CDASH

CDASH Publication

Legend:

ODM
CDASH
SDTM
Terminology

Item Definitions

OID	Name	CDASH Alias Name	Codelist	Domain	CDASH Core	SDTM
Common_1_2011-10-24	Sponsor	SPONSOR		Common	Optional	-
Description:	A unique identifier for a study sponsor. An individual, company, institution, or organization that takes responsibility for the initiation and management of a clinical trial, although may or may not be the main funding organization. If there is also a secondary sponsor, this entity would be considered the primary sponsor. A corporation or agency whose employees conduct the investigation is considered a sponsor and the employees are considered investigators.					
Question:	Sponsor					
Completion instructions:	Not applicable					
Info. for Sponsors:	This is typically pre-printed. May be used as an identifier in external data warehouses (e.g. Janus) and in electronic medical records or other partnerships for sharing data. Not an SDTM variable.					
Common_2_2011-10-24	Protocol/Study	STUDYID		Common	Highly Recommended	STUDYID
Description:	Unique identifier for a study.					
Question:	Protocol/Study					
Completion instructions:	Not applicable.					
Info. for Sponsors:	This is typically pre-printed/pre-populated.					
Common_3_2011-10-24	Site	SITEID		Common	Highly Recommended	SITEID
Description:	Unique identifier for the study site; however, SITEID is also unique within a submission.					
Question:	Site					
Completion instructions:	Record your clinical site's identifier as defined by the sponsor.					
Info. for Sponsors:	Paper: This is typically pre-printed in the header of each CRF page for single site studies. For studies with multiple sites, this field is typically left blank so that the number can be recorded by the site. EDC: This should be pre-populated. If SITEID is not used, SITENO should be used to derive SITEID for SDTM, depending upon sponsor's site identification scheme.					
Common_4_2011-10-24	Subject	SUBJID		Common	Highly Recommended	SUBJID
Description:	Subject identifier for the study.					
Question:	Subject					
Completion instructions:	Record the identifier for the subject.					
Info. for Sponsors:	Paper: This is typically recorded in the header of each CRF page. EDC: The subject identifiers may be provided to the site using a pre-populated list in the system.					
Common_5_2011-10-24	Unique Subject ID	USUBJID		Common	Optional	USUBJID
Description:	Unique subject identifier within a submission.					
Question:	Unique Subject ID					
Completion instructions:	Record the identifier for the subject.					
Info. for Sponsors:	Paper: This is typically recorded in the header of each CRF page. EDC: The subject identifiers may be provided to the site using a pre-populated list in the system.					
Common_6_2011-10-24	Investigator	INVID		Common	Optional	INVID
Description:	Investigator identifier.					
Question:	Investigator					

Completion instructions:	Record the sponsor-defined identifier for your site investigator.					
Info. for Sponsors:	Study level – Not needed if SITEID is equivalent to INVID.					
Common_7_2011-10-24	Visit	VISIT		Common	Optional	VISIT
Description:	Visit Name / Visit Number.					
Question:	Visit					
Completion instructions:	When applicable (e.g., on paper CRFs), record the visit name and/or visit number.					
Info. for Sponsors:	This is typically pre-printed/prepopulated.					
Common_8_2011-10-24	Visit Date and Time	VISDTC		Common	Highly Recommended	VISDTC
Description:	Date and time the visit took place (or started).					
Question:	Visit Date and Time					
Completion instructions:	Record the date and time the visit took place or started.					
Common_9_2011-10-24	Visit Date	VISDAT		Common	Highly Recommended	VISDTC*
Description:	Date the visit took place (or started).					
Question:	Visit Date					
Completion instructions:	Record the date the visit took place or started.					
Info. for Sponsors:	This may be recorded in either the header of the CRF or in the body of the CRF.					
Common_10_2011-10-24	Visit End Date	VISENDAT		Common	Optional	-
Description:	End Date of the Visit					
Question:	Visit End Date					
Completion instructions:	Record the date the visit ended.					
Info. for Sponsors:	This is intended to be used only in cases where the start date and the end date of the visit may not be the same, e.g., sleep trials that run overnight. If this field is used, VISDAT functions as the visit start date.					
Common_11_2011-10-24	Visit Time	VISTIM		Common	Optional	VISDTC*
Description:	Time the visit took place (or started).					
Question:	Visit Time					
Completion instructions:	Record the time the visit took place (or started).					
Info. for Sponsors:	Collecting the visit time is only appropriate if it can be realistically determined and if there is a scientific reason for needing to know this level of detail. This may be useful in Phase I trials.					
AE_1_2011-10-24	Any AEs?	AEYN	No Yes Response	AE	Optional	-
Description:	General prompt question regarding whether or not any AEs were experienced during the study. This provides verification that all other fields on the CRF were deliberately left blank.					
Question:	Any AEs?					
Completion instructions:	Indicate if the subject experienced any adverse events. If yes, include the appropriate details where indicated on the CRF.					
Info. for Sponsors:	The intent/purpose of collecting this field is to help with data cleaning and monitoring. It provides verification that all other fields on the CRF were deliberately left blank. This field does not map directly to an SDTM variable.					
AE_2_2011-10-24	<line number> or <AE number>	AESPID		AE	Optional	AESPID
Description:	A sponsor-defined identifier that can be used for pre-printed numbers on the CRF.					
Question:	<line number> or <AE number>					
Completion instructions:	Example instruction: Record unique identifier for each adverse event for this subject. Number sequence for all following pages should not duplicate existing numbers for the subject.					
Info. for Sponsors:	It can be beneficial to use an identifier in a data query to communicate clearly to the site the specific record in question or to reconcile concomitant medications and/or medical history records with AEs. If CMAENO is used, this is the identifier to which CMAENO refers.					

