Clinical Data Acquisition Standards Harmonization (CDASH)

Library of Example CRFs

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1.0 Introduction

The purpose of this document is to provide example CDASH-Conformant Case Report Forms (CRFs) that have been developed for data collection in both paper and electronic data capture (eDC). The CRFs in this document are only examples and are not meant to imply any particular layout is preferable over another.

There are many eDC systems that are used in clinical research. To illustrate how to apply CDASH in these commercial packages, several different vendor-specific CRF examples are included. CDISC does not endorse any specific clinical data management software or vendor. The vendor-specific examples were developed and provided as a courtesy of the volunteer authors of this document and their sponsoring companies, with permission from the respective software vendors.

The examples have been created based on specific use cases which are described in each section. This document is intended to be a library to which conformant CRFs will be added as they are developed and reviewed by the CDASH team.

2.0 Medidata Rave®

There following examples were created using Medidata Rave's study build tool, Architect.

2.1 EX – Exposure

2.1.1 Example - IV Administration

This is an example of an IV Administration log form. The sponsor collects "Yes/No" response for "Was the infusion temporarily interrupted for more than 10 minutes at a time?" in the EXIVINTR variable which will map to SUPPEX. The actual time when the drug was interrupted is collected into the EXINTTIM variable which will map to SUPPEX. The column "RecordPo" (record position) indicates the log line position from the data extract and corresponds with the log line number on the eCRF. This could equate to EXSPID, depending upon the sponsor's data management system.

If the total dose was not administered due to an adverse event, the site can dynamically select the corresponding AE log line number, start date, and term into the AEDSL variable. The AEDSL value would not be submitted in SDTM. The "AE log line number" field will get populated automatically and the value will map to AESPID. If AESPID is populated then this EX record will be linked to related AE record via RELREC in SDTM.

- Row 1 shows a subject with IV administration given without an interruption longer than 10 minutes. The total dose was administered.
- Row 2 shows that subject 100001 had interruption for longer than 10 minutes due to an adverse event (AETERM=VOMITING, AESTDAT=06SEP2011) and this adverse event is recorded on the AE CRF with AESPID=2 (second log line).
- Row 3 shows a subject with an interruption longer than 10 minutes during the IV administration. However, the total dose was administered.

Row	SUBJID	RecordPo	EXSTDAT	EXSTTIM	EXENTIM	EXIVINTR	EXINTTIM	EXPOCCUR	EXVAMT	AEDSL	AESPID
1	100001	1	05-Sep-2011	8:30	10:00	N		Y			
2	100001	1	06-Sep-2011	8:15	9:00	Y	8:40	N	3	002 > 06 SEP 2011 > VOMITING	2
3	100002	1	02-Sep-2011	8:10	9:10	Y	8:35	Y			

Example Rave Annotation

EXSTDAT	Start Date (dd- MMM- yyyy)	_____
EXSTTIM	Actual Start Time	_____
EXENTIM	Actual End Time	_____
EXIVINTR	Was the infusion temporarily interrupted for more than 10 minutes at a time?	Yes ☐ No ☐
EXINTTIM	Actual Time of Interruption	_____
EXPOCCUR	Was the planned dose administered?	Yes ☐ No ☐
EXVAMT	If 'No,' specify the total amount administered (mL)	_____
AEDSL	If 'No' due to AE, select corresponding AE log line number, start date, and term	_____
AESPID	AE log line number	_____

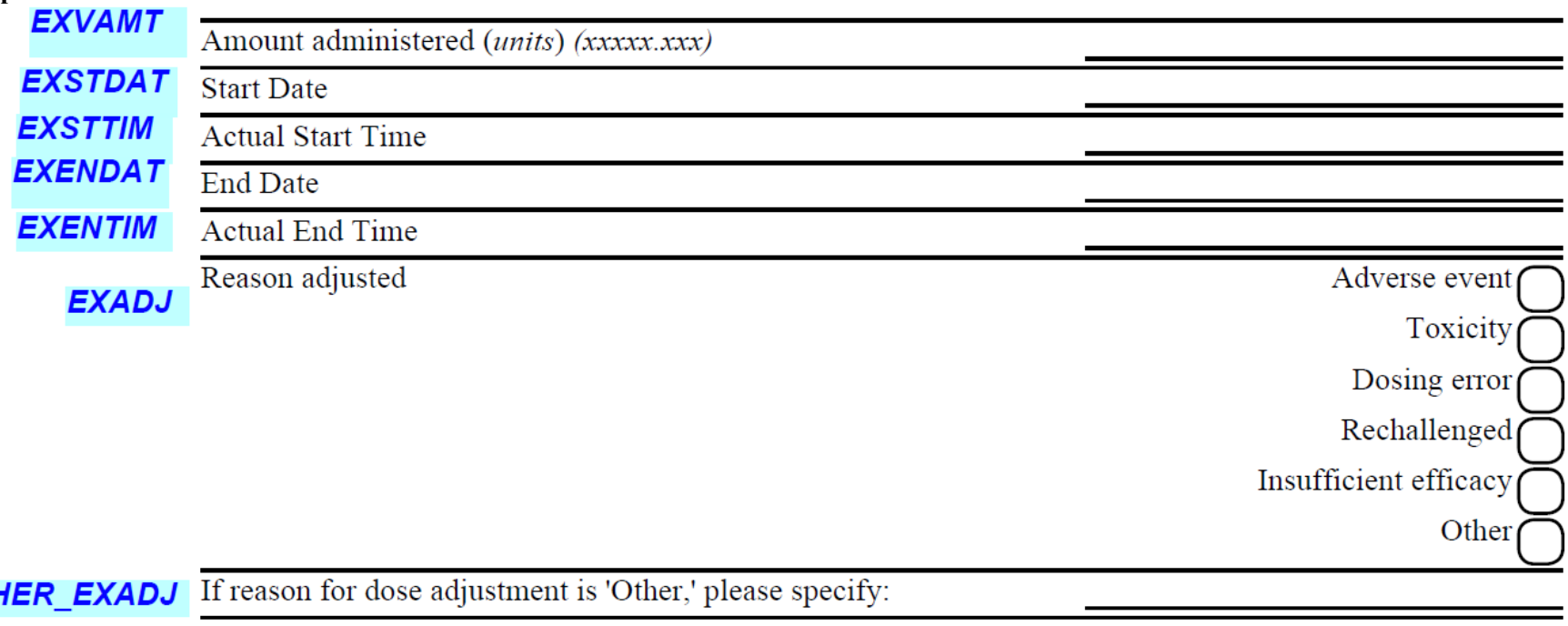
2.1.2 Example - Infusion

This is an example of an Exposure form collecting the infusion information. The "Reason adjusted" field has an option "Other," so the specifications for "Other" are being collected in a free text field and will be mapped to SUPPEX. The column "RecordPo" (record position) indicates the log line position from the data extract and corresponds with the log line number on the eCRF. This could equate to EXSPID, depending upon the sponsor's data management system.

- Row 1 shows a subject with administration adjusted due to an adverse event. The amount of 50 mg was administered.
- Row 2 shows that this subject also had a dose adjustment during the next study drug administration and the reason is collected in the "OTHER_EXADJ" variable.
- Row 3 shows that subject 100002 had a dose adjustment due to a "Toxicity" reason.

Row	SUBJID	RecordPo	EXSTDAT	EXSTTIM	EXENDAT	EXENTIM	EXADJ	OTHER_EXADJ	EXVAMT
1	100001	1	20-Feb-2011	8:30	20-Feb-2011	11:00	ADVERSE EVENT		50
2	100001	1	21-Feb-2011	8:15	21-Feb-2011	10:20	OTHER	IV PUMP FAILURE	60
3	100002	1	19-Feb-2011	8:02	19-Feb-2011	9:10	TOXICITY		60

Example Rave Annotation



2.1.3 Example - Subcutaneous Administration

The sponsor is collecting who administered the subcutaneous study agent. The value is collected in the EXADMAGN variable, which will map to SUPPEX. The column "RecordPo" (record position) indicates the log line position from the data extract and corresponds with the log line number on the eCRF. This could equate to EXSPID, depending upon the sponsor's data management system.

If the planned dose was not administered due to an adverse event, the site can dynamically select the corresponding AE log line number, start date, and term into the AEDSL variable. The AEDSL value would not be submitted in SDTM. The "AE log line number" field will get populated automatically and the value will map to AESPID. If AESPID is populated then this EX record will be linked to related AE record via RELREC in SDTM.

- Row 1 shows a subject with subcutaneous administration self administered into the abdomen. The planned dose was administered.
- Row 2 shows that subject 100001was administered by a health care provider and did not get the planned dose administered due to an adverse event (AETERM=NAUSEA, AESTDAT=06SEP2010). This adverse event is recorded on the AE CRF with AESPID=1 (first log line).
- Row 3 shows a subject who was administered the subcutaneous study agent by "Other" into the right thigh. The planned dose was administered.

Row	SUBJID	RecordPo	EXSTDAT	EXSTTIM	EXLOC	EXADMAGN	EXPOCCUR	AEDSL	AESPID
1	100001	1	05-Sep-2010	9:00	ABDOMEN	SUBJECT SELF ADMINISTERED	Y		
2	100001	1	06-Sep-2010	9:15	LEFT THIGH	HEALTH CARE PROVIDER	N	001 > 06 SEP 2010 > NAUSEA	1
3	100002	1	07-Sep-2010	9:10	RIGHT THIGH	OTHER	Y		

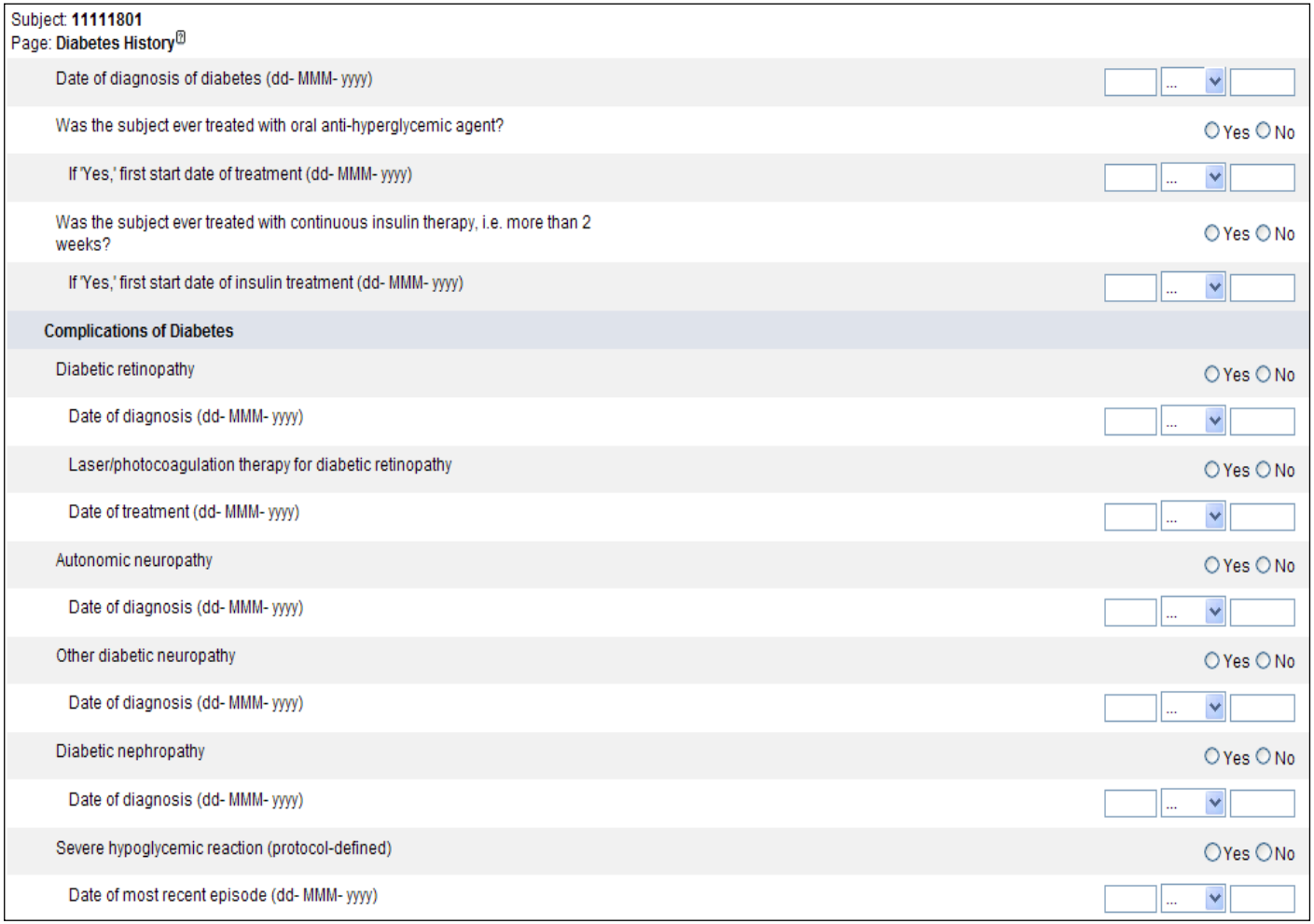
Example Rave Annotation

EXSTDAT	Start Date (dd- MMM- yyyy)	
EXSTTIM	Actual Start Time	
EXLOC	What was the anatomical location of the administration?	Upper right arm ☐ Upper left arm ☐ Abdomen ☐ Left thigh ☐ Right thigh ☐
EXADMAGN	Administrator of subcutaneous study agent	Health care provider ☐ Subject self administerd ☐ Other ☐
EXPOCCUR	Was the planned dose administered?	Yes ☐ No ☐
AEDSL	If 'No' due to AE, select corresponding AE log line number, start date, and term	
AESPID	AE log line number	

2.2 MH – Medical History

2.2.1 Example - Diabetes History

Screenshot from Medidata Rave tool:



Subject: **11111801**
Page: **Diabetes History**

Date of diagnosis of diabetes (dd- MMM- yyyy)	...
Was the subject ever treated with oral anti-hyperglycemic agent?	Yes No
If 'Yes,' first start date of treatment (dd- MMM- yyyy)	...
Was the subject ever treated with continuous insulin therapy, i.e. more than 2 weeks?	Yes No
If 'Yes,' first start date of insulin treatment (dd- MMM- yyyy)	...
Complications of Diabetes	
Diabetic retinopathy	Yes No
Date of diagnosis (dd- MMM- yyyy)	...
Laser/photocoagulation therapy for diabetic retinopathy	Yes No
Date of treatment (dd- MMM- yyyy)	...
Autonomic neuropathy	Yes No
Date of diagnosis (dd- MMM- yyyy)	...
Other diabetic neuropathy	Yes No
Date of diagnosis (dd- MMM- yyyy)	...
Diabetic nephropathy	Yes No
Date of diagnosis (dd- MMM- yyyy)	...
Severe hypoglycemic reaction (protocol-defined)	Yes No
Date of most recent episode (dd- MMM- yyyy)	...

The sponsor is collecting diabetes history and if a subject had the complications associated with diabetes. The sponsor is interested in the start date of each diagnosis/treatment. The format "(dd- MMM- yyyy)" requires the year but the month and date can be unknown. The occurrences of two concomitant medications are collected along with the SUOCCUR for the "Laser/photocoagulation therapy for diabetic retinopathy" and other medical histories. The MHOCCUR and MHSTDAT CDASH variables are named and annotated based on the terms specified in the labels. Other diabetic complications should be collected on general Medical History eCRF. The table below is the sample output from the operational database for two subjects' CRFs. The output has **not**

yet been converted to SDTM. The column "RecordPo" (record position) indicates the log line position from the data extract and corresponds with the log line number on the eCRF. This could equate to MHSPID, depending upon the sponsor's data management system.

Row 1 shows an example of a subject who was treated with oral anti-hyperglycemic agent and insulin treatment. This subject does not have any complications associated with diabetes.

Row 2 shows an example of a subject with only the known year of the diabetes diagnosis as well as the year of starting the treatment with oral anti-hyperglycemic agent. This subject was diagnosed with autonomic neuropathy in 2006.

Row	SUBJID	Record Po	DIABETES_ MHSTDAT	DIABETES_ CMOCCUR	DIABETES_ CMSTDAT	INSULIN_ CMOCCUR	INSULIN_ CMSTDAT	RETINOPATHY_ MHOCCUR	RETINOPATHY _MHSTDAT	SGOCCUR	SGSTDAT
1	100001	1	03-Jan-2003	Y	03-Jan-2003	Y	08-Mar-2011	N		N	
2	100002	1	UN-UNK-2005	Y	UN-UNK-2005	N		N		N	

Row	AUTONOMIC_ NEUROPATHY_ MHOCCUR	AUTONOMIC_ NEUROPATHY_ MHSTDAT	OTHER_DIABETIC_ NEUROPATHY_ MHOCCUR	OTHER_DIABETIC_ NEUROPATHY_ MHSTDAT	DIABETIC_ NEPHROPATHY_ MHOCCUR	DIABETIC_ NEPHROPATHY_ MHSTDAT	SEVERE_ HYPOGLYCEMIC_R EACTION_ MHOCCUR	SEVERE_ HYPOGLYCEMIC_R EACTION_ MHSTDAT
1 (cont)	N		N		N		N	
2 (cont)	Y	UN-UNK-2006	N		N		N	

Example Rave Annotation

Date of diagnosis of diabetes (dd- MMM- yyyy) DIABETES_MHSTDAT

Was the subject ever treated with oral anti-hyperglycemic agent? Yes ☐ No ☐
DIABETES_CMOCCUR

If 'Yes,' first start date of treatment (dd- MMM- yyyy) DIABETES_CMSTDAT

Was the subject ever treated with continuous insulin therapy, i.e. more than 2 weeks? Yes ☐ No ☐
INSULIN_CMOCCUR

If 'Yes,' first start date of insulin treatment (dd- MMM- yyyy) INSULIN_CMSTDAT

Complications of Diabetes

Diabetic retinopathy Yes ☐ No ☐
RETINOPATHY_MHOCCUR

Date of diagnosis (dd- MMM- yyyy) RETINOPATHY_MHSTDAT

Laser/photocoagulation therapy for diabetic retinopathy Yes ☐ No ☐
SGOCCUR

Date of treatment (dd- MMM- yyyy) SGSTDAT

Autonomic neuropathy Yes ☐ No ☐
AUTONOMIC_NEUROPATHY_MHOCCUR

Date of diagnosis (dd- MMM- yyyy) AUTONOMIC_NEUROPATHY_MHSTDAT

Other diabetic neuropathy Yes ☐ No ☐
OTHER_DIABETIC_NEUROPATHY_MHOCCUR

Date of diagnosis (dd- MMM- yyyy) OTHER_DIABETIC_NEUROPATHY_MHSTDAT

Diabetic nephropathy Yes ☐ No ☐
DIABETIC_NEPHROPATHY_MHOCCUR

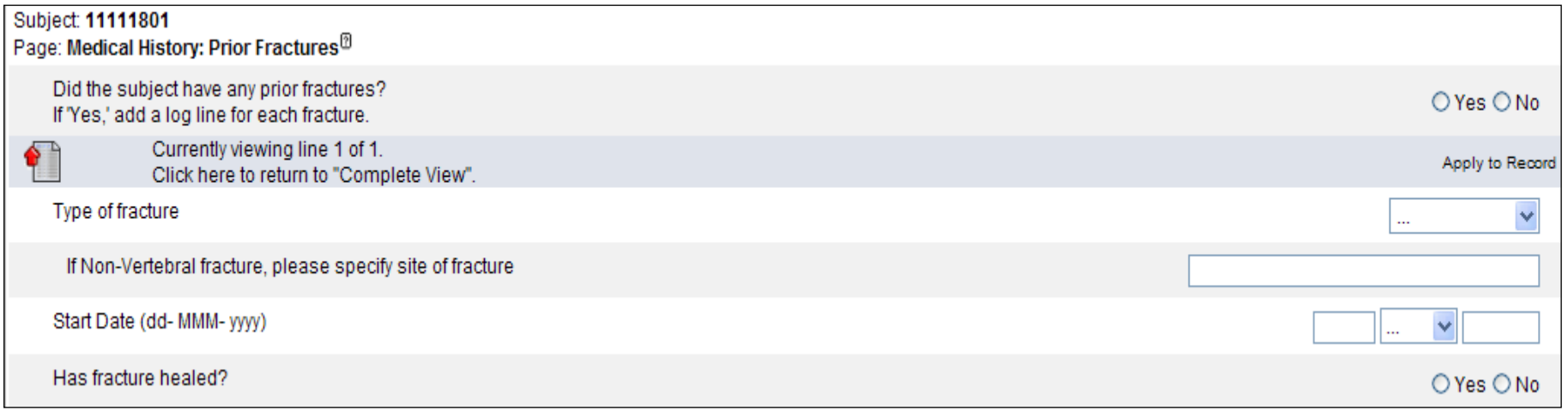
Date of diagnosis (dd- MMM- yyyy) DIABETIC_NEPHROPATHY_MHSTDAT

Severe hypoglycemic reaction (protocol-defined) Yes ☐ No ☐
SEVERE_HYPOGLYCEMIC_REACTION_MHOCCUR

Date of most recent episode (dd- MMM- yyyy) SEVERE_HYPOGLYCEMIC_REACTION_MHSTDAT

2.2.2 Example - Medical History: Prior Fractures

Screenshot from Medidata Rave tool:



The sponsor is collecting information regarding all fractures that a subject may have had. This CRF is a log form. A new log line should be added to enter fracture information. If a subject did not have any prior fractures, the answer to the leading question MHYN would be "No" and no log lines would be added. The data extract from the system includes the RecordPo (Record position) variable which corresponds with each entered log line on this CRF. This could equate to MHSPID, depending upon the sponsor's data management system. The MHONGO variable will be mapped into the SDTM MHENRTPT variable using the controlled terminology for MHENRTPT.

Row 1 shows an example of a subject that does not have any prior fractures to report. (This is for illustrative purposes. There would be no record in an SDTM data set.)

Rows 2-4 show a subject with two non-vertebral fractures and one vertebral fracture that did not yet heal. The MHLOC is being collected for the non-vertebral fractures.

