

# Clinical Study Data Report

Study Attributes :

Description :

File Type : Snapshot

Granularity : All

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## Study : 123-456-789

**Study Name** : CDISC Test Study II

**Study Description** : This file contains test data for the CDISC Connect-A-Thon event scheduled for the DIA 11th Annual European Workshop on Clinical Data Management.

**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 1.01**

**Include Prior MetaData Version**

Study ID : 123-456-789

Study Name : CDISC Test Study II

Prior MetaData Version ID : v1.00

Prior MetaData Version Name : Version 1.01

**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

Name	ID	Rep.?	Is Ref. Data ?
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 ?
Internal unique identifier for record	IT.REC_ID	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
Conmed Indication	IT.AETERM	7	No
Start Month - Enter Two Digits 01-12	IT.AESTMON	8	No
Start Day - Enter Two Digits 01-31	IT.AESTDAY	9	No
Start Year - Enter Four Digit Year	IT.AESTYR	10	No
Derived Start Date	IT.AESTDT	11	No
Stop Month - Enter Two Digits 01-12	IT.AEENMON	12	No

Item Name	Item ID	Order Number	Mandatory ?
Stop Day - Enter Two Digits 01-31	IT.AEENDAY	13	No
Stop Year - Enter Four Digit Year	IT.AEENYR	14	No
Derived Stop Date	IT.AEENDT	15	No
Severity	IT.AESEV	16	No
Relationship to study drug	IT.AEREL	17	No
Outcome	IT.AEOUT	18	No
Actions taken re study drug	IT.AEACTTRT	19	No
Actions taken, other	IT.AECONTRT	20	No

#### Items for Item Group : Concom Meds

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

Item Name	Item ID	Order Number	Mandatory ?
Conmed Indication	IT.INDIC	21	No
Check If Taken for AE	IT.AE_RELAT	22	No

#### Items for Item Group : Demography

Item Name	Item ID	Order Number	Mandatory ?
Internal unique identifier for record	IT.REC_ID	1	No
Compound	IT.R_DRUG	2	No
Therapeutic Area	IT.TAREA	3	No
Protocol Number	IT.PNO	4	No
Country	IT.SCTRY	5	No
Record status, 5 levels, internal use	IT.F_STATUS	6	No
Height	IT.HT	7	No
Weight	IT.WT	8	No
Gender	IT.SEX	9	No
Date of Birth	IT.DOB	10	No
Ethnic Group	IT.RACE	11	No
Height Units	IT.HTUNITS	12	No
Weight Units	IT.WTUNITS	13	No

#### Items for Item Group : Treatment Assignment

Item Name	Item ID	Order Number	Mandatory ?
Internal unique identifier for record	IT.REC_ID	1	No
Compound	IT.R_DRUG	2	No
Therapeutic Area	IT.TAREA	3	No
Protocol Number	IT.PNO	4	No
Country	IT.SCTRY	5	No
Record status, 5 levels, internal use	IT.F_STATUS	6	No
Assigned Study Drug Treatment	IT.DRUG_TRT	7	No

#### Items for Item Group : Pharmacokinetics

Item Name	Item ID	Order Number	Mandatory ?
Internal unique identifier for	IT.REC_ID	1	No

Item Name	Item ID	Order Number	Mandatory ?
record			
Compound	IT.R_DRUG	2	No
Therapeutic Area	IT.TAREA	3	No
Protocol Number	IT.PNO	4	No
Country	IT.SCTRY	5	No
Record status, 5 levels, internal use	IT.F_STATUS	6	No
Pretreatment yr	IT.PKYR0	7	No
1-h year	IT.PKYR1	8	No
2-h year	IT.PKYR2	9	No
3-h year	IT.PKYR3	10	No
4-h year	IT.PKYR4	11	No
8-h year	IT.PKYR8	12	No
16-h year	IT.PKYR16	13	No
24-h year	IT.PKYR24	14	No
Meal year	IT.MEALYR	15	No
Pretreatment mon	IT.PKMON0	16	No
1-h mon	IT.PKMON1	17	No
2-h mon	IT.PKMON2	18	No
3-h mon	IT.PKMON3	19	No
4-h mon	IT.PKMON4	20	No
8-h mon	IT.PKMON8	21	No
16-h mon	IT.PKMON16	22	No
24-h mon	IT.PKMON24	23	No
Meal mon	IT.MEALMON	24	No
Pretreatment day	IT.PKDAY0	25	No
1-h day	IT.PKDAY1	26	No
2-h day	IT.PKDAY2	27	No
3-h day	IT.PKDAY3	28	No
4-h day	IT.PKDAY4	29	No
8-h day	IT.PKDAY8	30	No
16-h day	IT.PKDAY16	31	No
24-h day	IT.PKDAY24	32	No
Meal day	IT.MEALDAY	33	No
Not done	IT.NOTDONE	34	No
Pretreatment date	IT.PK_DT0	35	No
1-h date	IT.PK_DT1	36	No
2-h date	IT.PK_DT2	37	No
3-h date	IT.PK_DT3	38	No
4-h date	IT.PK_DT4	39	No
8-h date	IT.PK_DT8	40	No
16-h date	IT.PK_DT16	41	No



Item Name	Item ID	Order Number	Mandatory ?
24-h date	IT.PK_DT24	42	No
Date of last meal	IT.MEAL_DT	43	No
Pretreatment time	IT.PK_TIM0	44	No
1-h time	IT.PK_TIM1	45	No
2-h time	IT.PK_TIM2	46	No
3-h time	IT.PK_TIM3	47	No
4-h time	IT.PK_TIM4	48	No
8-h time	IT.PK_TIM8	49	No
16-h time	IT.PK_TIM16	50	No
24-h time	IT.PK_TIM24	51	No
Time of last meal	IT.MEALTIM	52	No

#### Items for Item Group : Physical Exam

Item Name	Item ID	Order Number	Mandatory ?
Internal unique identifier for record	IT.REC_ID	1	No
Compound	IT.R_DRUG	2	No
Therapeutic Area	IT.TAREA	3	No
Protocol Number	IT.PNO	4	No
Country	IT.SCTRY	5	No
Record status, 5 levels, internal use	IT.F_STATUS	6	No
Physical Exam Body System	IT.BODY_SYS	7	No
Normal/Abnormal/Not Done	IT.ABNORM	8	No
Comment	IT.COMMT1	9	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	2	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 Digits 01-31	IT.AESTDAY	text	2	
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		
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		
Record status, 5 levels, internal use	IT.F_STATUS	text	1	
Height	IT.HT	float		
Height Units	IT.HTUNITS	text	2	
Conmed Indication	IT.INDIC	text	100	
Line Number	IT.LINE_NO	float		
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	

Name	ID	Data Type	Length	Signif. Digits
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	
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	

Name	ID	Data Type	Length	Signif. Digits
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	
Internal unique identifier for record	IT.REC_ID	text	40	
Conmed Regimen	IT.REGIMEN	integer		
Conmed Route	IT.ROUTE	integer		
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	
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		
Weight Units	IT.WTUNITS	text	2	
Record Number	IT.REF1	integer		
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	
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	

