Physical Exam Body System	7		
Normal/Abnormal/Not Done	1		

Audit Record for this Item Group :

User : John Smith

Location : Roswell Park

Date- and Timestamp : 2002-02-04T15:21:32-05:00

Source ID : 46901104

Item Group : Physical Exam

Repeat key: 8

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Physical Exam Body System	8		
Normal/Abnormal/Not Done	3		

Audit Record for this Item Group :

User : John Smith

Location : Roswell Park

Date- and Timestamp : 2002-02-04T15:21:32-05:00

Source ID : 46901204

Item Group : Physical Exam

Repeat key: 9

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		

Item	Value	is Null?	Trans.Type
Physical Exam Body System	9		
Normal/Abnormal/Not Done	1		

Audit Record for this Item Group :

User : John Smith

Location : Roswell Park

Date- and Timestamp : 2002-02-04T15:21:32-05:00

Source ID : 46901504

Item Group : Physical Exam

Repeat key: 10

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Physical Exam Body System	10		
Normal/Abnormal/Not Done	1		

Audit Record for this Item Group :

User : John Smith

Location : Roswell Park

Date- and Timestamp : 2002-02-04T15:21:32-05:00

Source ID : 46901604

Item Group : Physical Exam

Repeat key: 11

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Physical Exam Body System	11		
Normal/Abnormal/Not Done	1		

Audit Record for this Item Group :

User : John Smith

Location : Roswell Park

Date- and Timestamp : 2002-02-04T15:21:32-05:00

Source ID : 46901704

Item Group : Physical Exam

Repeat key: 12

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		

Item	Value	is Null?	Trans.Type
Physical Exam Body System	12		
Normal/Abnormal/Not Done	1		

Audit Record for this Item Group :

User : John Smith

Location : Roswell Park

Date- and Timestamp : 2002-02-04T15:21:32-05:00

Source ID : 46901804

Item Group : Physical Exam

Repeat key: 13

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Physical Exam Body System	13		
Normal/Abnormal/Not Done	1		

Audit Record for this Item Group :

User : John Smith

Location : Roswell Park

Date- and Timestamp : 2002-02-04T15:21:32-05:00

Source ID : 46901904

Subject Data:

Subject Key = 004

Investigator for this subject : John Smith, M.D.

Last Name : Smith

First Name : John

Location : Roswell Park

Site for this subject: Roswell Park

Study Event Data:

Study Event = Pre-treatment

Form Data:

ID = Demography

Item Group : Demography

Repeat key: 1

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Height	69		
Weight	185		
Gender	M		
Date of Birth	19480619		
Ethnic Group	Caucasian		
Height Units	in		
Weight Units	lb		

[Audit Record for this Item Group :](#)

[User :](#) John Smith

[Location :](#) Roswell Park

[Date- and Timestamp :](#) 2002-02-04T15:26:32-05:00

[Source ID :](#) 46841204

Form Data:

ID = Treatment Assignment

[Item Group :](#) Treatment Assignment

[Repeat key:](#) 1

[Transaction type:](#) Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		

Item	Value	is Null?	Trans.Type
Record status, 5 levels, internal use	S		
Assigned Study Drug Treatment	1		

Audit Record for this Item Group :

User : John Smith

Location : Roswell Park

Date- and Timestamp : 2002-02-04T15:31:32-05:00

Source ID : 46876104

Form Data:

ID = Pharmacokinetics

Item Group : Pharmacokinetics

Repeat key: 1

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	V		
Pretreatment yr	1999		
1-h year	1999		
2-h year	1999		
3-h year	1999		
4-h year	1999		
8-h year	1999		
16-h year	1999		

Item	Value	is Null?	Trans.Type
24-h year	1999		
Meal year	1999		
Pretreatment mon	06		
1-h mon	06		
2-h mon	06		
3-h mon	06		
4-h mon	06		
8-h mon	06		
16-h mon	06		
24-h mon	06		
Meal mon	06		
Pretreatment day	20		
1-h day	20		
2-h day	20		
3-h day	20		
4-h day	20		
8-h day	20		
16-h day	20		
24-h day	21		
Meal day	20		
Pretreatment date	19990620		
1-h date	19990620		
2-h date	19990620		
3-h date	19990620		
4-h date	19990620		
8-h date	19990620		
16-h date	19990620		
24-h date	19990621		
Date of last meal	19990620		
Pretreatment time	0600		
1-h time	0700		
2-h time	0800		
3-h time	0900		
4-h time	1000		
8-h time	1400		
16-h time	1800		
24-h time	0600		
Time of last meal	0500		

Audit Record for this Item Group :

User : John Smith

Location : Roswell Park

Date- and Timestamp : 2002-02-04T15:36:32-05:00

Source ID : 46877104

Form Data:

ID = Physical Exam

Item Group : Physical Exam

Repeat key: 1

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Physical Exam Body System	1		
Normal/Abnormal/Not Done	1		

Audit Record for this Item Group :

User : John Smith

Location : Roswell Park

Date- and Timestamp : 2002-02-04T15:41:32-05:00

Source ID : 46861804

Item Group : Physical Exam

Repeat key: 2

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Physical Exam Body System	2		
Normal/Abnormal/Not Done	1		

Audit Record for this Item Group :

User : John Smith

Location : Roswell Park

Date- and Timestamp : 2002-02-04T15:41:32-05:00

Source ID : 46862204

Item Group : Physical Exam

Repeat key: 3

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Physical Exam Body System	3		

Item	Value	is Null?	Trans.Type
Normal/Abnormal/Not Done	1		

Audit Record for this Item Group :

User : John Smith

Location : Roswell Park

Date- and Timestamp : 2002-02-04T15:41:32-05:00

Source ID : 46862604

Item Group : Physical Exam

Repeat key: 4

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Physical Exam Body System	4		
Normal/Abnormal/Not Done	2		
Comment	MILD WHEEZING		

Audit Record for this Item Group :

User : John Smith

Location : Roswell Park

Date- and Timestamp : 2002-02-04T15:41:32-05:00

Source ID : 46864104

Item Group : Physical Exam

Repeat key: 5

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Physical Exam Body System	5		
Normal/Abnormal/Not Done	2		
Comment	TACHYCARDIA		

Audit Record for this Item Group :

User : John Smith

Location : Roswell Park

Date- and Timestamp : 2002-02-04T15:41:32-05:00

Source ID : 46864704

Item Group : Physical Exam

Repeat key: 6

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels,	S		

Item	Value	is Null?	Trans.Type
internal use			
Physical Exam Body System	6		
Normal/Abnormal/Not Done	2		
Comment	SLIGHTLY ENLARGED-NCS		

Audit Record for this Item Group :

User : John Smith

Location : Roswell Park

Date- and Timestamp : 2002-02-04T15:41:32-05:00

Source ID : 46865804

Item Group : Physical Exam

Repeat key: 7

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Physical Exam Body System	7		
Normal/Abnormal/Not Done	1		

Audit Record for this Item Group :

User : John Smith

Location : Roswell Park

Date- and Timestamp : 2002-02-04T15:41:32-05:00

Source ID : 46866604

Item Group : Physical Exam

Repeat key: 8

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Physical Exam Body System	8		
Normal/Abnormal/Not Done	3		

Audit Record for this Item Group :

User : John Smith

Location : Roswell Park

Date- and Timestamp : 2002-02-04T15:41:32-05:00

Source ID : 46867404

Item Group : Physical Exam

Repeat key: 9

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		

Item	Value	is Null?	Trans.Type
Country	USA		
Record status, 5 levels, internal use	S		
Physical Exam Body System	9		
Normal/Abnormal/Not Done	1		

Audit Record for this Item Group :

User : John Smith

Location : Roswell Park

Date- and Timestamp : 2002-02-04T15:41:32-05:00

Source ID : 46867704

Item Group : Physical Exam

Repeat key: 10

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Physical Exam Body System	10		
Normal/Abnormal/Not Done	2		
Comment	PETECHIA		

Audit Record for this Item Group :

User : John Smith

Location : Roswell Park

Date- and Timestamp : 2002-02-04T15:41:32-05:00

Source ID : 46868504

Item Group : Physical Exam

Repeat key: 11

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Physical Exam Body System	11		
Normal/Abnormal/Not Done	1		

Audit Record for this Item Group :

User : John Smith

Location : Roswell Park

Date- and Timestamp : 2002-02-04T15:41:32-05:00

Source ID : 46868604

Item Group : Physical Exam

Repeat key: 12

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		

Item	Value	is Null?	Trans.Type
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Physical Exam Body System	12		
Normal/Abnormal/Not Done	1		

[Audit Record for this Item Group :](#)

[User :](#) John Smith

[Location :](#) Roswell Park

[Date- and Timestamp :](#) 2002-02-04T15:41:32-05:00

[Source ID :](#) 46868704

[Item Group :](#) Physical Exam

[Repeat key:](#) 13

[Transaction type:](#) Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Physical Exam Body System	13		
Normal/Abnormal/Not Done	1		

[Audit Record for this Item Group :](#)

[User :](#) John Smith

[Location :](#) Roswell Park

Date- and Timestamp : 2002-02-04T15:41:32-05:00

Source ID : 46869004

Study Event Data:

Study Event = Post-treatment

Form Data:

ID = Concom Meds

Item Group : Concom Meds

Repeat key: 1

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Line Number	1		
Medication For Conmed	TYLENOL		
Start Month - Enter Two Digits 01-12	06		
Start Day - Enter Two Digits 01-31	10		
Start Year - Enter Four Digit Year	1999		
Derived Start Date	19990610		
Stop Month - Enter Two Digits 01-12	06		
Stop Day - Enter Two	14		

Item	Value	is Null?	Trans.Type
Digits 01-31			
Stop Year - Enter Four Digit Year	1999		
Derived Stop Date	19990614		
Dose and Unit	325MG		
Conmed Route	3		
Conmed Regimen	8		
Conmed Indication	HEADACHE		
Check If Taken for AE	0		

Audit Record for this Item Group :

User : John Smith

Location : Roswell Park

Date- and Timestamp : 2002-02-04T15:46:32-05:00

Source ID : 46903304

Form Data:

ID = Physical Exam

Item Group : Physical Exam

Repeat key: 1

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Physical Exam Body System	1		

Item	Value	is Null?	Trans.Type
Normal/Abnormal/Not Done	1		

Audit Record for this Item Group :

User : John Smith

Location : Roswell Park

Date- and Timestamp : 2002-02-04T15:51:32-05:00

Source ID : 46896704

Item Group : Physical Exam

Repeat key: 2

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Physical Exam Body System	2		
Normal/Abnormal/Not Done	1		

Audit Record for this Item Group :

User : John Smith

Location : Roswell Park

Date- and Timestamp : 2002-02-04T15:51:32-05:00

Source ID : 46896804

Item Group : Physical Exam

Repeat key: 3

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Physical Exam Body System	3		
Normal/Abnormal/Not Done	1		

Audit Record for this Item Group :

User : John Smith

Location : Roswell Park

Date- and Timestamp : 2002-02-04T15:51:32-05:00

Source ID : 46896904

Item Group : Physical Exam

Repeat key: 4

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Physical Exam Body System	4		

Item	Value	is Null?	Trans.Type
Normal/Abnormal/Not Done	1		

Audit Record for this Item Group :

User : John Smith

Location : Roswell Park

Date- and Timestamp : 2002-02-04T15:51:32-05:00

Source ID : 46897004

Item Group : Physical Exam

Repeat key: 5

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Physical Exam Body System	5		
Normal/Abnormal/Not Done	1		

Audit Record for this Item Group :

User : John Smith

Location : Roswell Park

Date- and Timestamp : 2002-02-04T15:51:32-05:00

Source ID : 46897104

Item Group : Physical Exam

Repeat key: 6

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Physical Exam Body System	6		
Normal/Abnormal/Not Done	1		

Audit Record for this Item Group :

User : John Smith

Location : Roswell Park

Date- and Timestamp : 2002-02-04T15:51:32-05:00

Source ID : 46897204

Item Group : Physical Exam

Repeat key: 7

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Physical Exam Body System	7		

Item	Value	is Null?	Trans.Type
Normal/Abnormal/Not Done	1		

Audit Record for this Item Group :

User : John Smith

Location : Roswell Park

Date- and Timestamp : 2002-02-04T15:51:32-05:00

Source ID : 46897304

Item Group : Physical Exam

Repeat key: 8

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Physical Exam Body System	8		
Normal/Abnormal/Not Done	3		

Audit Record for this Item Group :

User : John Smith

Location : Roswell Park

Date- and Timestamp : 2002-02-04T15:51:32-05:00

Source ID : 46897504

Item Group : Physical Exam

Repeat key: 9

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Physical Exam Body System	9		
Normal/Abnormal/Not Done	1		

Audit Record for this Item Group :

User : John Smith

Location : Roswell Park

Date- and Timestamp : 2002-02-04T15:51:32-05:00

Source ID : 46897604

Item Group : Physical Exam

Repeat key: 10

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Physical Exam Body System	10		

Item	Value	is Null?	Trans.Type
Normal/Abnormal/Not Done	1		

Audit Record for this Item Group :

User : John Smith

Location : Roswell Park

Date- and Timestamp : 2002-02-04T15:51:32-05:00

Source ID : 46897804

Item Group : Physical Exam

Repeat key: 11

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Physical Exam Body System	11		
Normal/Abnormal/Not Done	1		

Audit Record for this Item Group :

User : John Smith

Location : Roswell Park

Date- and Timestamp : 2002-02-04T15:51:32-05:00

Source ID : 46898004

Item Group : Physical Exam

Repeat key: 12

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Physical Exam Body System	12		
Normal/Abnormal/Not Done	1		

Audit Record for this Item Group :

User : John Smith

Location : Roswell Park

Date- and Timestamp : 2002-02-04T15:51:32-05:00

Source ID : 46898104

Item Group : Physical Exam

Repeat key: 13

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Physical Exam Body System	13		

Item	Value	is Null?	Trans.Type
Normal/Abnormal/Not Done	1		

Audit Record for this Item Group :

User : John Smith

Location : Roswell Park

Date- and Timestamp : 2002-02-04T15:51:32-05:00

Source ID : 46898304

Subject Data:

Subject Key = 005

Investigator for this subject : John Smith, M.D.