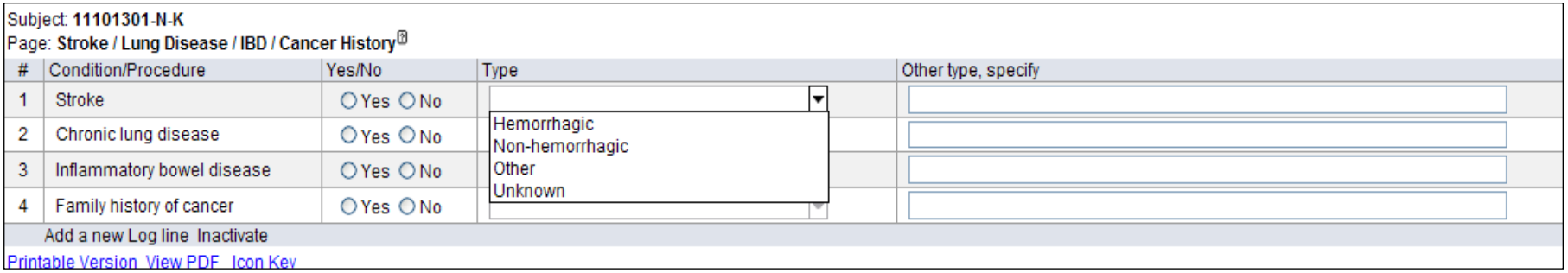
Row	SUBJID	RecordPo	MHYN	FRACTURE_MHTERM	MHLOC	MHSTDAT	MHONGO
1	100001	1	N				
2	100002	1	Y	NON-VERTEBRAL FRACTURE	LEFT ARM	UN-UNK-2001	Y
3	100002	2	Y	VERTEBRAL FRACTURE		UN-UNK-1987	N
4	100002	3	Y	NON-VERTEBRAL FRACTURE	NOSE	UN-UNK-1967	Y

Example Rave Annotation

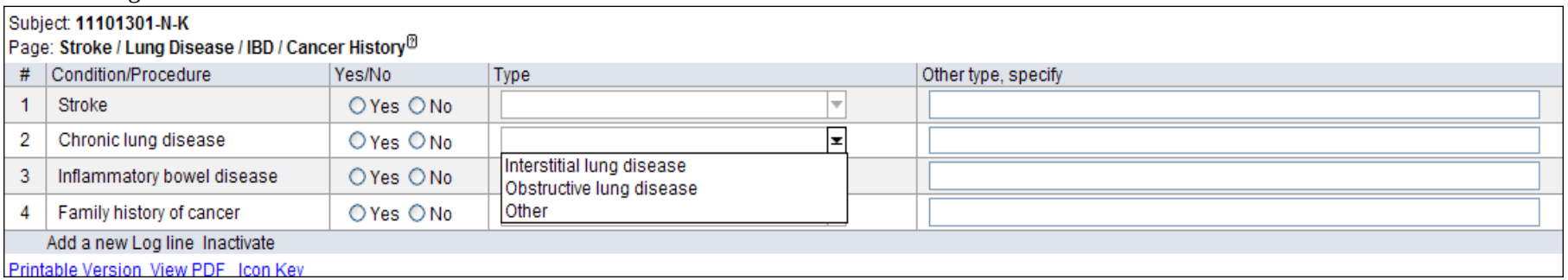
MHYN	Did the subject have any prior fractures? If 'Yes,' add a log line for each fracture.	Yes ☐ No ☐
FRACTURE_MHTERM	Type of fracture	Non-vertebral ☐ Vertebral ☐
MHLOC	If Non-Vertebral fracture, please specify site of fracture	_____
MHSTDAT	Start Date (dd- MMM- yyyy)	_____
MHONGO	Has fracture healed?	Yes ☐ No ☐

2.2.3 Example - Stroke / Lung Disease / IBD / Cancer History

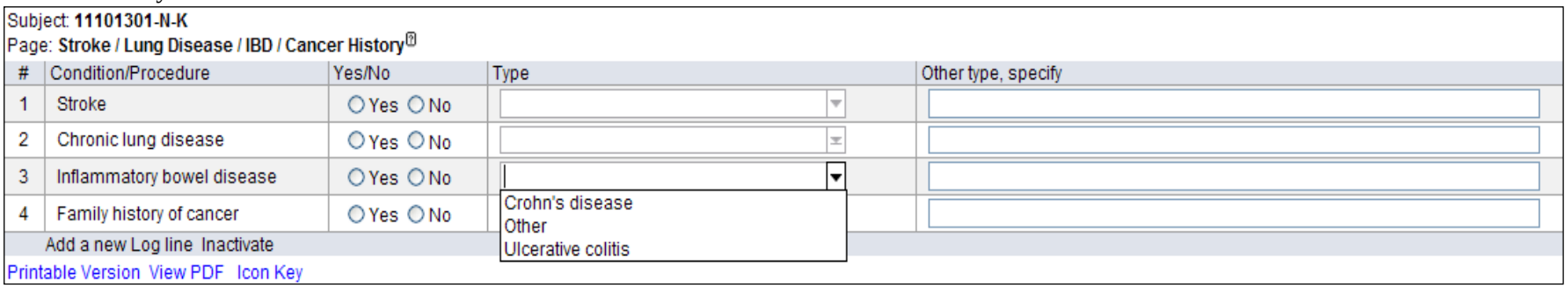
The type drop-down list is based on Rave's dynamic searchlist functionality, set up with different values based on the condition.
See the screenshots below showing the values generated for each condition:
Stroke:



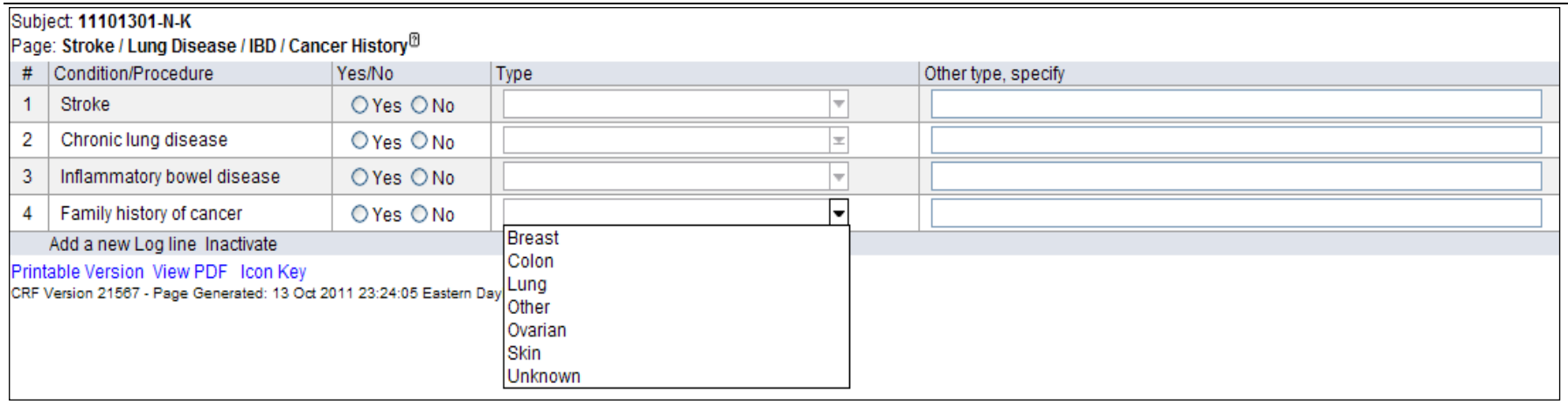
Chronic lung disease:



3. Inflammatory bowel disease:



4. Family history of cancer:



This CRF has four pre-printed four conditions. The data extract from the system includes the RecordPo (Record position) variable which corresponds with each pre-printed log line number. This could equate to MHSPID, depending upon the sponsor's data management system. The MHTYP and MHTYPOTH are sponsor defined variables which will map to SUPPMH. It is possible to enter only one case of a family history of cancer. Therefore, the physician will decide on the most severe case that will be entered.

Rows 1-4 show a subject with MHOCCUR value of "Y" for two conditions. The values "CERVICAL" and "INTERSTITIAL LUNG DISEASE" will map to the sponsor-defined MHTYP variable in SUPPMH.
Rows 5-8 show a subject with only one confirmed condition. The type of stroke will map to the sponsor-defined MHTYP variable in SUPPMH.

Row	SUBJID	RecordPo	MHTERM	MHOCCUR	MHTYP	MHTYPOTH
1	100001	1	STROKE	N		
2	100001	2	CHRONIC LUNG DISEASE	Y	INTERSTITIAL LUNG DISEASE	
3	100001	3	INFLAMMATORY BOWEL DISEASE	N		
4	100001	4	FAMILY HISTORY OF CANCER	Y	OTHER	CERVICAL
5	100002	1	STROKE	Y	NON-HEMORRHAGIC	
6	100002	2	CHRONIC LUNG DISEASE	N		
7	100002	3	INFLAMMATORY BOWEL DISEASE	N		
8	100002	4	FAMILY HISTORY OF CANCER	N		

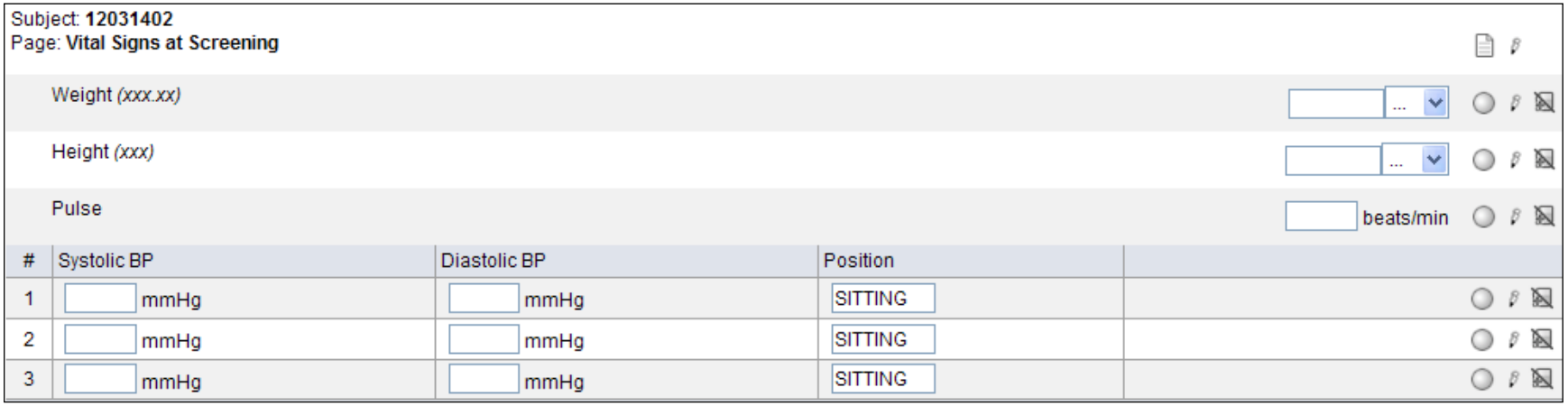
Example Rave Annotation

Condition/Procedure **MHTERM**	Stroke ■ Chronic lung disease ☐ Inflammatory bowel disease ☐ Family history of cancer ☐
Yes/No **MHOCCUR**	Yes ☐ No ☐
Type **MHTYP**	
Other type, specify **MHTYPOTH**	

2.3 VS – Vital Signs

2.3.1 Example - Vital Signs at Screening

Screenshot from Medidata Rave tool:



This is an example of a vitals CRF collecting weight, height, pulse and triplicate blood pressure measurements at a screening visit. The "(xxx.xx)" part of the field's label indicates the acceptable numeric format of the result. The sponsor collects triplicate blood pressure measurements in sitting position based on the trial's protocol. Therefore, the position values are defaulted and are not enterable by a site. The fixed unit values are printed on the CRF. The column "RecordPo" (record position) indicates the log line position from the data extract and corresponds with the log line number on the eCRF. This could equate to VSSPID depending upon the sponsor's data management system. The values for weight, height, and pulse are collected on the flat part of the form and are repeated for each record position. The table below is the sample output from the operational database for two subjects' CRFs.

Rows 1-3 show an example for subject 100001.

Rows 4-6 show an example for subject 100002.

Row	SUBJID	RecordPo	WEIGHT_VSORRES	WEIGHT_VSORRESU	HEIGHT_VSORRES	HEIGHT_VSORRESU	PULSE_VSORRES	PULSE_VSORRESU
1	100001	1	82.6	kg	167	cm	60	BEATS/MIN
2	100001	2	82.6	kg	167	cm	60	BEATS/MIN
3	100001	3	82.6	kg	167	cm	60	BEATS/MIN
4	100002	1	84.5	kg	174	cm	64	BEATS/MIN
5	100002	2	84.5	kg	174	cm	64	BEATS/MIN
6	100002	3	84.5	kg	174	cm	64	BEATS/MIN

Row	BP_SYSBP_VSORRES	BP_SYSBP_VSORRESU	BP_DIABP_VSORRES	BP_DIABP_VSORRESU	BP_VSPOS

1 (cont)	138	mmHg	88	mmHg	SITTING
2 (cont)	132	mmHg	84	mmHg	SITTING
3 (cont)	136	mmHg	82	mmHg	SITTING
4 (cont)	130	mmHg	62	mmHg	SITTING
5 (cont)	134	mmHg	64	mmHg	SITTING
6 (cont)	136	mmHg	68	mmHg	SITTING

Example Rave Annotation

Weight *(xxx.xx)* **kg** ☐
WEIGHT_VSORRES WEIGHT_VSORRESU LB ☐

Height *(xxx)* **cm** ☐
HEIGHT_VSORRES HEIGHT_VSORRESU IN ☐

Pulse Fixed Unit: beats/min
PULSE_VSORRES

Pulse Unit PULSE_VSORRESU

Systolic Blood Pressure Fixed Unit: mmHg
BP_SYSBP_VSORRES

Blood Pressure Unit BP_SYSBP_VSORRESU mmHg

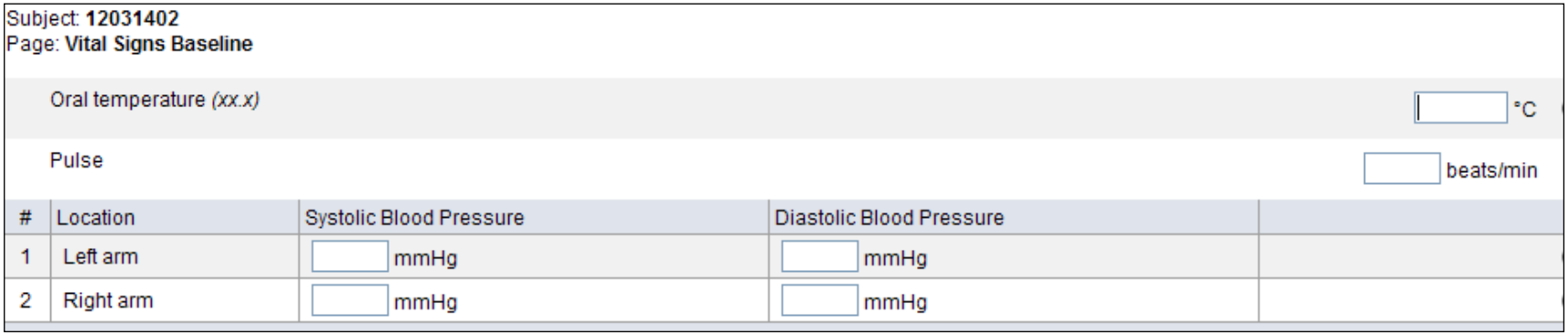
Diastolic Blood Pressure Fixed Unit: mmHg
BP_DIABP_VSORRES

Blood Pressure Unit BP_DIABP_VSORRESU mmHg

Position BP_VSPOS SITTING

2.3.2 Example - Vital Signs at Baseline

Screenshot from Medidata Rave tool:



In this example, the sponsor is collecting oral temperature and pulse once on the top part (flat part) of the above CRF. The blood pressure measurements are collected on both arms. The "(xx.x)" part of the field's label indicates the acceptable numeric format of the result.

The table below is the sample output from the operational database for two subjects' CRFs. The location values for the blood pressure measurements are defaulted and are not enterable by a site. The fixed unit values are printed on the CRF but the fields with defaulted unit values are view restricted and not visible to the site. However, the defaulted unit values appear in the output as shown below. The column "RecordPo" (record position) indicates the log line position from the data extract and corresponds with the log line number on the eCRF. This could equate to VSSPID, depending upon the sponsor's data management system. The values for temperature and pulse are collected on the flat part of the form and are repeated for each record position.

Rows 1-2 show an example for subject 100001.

Rows 3-4 show an example for subject 100002.

Row	SUBJID	RecordPo	TEMP_ VSORRES	TEMP_ VSORRESU	PULSE_ VSORRES	PULSE_ VSORRESU	VSLOC	BP_SYSBP_ VSORRES	BP_SYSBP_ VSORRESU	BP_DIABP_ VSORRES	BP_DIABP_ VSORRESU
1	100001	1	36.8	C	60	BEATS/MIN	LEFT ARM	138	mmHg	88	mmHg
2	100001	2	36.8	C	60	BEATS/MIN	RIGHT ARM	136	mmHg	84	mmHg
3	100002	1	36.2	C	64	BEATS/MIN	LEFT ARM	120	mmHg	80	mmHg
4	100002	2	36.2	C	64	BEATS/MIN	RIGHT ARM	120	mmHg	80	mmHg

Example Rave Annotation

Oral temperature *(xx.x)* **TEMP_VSORRES**	Fixed Unit: °C
Temperature unit	**TEMP_VSORRESU**
Pulse **PULSE_VSORRES**	Fixed Unit: beats/min
Pulse Unit	**PULSE_VSORRESU**
Location **VSLOC**	Left arm ■ Right arm ☐
Systolic Blood Pressure **BP_SYSBP_VSORRES**	Fixed Unit: mmHg
Blood Pressure Unit	**BP_SYSBP_VSORRESU** mmHg
Diastolic Blood Pressure **BP_DIABP_VSORRES**	Fixed Unit: mmHg
Blood Pressure Unit	**BP_DIABP_VSORRESU** mmHg

3.0 Oracle Health Sciences InForm®

There following examples were created using Oracle Health Sciences' study build tool for InForm, Central Designer.

3.1 AE – Adverse Events

3.1.1 Example - General Adverse Events

This is an example of an AE CRF collecting data as an ancillary log. The sponsor wishes to track all changes of severity for a continuous event **and** analyze each severity change as an individual record. Upon an affirmative response to AEYN for a subject, the data management system creates a parent record for the AETERM and generates an AEGRPID. An add-entry, child record is entered for the initial severity and any subsequent severities. The data management system creates an AESPID for each child record and applies the parent record's AEGRPID as a foreign key. The sponsor has defined a code list for AERELNST. The sponsor has created their own variable to denote if the event is a dose limiting toxicity, which will map to SUPPAE.

- Row 1 shows an example of a subject that does not have any AEs to report.
- Row 2 shows an example of an event that has only one severity.
- Row 3 shows an example of an event that has only one severity, but is attributed to one of the sponsor defined AERELNST values.
- Rows 4-6 show an example of a subject that has an AE with multiple severity changes, and is continuing at the time of Disposition.

Row	SUBJID	AEYN	AEGRPID	AETERM	AESPID	AESTDAT	AEONGO	AEENDAT	AETOXGR	AESER	AESCONG
1	101	N									
2	102	Y	1	HEADACHE	1	02-JAN-2012	N	02-JAN-2012	1	N	N
3	103	Y	1	RASH	1	05-JAN-2012	N	6-JAN-2012	1	N	N
4	103	Y	2	HYPERTENSION	1	07-JAN-2012	N	09-JAN-2012	2	N	N
5	103	Y	2	HYPERTENSION	2	09-JAN-2012	N	11-JAN-2012	4	Y	N
6	103	Y	2	HYPERTENSION	3	11-JAN-2012	Y		1	Y	N

Row	AEDISAB	AESDTH	AESHOSP	AESLIFE	AESMIE	AEREL	AERELNST	AEOUT	AEACN	AEDLTOXFLG
1 (cont)										
2 (cont)	N	N	N	N	N	N		RECOVERED/RESOLVED	DOSE NOT CHANGED	N
3 (cont)	N	N	N	N	N	N	STUDY DEVICE	RECOVERED/RESOLVED	DOSE NOT CHANGED	N
4 (cont)	N	N	N	N	N	Y		NOT RECOVERED/NOT RESOLVED	DOSE REDUCED	Y
5 (cont)	N	N	Y	Y	N	Y		RECOVERING/RESOLVING	DRUG INTERRUPTED	Y
6 (cont)	N	N	N	N	N	Y		RECOVERED/RESOLVED WITH SEQUELAE	DRUG WITHDRAWN	Y

StudyDesign: Adverse Events (AE_UseCase1) [AE_UseCase1]

Event Experienced [igAE_UseCase1_YN]

1.	Were any adverse events experienced? [Any AEs?]	**[AEYN]** *[A:N]* ◯ No *[A:Y]* ◯ Yes

	AE Group ID	Adverse Event
2.		

Event Term Entry [igAE_UseCase1_H]

2.1*	AE Group ID *[read-only]* [AE Group ID]	**[AEGRPID]** N4
2.2*	What is the adverse event term? [Adverse Event]	**[AETERM]** A200

	AE Number	Start Date	Ongoing	Toxicity Grade	Serious	Relationship to Study Treatment	Relationship to Non-Study Treatment	Outcome	Action Taken with Study Treatment	Dose Limiting Toxicity
3.										

Event Details Entry [igAE_UseCase1_D]

3.1*	AE Identifier *[read-only]* [AE Number]	**[AESPID]** N4
3.2*	What is the date the adverse event started? [Start Date]	**[AESTDAT]** Req / Req/Unk / Req (2012-2014)
3.3	Is the adverse event still ongoing? [Ongoing]	**[AEONGO]** *[A:N]* ◯ **[AEENDAT]** No End Date Req / Req / Req (2012-2014) *[A:Y]* ◯ Yes
3.4*	What is the toxicity grade of the adverse event? [Toxicity Grade]	**[AETOXGR]** **[clTOXGR]**
3.5*	Is the adverse event serious? [Serious]	**[AESER]** *[A:N]* ◯ No *[A:Y]* ◯ **[AESER_CMDP]** Yes, Answer all Seriousness Categories Below **[AESCONG]** *[A:N]* ◯ No *[A:Y]* ◯ Yes Congenital Anomaly or Birth Defect **[AESDISAB]** *[A:N]* ◯ No *[A:Y]* ◯ Yes Significant Disability **[AESDTH]** *[A:N]* ◯ No *[A:Y]* ◯ Yes Death **[AESHOSP]** *[A:N]* ◯ No *[A:Y]* ◯ Yes Hospitalization **[AESLIFE]** *[A:N]* ◯ No *[A:Y]* ◯ Yes Life Threatening **[AESMIE]** *[A:N]* ◯ No *[A:Y]* ◯ Yes Other Medically Important Event
3.6*	Is this event related to study treatment? [Relationship to Study Treatment]	**[AEREL]** *[A:N]* ◯ No *[A:Y]* ◯ Yes
3.7	Relationship to Non-Study Treatment [Relationship to Non-Study Treatment]	**[AERELNST]** *[A:ADJUNCT THERAPY]* ☐ Adjunct Therapy *[A:CONCOMITANT THERAPY]* ☐ Concomitant Therapy *[A:STUDY DEVICE]* ☐ Study Device *[A:STUDY DISEASE]* ☐ Study Disease

		[A:STUDY PROCEDURE] ☐ Study Procedure *[A:OTHER MEDICAL CONDITION]* ☐ Other Medical Condition
3.8*	What was the outcome of this adverse event? [Outcome]	**[AEOUT]** **[clOUT]**
3.9	What action was taken with study treatment? [Action Taken with Study Treatment]	**[AEACN]** **[clAEACN]**
3.10	Is this event a dose limiting toxicity? [Dose Limiting Toxicity]	**[AEDLTOXFLG]** *[A:N]* ◯ No *[A:Y]* ◯ Yes
3.11	AE Group ID *[hidden]* [AE Group ID]	**[AEGRPID_FK]** N10

Key: [*] = Item is required [✔] = Source verification required

Study Object Descriptions: Adverse Events

Type	RefName	Description
Form	AE_UseCase1	Adverse Events CRF using AETOXGR.
Item	AEYN	Does not map to SDTM. The CRF should be annotated to indicate that this field is NOT SUBMITTED.
Section	igAE_UseCase1_H	Oncology Adverse Events - Header
Item	AEGRPID	AEGRPID
Item	AETERM	AETERM
Section	igAE_UseCase1_D	Oncology Adverse Event - Details
Item	AESPID	AESPID
Item	AESTDAT	AESTDTC
Item	AEONGO	Used to derive AEENRF or AEENRTPT.
Item	AEENDAT	AEENDTC
Item	AETOXGR	AETOXGR
Item	AESER	AESER
Item	AESCONG	AESCONG
Item	AESDISAB	AESDISAB
Item	AESDTH	AESDTH
Item	AESHOSP	AESHOSP
Item	AESLIFE	AESLIFE
Item	AESMIE	AESMIE
Item	AEREL	AEREL
Item	AERELNST	Sponsor-defined example using a codelist for AERELNST. If more than one AERELNST value is selected, AERELNST is derived to equal 'MULTIPLE' and individual responses may be mapped to SUPPAE.
Item	AEOUT	AEOUT
Item	AEACN	AEACN
Item	AEDLTOXFLG	Sponsor-defined variable. Maps to SUPPAE.QVAL where QNAM = AEDLTOXF
Item	AEGRPID_FK	System Foreign Key to tie child records to parent AEGRPID record.