Name	Code List Ref.	SAS Field Name	SDS Var Name
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 System	CL.PE_TEST	BODY_SYS	
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	

Name	Code List Ref.	SAS Field Name	SDS Var Name
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	
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	
Internal unique identifier for record		REC_ID	
Conmed Regimen	CL.REGF	REGIMEN	
Conmed Route	CL.ROUTEF	ROUTE	
Compound		R_DRUG	

Name	Code List Ref.	SAS Field Name	SDS Var Name
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	
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			

Name	Origin	Role	Comment
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			
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			



Name	Origin	Role	Comment
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			
16-h time			
2-h time			
24-h time			
3-h time			
4-h time			
8-h time			
Protocol Number			
Ethnic Group			
Internal unique identifier for record			
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			

Name	Origin	Role	Comment
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

Units of Measure :

Measurement Unit Name
dilberts/ml
filberts/ml

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

Comparator	Soft/ Hard	Check Value	Measurement Unit Name	Error Message	Language
				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
<a href="#">AE Action Taken, Study Drug</a>	CL.AEACTTR	text	AEACTTR
<a href="#">AE Action Taken, Other</a>	CL.AECONTR	text	AECONTR
<a href="#">AE Outcome</a>	CL.AEOUT	text	AEOUT
<a href="#">AE Relationship to Study Drug</a>	CL.AEREL	text	AEREL
<a href="#">AE Severity</a>	CL.AESEV	text	AESEV
<a href="#">Assigned Study Drug</a>	CL.DRUGTRTF	integer	DRUGTRTF
<a href="#">Record Status, Internal</a>	CL.F_STATU	text	F_STATU
<a href="#">Normal/Abnormal/Not Done</a>	CL.N_A_ND	integer	N_A_ND
<a href="#">PE Body System</a>	CL.PE_TEST	integer	PE_TEST
<a href="#">Conmed Regimen</a>	CL.REGF	integer	REGF
<a href="#">Conmed Route</a>	CL.ROUTEF	integer	ROUTEF
<a href="#">Country</a>	CL.SCTRYF	text	SCTRYF
<a href="#">Gender</a>	CL.SEXF	text	SEXF
<a href="#">Therapeutic Area</a>	CL.TAREAF	text	TAREAF
<a href="#">LOINC Version 2.0</a>	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
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

Coded Value	Decoded Value	Language
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
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

Coded Value	Decoded Value	Language
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

Presentation	ID	Language
French	PRS.FR	fr
Spanish	PRS.ES	es

## Administration Data :

Study = 123-456-789

User : ID = USR.cdisc001

Full Name : Shirley Williams

First Name : Shirley

Last Name : Williams

Organization: CDISC

Location Reference : CDISC Headquarters

User : ID = USR.inv001

Full Name : John Smith, M.D.

First Name : John

Last Name : Smith

Organization: Roswell Park

Location Reference : Roswell Park

User : ID = USR.inv002



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 : v1.01

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 : v1.01

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 : v1.01

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

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

Item Group : Sample Reference Data

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

Repeat key: 2

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

Clinical Data: Study = 123-456-789

MetaDataVersion ID = v1.01

## 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

Signature for this Form :

User : Shirley Williams

Location : CDISC Headquarters

Signature Methodology : Electronic

Date- and Timestamp : 20010530T10:06:32

Item Group : Demography

Repeat key: 1

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46902604		
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		

## Form Data:

ID = Treatment Assignment

Signature for this Form :

User : Shirley Williams

Location : CDISC Headquarters

Signature Methodology : Electronic

Date- and Timestamp : 20010530T10:06:32

Item Group : Treatment Assignment

Repeat key: 1

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46878904		
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	V		
Assigned Study Drug Treatment	1		

## Form Data:

ID = Pharmacokinetics

Signature for this Form :

User : Shirley Williams

Location : CDISC Headquarters

Signature Methodology : Electronic

Date- and Timestamp : 20010530T10:06:32

Item Group : Pharmacokinetics

Repeat key: 1

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46881304		
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	V		
Pretreatment yr	1999		

Item	Value	is Null?	Trans.Type
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	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		



Item	Value	is Null?	Trans.Type
24-h time	0600		
Time of last meal	0500		

## Form Data:

ID = Physical Exam

Signature for this Form :

User : Shirley Williams

Location : CDISC Headquarters

Signature Methodology : Electronic

Date- and Timestamp : 20010530T10:06:32

Item Group : Physical Exam

Repeat key: 1

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46869304		
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		

Item Group : Physical Exam

Repeat key: 2

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46869504		
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		

Item Group : Physical Exam

Repeat key: 3

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46869604		
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		

Item Group : Physical Exam

Repeat key: 4

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46869804		

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		

Item Group : Physical Exam

Repeat key: 5

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46869904		
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		

Item Group : Physical Exam

Repeat key: 6

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46870604		

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		

Item Group : Physical Exam

Repeat key: 7

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46870904		
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		

Item Group : Physical Exam

Repeat key: 8

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46871004		

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		

Item Group : Physical Exam

Repeat key: 9

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46871204		
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	1		

Item Group : Physical Exam

Repeat key: 10

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46871504		
Compound	SDP		
Therapeutic Area	ONC		

Item	Value	is Null?	Trans.Type
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		

Item Group : Physical Exam

Repeat key: 11

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46871704		
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		

Item Group : Physical Exam

Repeat key: 12

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46872504		
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	12		
Normal/Abnormal/Not Done	1		

Item Group : Physical Exam

Repeat key: 13

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46873104		
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		

## Study Event Data:

Study Event = Post-treatment

## Form Data:

ID = Adverse Events

Signature for this Form :

User : Shirley Williams

Location : CDISC Headquarters

Signature Methodology : Electronic

Date- and Timestamp : 20010530T10:06:32

Item Group : Adverse Events

Repeat key: 1

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46898304		
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		
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		



Item Group : Adverse Events

Repeat key: 2

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46903404		
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		
Severity	1		
Relationship to study drug	0		
Outcome	2		
Actions taken re study drug	0		
Actions taken, other	1		

### Form Data:

ID = Concom Meds

Signature for this Form :

User : Shirley Williams

Location : CDISC Headquarters

Signature Methodology : Electronic

Date- and Timestamp : 20010530T10:06:32



Item Group : Concom Meds

Repeat key: 1

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46896304		
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 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		

Item Group : Concom Meds

Repeat key: 2

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46901404		
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	V		
Line Number	2		
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		

## 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

Signature for this Form :

User : Shirley Williams

Location : CDISC Headquarters

Signature Methodology : Electronic

Date- and Timestamp : 20010530T10:06:32

Item Group : Demography

Repeat key: 1

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46851404		
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		

## Form Data:

ID = Treatment Assignment

Signature for this Form :

User : Shirley Williams

Location : CDISC Headquarters

Signature Methodology : Electronic

Date- and Timestamp : 20010530T10:06:32

Item Group : Treatment Assignment

Repeat key: 1

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46918304		
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Assigned Study Drug Treatment	1		

## Form Data:

ID = Pharmacokinetics

Signature for this Form :

User : Shirley Williams

Location : CDISC Headquarters

Signature Methodology : Electronic

Date- and Timestamp : 20010530T10:06:32

Item Group : Pharmacokinetics

Repeat key: 1

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46921804		
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	V		
Pretreatment yr	1999		