Last Name : Smith

First Name : John

Location : Roswell Park

Site for this subject: Roswell Park

Study Event Data:

Study Event = Pre-treatment

Form Data:

ID = Demography

Item Group : Demography

Repeat key: 1

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Height	71		
Weight	244		
Gender	M		
Date of Birth	19630820		
Ethnic Group	Black		
Height Units	in		
Weight Units	lb		

[Audit Record for this Item Group :](#)

[User :](#) John Smith

[Location :](#) Roswell Park

[Date- and Timestamp :](#) 2002-02-04T15:56:32-05:00

[Source ID :](#) 46731304

Form Data:

ID = Treatment Assignment

[Item Group :](#) Treatment Assignment

[Repeat key:](#) 1

[Transaction type:](#) Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		

Item	Value	is Null?	Trans.Type
Record status, 5 levels, internal use	V		
Assigned Study Drug Treatment	2		

Audit Record for this Item Group :

User : John Smith

Location : Roswell Park

Date- and Timestamp : 2002-02-04T16:01:32-05:00

Source ID : 46676604

Item Group : Treatment Assignment

Repeat key: 2

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Assigned Study Drug Treatment	2		

Audit Record for this Item Group :

User : John Smith

Location : Roswell Park

Date- and Timestamp : 2002-02-04T16:01:32-05:00

Source ID : 46918704

Form Data:

ID = Pharmacokinetics

Item Group : Pharmacokinetics

Repeat key: 1

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	V		
Pretreatment yr	1999		
1-h year	1999		
2-h year	1999		
3-h year	1999		
4-h year	1999		
8-h year	1999		
16-h year	1999		
24-h year	1999		
Meal year	1999		
Pretreatment mon	03		
1-h mon	03		
2-h mon	03		
3-h mon	03		
4-h mon	03		
8-h mon	03		
16-h mon	03		
24-h mon	03		
Meal mon	03		
Pretreatment day	20		
1-h day	20		
2-h day	20		
3-h day	20		
4-h day	20		

Item	Value	is Null?	Trans.Type
8-h day	20		
16-h day	20		
24-h day	21		
Meal day	20		
Pretreatment date	19990320		
1-h date	19990320		
2-h date	19990320		
3-h date	19990320		
4-h date	19990320		
8-h date	19990320		
16-h date	19990320		
24-h date	19990321		
Date of last meal	19990320		
Pretreatment time	0600		
1-h time	0700		
2-h time	0800		
3-h time	0900		
4-h time	1000		
8-h time	1400		
16-h time	1800		
24-h time	0600		
Time of last meal	0500		

[Audit Record for this Item Group :](#)

[User :](#) John Smith

[Location :](#) Roswell Park

[Date- and Timestamp :](#) 2002-02-04T16:06:32-05:00

[Source ID :](#) 46676704

Form Data:

ID = Physical Exam

Item Group : Physical Exam

Repeat key: 1

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	V		
Physical Exam Body System	1		
Normal/Abnormal/Not Done	1		

Audit Record for this Item Group :

User : John Smith

Location : Roswell Park

Date- and Timestamp : 2002-02-04T16:11:32-05:00

Source ID : 46674704

Item Group : Physical Exam

Repeat key: 2

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	V		
Physical Exam Body System	2		
Normal/Abnormal/Not Done	1		

Audit Record for this Item Group :

User : John Smith

Location : Roswell Park

Date- and Timestamp : 2002-02-04T16:11:32-05:00

Source ID : 46674804

Item Group : Physical Exam

Repeat key: 3

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	V		
Physical Exam Body System	3		
Normal/Abnormal/Not Done	1		

Audit Record for this Item Group :

User : John Smith

Location : Roswell Park

Date- and Timestamp : 2002-02-04T16:11:32-05:00

Source ID : 46674904

Item Group : Physical Exam

Repeat key: 4

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	V		
Physical Exam Body System	4		
Normal/Abnormal/Not Done	2		
Comment	MILD WHEEZING		

Audit Record for this Item Group :

User : John Smith

Location : Roswell Park

Date- and Timestamp : 2002-02-04T16:11:32-05:00

Source ID : 46675004

Item Group : Physical Exam

Repeat key: 5

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	V		
Physical Exam Body System	5		
Normal/Abnormal/Not Done	2		

Item	Value	is Null?	Trans.Type
Done			
Comment	TACHYCARDIA		

Audit Record for this Item Group :

User : John Smith

Location : Roswell Park

Date- and Timestamp : 2002-02-04T16:11:32-05:00

Source ID : 46675104

Item Group : Physical Exam

Repeat key: 6

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	V		
Physical Exam Body System	6		
Normal/Abnormal/Not Done	2		
Comment	SLIGHTLY ENLARGED - NCS		

Audit Record for this Item Group :

User : John Smith

Location : Roswell Park

Date- and Timestamp : 2002-02-04T16:11:32-05:00

Source ID : 46675204

Item Group : Physical Exam

Repeat key: 7

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	V		
Physical Exam Body System	7		
Normal/Abnormal/Not Done	1		

Audit Record for this Item Group :

User : John Smith

Location : Roswell Park

Date- and Timestamp : 2002-02-04T16:11:32-05:00

Source ID : 46675304

Item Group : Physical Exam

Repeat key: 8

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	V		

Item	Value	is Null?	Trans.Type
Physical Exam Body System	8		
Normal/Abnormal/Not Done	3		

Audit Record for this Item Group :

User : John Smith

Location : Roswell Park

Date- and Timestamp : 2002-02-04T16:11:32-05:00

Source ID : 46675404

Item Group : Physical Exam

Repeat key: 9

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	V		
Physical Exam Body System	9		
Normal/Abnormal/Not Done	2		

Audit Record for this Item Group :

User : John Smith

Location : Roswell Park

Date- and Timestamp : 2002-02-04T16:11:32-05:00

Source ID : 46675504

Item Group : Physical Exam

Repeat key: 10

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	V		
Physical Exam Body System	10		
Normal/Abnormal/Not Done	2		
Comment	PETECHIA		

Audit Record for this Item Group :

User : John Smith

Location : Roswell Park

Date- and Timestamp : 2002-02-04T16:11:32-05:00

Source ID : 46675604

Item Group : Physical Exam

Repeat key: 11

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels,	V		

Item	Value	is Null?	Trans.Type
internal use			
Physical Exam Body System	11		
Normal/Abnormal/Not Done	1		

Audit Record for this Item Group :

User : John Smith

Location : Roswell Park

Date- and Timestamp : 2002-02-04T16:11:32-05:00

Source ID : 46675704

Item Group : Physical Exam

Repeat key: 12

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	V		
Physical Exam Body System	12		
Normal/Abnormal/Not Done	1		

Audit Record for this Item Group :

User : John Smith

Location : Roswell Park

Date- and Timestamp : 2002-02-04T16:11:32-05:00

Source ID : 46675804

Item Group : Physical Exam

Repeat key: 13

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	V		
Physical Exam Body System	13		
Normal/Abnormal/Not Done	1		

Audit Record for this Item Group :

User : John Smith

Location : Roswell Park

Date- and Timestamp : 2002-02-04T16:11:32-05:00

Source ID : 46675904

Item Group : Physical Exam

Repeat key: 14

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		

Item	Value	is Null?	Trans.Type
Physical Exam Body System	1		
Normal/Abnormal/Not Done	1		

Audit Record for this Item Group :

User : John Smith

Location : Roswell Park

Date- and Timestamp : 2002-02-04T16:11:32-05:00

Source ID : 46682904

Item Group : Physical Exam

Repeat key: 15

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Physical Exam Body System	2		
Normal/Abnormal/Not Done	1		

Audit Record for this Item Group :

User : John Smith

Location : Roswell Park

Date- and Timestamp : 2002-02-04T16:11:32-05:00

Source ID : 46683004

Item Group : Physical Exam

Repeat key: 16

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Physical Exam Body System	3		
Normal/Abnormal/Not Done	1		

Audit Record for this Item Group :

User : John Smith

Location : Roswell Park

Date- and Timestamp : 2002-02-04T16:11:32-05:00

Source ID : 46683104

Item Group : Physical Exam

Repeat key: 17

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		

Item	Value	is Null?	Trans.Type
Physical Exam Body System	4		
Normal/Abnormal/Not Done	2		
Comment	MILD WHEEZING		

Audit Record for this Item Group :

User : John Smith

Location : Roswell Park

Date- and Timestamp : 2002-02-04T16:11:32-05:00

Source ID : 46683204

Item Group : Physical Exam

Repeat key: 18

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Physical Exam Body System	5		
Normal/Abnormal/Not Done	2		
Comment	TACHYCARDIA		

Audit Record for this Item Group :

User : John Smith

Location : Roswell Park

Date- and Timestamp : 2002-02-04T16:11:32-05:00

Source ID : 46683304

Item Group : Physical Exam

Repeat key: 19

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Physical Exam Body System	6		
Normal/Abnormal/Not Done	2		
Comment	SLIGHTLY ENLARGED - NCS		

Audit Record for this Item Group :

User : John Smith

Location : Roswell Park

Date- and Timestamp : 2002-02-04T16:11:32-05:00

Source ID : 46683404

Item Group : Physical Exam

Repeat key: 20

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		

Item	Value	is Null?	Trans.Type
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Physical Exam Body System	7		
Normal/Abnormal/Not Done	1		

[Audit Record for this Item Group :](#)

[User :](#) John Smith

[Location :](#) Roswell Park

[Date- and Timestamp :](#) 2002-02-04T16:11:32-05:00

[Source ID :](#) 46683504

[Item Group :](#) Physical Exam

[Repeat key:](#) 21

[Transaction type:](#) Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Physical Exam Body System	8		
Normal/Abnormal/Not Done	3		

[Audit Record for this Item Group :](#)

[User :](#) John Smith

[Location :](#) Roswell Park

Date- and Timestamp : 2002-02-04T16:11:32-05:00

Source ID : 46683604

Item Group : Physical Exam

Repeat key: 22

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Physical Exam Body System	9		
Normal/Abnormal/Not Done	1		

Audit Record for this Item Group :

User : John Smith

Location : Roswell Park

Date- and Timestamp : 2002-02-04T16:11:32-05:00

Source ID : 46683704

Item Group : Physical Exam

Repeat key: 23

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		

Item	Value	is Null?	Trans.Type
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Physical Exam Body System	10		
Normal/Abnormal/Not Done	2		
Comment	PETECHIA		

Audit Record for this Item Group :

User : John Smith

Location : Roswell Park

Date- and Timestamp : 2002-02-04T16:11:32-05:00

Source ID : 46683804

Item Group : Physical Exam

Repeat key: 24

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Physical Exam Body System	11		
Normal/Abnormal/Not Done	1		

Audit Record for this Item Group :

User : John Smith

Location : Roswell Park

Date- and Timestamp : 2002-02-04T16:11:32-05:00

Source ID : 46683904

Item Group : Physical Exam

Repeat key: 25

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Physical Exam Body System	12		
Normal/Abnormal/Not Done	1		

Audit Record for this Item Group :

User : John Smith

Location : Roswell Park

Date- and Timestamp : 2002-02-04T16:11:32-05:00

Source ID : 46684004

Item Group : Physical Exam

Repeat key: 26

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Physical Exam Body System	13		
Normal/Abnormal/Not Done	1		

Audit Record for this Item Group :

User : John Smith

Location : Roswell Park

Date- and Timestamp : 2002-02-04T16:11:32-05:00

Source ID : 46684104

Item Group : Physical Exam

Repeat key: 27

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Physical Exam Body System	1		
Normal/Abnormal/Not Done	1		

Audit Record for this Item Group :

User : John Smith

Location : Roswell Park

Date- and Timestamp : 2002-02-04T16:11:32-05:00

Source ID : 46758204

Item Group : Physical Exam

Repeat key: 28

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Physical Exam Body System	2		
Normal/Abnormal/Not Done	1		

Audit Record for this Item Group :

User : John Smith

Location : Roswell Park

Date- and Timestamp : 2002-02-04T16:11:32-05:00

Source ID : 46758304

Item Group : Physical Exam

Repeat key: 29

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Physical Exam Body System	3		
Normal/Abnormal/Not Done	1		

Audit Record for this Item Group :

User : John Smith

Location : Roswell Park

Date- and Timestamp : 2002-02-04T16:11:32-05:00

Source ID : 46758404

Item Group : Physical Exam

Repeat key: 30

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Physical Exam Body System	4		
Normal/Abnormal/Not Done	2		
Comment	WHEEZING		

Audit Record for this Item Group :

User : John Smith

Location : Roswell Park

Date- and Timestamp : 2002-02-04T16:11:32-05:00

Source ID : 46758504

Item Group : Physical Exam

Repeat key: 31

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Physical Exam Body System	5		
Normal/Abnormal/Not Done	1		