Codelist Values and Tables: Adverse Events

Codelist RefName	Codelist Data Type	Label	Code	Codelist Item RefName	Data Variable RefName
clNY_NY	String	No	N	C49487	AEYN, AEONGO, AESER, AESCONG, AESDISAB, AESDTH, AESHOSP,
		Yes	Y	C49488	

					AESLIFE, AESMIE, AEREL, AEDLTOXFLG
clTOXGR	Integer	Absent	0	C75533	AETOXGR
		Mild	1	C84263	
		Moderate	2	C84264	
		Severe	3	C84265	
		Life Threatening	4	C84266	
		Fatal	5	C48275_C87162	
clAERELNST	String	Adjunct Therapy	ADJUNCT THERAPY	AERELNST_1	AERELNST
		Concomitant Therapy	CONCOMITANT THERAPY	AERELNST_2	
		Study Device	STUDY DEVICE	AERELNST_3	
		Study Disease	STUDY DISEASE	AERELNST_4	
		Study Procedure	STUDY PROCEDURE	AERELNST_5	
		Other Medical Condition	OTHER MEDICAL CONDITION	AERELNST_6	
clOUT	String	Death Related to Adverse Event	FATAL	C48275	AEOUT
		Not Recovered or Not Resolved	NOT RECOVERED/NOT RESOLVED	C49494	
		Recovered or Resolved	RECOVERED/RESOLVED	C49498	
		Recovered or Resolved with Sequelae	RECOVERED/RESOLVED WITH SEQUELAE	C49495	
		Recovering or Resolving	RECOVERING/RESOLVING	C49496	
		Unknown	UNKNOWN	C17998	
clAEACN	String	Dose Increased	DOSE INCREASED	C49503	AEACN
		Dose Not Changed	DOSE NOT CHANGED	C49504	
		Dose Reduced	DOSE REDUCED	C49505	
		Drug Interrupted	DRUG INTERRUPTED	C49501	
		Drug Withdrawn	DRUG WITHDRAWN	C49502	
		Not Applicable	NOT APPLICABLE	C48660	
		Unknown	UNKNOWN	C17998	

3.2 CM – Concomitant Medications

3.2.1 Example – Concomitant Therapy

This is an example of a CM CRF collecting General Medications that were ongoing at the time of study entry and/or started after study entry. The sponsor has a separate page for General Medications that were stopped prior to study entry.

Row 1 shows an example of a subject that does not have any CMs to report.

Row 2 shows an example of a subject who takes an aspirin every day, prophylactically. The use of this medication started before study entry.

Row 3 shows an example of a subject who took Motrin to treat an adverse event.

Row 4 shows an example of a subject who took Benadryl to treat an adverse event.

Row 5 shows an example of a subject who took Nifedipine to treat an adverse event. Use of this medication is continuing at disposition.

Row	SUBJID	CMYN	CMSPID	CMTRT	CMSTDAT	CMONGO	CMENDAT	CMDOSE	CMDOSU	CMDOSFRM	CMDOSFRQ
1	101	N									
2	102	Y	1	ASPIRIN	2006	Y		80	mg	TABLET	QD
3	102	Y	2	MOTRIN	2-JAN-2012	N	2-JAN-2012	400	mg	CAPSULE	PRN
4	103	Y	1	BENADRYL	5-JAN-2012	N	6-JAN-2012	25	mg	TABLET	TID
5	103	Y	2	NIFEDIPINE	7-JAN-2012	Y		30	mg	CAPSULE	QD

Row	CMROUTE	CMINDC	CMAENO
1 (cont)			
2 (cont)	ORAL	PROPHYLAXIS	
3 (cont)	ORAL	ADVERSE EVENT	1
4 (cont)	ORAL	ADVERSE EVENT	1
5 (cont)	ORAL	ADVERSE EVENT	2

StudyDesign: Concomitant Medication - General Concomitant Medications (CM_UseCase1a) - Repeating Form [CM_UseCase1a]

#	Were any medications taken?	Concomitant Medication Details
1		

Concomitant Medications Taken [igCM_UseCase1a_YN]

1.	Were any medications taken?	**[CMYN]** *[A:N]* ◯ No *[A:Y]* ◯ Yes

	CM Number	Medication	Start Date	Ongoing	Dose	Dose Units	Dose Form	Frequency	Route	Indication	AE ID
2.											

2.1*	What is the medication / treatment identifier? *[read-only]* [CM Number]	**[CMSPID]** N3
2.2*	What was the term for the medication / therapy taken? [Medication]	**[CMTRT]** A200
2.3	What was the start date of the medication / therapy? [Start Date]	**[CMSTDAT]** NReq/Unk / NReq/Unk / NReq (2012-2014)
2.4	Is the medication / therapy still ongoing? [Ongoing]	**[CMONGO]** *[A:N]* ◯ **[CMENDAT]** No End Date NReq/Unk / NReq/Unk / Req (2012-2014) *[A:Y]* ◯ Yes
2.5	What was the individual dose of the medication / therapy? [Dose]	**[CMDSTXT]** A20
2.6	What was the unit of the medication / therapy? [Dose Units]	**[CMDOSU]** **[clCMDOSU]**
2.7	What was the dose form of the medication / therapy? [Dose Form]	**[CMDOSFRM]** **[clCMDOSFRM]**
2.8	What was the frequency of the medication / therapy? [Frequency]	**[CMDOSFRQ]** **[clCMDOSFRQ]**
2.9	What was the route of administration of the medication / therapy? [Route]	**[CMROUTE]** **[clCMROUTE]**
2.10	For what indication was the medication / therapy taken? [Indication]	**[CMINDC]** A50
2.11	What was the ID for the adverse event(s) for which the medication was taken? [AE ID]	**[CMAENO]** N4

Key: [*] = Item is required

Study Object Descriptions: Concomitant Medication - General Concomitant Medications

Type	RefName	Description
Form	CM_UseCase1a	CMCAT = CONCOMITANT THERAPY and CMSCAT = GENERAL MEDICATIONS
Item	CMYN	Does not map to SDTM. The CRF should be annotated to indicate that this field is NOT SUBMITTED.
Item	CMSPID	CMSPID
Item	CMTRT	CMTRT
Item	CMSTDAT	CMSTDTC
Item	CMONGO	May be used to derive a value into an SDTM relative timing variable such as CMENRF or CMENRTPT.
Item	CMENDAT	CMENDTC
Item	CMDSTXT	CMDOSE if numeric or CMDOSTXT if text.
Item	CMDOSU	CMDOSU
Item	CMDOSFRM	CMDOSFRM
Item	CMDOSFRQ	CMDOSFRQ
Item	CMROUTE	CMROUTE
Item	CMINDC	CMINDC
Item	CMAENO	May be used to create RELREC to link this record with a record in another domain.

Codelist Values and Tables: Concomitant Medication - General Concomitant Medications

Codelist RefName	Codelist Data Type	Label	Code	Codelist Item RefName	Data Variable RefName
clNY_NY	String	No	N	C49487	CMYN, CMONGO
		Yes	Y	C49488	
clCMDOSU	String	milligram	mg	C28253	CMDOSU
		microgram	ug	C48152	
		milliliter	mL	C28254	
		gram	g	C48155	
		International Unit	IU	C48579	
		tablet	TABLET	C48542	
		capsule	CAPSULE	C48480	
		puff	PUFF	C65060	
clCMDOSFRM	String	tablet	TABLET	C42998	CMDOSFRM
		capsule	CAPSULE	C25158	
		ointment	OINTMENT	C42966	
		suppository	SUPPOSITORY	C42993	
		aerosol	AEROSOL	C42887	
		spray	SPRAY	C42989	
		suspension	SUSPENSION	C42994	
		patch	PATCH	C42968	
		gas	GAS	C42933	
		cream	CREAM	C28944	
		powder	POWDER	C42972	
clCMDOSFRQ	String	Daily	QD	C25473	CMDOSFRQ
		twice daily	BID	C64496	
		three times a day	TID	C64527	
		four times daily	QID	C64530	
		every other day	QOD	C64525	
		Every month	QM	C64498	

		as needed	PRN	C64499	
		Unknown	UNKNOWN	C17998	
clCMROUTE	String	oral	ORAL	C38288	CMROUTE
		topical	TOPICAL	C38304	
		subcutaneous	SUBCUTANEOUS	C38299	
		transdermal	TRANSDERMAL	C38305	
		intraocular	INTRAOCULAR	C38255	
		intramuscular	INTRAMUSCULAR	C28161	
		inhalation	RESPIRATORY (INHALATION)	C38216	
		intralesion	INTRALESIONAL	C38250	
		intraperiteoneal	Intraperiteoneal	C38258	
		nasal	Nasal	C38284	
		vaginal	Vaginal	C38313	
		rectal	Rectal	C38295	

3.2.2 Example - Previous Therapy

This is an example of a CM CRF collecting data as an ancillary log. The sponsor chooses to have a CRF page for Previous Therapies that were stopped prior to study entry. They have defined a variable to collect the reason for therapy discontinuation, which will map to SUPPCM. The sponsor has a separate page for General Medications that were ongoing at study entry or started after study entry.

Row 1 shows an example of a subject that does not have any CMs to report.

Row 2 shows an example of a subject who previously took Wellbutrin.

Row 3 shows an example of a subject who previously took Prozac.

Row 4 shows an example of a subject who previously took Avandia.

Row	SUBJID	CMYN	CMSPID	CMTRT	CMSTDAT	CMENDAT	CMINDC	CMMHNO	CMNCOMPLT
1	101	N							
2	102	Y	1	WELLBUTRIN	JAN-1998	SEP-1998	DEPRESSION	2	LACK OF EFFICACY
3	102	Y	2	PROZAC	SEP-1998	MAY-2001	DEPRESSION	2	RECOVERY
4	103	Y	1	AVANDIA	APR-2008	JAN-2012	TYPE II DIABETES	1	TO ENTER THIS TRIAL

StudyDesign: Previous Therapy - General Medications (Previous Therapy - General Medications) [CM_UseCase1b]

Previous Therapy - General Medications Taken [igCM_UseCase1b_YN]

1.	Were any medications taken?	**[CMYN]** *[A:N]* ◯ No *[A:Y]* ◯ Yes

	CM Number	Medication	Start Date	End Date	Indication	MH ID	Reason for Discontinuation
2.							

Previous Medication Entry Entry [igCM_UseCase1b_D]

2.1*	What is the medication / treatment identifier? *[read-only]* [CM Number]	**[CMSPID]** N3
2.2*	What was the term for the medication / therapy taken? [Medication]	**[CMTRT]** A200
2.3	What was the start date of the medication / therapy? [Start Date]	**[CMSTDAT]** NReq/Unk / NReq/Unk / NReq (2012-2014)
2.4	What was the end date of the medication / therapy? [End Date]	**[CMENDAT]** NReq/Unk / NReq/Unk / Req (2012-2014)
2.5	For what indication was the medication / therapy taken? [Indication]	**[CMINDC]** A50
2.6	What was the ID of the medical history condition(s) for which the medication was taken? [MH ID]	**[CMMHNO]** N4
2.7	What was the reason for medication / therapy discontinuation [Reason for Discontinuation]	**[CMNCOMPLT]** **[clCMNCOMPLT]**

Key: [*] = Item is required

Study Object Descriptions: Previous Therapy - General Medications

Type	RefName	Description
Form	CM_UseCase1b	CMCAT = PRIOR THERAPY and CMSCAT = GENERAL MEDICATIONS
Item	CMYN	Does not map to SDTM. The CRF should be annotated to indicate that this field is NOT SUBMITTED.
Item	CMSPID	CMSPID
Item	CMTRT	CMTRT
Item	CMSTDAT	CMSTDTC
Item	CMENDAT	CMENDTC

Item	CMINDC	CMINDC
Item	CMMHNO	May be used to create RELREC to link this record with an associated record in the MH domain.
Item	CMNCOMPLT	Sponsor-defined variable that may map to SUPPCM.QVAL where QNAM = CMNCMPLT

Codelist Values and Tables: Previous Therapy - General Medications

Codelist RefName	Codelist Data Type	Label	Code	Codelist Item RefName	Data Variable RefName
clNY_NY	String	No	N	C49487	CMYN
		Yes	Y	C49488	
clCMNCOMPLT	String	Lack of efficacy	LACK OF EFFICACY	CMNCOMPLT_1	CMNCOMPLT
		Recovery	RECOVERY	CMNCOMPLT_2	
		Progressive disease	PROGRESSIVE DISEASE	CMNCOMPLT_3	
		Adverse event	ADVERSE EVENT	CMNCOMPLT_4	
		Physician decision	PHYSICIAN DECISION	CMNCOMPLT_5	
		To enter this trial	TO ENTER THIS TRIAL	CMNCOMPLT_6	
		Procedure	PROCEDURE	CMNCOMPLT_7	
		Completed treatement	COMPLETED TREATEMENT	CMNCOMPLT_8	
		Subject decision	SUBJECT DECISION	CMNCOMPLT_9	

3.2.3 Example - Previous and Concomitant Therapy

This is an example of a CM CRF collecting data as an ancillary log. The sponsor chooses to have one CRF page for the collection of all Concomitant Medications. The sponsor has defined a variable to collect the reason for therapy discontinuation, which will map to SUPPCM.

Row 1 shows an example of a subject that does not have any CMs to report.

Row 2 shows an example of a subject who previously took Wellbutrin.

Row 3 shows an example of a subject who previously took Prozac.

Row 4 shows an example of a subject who takes an aspirin every day, prophylactically. The use of this medication started before study entry.

Row 5 shows an example of a subject who took Motrin to treat an adverse event.

Row 6 shows an example of a subject who previously took Avandia.

Row 7 shows an example of a subject who took Benadryl to treat an adverse event.

Row 8 shows an example of a subject who took Nifedipine to treat an adverse event. Use of this medication is continuing at disposition.

Row	SUBJID	CMYN	CMSPID	CMTRT	CMPRIOR	CMSTDAT	CMONGO	CMENDAT	CMDSTXT	CMDOSU	CMDOSFRM
1	101	N									
2	102	Y	1	WELLBUTRIN	Y	JAN-1998	N	SEP-1998	300	mg	TABLET
3	102	Y	2	PROZAC	Y	SEP-1998	N	MAY-2001	20	mg`	CAPSULE
4	102	Y	3	ASPIRIN	N	2006	Y		80	mg	TABLET
5	102	Y	4	MOTRIN	N	2-JAN-2012	N	2-JAN-2012	400	mg	CAPSULE
6	103	Y	1	AVANDIA	Y	APR-2008	N	JAN-2012	4	mg	TABLET
7	103	Y	2	BENADRYL	N	5-JAN-2012	N	6-JAN-2012	25	mg	TABLET
8	103	Y	3	NIFEDIPINE	N	7-JAN-2012	Y		30	mg	CAPSULE

Row	CMROUTE	CMDOSFRQ	CMINDC	CMAENO	CMMHNO	CMNCOMPLT
1 (cont)						
2 (cont)	ORAL	QD	DEPRESSION		2	LACK OF EFFICACY
3 (cont)	ORAL	BID	DEPRESSION		2	RECOVERY
4 (cont)	ORAL	QD	PROPHYLAXIS			
5 (cont)	ORAL	PRN	ADVERSE EVENT	1		RECOVERY
6 (cont)	ORAL	QD	TYPE II DIABETES		1	TO ENTER THIS TRIAL
7 (cont)	ORAL	QD	ADVERSE EVENT	1		RECOVERY
8 (cont)	ORAL	QD	ADVERSE EVENT	2		

StudyDesign: Prior and Concomitant Medications (CM_UseCase2) [CM_UseCase2]

Prior and Concomitant Medications - Taken [igCM_UseCase2_YN]

1.	Were any medications taken?	**[CMYN]** *[A:N]* ◯ No *[A:Y]* ◯ Yes

	CM Number	Medication	Taken Prior to Study	Start Date	Ongoing	Dose	Dose Units	Dose Form	Route	Frequency	Indication	AE ID	MH ID	Reason for Discontinuation
2.														

Prior and Concomitant Medications - Details Entry [igCM_UseCase2_D]

2.1*	What is the medication / treatment identifier? *[read-only]* [CM Number]	**[CMSPID]** N3
2.2*	What was the term for the medication / therapy taken? [Medication]	**[CMTRT]** A200
2.3	Taken Prior to Study? [Taken Prior to Study]	**[CMPRIOR]** *[A:N]* ◯ No *[A:Y]* ◯ Yes
2.4	What was the start date of the medication / therapy? [Start Date]	**[CMSTDAT]** NReq/Unk / NReq/Unk / NReq (2012-2014)
2.5	Is the medication / therapy still ongoing? [Ongoing]	**[CMONGO]** *[A:N]* ◯ **[CMENDAT]** No End Date NReq/Unk / NReq/Unk / Req (2012-2014) *[A:Y]* ◯ Yes
2.6	What was the individual dose of the medication / therapy? [Dose]	**[CMDSTXT]** A20
2.7	What was the unit of the medication / therapy? [Dose Units]	**[CMDOSU]** **[clCMDOSU]**
2.8	What was the dose form of the medication / therapy? [Dose Form]	**[CMDOSFRM]** **[clCMDOSFRM]**
2.9	What was the route of administration of the medication / therapy? [Route]	**[CMROUTE]** **[clCMROUTE]**
2.10	What was the frequency of the medication / therapy? [Frequency]	**[CMDOSFRQ]** **[clCMDOSFRQ]**
2.11	For what indication was the medication / therapy taken? [Indication]	**[CMINDC]** A50
2.12	What was the ID for the adverse event(s) for which the medication was taken? [AE ID]	**[CMAENO]** N4

2.13	What was the ID of the medical history condition(s) for which the medication was taken? [MH ID]	**[CMMHNO]** N4
2.14	What was the reason for medication / therapy discontinuation [Reason for Discontinuation]	**[CMNCOMPLT]** **[clCMNCOMPLT]**

Key: [*] = Item is required

Study Object Descriptions: Prior and Concomitant Medications

Type	RefName	Description
Form	CM_UseCase2	CMCAT = PRIOR AND CONCOMITANT THERAPY and CMSCAT = GENERAL MEDICATIONS
Item	CMYN	Does not map to SDTM. The CRF should be annotated to indicate that this field is NOT SUBMITTED.
Item	CMSPID	CMSPID
Item	CMTRT	CMTRT
Item	CMPRIOR	May be used to derive a value into an SDTM relative timing variable such as CMSTRF or CMSTRTPT.
Item	CMSTDAT	CMSTDTC
Item	CMONGO	May be used to derive a value into an SDTM relative timing variable such as CMENRF or CMENRTPT.
Item	CMENDAT	CMENDTC
Item	CMDSTXT	CMDOSE if numeric or CMDOSTXT if text.
Item	CMDOSU	CMDOSU
Item	CMDOSFRM	CMDOSFRM
Item	CMROUTE	CMROUTE
Item	CMDOSFRQ	CMDOSFRQ
Item	CMINDC	CMINDC
Item	CMAENO	May be used to create RELREC to link this record with a record in another domain.
Item	CMMHNO	May be used to create RELREC to link this record with an associated record in the MH domain.
Item	CMNCOMPLT	Sponsor-defined variable that may map to SUPPCM.QVAL where QNAM = CMNCMPLT

Codelist Values and Tables: Prior and Concomitant Medications

Codelist RefName	Codelist Data Type	Label	Code	Codelist Item RefName	Data Variable RefName
clNY_NY	String	No	N	C49487	CMYN, CMPRIOR, CMONGO
		Yes	Y	C49488	
clCMDOSU	String	milligram	mg	C28253	CMDOSU
		microgram	ug	C48152	
		milliliter	mL	C28254	
		gram	g	C48155	
		International Unit	IU	C48579	
		tablet	TABLET	C48542	
		capsule	CAPSULE	C48480	
		puff	PUFF	C65060	
clCMDOSFRM	String	tablet	TABLET	C42998	CMDOSFRM
		capsule	CAPSULE	C25158	
		ointment	OINTMENT	C42966	

		suppository	SUPPOSITORY	C42993	
		aerosol	AEROSOL	C42887	
		spray	SPRAY	C42989	
		suspension	SUSPENSION	C42994	
		patch	PATCH	C42968	
		gas	GAS	C42933	
		cream	CREAM	C28944	
		powder	POWDER	C42972	
clCMROUTE	String	oral	ORAL	C38288	CMROUTE
		topical	TOPICAL	C38304	
		subcutaneous	SUBCUTANEOUS	C38299	
		transdermal	TRANSDERMAL	C38305	
		intraocular	INTRAOCULAR	C38255	
		intramuscular	INTRAMUSCULAR	C28161	
		inhalation	RESPIRATORY (INHALATION)	C38216	
		intralesion	INTRALESIONAL	C38250	
		intraperiteoneal	Intraperiteoneal	C38258	
		nasal	Nasal	C38284	
		vaginal	Vaginal	C38313	
		rectal	Rectal	C38295	
clCMDOSFRQ	String	Daily	QD	C25473	CMDOSFRQ
		twice daily	BID	C64496	
		three times a day	TID	C64527	
		four times daily	QID	C64530	
		every other day	QOD	C64525	
		Every month	QM	C64498	
		as needed	PRN	C64499	
		Unknown	UNKNOWN	C17998	
clCMNCOMPLT	String	Lack of efficacy	LACK OF EFFICACY	CMNCOMPLT_1	CMNCOMPLT
		Recovery	RECOVERY	CMNCOMPLT_2	
		Progressive disease	PROGRESSIVE DISEASE	CMNCOMPLT_3	
		Adverse event	ADVERSE EVENT	CMNCOMPLT_4	
		Physician decision	PHYSICIAN DECISION	CMNCOMPLT_5	
		To enter this trial	TO ENTER THIS TRIAL	CMNCOMPLT_6	
		Procedure	PROCEDURE	CMNCOMPLT_7	
		Completed treatement	COMPLETED TREATEMENT	CMNCOMPLT_8	
		Subject decision	SUBJECT DECISION	CMNCOMPLT_9	

3.2.4 Example - Concomitant Radiotherapy

This is an example of a CM CRF collecting concomitant radiotherapy that is administered during the study. The sponsor chooses to have a separate CRF for radiotherapy that was administered prior to study. The sponsor has defined supplemental qualifier variables to collect the Reason for Regimen and the Number of Fractions Received.

Row 1 shows an example of a subject who did not have radiotherapy during the study.

Rows 2 – 5 show various examples of subjects who had radiotherapy during the study.

Row	SUBJID	CMYN	CMSPID	VISITNUM	CMSTDAT	CMENDAT	CMREASRGM	CMLOC	CMNUMFRAC	CMDOSE	CMDOSU
1	101	N									
2	102	Y	1	3	13FEB2012	17FEB2012	PALLIATIVE	LIVER	5	25	Gray
3	102	Y	2	4	05MAR2012	16MAR2012	PALLIATIVE	BONE	10	50	Gray
4	103	Y	1	5	22FEB2012	24FEB2012	PALLIATIVE	BRAIN	3	30	Gray
5	103	Y	2	6	14MAR2012	15MAR2012	PALLIATIVE	PELVIS	2	20	Gray

StudyDesign: Concomitant Therapy - Radiotherapy (Concomitant Therapy - Radiotherapy) [CM_UseCase3a]

Concomitant Therapy - Radiotherapy Given [igCM_UseCase3a_YN]

1.	Was any radiotherapy given? [Any radiotherapy?]	**[CMYN_UseCase3a]** *[A:N]* ◯ No *[A:Y]* ◯ Yes

	CM Number	Visit Number	Start Date	End Date	Reason for Regimen	Location of Administration	Number Fractions	Total Dose
2.								