AE_3_2011-10-24	Adverse Event	AETERM		AE	Highly Recommended	AETERM
Description:	Verbatim (i.e., investigator-reported term) description of the adverse event.					
Question:	Adverse Event					
Completion instructions:	Record only one diagnosis, sign or symptom per line (e.g., nausea and vomiting should not be recorded in the same entry, but as two separate entries). Using accepted medical terminology, enter the diagnosis (if known); otherwise enter a sign or symptom. If a diagnosis subsequently becomes available, then this diagnosis should be entered on the AE form, replacing the original entries, where appropriate. Death should not be recorded as an event but should be recorded as the outcome of the event. The condition that resulted in the death should be recorded as the event. Do not use abbreviations.					
Info. for Sponsors:	In most cases, the verbatim term (i.e., investigator-reported term) will be coded to a standard medical dictionary such as MedDRA, WHO ART, after the data have been collected on the CRF. The coded data will be stored in field(s) not defined by CDASH.					
AE_4_2011-10-24	<specific adverse event>	AEOCCUR	No Yes Response	AE	Optional	-
Description:	Used when the occurrence of a specific adverse event is solicited to indicate whether or not (N/Y) the event (AETERM) occurred.					
Question:	<specific adverse event>					
Completion instructions:	Please indicate if <specific adverse event> has occurred /is occurring by checking “Yes” or “No”.					
Info. for Sponsors:	AEOCCUR should only be used for pre-specified adverse events as defined by the protocol. AEOCCUR should not be used for spontaneously reported adverse events. This field does not map directly to an SDTM variable.					
AE_5_2011-10-24	Start Date and Time	AESTDTC		AE	Highly Recommended	AESTDTC
Description:	Date and Time when the adverse event started.					
Question:	Start Date and Time					
Completion instructions:	See AESTDAT/AESTTIM					
Info. for Sponsors:	See AESTDAT/AESTTIM					
AE_6_2011-10-24	Start Date	AESTDAT		AE	Highly Recommended	AESTDTC*
Description:	Date when the adverse event started.					
Question:	Start Date					
Completion instructions:	Record the start date of the AE using this format (DD-MON-YYYY).					
Info. for Sponsors:	For the SDTM-based dataset, the SDTM IG variable AESTDTC is derived by concatenating CDASH Start Date (AESTDAT) and Time (AESTTIM if time is collected) and converting to the ISO 8601 format. For more detail see the Best Practice section. This field does not map directly to an SDTM variable.					
AE_7_2011-10-24	Start Time	AESTTIM		AE	Recommended/Conditional	AESTDTC*
Description:	Time when the adverse event started.					
Question:	Start Time					
Completion instructions:	If appropriate, record the time (as complete as possible) that the AE began.					
Info. for Sponsors:	Collecting the time an AE was started is only appropriate if it can be realistically determined and if there is a scientific reason for needing to know this level of detail. An example is where the subject is under the direct care of the site at the time the event started and the study design is such that it is important to know the AE start time with respect to dosing. For the SDTM-based dataset, the SDTM IG variable AESTDTC is derived by concatenating CDASH Start Date (AESTDAT) and Time (AESTTIM if time is collected) into AESTDTC using the ISO 8601 format. For more detail see the Best Practice section.					
AE_8_2011-10-24	End Date and Time	AEENDTC		AE	Highly Recommended	AEENDTC
Description:	Date and time when the adverse event resolved.					
Question:	End Date and Time					

Completion instructions:	See AEENDAT/AEENTIM					
Info. for Sponsors:	See AEENDAT/AEENTIM					
AE_9_2011-10-24	End Date	AEENDAT		AE	Highly Recommended	AEENDTC*
Description:	Date when the adverse event resolved.					
Question:	End Date					
Completion instructions:	Record the date that the AE resolved using this format (DD-MON-YYYY). If the AE is ongoing, leave the field blank.					
Info. for Sponsors:	For the SDTM-based dataset, the SDTM IG variable AEENDTC is derived by concatenating CDASH End Date (AEENDAT) and Time (AEENTIM if time is collected) into AEENDTC using the ISO 8601 format. The definition of “resolved” is Sponsor specific. For more detail see the Best Practice section. This field does not map directly to an SDTM variable.					
AE_10_2011-10-24	End Time	AEENTIM		AE	Recommended/Conditional	AEENDTC*
Description:	Time when the adverse event resolved.					
Question:	End Time					
Completion instructions:	If appropriate, record the time (as complete as possible) that the AE resolved.					
Info. for Sponsors:	Collecting the time an AE resolved is only appropriate if it can be realistically determined and if there is a scientific reason for needing to know this level of detail. An example is where the subject is under the direct care of the site at the time the event resolved and the study design is such that it is important to know the AE end time with respect to dosing. For the SDTM-based dataset, the SDTM IG variable AEENDTC is derived by concatenating CDASH End Date (AEENDAT) and Time (AEENTIM if time is collected) into AEENDTC using the ISO 8601 format. For more detail see the Best Practice section. This field does not map directly to an SDTM variable.					
AE_11_2011-10-24	Ongoing?	AEONGO	No Yes Response	AE	Optional	AEENRF*
Description:	Indicates AE is ongoing when no End Date is provided.					
Question:	Ongoing?					
Completion instructions:	Check the box if the adverse event has not resolved at the time of data collection; leave the End Date blank.					
Info. for Sponsors:	See section 2.1.3 Mapping Relative Times from Collection to Submissions for more information. This field will be completed to indicate that the AE has not resolved at the time of data collection, when no End Date is collected. In some cases the ongoing status may be determined from AE Outcome The purpose of collecting this field is to help with data cleaning and monitoring, since this field provides further confirmation that the End Date was deliberately left blank. As described in Section 3.4.1, Best Practices, this is a special use case of “Yes/No”. Please refer to Section 3.4.1 for additional information. Reference Section 4.1.4 of the SDTM IG V3.1.2 for information about mapping relative times. This field does not map directly to an SDTM variable.					
AE_12_2011-10-24	Severity	AESEV	Severity/Intensity Scale for Adverse Events	AE	Recommended/Conditional	AESEV
Description:	Description of the severity of the adverse event.					
Question:	Severity					
Completion instructions:	The reporting physician/healthcare professional will assess the severity of the event using the sponsor-defined categories. This assessment is subjective and the reporting physician/ healthcare professional should use medical judgment to compare the reported Adverse Event to similar type events observed in clinical practice. Severity is not					

	equivalent to seriousness.					
Info. for Sponsors:	Either AESEV or AETOXGR must appear on the CRF. Some studies may mandate the collection of both. Refer to ICH E3 guidelines for CSR Section 12.2.4.					
AE_13_2011-10-24	Toxicity Grade	AETOXGR		AE	Recommended/Conditional	AETOXGR
Description:	Description of the toxicity grade of the adverse event.					
Question:	Toxicity Grade					
Completion instructions:	Severity CTCAE Grade The reporting physician/healthcare professional will assess the severity of the adverse event using the toxicity grades.					
Info. for Sponsors:	Either AESEV or AETOXGR must appear on the CRF. Some studies may mandate the collection of both. Refer to ICH E3 guidelines for CSR Section 12.2.4. CTCAE grade is commonly used in oncology studies although it can also be used elsewhere.					
AE_14_2011-10-24	Serious	AESER	No Yes Response	AE	Recommended/Conditional	AESER
Description:	Indicates whether or not the adverse event is determined to be “serious” based on what is defined in the protocol.					
Question:	Serious					
Completion instructions:	Assess if an adverse event should be classified as serious based on the “serious” criteria defined in the protocol.					
Info. for Sponsors:	This field is related to the individual serious adverse event type fields (reference 11a to 11f), which may or may not be collected on the CRF. Either AESER or all the AESxxx fields (12a-12f) must be present on the CRF.					
AE_15_2011-10-24	Congenital Anomaly or Birth Defect	AESCONG	No Yes Response	AE	Recommended/Conditional	AESCONG
Description:	Indicates if a “serious” adverse event was associated with a congenital anomaly or birth defect.					
Question:	Congenital Anomaly or Birth Defect					
Completion instructions:	Record whether the “serious” adverse event was associated with congenital anomaly or birth defect.					
Info. for Sponsors:	If the details regarding a Serious AE should be collected in the clinical database, then it is recommended that a separate Yes/No variable be defined for each Serious AE type. In many cases sponsors will only collect the AESER field because the individual serious adverse event types might be collected in a separate pharmacovigilance database and therefore do not need to be collected in the clinical database.					
AE_16_2011-10-24	Significant Disability	AESDISAB	No Yes Response	AE	Recommended/Conditional	AESDISAB
Description:	Indicates if a “serious” adverse event was associated with a persistent or significant disability or incapacity.					
Question:	Significant Disability					
Completion instructions:	Record whether the “serious” adverse event resulted in a persistent or significant disability or incapacity.					
Info. for Sponsors:	If the details regarding a Serious AE should be collected in the clinical database, then it is recommended that a separate Yes/No variable be defined for each Serious AE type. In many cases sponsors will only collect the AESER field because the individual serious adverse event types might be collected in a separate pharmacovigilance database and therefore do not need to be collected in the clinical database.					
AE_17_2011-10-24	Death	AESDTH	No Yes Response	AE	Recommended/Conditional	AESDTH
Description:	Indicates if a “serious” adverse event resulted in death.					
Question:	Death					
Completion instructions:	Record whether the “serious” adverse event resulted in death.					
Info. for Sponsors:	If the details regarding a Serious AE should be collected in the clinical database, then it is recommended that a separate Yes/No variable be defined for each Serious AE type. In many cases sponsors will only collect the AESER field because the individual serious adverse event types might be collected in a separate pharmacovigilance database and therefore do not need to be collected in the clinical database.					
AE_18_2011-10-24	Hospitalization	AESHOSP	No Yes Response	AE	Recommended/Conditional	AESHOSP
Description:	Indicates if a “serious” adverse event resulted in an initial or prolonged hospitalization for the subject.					
Question:	Hospitalization					
Completion instructions:	Record whether the “serious” adverse event resulted in an initial or prolonged hospitalization.					
Info. for Sponsors:	If the details regarding a Serious AE should be collected in the clinical database, then it is recommended that a separate Yes/No variable be defined for each Serious AE type. In many cases sponsors will only collect the AESER field because the individual serious adverse event types might be collected in a separate pharmacovigilance					