Audit Record for this Item Group :

User : John Smith

Location : Roswell Park

Date- and Timestamp : 2002-02-04T16:11:32-05:00

Source ID : 46758604

Item Group : Physical Exam

Repeat key: 32

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Physical Exam Body System	6		
Normal/Abnormal/Not Done	1		

Audit Record for this Item Group :

User : John Smith

Location : Roswell Park

Date- and Timestamp : 2002-02-04T16:11:32-05:00

Source ID : 46758704

Item Group : Physical Exam

Repeat key: 33

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Physical Exam Body System	7		
Normal/Abnormal/Not Done	1		

Audit Record for this Item Group :

User : John Smith

Location : Roswell Park

Date- and Timestamp : 2002-02-04T16:11:32-05:00

Source ID : 46758804

Item Group : Physical Exam

Repeat key: 34

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Physical Exam Body System	8		
Normal/Abnormal/Not Done	2		

Audit Record for this Item Group :

User : John Smith

Location : Roswell Park

Date- and Timestamp : 2002-02-04T16:11:32-05:00

Source ID : 46758904

Item Group : Physical Exam

Repeat key: 35

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Physical Exam Body System	9		
Normal/Abnormal/Not Done	2		

Audit Record for this Item Group :

User : John Smith

Location : Roswell Park

Date- and Timestamp : 2002-02-04T16:11:32-05:00

Source ID : 46759004

Item Group : Physical Exam

Repeat key: 36

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Physical Exam Body System	10		
Normal/Abnormal/Not Done	1		

Audit Record for this Item Group :

User : John Smith

Location : Roswell Park

Date- and Timestamp : 2002-02-04T16:11:32-05:00

Source ID : 46759104

Item Group : Physical Exam

Repeat key: 37

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Physical Exam Body System	11		
Normal/Abnormal/Not Done	1		

Audit Record for this Item Group :

User : John Smith

Location : Roswell Park

Date- and Timestamp : 2002-02-04T16:11:32-05:00

Source ID : 46759204

Item Group : Physical Exam

Repeat key: 38

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Physical Exam Body System	12		
Normal/Abnormal/Not Done	1		

Audit Record for this Item Group :

User : John Smith

Location : Roswell Park

Date- and Timestamp : 2002-02-04T16:11:32-05:00

Source ID : 46759304

Item Group : Physical Exam

Repeat key: 39

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Physical Exam Body System	13		
Normal/Abnormal/Not Done	1		

Audit Record for this Item Group :

User : John Smith

Location : Roswell Park

Date- and Timestamp : 2002-02-04T16:11:32-05:00

Source ID : 46759404

Item Group : Physical Exam

Repeat key: 40

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Physical Exam Body System	1		
Normal/Abnormal/Not Done	1		

Audit Record for this Item Group :

User : John Smith

Location : Roswell Park

Date- and Timestamp : 2002-02-04T16:11:32-05:00

Source ID : 46941604

Item Group : Physical Exam

Repeat key: 41

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Physical Exam Body System	2		
Normal/Abnormal/Not Done	1		

Audit Record for this Item Group :

User : John Smith

Location : Roswell Park

Date- and Timestamp : 2002-02-04T16:11:32-05:00

Source ID : 46941704

Item Group : Physical Exam

Repeat key: 42

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Physical Exam Body System	3		
Normal/Abnormal/Not Done	1		

Audit Record for this Item Group :

User : John Smith

Location : Roswell Park

Date- and Timestamp : 2002-02-04T16:11:32-05:00

Source ID : 46941804

Item Group : Physical Exam

Repeat key: 43

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Physical Exam Body System	4		
Normal/Abnormal/Not Done	2		
Comment	MILD WHEEZING		

Audit Record for this Item Group :

User : John Smith

Location : Roswell Park

Date- and Timestamp : 2002-02-04T16:11:32-05:00

Source ID : 46942204

Item Group : Physical Exam

Repeat key: 44

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Physical Exam Body System	5		
Normal/Abnormal/Not Done	2		
Comment	TACHYCARDIA		

Audit Record for this Item Group :

User : John Smith

Location : Roswell Park

Date- and Timestamp : 2002-02-04T16:11:32-05:00

Source ID : 46942304

Item Group : Physical Exam

Repeat key: 45

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Physical Exam Body System	6		
Normal/Abnormal/Not Done	2		
Comment	SLIGHTLY ENLARGED-NCS		

Audit Record for this Item Group :

User : John Smith

Location : Roswell Park

Date- and Timestamp : 2002-02-04T16:11:32-05:00

Source ID : 46942404

Item Group : Physical Exam

Repeat key: 46

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Physical Exam Body System	7		
Normal/Abnormal/Not Done	1		

Audit Record for this Item Group :

User : John Smith

Location : Roswell Park

Date- and Timestamp : 2002-02-04T16:11:32-05:00

Source ID : 46942504

Item Group : Physical Exam

Repeat key: 47

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Physical Exam Body System	8		
Normal/Abnormal/Not Done	3		

Audit Record for this Item Group :

User : John Smith

Location : Roswell Park

Date- and Timestamp : 2002-02-04T16:11:32-05:00

Source ID : 46942704

Item Group : Physical Exam

Repeat key: 48

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Physical Exam Body System	9		
Normal/Abnormal/Not Done	1		

Audit Record for this Item Group :

User : John Smith

Location : Roswell Park

Date- and Timestamp : 2002-02-04T16:11:32-05:00

Source ID : 46942804

Item Group : Physical Exam

Repeat key: 49

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Physical Exam Body System	10		
Normal/Abnormal/Not Done	2		
Comment	PETECHIA		

Audit Record for this Item Group :

User : John Smith

Location : Roswell Park

Date- and Timestamp : 2002-02-04T16:11:32-05:00

Source ID : 46942904

Item Group : Physical Exam

Repeat key: 50

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Physical Exam Body System	11		
Normal/Abnormal/Not Done	1		

Audit Record for this Item Group :

User : John Smith

Location : Roswell Park

Date- and Timestamp : 2002-02-04T16:11:32-05:00

Source ID : 46943004

Item Group : Physical Exam

Repeat key: 51

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Physical Exam Body System	12		
Normal/Abnormal/Not Done	1		

Audit Record for this Item Group :

User : John Smith

Location : Roswell Park

Date- and Timestamp : 2002-02-04T16:11:32-05:00

Source ID : 46943204

Item Group : Physical Exam

Repeat key: 52

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Physical Exam Body System	13		
Normal/Abnormal/Not Done	1		

Audit Record for this Item Group :

User : John Smith

Location : Roswell Park

Date- and Timestamp : 2002-02-04T16:11:32-05:00

Source ID : 46943304

Study Event Data:

Study Event = Post-treatment

Form Data:

ID = Concom Meds

Item Group : Concom Meds

Repeat key: 1

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	V		
Line Number	1		
Medication For Conmed	TYLENOL		
Start Month - Enter Two Digits 01-12	03		
Start Day - Enter Two Digits 01-31	10		
Start Year - Enter Four Digit Year	1999		
Derived Start Date	19990310		
Stop Month - Enter Two Digits 01-12	03		
Stop Day - Enter Two Digits 01-31	14		
Stop Year - Enter Four Digit Year	1999		
Derived Stop Date	19990314		
Dose and Unit	325 MG		
Conmed Route	3		
Conmed Regimen	8		
Conmed Indication	HEADACHE		
Check If Taken for AE	0		

Audit Record for this Item Group :

User : John Smith

Location : Roswell Park

Date- and Timestamp : 2002-02-04T16:16:32-05:00

Source ID : 46678404

Item Group : Concom Meds

Repeat key: 2

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Line Number	1		
Medication For Conmed	TYLENOL		
Start Month - Enter Two Digits 01-12	03		
Start Day - Enter Two Digits 01-31	10		
Start Year - Enter Four Digit Year	1999		
Derived Start Date	19990310		
Stop Month - Enter Two Digits 01-12	03		
Stop Day - Enter Two Digits 01-31	14		
Stop Year - Enter Four Digit Year	1999		
Derived Stop Date	19990314		
Dose and Unit	325MG		
Conmed Route	3		
Conmed Regimen	8		
Conmed Indication	HEADACHE		

Item	Value	is Null?	Trans.Type
Check If Taken for AE	0		

Audit Record for this Item Group :

User : John Smith

Location : Roswell Park

Date- and Timestamp : 2002-02-04T16:16:32-05:00

Source ID : 46685104

Item Group : Concom Meds

Repeat key: 3

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Line Number	1		
Medication For Conmed	TYLENOL		
Start Month - Enter Two Digits 01-12	06		
Start Day - Enter Two Digits 01-31	10		
Start Year - Enter Four Digit Year	1999		
Derived Start Date	19990610		
Stop Month - Enter Two Digits 01-12	06		
Stop Day - Enter Two Digits 01-31	14		
Stop Year - Enter Four Digit Year	1999		
Derived Stop Date	19990614		
Dose and Unit	325MG		

Item	Value	is Null?	Trans.Type
Conmed Route	3		
Conmed Regimen	8		
Conmed Indication	HEADACHE		
Check If Taken for AE	0		

Audit Record for this Item Group :

User : John Smith

Location : Roswell Park

Date- and Timestamp : 2002-02-04T16:16:32-05:00

Source ID : 46932804

Form Data:

ID = Physical Exam

Item Group : Physical Exam

Repeat key: 1

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Physical Exam Body System	1		
Normal/Abnormal/Not Done	1		

Audit Record for this Item Group :

User : John Smith

Location : Roswell Park

Date- and Timestamp : 2002-02-04T16:21:32-05:00

Source ID : 46927704

Item Group : Physical Exam

Repeat key: 2

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Physical Exam Body System	2		
Normal/Abnormal/Not Done	1		

Audit Record for this Item Group :

User : John Smith

Location : Roswell Park

Date- and Timestamp : 2002-02-04T16:21:32-05:00

Source ID : 46927804

Item Group : Physical Exam

Repeat key: 3

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Physical Exam Body System	3		
Normal/Abnormal/Not Done	1		

Audit Record for this Item Group :

User : John Smith

Location : Roswell Park

Date- and Timestamp : 2002-02-04T16:21:32-05:00

Source ID : 46927904

Item Group : Physical Exam

Repeat key: 4

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Physical Exam Body System	4		
Normal/Abnormal/Not Done	1		

Audit Record for this Item Group :

User : John Smith

Location : Roswell Park

Date- and Timestamp : 2002-02-04T16:21:32-05:00

Source ID : 46928004

Item Group : Physical Exam

Repeat key: 5

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Physical Exam Body System	5		
Normal/Abnormal/Not Done	1		

Audit Record for this Item Group :

User : John Smith

Location : Roswell Park

Date- and Timestamp : 2002-02-04T16:21:32-05:00

Source ID : 46928104

Item Group : Physical Exam

Repeat key: 6

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Physical Exam Body System	6		
Normal/Abnormal/Not Done	1		

Audit Record for this Item Group :

User : John Smith

Location : Roswell Park

Date- and Timestamp : 2002-02-04T16:21:32-05:00

Source ID : 46928204

Item Group : Physical Exam

Repeat key: 7

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Physical Exam Body System	7		
Normal/Abnormal/Not Done	1		

Audit Record for this Item Group :

User : John Smith

Location : Roswell Park

Date- and Timestamp : 2002-02-04T16:21:32-05:00

Source ID : 46928304

Item Group : Physical Exam

Repeat key: 8

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Physical Exam Body System	8		
Normal/Abnormal/Not Done	3		

Audit Record for this Item Group :

User : John Smith

Location : Roswell Park

Date- and Timestamp : 2002-02-04T16:21:32-05:00

Source ID : 46928404

Item Group : Physical Exam

Repeat key: 9

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Physical Exam Body System	9		
Normal/Abnormal/Not Done	1		

Audit Record for this Item Group :

User : John Smith

Location : Roswell Park

Date- and Timestamp : 2002-02-04T16:21:32-05:00

Source ID : 46928504

Item Group : Physical Exam

Repeat key: 10

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Physical Exam Body System	10		
Normal/Abnormal/Not Done	1		

Audit Record for this Item Group :

User : John Smith

Location : Roswell Park

Date- and Timestamp : 2002-02-04T16:21:32-05:00

Source ID : 46928604

Item Group : Physical Exam

Repeat key: 11

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Physical Exam Body System	11		
Normal/Abnormal/Not Done	1		

Audit Record for this Item Group :

User : John Smith

Location : Roswell Park

Date- and Timestamp : 2002-02-04T16:21:32-05:00

Source ID : 46928704

Item Group : Physical Exam

Repeat key: 12

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Physical Exam Body System	12		
Normal/Abnormal/Not Done	1		

Audit Record for this Item Group :

User : John Smith

Location : Roswell Park

Date- and Timestamp : 2002-02-04T16:21:32-05:00

Source ID : 46928804

Item Group : Physical Exam

Repeat key: 13

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Physical Exam Body System	13		
Normal/Abnormal/Not Done	1		

Audit Record for this Item Group :

User : John Smith

Location : Roswell Park

Date- and Timestamp : 2002-02-04T16:21:32-05:00

Source ID : 46928904

Subject Data:

Subject Key = 006

Investigator for this subject : John Smith, M.D.