Concomitant Therapy - Radiotherapy Details Entry [igCM_UseCase3a_D]

2.1*	What is the medication / treatment identifier? *[read-only]* [CM Number]	**[CMSPID]** N3
2.2	What is the visit number? [Visit Number]	**[VISITNUM]** N4
2.3	What was the start date of the medication / therapy? [Start Date]	**[CMSTDAT]** NReq/Unk / NReq/Unk / NReq (2012-2014)
2.4	What was the end date of the medication / therapy? [End Date]	**[CMENDAT]** NReq/Unk / NReq/Unk / Req (2012-2014)
2.5	What was the Reason for Regimen [Reason for Regimen]	**[CMREASRGM]** *[A:ADJUVANT]* ◯ Adjuvant *[A:ADJUVANT / CURATIVE]* ◯ Adjuvant / Curative *[A:NEOADJUVANT]* ◯ Neoadjuvant *[A:PALLIATIVE]* ◯ Palliative
2.6	What was the anatomical location of the administration? [Location of Administration]	**[CMLOC_UseCase3]** **[clLOC_CMLOC_3]**
2.7	Number of Fractions Received [Number Fractions]	**[CMNUMFRAC]** N3
2.8	Total Dose [Total Dose]	**[CMDOSE_UseCase3]** .xx Gray

Key: [*] = Item is required

Study Object Descriptions: Concomitant Therapy - Radiotherapy

Type	RefName	Description
Form	CM_UseCase3a	CMCAT = CONCOMITANT THERAPY. CMSCAT = RADIOTHERAPY. CMTRT = RADIOTHERAPY.
Item	CMYN_UseCase3a	Does not map to SDTM. The CRF should be annotated to indicate that this field is NOT SUBMITTED.
Item	CMSPID	CMSPID
Item	VISITNUM	VISITNUM
Item	CMSTDAT	CMSTDTC
Item	CMENDAT	CMENDTC
Item	CMREASRGM	Sponsor-defined variable that may map to SUPPCM.QVAL where QNAM = CMRESRGM
Item	CMLOC_UseCase3	CMLOC
Item	CMNUMFRAC	Sponsor-defined variable that may map to SUPPCM.QVAL where QNAM = CMNUMFRC
Item	CMDOSE_UseCase3	CMDOSE

Codelist Values and Tables: Concomitant Therapy - Radiotherapy

Codelist RefName	Codelist Data Type	Label	Code	Codelist Item RefName	Data Variable RefName

clNY_NY	String	No	N	C49487	CMYN_UseCase3a
		Yes	Y	C49488	
clCMREASRGM	String	Adjuvant	ADJUVANT	CMREASRGM_1	CMREASRGM
		Adjuvant / Curative	ADJUVANT / CURATIVE	CMREASRGM_2	
		Neoadjuvant	NEOADJUVANT	CMREASRGM_3	
		Palliative	PALLIATIVE	CMREASRGM_4	
clLOC_CMLOC_3	String	Abdominal Cavity	ABDOMINAL CAVITY	C12664	CMLOC_UseCase3
		Arm	ARM	C32141	
		Brain	BRAIN	C12439	
		Breast	BREAST	C12971	
		Chest	CHEST	C25389	
		Esophagus	ESOPHAGUS	C12389	
		Liver	LIVER	C12392	
		Lung	LUNG	C12468	
		Lymph Node	LYMPH NODE	C12745	
		Neck	NECK	C13063	
		Ovary	OVARY	C12404	
		Pancreas	PANCREAS	C12393	
		Pelvis	PELVIS	C12767	
		Pharynx	PHARYNX	C12425	
		Prostate Gland	PROSTATE GLAND	C12410	
		Stomach	STOMACH	C12391	
		Thorax	THORAX	C12799	
		Thyroid Gland	THYROID GLAND	C12400	
		Uterus	UTERUS	C12405	

3.2.5 Example - Prior Radiotherapy

This is an example of a CM CRF collecting concomitant radiotherapy was administered prior to study. The sponsor chooses to have a separate CRF for radiotherapy that was conducted during the study. The sponsor has defined supplemental qualifier variables to collect the Reason for Regimen and the Number of Fractions Received.

Row 1 shows an example of a subject who did not have prior radiotherapy.

Rows 2 – 5 show various examples of subjects who had prior radiotherapy.

Row	SUBJID	CMYN	CMSPID	CMSTDAT	CMENDAT	CMREASRGM	CMLOC	CMNUMFRAC	CMDOSE	CMDOSU
1	101	N								
2	102	Y	1	UNKDEC2011	22DEC2011	NEOADJUVANT	LUNG	10	50	Gray
3	102	Y	2	UNKUNK2010	UNKUNK2010	ADJUVANT/CURATIVE	LIVER	9	54	Gray
4	103	Y	1	15NOV2011	06DEC2011	PALLIATIVE	BONE	10	30	Gray
5	103	Y	2	01FEB2012	29FEB2012	NEOADJUVANT	OVARY	15	60	Gray

StudyDesign: Previous Therapy - Radiotherapy (Previous Therapy - Radiotherapy) [CM_UseCase3b]

Previous Therapy - Radiotherapy Given [igCM_UseCase3b_YN]

1.	Was any prior radiotherapy given for this cancer? [Prior radiotherapy for this cancer?]	**[CMYN_UseCase2b]** *[A:N]* ◯ No *[A:Y]* ◯ Yes

	CM Number	Start Date	End Date	Reason for Regimen	Location of Administration	Number Fractions	Total Dose
2.							

Previous Therapy - Radiotherapy Details Entry [igCM_UseCase3b_D]

2.1*	What is the medication / treatment identifier? *[read-only]* [CM Number]	**[CMSPID]** N3
2.2	What was the start date of the medication / therapy? [Start Date]	**[CMSTDAT]** NReq/Unk / NReq/Unk / NReq (2012-2014)
2.3	What was the end date of the medication / therapy? [End Date]	**[CMENDAT]** NReq/Unk / NReq/Unk / Req (2012-2014)
2.4	What was the Reason for Regimen [Reason for Regimen]	**[CMREASRGM]** *[A:ADJUVANT]* ◯ Adjuvant *[A:ADJUVANT / CURATIVE]* ◯ Adjuvant / Curative *[A:NEOADJUVANT]* ◯ Neoadjuvant *[A:PALLIATIVE]* ◯ Palliative
2.5	What was the anatomical location of the administration? [Location of Administration]	**[CMLOC_UseCase3]** **[clLOC_CMLOC_3]**
2.6	Number of Fractions Received [Number Fractions]	**[CMNUMFRAC]** N3
2.7	Total Dose [Total Dose]	**[CMDOSE_UseCase3]** .xx Gray

Key: [*] = Item is required

Study Object Descriptions: Previous Therapy - Radiotherapy

Type	RefName	Description
Form	CM_UseCase3b	CMCAT = PRIOR THERAPY. CMSCAT = RADIOTHERAPY. CMTRT = RADIOTHERAPY
Item	CMYN_UseCase2b	Does not map to SDTM. The CRF should be annotated to indicate that this field is NOT SUBMITTED.
Item	CMSPID	CMSPID
Item	CMSTDAT	CMSTDTC
Item	CMENDAT	CMENDTC
Item	CMREASRGM	Sponsor-defined variable that may map to SUPPCM.QVAL where QNAM = CMRESRGM
Item	CMLOC_UseCase3	CMLOC
Item	CMNUMFRAC	Sponsor-defined variable that may map to SUPPCM.QVAL where QNAM = CMNUMFRC
Item	CMDOSE_UseCase3	CMDOSE

Codelist Values and Tables: Previous Therapy - Radiotherapy

Codelist RefName	Codelist Data Type	Label	Code	Codelist Item RefName	Data Variable RefName
clNY_NY	String	No	N	C49487	CMYN_UseCase2b
		Yes	Y	C49488	
clCMREASRGM	String	Adjuvant	ADJUVANT	CMREASRGM_1	CMREASRGM

		Adjuvant / Curative	ADJUVANT / CURATIVE	CMREASRGM_2	
		Neoadjuvant	NEOADJUVANT	CMREASRGM_3	
		Palliative	PALLIATIVE	CMREASRGM_4	
clLOC_CMLOC_3	String	Abdominal Cavity	ABDOMINAL CAVITY	C12664	CMLOC_UseCase3
		Arm	ARM	C32141	
		Brain	BRAIN	C12439	
		Breast	BREAST	C12971	
		Chest	CHEST	C25389	
		Esophagus	ESOPHAGUS	C12389	
		Liver	LIVER	C12392	
		Lung	LUNG	C12468	
		Lymph Node	LYMPH NODE	C12745	
		Neck	NECK	C13063	
		Ovary	OVARY	C12404	
		Pancreas	PANCREAS	C12393	
		Pelvis	PELVIS	C12767	
		Pharynx	PHARYNX	C12425	
		Prostate Gland	PROSTATE GLAND	C12410	
		Stomach	STOMACH	C12391	
		Thorax	THORAX	C12799	
		Thyroid Gland	THYROID GLAND	C12400	
		Uterus	UTERUS	C12405	

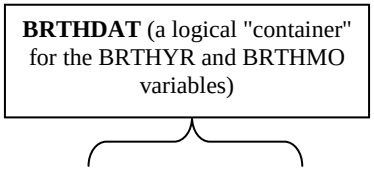
3.3 DM – Demographics

3.3.1 Example - Simple Demographics page

This is an example of a Demographics CRF collecting Birth Date (with an incomplete precision of only the year and the month of birth), Sex, Ethnicity and a single value for Race.

The birth date can be thought to be composed of one or more of the elements of year, month, day and time. These components can be stored in one variable (BRTHDAT) or as a separate variable for each of the components (BRTHDY, BRTHMO, BRTHYR). In this example, the sponsor has created two separate fields for BRTHMO and BRTHYR and BRTHDAT is just a logical variable to organize the year and month components and provide a logical link to the concept of the birth date.

- Rows 1 - 5 show examples subjects with various birth date, sex, ethnicity, and race values.
- Row 2 shows a subject who self reported as being ‘Hispanic or Latino’ in her ethnicity. The "American Indian or Alaska Native" race value is not limited to native tribes of North America, but includes persons native to Central and South America.
- Row 3 shows an example of a subject who self reported as being of ‘Hispanic or Latino’ of White (European) origin.



Row	SUBJID	BRTHYR	BRTHMO	SEX	ETHNIC	RACE
1	100008	1930	Aug	M	NOT HISPANIC OR LATINO	ASIAN
2	100014	1936	Nov	F	HISPANIC OR LATINO	AMERICAN INDIAN OR ALASKA NATIVE
3	200001	1923	Sep	M	HISPANIC OR LATINO	WHITE
4	200002	1933	Jul	F	NOT HISPANIC OR LATINO	BLACK OR AFRICAN AMERICAN
5	200005	1937	Feb	M	NOT HISPANIC OR LATINO	WHITE

StudyDesign: Demographics (DM_1) [DM_UseCase1]

Demographics [DM_UseCase1]

1.*	Birth Date [Birth Date]	**[BRTHDAT]** **[BRTHYR]** Birth Year Req (2012-2014) **[BRTHMO]** Birth Month NReq
2.*	Sex [Sex]	**[SEX]** *[A:F]* Female *[A:M]* Male
3.*	Ethnicity [Ethnicity]	**[ETHNIC]** *[A:HISPANIC OR LATINO]* Hispanic or Latino *[A:NOT HISPANIC OR LATINO]* Not Hispanic or Latino *[A:NOT REPORTED]* Not reported *[A:UNKNOWN]* Unknown
4.*	Race [Race]	**[RACE]** *[A:AMERICAN INDIAN OR ALASKA NATIVE]* American Indian or Alaska Native *[A:ASIAN]* Asian *[A:BLACK OR AFRICAN AMERICAN]* Black or African American *[A:NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER]* Native Hawaiian or Other Pacific Islander *[A:WHITE]* White

Key: [*] = Item is required

Study Object Descriptions: Demographics

Type	RefName	Description
Form	DM_UseCase1	Simple Demographics CRF with Birth Date, Sex, Ethnicity, and "Select Only One" Race.
Item	BRTHYR	BRTHDTC
Item	BRTHMO	BRTHDTC
Item	SEX	Sex
Item	ETHNIC	Ethnic
Item	RACE	Race

Codelist Values and Tables: Demographics

Codelist RefName	Codelist Data Type	Label	Code	Codelist Item RefName	Data Variable RefName
clSEX	String	Female	F	C16576	SEX
		Male	M	C20197	
clETHNIC	String	Hispanic or Latino	HISPANIC OR LATINO	C17459	ETHNIC
		Not Hispanic or Latino	NOT HISPANIC OR LATINO	C41222	
		Not reported	NOT REPORTED	C43234	
		Unknown	UNKNOWN	C17998	
clRACE	String	American Indian or	AMERICAN INDIAN	C41259	RACE

		Alaska Native	OR ALASKA NATIVE		
		Asian	ASIAN	C41260	
		Black or African American	BLACK OR AFRICAN AMERICAN	C16352	
		Native Hawaiian or Other Pacific Islander	NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER	C41219	
		White	WHITE	C41261	

3.3.2 Example –Expanded Demographics CRF

This is an example of a Demographics CRF collecting: Birth Year, Birth Month, Sex, Ethnicity, "Select All That Apply" Race, and Specified Race. The sponsor has also chosen to collect "Select All That Apply" Ethnicity Subcategories and "Select All That Apply" Race Subcategories using the terminologies provided by HL7.

The sponsor has defined their own fields with associated controlled terminologies to enable the "Select All That Apply" functionality. They are leveraging the Controlled Terminology C-Codes to help create the variable names with a consistent methodology. For example, 'C41259' is the code for "American Indian or Alaska Native" and they have named the field, 'RACE_C41259'.

- Row 1 shows a subject who self reported as being NOT HISPANIC OR LATINO, ASIAN, and WHITE. He did not disclose any particular Race subcategory.
- Row 2 shows a subject who self reported as being HISPANIC OR LATINO, with a further categorization of CENTRAL AMERICAN and MEXICAN. She reported her race as being AMERICAN INDIAN OR ALASKA NATIVE.
- Row 3 shows a subject who self reported as being HISPANIC OR LATINO, with a further categorization of SPANIARD. He reported her race as being WHITE.
- Row 4 shows a subject who self reported as being NOT HISPANIC OR LATINO and WHITE.
- Row 4 shows a subject who self reported as being NOT HISPANIC OR LATINO and BLACK OR AFRICAN AMERICAN, with a further race categorization of HAITIAN and JAMAICAN.

Row	SUBJID	BRTHYR	BRTHMO	SEX	ETHNIC	ETHNIC_C17459_1	ETHNIC_C17459_5	ETHNIC_C17459_8	RACE_C41259
1	100008	1930	Aug	M	NOT HISPANIC OR LATINO				
2	100014	1936	Nov	F	HISPANIC OR LATINO	CENTRAL AMERICAN	MEXICAN		AMERICAN INDIAN OR ALASKA NATIVE
3	200001	1923	Sep	M	HISPANIC OR LATINO			SPANIARD	
4	200002	1933	Jul	F	NOT HISPANIC OR LATINO				
5	200005	1937	Feb	M	NOT HISPANIC OR LATINO				

Row	RACE_C41260	RACE_C16352	RACE_C16352	RACE_C16352	RACEOTH	RACE_C16352_RACESCAT_8	RACE_C16352_RACESCAT_9
1 (cont)	ASIAN		WHITE				
2 (cont)							
3 (cont)			WHITE				
4 (cont)		BLACK OR AFRICAN AMERICAN				HAITIAN	JAMAICAN
5 (cont)				OTHER	ABORIGONAL		

StudyDesign: Demographics (DM) [DM_UseCase2]

1.*	Birth Date [Birth Date]	**[BRTHDAT]** **[BRTHYR]** **[BRTHMO]** Birth Year Req (2012-2014) Birth Month NReq
2.* ✔	What is the sex of the subject? [Sex]	**[SEX]** *[A:F]* ◯ Female *[A:M]* ◯ Male
3.* ✔	What is the ethnicity of the subject? [Ethnicity]	**[ETHNIC]** *[A:HISPANIC OR LATINO]* ◯ **[ETHNIC_CMPD]** HISPANIC OR LATINO **[ETHNIC_C17459_1]** *[A:CENTRAL AMERICAN]* ☐ CENTRAL AMERICAN **[ETHNIC_C17459_2]** *[A:CUBAN]* ☐ CUBAN **[ETHNIC_C17459_3]** *[A:LATIN AMERICAN]* ☐ LATIN AMERICAN **[ETHNIC_C17459_4]** *[A:DOMINICAN]* ☐ DOMINICAN **[ETHNIC_C17459_5]** *[A:MEXICAN]* ☐ MEXICAN **[ETHNIC_C17459_6]** *[A:PUERTO RICAN]* ☐ PUERTO RICAN **[ETHNIC_C17459_7]** *[A:SOUTH AMERICAN]* ☐ SOUTH AMERICAN **[ETHNIC_C17459_8]** *[A:SPANIARD]* ☐ SPANIARD *[A:NOT HISPANIC OR LATINO]* ◯ Not Hispanic or Latino *[A:NOT REPORTED]* ◯ Not reported *[A:UNKNOWN]* ◯ Unknown
4.* ✔	What is the race of the subject? [Race]	**[RACE_CMPD]** **[RACE_C41259]** *[A:AMERICAN INDIAN OR ALASKA NATIVE]* ☐ American Indian or Alaska Native **[RACE_C41260]** *[A:ASIAN]* ☐ Asian **[RACE_C16352]** *[A:BLACK OR AFRICAN AMERICAN]* ☐ Black or African American **[RACE_C41219]** *[A:NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER]* ☐ Native Hawaiian or Other Pacific Islander **[RACE_C41261]** *[A:WHITE]* ☐ White **[RACE_C17649]** *[A:OTHER]* ☐ Other **[RACEOTH]** Specify other race A50
5. ✔	American Indian or Alaska Native Subcategory [American Indian or Alaska Native Subcategory]	**[RACE_C41259_CMPD]** **[RACE_C41259_RACESCAT_1]** *[A:ALASKA NATIVE]* ☐ ALASKA NATIVE **[RACE_C41259_RACESCAT_2]** *[A:ALEUT]* ☐ ALEUT **[RACE_C41259_RACESCAT_3]** *[A:AMERICAN INDIAN]* ☐ AMERICAN INDIAN **[RACE_C41259_RACESCAT_4]** *[A:ESKIMO]* ☐ ESKIMO
6. ✔	Asian Subcategory [Asian Subcategory]	**[RACE_C41260_CMPD]** **[RACE_C41260_RACESCAT_1]** *[A:ASIAN INDIAN]* ☐ ASIAN INDIAN **[RACE_C41260_RACESCAT_2]** *[A:BANGLADESHI]* ☐ BANGLADESHI **[RACE_C41260_RACESCAT_3]** *[A:BHUTANESE]* ☐ BHUTANESE **[RACE_C41260_RACESCAT_4]** *[A:BURMESE]* ☐ BURMESE **[RACE_C41260_RACESCAT_5]** *[A:CAMBODIAN]* ☐ CAMBODIAN **[RACE_C41260_RACESCAT_6]**

		[A:CHINESE] ☐ CHINESE **[RACE_C41260_RACESCAT_7]** *[A:FILIPINO]* ☐ FILIPINO **[RACE_C41260_RACESCAT_8]** *[A:HMONG]* ☐ HMONG **[RACE_C41260_RACESCAT_9]** *[A:INDONESIAN]* ☐ INDONESIAN **[RACE_C41260_RACESCAT_10]** *[A:IWO JIMAN]* ☐ IWO JIMAN **[RACE_C41260_RACESCAT_11]** *[A:JAPANESE]* ☐ JAPANESE **[RACE_C41260_RACESCAT_12]** *[A:KOREAN]* ☐ KOREAN **[RACE_C41260_RACESCAT_13]** *[A:LAOTIAN]* ☐ LAOTIAN **[RACE_C41260_RACESCAT_14]** *[A:MADAGASCAR]* ☐ MADAGASCAR **[RACE_C41260_RACESCAT_15]** *[A:MALAYSIAN]* ☐ MALAYSIAN **[RACE_C41260_RACESCAT_16]** *[A:MALDIVIAN]* ☐ MALDIVIAN **[RACE_C41260_RACESCAT_17]** *[A:NEPALESE]* ☐ NEPALESE **[RACE_C41260_RACESCAT_18]** *[A:NEPALESE]* ☐ NEPALESE **[RACE_C41260_RACESCAT_19]** *[A:PAKISTANI]* ☐ PAKISTANI **[RACE_C41260_RACESCAT_20]** *[A:SINGAPOREAN]* ☐ SINGAPOREAN **[RACE_C41260_RACESCAT_21]** *[A:SRI LANKAN]* ☐ SRI LANKAN **[RACE_C41260_RACESCAT_22]** *[A:TAIWANESE]* ☐ TAIWANESE **[RACE_C41260_RACESCAT_23]** *[A:THAI]* ☐ THAI **[RACE_C41260_RACESCAT_24]** *[A:VIETNAMESE]* ☐ VIETNAMESE
7. ✔	Black or African American Subcategory [Black or African American Subcategory]	**[RACE_C16352_CMPD]** **[RACE_C16352_RACESCAT_1]** *[A:AFRICAN]* ☐ AFRICAN **[RACE_C16352_RACESCAT_2]** *[A:AFRICAN AMERICAN]* ☐ AFRICAN AMERICAN **[RACE_C16352_RACESCAT_3]** *[A:BAHAMIAN]* ☐ BAHAMIAN **[RACE_C16352_RACESCAT_4]** *[A:BARBADIAN]* ☐ BARBADIAN **[RACE_C16352_RACESCAT_5]** *[A:BLACK]* ☐ BLACK **[RACE_C16352_RACESCAT_6]** *[A:DOMINICA ISLANDER]* ☐ DOMINICA ISLANDER **[RACE_C16352_RACESCAT_7]** *[A:DOMINICAN REPUBLIC]* ☐ DOMINICAN REPUBLIC **[RACE_C16352_RACESCAT_8]** *[A:HAITIAN]* ☐ HAITIAN **[RACE_C16352_RACESCAT_9]** *[A:JAMAICAN]* ☐ JAMAICAN **[RACE_C16352_RACESCAT_10]** *[A:TOBAGOAN]* ☐ TOBAGOAN **[RACE_C16352_RACESCAT_11]** *[A:TRINIDADIAN]* ☐ TRINIDADIAN **[RACE_C16352_RACESCAT_12]** *[A:WEST INDIAN]* ☐ WEST INDIAN
8. ✔	Native Hawaiian or Other Pacific Islander Subcategory [Native Hawaiian or Other Pacific Islander Subcategory]	**[RACE_C41219_CMPD]** **[RACE_C41219_RACESCAT_1]** *[A:GUAMANIAN]* ☐ GUAMANIAN **[RACE_C41219_RACESCAT_2]**

		[A:MELANESIAN] ☐ MELANESIAN **[RACE_C41219_RACESCAT_3]** *[A:MICRONESIAN]* ☐ MICRONESIAN **[RACE_C41219_RACESCAT_4]** *[A:NATIVE HAWAIIAN]* ☐ NATIVE HAWAIIAN **[RACE_C41219_RACESCAT_5]** *[A:POLYNESIAN]* ☐ POLYNESIAN **[RACE_C41219_RACESCAT_6]** *[A:SAMOAN]* ☐ SAMOAN **[RACE_C41219_RACESCAT_7]** *[A:OTHER PACIFIC ISLANDER]* ☐ OTHER PACIFIC ISLANDER **[RACE_C41219_RACESCAT_8]** *[A:ABORIGINAL]* ☐ ABORIGINAL
9. ✔	White Subcategory [White Subcategory]	**[RACE_C41261_CMPD]** **[RACE_C41261_RACESCAT_1]** *[A:ARAB]* ☐ ARAB **[RACE_C41261_RACESCAT_2]** *[A:EUROPEAN]* ☐ EUROPEAN **[RACE_C41261_RACESCAT_3]** *[A:MIDDLE EASTERN OR NORTH AFRICAN]* ☐ MIDDLE EASTERN OR NORTH AFRICAN