Item	Value	is Null?	Trans.Type
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	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		

Item	Value	is Null?	Trans.Type
24-h time	0600		
Time of last meal	0500		

## Form Data:

ID = Physical Exam

Signature for this Form :

User : Shirley Williams

Location : CDISC Headquarters

Signature Methodology : Electronic

Date- and Timestamp : 20010530T10:06:32

Item Group : Physical Exam

Repeat key: 1

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46903804		
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		

Item Group : Physical Exam

Repeat key: 2



Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46903904		
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		

Item Group : Physical Exam

Repeat key: 3

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46904004		
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		

Item Group : Physical Exam

Repeat key: 4

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46905504		

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		

Item Group : Physical Exam

Repeat key: 5

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46906204		
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		

Item Group : Physical Exam

Repeat key: 6

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46907204		

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		

Item Group : Physical Exam

Repeat key: 7

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46907404		
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		

Item Group : Physical Exam

Repeat key: 8

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46907804		

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		

Item Group : Physical Exam

Repeat key: 9

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46907904		
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		

Item Group : Physical Exam

Repeat key: 10

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46908204		
Compound	SDP		
Therapeutic Area	ONC		

Item	Value	is Null?	Trans.Type
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		

Item Group : Physical Exam

Repeat key: 11

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46908304		
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		

Item Group : Physical Exam

Repeat key: 12

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46909704		
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	12		
Normal/Abnormal/Not Done	1		

Item Group : Physical Exam

Repeat key: 13

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46909804		
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		

## Study Event Data:

Study Event = Post-treatment

## Form Data:

ID = Concom Meds

Signature for this Form :

User : Shirley Williams

Location : CDISC Headquarters

Signature Methodology : Electronic

Date- and Timestamp : 20010530T10:06:32

Item Group : Concom Meds

Repeat key: 1

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46935504		
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		
Conmed Route	3		
Conmed Regimen	8		
Conmed Indication	HEADACHE		
Check If Taken for AE	0		

## 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

Signature for this Form :

User : Shirley Williams

Location : CDISC Headquarters

Signature Methodology : Electronic

Date- and Timestamp : 20010530T10:06:32



Item Group : Demography

Repeat key: 1

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46841804		
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		

### Form Data:

ID = Treatment Assignment

Signature for this Form :

User : Shirley Williams

Location : CDISC Headquarters

Signature Methodology : Electronic

Date- and Timestamp : 20010530T10:06:32

Item Group : Treatment Assignment

Repeat key: 1

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46880504		
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Assigned Study Drug Treatment	2		

## Form Data:

ID = Pharmacokinetics

Signature for this Form :

User : Shirley Williams

Location : CDISC Headquarters

Signature Methodology : Electronic

Date- and Timestamp : 20010530T10:06:32

Item Group : Pharmacokinetics

Repeat key: 1

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46882404		
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	V		
Pretreatment yr	1999		

Item	Value	is Null?	Trans.Type
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	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		

Item	Value	is Null?	Trans.Type
24-h time	0600		
Time of last meal	0500		

## Form Data:

ID = Physical Exam

Signature for this Form :

User : Shirley Williams

Location : CDISC Headquarters

Signature Methodology : Electronic

Date- and Timestamp : 20010530T10:06:32

Item Group : Physical Exam

Repeat key: 1

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46870204		
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		

Item Group : Physical Exam

Repeat key: 2

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46870404		
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		

Item Group : Physical Exam

Repeat key: 3

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46870504		
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		

Item Group : Physical Exam

Repeat key: 4

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46870804		

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		

Item Group : Physical Exam

Repeat key: 5

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46871304		
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		

Item Group : Physical Exam

Repeat key: 6

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46871904		

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		

Item Group : Physical Exam

Repeat key: 7

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46872004		
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		

Item Group : Physical Exam

Repeat key: 8

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46872104		

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		

Item Group : Physical Exam

Repeat key: 9

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46872204		
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		

Item Group : Physical Exam

Repeat key: 10

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46872704		
Compound	SDP		
Therapeutic Area	ONC		



Item	Value	is Null?	Trans.Type
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		

Item Group : Physical Exam

Repeat key: 11

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46872904		
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		

Item Group : Physical Exam

Repeat key: 12

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46873004		
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	12		
Normal/Abnormal/Not Done	1		

Item Group : Physical Exam

Repeat key: 13

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46873604		
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		

## Study Event Data:

Study Event = Post-treatment

## Form Data:

ID = Concom Meds

Signature for this Form :

User : Shirley Williams

Location : CDISC Headquarters

Signature Methodology : Electronic

Date- and Timestamp : 20010530T10:06:32

Item Group : Concom Meds

Repeat key: 1

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46741604		
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	19998 10		
Conmed Route	3		
Conmed Regimen	8		
Check If Taken for AE	0		

### Form Data:

ID = Physical Exam

Signature for this Form :

User : Shirley Williams

Location : CDISC Headquarters

Signature Methodology : Electronic

Date- and Timestamp : 20010530T10:06:32

Item Group : Physical Exam

Repeat key: 1

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46900504		
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		

Item Group : Physical Exam

Repeat key: 2

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46900604		
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Physical Exam Body System	2		

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

Item Group : Physical Exam

Repeat key: 3

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46900704		
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		

Item Group : Physical Exam

Repeat key: 4

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46900804		
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		

Item Group : Physical Exam

Repeat key: 5

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46900904		
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		

Item Group : Physical Exam

Repeat key: 6

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46901004		
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		

Item Group : Physical Exam

Repeat key: 7

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46901104		
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		

Item Group : Physical Exam

Repeat key: 8

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46901204		
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		

Item Group : Physical Exam

Repeat key: 9

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46901504		

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		

Item Group : Physical Exam

Repeat key: 10

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46901604		
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		

Item Group : Physical Exam

Repeat key: 11

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46901704		
Compound	SDP		
Therapeutic Area	ONC		



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

Item Group : Physical Exam

Repeat key: 12

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46901804		
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		

Item Group : Physical Exam

Repeat key: 13

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46901904		
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		

Item	Value	is Null?	Trans.Type
Record status, 5 levels, internal use	S		
Physical Exam Body System	13		
Normal/Abnormal/Not Done	1		

## 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

Signature for this Form :

User : Shirley Williams

Location : CDISC Headquarters

Signature Methodology : Electronic

Date- and Timestamp : 20010530T10:06:32

Item Group : Demography

Repeat key: 1

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46841204		
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		

### Form Data:

ID = Treatment Assignment

Signature for this Form :

User : Shirley Williams

Location : CDISC Headquarters

Signature Methodology : Electronic

Date- and Timestamp : 20010530T10:06:32

Item Group : Treatment Assignment

Repeat key: 1

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46876104		
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Assigned Study Drug Treatment	1		

## Form Data:

ID = Pharmacokinetics

Signature for this Form :

User : Shirley Williams

Location : CDISC Headquarters

Signature Methodology : Electronic

Date- and Timestamp : 20010530T10:06:32

Item Group : Pharmacokinetics

Repeat key: 1

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46877104		
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	V		
Pretreatment yr	1999		