Last Name : Smith

First Name : John

Location : Roswell Park

Site for this subject: Roswell Park

Study Event Data:

Study Event = Pre-treatment

Form Data:

ID = Demography

Item Group : Demography

Repeat key: 1

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Height	71		
Weight	175		
Gender	F		
Date of Birth	19550101		
Ethnic Group	Black		
Height Units	in		
Weight Units	lb		

[Audit Record for this Item Group :](#)

[User :](#) John Smith

[Location :](#) Roswell Park

[Date- and Timestamp :](#) 2002-02-04T16:26:32-05:00

[Source ID :](#) 46871804

Form Data:

ID = Treatment Assignment

[Item Group :](#) Treatment Assignment

[Repeat key:](#) 1

[Transaction type:](#) Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		

Item	Value	is Null?	Trans.Type
Record status, 5 levels, internal use	S		
Assigned Study Drug Treatment	2		

Audit Record for this Item Group :

User : John Smith

Location : Roswell Park

Date- and Timestamp : 2002-02-04T16:31:32-05:00

Source ID : 46898504

Form Data:

ID = Pharmacokinetics

Item Group : Pharmacokinetics

Repeat key: 1

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	V		
Pretreatment yr	1999		
1-h year	1999		
2-h year	1999		
3-h year	1999		
4-h year	1999		
8-h year	1999		
16-h year	1999		

Item	Value	is Null?	Trans.Type
24-h year	1999		
Meal year	1999		
Pretreatment mon	06		
1-h mon	06		
2-h mon	06		
3-h mon	06		
4-h mon	06		
8-h mon	06		
16-h mon	06		
24-h mon	06		
Meal mon	06		
Pretreatment day	20		
1-h day	20		
2-h day	20		
3-h day	20		
4-h day	20		
8-h day	20		
16-h day	20		
24-h day	21		
Meal day	20		
Pretreatment date	19990620		
1-h date	19990620		
2-h date	19990620		
3-h date	19990620		
4-h date	19990620		
8-h date	19990620		
16-h date	19990620		
24-h date	19990621		
Date of last meal	19990620		
Pretreatment time	0600		
1-h time	0700		
2-h time	0800		
3-h time	0900		
4-h time	1000		
8-h time	1400		
16-h time	1800		
24-h time	0600		
Time of last meal	0500		

Audit Record for this Item Group :

User : John Smith

Location : Roswell Park

Date- and Timestamp : 2002-02-04T16:36:32-05:00

Source ID : 46911504

Form Data:

ID = Physical Exam

Item Group : Physical Exam

Repeat key: 1

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Physical Exam Body System	1		
Normal/Abnormal/Not Done	1		

Audit Record for this Item Group :

User : John Smith

Location : Roswell Park

Date- and Timestamp : 2002-02-04T16:41:32-05:00

Source ID : 46883504

Item Group : Physical Exam

Repeat key: 2

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Physical Exam Body System	2		
Normal/Abnormal/Not Done	1		

Audit Record for this Item Group :

User : John Smith

Location : Roswell Park

Date- and Timestamp : 2002-02-04T16:41:32-05:00

Source ID : 46883704

Item Group : Physical Exam

Repeat key: 3

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Physical Exam Body System	3		

Item	Value	is Null?	Trans.Type
Normal/Abnormal/Not Done	1		

Audit Record for this Item Group :

User : John Smith

Location : Roswell Park

Date- and Timestamp : 2002-02-04T16:41:32-05:00

Source ID : 46883904

Item Group : Physical Exam

Repeat key: 4

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Physical Exam Body System	4		
Normal/Abnormal/Not Done	2		
Comment	MILD WHEEZING		

Audit Record for this Item Group :

User : John Smith

Location : Roswell Park

Date- and Timestamp : 2002-02-04T16:41:32-05:00

Source ID : 46885004

Item Group : Physical Exam

Repeat key: 5

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Physical Exam Body System	5		
Normal/Abnormal/Not Done	2		
Comment	TACHYCARDIA		

Audit Record for this Item Group :

User : John Smith

Location : Roswell Park

Date- and Timestamp : 2002-02-04T16:41:32-05:00

Source ID : 46886604

Item Group : Physical Exam

Repeat key: 6

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels,	S		

Item	Value	is Null?	Trans.Type
internal use			
Physical Exam Body System	6		
Normal/Abnormal/Not Done	2		
Comment	SLIGHTLY ENLARGED - NCS		

Audit Record for this Item Group :

User : John Smith

Location : Roswell Park

Date- and Timestamp : 2002-02-04T16:41:32-05:00

Source ID : 46888504

Item Group : Physical Exam

Repeat key: 7

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Physical Exam Body System	7		
Normal/Abnormal/Not Done	1		

Audit Record for this Item Group :

User : John Smith

Location : Roswell Park

Date- and Timestamp : 2002-02-04T16:41:32-05:00

Source ID : 46888704

Item Group : Physical Exam

Repeat key: 8

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Physical Exam Body System	8		
Normal/Abnormal/Not Done	3		

Audit Record for this Item Group :

User : John Smith

Location : Roswell Park

Date- and Timestamp : 2002-02-04T16:41:32-05:00

Source ID : 46888804

Item Group : Physical Exam

Repeat key: 9

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		

Item	Value	is Null?	Trans.Type
Country	USA		
Record status, 5 levels, internal use	S		
Physical Exam Body System	9		
Normal/Abnormal/Not Done	1		

Audit Record for this Item Group :

User : John Smith

Location : Roswell Park

Date- and Timestamp : 2002-02-04T16:41:32-05:00

Source ID : 46889104

Item Group : Physical Exam

Repeat key: 10

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Physical Exam Body System	10		
Normal/Abnormal/Not Done	2		
Comment	PETECHIA		

Audit Record for this Item Group :

User : John Smith

Location : Roswell Park

Date- and Timestamp : 2002-02-04T16:41:32-05:00

Source ID : 46889504

Item Group : Physical Exam

Repeat key: 11

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Physical Exam Body System	11		
Normal/Abnormal/Not Done	1		

Audit Record for this Item Group :

User : John Smith

Location : Roswell Park

Date- and Timestamp : 2002-02-04T16:41:32-05:00

Source ID : 46889604

Item Group : Physical Exam

Repeat key: 12

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		

Item	Value	is Null?	Trans.Type
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Physical Exam Body System	12		
Normal/Abnormal/Not Done	1		

[Audit Record for this Item Group :](#)

[User :](#) John Smith

[Location :](#) Roswell Park

[Date- and Timestamp :](#) 2002-02-04T16:41:32-05:00

[Source ID :](#) 46890504

[Item Group :](#) Physical Exam

[Repeat key:](#) 13

[Transaction type:](#) Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Physical Exam Body System	13		
Normal/Abnormal/Not Done	1		

[Audit Record for this Item Group :](#)

[User :](#) John Smith

[Location :](#) Roswell Park

Date- and Timestamp : 2002-02-04T16:41:32-05:00

Source ID : 46890704

Study Event Data:

Study Event = Post-treatment

Form Data:

ID = Concom Meds

Item Group : Concom Meds

Repeat key: 1

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Line Number	1		
Medication For Conmed	TYLENOL		
Start Month - Enter Two Digits 01-12	06		
Start Day - Enter Two Digits 01-31	10		
Start Year - Enter Four Digit Year	1999		
Derived Start Date	19990610		
Stop Month - Enter Two Digits 01-12	06		
Stop Day - Enter Two	14		

Item	Value	is Null?	Trans.Type
Digits 01-31			
Stop Year - Enter Four Digit Year	1999		
Derived Stop Date	19990614		
Dose and Unit	325 MG		
Conmed Route	3		
Conmed Regimen	8		
Conmed Indication	HEADACHE		
Check If Taken for AE	0		

Audit Record for this Item Group :

User : John Smith

Location : Roswell Park

Date- and Timestamp : 2002-02-04T16:46:32-05:00

Source ID : 46920904

Subject Data:

Subject Key = 007

Investigator for this subject : Jane Doe, M.D.

Last Name : Doe

First Name : Jane

Location : Fred Hutchinson

Site for this subject: Fred Hutchinson

Study Event Data:

Study Event = Pre-treatment

Form Data:

ID = Demography

Item Group : Demography

Repeat key: 1

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Height	72		
Weight	168		
Gender	M		
Date of Birth	19700809		
Ethnic Group	Caucasian		
Height Units	in		
Weight Units	lb		

[Audit Record for this Item Group :](#)

[User :](#) Jane Doe

[Location :](#) Fred Hutchinson

[Date- and Timestamp :](#) 2002-03-15T09:00:43-06:00

[Source ID :](#) 46948504

Form Data:

ID = Treatment Assignment

[Item Group :](#) Treatment Assignment

[Repeat key:](#) 1

[Transaction type:](#) Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		

Item	Value	is Null?	Trans.Type
Record status, 5 levels, internal use	S		
Assigned Study Drug Treatment	1		

Audit Record for this Item Group :

User : Jane Doe

Location : Fred Hutchinson

Date- and Timestamp : 2002-03-15T09:05:43-06:00

Source ID : 46794204

Form Data:

ID = Physical Exam

Item Group : Physical Exam

Repeat key: 1

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Physical Exam Body System	1		
Normal/Abnormal/Not Done	1		

Audit Record for this Item Group :

User : Jane Doe

Location : Fred Hutchinson

Date- and Timestamp : 2002-03-15T09:10:43-06:00

Source ID : 46764204

Item Group : Physical Exam

Repeat key: 2

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Physical Exam Body System	2		
Normal/Abnormal/Not Done	1		

Audit Record for this Item Group :

User : Jane Doe

Location : Fred Hutchinson

Date- and Timestamp : 2002-03-15T09:10:43-06:00

Source ID : 46764304

Item Group : Physical Exam

Repeat key: 3

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Physical Exam Body System	3		
Normal/Abnormal/Not Done	1		

Audit Record for this Item Group :

User : Jane Doe

Location : Fred Hutchinson

Date- and Timestamp : 2002-03-15T09:10:43-06:00

Source ID : 46764404

Item Group : Physical Exam

Repeat key: 4

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Physical Exam Body System	4		
Normal/Abnormal/Not Done	1		

Audit Record for this Item Group :

User : Jane Doe

Location : Fred Hutchinson

Date- and Timestamp : 2002-03-15T09:10:43-06:00

Source ID : 46764504

Item Group : Physical Exam

Repeat key: 5

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Physical Exam Body System	5		
Normal/Abnormal/Not Done	1		

Audit Record for this Item Group :

User : Jane Doe

Location : Fred Hutchinson

Date- and Timestamp : 2002-03-15T09:10:43-06:00

Source ID : 46764604

Item Group : Physical Exam

Repeat key: 6

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Physical Exam Body System	6		
Normal/Abnormal/Not Done	2		

Audit Record for this Item Group :

User : Jane Doe

Location : Fred Hutchinson

Date- and Timestamp : 2002-03-15T09:10:43-06:00

Source ID : 46764704

Item Group : Physical Exam

Repeat key: 7

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Physical Exam Body System	7		
Normal/Abnormal/Not Done	1		

Audit Record for this Item Group :

User : Jane Doe

Location : Fred Hutchinson

Date- and Timestamp : 2002-03-15T09:10:43-06:00

Source ID : 46764804

Item Group : Physical Exam

Repeat key: 8

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Physical Exam Body System	8		
Normal/Abnormal/Not Done	1		

Audit Record for this Item Group :

User : Jane Doe

Location : Fred Hutchinson

Date- and Timestamp : 2002-03-15T09:10:43-06:00

Source ID : 46764904

Item Group : Physical Exam

Repeat key: 9

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Physical Exam Body System	9		
Normal/Abnormal/Not Done	1		

Audit Record for this Item Group :

User : Jane Doe

Location : Fred Hutchinson

Date- and Timestamp : 2002-03-15T09:10:43-06:00

Source ID : 46765004

Item Group : Physical Exam

Repeat key: 10

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Physical Exam Body System	10		
Normal/Abnormal/Not Done	1		

Audit Record for this Item Group :

User : Jane Doe

Location : Fred Hutchinson

Date- and Timestamp : 2002-03-15T09:10:43-06:00

Source ID : 46765104

Item Group : Physical Exam

Repeat key: 11

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Physical Exam Body System	11		
Normal/Abnormal/Not Done	1		

Audit Record for this Item Group :

User : Jane Doe

Location : Fred Hutchinson

Date- and Timestamp : 2002-03-15T09:10:43-06:00

Source ID : 46765204

Item Group : Physical Exam

Repeat key: 12

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Physical Exam Body System	12		
Normal/Abnormal/Not Done	1		

Audit Record for this Item Group :

User : Jane Doe

Location : Fred Hutchinson

Date- and Timestamp : 2002-03-15T09:10:43-06:00

Source ID : 46765304

Item Group : Physical Exam

Repeat key: 13

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Physical Exam Body System	13		
Normal/Abnormal/Not Done	2		

Audit Record for this Item Group :

User : Jane Doe

Location : Fred Hutchinson

Date- and Timestamp : 2002-03-15T09:10:43-06:00

Source ID : 46765404

Subject Data:

Subject Key = 008

Investigator for this subject : John Smith, M.D.