	database and therefore do not need to be collected in the clinical database.					
AE_19_2011-10-24	Life threatening	AESLIFE	No Yes Response	AE	Recommended/Conditional	AESLIFE
Description:	Indicates if a “serious” adverse event was life threatening.					
Question:	Life threatening					
Completion instructions:	Record whether the “serious” adverse event is life threatening.					
Info. for Sponsors:	If the details regarding a Serious AE should be collected in the clinical database, then it is recommended that a separate Yes/No variable be defined for each Serious AE type. In many cases sponsors will only collect the AESER field because the individual serious adverse event types might be collected in a separate pharmacovigilance database and therefore do not need to be collected in the clinical database.					
AE_20_2011-10-24	Other Medically Important Event	AESMIE	No Yes Response	AE	Recommended/Conditional	AESMIE
Description:	Indicates if a “serious” adverse event is associated with other serious or important medical events.					
Question:	Other Medically Important Event					
Completion instructions:	Record whether the “serious” adverse event is an important medical event, which may be defined in the protocol or in the Investigator Brochure.					
Info. for Sponsors:	If the details regarding a Serious AE should be collected in the clinical database, then it is recommended that a separate Yes/No variable be defined for each Serious AE type. In many cases sponsors will only collect the AESER field because the individual serious adverse event types might be collected in a separate pharmacovigilance database and therefore do not need to be collected in the clinical database.					
AE_21_2011-10-24	Relationship to Study Treatment	AEREL	Relationship to Study Treatment	AE	Highly Recommended	AEREL
Description:	Indication of whether the study treatment had a causal effect on the adverse event, as reported by the clinician/investigator.					
Question:	Relationship to Study Treatment					
Completion instructions:	Indicate if the cause of the adverse event is related to the study treatment and cannot be reasonably explained by other factors (e.g., subject’s clinical state, concomitant therapy, and/or other interventions).					
Info. for Sponsors:	Sponsored-defined terminology will be used to indicate the relationship between the AE and the study treatment (e.g. ICH E2B examples: Not Related, Unlikely Related, Possibly Related, Related).					
AE_22_2011-10-24	Action Taken with Study Treatment	AEACN	Action Taken with Study Treatment	AE	Highly Recommended	AEACN
Description:	Changes made to the study treatment in response to the adverse event.					
Question:	Action Taken with Study Treatment					
Completion instructions:	Record changes made to the study treatment resulting from the adverse event.					
Info. for Sponsors:	CDISC controlled terminology should be used to indicate the action taken with the study treatment in response to the AE.					
AE_23_2011-10-24	Other Action Taken	AEACNOTH		AE	Optional	AEACNOTH
Description:	Describes Other Action(s) taken in response to the adverse event that are unrelated to study treatment dose changes.					
Question:	Other Action Taken					
Completion instructions:	Record all other action(s) taken resulting from the adverse event that are unrelated to study treatment.					
Info. for Sponsors:	This field is usually reported as a free text field. Example: Treatment Unblinded, Primary Care Physician Notified.					
AE_24_2011-10-24	Outcome	AEOUT	Outcome of Event	AE	Highly Recommended	AEOUT
Description:	Description of the subject’s status associated with an event.					
Question:	Outcome					
Completion instructions:	Record the appropriate outcome of the event in relation to the subject’s status.					
Info. for Sponsors:	CDISC controlled terminology should be used to indicate the outcome of the event as it relates to the subject’s status. The Outcome controlled terminology includes ICH E2B values.					
AE_25_2011-10-24	Caused Study Discontinuation	AEDIS	No Yes Response	AE	Optional	-
Description:	Indication of whether the adverse event caused the subject to discontinue from the study.					
Question:	Caused Study Discontinuation					
Completion instructions:	Record if the AE caused the subject to discontinue from the study.					
Info. for Sponsors:	Since the Action Taken field was defined to only collect the changes made to the study treatment due to the AE, an additional field was created to identify the AE(s) that					