Item	Value	is Null?	Trans.Type
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	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		

Item	Value	is Null?	Trans.Type
24-h time	0600		
Time of last meal	0500		

## Form Data:

ID = Physical Exam

Signature for this Form :

User : Shirley Williams

Location : CDISC Headquarters

Signature Methodology : Electronic

Date- and Timestamp : 20010530T10:06:32

Item Group : Physical Exam

Repeat key: 1

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46861804		
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		

Item Group : Physical Exam

Repeat key: 2

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46862204		
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		

Item Group : Physical Exam

Repeat key: 3

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46862604		
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		

Item Group : Physical Exam

Repeat key: 4

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46864104		



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		

Item Group : Physical Exam

Repeat key: 5

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46864704		
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		

Item Group : Physical Exam

Repeat key: 6

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46865804		

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		

Item Group : Physical Exam

Repeat key: 7

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46866604		
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		

Item Group : Physical Exam

Repeat key: 8

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46867404		

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		

Item Group : Physical Exam

Repeat key: 9

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46867704		
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		

Item Group : Physical Exam

Repeat key: 10

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46868504		
Compound	SDP		
Therapeutic Area	ONC		

Item	Value	is Null?	Trans.Type
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		

Item Group : Physical Exam

Repeat key: 11

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46868604		
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		

Item Group : Physical Exam

Repeat key: 12

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46868704		
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	12		
Normal/Abnormal/Not Done	1		

Item Group : Physical Exam

Repeat key: 13

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46869004		
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		

## Study Event Data:

Study Event = Post-treatment

## Form Data:

ID = Concom Meds

Signature for this Form :

User : Shirley Williams

Location : CDISC Headquarters

Signature Methodology : Electronic

Date- and Timestamp : 20010530T10:06:32

Item Group : Concom Meds

Repeat key: 1

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46903304		
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		
Conmed Route	3		
Conmed Regimen	8		
Conmed Indication	HEADACHE		
Check If Taken for AE	0		

**Form Data:**

ID = Physical Exam

Signature for this Form :

User : Shirley Williams

Location : CDISC Headquarters

Signature Methodology : Electronic

Date- and Timestamp : 20010530T10:06:32

Item Group : Physical Exam

Repeat key: 1

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46896704		
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		

Item Group : Physical Exam

Repeat key: 2

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46896804		

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		

Item Group : Physical Exam

Repeat key: 3

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46896904		
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		

Item Group : Physical Exam

Repeat key: 4

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46897004		
Compound	SDP		
Therapeutic Area	ONC		



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

Item Group : Physical Exam

Repeat key: 5

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46897104		
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		

Item Group : Physical Exam

Repeat key: 6

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46897204		
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		

Item	Value	is Null?	Trans.Type
Record status, 5 levels, internal use	S		
Physical Exam Body System	6		
Normal/Abnormal/Not Done	1		

Item Group : Physical Exam

Repeat key: 7

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46897304		
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		

Item Group : Physical Exam

Repeat key: 8

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46897504		
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	8		
Normal/Abnormal/Not Done	3		

Item Group : Physical Exam

Repeat key: 9

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46897604		
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		

Item Group : Physical Exam

Repeat key: 10

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46897804		
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		

Item Group : Physical Exam

Repeat key: 11

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46898004		
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		

Item Group : Physical Exam

Repeat key: 12

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46898104		
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		

Item Group : Physical Exam

Repeat key: 13

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46898304		
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		

## 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

Signature for this Form :

User : Shirley Williams

Location : CDISC Headquarters

Signature Methodology : Electronic

Date- and Timestamp : 20010530T10:06:32

Item Group : Demography

Repeat key: 1

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46731304		
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		

## Form Data:

ID = Treatment Assignment

Signature for this Form :

User : Shirley Williams

Location : CDISC Headquarters

Signature Methodology : Electronic

Date- and Timestamp : 20010530T10:06:32

Item Group : Treatment Assignment

Repeat key: 1

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46676604		
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	V		
Assigned Study Drug Treatment	2		

Item Group : Treatment Assignment

Repeat key: 2

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46918704		
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Assigned Study Drug Treatment	2		

### Form Data:

ID = Pharmacokinetics

Signature for this Form :

User : Shirley Williams

Location : CDISC Headquarters

Signature Methodology : Electronic

Date- and Timestamp : 20010530T10:06:32



Item Group : Pharmacokinetics

Repeat key: 1

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46676704		
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		
8-h day	20		
16-h day	20		
24-h day	21		
Meal day	20		
Pretreatment date	19990320		
1-h date	19990320		

Item	Value	is Null?	Trans.Type
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		

## Form Data:

ID = Physical Exam

Signature for this Form :

User : Shirley Williams

Location : CDISC Headquarters

Signature Methodology : Electronic

Date- and Timestamp : 20010530T10:06:32

Item Group : Physical Exam

Repeat key: 1

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46674704		
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	1		
Normal/Abnormal/Not Done	1		

Item Group : Physical Exam

Repeat key: 2

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46674804		
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		

Item Group : Physical Exam

Repeat key: 3

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46674904		
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	3		
Normal/Abnormal/Not Done	1		

Item Group : Physical Exam

Repeat key: 4

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46675004		
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		

Item Group : Physical Exam

Repeat key: 5

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46675104		
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		

Item	Value	is Null?	Trans.Type
Record status, 5 levels, internal use	V		
Physical Exam Body System	5		
Normal/Abnormal/Not Done	2		
Comment	TACHYCARDIA		

Item Group : Physical Exam

Repeat key: 6

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46675204		
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		

Item Group : Physical Exam

Repeat key: 7

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46675304		
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	7		
Normal/Abnormal/Not Done	1		

Item Group : Physical Exam

Repeat key: 8

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46675404		
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		

Item Group : Physical Exam

Repeat key: 9

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46675504		
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	9		
Normal/Abnormal/Not Done	2		

Item Group : Physical Exam

Repeat key: 10

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46675604		
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		

Item Group : Physical Exam

Repeat key: 11

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46675704		
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	11		
Normal/Abnormal/Not Done	1		

Item Group : Physical Exam

Repeat key: 12

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46675804		
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		

Item Group : Physical Exam

Repeat key: 13

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46675904		
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	V		
Physical Exam Body System	13		



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

Item Group : Physical Exam

Repeat key: 14

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46682904		
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		

Item Group : Physical Exam

Repeat key: 15

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46683004		
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		

Item Group : Physical Exam

Repeat key: 16

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46683104		
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		

Item Group : Physical Exam

Repeat key: 17

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46683204		
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		

Item Group : Physical Exam

Repeat key: 18

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46683304		
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		

Item Group : Physical Exam

Repeat key: 19

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46683404		
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		

Item Group : Physical Exam

Repeat key: 20

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46683504		
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		

Item Group : Physical Exam

Repeat key: 21

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46683604		
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		

Item Group : Physical Exam

Repeat key: 22

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46683704		
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		

Item Group : Physical Exam

Repeat key: 23

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46683804		
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		

Item Group : Physical Exam

Repeat key: 24

Item	Value	is Null?	Trans.Type
Internal unique identifier	46683904		

Item	Value	is Null?	Trans.Type
for record			
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		