Last Name : Smith

First Name : John

Location : Roswell Park

Site for this subject: Roswell Park

Study Event Data:

Study Event = Pre-treatment

Form Data:

ID = Demography

Item Group : Demography

Repeat key: 1

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Height	62		
Weight	97		
Gender	F		
Date of Birth	19370209		
Ethnic Group	Caucasian		
Height Units	in		
Weight Units	lb		

[Audit Record for this Item Group :](#)

[User :](#) Jane Doe

[Location :](#) Fred Hutchinson

[Date- and Timestamp :](#) 2002-03-15T09:15:43-06:00

[Source ID :](#) 46768104

Form Data:

ID = Treatment Assignment

[Item Group :](#) Treatment Assignment

[Repeat key:](#) 1

[Transaction type:](#) Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		

Item	Value	is Null?	Trans.Type
Record status, 5 levels, internal use	S		
Assigned Study Drug Treatment	1		

Audit Record for this Item Group :

User : Jane Doe

Location : Fred Hutchinson

Date- and Timestamp : 2002-03-15T09:20:43-06:00

Source ID : 46774204

Item Group : Treatment Assignment

Repeat key: 2

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Assigned Study Drug Treatment	1		

Audit Record for this Item Group :

User : Jane Doe

Location : Fred Hutchinson

Date- and Timestamp : 2002-03-15T09:20:43-06:00

Source ID : 46776004

Form Data:

ID = Pharmacokinetics

Item Group : Pharmacokinetics

Repeat key: 1

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	V		
Pretreatment yr	1999		
1-h year	1999		
2-h year	1999		
3-h year	1999		
4-h year	1999		
8-h year	1999		
16-h year	1999		
24-h year	1999		
Meal year	1999		
Pretreatment mon	07		
1-h mon	07		
2-h mon	07		
3-h mon	07		
4-h mon	07		
8-h mon	07		
16-h mon	07		
24-h mon	07		
Meal mon	07		
Pretreatment day	06		
1-h day	06		
2-h day	06		
3-h day	06		
4-h day	06		

Item	Value	is Null?	Trans.Type
8-h day	06		
16-h day	06		
24-h day	07		
Meal day	06		
Pretreatment date	19990706		
1-h date	19990706		
2-h date	19990706		
3-h date	19990706		
4-h date	19990706		
8-h date	19990706		
16-h date	19990706		
24-h date	19990707		
Date of last meal	19990706		
Pretreatment time	0600		
1-h time	0700		
2-h time	0800		
3-h time	0900		
4-h time	1000		
8-h time	1400		
16-h time	1800		
24-h time	0600		
Time of last meal	0500		

[Audit Record for this Item Group :](#)

[User :](#) Jane Doe

[Location :](#) Fred Hutchinson

[Date- and Timestamp :](#) 2002-03-15T09:25:43-06:00

[Source ID :](#) 46774304

Form Data:

ID = Physical Exam

Item Group : Physical Exam

Repeat key: 1

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Physical Exam Body System	1		
Normal/Abnormal/Not Done	1		

Audit Record for this Item Group :

User : Jane Doe

Location : Fred Hutchinson

Date- and Timestamp : 2002-03-15T09:30:43-06:00

Source ID : 46769904

Item Group : Physical Exam

Repeat key: 2

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Physical Exam Body System	2		
Normal/Abnormal/Not Done	1		

Audit Record for this Item Group :

User : Jane Doe

Location : Fred Hutchinson

Date- and Timestamp : 2002-03-15T09:30:43-06:00

Source ID : 46770004

Item Group : Physical Exam

Repeat key: 3

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Physical Exam Body System	3		
Normal/Abnormal/Not Done	1		

Audit Record for this Item Group :

User : Jane Doe

Location : Fred Hutchinson

Date- and Timestamp : 2002-03-15T09:30:43-06:00

Source ID : 46770104

Item Group : Physical Exam

Repeat key: 4

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Physical Exam Body System	4		
Normal/Abnormal/Not Done	1		

Audit Record for this Item Group :

User : Jane Doe

Location : Fred Hutchinson

Date- and Timestamp : 2002-03-15T09:30:43-06:00

Source ID : 46770204

Item Group : Physical Exam

Repeat key: 5

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Physical Exam Body System	5		
Normal/Abnormal/Not Done	2		

Item	Value	is Null?	Trans.Type
Comment	TACHYCARDIA AND INCREASED.....		

Audit Record for this Item Group :

User : Jane Doe

Location : Fred Hutchinson

Date- and Timestamp : 2002-03-15T09:30:43-06:00

Source ID : 46770304

Item Group : Physical Exam

Repeat key: 6

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Physical Exam Body System	6		
Normal/Abnormal/Not Done	1		

Audit Record for this Item Group :

User : Jane Doe

Location : Fred Hutchinson

Date- and Timestamp : 2002-03-15T09:30:43-06:00

Source ID : 46770404

Item Group : Physical Exam

Repeat key: 7

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Physical Exam Body System	7		
Normal/Abnormal/Not Done	1		

Audit Record for this Item Group :

User : Jane Doe

Location : Fred Hutchinson

Date- and Timestamp : 2002-03-15T09:30:43-06:00

Source ID : 46770504

Item Group : Physical Exam

Repeat key: 8

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Physical Exam Body System	8		

Item	Value	is Null?	Trans.Type
Normal/Abnormal/Not Done	3		

Audit Record for this Item Group :

User : Jane Doe

Location : Fred Hutchinson

Date- and Timestamp : 2002-03-15T09:30:43-06:00

Source ID : 46770604

Item Group : Physical Exam

Repeat key: 9

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Physical Exam Body System	9		
Normal/Abnormal/Not Done	3		

Audit Record for this Item Group :

User : Jane Doe

Location : Fred Hutchinson

Date- and Timestamp : 2002-03-15T09:30:43-06:00

Source ID : 46770704

Item Group : Physical Exam

Repeat key: 10

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Physical Exam Body System	10		
Normal/Abnormal/Not Done	2		

Audit Record for this Item Group :

User : Jane Doe

Location : Fred Hutchinson

Date- and Timestamp : 2002-03-15T09:30:43-06:00

Source ID : 46770804

Item Group : Physical Exam

Repeat key: 11

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Physical Exam Body System	11		

Item	Value	is Null?	Trans.Type
Normal/Abnormal/Not Done	1		

Audit Record for this Item Group :

User : Jane Doe

Location : Fred Hutchinson

Date- and Timestamp : 2002-03-15T09:30:43-06:00

Source ID : 46770904

Item Group : Physical Exam

Repeat key: 12

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Physical Exam Body System	12		
Normal/Abnormal/Not Done	2		
Comment	MIGRAINE OCCASIONALLY		

Audit Record for this Item Group :

User : Jane Doe

Location : Fred Hutchinson

Date- and Timestamp : 2002-03-15T09:30:43-06:00

Source ID : 46771004

Item Group : Physical Exam

Repeat key: 13

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Physical Exam Body System	13		
Normal/Abnormal/Not Done	3		

Audit Record for this Item Group :

User : Jane Doe

Location : Fred Hutchinson

Date- and Timestamp : 2002-03-15T09:30:43-06:00

Source ID : 46771104

Study Event Data:

Study Event = Post-treatment

Form Data:

ID = Concom Meds

Item Group : Concom Meds

Repeat key: 1

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Line Number	1		
Medication For Conmed	TYLENOL		
Start Month - Enter Two Digits 01-12	07		
Start Day - Enter Two Digits 01-31	07		
Start Year - Enter Four Digit Year	1999		
Derived Start Date	19990707		
Stop Month - Enter Two Digits 01-12	07		
Stop Day - Enter Two Digits 01-31	08		
Stop Year - Enter Four Digit Year	1999		
Derived Stop Date	19990708		
Dose and Unit	325 MG		
Conmed Route	3		
Conmed Regimen	8		
Conmed Indication	INCREASED		
Check If Taken for AE	0		

Audit Record for this Item Group :

User : Jane Doe

Location : Fred Hutchinson

Date- and Timestamp : 2002-03-15T09:35:43-06:00

Source ID : 46772404

Subject Data:

Subject Key = 009

Investigator for this subject : Jane Doe, M.D.

Last Name : Doe

First Name : Jane

Location : Fred Hutchinson

Site for this subject: Fred Hutchinson

Study Event Data:

Study Event = Pre-treatment

Form Data:

ID = Demography

Item Group : Demography

Repeat key: 1

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Height	66		
Weight	171		
Gender	M		
Date of Birth	19541116		
Ethnic Group	Caucasian		
Height Units	in		
Weight Units	lb		

[Audit Record for this Item Group :](#)

[User :](#) Jane Doe

[Location :](#) Fred Hutchinson

[Date- and Timestamp :](#) 2002-03-15T09:40:43-06:00

[Source ID :](#) 46845704

Form Data:

ID = Treatment Assignment

[Item Group :](#) Treatment Assignment

[Repeat key:](#) 1

[Transaction type:](#) Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		

Item	Value	is Null?	Trans.Type
Record status, 5 levels, internal use	S		
Assigned Study Drug Treatment	2		

Audit Record for this Item Group :

User : Jane Doe

Location : Fred Hutchinson

Date- and Timestamp : 2002-03-15T09:45:43-06:00

Source ID : 46939304

Form Data:

ID = Pharmacokinetics

Item Group : Pharmacokinetics

Repeat key: 1

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	V		
Pretreatment yr	1999		
1-h year	1999		
2-h year	1999		
3-h year	1999		
4-h year	1999		
8-h year	1999		
16-h year	1999		

Item	Value	is Null?	Trans.Type
24-h year	1999		
Meal year	1999		
Pretreatment mon	06		
1-h mon	06		
2-h mon	06		
3-h mon	06		
4-h mon	06		
8-h mon	06		
16-h mon	06		
24-h mon	06		
Meal mon	06		
Pretreatment day	20		
1-h day	20		
2-h day	20		
3-h day	20		
4-h day	20		
8-h day	20		
16-h day	20		
24-h day	21		
Meal day	20		
Pretreatment date	19990620		
1-h date	19990620		
2-h date	19990620		
3-h date	19990620		
4-h date	19990620		
8-h date	19990620		
16-h date	19990620		
24-h date	19990621		
Date of last meal	19990620		
Pretreatment time	0600		
1-h time	0700		
2-h time	0800		
3-h time	0900		
4-h time	1000		
8-h time	1400		
16-h time	1800		
24-h time	0600		
Time of last meal	0500		

Audit Record for this Item Group :

User : Jane Doe

Location : Fred Hutchinson

Date- and Timestamp : 2002-03-15T09:50:43-06:00

Source ID : 46940004

Form Data:

ID = Physical Exam

Item Group : Physical Exam

Repeat key: 1

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Physical Exam Body System	1		
Normal/Abnormal/Not Done	1		

Audit Record for this Item Group :

User : Jane Doe

Location : Fred Hutchinson

Date- and Timestamp : 2002-03-15T09:55:43-06:00

Source ID : 46935704

Item Group : Physical Exam

Repeat key: 2

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Physical Exam Body System	2		
Normal/Abnormal/Not Done	1		

Audit Record for this Item Group :

User : Jane Doe

Location : Fred Hutchinson

Date- and Timestamp : 2002-03-15T09:55:43-06:00

Source ID : 46935804

Item Group : Physical Exam

Repeat key: 3

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Physical Exam Body System	3		

Item	Value	is Null?	Trans.Type
Normal/Abnormal/Not Done	1		

Audit Record for this Item Group :

User : Jane Doe

Location : Fred Hutchinson

Date- and Timestamp : 2002-03-15T09:55:43-06:00

Source ID : 46935904

Item Group : Physical Exam

Repeat key: 4

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Physical Exam Body System	4		
Normal/Abnormal/Not Done	2		
Comment	MILD WHEEZING		

Audit Record for this Item Group :

User : Jane Doe

Location : Fred Hutchinson

Date- and Timestamp : 2002-03-15T09:55:43-06:00

Source ID : 46936004

Item Group : Physical Exam

Repeat key: 5

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Physical Exam Body System	5		
Normal/Abnormal/Not Done	2		
Comment	TACHYCARDIA		

Audit Record for this Item Group :

User : Jane Doe

Location : Fred Hutchinson

Date- and Timestamp : 2002-03-15T09:55:43-06:00

Source ID : 46936304

Item Group : Physical Exam

Repeat key: 6

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels,	S		

Item	Value	is Null?	Trans.Type
internal use			
Physical Exam Body System	6		
Normal/Abnormal/Not Done	2		
Comment	SLIGHTLY ENLARGED HEART-NCS		

Audit Record for this Item Group :

User : Jane Doe

Location : Fred Hutchinson

Date- and Timestamp : 2002-03-15T09:55:43-06:00

Source ID : 46936404

Item Group : Physical Exam

Repeat key: 7

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Physical Exam Body System	7		
Normal/Abnormal/Not Done	1		

Audit Record for this Item Group :

User : Jane Doe

Location : Fred Hutchinson

Date- and Timestamp : 2002-03-15T09:55:43-06:00

Source ID : 46936504

Item Group : Physical Exam

Repeat key: 8

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Physical Exam Body System	8		
Normal/Abnormal/Not Done	3		

Audit Record for this Item Group :

User : Jane Doe

Location : Fred Hutchinson

Date- and Timestamp : 2002-03-15T09:55:43-06:00

Source ID : 46936604

Item Group : Physical Exam

Repeat key: 9

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		

Item	Value	is Null?	Trans.Type
Country	USA		
Record status, 5 levels, internal use	S		
Physical Exam Body System	9		
Normal/Abnormal/Not Done	1		

Audit Record for this Item Group :

User : Jane Doe

Location : Fred Hutchinson

Date- and Timestamp : 2002-03-15T09:55:43-06:00

Source ID : 46936704

Item Group : Physical Exam

Repeat key: 10

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Physical Exam Body System	10		
Normal/Abnormal/Not Done	2		
Comment	PETECHIA		

Audit Record for this Item Group :