	caused the subject to discontinue from the study. Some sponsors opt to capture this information only on the Subject Disposition CRF while others choose to collect this data on both the Subject Disposition and AE CRFs, so the specific AE term(s) and related data can be identified. This field does not map directly to an SDTM variable. If the CRF is designed to link the DS and AE records then RELREC can be used to identify that relationship. See section 8.2 in the SDTM IG V3.1.2 for information on RELREC.					
CM_1_2011-10-24	Any meds?	CMYN	No Yes Response	CM	Optional	-
Description:	General prompt question to aid in monitoring and data cleaning.					
Question:	Any meds?					
Completion instructions:	Indicate if the subject took any medications. If “Yes”, include the appropriate details where indicated.					
Info. for Sponsors:	The intent/purpose of collecting this field is to help with data cleaning and monitoring. This field does not map directly to an SDTM variable.					
CM_2_2011-10-24	<line number> or <CM number>	CMSPID		CM	Optional	CMSPID
Description:	A sponsor-defined identifier which can be used for pre-printed numbers on the CRF.					
Question:	<line number> or <CM number>					
Completion instructions:	Example instruction: Record unique identifier for each medication for this subject. Number sequence for all following pages should not duplicate existing numbers for the subject.					
Info. for Sponsors:	It can be beneficial to use an identifier in a data query to communicate clearly to the site the specific record in question or to reconcile concomitant medications and/or medical history records with AEs.					
CM_3_2011-10-24	Medication or Therapy	CMTRT		CM	Highly Recommended	CMTRT
Description:	Verbatim drug name or therapy (include only therapies with data collection characteristics similar medications).					
Question:	Medication or Therapy					
Completion instructions:	Record only one medication per line. Provide the full trade or proprietary name of the drug or therapy; otherwise the generic name may be recorded.					
Info. for Sponsors:	In most cases, the verbatim drug names or therapy will be coded to a standard dictionary such as WHO DRUG after the data have been collected on the CRF. For the collection of verbatim drug name or therapy, the recommendation is to ask the sites to provide the full trade or proprietary name since it is more exact than the generic. The full trade name provides the base generic and the appropriate salt for that particular drug. In addition, for coding purposes it helps with ATC selection. For example the medication Tylenol with codeine #1 has a different ATC code from Tylenol with codeine #3.					
CM_4_2011-10-24	<specific medication/treatment>	CMOCCUR	No Yes Response	CM	Optional	CMOCCUR
Description:	Used when the occurrence of a specific medication or treatment is solicited to indicate whether or not (N/Y) the treatment or medication (CMTRT) was taken or given. This field can be used for either prior or concomitant medication / treatments. {NY} (See Section 2.2.)					
Question:	<specific medication/treatment>					
Completion instructions:	Please indicate if < specific medication/treatment > was taken by checking “Yes” or “No”.					
Info. for Sponsors:	CMOCCUR should only be used for specific medications as defined by the protocol. CMOCCUR should not be used for spontaneously reported concomitant medication/treatments.					
CM_5_2011-10-24	Active Ingredients	CMINGRD		CM	Optional	-
Description:	Medication Ingredients.					
Question:	Active Ingredients					
Completion instructions:	Prior to a subject’s clinical visit, remind all subjects to bring all medications bottles, packs etc. they are taking with them to their clinical visit. Record all active ingredient(s) off the medication label and separate each ingredient with a comma for the name of drug medication or therapy taken. For example, the medication Dolmen, if manufactured in Spain, the active ingredients should be collected as noted below: Active Ingredient: Acetylsalicylic Acid, Ascorbic acid, codeine phosphate					

Info. for Sponsors:	This may be collected in addition to the “Medication/Therapy Name”. Collecting this provides more detailed information when coding to a medication dictionary like WHO Drug Enhanced format C which now codes to the ingredient level for many trade named medications. For example, the medication Dolmen, depending on the country where it is manufactured, the active ingredients may be different. Spain: Acetylsalicylic Acid, Ascorbic acid, codeine phosphate Italy and Czech Republic: contains Tenoxicam Estonia and Latvia: contains Dexketoprofen trometamol CMINGRD is not a field defined in the SDTMIG. If collected, it should be submitted in the SUPPCM dataset.					
CM_6_2011-10-24	Indication	CMINDC		CM	Recommended/Conditional	CMINDC
Description:	The reason for administration of a concomitant (non-study) medication. (e.g., Nausea, Hypertension) This is not the pharmacological/ therapeutic classification of an agent (e.g., antibiotic, analgesic, etc.), but the reason for its administration to the subject.					
Question:	Indication					
Completion instructions:	Record the reason the medication was taken based on clinical investigator’s evaluation. If taken to treat a condition, and a diagnosis was made, the indication should be the diagnosis. If taken to treat a condition, and no diagnosis was made, the indication should be the signs and symptoms. If taken as prophylaxis, report as “Prophylaxis for…”					
Info. for Sponsors:	This additional information is collected on the CRF when the sponsor would want to capture the reason(s) why a subject took a medication. This information can then be used as deemed appropriate for coding, analysis (i.e., in the classification of medications), for reconciling the medications taken by a subject with their provided medical history and/or AEs/SAEs as part of the data clean-up and monitoring process, etc.					
CM_7_2011-10-24	AE ID	CMAENO		CM	Optional	-
Description:	Identifier for the adverse event that is the indication for this medication.					
Question:	AE ID					
Completion instructions:	Record the identifier of the Adverse Event for which this medication was taken.					
Info. for Sponsors:	Intent is to establish a link between the adverse event and the medication taken for the adverse event. This field does not map directly to an SDTM variable. CMAENO can be used in RELREC to identify a relationship between records in CM dataset and records in the AE dataset. See section 8.2 in the SDTM IG V3.1.2 for information on RELREC.					
CM_8_2011-10-24	MH ID	CMMHNO		CM	Optional	-
Description:	Identifier for the medical history condition that is the indication for this medication.					
Question:	MH ID					
Completion instructions:	Record the identifier of the medical history event for which this medication was taken.					
Info. for Sponsors:	Intent is to establish a link between the medical history condition and the medication taken for the medical history condition. This field does not map directly to an SDTM variable. CMMHNO can be used to identify a relationship between records in the CM dataset and records in the MH dataset. See section 8.2 in the SDTMIG V3.1.2 for information on RELREC.					
CM_9_2011-10-24	Dose	CMDOSE		CM	Optional	CMDOSE+CMDOSU
Description:	The dose of medication taken per administration.					
Question:	Dose					
Measurement Units:	mg, ug, mL, g, IU					
Completion instructions:	See CMDOSTXT/CMDOSTXTU					
Info. for Sponsors:	See CMDOSTXT/CMDOSTXTU					
CM_10_2011-10-24	Dose	CMDOSTXT		CM	Optional	CMDOSTXT
Description:	The dose of medication taken per administration.					
Question:	Dose					
Completion instructions:	Record the dose of medication taken per administration (e.g., 200).					

Info. for Sponsors:	Where this level of dosing information is required by a sponsor, this field may be included. Defining this data collection field as a dose text field allows for flexibility in capturing dose entries as numbers, text or ranges. This field does not map directly to an SDTM variable. The data collected in this dose text-format field should be separated or mapped to either SDTM IG CMDOSE if numeric or CMDOSTXT if text.					
CM_11_2011-10-24	Total Daily Dose	CMDOSTOT		CM	Optional	CMDOSTOT
Description:	Total daily dose taken.					
Question:	Total Daily Dose					
Measurement Units:	mg, ug, mL, g, IU					
Completion instructions:	Record the total dose of medication taken daily.					
Info. for Sponsors:	For use when only total daily dose is collected in the CRF. For general medication, it is not recommended to use “Total Daily Dose”. Instead, this can be calculated or derived from other fields such as Units, Dose, and Frequency.					
CM_13_2011-10-24	Dose Form	CMDOSFRM	Pharmaceutical Dosage Form	CM	Optional	CMDOSFRM
Description:	Name of the pharmaceutical dosage form (e.g., TABLET CAPSULE, SYRUP) of delivery for the drug.					
Question:	Dose Form					
Completion instructions:	Record the pharmaceutical dosage form (e.g., TABLET CAPSULE, SYRUP) of delivery for the medication taken.					
Info. for Sponsors:	Some drugs have multiple forms and this field may be needed to code the drug to an ATC level. However, in general, this level of detail should not be necessary except for medications of interest.					
CM_14_2011-10-24	Frequency	CMDOSFRQ	Frequency	CM	Optional	CMDOSFRQ
Description:	How often the medication was taken (e.g., BID, PRN).					
Question:	Frequency					
Completion instructions:	Record how often the medication or therapy was taken. (e.g., BID, PRN).					
Info. for Sponsors:	When collected, the recommendation is to collect dosing information in separate fields for specific and consistent data collection and to enable programmatically utilizing these data. See below for the rest of the dosing information components (Dose per Administration, and Unit.)					
CM_15_2011-10-24	Route	CMROUTE	Route of Administration	CM	Recommended/Conditional	CMROUTE
Description:	Identifies the route of administration of the drug.					
Question:	Route					
Completion instructions:	Provide the route of administration for the drug.					
Info. for Sponsors:	This additional information may be important to collect on the CRF when the sponsor would want to capture a medication’s route of administration for purposes such as coding and the medication may have more than one route. Some companies may use route in coding medications to be able to choose a precise preferred name and ATC code.					
CM_16_2011-10-24	Start Date and Time	CMSTDTC		CM	Highly Recommended	CMSTDTC
Description:	Date and Time when the medication was first taken.					
Question:	Start Date and Time					
Completion instructions:	See CMSTDAT/CMSTTIM					
Info. for Sponsors:	See CMSTDAT/CMSTTIM					
CM_17_2011-10-24	Start Date	CMSTDAT		CM	Highly Recommended	CMSTDTC*
Description:	Date when the medication was first taken.					
Question:	Start Date					
Completion instructions:	Record the date the medication or therapy was first taken using this format (DD-MON-YYYY). If the subject has been taking the medication for a considerable amount of time prior to the start of the study, it is acceptable to have an incomplete date. Medications taken during the study are expected to have a complete start date.					