Item Group : Physical Exam

Repeat key: 25

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46684004		
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		

Item Group : Physical Exam

Repeat key: 26

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46684104		
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	13		
Normal/Abnormal/Not Done	1		

Item Group : Physical Exam

Repeat key: 27

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46758204		
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		

Item Group : Physical Exam

Repeat key: 28

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46758304		
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	2		
Normal/Abnormal/Not Done	1		

Item Group : Physical Exam

Repeat key: 29

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46758404		
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		

Item Group : Physical Exam

Repeat key: 30

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46758504		
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	4		
Normal/Abnormal/Not Done	2		
Comment	WHEEZING		

Item Group : Physical Exam

Repeat key: 31

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46758604		
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		

Item Group : Physical Exam

Repeat key: 32

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46758704		
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		

Item Group : Physical Exam

Repeat key: 33

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46758804		
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		

Item Group : Physical Exam

Repeat key: 34

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46758904		
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	2		

Item Group : Physical Exam

Repeat key: 35

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46759004		
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		

Item Group : Physical Exam

Repeat key: 36

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46759104		
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		

Item Group : Physical Exam

Repeat key: 37

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46759204		
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		

Item Group : Physical Exam

Repeat key: 38

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46759304		
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		

Item Group : Physical Exam

Repeat key: 39

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46759404		
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		

Item Group : Physical Exam

Repeat key: 40

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46941604		
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		

Item Group : Physical Exam

Repeat key: 41

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46941704		

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		

Item Group : Physical Exam

Repeat key: 42

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46941804		
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		

Item Group : Physical Exam

Repeat key: 43

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46942204		
Compound	SDP		
Therapeutic Area	ONC		

Item	Value	is Null?	Trans.Type
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		

Item Group : Physical Exam

Repeat key: 44

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46942304		
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		

Item Group : Physical Exam

Repeat key: 45

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46942404		
Compound	SDP		
Therapeutic Area	ONC		

Item	Value	is Null?	Trans.Type
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		

Item Group : Physical Exam

Repeat key: 46

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46942504		
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		

Item Group : Physical Exam

Repeat key: 47

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46942704		
Compound	SDP		
Therapeutic Area	ONC		



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

Item Group : Physical Exam

Repeat key: 48

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46942804		
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		

Item Group : Physical Exam

Repeat key: 49

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46942904		
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		

Item	Value	is Null?	Trans.Type
Record status, 5 levels, internal use	S		
Physical Exam Body System	10		
Normal/Abnormal/Not Done	2		
Comment	PETECHIA		

Item Group : Physical Exam

Repeat key: 50

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46943004		
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		

Item Group : Physical Exam

Repeat key: 51

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46943204		
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	12		
Normal/Abnormal/Not Done	1		

Item Group : Physical Exam

Repeat key: 52

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46943304		
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		

## Study Event Data:

Study Event = Post-treatment

## Form Data:

ID = Concom Meds

Signature for this Form :

User : Shirley Williams

Location : CDISC Headquarters

Signature Methodology : Electronic

Date- and Timestamp : 20010530T10:06:32

Item Group : Concom Meds

Repeat key: 1

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46678404		
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		

Item Group : Concom Meds

Repeat key: 2

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46685104		
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		
Check If Taken for AE	0		

Item Group : Concom Meds

Repeat key: 3

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46932804		
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		
Conmed Route	3		
Conmed Regimen	8		
Conmed Indication	HEADACHE		
Check If Taken for AE	0		

## Form Data:

ID = Physical Exam

Signature for this Form :

User : Shirley Williams

Location : CDISC Headquarters

Signature Methodology : Electronic

Date- and Timestamp : 20010530T10:06:32

Item Group : Physical Exam

Repeat key: 1

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46927704		
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		

Item Group : Physical Exam

Repeat key: 2

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46927804		
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		

Item Group : Physical Exam

Repeat key: 3

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46927904		
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		

Item Group : Physical Exam

Repeat key: 4

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46928004		
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		

Item Group : Physical Exam

Repeat key: 5



Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46928104		
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		

Item Group : Physical Exam

Repeat key: 6

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46928204		
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		

Item Group : Physical Exam

Repeat key: 7

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46928304		

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		

Item Group : Physical Exam

Repeat key: 8

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46928404		
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		

Item Group : Physical Exam

Repeat key: 9

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46928504		
Compound	SDP		
Therapeutic Area	ONC		

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

Item Group : Physical Exam

Repeat key: 10

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46928604		
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		

Item Group : Physical Exam

Repeat key: 11

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46928704		
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		

Item	Value	is Null?	Trans.Type
Record status, 5 levels, internal use	S		
Physical Exam Body System	11		
Normal/Abnormal/Not Done	1		

Item Group : Physical Exam

Repeat key: 12

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46928804		
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		

Item Group : Physical Exam

Repeat key: 13

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46928904		
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	13		
Normal/Abnormal/Not Done	1		

## 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

Signature for this Form :

User : Shirley Williams

Location : CDISC Headquarters

Signature Methodology : Electronic

Date- and Timestamp : 20010530T10:06:32

Item Group : Demography

Repeat key: 1

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46871804		
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		

## Form Data:

ID = Treatment Assignment

Signature for this Form :

User : Shirley Williams

Location : CDISC Headquarters

Signature Methodology : Electronic

Date- and Timestamp : 20010530T10:06:32

Item Group : Treatment Assignment

Repeat key: 1

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46898504		
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Assigned Study Drug Treatment	2		

## Form Data:

ID = Pharmacokinetics

Signature for this Form :

User : Shirley Williams

Location : CDISC Headquarters

Signature Methodology : Electronic

Date- and Timestamp : 20010530T10:06:32

Item Group : Pharmacokinetics

Repeat key: 1

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46911504		
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	V		
Pretreatment yr	1999		



Item	Value	is Null?	Trans.Type
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	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		

Item	Value	is Null?	Trans.Type
24-h time	0600		
Time of last meal	0500		

## Form Data:

ID = Physical Exam

Signature for this Form :

User : Shirley Williams

Location : CDISC Headquarters

Signature Methodology : Electronic

Date- and Timestamp : 20010530T10:06:32

Item Group : Physical Exam

Repeat key: 1

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46883504		
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		

Item Group : Physical Exam

Repeat key: 2

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46883704		
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		

Item Group : Physical Exam

Repeat key: 3

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46883904		
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		

Item Group : Physical Exam

Repeat key: 4

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46885004		

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		

Item Group : Physical Exam

Repeat key: 5

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46886604		
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		

Item Group : Physical Exam

Repeat key: 6

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46888504		

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		

Item Group : Physical Exam

Repeat key: 7

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46888704		
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		

Item Group : Physical Exam

Repeat key: 8

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46888804		

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		

Item Group : Physical Exam

Repeat key: 9

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46889104		
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		

Item Group : Physical Exam

Repeat key: 10

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46889504		
Compound	SDP		
Therapeutic Area	ONC		

Item	Value	is Null?	Trans.Type
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		

Item Group : Physical Exam

Repeat key: 11

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46889604		
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		