Key: [*] = Item is required [✔] = Source verification required

Study Object Descriptions: Demographics

Type	RefName	Description
Form	DM_UseCase2	Demographics CRF with: Birth Date, Sex, Ethnicity, "Select All That Apply" HL7 Subcategories for Ethnicity, "Select All That Apply" Race, and "Select All That Apply" HL7 Subcategories for Race
Item	BRTHYR	BRTHDTC
Item	BRTHMO	BRTHDTC
Item	SEX	SEX
Item	ETHNIC	ETHNIC
Item	ETHNIC_C17459_1	SUPPDM.QVALwhere QNAM = ETHSCT1
Item	ETHNIC_C17459_2	SUPPDM.QVALwhere QNAM = ETHSCT2
Item	ETHNIC_C17459_3	SUPPDM.QVALwhere QNAM = ETHSCT3
Item	ETHNIC_C17459_4	SUPPDM.QVALwhere QNAM = ETHSCT4
Item	ETHNIC_C17459_5	SUPPDM.QVALwhere QNAM = ETHSCT34
Item	ETHNIC_C17459_6	SUPPDM.QVALwhere QNAM = ETHSCT6
Item	ETHNIC_C17459_7	SUPPDM.QVALwhere QNAM = ETHSCT7
Item	ETHNIC_C17459_8	SUPPDM.QVALwhere QNAM = ETHSCT8
Item	RACE_C41259	RACE. If more than one RACE is reported, set RACE to 'MULTIPLE' and populate result in SUPPDM.QVAL where QNAM = RC41259
Item	RACE_C41260	RACE. If more than one RACE is reported, set RACE to 'MULTIPLE' and populate result in SUPPDM.QVAL where QNAM = RC41260
Item	RACE_C16352	RACE. If more than one RACE is reported, set RACE to 'MULTIPLE' and populate result in SUPPDM.QVAL where QNAM = RC16352
Item	RACE_C41219	RACE. If more than one RACE is reported, set RACE to 'MULTIPLE' and populate result in SUPPDM.QVAL where QNAM = RC41219
Item	RACE_C41261	RACE. If more than one RACE is reported, set RACE to 'MULTIPLE' and populate result in SUPPDM.QVAL where QNAM = RC41261
Item	RACE_C17649	RACE. If more than one RACE is reported, set RACE to 'MULTIPLE' and populate result in SUPPDM.QVAL where QNAM = RC17649
Item	RACEOTH	RACE. If more than one RACE is reported, set RACE to 'MULTIPLE' and populate result in SUPPDM.QVAL where QNAM = RACEOTH
Item	RACE_C41259_RACESCAT_1	SUPPDM.QVALwhere QNAM = C412591
Item	RACE_C41259_RACESCAT_2	SUPPDM.QVALwhere QNAM = C412592
Item	RACE_C41259_RACESCAT_3	SUPPDM.QVALwhere QNAM = C412593
Item	RACE_C41259_RACESCAT_4	SUPPDM.QVALwhere QNAM = C412594
Item	RACE_C41260_RACESCAT_1	SUPPDM.QVALwhere QNAM = C412601
Item	RACE_C41260_RACESCAT_2	SUPPDM.QVALwhere QNAM = C412602
Item	RACE_C41260_RACESCAT_3	SUPPDM.QVALwhere QNAM = C412603
Item	RACE_C41260_RACESCAT_4	SUPPDM.QVALwhere QNAM = C412604

Item	RACE_C41260_RACESCAT_5	SUPPDM.QVALwhere QNAM = C412605
Item	RACE_C41260_RACESCAT_6	SUPPDM.QVALwhere QNAM = C412606
Item	RACE_C41260_RACESCAT_7	SUPPDM.QVALwhere QNAM = C412607
Item	RACE_C41260_RACESCAT_8	SUPPDM.QVALwhere QNAM = C412608
Item	RACE_C41260_RACESCAT_9	SUPPDM.QVALwhere QNAM = C412609
Item	RACE_C41260_RACESCAT_10	SUPPDM.QVALwhere QNAM = C4126010
Item	RACE_C41260_RACESCAT_11	SUPPDM.QVALwhere QNAM = C4126011
Item	RACE_C41260_RACESCAT_12	SUPPDM.QVALwhere QNAM = C4126012
Item	RACE_C41260_RACESCAT_13	SUPPDM.QVALwhere QNAM = C4126013
Item	RACE_C41260_RACESCAT_14	SUPPDM.QVALwhere QNAM = C4126014
Item	RACE_C41260_RACESCAT_15	SUPPDM.QVALwhere QNAM = C4126015
Item	RACE_C41260_RACESCAT_16	SUPPDM.QVALwhere QNAM = C4126016
Item	RACE_C41260_RACESCAT_17	SUPPDM.QVALwhere QNAM = C4126017
Item	RACE_C41260_RACESCAT_18	SUPPDM.QVALwhere QNAM = C4126018
Item	RACE_C41260_RACESCAT_19	SUPPDM.QVALwhere QNAM = C4126019
Item	RACE_C41260_RACESCAT_20	SUPPDM.QVALwhere QNAM = C4126020
Item	RACE_C41260_RACESCAT_21	SUPPDM.QVALwhere QNAM = C4126021
Item	RACE_C41260_RACESCAT_22	SUPPDM.QVALwhere QNAM = C4126022
Item	RACE_C41260_RACESCAT_23	SUPPDM.QVALwhere QNAM = C4126023
Item	RACE_C41260_RACESCAT_24	SUPPDM.QVALwhere QNAM = C4126024
Item	RACE_C16352_RACESCAT_1	SUPPDM.QVALwhere QNAM = C163521
Item	RACE_C16352_RACESCAT_2	SUPPDM.QVALwhere QNAM = C163522
Item	RACE_C16352_RACESCAT_3	SUPPDM.QVALwhere QNAM = C163523
Item	RACE_C16352_RACESCAT_4	SUPPDM.QVALwhere QNAM = C163524
Item	RACE_C16352_RACESCAT_5	SUPPDM.QVALwhere QNAM = C163525
Item	RACE_C16352_RACESCAT_6	SUPPDM.QVALwhere QNAM = C163526
Item	RACE_C16352_RACESCAT_7	SUPPDM.QVALwhere QNAM = C163527
Item	RACE_C16352_RACESCAT_8	SUPPDM.QVALwhere QNAM = C163528
Item	RACE_C16352_RACESCAT_9	SUPPDM.QVALwhere QNAM = C163529
Item	RACE_C16352_RACESCAT_10	SUPPDM.QVALwhere QNAM = C1635210
Item	RACE_C16352_RACESCAT_11	SUPPDM.QVALwhere QNAM = C1635211
Item	RACE_C16352_RACESCAT_12	SUPPDM.QVALwhere QNAM = C1635212
Item	RACE_C41219_RACESCAT_1	SUPPDM.QVALwhere QNAM = C412191
Item	RACE_C41219_RACESCAT_2	SUPPDM.QVALwhere QNAM = C412192
Item	RACE_C41219_RACESCAT_3	SUPPDM.QVALwhere QNAM = C412193
Item	RACE_C41219_RACESCAT_4	SUPPDM.QVALwhere QNAM = C412194
Item	RACE_C41219_RACESCAT_5	SUPPDM.QVALwhere QNAM = C412195
Item	RACE_C41219_RACESCAT_6	SUPPDM.QVALwhere QNAM = C412196
Item	RACE_C41219_RACESCAT_7	SUPPDM.QVALwhere QNAM = C412197
Item	RACE_C41219_RACESCAT_8	SUPPDM.QVALwhere QNAM = C412198
Item	RACE_C41261_RACESCAT_1	SUPPDM.QVALwhere QNAM = C412611
Item	RACE_C41261_RACESCAT_2	SUPPDM.QVALwhere QNAM = C412612
Item	RACE_C41261_RACESCAT_3	SUPPDM.QVALwhere QNAM = C412613

Codelist Values and Tables: Demographics

Codelist RefName	Codelist Data Type	Label	Code	Codelist Item RefName	Data Variable RefName
clSEX	String	Female	F	C16576	SEX
		Male	M	C20197	
clETHNIC	String	Hispanic or Latino	HISPANIC OR LATINO	C17459	ETHNIC
		Not Hispanic or Latino	NOT HISPANIC OR LATINO	C41222	
		Not reported	NOT REPORTED	C43234	
		Unknown	UNKNOWN	C17998	

clETHNIC_C17459_1	String	CENTRAL AMERICAN	CENTRAL AMERICAN	clitmETHNIC_C17459_1	ETHNIC_C17459_1
clETHNIC_C17459_2	String	CUBAN	CUBAN	clitmETHNIC_C17459_2	ETHNIC_C17459_2
clETHNIC_C17459_3	String	LATIN AMERICAN	LATIN AMERICAN	clitmETHNIC_C17459_3	ETHNIC_C17459_3
clETHNIC_C17459_4	String	DOMINICAN	DOMINICAN	clitmETHNIC_C17459_4	ETHNIC_C17459_4
clETHNIC_C17459_5	String	MEXICAN	MEXICAN	clitmETHNIC_C17459_5	ETHNIC_C17459_5
clETHNIC_C17459_6	String	PUERTO RICAN	PUERTO RICAN	clitmETHNIC_C17459_6	ETHNIC_C17459_6
clETHNIC_C17459_7	String	SOUTH AMERICAN	SOUTH AMERICAN	clitmETHNIC_C17459_7	ETHNIC_C17459_7
clETHNIC_C17459_8	String	SPANIARD	SPANIARD	clitmETHNIC_C17459_8	ETHNIC_C17459_8
clRACE_C41259	String	American Indian or Alaska Native	AMERICAN INDIAN OR ALASKA NATIVE	C41259	RACE_C41259
clRACE_C41260	String	Asian	ASIAN	C41260	RACE_C41260
clRACE_C16352	String	Black or African American	BLACK OR AFRICAN AMERICAN	C16352	RACE_C16352
clRACE_C41219	String	Native Hawaiian or Other Pacific Islander	NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER	C41219	RACE_C41219
clRACE_C41261	String	White	WHITE	C41261	RACE_C41261
clRACE_C17649	String	Other	OTHER	C17649	RACE_C17649
clRACE_C41259_RACESCAT_1	String	ALASKA NATIVE	ALASKA NATIVE	clitmRACE_C41259_RACESCAT_1	RACE_C41259_RACESCAT_1
clRACE_C41259_RACESCAT_2	String	ALEUT	ALEUT	clitmRACE_C41259_RACESCAT_2	RACE_C41259_RACESCAT_2
clRACE_C41259_RACESCAT_3	String	AMERICAN INDIAN	AMERICAN INDIAN	clitmRACE_C41259_RACESCAT_3	RACE_C41259_RACESCAT_3
clRACE_C41259_RACESCAT_4	String	ESKIMO	ESKIMO	clitmRACE_C41259_RACESCAT_4	RACE_C41259_RACESCAT_4
clRACE_C41260_RACESCAT_1	String	ASIAN INDIAN	ASIAN INDIAN	clitmRACE_C41260_RACESCAT_1	RACE_C41260_RACESCAT_1
clRACE_C41260_RACESCAT_2	String	BANGLADESHI	BANGLADESHI	clitmRACE_C41260_RACESCAT_2	RACE_C41260_RACESCAT_2
clRACE_C41260_RACESCAT_3	String	BHUTANESE	BHUTANESE	clitmRACE_C41260_RACESCAT_3	RACE_C41260_RACESCAT_3
clRACE_C41260_RACESCAT_4	String	BURMESE	BURMESE	clitmRACE_C41260_RACESCAT_4	RACE_C41260_RACESCAT_4
clRACE_C41260_RACESCAT_5	String	CAMBODIAN	CAMBODIAN	clitmRACE_C41260_RACESCAT_5	RACE_C41260_RACESCAT_5
clRACE_C41260_RACESCAT_6	String	CHINESE	CHINESE	clitmRACE_C41260_RACESCAT_6	RACE_C41260_RACESCAT_6
clRACE_C41260_RACESCAT_7	String	FILIPINO	FILIPINO	clitmRACE_C41260_RACESCAT_7	RACE_C41260_RACESCAT_7
clRACE_C41260_RACESCAT_8	String	HMONG	HMONG	clitmRACE_C41260_RACESCAT_8	RACE_C41260_RACESCAT_8
clRACE_C41260_RACESCAT_9	String	INDONESIAN	INDONESIAN	clitmRACE_C41260_RACESCAT_9	RACE_C41260_RACESCAT_9
clRACE_C41260_RACESCAT_10	String	IWO JIMAN	IWO JIMAN	clitmRACE_C41260_RACESCAT_10	RACE_C41260_RACESCAT_10
clRACE_C41260_RACESCAT_11	String	JAPANESE	JAPANESE	clitmRACE_C41260_RACESCAT_11	RACE_C41260_RACESCAT_11
clRACE_C41260_RACESCAT_12	String	KOREAN	KOREAN	clitmRACE_C41260_RACESCAT_12	RACE_C41260_RACESCAT_12
clRACE_C41260_RACESCAT_13	String	LAOTIAN	LAOTIAN	clitmRACE_C41260_RACESCAT_13	RACE_C41260_RACESCAT_13
clRACE_C41260_RACESCAT_14	String	MADAGASCAR	MADAGASCAR	clitmRACE_C41260_RACESCAT_14	RACE_C41260_RACESCAT_14
clRACE_C41260_RACESCAT_15	String	MALAYSIAN	MALAYSIAN	clitmRACE_C41260_RACESCAT_15	RACE_C41260_RACESCAT_15
clRACE_C41260_RACESCAT_16	String	MALDIVIAN	MALDIVIAN	clitmRACE_C41260_RACESCAT_16	RACE_C41260_RACESCAT_16
clRACE_C41260_RACESCAT_17	String	NEPALESE	NEPALESE	clitmRACE_C41260_RACESCAT_17	RACE_C41260_RACESCAT_17
clRACE_C41260_RACESCAT_18	String	NEPALESE	NEPALESE	clitmRACE_C41260_RACESCAT_18	RACE_C41260_RACESCAT_18
clRACE_C41260_RACESCAT_19	String	PAKISTANI	PAKISTANI	clitmRACE_C41260_RACESCAT_19	RACE_C41260_RACESCAT_19
clRACE_C41260_RACESCAT_20	String	SINGAPOREAN	SINGAPOREAN	clitmRACE_C41260_RACESCAT_20	RACE_C41260_RACESCAT_20
clRACE_C41260_RACESCAT_21	String	SRI LANKAN	SRI LANKAN	clitmRACE_C41260_RACESCAT_21	RACE_C41260_RACESCAT_21
clRACE_C41260_RACESCAT_22	String	TAIWANESE	TAIWANESE	clitmRACE_C41260_RACESCAT_22	RACE_C41260_RACESCAT_22
clRACE_C41260_RACESCAT_23	String	THAI	THAI	clitmRACE_C41260_RACESCAT_23	RACE_C41260_RACESCAT_23
clRACE_C41260_RACESCAT_24	String	VIETNAMESE	VIETNAMESE	clitmRACE_C41260_RACESCAT_24	RACE_C41260_RACESCAT_24
clRACE_C16352_RACESCAT_1	String	AFRICAN	AFRICAN	clitmRACE_C16352_RACESCAT_1	RACE_C16352_RACESCAT_1
clRACE_C16352_RACESCAT_2	String	AFRICAN AMERICAN	AFRICAN AMERICAN	clitmRACE_C16352_RACESCAT_2	RACE_C16352_RACESCAT_2

clRACE_C16352_RACESCAT_3	String	BAHAMIAN	BAHAMIAN	clitmRACE_C16352_RACESCAT_3	RACE_C16352_RACESCAT_3
clRACE_C16352_RACESCAT_4	String	BARBADIAN	BARBADIAN	clitmRACE_C16352_RACESCAT_4	RACE_C16352_RACESCAT_4
clRACE_C16352_RACESCAT_5	String	BLACK	BLACK	clitmRACE_C16352_RACESCAT_5	RACE_C16352_RACESCAT_5
clRACE_C16352_RACESCAT_6	String	DOMINICA ISLANDER	DOMINICA ISLANDER	clitmRACE_C16352_RACESCAT_6	RACE_C16352_RACESCAT_6
clRACE_C16352_RACESCAT_7	String	DOMINICAN REPUBLIC	DOMINICAN REPUBLIC	clitmRACE_C16352_RACESCAT_7	RACE_C16352_RACESCAT_7
clRACE_C16352_RACESCAT_8	String	HAITIAN	HAITIAN	clitmRACE_C16352_RACESCAT_8	RACE_C16352_RACESCAT_8
clRACE_C16352_RACESCAT_9	String	JAMAICAN	JAMAICAN	clitmRACE_C16352_RACESCAT_9	RACE_C16352_RACESCAT_9
clRACE_C16352_RACESCAT_10	String	TOBAGOAN	TOBAGOAN	clitmRACE_C16352_RACESCAT_10	RACE_C16352_RACESCAT_10
clRACE_C16352_RACESCAT_11	String	TRINIDADIAN	TRINIDADIAN	clitmRACE_C16352_RACESCAT_11	RACE_C16352_RACESCAT_11
clRACE_C16352_RACESCAT_12	String	WEST INDIAN	WEST INDIAN	clitmRACE_C16352_RACESCAT_12	RACE_C16352_RACESCAT_12
clRACE_C41219_RACESCAT_1	String	GUAMANIAN	GUAMANIAN	clitmRACE_C41219_RACESCAT_1	RACE_C41219_RACESCAT_1
clRACE_C41219_RACESCAT_2	String	MELANESIAN	MELANESIAN	clitmRACE_C41219_RACESCAT_2	RACE_C41219_RACESCAT_2
clRACE_C41219_RACESCAT_3	String	MICRONESIAN	MICRONESIAN	clitmRACE_C41219_RACESCAT_3	RACE_C41219_RACESCAT_3
clRACE_C41219_RACESCAT_4	String	NATIVE HAWAIIAN	NATIVE HAWAIIAN	clitmRACE_C41219_RACESCAT_4	RACE_C41219_RACESCAT_4
clRACE_C41219_RACESCAT_5	String	POLYNESIAN	POLYNESIAN	clitmRACE_C41219_RACESCAT_5	RACE_C41219_RACESCAT_5
clRACE_C41219_RACESCAT_6	String	SAMOAN	SAMOAN	clitmRACE_C41219_RACESCAT_6	RACE_C41219_RACESCAT_6
clRACE_C41219_RACESCAT_7	String	OTHER PACIFIC ISLANDER	OTHER PACIFIC ISLANDER	clitmRACE_C41219_RACESCAT_7	RACE_C41219_RACESCAT_7
clRACE_C41219_RACESCAT_8	String	ABORIGINAL	ABORIGINAL	clitmRACE_C41219_RACESCAT_8	RACE_C41219_RACESCAT_8
clRACE_C41261_RACESCAT_1	String	ARAB	ARAB	clitmRACE_C41261_RACESCAT_1	RACE_C41261_RACESCAT_1
clRACE_C41261_RACESCAT_2	String	EUROPEAN	EUROPEAN	clitmRACE_C41261_RACESCAT_2	RACE_C41261_RACESCAT_2
clRACE_C41261_RACESCAT_3	String	MIDDLE EASTERN OR NORTH AFRICAN	MIDDLE EASTERN OR NORTH AFRICAN	clitmRACE_C41261_RACESCAT_3	RACE_C41261_RACESCAT_3

3.4 DS – Disposition

3.4.1 Example - Study Disposition

This is an example of a DS CRF for Study Disposition. The sponsor has created additional variables, including those to support the collection of DSTERMs for select DSDECODs.

Row 1 shows an example of a subject with a DSDECOD of 'COMPLETED'.

Row 2 shows an example of a subject with a DSDECOD of 'PROTOCOL VIOLATION' and specify text in a DSTERM field that is specific to the DSDCODE of 'PROTOCOL VIOLATION'.

Row 3 shows an example of a subject with a DSDECOD of 'ADVERSE EVENT' and a sponsor defined DSAENO field to collect the AE ID which prompted the discontinuation.

Row 4 shows an example of a subject with a DSDECOD of 'DEATH' and a sponsor defined field to collect Death Date.

Row 5 shows an example of a subject with a DSDECOD of 'WITHDRAWAL BY SUBJECT' and specify text in a DSTERM field that is specific to the DSDCODE of 'WITHDRAWAL BY SUBJECT'.

Row	SUBJID	DSSTDAT	DSDECOD	DSAENO	DTHDAT	DSTERM_C48250	DSTERM_C48251	DSTERM_C49634	DSTERM_C17649
1	101	27-Mar-2012	COMPLETED						
2	102	9-APR-2012	PROTOCOL VIOLATION				USE OF RECREATIONAL DRUGS		
3	103	1-APR-2012	ADVERSE EVENT	2					
4	104	13-APR-2012	DEATH		13-APR-2012				
5	105	1-MAY-2012	WITHDRAWAL BY SUBJECT					SCHEDULING CONFLICTS	

StudyDesign: Disposition - Study Discontinuation () [DS_UseCase1]

Disposition - Study Discontinuation [igDS_UseCase_1]

1.*	What was the date of Completion / Discontinuation? [Completion / Discontinuation Date]	**[DSSTDAT]** Req / Req / Req (2012-2014)
2.*	What was the subject's status? [Status]	**[DSDECOD]** *[A:ADVERSE EVENT]* ○ **[DSAENO]** Adverse Event Specify AE ID N10 *[A:COMPLETED]* ○ Completed *[A:DEATH]* ○ **[DTHDAT]** Death Death Date Req / Req/Unk / Req (2012-2014) *[A:LACK OF EFFICACY]* ○ Lack of Efficacy *[A:LOST TO FOLLOW-UP]* ○ Lost To Follow-up *[A:NON-COMPLIANCE WITH STUDY DRUG]* ○ Non-Compliance With Study Drug *[A:PHYSICIAN DECISION]* ○ **[DSTERM_C48250]** Physician Decision Specify Physician Decision A50 *[A:PREGNANCY]* ○ Pregnancy *[A:PROGRESSIVE DISEASE]* ○ Progressive Disease *[A:PROTOCOL VIOLATION]* ○ **[DSTERM_C48251]** Protocol Violation Specify Protocol Violation A50 *[A:RECOVERY]* ○ Recovery *[A:SCREEN FAILURE]* ○ Trial Screen Failure *[A:STUDY TERMINATED BY SPONSOR]* ○ Study Terminated By Sponsor *[A:TECHNICAL PROBLEMS]* ○ Technical Problems *[A:WITHDRAWAL BY SUBJECT]* ○ **[DSTERM_C49634]** Withdrawal by Subject Specify Withdrawal by Subject A50 *[A:OTHER]* ○ **[DSTERM_C17649]** Other Specify Other A50

Key: [*] = Item is required

Study Object Descriptions: Disposition - Study Discontinuation

Type	RefName	Description
Form	DS_UseCase1	DSCAT = DISPOSITION EVENT, DSSCAT = STUDY DISCONTINUATION
Item	DSSTDAT	DSSTDTC
Item	DSDECOD	DSDECOD
Item	DSAENO	May be used to create RELREC to link this record with a record in another domain.
Item	DTHDAT	DTHDTC
Item	DSTERM_C48250	DSTERM
Item	DSTERM_C48251	DSTERM
Item	DSTERM_C49634	DSTERM
Item	DSTERM_C17649	DSTERM

Codelist Values and Tables: Disposition - Study Discontinuation					
Codelist RefName	**Codelist Data Type**	**Label**	**Code**	**Codelist Item RefName**	**Data Variable RefName**
cINCOMPLT	String	Adverse Event	ADVERSE EVENT	C41331	DSDECOD
		Completed	COMPLETED	C25250	
		Death	DEATH	C28554	
		Lack of Efficacy	LACK OF EFFICACY	C48226	
		Lost To Follow-up	LOST TO FOLLOW-UP	C48227	
		Non-Compliance With Study Drug	NON-COMPLIANCE WITH STUDY DRUG	C49631	
		Physician Decision	PHYSICIAN DECISION	C48250	
		Pregnancy	PREGNANCY	C25742	
		Progressive Disease	PROGRESSIVE DISEASE	C35571	
		Protocol Violation	PROTOCOL VIOLATION	C48251	
		Recovery	RECOVERY	C25746	
		Trial Screen Failure	SCREEN FAILURE	C49628	
		Study Terminated By Sponsor	STUDY TERMINATED BY SPONSOR	C49632	
		Technical Problems	TECHNICAL PROBLEMS	C49633	
		Withdrawal by Subject	WITHDRAWAL BY SUBJECT	C49634	
		Other	OTHER	C17649	

3.4.2 Example - Mortality Status

This is an example of a DS CRF for Post Discontinuation, Mortality Status Follow-up. The sponsor has defined additional variables and controlled terminologies, including those to support the collection of DSTERMs for select DSDECODs.