	Prior medications that are exclusionary should have both a start and end date.					
Info. for Sponsors:	The preferred method is to collect a complete Start Date. Partial dates (e.g., providing year only) for medications started a considerable amount of time prior to the start of study are acceptable. For the SDTM-based dataset, the SDTM IG variable CMSTDTC is derived by concatenating CDASH Start Date (CMSTDAT) and Time (CMSTTIM if time is collected) and converting into ISO 8601 format. For more detail see the Best Practice section. This field does not map directly to an SDTM variable.					
CM_18_2011-10-24	Start Time	CMSTTIM		CM	Recommended/Conditional	CMSTDTC*
Description:	Time the medication was started.					
Question:	Start Time					
Completion instructions:	Record the time (as complete as possible) that the medication or therapy was started.					
Info. for Sponsors:	Recommend collecting the time a medication was started when a protocol or data collection scenarios supports it. Typically, a start time is not collected unless the subject is under the direct care of the site at the time a medication or therapy is administered. For the SDTM-based dataset, the SDTM IG variable CMSTDTC is derived by concatenating CDASH Start Date (CMSTDAT) and Time (CMSTTM if time is collected) and converting ISO 8601 format. For more detail see the Best Practice section. This field does not map directly to an SDTM variable.					
CM_19_2011-10-24	Taken Prior to Study?	CMPRIOR	No Yes Response	CM	Recommended/Conditional	CMSTRF*
Description:	To determine if medications were taken prior to study start.					
Question:	Taken Prior to Study?					
Completion instructions:	Check if the medication or therapy was started before the study.					
Info. for Sponsors:	See section 2.1.3 Mapping Relative Times from Collection to Submissions and the SDTM IG for more information. This field does not map directly to an SDTM variable.					
CM_20_2011-10-24	End Date and Time	CMENDTC		CM	Recommended/Conditional	CMENDTC
Description:	Date and time that the subject stopped taking the medication or therapy.					
Question:	End Date and Time					
Completion instructions:	See CMENDAT/CMENTIM					
Info. for Sponsors:	See CMENDAT/CMENTIM					
CM_21_2011-10-24	End Date	CMENDAT		CM	Recommended/Conditional	CMENDTC*
Description:	Date that the subject stopped taking the medication or therapy.					
Question:	End Date					
Completion instructions:	Record the date the subject stopped taking the medication or therapy using this format (DD-MON-YYYY). If the subject has not stopped taking the medication leave this field blank.					
Info. for Sponsors:	The assumption is that sponsors should either have a complete end date or will indicate that the medication or therapy was ongoing at the time of collection or at the end of the study. However, in cases where the End Date can be determined from dates collected elsewhere in the CRF it is not necessary to include an End Date in the CRF. For example, if all concomitant medications are administered as a single dose, the End Date will be the same as the Start Date. For the SDTM-based dataset, the SDTM IG variable CMENDTC is derived by concatenating CDASH End Date (CMENDAT) and Time (CMENTIM if time is collected) and converting to ISO 8601 format. For more detail see the Best Practice section. This field does not map directly to an SDTM variable.					

CM_22_2011-10-24	End Time	CMENTIM		CM	Recommended/Conditional	CMENDTC*
Description:	Time when the subject stopped taking the medication or therapy.					
Question:	End Time					
Completion instructions:	Record the time (as complete as possible) that the medication or therapy was stopped.					
Info. for Sponsors:	Recommend collecting the time a medication or therapy was ended when a protocol or data collection scenarios supports it. Typically, an end time is not collected unless the subject is under the direct care of the site at the time a medication or therapy is stopped. For the SDTM-based dataset, the SDTM IG variable CMENDTC is derived by concatenating CDASH End Date (CMENDAT) and Time (CMENTIM if time is collected) and converted to ISO 8601 format. For more detail see the Best Practice section. This field does not map directly to an SDTM variable.					
CM_23_2011-10-24	Ongoing	CMONGO	No Yes Response	CM	Optional	CMENRF*
Description:	Indicates medication or therapy is ongoing when no End Date is provided.					
Question:	Ongoing					
Completion instructions:	Record the medication or therapy as ongoing if the subject has not stopped taking the medication or therapy at the time of data collection and the end date should be left blank.					
Info. for Sponsors:	This box should be checked to indicate that the medication or therapy has not stopped at the time of data collection. It is expected that every recorded medication or therapy should have either an End Date or be checked as Ongoing, but not both. However, in cases where ongoing concomitant medications are not permitted, it may not be necessary to include an Ongoing field in the CRF. Reference section 2.1.3 for more information about collecting relative date/time and see section 4.1.4 of the SDTM IG V. 3.1.2 for information about mapping relative times. This field does not map directly to an SDTM variable.					
DM_1_2011-10-24	Birth Date and Time	BRTHDTC		DM	Highly Recommended	BRTHDTC
Description:	A subject's date and time of birth.					
Question:	Birth Date and Time					
Completion instructions:	See BRTHDAT/BRTHTIM					
Info. for Sponsors:	See BRTHDAT/BRTHTIM					
DM_2_2011-10-24	Birth Date	BRTHDAT		DM	Highly Recommended	BRTHDTC*
Description:	A subject's date of birth (with or without the time of birth). The complete Date of Birth is made from the temporal components of Birth Year, Birth Month, Birth Day and Birth Time.					
Question:	Birth Date					
Completion instructions:	Record the date of birth to the level of precision known (e.g., day/month/year, year, month/year, etc) in this format (DD-MON-YYYY).					
Info. for Sponsors:	See Section 5.6.1 Collection of Age vs. Date of Birth and also Section 3.4. FAQs on Best Practices for Creating Data Collection Instruments) This field does not map directly to an SDTM variable.					
DM_3_2011-10-24	Birth Year	BRTHYR		DM	Highly Recommended	BRTHDTC*
Description:	Year of the subject's birth.					
Question:	Birth Year					
Completion instructions:	Record the subject's year of birth (e.g., YYYY, a four digit year).					
Info. for Sponsors:	Year of Birth is the collected variable used for recording the year component of the "Date of Birth". (See Section 5.6.1 Collection of Age vs. Date of Birth and also Section 3.4. FAQs on Best Practices for Creating Data Collection Instruments) This field does not map directly to an SDTM variable.					
DM_4_2011-10-24	Birth Month	BRTHMO		DM	Recommended/Conditional	BRTHDTC*

