

Clinical Study Data Report

Study Attributes :

Description :

File Type : Snapshot

Granularity : All

File OID : 987-654-321

Creation date and time :
2001-10-16T13:27:45

Prior File OID : 987-654-320

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

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
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
Therapeutic Area	CL.TAREAF	text	TAREAF
LOINC Version 2.0	LOINC	text	LOINC

Additional information for CodeList : AE Action Taken, Study Drug

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

Additional information for CodeList : AE Action Taken, Other

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

Additional information for CodeList : AE Outcome

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

Additional information for CodeList : AE Relationship to Study Drug

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

Picture :



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		

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		

Item	Value	is Null?	Trans.Type
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		

Item	Value	is Null?	Trans.Type
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		

Table of Contents

(automatically generated, layout still needs some improvement)

Study : 123-456-789.....	2
Global Variables	2
Basic Definitions	2
Metadata Version	3
Administration Data : 123-456-789.....	24
User : Shirley Williams.....	24
User : John Smith.....	24
User : Jane Doe.....	25
Location : CDISC Headquarters.....	25
Location : Fred Hutchinson.....	25
Location : Roswell Park.....	26
Signature Definition : Electronic.....	26
Reference Data : 123-456-789.....	27
Item Group Data : Sample Reference Data : Repeat Key : 1.....	27
Item Group Data : Sample Reference Data : Repeat Key : 2.....	27
Clinical Data : 123-456-789.....	28
Subject Data : 001	29
Investigator Reference : John Smith.....	29
Site Reference : Roswell Park.....	29
Study Event Data : Pre-treatment.....	29
Study Event Data : Post-treatment.....	31