Row 1 shows an example of a subject with a DSDECOD of 'ALIVE'.

Row 2 shows an example of a subject with a DSDECOD of 'DEATH', a corresponding Death Date and a sponsor defined Primary Cause of Death.

Row 3 shows an example of a subject with a DSDECOD of 'LOST TO FOLLOW-UP'.

Row 4 shows an example of a subject with a DSDECOD of 'DEATH', a corresponding Death Date, a sponsor defined Primary Cause of Death, and the AE ID associated with the Primary Cause of Death.

Row	SUBJID	DSDAT	DSDECOD_MORTALITY	DSSTTPT_LKALVDAT	DTHDAT	DSTERM_PRICOD	DSAENO
1	106	27-Mar-2012	ALIVE				
2	107	9-APR-2012	DEATH		2-MAR-2012	STUDY DISEASE	
3	108	1-APR-2012	LOST TO FOLLOW-UP	3-MAR-2012			
4	109	15-APR-2012	DEATH			ADVERSE EVENT	10

StudyDesign: Disposition - Mortality Status () [DS_UseCase2]

Disposition - Mortality Status [igDS_UseCase_2]

1.	What is the date of collection? [Collection Date]	**[DSDAT]** Req / Req / Req (2012-2014)
2.*	What was the subject's status? [Status]	**[DSDECOD_MORTALITY]** *[A:ALIVE]* ◯ **[DSSTTPT_LKALVDAT]** Alive Date Last Known Alive Req/Unk / Req/Unk / Req (2012-2014) *[A:DEATH]* ◯ **[DTH_CMPD]** Death **[DTHDAT]** Death Date Req / Req/Unk / Req (2012-2014) **[DSTERM_PRICOD]** Primary Cause of Death *[A:CLINICAL OUTCOME]* ◯ Clinical Outcome *[A:STUDY DISEASE]* ◯ Study Disease *[A:STUDY DRUG TOXICITY]* ◯ Study Drug Toxicity *[A:PROCEDURE RELATED]* ◯ Procedure Related *[A:INDETERMINATE]* ◯ Indeterminate *[A:NOT STUDY RELATED]* ◯ Not Study Related *[A:SUICIDE]* ◯ Suicide *[A:ADVERSE EVENT]* ◯ **[DSAENO]** Adverse Event Specify AE ID N10 *[A:RADIOTHERAPY RELATED]* ◯ Radiotherapy Related *[A:CHEMOTHERAPY RELATED]* ◯ Chemotherapy Related *[A:CHEMORADIOTHERAPY RELATED]* ◯ Chemoradiotherapy Related *[A:LOST TO FOLLOW-UP]* ◯ Lost To Follow-up *[A:UNKNOWN]* ◯ Unknown

Key: [*] = Item is required

Study Object Descriptions: Disposition - Mortality Status

Type	RefName	Description
Form	DS_UseCase2	DSCAT = DISPOSITION EVENT, DSSCAT = MORTALITY STATUS
Item	DSDAT	DSDTC
Item	DSDECOD_MORTALITY	DSDECOD
Item	DSSTTPT_LKALVDAT	DSSTTPT
Item	DTHDAT	DTHDTC
Item	DSTERM_PRICOD	DSTERM
Item	DSAENO	May be used to create RELREC to link this record with a record in another domain.

Codelist Values and Tables: Disposition - Mortality Status

Codelist RefName	Codelist Data Type	Label	Code	Codelist Item RefName	Data Variable RefName
clNCOMPLT_MORTALITY	String	Alive	ALIVE	NCOMPLT_ALIVE	DSDECOD_MORTALITY
		Death	DEATH	C28554	
		Lost To Follow-up	LOST TO FOLLOW-UP	C48227	
		Unknown	UNKNOWN	C17998	
clCOD	String	Clinical Outcome	CLINICAL OUTCOME	COD_1	DSTERM_PRICOD
		Study Disease	STUDY DISEASE	COD_2	
		Study Drug Toxicity	STUDY DRUG TOXICITY	COD_4	
		Procedure Related	PROCEDURE RELATED	COD_5	
		Indeterminate	INDETERMINATE	COD_6	
		Not Study Related	NOT STUDY RELATED	COD_7	
		Suicide	SUICIDE	COD_8	
		Adverse Event	ADVERSE EVENT	COD_3	
		Radiotherapy	RADIOTHERAPY	COD_9	

		Related	RELATED		
		Chemotherapy Related	CHEMOTHERAPY RELATED	COD_10	
		Chemoradiotherapy Related	CHEMORADIOTHERAPY RELATED	COD_11	

3.4.3 Example – Informed Consent

This is an example of a DS CRF for Informed Consent and Informed Assent. In this scenario, Informed Assent was added since the sponsor's study included subjects under the age of18. The sponsor has defined variables to support the collection of both dispositions and defined controlled terminologies for DSDEOD.

Row 1 shows an example of a subject, over age 18, who signed Informed Consent.

Row 2 shows an example of the same subject from Row 1 withdrawing consent at a later date.

Row 3 shows an example of a subject, underage 18, who signed Informed Assent. Her legal guardian signed Informed Consent.

Row	SUBJID	DSSPID	DSDECOD_IC	DSSTDAT_IC	DSSTTIM_IC	DSDECOD_IC	DSSTDAT_IC	DSSTTIM_IC
1	101	1	INFORMED CONSENT OBTAINED	13-SEP-2012	08:00			
2	101	2	INFORMED CONSENT WITHDRAWN	11-NOV-2012	13:30			
3	102	1	INFORMED CONSENT OBTAINED	12-DEC-2012	13:00	INFORMED ASSENT OBTAINED	12-DEC-2012	13:00

StudyDesign: Disposition - Study Informed Consent () [DS_UseCase3]		
Disposition - Study Informed Consent [igDS_Use_Case_3_IC]		
1.*	DS Identifier *[read-only]* [DS Number]	**[DSSPID]** N3
2.*	Informed Consent Status	**[DSDECOD_IC]** *[A:INFORMED CONSENT OBTAINED]* Informed Consent Obtained *[A:INFORMED CONSENT WITHDRAWN]* Informed Consent Withdrawn *[A:INFORMED CONSENT REVOKED]* Informed Consent Revoked
3.*	What was the date of Informed Consent? [Informed Consent Date]	**[DSSTDAT_IC]** Req / Req / Req (2012-2014)
4.	What was the time of Informed Consent? [Informed Consent Time]	**[DSSTTIM_IC]** NReq/Unk : NReq/Unk *24-hour clock*
Disposition - Study Informed Assent [igDS_Use_Case_3_IA]		
5.	Informed Consent Status	**[DSDECOD_IA]** *[A:INFORMED ASSENT OBTAINED]* Informed Assent Obtained *[A:INFORMED ASSENT WITHDRAWN]* Informed Assent Withdrawn *[A:INFORMED ASSENT REVOKED]* Informed Assent Revoked
6.	What was the date of Informed Assent? [Informed Assent Date]	**[DSSTDAT_IA]** Req / Req / Req (2012-2014)
7.	What was the time of Informed Assent? [Informed Assent Time]	**[DSSTTIM_IA]** NReq/Unk : NReq/Unk *24-hour clock*
Key: [*] = Item is required		

Study Object Descriptions: Disposition - Study Informed Consent		
Type	**RefName**	**Description**
Form	DS_UseCase3	DSCAT = PROTOCOL MILESTONE, DSSCAT = STUDY ENROLLMENT
Item	DSSPID	DSSPID
Item	DSDECOD_IC	DSDECOD
Item	DSSTDAT_IC	DSSTDTC
Item	DSSTTIM_IC	DSSTDTC
Item	DSDECOD_IA	DSDECOD
Item	DSSTDAT_IA	DSSTDTC
Item	DSSTTIM_IA	DSSTDTC

Codelist Values and Tables: Disposition - Study Informed Consent					
Codelist RefName	**Codelist Data Type**	**Label**	**Code**	**Codelist Item RefName**	**Data Variable RefName**
clDSDECOD_IC	String	Informed Consent Obtained	INFORMED CONSENT OBTAINED	DSDECOD_IC_1	DSDECOD_IC
		Informed Consent Withdrawn	INFORMED CONSENT WITHDRAWN	DSDECOD_IC_2	
		Informed Consent	INFORMED CONSENT	DSDECOD_IC_3	

		Revoked	REVOKED		
clDSDECOD_IA	String	Informed Assent Obtained	INFORMED ASSENT OBTAINED	DSDECOD_IA_1	DSDECOD_IA
		Informed Assent Withdrawn	INFORMED ASSENT WITHDRAWN	DSDECOD_IA_2	
		Informed Assent Revoked	INFORMED ASSENT REVOKED	DSDECOD_IA_3	

3.5 EG – ECG Test Results

3.5.1 Example – Local Reading; Overall Assessment

This is an example of a local EG CRF collecting overall assessment.

Row 1 shows an example of a subject who did not have any ECGs performed.

Row 2 - 3 show examples of a subject having two ECGs with normal findings.

Row 4 - 5 show examples of a subject having two ECGs with abnormal findings. The first wasn't clinically significant. The second was clinically significant.

Row	SUBJID	EGPERF	EGDAT	EGTIM	EGORRES	EGCLSIG
1	101	N				
2	102	Y	9-APR-2012	10:30	NORMAL	
3	102	Y	1-JUL-2012	14:45	NORMAL	
4	103	Y	2-APR-2012	9:15	ABNORMAL	N
5	103	Y	26-MAY-2012	16:00	ABNORMAL	Y

StudyDesign: EG_UseCase1 () [EG_UseCase1]

ECG Performed [igEG_UseCase1_YN]

1.	Was the ECG performed? [ECG Performed]	**[EGPERF]** *[A:N]* ◯ No *[A:Y]* ◯ Yes

	ECG Date	ECG Time	Result
2.			

ECG Assessment Entry [igEG_UseCase1_D]

2.1*	What was the ECG date? [ECG Date]	**[EGDAT]** Req / Req / Req (2012-2014)
2.2	What was the ECG time? [ECG Time]	**[EGTIM]** NReq : NReq *24-hour clock*
2.3*	What was the result of the ECG? [Result]	**[EGINTP]** *[A:NORMAL]* ◯ Normal *[A:ABNORMAL]* ◯ **[EGCLSIG]** Abnormal Was the ECG clinically significant? *[A:N]* ◯ No *[A:Y]* ◯ Yes

Key: [*] = Item is required

Study Object Descriptions: EG_UseCase1

Type	RefName	Description
Form	EG_UseCase1	Local Reading; Overall assessment
Item	EGPERF	EGSTAT where EGTESTCD = EGALL. If EGPERF = 'N', EGSTAT = 'NOT DONE'
Item	EGDAT	EGDTC
Item	EGTIM	EGDTC
Item	EGINTP	EGORRES where EGTESTCD = EGINTP
Item	EGCLSIG	SUPPEG.QVAL where QNAM = EGCLSIG

Codelist Values and Tables: EG_UseCase1

Codelist RefName	Codelist Data Type	Label	Code	Codelist Item RefName	Data Variable RefName
clNY_NY	String	No	N	C49487	EGPERF, EGCLSIG
		Yes	Y	C49488	
clNRIND_EGINTP	String	Normal	NORMAL	C78727	EGINTP
		Abnormal	ABNORMAL	C78802	

3.6 MH – Medical History

3.6.1 Example – General Medical History

This is an example of an MH CRF collecting general medical history. The sponsor added a field to collect Toxicity, as permissible within the Events class. The sponsor is not coding the medical history event terms, therefore is collecting MHBODSYS facilitate grouping of related events.

Row 1 shows an example of a subject that does not have any MHs to report.

Row 2 shows an example of a medical history event that has stopped.

Row 3 - 4 show examples of medical history events which are ongoing.

Row 5 – 6 show examples a medical history event with a related surgical procedure

Row	SUBJID	MHYN	MHSPID	MHBODSYS	MHTERM	MHSTDAT	MHONGO	MHENDAT	MHTOXGR	MHDAT
1	101	N								
2	102	Y	1	VASCULAR	DEEP VEIN THROMBOSIS	APR-2008	N	MAY-2008	SEVERE	11-NOV-2011
3	102	Y	2	REPRODUCTIVE SYSTEM AND BREAST	BENIGN PROSTATIC HYPERPLASIA	OCT-2009	Y		MODERATE	11-NOV-2011
4	103	Y	1	EYE	GLAUCOMA	JAN-2002	Y		MILD	12-DEC-2011
5	103	Y	2	CARDIAC	HEART VALVE STENOSIS	APR-2005	N	DEC-2005	SEVERE	12-DEC-2011
6	103	Y	3	CARDIAC	HEART VALVE REPLACEMENT	DEC-2005	N			12-DEC-2011

StudyDesign: General Medical History () [MH_UseCase1]

Medical History Present [igMH_UseCase_YN]

1.	Has the subject experienced any past and/or concomitant diseases or past surgeries? [Any medical history?]	**[MHYN]** *[A:N]* ◯ No *[A:Y]* ◯ Yes

	MH Number	Body System	Medical History Term	Start Date	Ongoing	Collection Date
2.						

Medical History Details Entry [igMH_UseCase1_Details]

2.1	What is the medical history identifier? *[read-only]* [MH Number]	**[MHSPID]** N4
2.2	Body System or Organ Class [Body System]	**[MHBODSYS]** **[clMHBODSYS]**
2.3*	What is the verbatim term for the medical history condition/event? [Medical History Term]	**[MHTERM]** A200
2.4	What was the date the medical history event or condition started? [Start Date]	**[MHSTDAT]** NReq/Unk / NReq/Unk / Req (2012-2014)
2.5	Is the medical history disease/condition or event still ongoing? [Ongoing]	**[MHONGO]** *[A:N]* ◯ **[MHENDAT]** No End Date NReq/Unk / NReq/Unk / Req (2012-2014) *[A:Y]* ◯ **[MHTOXGR]** Yes Medical History Toxicity **[clTOXGR]**
2.6	What was the date that the medical history was collected? [Collection Date]	**[MHDAT]** NReq / NReq / NReq (2012-2014)

Key: [*] = Item is required

Study Object Descriptions: General Medical History

Type	RefName	Description
Form	MH_UseCase1	MHCAT = GENERAL MEDICAL HISTORY
Item	MHYN	Does not map to SDTM. The CRF should be annotated to indicate that this field is NOT SUBMITTED.
Item	MHSPID	MHSPID
Item	MHBODSYS	MHBODSYS
Item	MHTERM	MHTERM
Item	MHSTDAT	MHSTDTC
Item	MHONGO	This field does not map directly to an SDTM variable. May be used to derive MHENRF.
Item	MHENDAT	MHENDTC
Item	MHTOXGR	Example of Sponsor Defined Variable. Permissible to use within the Events class.
Item	MHDAT	MHDTC

Codelist Values and Tables: General Medical History

Codelist RefName	Codelist Data Type	Label	Code	Codelist Item RefName	Data Variable RefName
clNY_NY	String	No	N	C49487	MHYN, MHONGO
		Yes	Y	C49488	
clMHBODSYS	String	Cardiac	CARDIAC	MHBODSYS_CARDIAC	MHBODSYS
		Ear and Labyrinth	EAR AND LABYRINTH	MHBODSYS_EARANDLABYRINTH	
		Endocrine and Lymph	ENDOCRINE AND LYMPH	MHBODSYS_ENDOCRINEANDLYMPH	
		Eye	EYE	MHBODSYS_EYE	
		Hepatobiliary, Renal and Urinary	HEPATOBILIARY, RENAL AND URINARY	MHBODSYS_HEPATOBILIARYRENALANDURINARY	
		Mouth, Throat and Gastrointestinal	MOUTH, THROAT AND GASTROINTESTINAL	MHBODSYS_MOUTHTHROATANDGASTROINTESTINAL	
		Musculoskeletal and Connective Tissue	MUSCULOSKELETAL AND CONNECTIVE TISSUE	MHBODSYS_MUSCULOSKELETALANDCONNECTIVETISSUE	
		Nervous	NERVOUS SYSTEM	MHBODSYS_NERVOUSSYSTEM	

		System			
		Reproductive System and Breast	REPRODUCTIVE SYSTEM AND BREAST	MHBODSYS_REPRODUCTIVESYSTEMANDBREAST	
		Respiratory, Thoracic and Mediastinal	RESPIRATORY, THORACIC AND MEDIASTINAL	MHBODSYS_RESPIRATORYTHORACICANDMEDIASTINAL	
		Skin and Subcutaneous Tissue	SKIN AND SUBCUTANEOUS TISSUE	MHBODSYS_SKINANDSUBCUTANEOUSTISSUE	
		Vascular	VASCULAR	MHBODSYS_VASCULAR	
		Other	OTHER	MHBODSYS_OTHER	
clTOXGR	Integer	Absent	0	C75533	MHTOXGR
		Mild	1	C84263	
		Moderate	2	C84264	
		Severe	3	C84265	
		Life Threatening	4	C84266	
		Fatal	5	C48275_C87162	

3.7 SC – Subject Characteristics

3.7.1 Example – SocioEconomic Factors

This is an example of an SC CRF collecting socioeconomic factors. The sponsor has created their own controlled terminologies for Education Level, Salary Type, Income Level, and Occupation. They are using CDISC Controlled Terminologies for Marital Status.

Row 1 shows a subject who is married with a master's degree and a salaried job in Heath care making $50 – 75K per year.

Row 2 shows a subject who works on commission for a computer firm making 100-150K per year, has a bachelor's degree and is divorced.

Row	SUBJID	EDLEVEL	MARISTAT	SALTYP	INCLEVEL	EMPJOB
1	101	MASTERS DEGREE	MARRIED	SALARY	50,000 - 74,999	HEALTHCARE SUPPORT
2	102	BACHELORS DEGREE	DIVORCED	COMMISSION	100,000-149,999	COMPUTER AND MATHEMATICAL

StudyDesign: Subject Characteristics - SocioEconomic Factors () [SC_UseCase1]		
SocioEconomic Factors [igSC_UseCase1]		
1.	Education Level [Education Level]	**[EDLEVEL]** **[clEDLEVEL]**
2.	Marital Status [Marital Status]	**[MARISTAT]** **[clMARISTAT]**
3.	Salary Type [Salary Type]	**[SALTYP]** **[clSALTYP]**
4.	Income Level [Income Level]	**[INCLEVEL]** **[clINCLEVEL]**
5.	Occupation [Occupation]	**[EMPJOB]** **[clEMPJOB]**

Study Object Descriptions: Subject Characteristics - SocioEconomic Factors		
Type	**RefName**	**Description**
Item	EDLEVEL	SCORRES where SCTESTCD = EDLEVEL
Item	MARISTAT	SCORRES where SCTESTCD = MARISTAT
Item	SALTYP	SCORRES where SCTESTCD = SALTYP
Item	INCLEVEL	SCORRES where SCTESTCD = INCLEVEL
Item	EMPJOB	SCORRES where SCTESTCD = EMPJOB

Codelist Values and Tables: Subject Characteristics - SocioEconomic Factors					
Codelist RefName	**Codelist Data Type**	**Label**	**Code**	**Codelist Item RefName**	**Data Variable Ref**
clEDLEVEL	String	None	NONE	EDLEVEL_0	EDLEVEL
		Nursery School	NURSERY SCHOOL	EDLEVEL_NS	
		Kindergarten	KINDERGARTEN	EDLEVEL_K	
		1st Grade	ELEMENTARY 1	EDLEVEL_1	
		2nd Grade	ELEMENTARY 2	EDLEVEL_2	
		3rd Grade	ELEMENTARY 3	EDLEVEL_3	
		4th Grade	ELEMENTARY 4	EDLEVEL_4	
		5th Grade	ELEMENTARY 5	EDLEVEL_5	
		6th Grade	ELEMENTARY 6	EDLEVEL_6	
		7th Grade	ELEMENTARY 7	EDLEVEL_7	
		8th Grade	ELEMENTARY 8	EDLEVEL_8	
		9th Grade	HIGH SCHOOL 1	EDLEVEL_9	
		10th Grade	HIGH SCHOOL 2	EDLEVEL_10	
		11th Grade	HIGH SCHOOL 3	EDLEVEL_11	
		12th Grade	HIGH SCHOOL 4 NO DIPLOMA	EDLEVEL_12_ND	
		12th Grade Diploma or GED	HIGH SCHOOL 4 DIPLOMA OR GED	EDLEVEL_12	
		Some college, no degree	SOME COLLEGE NO DEGREE	EDLEVEL_13	
		Occupational Associate Degree	OCCUPATIONAL ASSOCIATE DEGREE	EDLEVEL_14	
		Academic Associate Degree	ACADEMIC ASSOCIATE DEGREE	EDLEVEL_15	
		Bachelors Degree	BACHELORS DEGREE	EDLEVEL_16	
		Masters Degree	MASTERS DEGREE	EDLEVEL_17	
		Professional Degree	PROFESSIONAL DEGREE	EDLEVEL_18	
		Doctoral Degree	DOCTORAL DEGREE	EDLEVEL_19	
clMARISTAT	String	Annulled	ANNULLED	C76240	MARISTAT
		Divorced	DIVORCED	C51776	
		Legally Separated	LEGALLY SEPARATED	C51777	
		Married	MARRIED	C51773	
		Never Married	NEVER MARRIED	C51774	
		Widowed	WIDOWED	C51775	
		Polygomous	POLYGAMOUS	C76242	
		Domestic Partner	DOMESTIC PARTNER	C53262	
clSALTYP	String	Commission	COMMISSION	SALTYP_COMMISSION	SALTYP
		Hourly	HOURLY	SALTYP_HOURLY	