Item Group : Physical Exam

Repeat key: 12

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46890504		
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	12		
Normal/Abnormal/Not Done	1		

Item Group : Physical Exam

Repeat key: 13

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46890704		
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		

## Study Event Data:

Study Event = Post-treatment

## Form Data:

ID = Concom Meds

Signature for this Form :

User : Shirley Williams



Location : CDISC Headquarters

Signature Methodology : Electronic

Date- and Timestamp : 20010530T10:06:32

Item Group : Concom Meds

Repeat key: 1

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46920904		
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	325 MG		
Conmed Route	3		
Conmed Regimen	8		
Conmed Indication	HEADACHE		
Check If Taken for AE	0		

## 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

Signature for this Form :

User : Shirley Williams

Location : CDISC Headquarters

Signature Methodology : Electronic

Date- and Timestamp : 20010530T10:06:32

Item Group : Demography

Repeat key: 1

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46948504		
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		

## Form Data:

ID = Treatment Assignment

Signature for this Form :

User : Shirley Williams

Location : CDISC Headquarters

Signature Methodology : Electronic

Date- and Timestamp : 20010530T10:06:32

Item Group : Treatment Assignment

Repeat key: 1

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46794204		
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Assigned Study Drug Treatment	1		

## Form Data:

ID = Physical Exam

Signature for this Form :

User : Shirley Williams

Location : CDISC Headquarters

Signature Methodology : Electronic

Date- and Timestamp : 20010530T10:06:32

Item Group : Physical Exam

Repeat key: 1

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46764204		
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Physical Exam Body	1		

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

Item Group : Physical Exam

Repeat key: 2

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46764304		
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		

Item Group : Physical Exam

Repeat key: 3

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46764404		
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		

Item	Value	is Null?	Trans.Type
Done			

Item Group : Physical Exam

Repeat key: 4

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46764504		
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		

Item Group : Physical Exam

Repeat key: 5

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46764604		
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		

Item Group : Physical Exam

Repeat key: 6

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46764704		
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		

Item Group : Physical Exam

Repeat key: 7

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46764804		
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		

Item Group : Physical Exam

Repeat key: 8

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46764904		
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		

Item Group : Physical Exam

Repeat key: 9

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46765004		
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		

Item Group : Physical Exam

Repeat key: 10

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46765104		



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		

Item Group : Physical Exam

Repeat key: 11

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46765204		
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		

Item Group : Physical Exam

Repeat key: 12

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46765304		
Compound	SDP		
Therapeutic Area	ONC		

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

Item Group : Physical Exam

Repeat key: 13

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46765404		
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		

## 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

Signature for this Form :

User : Shirley Williams

Location : CDISC Headquarters

Signature Methodology : Electronic

Date- and Timestamp : 20010530T10:06:32

Item Group : Demography

Repeat key: 1

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46768104		
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		

### Form Data:

ID = Treatment Assignment

Signature for this Form :

User : Shirley Williams

Location : CDISC Headquarters

Signature Methodology : Electronic

Date- and Timestamp : 20010530T10:06:32

Item Group : Treatment Assignment

Repeat key: 1

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46774204		
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Assigned Study Drug Treatment	1		

Item Group : Treatment Assignment

Repeat key: 2

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46776004		
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Assigned Study Drug Treatment	1		

### Form Data:

ID = Pharmacokinetics

Signature for this Form :

User : Shirley Williams

Location : CDISC Headquarters

Signature Methodology : Electronic

Date- and Timestamp : 20010530T10:06:32

Item Group : Pharmacokinetics

Repeat key: 1

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46774304		
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		
8-h day	06		
16-h day	06		
24-h day	07		
Meal day	06		
Pretreatment date	19990706		
1-h date	19990706		

Item	Value	is Null?	Trans.Type
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		

## Form Data:

ID = Physical Exam

Signature for this Form :

User : Shirley Williams

Location : CDISC Headquarters

Signature Methodology : Electronic

Date- and Timestamp : 20010530T10:06:32

Item Group : Physical Exam

Repeat key: 1

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46769904		
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	1		
Normal/Abnormal/Not Done	1		

Item Group : Physical Exam

Repeat key: 2

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46770004		
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		

Item Group : Physical Exam

Repeat key: 3

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46770104		
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	3		
Normal/Abnormal/Not Done	1		

Item Group : Physical Exam

Repeat key: 4

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46770204		
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		

Item Group : Physical Exam

Repeat key: 5

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46770304		
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	5		
Normal/Abnormal/Not Done	2		
Comment	TACHYCARDIA AND INCREASED.....		

Item Group : Physical Exam

Repeat key: 6

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46770404		
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		

Item Group : Physical Exam

Repeat key: 7

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46770504		
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	7		
Normal/Abnormal/Not Done	1		

Item Group : Physical Exam

Repeat key: 8

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46770604		
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		

Item Group : Physical Exam

Repeat key: 9

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46770704		
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Physical Exam Body	9		

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

Item Group : Physical Exam

Repeat key: 10

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46770804		
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		

Item Group : Physical Exam

Repeat key: 11

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46770904		
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		

Item	Value	is Null?	Trans.Type
Done			

Item Group : Physical Exam

Repeat key: 12

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46771004		
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		

Item Group : Physical Exam

Repeat key: 13

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46771104		
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	3		

Item	Value	is Null?	Trans.Type
Done			

## Study Event Data:

Study Event = Post-treatment

## Form Data:

ID = Concom Meds

Signature for this Form :

User : Shirley Williams

Location : CDISC Headquarters

Signature Methodology : Electronic

Date- and Timestamp : 20010530T10:06:32

Item Group : Concom Meds

Repeat key: 1

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46772404		
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		

Item	Value	is Null?	Trans.Type
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		

## 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

Signature for this Form :

User : Shirley Williams

Location : CDISC Headquarters

Signature Methodology : Electronic

Date- and Timestamp : 20010530T10:06:32



Item Group : Demography

Repeat key: 1

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46845704		
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		

### Form Data:

ID = Treatment Assignment

Signature for this Form :

User : Shirley Williams

Location : CDISC Headquarters

Signature Methodology : Electronic

Date- and Timestamp : 20010530T10:06:32

Item Group : Treatment Assignment

Repeat key: 1

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46939304		
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Assigned Study Drug Treatment	2		

## Form Data:

ID = Pharmacokinetics

Signature for this Form :

User : Shirley Williams

Location : CDISC Headquarters

Signature Methodology : Electronic

Date- and Timestamp : 20010530T10:06:32

Item Group : Pharmacokinetics

Repeat key: 1

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46940004		
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	V		
Pretreatment yr	1999		

Item	Value	is Null?	Trans.Type
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	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		

Item	Value	is Null?	Trans.Type
24-h time	0600		
Time of last meal	0500		

## Form Data:

ID = Physical Exam

Signature for this Form :

User : Shirley Williams

Location : CDISC Headquarters

Signature Methodology : Electronic

Date- and Timestamp : 20010530T10:06:32

Item Group : Physical Exam

Repeat key: 1

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46935704		
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		

Item Group : Physical Exam

Repeat key: 2

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46935804		
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		

Item Group : Physical Exam

Repeat key: 3

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46935904		
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		