User : Jane Doe

Location : Fred Hutchinson

Date- and Timestamp : 2002-03-15T09:55:43-06:00

Source ID : 46936904

Item Group : Physical Exam

Repeat key: 11

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Physical Exam Body System	11		
Normal/Abnormal/Not Done	1		

Audit Record for this Item Group :

User : Jane Doe

Location : Fred Hutchinson

Date- and Timestamp : 2002-03-15T09:55:43-06:00

Source ID : 46937004

Item Group : Physical Exam

Repeat key: 12

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		

Item	Value	is Null?	Trans.Type
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Physical Exam Body System	12		
Normal/Abnormal/Not Done	1		

[Audit Record for this Item Group :](#)

[User :](#) Jane Doe

[Location :](#) Fred Hutchinson

[Date- and Timestamp :](#) 2002-03-15T09:55:43-06:00

[Source ID :](#) 46937204

[Item Group :](#) Physical Exam

[Repeat key:](#) 13

[Transaction type:](#) Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Physical Exam Body System	13		
Normal/Abnormal/Not Done	1		

[Audit Record for this Item Group :](#)

[User :](#) Jane Doe

[Location :](#) Fred Hutchinson

Date- and Timestamp : 2002-03-15T09:55:43-06:00

Source ID : 46937704

Study Event Data:

Study Event = Post-treatment

Form Data:

ID = Concom Meds

Item Group : Concom Meds

Repeat key: 1

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Line Number	1		
Medication For Conmed	TYLENOL		
Start Month - Enter Two Digits 01-12	06		
Start Day - Enter Two Digits 01-31	10		
Start Year - Enter Four Digit Year	1999		
Derived Start Date	19990610		
Stop Month - Enter Two Digits 01-12	06		
Stop Day - Enter Two	14		

Item	Value	is Null?	Trans.Type
Digits 01-31			
Stop Year - Enter Four Digit Year	1999		
Derived Stop Date	19990614		
Dose and Unit	325MG		
Conmed Route	3		
Conmed Regimen	8		
Conmed Indication	HEADACHE		
Check If Taken for AE	0		

Audit Record for this Item Group :

User : Jane Doe

Location : Fred Hutchinson

Date- and Timestamp : 2002-03-15T10:00:43-06:00

Source ID : 46945104

Form Data:

ID = Physical Exam

Item Group : Physical Exam

Repeat key: 1

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Physical Exam Body System	1		

Item	Value	is Null?	Trans.Type
Normal/Abnormal/Not Done	1		

Audit Record for this Item Group :

User : Jane Doe

Location : Fred Hutchinson

Date- and Timestamp : 2002-03-15T10:05:43-06:00

Source ID : 46943804

Item Group : Physical Exam

Repeat key: 2

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Physical Exam Body System	2		
Normal/Abnormal/Not Done	1		

Audit Record for this Item Group :

User : Jane Doe

Location : Fred Hutchinson

Date- and Timestamp : 2002-03-15T10:05:43-06:00

Source ID : 46943904

Item Group : Physical Exam

Repeat key: 3

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Physical Exam Body System	3		
Normal/Abnormal/Not Done	1		

Audit Record for this Item Group :

User : Jane Doe

Location : Fred Hutchinson

Date- and Timestamp : 2002-03-15T10:05:43-06:00

Source ID : 46944004

Item Group : Physical Exam

Repeat key: 4

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Physical Exam Body System	4		

Item	Value	is Null?	Trans.Type
Normal/Abnormal/Not Done	1		

Audit Record for this Item Group :

User : Jane Doe

Location : Fred Hutchinson

Date- and Timestamp : 2002-03-15T10:05:43-06:00

Source ID : 46944104

Item Group : Physical Exam

Repeat key: 5

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Physical Exam Body System	5		
Normal/Abnormal/Not Done	1		

Audit Record for this Item Group :

User : Jane Doe

Location : Fred Hutchinson

Date- and Timestamp : 2002-03-15T10:05:43-06:00

Source ID : 46944204

Item Group : Physical Exam

Repeat key: 6

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Physical Exam Body System	6		
Normal/Abnormal/Not Done	1		

Audit Record for this Item Group :

User : Jane Doe

Location : Fred Hutchinson

Date- and Timestamp : 2002-03-15T10:05:43-06:00

Source ID : 46944304

Item Group : Physical Exam

Repeat key: 7

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Physical Exam Body System	7		

Item	Value	is Null?	Trans.Type
Normal/Abnormal/Not Done	1		

Audit Record for this Item Group :

User : Jane Doe

Location : Fred Hutchinson

Date- and Timestamp : 2002-03-15T10:05:43-06:00

Source ID : 46944404

Item Group : Physical Exam

Repeat key: 8

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Physical Exam Body System	8		
Normal/Abnormal/Not Done	3		

Audit Record for this Item Group :

User : Jane Doe

Location : Fred Hutchinson

Date- and Timestamp : 2002-03-15T10:05:43-06:00

Source ID : 46944504

Item Group : Physical Exam

Repeat key: 9

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Physical Exam Body System	9		
Normal/Abnormal/Not Done	1		

Audit Record for this Item Group :

User : Jane Doe

Location : Fred Hutchinson

Date- and Timestamp : 2002-03-15T10:05:43-06:00

Source ID : 46944604

Item Group : Physical Exam

Repeat key: 10

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Physical Exam Body System	10		

Item	Value	is Null?	Trans.Type
Normal/Abnormal/Not Done	1		

Audit Record for this Item Group :

User : Jane Doe

Location : Fred Hutchinson

Date- and Timestamp : 2002-03-15T10:05:43-06:00

Source ID : 46944704

Item Group : Physical Exam

Repeat key: 11

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Physical Exam Body System	11		
Normal/Abnormal/Not Done	1		

Audit Record for this Item Group :

User : Jane Doe

Location : Fred Hutchinson

Date- and Timestamp : 2002-03-15T10:05:43-06:00

Source ID : 46944804

Item Group : Physical Exam

Repeat key: 12

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Physical Exam Body System	12		
Normal/Abnormal/Not Done	1		

Audit Record for this Item Group :

User : Jane Doe

Location : Fred Hutchinson

Date- and Timestamp : 2002-03-15T10:05:43-06:00

Source ID : 46944904

Item Group : Physical Exam

Repeat key: 13

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Physical Exam Body System	13		

Item	Value	is Null?	Trans.Type
Normal/Abnormal/Not Done	1		

Audit Record for this Item Group :

User : Jane Doe

Location : Fred Hutchinson

Date- and Timestamp : 2002-03-15T10:05:43-06:00

Source ID : 46945004

Subject Data:

Subject Key = 010

Investigator for this subject : Jane Doe, M.D.

Last Name : Doe

First Name : Jane

Location : Fred Hutchinson

Site for this subject: Fred Hutchinson

Study Event Data:

Study Event = Pre-treatment

Form Data:

ID = Demography

Item Group : Demography

Repeat key: 1

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Height	69		
Weight	163		
Gender	M		
Date of Birth	19580917		
Ethnic Group	Caucasian		
Height Units	in		
Weight Units	lb		

[Audit Record for this Item Group :](#)

[User :](#) Jane Doe

[Location :](#) Fred Hutchinson

[Date- and Timestamp :](#) 2002-03-15T10:10:43-06:00

[Source ID :](#) 46846504

Form Data:

ID = Treatment Assignment

[Item Group :](#) Treatment Assignment

[Repeat key:](#) 1

[Transaction type:](#) Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		

Item	Value	is Null?	Trans.Type
Record status, 5 levels, internal use	S		
Assigned Study Drug Treatment	2		

Audit Record for this Item Group :

User : Jane Doe

Location : Fred Hutchinson

Date- and Timestamp : 2002-03-15T10:15:43-06:00

Source ID : 46918004

Form Data:

ID = Pharmacokinetics

Item Group : Pharmacokinetics

Repeat key: 1

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	V		
Pretreatment yr	1999		
1-h year	1999		
2-h year	1999		
3-h year	1999		
4-h year	1999		
8-h year	1999		
16-h year	1999		

Item	Value	is Null?	Trans.Type
24-h year	1999		
Meal year	1999		
Pretreatment mon	06		
1-h mon	06		
2-h mon	06		
3-h mon	06		
4-h mon	06		
8-h mon	06		
16-h mon	06		
24-h mon	06		
Meal mon	06		
Pretreatment day	20		
1-h day	20		
2-h day	20		
3-h day	20		
4-h day	20		
8-h day	20		
16-h day	20		
24-h day	21		
Meal day	20		
Pretreatment date	19990620		
1-h date	19990620		
2-h date	19990620		
3-h date	19990620		
4-h date	19990620		
8-h date	19990620		
16-h date	19990620		
24-h date	19990621		
Date of last meal	19990620		
Pretreatment time	0600		
1-h time	0700		
2-h time	0800		
3-h time	0900		
4-h time	1000		
8-h time	1400		
16-h time	1800		
24-h time	0600		
Time of last meal	0500		

Audit Record for this Item Group :

User : Jane Doe

Location : Fred Hutchinson

Date- and Timestamp : 2002-03-15T10:20:43-06:00

Source ID : 46918804

Form Data:

ID = Physical Exam

Item Group : Physical Exam

Repeat key: 1

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Physical Exam Body System	1		
Normal/Abnormal/Not Done	1		

Audit Record for this Item Group :

User : Jane Doe

Location : Fred Hutchinson

Date- and Timestamp : 2002-03-15T10:25:43-06:00

Source ID : 46909904

Item Group : Physical Exam

Repeat key: 2

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Physical Exam Body System	2		
Normal/Abnormal/Not Done	1		

Audit Record for this Item Group :

User : Jane Doe

Location : Fred Hutchinson

Date- and Timestamp : 2002-03-15T10:25:43-06:00

Source ID : 46910004

Item Group : Physical Exam

Repeat key: 3

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Physical Exam Body System	3		

Item	Value	is Null?	Trans.Type
Normal/Abnormal/Not Done	1		

Audit Record for this Item Group :

User : Jane Doe

Location : Fred Hutchinson

Date- and Timestamp : 2002-03-15T10:25:43-06:00

Source ID : 46910204

Item Group : Physical Exam

Repeat key: 4

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Physical Exam Body System	4		
Normal/Abnormal/Not Done	2		
Comment	MILD WHEEZING		

Audit Record for this Item Group :

User : Jane Doe

Location : Fred Hutchinson

Date- and Timestamp : 2002-03-15T10:25:43-06:00

Source ID : 46910304

Item Group : Physical Exam

Repeat key: 5

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Physical Exam Body System	5		
Normal/Abnormal/Not Done	2		
Comment	TACHYCARDIA		

Audit Record for this Item Group :

User : Jane Doe

Location : Fred Hutchinson

Date- and Timestamp : 2002-03-15T10:25:43-06:00

Source ID : 46910504

Item Group : Physical Exam

Repeat key: 6

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels,	S		

Item	Value	is Null?	Trans.Type
internal use			
Physical Exam Body System	6		
Normal/Abnormal/Not Done	2		
Comment	SLIGHTLY ENLARGED-N S		

Audit Record for this Item Group :

User : Jane Doe

Location : Fred Hutchinson

Date- and Timestamp : 2002-03-15T10:25:43-06:00

Source ID : 46910604

Item Group : Physical Exam

Repeat key: 7

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Physical Exam Body System	7		
Normal/Abnormal/Not Done	1		

Audit Record for this Item Group :

User : Jane Doe

Location : Fred Hutchinson

Date- and Timestamp : 2002-03-15T10:25:43-06:00

Source ID : 46910704

Item Group : Physical Exam

Repeat key: 8

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Physical Exam Body System	8		
Normal/Abnormal/Not Done	3		

Audit Record for this Item Group :

User : Jane Doe

Location : Fred Hutchinson

Date- and Timestamp : 2002-03-15T10:25:43-06:00

Source ID : 46910804

Item Group : Physical Exam

Repeat key: 9

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		

Item	Value	is Null?	Trans.Type
Country	USA		
Record status, 5 levels, internal use	S		
Physical Exam Body System	9		
Normal/Abnormal/Not Done	1		

Audit Record for this Item Group :

User : Jane Doe

Location : Fred Hutchinson

Date- and Timestamp : 2002-03-15T10:25:43-06:00

Source ID : 46910904

Item Group : Physical Exam

Repeat key: 10

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Physical Exam Body System	10		
Normal/Abnormal/Not Done	2		
Comment	PETECHIA		

Audit Record for this Item Group :

User : Jane Doe

Location : Fred Hutchinson

Date- and Timestamp : 2002-03-15T10:25:43-06:00

Source ID : 46911004

Item Group : Physical Exam

Repeat key: 11

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Physical Exam Body System	11		
Normal/Abnormal/Not Done	1		

Audit Record for this Item Group :

User : Jane Doe

Location : Fred Hutchinson

Date- and Timestamp : 2002-03-15T10:25:43-06:00

Source ID : 46911104

Item Group : Physical Exam

Repeat key: 12

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		

Item	Value	is Null?	Trans.Type
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Physical Exam Body System	12		
Normal/Abnormal/Not Done	1		

[Audit Record for this Item Group :](#)

[User :](#) Jane Doe

[Location :](#) Fred Hutchinson

[Date- and Timestamp :](#) 2002-03-15T10:25:43-06:00

[Source ID :](#) 46911704

[Item Group :](#) Physical Exam

[Repeat key:](#) 13

[Transaction type:](#) Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Physical Exam Body System	13		
Normal/Abnormal/Not Done	1		

