

Clinical Study Data Report

Study Attributes :

Description : Two visits for patients P001 and P027, plus updates of data for P001

File Type : Transactional

Granularity : All

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 : HarrisonA

Study Description : Phase II initial efficacy

Protocol Name : B00-2136

Basic Definitions : Units of Measure

There are no Units of Measure defined

Study : 123-456-789

Metadata Version : Release 1

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

Protocol Study Events :

Study Event ID	Order Number	Mandatory ?
VISIT_1		Yes
VISIT_2		Yes

Study Event Definitions :

Name	ID	Repeating ?	Type	Category
Visit1	VISIT_1	No	Scheduled	
Visit2	VISIT_2	No	Scheduled	

Form Definitions :

Name	ID	Repeating ?
Demog and Vitals	PAGE_1	No
Vitals Only	PAGE_2	No

Item Group References for Form : Demog and Vitals

Item Group Name	Item Group ID	Order Number	Mandatory ?
Demog and Vitals	DEMOG		No
Demog and Vitals	VITALS		No

Item Group References for Form : Vitals Only

Item Group Name	Item Group ID	Order Number	Mandatory ?
Vitals Only	VITALS		No

Item Groups :

Part 1 :

Name	ID	Rep.?	Is Ref. Data ?
Demographics	DEMOG	Yes	No
Vital Signs	VITALS	Yes	No

Part 2 :

Name	SAS Dataset	Domain	Origin	Role	Comment
Demographics	DEMOG				
Vital Signs	VITALS				

Items for Item Group : Demographics

Item Name	Item ID	Order Number	Mandatory ?
PT	PT		No
Initials	INITIALS		No
Sex	SEX		No
Date of Birth	DOB		No
Sponsor Patient ID	SPONSOR_PTID		No
Weight in pounds	WEIGHT_LB		No
Weight in kilograms	WEIGHT_KG		No

Items for Item Group : Vital Signs

Item Name	Item ID	Order Number	Mandatory ?
PT	PT		No
Visit	VISITNAME		No
Systolic Blood Pressure	SBP		No
Diastolic Blood Pressure	DBP		No
Sponsor Patient ID	SPONSOR_PTID		No
Occurrence Number	OCCUR_NUM		No

Items :

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

Part 1 :

Name	ID	Data Type	Length	Signif. Digits
PT	PT	text	4	
Initials	INITIALS	text	5	
Date of Birth	DOB	date		
Sex	SEX	text	1	
Systolic Blood Pressure	SBP	integer		
Diastolic Blood Pressure	DBP	integer		
Visit	VISITNAME	text	20	
Sponsor Patient ID	SPONSOR_PTID	text	12	
Numeric Version fo Visit	VISITNUM	integer		
Occurence Number	OCCUR_NUM	integer		
Weight in pounds	WEIGHT_LB	float		
Weight in kilograms	WEIGHT_KG	float		

Part 2 :

Name	Code List Ref.	SAS Field Name	SDS Var Name
PT		PT	
Initials		INITIALS	
Date of Birth		DOB	
Sex	CodeList.001	SEX	
Systolic Blood Pressure		SBP	
Diastolic Blood Pressure		DBP	
Visit		VISNAME	
Sponsor Patient ID		SPONPTID	
Numeric Version fo Visit		VISITNUM	
Occurence Number		OCCURNUM	
Weight in pounds		WEIGHTLB	
Weight in kilograms		WEIGHTKG	

Part 3 :

Name	Origin	Role	Comment
PT			
Initials			
Date of Birth			
Sex			
Systolic Blood Pressure			
Diastolic Blood Pressure			
Visit			
Sponsor Patient ID			

Name	Origin	Role	Comment
Numeric Version fo Visit			
Occurence Number			
Weight in pounds			
Weight in kilograms			

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
Sex	CodeList.001	text	CL001

Additional information for CodeList : Sex

Coded Value	Decoded Value	Language
m	Male	en
f	Female	en

Presentations :

Presentation	ID	Language
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Administration Data :

User : ID = User.001

First Name : John

Last Name : Doe

User : ID = User.002

First Name : Mary

Last Name : Brown

Location : ID = Location.001

Location Name : General Hospital

Location Type : Site

Metadata Version Reference :

Study ID : 123-456-789

Metadata Version ID : MetaDataVersion.001

Effective Date : 2001-10-19T10:45:57-05:00

Signature Definition : ID = SignatureDef.001

Methodology : Electronic

Signature Meaning : Entry

Legal Reason : Signer accepts responsibility for initial data entry

Clinical Data: Study = 123-456-789

MetaDataVersion ID = MetaDataVersion.001

Subject Data:

Subject Key = P001

Transaction Type = Insert

Study Event Data:

Study Event = Visit1

Form Data:

ID = Demog and Vitals

Audit Record for this Form :

User : Mary Brown

Location : General Hospital

Date- and Timestamp : 2001-05-31-T10:08:40-05:00

Signature for this Form :