Item Group : Physical Exam

Repeat key: 4

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46936004		

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		

Item Group : Physical Exam

Repeat key: 5

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46936304		
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		

Item Group : Physical Exam

Repeat key: 6

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46936404		

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 HEART-NCS		

Item Group : Physical Exam

Repeat key: 7

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46936504		
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		

Item Group : Physical Exam

Repeat key: 8

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46936604		

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		

Item Group : Physical Exam

Repeat key: 9

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46936704		
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		

Item Group : Physical Exam

Repeat key: 10

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46936904		
Compound	SDP		
Therapeutic Area	ONC		



Item	Value	is Null?	Trans.Type
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		

Item Group : Physical Exam

Repeat key: 11

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46937004		
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		

Item Group : Physical Exam

Repeat key: 12

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46937204		
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	12		
Normal/Abnormal/Not Done	1		

Item Group : Physical Exam

Repeat key: 13

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46937704		
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		

## Study Event Data:

Study Event = Post-treatment

## Form Data:

ID = Concom Meds

Signature for this Form :

User : Shirley Williams

Location : CDISC Headquarters

Signature Methodology : Electronic

Date- and Timestamp : 20010530T10:06:32

Item Group : Concom Meds

Repeat key: 1

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46945104		
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		
Conmed Route	3		
Conmed Regimen	8		
Conmed Indication	HEADACHE		
Check If Taken for AE	0		

**Form Data:**

ID = Physical Exam

Signature for this Form :

User : Shirley Williams

Location : CDISC Headquarters

Signature Methodology : Electronic

Date- and Timestamp : 20010530T10:06:32

Item Group : Physical Exam

Repeat key: 1

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46943804		
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		

Item Group : Physical Exam

Repeat key: 2

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46943904		

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		

Item Group : Physical Exam

Repeat key: 3

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46944004		
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		

Item Group : Physical Exam

Repeat key: 4

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46944104		
Compound	SDP		
Therapeutic Area	ONC		

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

Item Group : Physical Exam

Repeat key: 5

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46944204		
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		

Item Group : Physical Exam

Repeat key: 6

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46944304		
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		

Item	Value	is Null?	Trans.Type
Record status, 5 levels, internal use	S		
Physical Exam Body System	6		
Normal/Abnormal/Not Done	1		

Item Group : Physical Exam

Repeat key: 7

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46944404		
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		

Item Group : Physical Exam

Repeat key: 8

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46944504		
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	8		
Normal/Abnormal/Not Done	3		

Item Group : Physical Exam

Repeat key: 9

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46944604		
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		

Item Group : Physical Exam

Repeat key: 10

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46944704		
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		

Item Group : Physical Exam

Repeat key: 11

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46944804		
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		

Item Group : Physical Exam

Repeat key: 12

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46944904		
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		

Item Group : Physical Exam

Repeat key: 13

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46945004		
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		

## 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

Signature for this Form :

User : Shirley Williams

Location : CDISC Headquarters

Signature Methodology : Electronic

Date- and Timestamp : 20010530T10:06:32

Item Group : Demography

Repeat key: 1

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46846504		
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		

## Form Data:

ID = Treatment Assignment

Signature for this Form :

User : Shirley Williams

Location : CDISC Headquarters

Signature Methodology : Electronic

Date- and Timestamp : 20010530T10:06:32

Item Group : Treatment Assignment

Repeat key: 1

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46918004		
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Assigned Study Drug Treatment	2		

## Form Data:

ID = Pharmacokinetics

Signature for this Form :

User : Shirley Williams

Location : CDISC Headquarters

Signature Methodology : Electronic

Date- and Timestamp : 20010530T10:06:32

Item Group : Pharmacokinetics

Repeat key: 1

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46918804		
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	V		
Pretreatment yr	1999		

Item	Value	is Null?	Trans.Type
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	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		

Item	Value	is Null?	Trans.Type
24-h time	0600		
Time of last meal	0500		

## Form Data:

ID = Physical Exam

Signature for this Form :

User : Shirley Williams

Location : CDISC Headquarters

Signature Methodology : Electronic

Date- and Timestamp : 20010530T10:06:32

Item Group : Physical Exam

Repeat key: 1

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46909904		
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		

Item Group : Physical Exam

Repeat key: 2

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46910004		
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		

Item Group : Physical Exam

Repeat key: 3

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46910204		
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		

Item Group : Physical Exam

Repeat key: 4

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46910304		



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		

Item Group : Physical Exam

Repeat key: 5

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46910504		
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		

Item Group : Physical Exam

Repeat key: 6

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46910604		

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-N S		

Item Group : Physical Exam

Repeat key: 7

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46910704		
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		

Item Group : Physical Exam

Repeat key: 8

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46910804		

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		

Item Group : Physical Exam

Repeat key: 9

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46910904		
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		

Item Group : Physical Exam

Repeat key: 10

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46911004		
Compound	SDP		
Therapeutic Area	ONC		

Item	Value	is Null?	Trans.Type
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		

Item Group : Physical Exam

Repeat key: 11

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46911104		
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		

Item Group : Physical Exam

Repeat key: 12

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46911704		
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	12		
Normal/Abnormal/Not Done	1		

Item Group : Physical Exam

Repeat key: 13

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46913504		
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		

## Study Event Data:

Study Event = Post-treatment

## Form Data:

ID = Concom Meds

Signature for this Form :

User : Shirley Williams

Location : CDISC Headquarters

Signature Methodology : Electronic

Date- and Timestamp : 20010530T10:06:32

Item Group : Concom Meds

Repeat key: 1

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46934204		
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		
Conmed Route	3		
Conmed Regimen	8		
Conmed Indication	HEADACHE		
Check If Taken for AE	0		

**Form Data:**

ID = Physical Exam

Signature for this Form :

User : Shirley Williams

Location : CDISC Headquarters

Signature Methodology : Electronic

Date- and Timestamp : 20010530T10:06:32

Item Group : Physical Exam

Repeat key: 1

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46930904		
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		

Item Group : Physical Exam

Repeat key: 2

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46931004		

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		

Item Group : Physical Exam

Repeat key: 3

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46931104		
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		

Item Group : Physical Exam

Repeat key: 4

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46931204		
Compound	SDP		
Therapeutic Area	ONC		



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

Item Group : Physical Exam

Repeat key: 5

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46931304		
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		

Item Group : Physical Exam

Repeat key: 6

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46931404		
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		

Item	Value	is Null?	Trans.Type
Record status, 5 levels, internal use	S		
Physical Exam Body System	6		
Normal/Abnormal/Not Done	1		

Item Group : Physical Exam

Repeat key: 7

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46931504		
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		

Item Group : Physical Exam

Repeat key: 8

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46932004		
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	8		
Normal/Abnormal/Not Done	3		

Item Group : Physical Exam

Repeat key: 9

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46932104		
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		

Item Group : Physical Exam

Repeat key: 10

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46932204		
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		

Item Group : Physical Exam

Repeat key: 11

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46932304		
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		

Item Group : Physical Exam

Repeat key: 12

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46932504		
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		

Item Group : Physical Exam

Repeat key: 13

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46932604		
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		

## 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

Signature for this Form :