[Audit Record for this Item Group :](#)

[User :](#) Jane Doe

[Location :](#) Fred Hutchinson

Date- and Timestamp : 2002-03-15T10:25:43-06:00

Source ID : 46913504

Study Event Data:

Study Event = Post-treatment

Form Data:

ID = Concom Meds

Item Group : Concom Meds

Repeat key: 1

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Line Number	1		
Medication For Conmed	TYLENOL		
Start Month - Enter Two Digits 01-12	06		
Start Day - Enter Two Digits 01-31	10		
Start Year - Enter Four Digit Year	1999		
Derived Start Date	19990610		
Stop Month - Enter Two Digits 01-12	06		
Stop Day - Enter Two	14		

Item	Value	is Null?	Trans.Type
Digits 01-31			
Stop Year - Enter Four Digit Year	1999		
Derived Stop Date	19990614		
Dose and Unit	325MG		
Conmed Route	3		
Conmed Regimen	8		
Conmed Indication	HEADACHE		
Check If Taken for AE	0		

Audit Record for this Item Group :

User : Jane Doe

Location : Fred Hutchinson

Date- and Timestamp : 2002-03-15T10:30:43-06:00

Source ID : 46934204

Form Data:

ID = Physical Exam

Item Group : Physical Exam

Repeat key: 1

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Physical Exam Body System	1		

Item	Value	is Null?	Trans.Type
Normal/Abnormal/Not Done	1		

Audit Record for this Item Group :

User : Jane Doe

Location : Fred Hutchinson

Date- and Timestamp : 2002-03-15T10:35:43-06:00

Source ID : 46930904

Item Group : Physical Exam

Repeat key: 2

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Physical Exam Body System	2		
Normal/Abnormal/Not Done	1		

Audit Record for this Item Group :

User : Jane Doe

Location : Fred Hutchinson

Date- and Timestamp : 2002-03-15T10:35:43-06:00

Source ID : 46931004

Item Group : Physical Exam

Repeat key: 3

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Physical Exam Body System	3		
Normal/Abnormal/Not Done	1		

Audit Record for this Item Group :

User : Jane Doe

Location : Fred Hutchinson

Date- and Timestamp : 2002-03-15T10:35:43-06:00

Source ID : 46931104

Item Group : Physical Exam

Repeat key: 4

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Physical Exam Body System	4		

Item	Value	is Null?	Trans.Type
Normal/Abnormal/Not Done	1		

Audit Record for this Item Group :

User : Jane Doe

Location : Fred Hutchinson

Date- and Timestamp : 2002-03-15T10:35:43-06:00

Source ID : 46931204

Item Group : Physical Exam

Repeat key: 5

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Physical Exam Body System	5		
Normal/Abnormal/Not Done	1		

Audit Record for this Item Group :

User : Jane Doe

Location : Fred Hutchinson

Date- and Timestamp : 2002-03-15T10:35:43-06:00

Source ID : 46931304

Item Group : Physical Exam

Repeat key: 6

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Physical Exam Body System	6		
Normal/Abnormal/Not Done	1		

Audit Record for this Item Group :

User : Jane Doe

Location : Fred Hutchinson

Date- and Timestamp : 2002-03-15T10:35:43-06:00

Source ID : 46931404

Item Group : Physical Exam

Repeat key: 7

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Physical Exam Body System	7		

Item	Value	is Null?	Trans.Type
Normal/Abnormal/Not Done	1		

Audit Record for this Item Group :

User : Jane Doe

Location : Fred Hutchinson

Date- and Timestamp : 2002-03-15T10:35:43-06:00

Source ID : 46931504

Item Group : Physical Exam

Repeat key: 8

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Physical Exam Body System	8		
Normal/Abnormal/Not Done	3		

Audit Record for this Item Group :

User : Jane Doe

Location : Fred Hutchinson

Date- and Timestamp : 2002-03-15T10:35:43-06:00

Source ID : 46932004

Item Group : Physical Exam

Repeat key: 9

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Physical Exam Body System	9		
Normal/Abnormal/Not Done	1		

Audit Record for this Item Group :

User : Jane Doe

Location : Fred Hutchinson

Date- and Timestamp : 2002-03-15T10:35:43-06:00

Source ID : 46932104

Item Group : Physical Exam

Repeat key: 10

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Physical Exam Body System	10		

Item	Value	is Null?	Trans.Type
Normal/Abnormal/Not Done	1		

Audit Record for this Item Group :

User : Jane Doe

Location : Fred Hutchinson

Date- and Timestamp : 2002-03-15T10:35:43-06:00

Source ID : 46932204

Item Group : Physical Exam

Repeat key: 11

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Physical Exam Body System	11		
Normal/Abnormal/Not Done	1		

Audit Record for this Item Group :

User : Jane Doe

Location : Fred Hutchinson

Date- and Timestamp : 2002-03-15T10:35:43-06:00

Source ID : 46932304

Item Group : Physical Exam

Repeat key: 12

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Physical Exam Body System	12		
Normal/Abnormal/Not Done	1		

Audit Record for this Item Group :

User : Jane Doe

Location : Fred Hutchinson

Date- and Timestamp : 2002-03-15T10:35:43-06:00

Source ID : 46932504

Item Group : Physical Exam

Repeat key: 13

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Physical Exam Body System	13		

Item	Value	is Null?	Trans.Type
Normal/Abnormal/Not Done	1		

Audit Record for this Item Group :

User : Jane Doe

Location : Fred Hutchinson

Date- and Timestamp : 2002-03-15T10:35:43-06:00

Source ID : 46932604

Subject Data:

Subject Key = 011

Investigator for this subject : Jane Doe, M.D.

Last Name : Doe

First Name : Jane

Location : Fred Hutchinson

Site for this subject: Fred Hutchinson

Study Event Data:

Study Event = Pre-treatment

Form Data:

ID = Demography

Item Group : Demography

Repeat key: 1

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	V		
Height	61		
Weight	114		
Gender	F		
Date of Birth	19661111		
Ethnic Group	Latino		
Height Units	in		
Weight Units	lb		

[Audit Record for this Item Group :](#)

[User :](#) Jane Doe

[Location :](#) Fred Hutchinson

[Date- and Timestamp :](#) 2002-03-15T10:40:43-06:00

[Source ID :](#) 46841404

Form Data:

ID = Treatment Assignment

[Item Group :](#) Treatment Assignment

[Repeat key:](#) 1

[Transaction type:](#) Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		

Item	Value	is Null?	Trans.Type
Record status, 5 levels, internal use	V		
Assigned Study Drug Treatment	2		

Audit Record for this Item Group :

User : Jane Doe

Location : Fred Hutchinson

Date- and Timestamp : 2002-03-15T10:45:43-06:00

Source ID : 46881704

Form Data:

ID = Pharmacokinetics

Item Group : Pharmacokinetics

Repeat key: 1

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	V		
Pretreatment yr	1999		
1-h year	1999		
2-h year	1999		
3-h year	1999		
4-h year	1999		
8-h year	1999		
16-h year	1999		

Item	Value	is Null?	Trans.Type
24-h year	1999		
Meal year	1999		
Pretreatment mon	06		
1-h mon	06		
2-h mon	06		
3-h mon	06		
4-h mon	06		
8-h mon	06		
16-h mon	06		
24-h mon	06		
Meal mon	06		
Pretreatment day	20		
1-h day	20		
2-h day	20		
3-h day	20		
4-h day	20		
8-h day	20		
16-h day	20		
24-h day	21		
Meal day	20		
Pretreatment date	19990620		
1-h date	19990620		
2-h date	19990620		
3-h date	19990620		
4-h date	19990620		
8-h date	19990620		
16-h date	19990620		
24-h date	19990621		
Date of last meal	19990620		
Pretreatment time	0600		
1-h time	0700		
2-h time	0800		
3-h time	0900		
4-h time	1000		
8-h time	1400		
16-h time	1800		
24-h time	0600		
Time of last meal	0500		

Audit Record for this Item Group :

User : Jane Doe

Location : Fred Hutchinson

Date- and Timestamp : 2002-03-15T10:50:43-06:00

Source ID : 46887604

Form Data:

ID = Physical Exam

Item Group : Physical Exam

Repeat key: 1

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	V		
Physical Exam Body System	1		
Normal/Abnormal/Not Done	1		

Audit Record for this Item Group :

User : Jane Doe

Location : Fred Hutchinson

Date- and Timestamp : 2002-03-15T10:55:43-06:00

Source ID : 46857804

Item Group : Physical Exam

Repeat key: 2

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	V		
Physical Exam Body System	2		
Normal/Abnormal/Not Done	1		

Audit Record for this Item Group :

User : Jane Doe

Location : Fred Hutchinson

Date- and Timestamp : 2002-03-15T10:55:43-06:00

Source ID : 46857904

Item Group : Physical Exam

Repeat key: 3

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	V		
Physical Exam Body System	3		

Item	Value	is Null?	Trans.Type
Normal/Abnormal/Not Done	1		

Audit Record for this Item Group :

User : Jane Doe

Location : Fred Hutchinson

Date- and Timestamp : 2002-03-15T10:55:43-06:00

Source ID : 46858104

Item Group : Physical Exam

Repeat key: 4

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	V		
Physical Exam Body System	4		
Normal/Abnormal/Not Done	2		
Comment	MILD WHEEZING		

Audit Record for this Item Group :

User : Jane Doe

Location : Fred Hutchinson

Date- and Timestamp : 2002-03-15T10:55:43-06:00

Source ID : 46859004

Item Group : Physical Exam

Repeat key: 5

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	V		
Physical Exam Body System	5		
Normal/Abnormal/Not Done	2		
Comment	TACHCARDIA		

Audit Record for this Item Group :

User : Jane Doe

Location : Fred Hutchinson

Date- and Timestamp : 2002-03-15T10:55:43-06:00

Source ID : 46859404

Item Group : Physical Exam

Repeat key: 6

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels,	V		

Item	Value	is Null?	Trans.Type
internal use			
Physical Exam Body System	6		
Normal/Abnormal/Not Done	2		
Comment	SLIGHTLY ENLARGED-NCS		

Audit Record for this Item Group :

User : Jane Doe

Location : Fred Hutchinson

Date- and Timestamp : 2002-03-15T10:55:43-06:00

Source ID : 46860804

Item Group : Physical Exam

Repeat key: 7

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	V		
Physical Exam Body System	7		
Normal/Abnormal/Not Done	1		

Audit Record for this Item Group :

User : Jane Doe

Location : Fred Hutchinson

Date- and Timestamp : 2002-03-15T10:55:43-06:00

Source ID : 46860904

Item Group : Physical Exam

Repeat key: 8

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	V		
Physical Exam Body System	8		
Normal/Abnormal/Not Done	3		

Audit Record for this Item Group :

User : Jane Doe

Location : Fred Hutchinson

Date- and Timestamp : 2002-03-15T10:55:43-06:00

Source ID : 46861404

Item Group : Physical Exam

Repeat key: 9

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		

Item	Value	is Null?	Trans.Type
Country	USA		
Record status, 5 levels, internal use	V		
Physical Exam Body System	9		
Normal/Abnormal/Not Done	1		

Audit Record for this Item Group :

User : Jane Doe

Location : Fred Hutchinson

Date- and Timestamp : 2002-03-15T10:55:43-06:00

Source ID : 46861704

Item Group : Physical Exam

Repeat key: 10

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	V		
Physical Exam Body System	10		
Normal/Abnormal/Not Done	2		
Comment	PETECHIA		

Audit Record for this Item Group :

User : Jane Doe

Location : Fred Hutchinson

Date- and Timestamp : 2002-03-15T10:55:43-06:00

Source ID : 46863704

Item Group : Physical Exam

Repeat key: 11

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	V		
Physical Exam Body System	11		
Normal/Abnormal/Not Done	1		

Audit Record for this Item Group :

User : Jane Doe

Location : Fred Hutchinson

Date- and Timestamp : 2002-03-15T10:55:43-06:00

Source ID : 46864004

Item Group : Physical Exam

Repeat key: 12

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		

Item	Value	is Null?	Trans.Type
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	V		
Physical Exam Body System	12		
Normal/Abnormal/Not Done	1		

[Audit Record for this Item Group :](#)

[User :](#) Jane Doe

[Location :](#) Fred Hutchinson

[Date- and Timestamp :](#) 2002-03-15T10:55:43-06:00

[Source ID :](#) 46867804

[Item Group :](#) Physical Exam

[Repeat key:](#) 13

[Transaction type:](#) Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	V		
Physical Exam Body System	13		
Normal/Abnormal/Not Done	1		

[Audit Record for this Item Group :](#)

[User :](#) Jane Doe

[Location :](#) Fred Hutchinson

Date- and Timestamp : 2002-03-15T10:55:43-06:00

Source ID : 46867904

Study Event Data:

Study Event = Post-treatment

Form Data:

ID = Concom Meds

Item Group : Concom Meds

Repeat key: 1

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	V		
Line Number	1		
Medication For Conmed	TYLENOL		
Start Month - Enter Two Digits 01-12	06		
Start Day - Enter Two Digits 01-31	10		
Start Year - Enter Four Digit Year	1999		
Derived Start Date	19990610		
Stop Month - Enter Two Digits 01-12	06		
Stop Day - Enter Two	14		

Item	Value	is Null?	Trans.Type
Digits 01-31			
Stop Year - Enter Four Digit Year	1999		
Derived Stop Date	19990614		
Dose and Unit	325MG		
Conmed Route	3		
Conmed Regimen	8		
Conmed Indication	HEADACHE		
Check If Taken for AE	0		

Audit Record for this Item Group :

User : Jane Doe

Location : Fred Hutchinson

Date- and Timestamp : 2002-03-15T11:00:43-06:00

Source ID : 46903504

Subject Data:

Subject Key = 012

Investigator for this subject : Jane Doe, M.D.

