

Clinical Study Data Report

Study Attributes :

Description :

File Type : Snapshot

Granularity :

File OID : 987-654-321

Creation date and time :

2001-11-15T16:37:21-05:00

Prior File OID :

As of Date and Time :

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

There are no Units of Measure defined

Study : 123-456-789

Metadata Version : Version 1.01

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

Protocol Study Events :

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

Study Event Definitions :

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

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		No

Item Group References for Form : Concom Meds

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

Item Group References for Form : Demography

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

Item Group References for Form : Treatment Assignment

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

Item Group References for Form : Pharmacokinetics

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

Item Group References for Form : Physical Exam

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

Item Groups :

Part 1 :

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

Part 2 :

Name	SAS Dataset	Domain	Origin	Role	Comment
Adverse Events	AE				

Name	SAS Dataset	Domain	Origin	Role	Comment
Concom Meds	CONMED				
Demography	DEMOG				
Treatment Assignment	DRUG_TRT				
Pharmacokinetics	PHARMO1				
Physical Exam	PHYEX				

Items for Item Group : Adverse Events

Item Name	Item ID	Order Number	Mandatory ?
Internal unique identifier for record	IT.REC_ID		No
Therapeutic Area	IT.TAREA		No
Protocol Number	IT.PNO		No
Country	IT.SCTRY		No
Record status, 5 levels, internal use	IT.F_STATUS		No
Line Number	IT.LINE_NO		No
Conmed Indication	IT.AETERM		No
Start Month - Enter Two Digits 01-12	IT.AESTMON		No
Start Day - Enter Two Digits 01-31	IT.AESTDAY		No
Start Year - Enter Four Digit Year	IT.AESTYR		No
Derived Start Date	IT.AESTDT		No
Stop Month - Enter Two Digits 01-12	IT.AEENMON		No
Stop Day - Enter Two Digits 01-31	IT.AEENDAY		No
Stop Year - Enter Four Digit Year	IT.AEENYR		No
Derived Stop Date	IT.AEENDT		No
Severity	IT.AESEV		No
Relationship to study drug	IT.AEREL		No
Outcome	IT.AEOUT		No
Actions taken re study drug	IT.AEACTTRT		No
Actions taken, other	IT.AECONTRT		No
Investigational Site	IT.SITE		No

Items for Item Group : Concom Meds

Item Name	Item ID	Order Number	Mandatory ?
Internal unique identifier for record	IT.REC_ID		No
Compound	IT.R_DRUG		No
Therapeutic Area	IT.TAREA		No
Protocol Number	IT.PNO		No
Country	IT.SCTRY		No
Record status, 5 levels, internal use	IT.F_STATUS		No
Line Number	IT.LINE_NO		No
Medication For Conmed	IT.MEDIC		No
Start Month - Enter Two Digits 01-12	IT.STRTMON		No
Start Day - Enter Two Digits 01-31	IT.STRTDAY		No
Start Year - Enter Four Digit Year	IT.STRTYR		No
Derived Start Date	IT.STRT_DT		No
Check if Ongoing	IT.ONGOING		No
Stop Month - Enter Two Digits 01-12	IT.STOPMON		No
Stop Day - Enter Two Digits 01-31	IT.STOPDAY		No
Stop Year - Enter Four Digit Year	IT.STOPYR		No
Derived Stop Date	IT.STOP_DT		No
Dose and Unit	IT.DOSEUNIT		No
Conmed Route	IT.ROUTE		No
Conmed Regimen	IT.REGIMEN		No
Conmed Indication	IT.INDIC		No
Check If Taken for AE	IT.AE_RELAT		No
Investigational Site	IT.SITE		No

Items for Item Group : Demography

Item Name	Item ID	Order Number	Mandatory ?
Internal unique identifier for record	IT.REC_ID		No
Compound	IT.R_DRUG		No
Therapeutic Area	IT.TAREA		No
Protocol Number	IT.PNO		No
Country	IT.SCTRY		No
Record status, 5 levels,	IT.F_STATUS		No