User : John Doe

Location : General Hospital

Signature Methodology : Electronic

Date- and Timestamp : 2001-05-30T10:06:32-05:00

Item Group : Demographics

Repeat key: 1

Item	Value	is Null?	Trans.Type
PT	P001		
Initials	AMH		
Sex	f		
Date of Birth	1947-07-16		
Sponsor Patient ID	B00-2136-001		
Weight in pounds	150		
Weight in kilograms	68.18		

Item Group : Vital Signs

Repeat key:

Item	Value	is Null?	Trans.Type
PT	P001		
Visit	Visit1		
Systolic Blood Pressure	120		
Diastolic Blood Pressure	80		
Sponsor Patient ID	B00-2136-001		
Occurrence Number	1		

Study Event Data:

Study Event = Visit2

Form Data:

ID = Vitals Only

Audit Record for this Form :

User : Mary Brown

Location : General Hospital

Date- and Timestamp : 2001-05-31T9:06:45-05:00

Signature for this Form :

User : John Doe

Location : General Hospital

Signature Methodology : Electronic

Date- and Timestamp : 2001-05-30T10:06:32-05:00

Item Group : Vital Signs

Repeat key: 1

Item	Value	is Null?	Trans.Type
PT	P001		
Visit	Visit2		
Systolic Blood Pressure	130		
Diastolic Blood Pressure	90		
Sponsor Patient ID	B00-2136-001		
Occurrence Number	1		

Item Group : Vital Signs

Repeat key: 2

Item	Value	is Null?	Trans.Type
PT	P001		
Visit	Visit2		
Systolic Blood Pressure	125		
Diastolic Blood Pressure	86		
Sponsor Patient ID	B00-2136-001		
Occurrence Number	2		

Item Group : Vital Signs

Repeat key: 3

Item	Value	is Null?	Trans.Type
PT	P001		
Visit	Visit2		
Systolic Blood Pressure	122		
Diastolic Blood Pressure	84		
Sponsor Patient ID	B00-2136-001		
Occurrence Number	3		

Subject Data:

Subject Key = P001

Transaction Type = Update

Study Event Data:

Study Event = Visit1

Form Data:

ID = Demog and Vitals

Audit Record for this Form :

User : Mary Brown

Location : General Hospital

Date- and Timestamp : 2001-05-31T08:47:07-05:00

Reason for Change : Error in initial data entry

Signature for this Form :

User : John Doe

Location : General Hospital

Signature Methodology : Electronic

Date- and Timestamp : 2001-05-30T10:06:32-05:00

Item Group : Vital Signs

Repeat key: 1

Item	Value	is Null?	Trans.Type
Systolic Blood Pressure	130		

Subject Data:

Subject Key = P027

Transaction Type = Insert

Study Event Data:

Study Event = Visit1

Form Data:

ID = Demog and Vitals

Audit Record for this Form :

User : Mary Brown

Location : General Hospital

Date- and Timestamp : 2001-05-31-T10:08:40-05:00

Signature for this Form :

User : John Doe

Location : General Hospital

Signature Methodology : Electronic

Date- and Timestamp : 2001-05-30T10:06:32-05:00

Item Group : Demographics

Repeat key: 1

Item	Value	is Null?	Trans.Type
PT	P027		
Initials	VLP		
Sex	f		
Date of Birth	1944-12-20		
Sponsor Patient ID	B00-2136-027		
Weight in pounds	139		
Weight in kilograms	63.04		

Item Group : Vital Signs

Repeat key:

Item	Value	is Null?	Trans.Type
PT	P027		
Visit	Visit1		
Systolic Blood Pressure	115		
Diastolic Blood Pressure	75		
Sponsor Patient ID	B00-2136-027		
Occurrence Number	1		

Study Event Data:

Study Event = Visit2

Form Data:

ID = Vitals Only

Audit Record for this Form :

User : Mary Brown

Location : General Hospital

Date- and Timestamp : 2001-05-31T9:06:45-05:00

Signature for this Form :

User : John Doe

Location : General Hospital

Signature Methodology : Electronic

Date- and Timestamp : 2001-05-30T10:06:32-05:00

Item Group : Vital Signs

Repeat key: 1

Item	Value	is Null?	Trans.Type
PT	P027		
Visit	Visit2		
Systolic Blood Pressure	120		
Diastolic Blood Pressure	90		
Sponsor Patient ID	B00-2136-027		
Occurrence Number	1		

Item Group : Vital Signs

Repeat key: 2

Item	Value	is Null?	Trans.Type
PT	P027		
Visit	Visit2		
Systolic Blood Pressure	120		
Diastolic Blood Pressure	80		
Sponsor Patient ID	B00-2136-027		
Occurrence Number	2		

Item Group : Vital Signs

Repeat key: 3

Item	Value	is Null?	Trans.Type
PT	P027		
Visit	Visit2		
Systolic Blood Pressure	125		
Diastolic Blood Pressure	80		
Sponsor Patient ID	B00-2136-027		
Occurrence Number	3		

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