Description:	Text value for the month of the subject's birth.					
Question:	Birth Month					
Completion instructions:	Record the subject's month of birth [e.g., (in local language short month format) (JAN-DEC) or (ENE-DIE) or (JAN-DEZ), etc.].					
Info. for Sponsors:	Month of Birth is the collected variable used for recording the year component of the "Date of Birth". (See Section 5.6.1 Collection of Age vs. Date of Birth and also Section 3.4. FAQs on Best Practices for Creating Data Collection Instruments) This field does not map directly to an SDTM variable.					
DM_5_2011-10-24	Birth Day	BRTHDY		DM	Recommended/Conditional	BRTHDTC*
Description:	Numeric day of the month of the subject's birth.					
Question:	Birth Day					
Completion instructions:	Record the subject's day of birth (e.g., 01 31).					
Info. for Sponsors:	Day of Birth is the collected variable used for recording the year component of the "Date of Birth". (See Section 5.6.1 Collection of Age vs. Date of Birth and also Section 3.4. FAQs on Best Practices for Creating Data Collection Instruments) This field does not map directly to an SDTM variable.					
DM_6_2011-10-24	Birth Time	BRTHTIM		DM	Optional	BRTHDTC*
Description:	Time of subject's birth.					
Question:	Birth Time					
Completion instructions:	Record the time of birth (as completely as possible).					
Info. for Sponsors:	The level of detail collected by Time of Birth may be necessary for analysis for some pediatric, natal or neonatal studies. (See Section 5.6.1 Collection of Age vs. Date of Birth and also Section 3.4. FAQs on Best Practices for Creating Data Collection Instruments) For more detail see the Best Practice section. This field does not map directly to an SDTM variable.					
DM_7_2011-10-24	Age	AGE		DM	Optional	AGE+AGEU
Description:	Numeric age of subject.					
Question:	Age					
Measurement Units:	DAYS, HOURS, MONTHS, WEEKS, YEARS					
Completion instructions:	See AGE/AGEU					
Info. for Sponsors:	See AGE/AGEU					
DM_8_2011-10-24	Age	AGE-AGEU		DM	Optional	AGE
Description:	Numeric age of subject.					
Question:	Age					
Completion instructions:	Record age of the subject.					
Info. for Sponsors:	If Age is collected, it should be collected as a number and, to be correctly interpreted, the age value should be associated to a variable for the Age Unit. It may be necessary to know when the age was collected as an age may need to be recalculated for analysis, such as deriving age at a reference start time (RFSTDTC for SDTM). If AGE is collected, then it is recommended that the date of collection also be recorded, either separately or by association to the date of the visit. (See Section 5.6.1 Collection of Age vs. Date of Birth)					
DM_9_2011-10-24	Age Unit	AGEU		DM	Optional	AGEU
Description:	Those units of time that are routinely used to express the age of a person. (NCI) {AGEU} (See Section 2.2.)					
Question:	Age Unit					
Measurement Units:	DAYS, HOURS, MONTHS, WEEKS, YEARS					
Completion instructions:	Record the appropriate age unit (e.g., YEARS, MONTHS, WEEKS, etc.).					

Info. for Sponsors:	If Age is captured on the CRF, the age unit must be known to make the “Age” value meaningful. The age unit might be collected on the CRF, in those cases where the protocol allows for any age group, or it may be pre-printed on the CRF (typically with the unit of “years"). (See Section 5.6.1 Collection of Age vs. Date of Birth)					
DM_10_2011-10-24	Collection Date	DMDAT		DM	Recommended/Conditional	DMDTC*
Description:	Date of collection.					
Question:	Collection Date					
Completion instructions:	Record the date the demographics data were collected in this format (DD-MON-YYYY).					
Info. for Sponsors:	The date of collection may be derived from the date of visit and if so, a separate date field is not needed. For the SDTM-based dataset, the SDTM IG variable DMDTC is derived via the CDASH Date of collection (DMDAT) and converting to the ISO 8601 format. (See AGE Additional Information for Sponsors.) This field does not map directly to an SDTM variable.					
DM_11_2011-10-24	Sex	SEX	Sex	DM	Highly Recommended	SEX
Description:	The assemblage of physical properties or qualities by which male is distinguished from female; the physical difference between male and female; the distinguishing peculiarity of male or female (NCI – CDISC Definition). {SEX} (See Section 2.2.)					
Question:	Sex					
Completion instructions:	Record the appropriate sex (e.g., F (female), M (male).					
Info. for Sponsors:	Collect the subject’s sex or gender, as reported by subject or caretaker. This is the self-reported sex of the individual and/or is the clinician’s assignment based on a physical examination. This is a phenotypic assessment and a genotypic assessment (see Section 5.6.2 Collecting Sex, Ethnicity and Race).					
DM_12_2011-10-24	Ethnicity	ETHNIC	Ethnic Group	DM	Recommended/Conditional	ETHNIC
Description:	A social group characterized by a distinctive social and cultural tradition maintained from generation to generation, a common history and origin and a sense of identification with the group; members of the group have distinctive features in their way of life, shared experiences and often a common genetic heritage; these features may be reflected in their experience of health and disease (NCI – CDISC Definition). {ETHNIC} (See Section 2.2.)					
Question:	Ethnicity					
Completion instructions:	Study participants should self-report ethnicity, with ethnicity being asked about before race.					
Info. for Sponsors:	If more detailed characterizations of ethnicity are collected to enhance data quality and consistency, it is recommended that they be “collapsible” up to the two categories for reportable ethnicity, as needed for reporting to FDA under its guidance. Other regulatory bodies may expect the reporting of ethnicity values (different than the US FDA) which more appropriately reflect the population of their areas (e.g., Japanese ancestry for MHLW reporting to Japan). These may be collected as an extension to the suggested NCI-CDISC code list.					
DM_13_2011-10-24	Race	RACE	Race	DM	Recommended/Conditional	RACE
Description:	An arbitrary classification based on physical characteristics; a group of persons related by common descent or heredity (U.S. Center for Disease Control). {RACE} (See Section 2.2.)					
Question:	Race					
Completion instructions:	Study participants should self-report race, with race being asked about after ethnicity. (The FDA guidance suggests “that individuals be permitted to designate a multiracial identity”. “Check all that apply” at the time of collection.)					
Info. for Sponsors:	Collect race when the data are used for an FDA submission or if needed for scientific analysis. If multiple races are collected, an alternate sponsor-defined variable structure would be required. The categories listed in the FDA Guidance are as follows: American Indian or Alaska Native Asian Black or African American* Native Hawaiian or Other Pacific Islander White *For studies where data are collected outside the US, the recommended categories are the same except for “Black” instead of “Black or African American”.					