		Hourly and Tips	HOURLY AND TIPS	SALTYP_HOURLYTIPS	
		Salary	SALARY	SALTYP_SALARY	
clINCLEVEL	String	<15,000	LT15000	INCLEVEL_LT15000	INCLEVEL
		15,000 - 24999	15000A24999	INCLEVEL_15000A24999	
		25,000 - 34,999	25000A34999	INCLEVEL_25000A34999	
		35,000 - 49,999	35000A49999	INCLEVEL_35000A49999	
		50,000 - 74,999	50000A74999	INCLEVEL_50000A74999	
		75,000 - 99,999	75000A99999	INCLEVEL_75000A99999	
		100,000 - 149,999	100000A149999	INCLEVEL_100000A149999	
		150,000 - 199,999	150000A199999	INCLEVEL_150000A199999	
		>200,000	GT200000	INCLEVEL_GT200000	
clEMPJOB	String	Architecture and Engineering	ARCHITECTURE AND ENGINEERING	EMPJOB_ARCHITECTURE_AND_ENGINEERING	EMPJOB
		Art, Design, Entertainment, Sports, and Media	ART DESIGN ENTERTAINMENT SPORTS AND MEDIA	EMPJOB_ART_DESIGN_ENTERTAINMENT_SPORTS_AND_MEDIA	
		Building and Grounds Cleaning and Maintenance	BUILDING AND GROUNDS CLEANING AND MAINTENANCE	EMPJOB_BUILDING_AND_GROUNDS_CLEANING_AND_MAINTENANCE	
		Business and Financial Operations	BUSINESS AND FINANCIAL OPERATIONS	EMPJOB_BUSINESS_AND_FINANCIAL_OPERATIONS	
		Community and Social Service	COMMUNITY AND SOCIAL SERVICE	EMPJOB_COMMUNITY_AND_SOCIAL_SERVICE	
		Computer and Mathematical Operations	COMPUTER AND MATHEMATICAL OPERATIONS	EMPJOB_COMPUTER_AND_MATHEMATICAL_OPERATIONS	
		Construction and Extraction	CONSTRUCTION AND EXTRACTION	EMPJOB_CONSTRUCTION_AND_EXTRACTION	
		Craftsman/Tradesman (i.e., plumber, electrician)	CRAFTSMAN TRADESMAN	EMPJOB_CRAFTSMAN_TRADESMAN	
		Education, Training, and Library	EDUCATION TRAINING AND LIBRARY	EMPJOB_EDUCATION_TRAINING_AND_LIBRARY	
		Factory /Laborer/Agriculture Worker	FACTORY LABORER AGRICULTURE WORKER	EMPJOB_FACTORY_LABORER_AGRICULTURE_WORKER	
		Farming, Fishing, and Forestry	FARMING FISHING AND FORESTRY	EMPJOB_FARMING_FISHING_AND_FORESTRY	
		Healthcare Practitioners and Technical	HEALTHCARE PRACTITIONERS AND TECHNICAL	EMPJOB_HEALTHCARE_PRACTITIONERS_AND_TECHNICAL	
		Healthcare Support	HEALTHCARE SUPPORT	EMPJOB_HEALTHCARE_SUPPORT	
		Homemaker	HOMEMAKER	EMPJOB_HOMEMAKER	
		Installation, Maintenance, and Repair	INSTALLATION MAINTENANCE AND REPAIR	EMPJOB_INSTALLATION_MAINTENANCE_AND_REPAIR	
		Legal	LEGAL	EMPJOB_LEGAL	
		Life, Physical, and Social Science	LIFE PHYSICAL AND SOCIAL SCIENCE	EMPJOB_LIFE_PHYSICAL_AND_SOCIAL_SCIENCE	
		Management	MANAGEMENT	EMPJOB_MANAGEMENT	
		Merchant	MERCHANT	EMPJOB_MERCHANT	
		Office and Administrative Support	OFFICE AND ADMINISTRATIVE SUPPORT	EMPJOB_OFFICE_AND_ADMINISTRATIVE_SUPPORT	
		Production	PRODUCTION	EMPJOB_PRODUCTION	
		Professional (i.e., physician, lawyer, manager)	PROFESSIONAL	EMPJOB_PROFESSIONAL	
		Protective Service	PROTECTIVE SERVICE	EMPJOB_PROTECTIVE_SERVICE	
		Restaurant/Hotel Services	RESTAURANT HOTEL SERVICES	EMPJOB_RESTAURANT_HOTEL_SERVICES	
		Sales and Related	SALES AND RELATED	EMPJOB_SALES_AND_RELATED	
		Secretarial/Clerical Worker	SECRETARIAL CLERICAL WORKER	EMPJOB_SECRETARIAL_CLERICAL_WORKER	
		Service occupation	SERVICE OCCUPATION	EMPJOB_SERVICE_OCCUPATION	
		Technical Support	TECHNICAL SUPPORT	EMPJOB_TECHNICAL_SUPPORT	
		Transportation and Material	TRANSPORTATION	EMPJOB_TRANSPORTATION_AND_MATERIAL_MOVING	

		Moving	AND MATERIAL MOVING		
		Other	OTHER	EMPJOB_OTHER	
		Not Applicable	NA	EMPJOB_NOT_APPLICABLE	

3.8 SU – Substance Use

3.8.1 Example – Alcohol

This is an example of an SU CRF collecting the optional information around specific types and amounts of alcoholic drinks the subject typically consumes. The sponsor has included instructions on the CRF to normalize units of consumption per type of alcohol consumed.

Row 1 shows a subject who has never used alcohol
Row 2 shows a subject is a current consumer of alcohol who occasionally drinks beer, wine and spirits.
Row 3 shows a subject who is a former consumer of alcohol who frequently drank beer and spirits.

Row	SUBJID	SUCAT	SUNCF_ALCOHOL	SUSTDAT_ALCOHOL	SUENDAT_ALCOHOL	SUDSTXT_BEER	SUDOSFRQ_BEER
1	101	ALCOHOL	NEVER				
2	102	ALCOHOL	CURRENT	AUG-1991		1	QM
3	103	ALCOHOL	FORMER	1985	2-JAN-2007	3	QD

Row	SUDSTXT_WINE	SUDOSFRQ_WINE	SUDSTXT_SPIRITS	SUDOSFRQ_SPIRITS
1 (cont)				
2 (cont)	1	QD	1	QS
3 (cont)	0		3	QD

StudyDesign: Substance Use - Alcohol (ALCOHOL) [SU_UseCase1]

Substance Use - Alcohol, Never Current Former [igSU_UseCase1_SUNCF]

1.*	Has the subject ever used alcohol [Alcohol Usage]	**[SUNCF_ALCOHOL]** *[A:NEVER]* ◯ Never *[A:CURRENT]* ◯ Current *[A:FORMER]* ◯ Former

Substance Use - Alcohol Consumption [igSU_UseCase1]

2.	What was the start date of alcohol consumption? [Start Date Alcohol]	**[SUSTDAT_ALCOHOL]** Req/Unk / Req/Unk / Req (2012-2014)
3.	What was the end date of alcohol consumption? [End Date Alcohol]	**[SUENDAT_ALCOHOL]** Req/Unk / Req/Unk / Req (2012-2014)
4.	What was the amount of beer consumed? 1 Beer = 12 oz or 360 ml [Amount Beer]	**[SU_BEER_CMPD]** **[SUDSTXT_BEER]** Amount A10 **[SUDOSFRQ_BEER]** Frequency *[A:QD]* ◯ Daily *[A:QS]* ◯ Every week *[A:QM]* ◯ Every month *[A:PA]* ◯ Per Year
5.	What was the amount of wine consumed? 1 Wine = 5 oz or 150 ml [Amount Wine]	**[SU_WINE_CMPD]** **[SUDSTXT_WINE]** Amount A10 **[SUDOSFRQ_WINE]** Frequency *[A:QD]* ◯ Daily *[A:QS]* ◯ Every week *[A:QM]* ◯ Every month *[A:PA]* ◯ Per Year
6.	What was the amount of spirits consumed? 1 Spirit = 1.5 oz or 45 ml [Amount Spirits]	**[SU_SPIRITS_CMPD]** **[SUDSTXT_SPIRITS]** Amount A10 **[SUDOSFRQ_SPIRITS]** Frequency *[A:QD]* ◯ Daily *[A:QS]* ◯ Every week *[A:QM]* ◯ Every month *[A:PA]* ◯ Per Year

Key: [*] = Item is required [✔] = Source verification required

Study Object Descriptions: Substance Use - Alcohol

Type	RefName	Description
Form	SU_UseCase1	SUCAT = ALCOHOL
Item	SUNCF_ALCOHOL	SUPPSU.QVAL where QNAM = SUNCF and SUCAT = ALCOHOL. May be used to derive SUOCCUR; Set SUOCCUR to 'Y' if SUNCF_ALCOHOL= "CURRENT" or "FORMER". Set SUOCCUR to 'N' of SUNCF_ALCOHOL= 'NEVER'.
Item	SUSTDAT_ALCOHOL	SUSTDTC
Item	SUENDAT_ALCOHOL	SUENDTC
Item	SUDSTXT_BEER	SUDOSE where SUTRT = BEER
Item	SUDOSFRQ_BEER	SUDOSFRQ where SUTRT = BEER
Item	SUDSTXT_WINE	SUDOSE where SUTRT = WINE

Item	SUDOSFRQ_WINE	SUDOSFRQ where SUTRT = WINE
Item	SUDSTXT_SPIRITS	SUDOSE where SUTRT = SPIRITS
Item	SUDOSFRQ_SPIRITS	SUDOSFRQ where SUTRT = SPIRITS

Codelist Values and Tables: Substance Use - Alcohol

Codelist RefName	Codelist Data Type	Label	Code	Codelist Item RefName	Data Variable RefName
clNCF	String	Never	NEVER	C70543	SUNCF_ALCOHOL
		Current	CURRENT	C25471	
		Former	FORMER	C25627	
clFREQ_SUBSTANCE_USE	String	Daily	QD	C25473	SUDOSFRQ_BEER, SUDOSFRQ_WINE, SUDOSFRQ_SPIRITS
		Every week	QS	C67069	
		Every month	QM	C64498	
		Per Year	PA	C74924	

3.8.2 Example – Caffeine

This is an example of an SU CRF collecting the optional information around specific types and amounts of caffeine the subject typically consumes. The sponsor has included instructions on the CRF to normalize units of consumption per type of caffeine consumed.

Row 1 shows a subject who has never consumed caffeinated products.
Row 2 shows a subject is a current consumer of caffeinated products who occasionally drinks coffee, soda and tea.
Row 3 shows a subject who is a former consumer of caffeinated products who frequently drank coffee and espresso.

Row	SUBJID	SUCAT	SUNCF_CAFFEINE	SUSTDAT_CAFFEINE	SUENDAT_CAFFEINE	SUDSTXT_COFFEE	SUDOSFRQ_COFFEE
1	101	CAFFEINE	NEVER				
2	102	CAFFEINE	CURRENT	1980		1	QD
3	103	CAFFEINE	FORMER	1985	2010	6	QD

Row	SUDSTXT_SODA	SUDOSFRQ_SODA	SUDSTXT_TEA	SUDOSFRQ_TEA	SUDSTXT_ESPRESSO	SUDOSFRQ_ESPRESSO
1 (cont)						
2 (cont)	2	QD	1	QW		
3 (cont)					2	QD

StudyDesign: Substance Use - Caffeine (CAFFEINE) [SU_UseCase2]

Substance Use - Caffeine, Never Current Former [igSU_UseCase2_SUNCF]

1.*	Has the subject ever used caffeine [Caffeine Usage]	**[SUNCF_CAFFEINE]** *[A:NEVER]* ◯ Never *[A:CURRENT]* ◯ Current *[A:FORMER]* ◯ Former

Substance Use - Caffeine Consumption [igSU_UseCase2]

2.	What was the start date of caffeine consumption? [Start Date Caffeine]	**[SUSTDAT_CAFFEINE]** NReq/Unk / NReq/Unk / Req (2012-2014)
3.	What was the end date of caffeine consumption? [End Date Caffeine]	**[SUENDAT_CAFFEINE]** Req/Unk / Req/Unk / Req (2012-2014)
4.	What was the amount of coffee consumed? 1 Coffee = 6 oz or 180 ml [Amount Coffee]	**[SU_COFFEE_CMPD]** **[SUDSTXT_COFFEE]** Amount A10 **[SUDOSFRQ_COFFEE]** Frequency *[A:QD]* ◯ Daily *[A:QS]* ◯ Every week *[A:QM]* ◯ Every month *[A:PA]* ◯ Per Year
5.	What was the amount of soda consumed? 1 Soda = 12 oz or 360 ml [Amount Soda]	**[SU_SODA_CMPD]** **[SUDSTXT_SODA]** Amount A10 **[SUDOSFRQ_SODA]** Frequency *[A:QD]* ◯ Daily *[A:QS]* ◯ Every week *[A:QM]* ◯ Every month *[A:PA]* ◯ Per Year
6.	What was the amount of tea consumed? 1 Tea = 6 oz or 180 ml [Amount Tea]	**[SU_TEA_CMPD]** **[SUDSTXT_TEA]** Amount A10 **[SUDOSFRQ_TEA]** Frequency *[A:QD]* ◯ Daily *[A:QS]* ◯ Every week *[A:QM]* ◯ Every month *[A:PA]* ◯ Per Year
7.	What was the amount of espresso consumed? 1 Espresso = 2 oz or 60 ml [Amount Espresso]	**[SU_ESPRESSO_CMPD]** **[SUDSTXT_ESPRESSO]** Amount A10 **[SUDOSFRQ_ESPRESSO]** Frequency *[A:QD]* ◯ Daily *[A:QS]* ◯ Every week *[A:QM]* ◯ Every month *[A:PA]* ◯ Per Year

Key: [*] = Item is required [✔] = Source verification required

Study Object Descriptions: Substance Use - Caffeine

Type	RefName	Description
Form	SU_UseCase2	SUCAT = CAFFEINE
Item	SUNCF_CAFFEINE	SUPPSU.QVAL where QNAM = SUNCF and SUCAT = CAFFEINE. May be used to derive

		SUOCCUR; Set SUOCCUR to 'Y' if SUNCF_CAFFEINE = "CURRENT" or "FORMER". Set SUOCCUR to 'N' of SUNCF_CAFFEINE = 'NEVER'.
Item	SUSTDAT_CAFFEINE	SUSTDTC
Item	SUENDAT_CAFFEINE	SUENDTC
Item	SUDSTXT_COFFEE	SUDOSE where SUTRT = COFFEE
Item	SUDOSFRQ_COFFEE	SUDOSFRQ where SUTRT = COFFEE
Item	SUDSTXT_SODA	SUDOSE where SUTRT = SODA
Item	SUDOSFRQ_SODA	SUDOSFRQ where SUTRT = SODA
Item	SUDSTXT_TEA	SUDOSE where SUTRT = TEA
Item	SUDOSFRQ_TEA	SUDOSFRQ where SUTRT = TEA
Item	SUDSTXT_ESPRESSO	SUDOSE where SUTRT = ESPRESSO
Item	SUDOSFRQ_ESPRESSO	SUDOSFRQ where SUTRT = ESPRESSO

Codelist Values and Tables: Substance Use - Caffeine

Codelist RefName	Codelist Data Type	Label	Code	Codelist Item RefName	Data Variable RefName
clNCF	String	Never	NEVER	C70543	SUNCF_CAFFEINE
		Current	CURRENT	C25471	
		Former	FORMER	C25627	
clFREQ_SUBSTANCE_USE	String	Daily	QD	C25473	SUDOSFRQ_COFFEE, SUDOSFRQ_SODA, SUDOSFRQ_TEA, SUDOSFRQ_ESPRESSO
		Every week	QS	C67069	
		Every month	QM	C64498	
		Per Year	PA	C74924	

3.8.3 Example – Tobacco

This is an example of an SU CRF collecting the optional information around specific types and amounts of tobacco the subject typically consumes. The sponsor has included instructions on the CRF to normalize units of consumption per type of tobacco consumed.

Row 1 shows a subject who has never consumed tobacco products.
Row 2 shows a subject is a current consumer of tobacco products who regularly smokes cigarettes and occasionally smokes a cigar.
Row 3 shows a subject who is a former consumer of tobacco products who frequently chewed tobacco and occasionally smoked a pipe.

Row	SUBJID	SUCAT	SUNCF_TOBACCO	SUSTDAT_TOBACCO	SUENDAT_TOBACCO	SUDSTXT_ CIGARETTES	SUDOSFRQ_ CIGARETTES
1	101	TOBACCO	NEVER				
2	102	TOBACCO	CURRENT	1984		15	QD
3	103	TOBACCO	FORMER	1975	2010		

Row	SUDSTXT_ CIGARS	SUDOSFRQ_ CIGARS	SUDSTXT_SMOKELESS	SUDOSFRQ_ SMOKELESS	SUDSTXT_PIPES	SUDOSFRQ_PIPES
1 (cont)						
2 (cont)	3	QS				
3 (cont)			8	QD	2	QS

StudyDesign: Substance Use - Tobacco () [SU_UseCase3]

Substance Use - Tobacco, Never Current Former [igSU_UseCase3_SUNCF]		
1.*	Has the subject ever used tobacco? [Tobacco Usage]	**[SUNCF_TOBACCO]** *[A:NEVER]* ◯ Never *[A:CURRENT]* ◯ Current *[A:FORMER]* ◯ Former
Substance Use - Tobacco Consumption [igSU_UseCase3]		
2.	Start date of tobacco consumption? [Start Date Tobacco]	**[SUSTDAT_TOBACCO]** NReq/Unk / NReq/Unk / Req (2012-2014)
3.	End date of tobacco consumption? [End Date Tobacco]	**[SUENDAT_TOBACCO]** Req/Unk / Req/Unk / Req (2012-2014)
4.	What was the amount of cigarettes consumed? [Amount Cigarettes]	**[SU_CIGARETTES_CMPD]** **[SUDSTXT_CIGARETTES]** Amount A10 **[SUDOSFRQ_CIGARETTES]** Frequency *[A:QD]* ◯ Daily *[A:QS]* ◯ Every week *[A:QM]* ◯ Every month *[A:PA]* ◯ Per Year
5.	What was the amount of cigars consumed? [Amount Cigars]	**[SU_CIGARS_CMPD]** **[SUDSTXT_CIGARS]** Amount A10 **[SUDOSFRQ_CIGARS]** Frequency *[A:QD]* ◯ Daily *[A:QS]* ◯ Every week *[A:QM]* ◯ Every month *[A:PA]* ◯ Per Year
6.	What was the amount of smokeless (pinches) tobacco consumed? [Amount Smokeless]	**[SU_SMOKELESS_CMPD]** **[SUDSTXT_SMOKELESS]** Amount A10 **[SUDOSFRQ_SMOKELESS]** Frequency *[A:QD]* ◯ Daily *[A:QS]* ◯ Every week *[A:QM]* ◯ Every month *[A:PA]* ◯ Per Year
7.	What was the amount of pipefuls consumed? [Amount Pipefuls]	**[SU_PIPES_CMPD]** **[SUDSTXT_PIPES]** Amount A10 **[SUDOSFRQ_PIPES]** Frequency *[A:QD]* ◯ Daily *[A:QS]* ◯ Every week *[A:QM]* ◯ Every month *[A:PA]* ◯ Per Year

Key: [*] = Item is required [✔] = Source verification required

Study Object Descriptions: Substance Use - Tobacco

Type	RefName	Description
Form	SU_UseCase3	SUCAT = TOBACCO
Item	SUNCF_TOBACCO	SUPPSU.QVAL where QNAM = SUNCF and SUCAT = TOBACCO. May be used to derive

		SUOCCUR; Set SUOCCUR to 'Y' if SUNCF_TOBACCO= "CURRENT" or "FORMER". Set SUOCCUR to 'N' of SUNCF_TOBACCO= 'NEVER'.
Item	SUSTDAT_TOBACCO	SUSTDTC
Item	SUENDAT_TOBACCO	SUENDTC
Item	SUDSTXT_CIGARETTES	SUDOSE where SUTRT = CIGARETTES
Item	SUDOSFRQ_CIGARETTES	SUDOSFRQ where SUTRT = CIGARETTES
Item	SUDSTXT_CIGARS	SUDOSE where SUTRT = CIGARS
Item	SUDOSFRQ_CIGARS	SUDOSFRQ where SUTRT = CIGARS
Item	SUDSTXT_SMOKELESS	SUDOSE where SUTRT = SMOKELESS
Item	SUDOSFRQ_SMOKELESS	SUDOSFRQ where SUTRT = SMOKELESS
Item	SUDSTXT_PIPES	SUDOSE where SUTRT = PIPES
Item	SUDOSFRQ_PIPES	SUDOSFRQ where SUTRT = PIPES

Codelist Values and Tables: Substance Use - Tobacco

Codelist RefName	Codelist Data Type	Label	Code	Codelist Item RefName	Data Variable RefName
clNCF	String	Never	NEVER	C70543	SUNCF_TOBACCO
		Current	CURRENT	C25471	
		Former	FORMER	C25627	
clFREQ_SUBSTANCE_USE	String	Daily	QD	C25473	SUDOSFRQ_CIGARETTES, SUDOSFRQ_CIGARS, SUDOSFRQ_SMOKELESS, SUDOSFRQ_PIPES
		Every week	QS	C67069	
		Every month	QM	C64498	
		Per Year	PA	C74924	

4.0 Octagon FUSE

There following examples were created using Octagon's eDC tool, FUSE

4.1 IE – Inclusion / Exclusion Criteria Not Met

4.1.1 Example - Inclusion / Exclusion Criteria Not Met

This is an example of an IE CRF collecting Inclusion / Exclusion Criteria defined for the study. The blank values in each of the Inclusion/Exclusion fields indicate that particular Inclusion/Exclusion question was not an ineligibility factor for the subject.

The table below represents the data captured in a vertical (normalized structure).
Row 1 shows an example of a subject who met all Inclusion / Exclusion criteria.

Row 2 shows an example of a subject who did not meet the inclusion criteria of being between the age of 18 and 70 inclusive

Row 3 shows an example of the same subject who met the exclusion criteria of diabetes history.

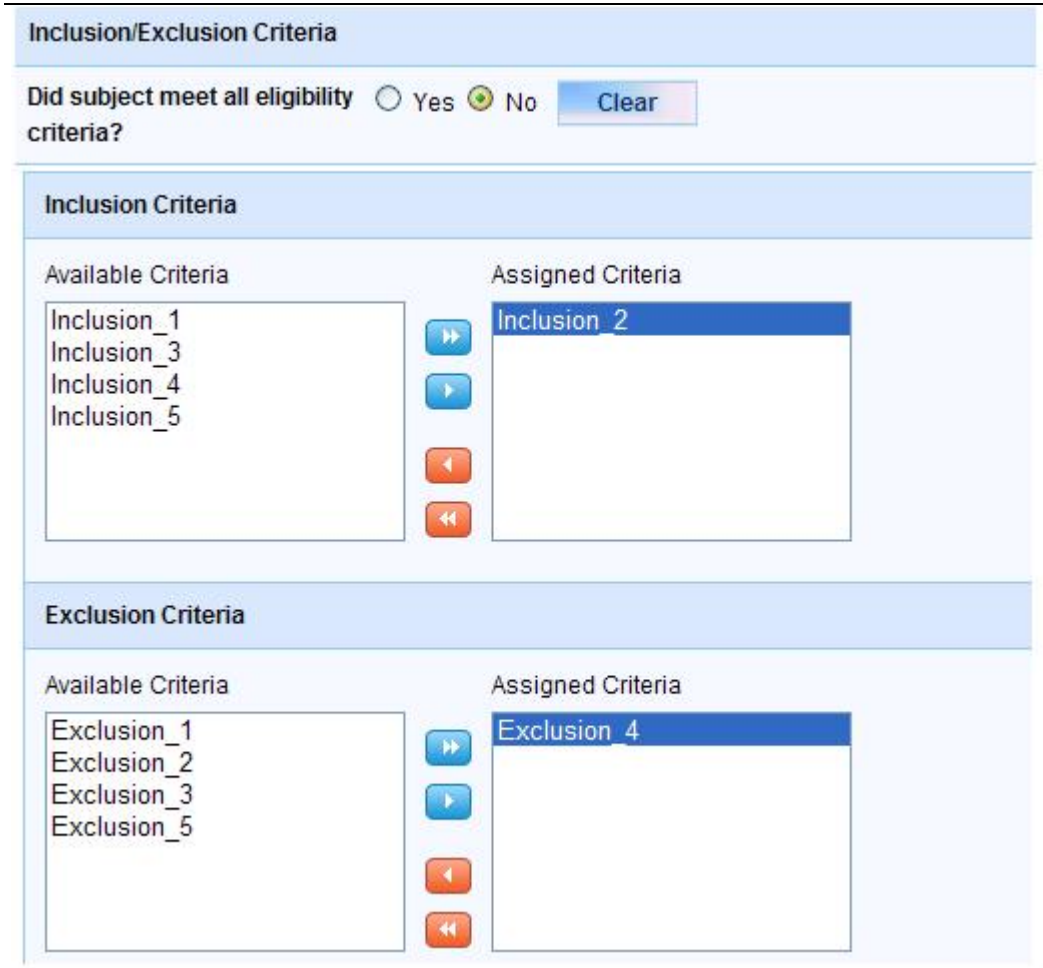
Row	SUBJID	VISIT	VISITNUM	IEYN	IETEST	IETESTCD	IECAT
1	101	Screening	1	Y			
2	102	Screening	1	N	Subject between the age of 18 and 70 inclusive	INC_002	INCLUSION
3	102	Screening	1	N	Subjects with a history of diabetes	EXC_004	EXCLUSION

The table below represents the data captured in a horizontal (de-normalized structure).
Row 1 shows an example of a subject who met all Inclusion / Exclusion criteria.