Item Name	Item ID	Order Number	Mandatory ?
internal use			
Height	IT.HT		No
Weight	IT.WT		No
Gender	IT.SEX		No
Date of Birth	IT.DOB		No
Ethnic Group	IT.RACE		No
Height Units	IT.HTUNITS		No
Weight Units	IT.WTUNITS		No
Investigational Site	IT.SITE		No

Items for Item Group : Treatment Assignment

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

Items for Item Group : Pharmacokinetics

Item Name	Item ID	Order Number	Mandatory ?
Internal unique identifier for record	IT.REC_ID		No
Compound	IT.R_DRUG		No
Therapeutic Area	IT.TAREA		No
Protocol Number	IT.PNO		No
Country	IT.SCTRY		No
Record status, 5 levels, internal use	IT.F_STATUS		No
Pretreatment yr	IT.PKYR0		No
1-h year	IT.PKYR1		No
2-h year	IT.PKYR2		No
3-h year	IT.PKYR3		No
4-h year	IT.PKYR4		No

Item Name	Item ID	Order Number	Mandatory ?
8-h year	IT.PKYR8		No
16-h year	IT.PKYR16		No
24-h year	IT.PKYR24		No
Meal year	IT.MEALYR		No
Pretreatment mon	IT.PKMON0		No
1-h mon	IT.PKMON1		No
2-h mon	IT.PKMON2		No
3-h mon	IT.PKMON3		No
4-h mon	IT.PKMON4		No
8-h mon	IT.PKMON8		No
16-h mon	IT.PKMON16		No
24-h mon	IT.PKMON24		No
Meal mon	IT.MEALMON		No
Pretreatment day	IT.PKDAY0		No
1-h day	IT.PKDAY1		No
2-h day	IT.PKDAY2		No
3-h day	IT.PKDAY3		No
4-h day	IT.PKDAY4		No
8-h day	IT.PKDAY8		No
16-h day	IT.PKDAY16		No
24-h day	IT.PKDAY24		No
Meal day	IT.MEALDAY		No
Not done	IT.NOTDONE		No
Pretreatment date	IT.PK_DT0		No
1-h date	IT.PK_DT1		No
2-h date	IT.PK_DT2		No
3-h date	IT.PK_DT3		No
4-h date	IT.PK_DT4		No
8-h date	IT.PK_DT8		No
16-h date	IT.PK_DT16		No
24-h date	IT.PK_DT24		No
Date of last meal	IT.MEAL_DT		No
Pretreatment time	IT.PK_TIM0		No
1-h time	IT.PK_TIM1		No
2-h time	IT.PK_TIM2		No
3-h time	IT.PK_TIM3		No
4-h time	IT.PK_TIM4		No
8-h time	IT.PK_TIM8		No
16-h time	IT.PK_TIM16		No
24-h time	IT.PK_TIM24		No
Time of last meal	IT.MEALTIM		No
Investigational Site	IT.SITE		No

Items for Item Group : Physical Exam

Item Name	Item ID	Order Number	Mandatory ?
Internal unique identifier for record	IT.REC_ID		No
Compound	IT.R_DRUG		No
Therapeutic Area	IT.TAREA		No
Protocol Number	IT.PNO		No
Country	IT.SCTRY		No
Record status, 5 levels, internal use	IT.F_STATUS		No
Physical Exam Body System	IT.BODY_SYS		No
Normal/Abnormal/Not Done	IT.ABNORM		No
Comment	IT.COMMT1		No
Investigational Site	IT.SITE		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		
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	

Name	ID	Data Type	Length	Signif. Digits
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	
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	