	If more detailed characterizations of race or ethnicity are collected to enhance data quality and consistency, it is recommended that they be “collapsible” up to the five minimum designations for race, as well as the two categories for reportable ethnicity, as needed for reporting to FDA under its guidance. When more detailed categorizations are desired, the use of race and vocabulary tables located within Health Level Seven’s Reference Information Model Structural Vocabulary Tables is recommended, as they are designed to collapse up in this manner.					
DM_14_2011-10-24	Specify Other	RACEOTH		DM	Optional	SUPPDM.QNAM
Description:	A free-text field to be used when none of the pre-printed values for RACE are applicable or if another, unprinted selection needs to be added to those pre-printed values.					
Question:	Specify Other					
Completion instructions:	If none of the pre-printed values for RACE are applicable or if another, unprinted selection needs to be added to those pre-printed values, record the value in this free text field.					
Info. for Sponsors:	When creating the Demographics form, it is suggested that you include the five standard race categories. If you choose, you might include another value of “Other, specify” with a free text field for extending the list of values. The RACEOTH variable contains the free text added by the site. The value(s) added in the optional variable might or might not “collapse up” into one of the five categories specified by the FDA Guidance. See SDTM V3.1.2 for examples of reporting this implementation. This field does not map directly to an SDTM variable.					
DM_15_2011-10-24	American Indian or Alaska Native	RACE.AMERICAN_INDIAN_OR_ALASKA_NATIVE		DM	Recommended/Conditional	SUPPDM.QNAM
Description:	An arbitrary classification based on physical characteristics; a group of persons related by common descent or heredity (U.S. Center for Disease Control). {RACE} (See Section 2.2.)					
Question:	American Indian or Alaska Native					
Completion instructions:	Study participants should self-report race, with race being asked about after ethnicity. If collecting RACE as a "Check all that apply", this field would be populated if the subject self identifies as being "American Indian or Alaska Native".					
Info. for Sponsors:	Collect race when the data are used for an FDA submission or if needed for scientific analysis. If multiple races are collected, an alternate sponsor-defined variable structure would be required. The categories listed in the FDA Guidance are as follows: American Indian or Alaska Native Asian Black or African American* Native Hawaiian or Other Pacific Islander White					
DM_16_2011-10-24	Asian	RACE.ASIAN		DM	Recommended/Conditional	SUPPDM.QNAM
Description:	An arbitrary classification based on physical characteristics; a group of persons related by common descent or heredity (U.S. Center for Disease Control). {RACE} (See Section 2.2.)					
Question:	Asian					
Completion instructions:	Study participants should self-report race, with race being asked about after ethnicity. If collecting RACE as a "Check all that apply", this field would be populated if the subject self identifies as being "Asian".					
Info. for Sponsors:	Collect race when the data are used for an FDA submission or if needed for scientific analysis. If multiple races are collected, an alternate sponsor-defined variable structure would be required. The categories listed in the FDA Guidance are as follows: American Indian or Alaska Native Asian Black or African American* Native Hawaiian or Other Pacific Islander White					
DM_17_2011-10-24	Black or African American	RACE.BLACK_OR_ AFRICAN_AMERICAN		DM	Recommended/Conditional	SUPPDM.QNAM
Description:	An arbitrary classification based on physical characteristics; a group of persons related by common descent or heredity (U.S. Center for Disease Control). {RACE} (See Section 2.2.)					

Question:	Black or African American					
Completion instructions:	Study participants should self-report race, with race being asked about after ethnicity. If collecting RACE as a "Check all that apply", this field would be populated if the subject self identifies as being "Black or African American".					
Info. for Sponsors:	Collect race when the data are used for an FDA submission or if needed for scientific analysis. If multiple races are collected, an alternate sponsor-defined variable structure would be required. The categories listed in the FDA Guidance are as follows: American Indian or Alaska Native Asian Black or African American* Native Hawaiian or Other Pacific Islander White *For studies where data are collected outside the US, the recommended categories are the same except for “Black” instead of “Black or African American”.					
DM_18_2011-10-24	Native Hawaiian or Other Pacific Islander	RACE.NATIVE_HAWAIIAN_OR_OTHER_PACIFIC_ISLANDER		DM	Recommended/Conditional	SUPPDM.QNAM
Description:	An arbitrary classification based on physical characteristics; a group of persons related by common descent or heredity (U.S. Center for Disease Control). {RACE} (See Section 2.2.)					
Question:	Native Hawaiian or Other Pacific Islander					
Completion instructions:	Study participants should self-report race, with race being asked about after ethnicity. If collecting RACE as a "Check all that apply", this field would be populated if the subject self identifies as being "Native Hawaiian or Other Pacific Islander".					
Info. for Sponsors:	Collect race when the data are used for an FDA submission or if needed for scientific analysis. If multiple races are collected, an alternate sponsor-defined variable structure would be required. The categories listed in the FDA Guidance are as follows: American Indian or Alaska Native Asian Black or African American* Native Hawaiian or Other Pacific Islander White					
DM_19_2011-10-24	White	RACE.WHITE		DM	Recommended/Conditional	SUPPDM.QNAM
Description:	An arbitrary classification based on physical characteristics; a group of persons related by common descent or heredity (U.S. Center for Disease Control). {RACE} (See Section 2.2.)					
Question:	White					
Completion instructions:	Study participants should self-report race, with race being asked about after ethnicity. If collecting RACE as a "Check all that apply", this field would be populated if the subject self identifies as being "White".					
Info. for Sponsors:	Collect race when the data are used for an FDA submission or if needed for scientific analysis. If multiple races are collected, an alternate sponsor-defined variable structure would be required. The categories listed in the FDA Guidance are as follows: American Indian or Alaska Native Asian Black or African American* Native Hawaiian or Other Pacific Islander White					
MH_1_2011-10-24	Any medical history?	MHYN	No Yes Response	MH	Optional	-
Description:	General prompt question to aid in monitoring and data cleaning. {NY} (See Section 2.2.)					
Question:	Any medical history?					
Completion instructions:	If the subject has experienced any past and/or concomitant diseases or has had any type of surgery, select “Yes” and provide the requested information. Otherwise, select					