Row 2 shows an example of a subject who did not meet the inclusion criteria of being between the age of 18 and 70 inclusive and met the exclusion criteria of diabetes history.

Row	SUBJID	VISIT	VISITNUM	IEYN	INC_001	INC_002	INC_003	INC_004	INC_005	EXC_001
1	101	Screening	1	Y						
2	102	Screening	1	N		Y				

Row	EXC_002	EXC_003	EXC_004	EXC_005
1 (cont)				
2 (cont)			Y	


Inclusion/Exclusion Criteria
Did subject meet all eligibility criteria?
Yes
No
Clear
Inclusion Criteria
Available Criteria
Inclusion_1
Inclusion_3
Inclusion_4
Inclusion_5
Assigned Criteria
Inclusion_2
Exclusion Criteria
Available Criteria
Exclusion_1
Exclusion_2
Exclusion_3
Exclusion_5
Assigned Criteria
Exclusion_4

4.2 DS – Disposition

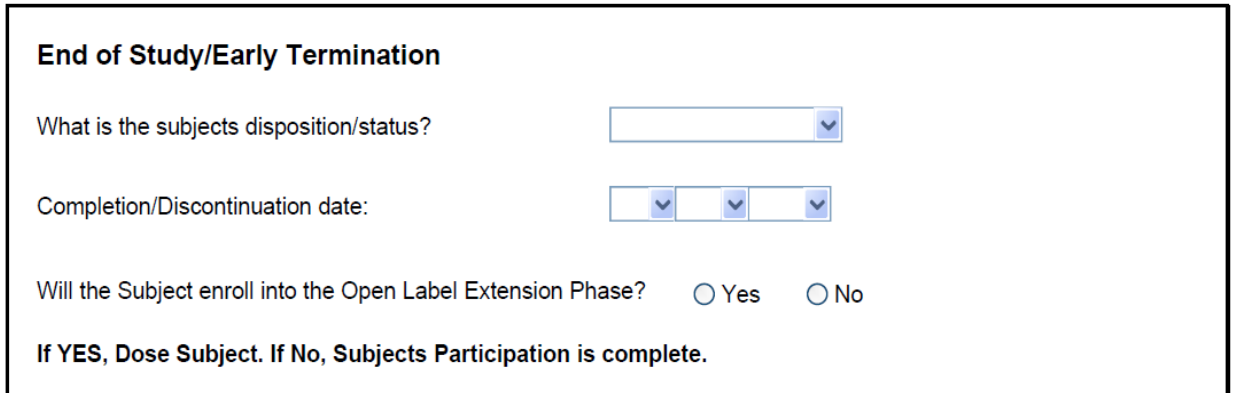
4.2.1 Example – End of Study / Early Termination

This is an example of a DS CRF where the End of Study form has been modified to capture if the Subject will enroll into the Open Label Extension phase of the protocol.

Row 1 shows a subject who completed and is continuing to the Open Label Extension.
Row 2 shows a subject who completed and is not continuing to the Open Label Extension.

Row	SUBJID	VISIT	VISITNUM	DSDECOD	DSSTDAT	DSCONT_OLE
1	301	Week 9	10	COMPLETED	21- JUN- 2011	Y
2	302	Week 8	9	COMPLETED	4-JUL-2012	N

End of Study/Early Termination



5.0 Paper CRFs

There following examples were created as software independent, paper CRFs

5.1 EX – Exposure

5.1.1 Example - Nicotine Patch Exposure

This is an example of an EX CRF collecting the information about nicotine patch exposure. The sponsor has defined a variable to capture the % of the patch that was still adhering to the skin at the time of removal, which will map to SUPPEX. The table below is the sample output from the operational database for six subjects' CRFs.

Row	SUBJID	EXTRT	EXTRT	EXDOSU	ADHERPERCENT	EXSTDAT	EXSTTIM	EXENDAT	EXENTIM
1	100001	NICOTINE	21	MG	75	12-JAN-2010	12:35	14-JAN-2010	8:00
2	100002	NICOTINE	21	MG	100	14-JAN-2010	9:45	15-JAN-2010	13:45
3	100003	NICOTINE	21	MG	100	11-JAN-2010	10:30	12-JAN-2010	12:00
4	100004	NICOTINE	21	MG	50	11-JAN-2010	11:30	14-JAN-2010	8:00
5	100005	NICOTINE	21	MG	100	12-JAN-2010	10:00	13-JAN-2010	11:30
6	100006	NICOTINE	21	MG	75	13-JAN-2010	8:30	14-JAN-2010	10:00

STUDY	SITE	SUBJECT

When was the patch applied and removed? Start date	__ __ - __ __ __ - __ __ __ __ (D D) - (M O N) - (Y Y Y Y)
Start time	__ __ : __ __ (HH) : (MM)
End date	__ __ - __ __ __ - __ __ __ __ (D D) - (M O N) - (Y Y Y Y)
Start time	__ __ : __ __ (HH) : (MM)
On the removal date, what % of the patch was adhering?	_____ %

5.1.2 Example – Infusion

This is an example of an EX CRF for an infusion at a planned study visit collecting the planned dose, actual dose administered, and if the dose was delayed, the reason for the delay.

The treatment name is printed on the CRF. The operational question to determine if the dose was actually administered is collected. If the dose was administered, the actual dosing start date and time, and dosing end date and time are collected. The planned infusion dose amount is recorded, though the units are fixed and printed on the CRF. Then the actual infusion dose amount is recorded, and the units are again fixed and printed on the CRF. If the infusion was delayed from the planned study day or time, the site may record a comment describing the reason for the dosing delay, using the sponsor defined variable, EXREAS, which will map to SUPPEX.

The table below is the sample output from the operational database for data from three subject visits.

Row	SUBJID	VISIT	VISDAT	EXYN	EXTRT	EXSTDAT	EXSTTIM	EXENDAT	EXENTIM
1	100-001	3	26-MAR-2011	Y	Panacea Hydrochloride	26-MAR-2011	9:30	26-MAR-2011	12:30
2	100-002	3	30-MAR-2011	N	Panacea Hydrochloride				
3	100-003	3	26-MAR-2011	Y	Panacea Hydrochloride	26-MAR-2011	15:30		18:30

Row	EXPDOSE	EXPDOSEU	EXDSTXT	EXDOSU	EXREAS
1 (cont)	12	mg	11.4	mg	
2 (cont)					
3 (cont)	12	mg	11.9	mg	Scheduling conflict

Protocol ABC123	Visit 3	Subject Number ___-___
Visit Date: __ / ___ / ____ dd / mmm / yyyy		

Panacea Hydrochloride Infusion

Is treatment data available? ☐ Yes ☐ No

Start Date __ / ____ / ____ (dd / mmm / yyyy) Start Time __ : __ (hh : ss)

End Date __ / ____ / ____ (dd / mmm / yyyy) End Time __ : __ (hh : ss)

Planned Dose [ ] mg

Administered Dose [ ] mg

If infusion was delayed, describe reason for delay

[ ]
[ ]
[ ]

5.1.3 Example – Opthalmic Solution

The majority of exposure data is derived from the study randomization and protocol, not from data collected at the subject level. This information would include for example, Dose per Administration, Dose Description, Dose Units, and Dose Form.

Exposure data that is collected at the subject level will include start date – which may be derived from the visit date and start time (if needed); and end date and time (if time is needed). In this example, the first drop is instilled at the investigative site and the time is collected, but the date of first drop is obtained from the visit date. For the last drop, the date and time are collected at the final visit. The date of last dose should be collected as this may or may not be associated with a visit date.

Row	SUBJID	VISIT	VISDAT	EXYN	EXTRT	EXSTDAT	EXSTTIM	EXENDAT	EXENTIM
1	100-001	3	26-MAR-2011	Y	Timolol Maleate	26-MAR-2011	18:05		
2	100-002	7	15-SEP-2011	Y	Timolol Maleate			15-SEP-2011	19:00
3	100-003	3	26-MAR-2011	Y	Panacea Hydrochloride	26-MAR-2011	15:30		18:30

First Date of Treatment:

STUDY	SITE	SUBJECT	Visit Date

First Dose: Start Time __ : __

hh : ss

Last Date of Treatment:

STUDY	SITE	SUBJECT	Visit Date

Last Dose: End Date __ / ____ / ____

dd / mmm / yyyy

End Time __ : __

hh : ss

5.2 LB – Laboratory Test Results

5.2.1 Example – Unscheduled Blood Chemistry

This paper CRF demonstrates collection of unscheduled blood chemistry tests. Blood chemistries performed by the local lab are recorded for any unscheduled visit. This example CRF also illustrates a log style collection form.

In this example, the laboratory name and reference ranges are handled separately from the CRF and entered into the sponsor's laboratory management system.

The laboratory panel name, and laboratory test names are pre-printed on the CRF. For each unscheduled visit, the sponsor enters unscheduled visit name as free text, and, for each test, collection date and time, and results. Pre-defined units allow the sponsor to select the appropriate unit provided by the local lab.

The table below is the sample output from the operational database for data from one subject for two unscheduled visits.

Row	SUBJID	VISIT	LBTPT	LBCAT	LBTEST	LBTESTCD
1	100-001	Unscheduled	Day 27	Blood Chemistry	Sodium	SODIUM
2	100-001	Unscheduled	Day 27	Blood Chemistry	Calcium	CA
3	100-001	Unscheduled	Day 27	Blood Chemistry	Phosphorus	PHOS
4	100-001	Unscheduled	Day 45 - 240 minutes post-dose	Blood Chemistry	Sodium	SODIUM
5	100-001	Unscheduled	Day 45 - 240 minutes post-dose	Blood Chemistry	Calcium	CA
6	100-001	Unscheduled	Day 45 - 240 minutes post-dose	Blood Chemistry	Phosphorus	PHOS

Row	LBDAT	LBTIM	LBORRES	LBORRESU
1 (cont)	26-MAR-2011	9:30	4.2	mmol/L
2 (cont)	26-MAR-2011	9:30	9.8	mg/dL
3 (cont)	26-MAR-2011	9:30	1.04	mmol/L
4 (cont)	26-MAR-2011	11:05	4.5	mmol/L
5 (cont)	26-MAR-2011	11:05	10.4	mg/dL
6 (cont)	26-MAR-2011	11:05	1.21	mmol/L

Mock paper CRF for Unscheduled Blood Chemistry local laboratory findings example:

Protocol ABC123	**Blood Chemistry**	Subject Number ___-___
Unscheduled		

Timepoint	Test	Collection Date (dd / mmm / yyyy)	Collection Time (hh : ss)	Result	Units
	Sodium	__ / ___ / ____	__ : __		☐ mmol/L ☐ mEq/L, MVAL/L
	Calcium	__ / ___ / ____	__ : __		☐ mg/dL, mg% ☐ mmol/L ☐ mEq/L, MVAL/L
	Phosphorus	__ / ___ / ____	__ : __		☐ mg/dL, mg% ☐ mmol/L ☐ mEq/L, MVAL/L
	Sodium	__ / ___ / ____	__ : __		☐ mmol/L ☐ mEq/L, MVAL/L
	Calcium	__ / ___ / ____	__ : __		☐ mg/dL, mg% ☐ mmol/L ☐ mEq/L, MVAL/L
	Phosphorus	__ / ___ / ____	__ : __		☐ mg/dL, mg% ☐ mmol/L ☐ mEq/L, MVAL/L
	Sodium	__ / ___ / ____	__ : __		☐ mmol/L ☐ mEq/L, MVAL/L
	Calcium	__ / ___ / ____	__ : __		☐ mg/dL, mg% ☐ mmol/L ☐ mEq/L, MVAL/L
	Phosphorus	__ / ___ / ____	__ : __		☐ mg/dL, mg% ☐ mmol/L ☐ mEq/L, MVAL/L

5.2.2 Example – Phase 1 Blood Chemistry with Repeated Timepoints

This LB CRF demonstrates collection of blood chemistry tests in a Phase I unit. Blood chemistries performed by the local lab are collected at three different timepoints at the study visit. This example CRF also illustrates a log style collection form.

In this example, the laboratory name and reference ranges are handled separately from the CRF and entered into the sponsor's laboratory management system.

The visit, timepoints, laboratory panel name, and laboratory test names are pre-printed on the CRF. For each occurrence of the tests, the sponsor indicates whether the test was performed, and if it is, the sponsor enters the collection date and time, and results. Pre-defined units allow the sponsor to select the appropriate unit provided by the local lab.

The table below is the sample output from the operational database for data from one subject visit.

Row	SUBJID	VISIT	LBTPT	LBCAT	LBTEST	LBTESTCD	LBPERF
1	100-001	Day 1	30 minutes pre-dose	Blood Chemistry	Sodium	SODIUM	Y
2	100-001	Day 1	30 minutes pre-dose	Blood Chemistry	Calcium	CA	Y
3	100-001	Day 1	30 minutes pre-dose	Blood Chemistry	Phosphorus	PHOS	Y
4	100-001	Day 1	60 minutes post-dose	Blood Chemistry	Sodium	SODIUM	Y
5	100-001	Day 1	60 minutes post-dose	Blood Chemistry	Calcium	CA	Y
6	100-001	Day 1	60 minutes post-dose	Blood Chemistry	Phosphorus	PHOS	Y
7	100-001	Day 1	180 minutes post-dose	Blood Chemistry	Sodium	SODIUM	N
8	100-001	Day 1	180 minutes post-dose	Blood Chemistry	Calcium	CA	N
9	100-001	Day 1	180 minutes post-dose	Blood Chemistry	Phosphorus	PHOS	N

Row	LBDAT	LBTIM	LBORRES	LBORRESU
1 (cont)	26-MAR-2011	9:30	4.1	mmol/L
2 (cont)	26-MAR-2011	9:30	9.2	mg/dL
3 (cont)	26-MAR-2011	9:30	0.89	mmol/L
4 (cont)	26-MAR-2011	11:05	4.8	mmol/L
5 (cont)	26-MAR-2011	11:05	10.1	mg/dL
6 (cont)	26-MAR-2011	11:05	1.03	mmol/L
7 (cont)				
8 (cont)				
9 (cont)				

Mock paper CRF for Phase I Blood Chemistry local laboratory findings example:

Protocol ABC123	**Blood Chemistry**	Subject Number ___-___
Day 1		

Timepoint	**Test**	**Lab performed (Y/N)**	**Collection Date (dd / mmm / yyyy)**	**Collection Time (hh : ss)**	**Result**	**Units**
30 minutes pre-dose	Sodium	☐ Yes ☐ No	__ / ___ / ____	__ : __		☐ mmol/L ☐ mEq/L, MVAL/L
30 minutes pre-dose	Calcium	☐ Yes ☐ No	__ / ___ / ____	__ : __		☐ mg/dL, mg% ☐ mmol/L ☐ mEq/L, MVAL/L
30 minutes pre-dose	Phosphorus	☐ Yes ☐ No	__ / ___ / ____	__ : __		☐ mg/dL, mg% ☐ mmol/L ☐ mEq/L, MVAL/L
60 minutes post-dose	Sodium	☐ Yes ☐ No	__ / ___ / ____	__ : __		☐ mmol/L ☐ mEq/L, MVAL/L
60 minutes post-dose	Calcium	☐ Yes ☐ No	__ / ___ / ____	__ : __		☐ mg/dL, mg% ☐ mmol/L ☐ mEq/L, MVAL/L
60 minutes post-dose	Phosphorus	☐ Yes ☐ No	__ / ___ / ____	__ : __		☐ mg/dL, mg% ☐ mmol/L ☐ mEq/L, MVAL/L
180 minutes post-dose	Sodium	☐ Yes ☐ No	__ / ___ / ____	__ : __		☐ mmol/L ☐ mEq/L, MVAL/L
180 minutes post-dose	Calcium	☐ Yes ☐ No	__ / ___ / ____	__ : __		☐ mg/dL, mg% ☐ mmol/L ☐ mEq/L, MVAL/L
180 minutes post-dose	Phosphorus	☐ Yes ☐ No	__ / ___ / ____	__ : __		☐ mg/dL, mg% ☐ mmol/L ☐ mEq/L, MVAL/L

5.3 PK – Pharmacokinetics

5.3.1 Example – Pharmacokinetic Sample Collection

This PK CRF demonstrates PK sample collection at multiple time points within a scheduled visit in a log style format. The visit, planned time points, and sample type category are pre-printed on the CRF. For each planned time point, the sponsor indicates whether the sample was collected. If the sample was collected, the sponsor if the subject was fasting at the time of sample collection, and enters the date and time the sampel was taken. This example also includes a field for the sponsor to include comments about each sample.

The table below is the sample output from the operational database for data from one subject visit.

Row	SUBJID	VISIT	LBTPT	LBCAT	LBPERF	LBFAST
1	100-001	Visit 6	30 minutes pre-dose	Pharmacokinetic	Y	Y
2	100-001	Visit 6	5 minutes post-dose	Pharmacokinetic	Y	Y
3	100-001	Visit 6	60 minutes post-dose	Pharmacokinetic	Y	N
4	100-001	Visit 6	120 minutes post-dose	Pharmacokinetic	Y	N
5	100-001	Visit 6	180 minutes post-dose	Pharmacokinetic	Y	N

Row	LBDAT	LBTIM	LBCOM
1 (cont)	5-JUN-2011	8:45	
2 (cont)	5-JUN-2011	9:23	
3 (cont)	5-JUN-2011	10:18	
4 (cont)	5-JUN-2011	11:14	
5 (cont)	5-JUN-2011	12:30	Subject went to lunch and got stuck in traffic jam

Mock paper CRF for sample collection for scheduled timepoints with sample dates and times example:

Protocol ABC123	**Pharmacokinetic Sample Collection**	Subject Number ___-___
Visit 6		

Planned Time Point	**Was the sample collected?**	**Fasting?**	**Collection Date (dd / mmm / yyyy)**	**Collection Time (hh : ss)**	**Comments (e.g. Sample hemolyzed)**
30 minutes pre-dose	☐ Yes ☐ No	☐ Yes ☐ No	__ / ___ / ____	__ : __	
5 minutes post-dose	☐ Yes ☐ No	☐ Yes ☐ No	__ / ___ / ____	__ : __	
60 minutes post-dose	☐ Yes ☐ No	☐ Yes ☐ No	__ / ___ / ____	__ : __	
120 minutes post-dose	☐ Yes ☐ No	☐ Yes ☐ No	__ / ___ / ____	__ : __	
180 minutes post-dose	☐ Yes ☐ No	☐ Yes ☐ No	__ / ___ / ____	__ : __	

5.4 SC – Subject Characteristcis

5.4.1 Example – Subject Characteristic – Eye Color, collected once per subject

This is an example of a subject characteristic, where iris (eye) color is collected for the subject at a screening visit. In this example, the eye color is collected by subject. For the very rare occurrence of heterochromia iritis (two different color irises) would be documented in the 'other-specify' field as shown for subject 10003 below.

Row	SUBJID	SCTESTCD	SCTEST	SCORRES
1	100001	EYECOLOR	EYE COLOR	BLUE
2	100002	EYECOLOR	EYE COLOR	BROWN
3	100003	EYECOLOR	EYE COLOR	OD: BLUE OS: GRAY
4	100004	EYECOLOR	EYE COLOR	BROWN
5	100005	EYECOLOR	EYE COLOR	BLUE-GRAY

Paper CRF

STUDY	SITE	SUBJECT

Iris Color

- ☐ Brown
- ☐ Hazel
- ☐ Green
- ☐ Blue
- ☐ Gray
- ☐ Other, specify _____

5.4.2 Example – Subject Characteristic – Eye Color, collected once per subject

This is an example of a subject characteristic, where iris (eye) color is collected separately for each eye at a screening visit. Because heterochromia iritis (different eye color) is classified as a rare occurrence (less than 200,000 people in the US), this is generally not recommended unless there are specific reasons that this level of detail would be needed for analysis purposes.

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Row	SUBJID	SCTESTCD	SCTEST	SCLOC	SCORRES
1	100001	EYECOLOR	EYE COLOR	OD	BLUE
2	100001	EYECOLOR	EYE COLOR	OS	BLUE
3	100002	EYECOLOR	EYE COLOR	OD	BROWN
4	100002	EYECOLOR	EYE COLOR	OS	BROWN
5	100003	EYECOLOR	EYE COLOR	OD	BLUE
6	100003	EYECOLOR	EYE COLOR	OS	GRAY
7	100004	EYECOLOR	EYE COLOR	OD	BROWN
8	100004	EYECOLOR	EYE COLOR	OS	BROWN
9	100005	EYECOLOR	EYE COLOR	OD	BLUE-GRAY
10	100005	EYECOLOR	EYE COLOR	OS	BLUE-GRAY

Paper CRF

STUDY	SITE	SUBJECT

Iris Color	**OD**	**OS**
	☐ Brown	☐ Brown
	☐ Hazel	☐ Hazel
	☐ Green	☐ Green
	☐ Blue	☐ Blue
	☐ Gray	☐ Gray
	☐ Other, specify _____	☐ Other, specify _____

5.5 SU – Substance Use

5.5.1 Example – Exposure to Second Hand Smoke

This is an example of an SU CRF collecting the subject's exposure to second hand smoke at a screening visit. The sponsor has defined variables to collect: if there has been a smoker in the subject's household in the past has 10 years and the number of hours per day the subject is exposed to the second-hand smoke, which will map to SUPPSU. The table below is the sample output from the operational database for six subjects' CRFs.

Row	SUBJID	SUTRT	SUNCF	HOUSESMOKE	HOURSDAY	SUEVLINT
1	100001	CIGARETTES	NEVER	Y	8	-P10Y
2	100002	CIGARETTES	NEVER	Y	10	-P10Y
3	100003	CIGARETTES	FORMER	Y	2	-P10Y
4	100004	CIGARETTES	CURRENT	N	5	-P10Y
5	100005	CIGARETTES	NEVER	Y	12	-P10Y
6	100006	CIGARETTES	NEVER	N	24	-P10Y

STUDY	SITE	SUBJECT
Usage: Has the subject ever smoked Cigarettes?		☐Never ☐Current ☐Former
During the past 10 years, has there been a smoker in the subject's household?		☐Yes ☐No
Hours per day subject is exposed to smoke		

5.5.2 Example – Risk Factor for Lung Cancer

This is an example of an SU CRF collecting the subject's risk factor for lung cancer. The information being collected in this form is whether the subject has ever smoked, and if they have whether they have smoked more than 100 cigarettes in their lifetime. The table below is the sample output from the operational database for six subjects' CRFs.

Row	SUBJID	SUTRT	SUNCF	SUDSTXT
1	100001	CIGARETTES	NEVER	
2	100002	CIGARETTES	NEVER	
3	100003	CIGARETTES	FORMER	< 100 CIGARETTES
4	100004	CIGARETTES	CURRENT	>/= CIGARETTES
5	100005	CIGARETTES	NEVER	
6	100006	CIGARETTES	NEVER	

STUDY	SITE	SUBJECT

Usage: Has the subject ever smoked Cigarettes?	☐Never ☐Current ☐Former
Amount: If **Current** or **Former**, indicate how many cigarettes they have smoked in their lifetime	☐ < 100 cigarettes ☐ >/= 100 cigarettes