Name	ID	Data Type	Length	Signif. Digits
4-h mon	IT.PKMON4	text	2	
8-h mon	IT.PKMON8	text	2	
Pretreatment yr	IT.PKYR0	text	4	
1-h year	IT.PKYR1	text	4	
16-h year	IT.PKYR16	text	4	
2-h year	IT.PKYR2	text	4	
24-h year	IT.PKYR24	text	4	
3-h year	IT.PKYR3	text	4	
4-h year	IT.PKYR4	text	4	
8-h year	IT.PKYR8	text	4	
Pretreatment date	IT.PK_DT0	text	8	
1-h date	IT.PK_DT1	text	8	
16-h date	IT.PK_DT16	text	8	
2-h date	IT.PK_DT2	text	8	
24-h date	IT.PK_DT24	text	8	
3-h date	IT.PK_DT3	text	8	
4-h date	IT.PK_DT4	text	8	
8-h date	IT.PK_DT8	text	8	
Pretreatment time	IT.PK_TIM0	text	4	
1-h time	IT.PK_TIM1	text	4	
16-h time	IT.PK_TIM16	text	4	
2-h time	IT.PK_TIM2	text	4	
24-h time	IT.PK_TIM24	text	4	
3-h time	IT.PK_TIM3	text	4	
4-h time	IT.PK_TIM4	text	4	
8-h time	IT.PK_TIM8	text	4	
Protocol Number	IT.PNO	text	15	
Ethnic Group	IT.RACE	text	10	
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	
Investigational Site	IT.SITE	text	15	
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	IT.STOPYR	text	4	

Name	ID	Data Type	Length	Signif. Digits
Digit Year				
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	

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	
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	

Name	Code List Ref.	SAS Field Name	SDS Var Name
Comment		COMMT1	
Date of Birth		DOB	
Dose and Unit		DOSEUNIT	
Assigned Study Drug Treatment	CL.DRUGTRTF	DRUG_TRT	
Record status, 5 levels, internal use	CL.F_STATU	F_STATUS	
Height		HT	
Height Units		HTUNITS	
Conmed Indication		INDIC	
Line Number		LINE_NO	
Meal day		MEALDAY	
Meal mon		MEALMON	
Time of last meal		MEALTIM	
Meal year		MEALYR	
Date of last meal		MEAL_DT	
Medication For Conmed		MEDIC	
Not done		NOTDONE	
Check if Ongoing		ONGOING	
Pretreatment day		PKDAY0	
1-h day		PKDAY1	
16-h day		PKDAY16	
2-h day		PKDAY2	
24-h day		PKDAY24	
3-h day		PKDAY3	
4-h day		PKDAY4	
8-h day		PKDAY8	
Pretreatment mon		PKMON0	
1-h mon		PKMON1	
16-h mon		PKMON16	
2-h mon		PKMON2	
24-h mon		PKMON24	
3-h mon		PKMON3	
4-h mon		PKMON4	
8-h mon		PKMON8	
Pretreatment yr		PKYR0	
1-h year		PKYR1	
16-h year		PKYR16	
2-h year		PKYR2	
24-h year		PKYR24	
3-h year		PKYR3	
4-h year		PKYR4	

Name	Code List Ref.	SAS Field Name	SDS Var Name
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	
Country	CL.SCTRYF	SCTRY	
Gender	CL.SEXF	SEX	
Investigational Site	CL.SITEF	SITE	
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	

Name	Code List Ref.	SAS Field Name	SDS Var Name
Weight		WT	
Weight Units		WTUNITS	

Part 3 :

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

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

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

Additional information for Items :

Code Lists :

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

Name	ID	Data Type	SAS Format Name
AE Action Taken, Study Drug	CL.AEACTTR	text	AEACTTR
AE Action Taken, Other	CL.AECONTR	text	AECONTR
AE Outcome	CL.AEOUT	text	AEOUT
AE Relationship to Study Drug	CL.AEREL	text	AEREL
AE Severity	CL.AESEV	text	AESEV
Assigned Study Drug	CL.DRUGTRTF	integer	DRUGTRTF
Record Status, Internal	CL.F_STATU	text	F_STATU
Normal/Abnormal/Not Done	CL.N_A_ND	integer	N_A_ND
PE Body System	CL.PE_TEST	integer	PE_TEST
Conmed Regimen	CL.REGF	integer	REGF
Conmed Route	CL.ROUTEF	integer	ROUTEF
Country	CL.SCTRYF	text	SCTRYF
Gender	CL.SEXF	text	SEXF
Investigational Site	CL.SITEF	text	SITEF
Therapeutic Area	CL.TAREAF	text	TAREAF