User : Shirley Williams

Location : CDISC Headquarters

Signature Methodology : Electronic

Date- and Timestamp : 20010530T10:06:32

Item Group : Demography

Repeat key: 1

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46841404		
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		

## Form Data:

ID = Treatment Assignment

Signature for this Form :

User : Shirley Williams

Location : CDISC Headquarters

Signature Methodology : Electronic

Date- and Timestamp : 20010530T10:06:32

Item Group : Treatment Assignment

Repeat key: 1

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46881704		
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	V		
Assigned Study Drug Treatment	2		

## Form Data:

ID = Pharmacokinetics

Signature for this Form :

User : Shirley Williams

Location : CDISC Headquarters

Signature Methodology : Electronic

Date- and Timestamp : 20010530T10:06:32

Item Group : Pharmacokinetics

Repeat key: 1

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46887604		
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	V		
Pretreatment yr	1999		



Item	Value	is Null?	Trans.Type
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	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		

Item	Value	is Null?	Trans.Type
24-h time	0600		
Time of last meal	0500		

## Form Data:

ID = Physical Exam

Signature for this Form :

User : Shirley Williams

Location : CDISC Headquarters

Signature Methodology : Electronic

Date- and Timestamp : 20010530T10:06:32

Item Group : Physical Exam

Repeat key: 1

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46857804		
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		

Item Group : Physical Exam

Repeat key: 2

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46857904		
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		

Item Group : Physical Exam

Repeat key: 3

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46858104		
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		

Item Group : Physical Exam

Repeat key: 4

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46859004		

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		

Item Group : Physical Exam

Repeat key: 5

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46859404		
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		

Item Group : Physical Exam

Repeat key: 6

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46860804		

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		

Item Group : Physical Exam

Repeat key: 7

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46860904		
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		

Item Group : Physical Exam

Repeat key: 8

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46861404		

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		

Item Group : Physical Exam

Repeat key: 9

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46861704		
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	1		

Item Group : Physical Exam

Repeat key: 10

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46863704		
Compound	SDP		
Therapeutic Area	ONC		

Item	Value	is Null?	Trans.Type
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		

Item Group : Physical Exam

Repeat key: 11

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46864004		
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		

Item Group : Physical Exam

Repeat key: 12

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46867804		
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	12		
Normal/Abnormal/Not Done	1		

Item Group : Physical Exam

Repeat key: 13

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46867904		
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		

## Study Event Data:

Study Event = Post-treatment

## Form Data:

ID = Concom Meds

Signature for this Form :

User : Shirley Williams



Location : CDISC Headquarters

Signature Methodology : Electronic

Date- and Timestamp : 20010530T10:06:32

Item Group : Concom Meds

Repeat key: 1

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46903504		
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 Digits 01-31	14		
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		

## 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

Signature for this Form :

User : Shirley Williams

Location : CDISC Headquarters

Signature Methodology : Electronic

Date- and Timestamp : 20010530T10:06:32

Item Group : Demography

Repeat key: 1

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46842404		
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		

## Form Data:

ID = Treatment Assignment

Signature for this Form :

User : Shirley Williams

Location : CDISC Headquarters

Signature Methodology : Electronic

Date- and Timestamp : 20010530T10:06:32

Item Group : Treatment Assignment

Repeat key: 1

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46911804		
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	S		
Assigned Study Drug Treatment	2		

## Form Data:

ID = Pharmacokinetics

Signature for this Form :

User : Shirley Williams

Location : CDISC Headquarters

Signature Methodology : Electronic

Date- and Timestamp : 20010530T10:06:32

Item Group : Pharmacokinetics

Repeat key: 1

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46913004		
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		
Record status, 5 levels, internal use	V		
Pretreatment yr	1999		

Item	Value	is Null?	Trans.Type
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	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		

Item	Value	is Null?	Trans.Type
24-h time	0600		
Time of last meal	0500		

## Form Data:

ID = Physical Exam

Signature for this Form :

User : Shirley Williams

Location : CDISC Headquarters

Signature Methodology : Electronic

Date- and Timestamp : 20010530T10:06:32

Item Group : Physical Exam

Repeat key: 1

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46904904		
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		

Item Group : Physical Exam

Repeat key: 2

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46905304		
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		

Item Group : Physical Exam

Repeat key: 3

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46905404		
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		

Item Group : Physical Exam

Repeat key: 4

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46905804		

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		

Item Group : Physical Exam

Repeat key: 5

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46906004		
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		

Item Group : Physical Exam

Repeat key: 6

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46906704		



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 HEART-NCS		

Item Group : Physical Exam

Repeat key: 7

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46906904		
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		

Item Group : Physical Exam

Repeat key: 8

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46907104		

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		

Item Group : Physical Exam

Repeat key: 9

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46907504		
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		

Item Group : Physical Exam

Repeat key: 10

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46908004		
Compound	SDP		
Therapeutic Area	ONC		

Item	Value	is Null?	Trans.Type
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		

Item Group : Physical Exam

Repeat key: 11

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46908104		
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		

Item Group : Physical Exam

Repeat key: 12

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46908504		
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	12		
Normal/Abnormal/Not Done	1		

Item Group : Physical Exam

Repeat key: 13

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46908704		
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		

## Study Event Data:

Study Event = Post-treatment

## Form Data:

ID = Concom Meds

Signature for this Form :

User : Shirley Williams

Location : CDISC Headquarters

Signature Methodology : Electronic

Date- and Timestamp : 20010530T10:06:32

Item Group : Concom Meds

Repeat key: 1

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46929004		
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		
Conmed Route	3		
Conmed Regimen	8		
Conmed Indication	HEADACHE		
Check If Taken for AE	0		

**Form Data:**

ID = Physical Exam

Signature for this Form :

User : Shirley Williams

Location : CDISC Headquarters

Signature Methodology : Electronic

Date- and Timestamp : 20010530T10:06:32

Item Group : Physical Exam

Repeat key: 1

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46924204		
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		

Item Group : Physical Exam

Repeat key: 2

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46924304		

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		

Item Group : Physical Exam

Repeat key: 3

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46924404		
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		

Item Group : Physical Exam

Repeat key: 4

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46924504		
Compound	SDP		
Therapeutic Area	ONC		

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

Item Group : Physical Exam

Repeat key: 5

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46924604		
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		

Item Group : Physical Exam

Repeat key: 6

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46924704		
Compound	SDP		
Therapeutic Area	ONC		
Protocol Number	143-02		
Country	USA		



Item	Value	is Null?	Trans.Type
Record status, 5 levels, internal use	S		
Physical Exam Body System	6		
Normal/Abnormal/Not Done	1		

Item Group : Physical Exam

Repeat key: 7

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46924804		
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		

Item Group : Physical Exam

Repeat key: 8

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46924904		
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	8		
Normal/Abnormal/Not Done	1		

Item Group : Physical Exam

Repeat key: 9

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46925004		
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		

Item Group : Physical Exam

Repeat key: 10

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46925204		
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		

Item Group : Physical Exam

Repeat key: 11

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46925304		
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		

Item Group : Physical Exam

Repeat key: 12

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46925404		
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		

Item Group : Physical Exam

Repeat key: 13

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46925504		
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		

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