Last Name : Doe

First Name : Jane

Location : Fred Hutchinson

Site for this subject: Fred Hutchinson

Study Event Data:

Study Event = Pre-treatment

Form Data:

ID = Demography

Item Group : Demography

Repeat key: 1

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Height	66		
Weight	193		
Gender	F		
Date of Birth	19490324		
Ethnic Group	Caucasian		
Height Units	in		
Weight Units	lb		

[Audit Record for this Item Group :](#)

[User :](#) Jane Doe

[Location :](#) Fred Hutchinson

[Date- and Timestamp :](#) 2002-03-15T11:05:43-06:00

[Source ID :](#) 46842404

Form Data:

ID = Treatment Assignment

[Item Group :](#) Treatment Assignment

[Repeat key:](#) 1

[Transaction type:](#) Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		

Item	Value	is Null?	Trans.Type
Record status, 5 levels, internal use	S		
Assigned Study Drug Treatment	2		

Audit Record for this Item Group :

User : Jane Doe

Location : Fred Hutchinson

Date- and Timestamp : 2002-03-15T11:10:43-06:00

Source ID : 46911804

Form Data:

ID = Pharmacokinetics

Item Group : Pharmacokinetics

Repeat key: 1

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	V		
Pretreatment yr	1999		
1-h year	1999		
2-h year	1999		
3-h year	1999		
4-h year	1999		
8-h year	1999		
16-h year	1999		

Item	Value	is Null?	Trans.Type
24-h year	1999		
Meal year	1999		
Pretreatment mon	06		
1-h mon	06		
2-h mon	06		
3-h mon	06		
4-h mon	06		
8-h mon	06		
16-h mon	06		
24-h mon	06		
Meal mon	06		
Pretreatment day	20		
1-h day	20		
2-h day	20		
3-h day	20		
4-h day	20		
8-h day	20		
16-h day	20		
24-h day	21		
Meal day	20		
Pretreatment date	19990620		
1-h date	19990620		
2-h date	19990620		
3-h date	19990620		
4-h date	19990620		
8-h date	19990620		
16-h date	19990620		
24-h date	19990621		
Date of last meal	19990620		
Pretreatment time	0600		
1-h time	0700		
2-h time	0800		
3-h time	0900		
4-h time	1000		
8-h time	1400		
16-h time	1800		
24-h time	0600		
Time of last meal	0500		

Audit Record for this Item Group :

User : Jane Doe

Location : Fred Hutchinson

Date- and Timestamp : 2002-03-15T11:15:43-06:00

Source ID : 46913004

Form Data:

ID = Physical Exam

Item Group : Physical Exam

Repeat key: 1

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Physical Exam Body System	1		
Normal/Abnormal/Not Done	1		

Audit Record for this Item Group :

User : Jane Doe

Location : Fred Hutchinson

Date- and Timestamp : 2002-03-15T11:20:43-06:00

Source ID : 46904904

Item Group : Physical Exam

Repeat key: 2

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Physical Exam Body System	2		
Normal/Abnormal/Not Done	1		

Audit Record for this Item Group :

User : Jane Doe

Location : Fred Hutchinson

Date- and Timestamp : 2002-03-15T11:20:43-06:00

Source ID : 46905304

Item Group : Physical Exam

Repeat key: 3

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Physical Exam Body System	3		

Item	Value	is Null?	Trans.Type
Normal/Abnormal/Not Done	1		

Audit Record for this Item Group :

User : Jane Doe

Location : Fred Hutchinson

Date- and Timestamp : 2002-03-15T11:20:43-06:00

Source ID : 46905404

Item Group : Physical Exam

Repeat key: 4

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Physical Exam Body System	4		
Normal/Abnormal/Not Done	2		
Comment	MILD WHEEZING		

Audit Record for this Item Group :

User : Jane Doe

Location : Fred Hutchinson

Date- and Timestamp : 2002-03-15T11:20:43-06:00

Source ID : 46905804

Item Group : Physical Exam

Repeat key: 5

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Physical Exam Body System	5		
Normal/Abnormal/Not Done	2		
Comment	TACHYCARDIA		

Audit Record for this Item Group :

User : Jane Doe

Location : Fred Hutchinson

Date- and Timestamp : 2002-03-15T11:20:43-06:00

Source ID : 46906004

Item Group : Physical Exam

Repeat key: 6

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels,	S		

Item	Value	is Null?	Trans.Type
internal use			
Physical Exam Body System	6		
Normal/Abnormal/Not Done	2		
Comment	SLIGHTLY ENLARGED HEART-NCS		

Audit Record for this Item Group :

User : Jane Doe

Location : Fred Hutchinson

Date- and Timestamp : 2002-03-15T11:20:43-06:00

Source ID : 46906704

Item Group : Physical Exam

Repeat key: 7

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Physical Exam Body System	7		
Normal/Abnormal/Not Done	1		

Audit Record for this Item Group :

User : Jane Doe

Location : Fred Hutchinson

Date- and Timestamp : 2002-03-15T11:20:43-06:00

Source ID : 46906904

Item Group : Physical Exam

Repeat key: 8

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Physical Exam Body System	8		
Normal/Abnormal/Not Done	3		

Audit Record for this Item Group :

User : Jane Doe

Location : Fred Hutchinson

Date- and Timestamp : 2002-03-15T11:20:43-06:00

Source ID : 46907104

Item Group : Physical Exam

Repeat key: 9

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		

Item	Value	is Null?	Trans.Type
Country	USA		
Record status, 5 levels, internal use	S		
Physical Exam Body System	9		
Normal/Abnormal/Not Done	1		

Audit Record for this Item Group :

User : Jane Doe

Location : Fred Hutchinson

Date- and Timestamp : 2002-03-15T11:20:43-06:00

Source ID : 46907504

Item Group : Physical Exam

Repeat key: 10

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Physical Exam Body System	10		
Normal/Abnormal/Not Done	2		
Comment	PETECHIA		

Audit Record for this Item Group :

User : Jane Doe

Location : Fred Hutchinson

Date- and Timestamp : 2002-03-15T11:20:43-06:00

Source ID : 46908004

Item Group : Physical Exam

Repeat key: 11

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Physical Exam Body System	11		
Normal/Abnormal/Not Done	1		

Audit Record for this Item Group :

User : Jane Doe

Location : Fred Hutchinson

Date- and Timestamp : 2002-03-15T11:20:43-06:00

Source ID : 46908104

Item Group : Physical Exam

Repeat key: 12

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		

Item	Value	is Null?	Trans.Type
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Physical Exam Body System	12		
Normal/Abnormal/Not Done	1		

[Audit Record for this Item Group :](#)

[User :](#) Jane Doe

[Location :](#) Fred Hutchinson

[Date- and Timestamp :](#) 2002-03-15T11:20:43-06:00

[Source ID :](#) 46908504

[Item Group :](#) Physical Exam

[Repeat key:](#) 13

[Transaction type:](#) Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Physical Exam Body System	13		
Normal/Abnormal/Not Done	1		

[Audit Record for this Item Group :](#)

[User :](#) Jane Doe

[Location :](#) Fred Hutchinson

Date- and Timestamp : 2002-03-15T11:20:43-06:00

Source ID : 46908704

Study Event Data:

Study Event = Post-treatment

Form Data:

ID = Concom Meds

Item Group : Concom Meds

Repeat key: 1

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Line Number	1		
Medication For Conmed	TYLENOL		
Start Month - Enter Two Digits 01-12	06		
Start Day - Enter Two Digits 01-31	10		
Start Year - Enter Four Digit Year	1999		
Derived Start Date	19990610		
Stop Month - Enter Two Digits 01-12	06		
Stop Day - Enter Two	14		

Item	Value	is Null?	Trans.Type
Digits 01-31			
Stop Year - Enter Four Digit Year	1999		
Derived Stop Date	19990614		
Dose and Unit	325MG		
Conmed Route	3		
Conmed Regimen	8		
Conmed Indication	HEADACHE		
Check If Taken for AE	0		

Audit Record for this Item Group :

User : Jane Doe

Location : Fred Hutchinson

Date- and Timestamp : 2002-03-15T11:25:43-06:00

Source ID : 46929004

Form Data:

ID = Physical Exam

Item Group : Physical Exam

Repeat key: 1

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Physical Exam Body System	1		

Item	Value	is Null?	Trans.Type
Normal/Abnormal/Not Done	1		

Audit Record for this Item Group :

User : Jane Doe

Location : Fred Hutchinson

Date- and Timestamp : 2002-03-15T11:30:43-06:00

Source ID : 46924204

Item Group : Physical Exam

Repeat key: 2

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Physical Exam Body System	2		
Normal/Abnormal/Not Done	1		

Audit Record for this Item Group :

User : Jane Doe

Location : Fred Hutchinson

Date- and Timestamp : 2002-03-15T11:30:43-06:00

Source ID : 46924304

Item Group : Physical Exam

Repeat key: 3

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Physical Exam Body System	3		
Normal/Abnormal/Not Done	1		

Audit Record for this Item Group :

User : Jane Doe

Location : Fred Hutchinson

Date- and Timestamp : 2002-03-15T11:30:43-06:00

Source ID : 46924404

Item Group : Physical Exam

Repeat key: 4

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Physical Exam Body System	4		

Item	Value	is Null?	Trans.Type
Normal/Abnormal/Not Done	1		

Audit Record for this Item Group :

User : Jane Doe

Location : Fred Hutchinson

Date- and Timestamp : 2002-03-15T11:30:43-06:00

Source ID : 46924504

Item Group : Physical Exam

Repeat key: 5

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Physical Exam Body System	5		
Normal/Abnormal/Not Done	1		

Audit Record for this Item Group :

User : Jane Doe

Location : Fred Hutchinson

Date- and Timestamp : 2002-03-15T11:30:43-06:00

Source ID : 46924604

Item Group : Physical Exam

Repeat key: 6

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Physical Exam Body System	6		
Normal/Abnormal/Not Done	1		

Audit Record for this Item Group :

User : Jane Doe

Location : Fred Hutchinson

Date- and Timestamp : 2002-03-15T11:30:43-06:00

Source ID : 46924704

Item Group : Physical Exam

Repeat key: 7

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Physical Exam Body System	7		

Item	Value	is Null?	Trans.Type
Normal/Abnormal/Not Done	1		

Audit Record for this Item Group :

User : Jane Doe

Location : Fred Hutchinson

Date- and Timestamp : 2002-03-15T11:30:43-06:00

Source ID : 46924804

Item Group : Physical Exam

Repeat key: 8

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Physical Exam Body System	8		
Normal/Abnormal/Not Done	1		

Audit Record for this Item Group :

User : Jane Doe

Location : Fred Hutchinson

Date- and Timestamp : 2002-03-15T11:30:43-06:00

Source ID : 46924904

Item Group : Physical Exam

Repeat key: 9

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Physical Exam Body System	9		
Normal/Abnormal/Not Done	1		

Audit Record for this Item Group :

User : Jane Doe

Location : Fred Hutchinson

Date- and Timestamp : 2002-03-15T11:30:43-06:00

Source ID : 46925004

Item Group : Physical Exam

Repeat key: 10

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Physical Exam Body System	10		

Item	Value	is Null?	Trans.Type
Normal/Abnormal/Not Done	1		

Audit Record for this Item Group :

User : Jane Doe

Location : Fred Hutchinson

Date- and Timestamp : 2002-03-15T11:30:43-06:00

Source ID : 46925204

Item Group : Physical Exam

Repeat key: 11

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Physical Exam Body System	11		
Normal/Abnormal/Not Done	1		

Audit Record for this Item Group :

User : Jane Doe

Location : Fred Hutchinson

Date- and Timestamp : 2002-03-15T11:30:43-06:00

Source ID : 46925304

Item Group : Physical Exam

Repeat key: 12

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Physical Exam Body System	12		
Normal/Abnormal/Not Done	1		

Audit Record for this Item Group :

User : Jane Doe

Location : Fred Hutchinson

Date- and Timestamp : 2002-03-15T11:30:43-06:00

Source ID : 46925404

Item Group : Physical Exam

Repeat key: 13

Transaction type: Insert

Item	Value	is Null?	Trans.Type
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Physical Exam Body System	13		

Item	Value	is Null?	Trans.Type
Normal/Abnormal/Not Done	1		

Audit Record for this Item Group :

User : Jane Doe

Location : Fred Hutchinson

Date- and Timestamp : 2002-03-15T11:30:43-06:00

Source ID : 46925504

Clinical Data: Study = 123-456-789

MetaDataVersion ID = v1.1.0

Subject Data:

Subject Key = 001

Investigator for this subject : John Smith, M.D.

Last Name : Smith

First Name : John

Location : Roswell Park

Site for this subject: Roswell Park

Study Event Data:

Study Event = Pre-treatment

Form Data:

ID = Demography

Item Group : Demography

Repeat key: 1

Transaction type: Update

Item	Value	is Null?	Trans.Type
Height	75		

Audit Record for this Item Group :

User : John Smith

Location : Roswell Park

Date- and Timestamp : 2002-02-12T10:17:01-05:00

Reason for Change : Data correction based on patient chart

Source ID : 46902604

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