Additional information for CodeList : AE Action Taken, Study Drug

Coded Value	Decoded Value	Language
0	None	en
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
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

Coded Value	Decoded Value	Language
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
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

Coded Value	Decoded Value	Language
M	Male	en

Additional information for CodeList : Investigational Site

Coded Value	Decoded Value	Language
FH	Fred Hutchinson	en
RP	Roswell Park	en

Additional information for CodeList : Therapeutic Area

Coded Value	Decoded Value	Language
ONC	Oncology	en

Presentations : There are no Presentations defined

Administration Data :

User : ID = USR.cdisc001

Full Name : Shirley Williams

First Name : Shirley

Last Name : Williams

Organization: CDISC

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

Signature Definition : ID = SD.cdisc001-es

Methodology : Electronic

Signature Meaning : Signature Meaning

Legal Reason : Legal Reason

Clinical Data: Study = 123-456-789

MetaDataVersion ID = v1.01

Subject Data:

Subject Key = 001

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,	V		

Item	Value	is Null?	Trans.Type
internal use			
Height	73		
Weight	204		
Gender	M		
Date of Birth	19600403		
Ethnic Group	Caucasian		
Height Units	in		
Weight Units	lb		
Investigational Site	RP		

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		

Item	Value	is Null?	Trans.Type
Investigational Site	RP		

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		
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		

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

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		
Investigational Site	RP		

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		

Item	Value	is Null?	Trans.Type
Country	USA		
Record status, 5 levels, internal use	V		
Physical Exam Body System	2		
Normal/Abnormal/Not Done	1		
Investigational Site	RP		

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		
Investigational Site	RP		

Item Group : Physical Exam

Repeat key: 4

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46869804		
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	4		
Normal/Abnormal/Not Done	2		
Comment	MILD WHEEZING		
Investigational Site	RP		

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		
Investigational Site	RP		

Item Group : Physical Exam

Repeat key: 6

Item	Value	is Null?	Trans.Type
Internal unique identifier for record	46870604		
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	6		
Normal/Abnormal/Not Done	2		
Comment	SLIGHTLY ENLARGED-NCS		
Investigational Site	RP		

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		
Investigational Site	RP		

Item Group : Physical Exam

Repeat key: 8

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

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	V		
Physical Exam Body System	8		
Normal/Abnormal/Not Done	3		
Investigational Site	RP		

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		
Investigational Site	RP		

Item Group : Physical Exam

Repeat key: 10

Item	Value	is Null?	Trans.Type
Internal unique identifier	46871504		

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	V		
Physical Exam Body System	10		
Normal/Abnormal/Not Done	2		
Comment	PET		
Investigational Site	RP		

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		
Investigational Site	RP		

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		
Country	USA		
Record status, 5 levels, internal use	V		
Physical Exam Body System	12		
Normal/Abnormal/Not Done	1		
Investigational Site	RP		

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		
Investigational Site	RP		

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		

Item	Value	is Null?	Trans.Type
Derived Stop Date	19990614		
Severity	1		
Relationship to study drug	0		
Outcome	1		
Actions taken re study drug	0		
Actions taken, other	1		
Investigational Site	RP		

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		
Investigational Site	RP		

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	1999		

Item	Value	is Null?	Trans.Type
Digit Year			
Derived Stop Date	19990614		
Dose and Unit	325/MG		
Conmed Route	3		
Conmed Regimen	8		
Conmed Indication	HEADACHE		
Check If Taken for AE	0		
Investigational Site	RP		

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		
Investigational Site	RP		

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