	"No" and leave the page blank.					
Info. for Sponsors:	The intent/purpose of collecting this field is to help with data cleaning and monitoring. MHYN will not be included as part of the SDTM IG MH Domain for submission. This field does not map directly to an SDTM variable.					
MH_2_2011-10-24	<line number> or <MH number>	MHSPID		MH	Optional	MHSPID
Description:	A sponsor-defined identifier which can be used for pre-printed numbers on the CRF.					
Question:	<line number> or <MH number>					
Completion instructions:	Record unique identifier for each medical history condition for this subject. Number sequence for all following pages should not duplicate existing numbers for the subject.					
Info. for Sponsors:	It can be beneficial to use an identifying number in a data query to clearly communicate to the site the specific record in question or to reconcile concomitant medications and/or medical history records with AEs. If CMMHNO is used, this is the identifier to which CMMHNO refers.					
MH_3_2011-10-24	<MH Category>	MHCAT		MH	Recommended/Conditional	MHCAT
Description:	Used to define a category of related records (e.g., CARDIAC or GENERAL).					
Question:	<MH Category>					
Completion instructions:	Not applicable.					
Info. for Sponsors:	The sponsor may or may not pre-print on the CRF the type of medical history being captured. If specific medical history (e.g., disease diagnosis) is captured in addition to the general medical history, it may be helpful to pre-print the history type on the CRF. Regardless, MHCAT may be populated in the database as a derived field.					
MH_4_2011-10-24	<MH Subcategory>	MHSCAT		MH	Recommended/Conditional	MHSCAT
Description:	A categorization of the condition or event pre-printed on the CRF or instructions.					
Question:	<MH Subcategory>					
Completion instructions:	The CRF instructions will depend upon the format of the CRF. Some sponsors ask the sites to use a numeric code (e.g., "123") to designate a particular category (e.g., "cardiovascular") while other sponsors will simply pre-print the categories on the CRF and provide space for the site to record the ailment, disease or surgery. Instruction examples: Use the (sponsor-defined) code list to group the past and/or concomitant medical conditions or surgeries. For example, if the subject has a history of high blood pressure, use code "123" for "cardiovascular". OR Record the concomitant medical conditions or past surgeries under the appropriate category. For example, "high blood pressure" should be recorded under "cardiovascular".					
Info. for Sponsors:	The pre-printed groupings should be used if the sponsor will not code medical history. The categories should be sponsor-defined as sponsors may have different needs. (Code "123" used in the instructions is simply an example.) The MedDRA SOCs should not be used as categories on the CRF for several reasons. Sites may not be familiar with the SOCs. It would be cumbersome to include the 26 organ classes on the CRF, entry screen or completion instructions. The reviewers expect this information to be submitd in MHBODSYS. Finally, the sponsor may only wish to inquire about particular groupings or specific diseases; not actual body systems. "123" would not be submitd in MHSCAT. In this example, "cardiovascular" is the MHSCAT. Numeric codes used on the CRF as an operational tactic to facilitate data entry are not submitted as they provide no meaning to the reviewer. MHCAT must be in the database if MHSCAT is used.					
MH_5_2011-10-24	<Medical History Term>	MHTERM		MH	Highly Recommended	MHTERM
Description:	Verbatim or preprinted CRF term for the medical condition or event.					
Question:	<Medical History Term>					
Completion instructions:	Record all relevant past and/or concomitant medical conditions and past surgeries, as defined in the protocol. Record only one condition or surgery per line. When recording a condition and surgery related to that condition, use one line for the condition and one line for the surgery. Ensure that any of the conditions listed on the Medical History page do not meet any of the exclusion criteria.					
Info. for Sponsors:	If sponsors need to capture more detailed surgery information (e.g., VNS implantation for Epilepsy studies), an additional CRF module should be used, modeled as an Interventions domain.					

	Sponsors should choose whatever term(s) for the column header is most appropriate for their study (e.g., condition, diagnosis, surgery, procedure).					
MH_6_2011-10-24	Ongoing	MHONGO	No Yes Response	MH	Optional	MHENRF or MHENRTPT**
Description:	Indicates medical history event is ongoing when no End Date is provided. {NY} (See Section 2.2.)					
Question:	Ongoing					
Completion instructions:	Select the most appropriate response.					
Info. for Sponsors:	This field will be completed to indicate that the condition has not resolved at the time of data collection. It is expected that every reported condition should have either an End Date or the Ongoing field marked “yes” (or checked), but not both. The purpose of collecting this field is to help with data cleaning and monitoring, since this field provides further confirmation that the End Date was deliberately left blank. As described in Section 3.4.1, Best Practices, this is a special use case of “Yes/No” where the question is usually presented as a single possible response of “Yes” in conjunction with an end date. In this case, if the box is checked, the field will contain “Yes” and if it is blank and there is an end date present, it can be mapped to “No”.’ The date of data collection in conjunction with a collected time point anchor Date and the MHONGO CDASH fields would determine how the SDTM IG variables would be populated. Reference Section 2.1.3 for more information. This field does not map directly to an SDTM variable.					
MH_7_2011-10-24	Controlled	MHCTRL	No Yes Response	MH	Optional	-
Description:	Indicates that the disease/symptoms are under control at the time of data collection.					
Question:	Controlled					
Completion instructions:	Select the most appropriate response.					
Info. for Sponsors:	MHCTRL is not defined in the SDTM IG MH domain. If collected, it should be submitted in the SUPPMH dataset. This field does not map directly to an SDTM variable.					
MH_8_2011-10-24	<specific condition> OR <specific procedure>	MHOCCUR	No Yes Response	MH	Optional	MHOCCUR
Description:	A response to a pre-printed term used to indicate whether or not a medical condition has occurred. {NY} (See Section 2.2.)					
Question:	<specific condition> OR <specific procedure>					
Completion instructions:	Please indicate if <specific condition> has occurred /is occurring by checking “Yes” or “No”.					
Info. for Sponsors:	MHOCCUR should only be used if the condition pre-printed on the CRF elicits a “Yes” or “No” response. MHOCCUR should not be used if the conditions are collected on the CRF in a manner that requires a free-flow text response.					
MH_9_2011-10-24	Start Date	MHSTDAT		MH	Optional	MHSTDTC*
Description:	Start date of Medical History event.					
Question:	Start Date					
Completion instructions:	Record the start date using this format (DD-MON-YYYY).					
Info. for Sponsors:	The sponsor may choose to capture a complete date or any variation thereof (e.g., month & year or year, etc.). For the SDTM-based dataset, the SDTM IG variable MHSTDTC is derived from the CDASH Start Date (MHSTDAT) using the ISO 8601 format. For more details see Best Practice Recommendations. This field does not map directly to an SDTM variable.					
MH_10_2011-10-24	End Date	MHENDAT		MH	Optional	MHENDTC*
Description:	End date of Medical History event.					
Question:	End Date					
Completion instructions:	Record the end date using this format (DD-MON-YYYY).					
Info. for Sponsors:	The sponsor may choose to capture a complete date or any variation thereof (month & year or year, etc.).					

	For the SDTM-based dataset, the SDTM IG variable MHENDTC is derived from the CDASH End Date (MHENDAT) using the ISO 8601 format. For more details see Best Practice Recommendations. This field does not map directly to an SDTM variable.					
MH_11_2011-10-24	Collection Date	MHDAT		MH	Optional	MHDTC*
Description:	The date on which the Medical History was taken.					
Question:	Collection Date					
Completion instructions:	Record the date on which the Medical History was taken using this format (DD-MON-YYYY).					
Info. for Sponsors:	This should be a complete date. The date of collection may be derived from a collected visit date. For the SDTM-based dataset, the SDTM IG variable MHDTC is derived from the CDASH End Date (MHDAT) using the ISO 8601 format. For more details see Best Practice Recommendations. This field does not map directly to an SDTM variable.					
MH_12_2011-10-24	High blood pressure	HBP.MHOCCUR	No Yes Response	MH	Optional	MHOCCUR
Description:	A response to a pre-printed term used to indicate whether or not a medical condition has occurred. {NY} (See Section 2.2.)					
Question:	High blood pressure					
Completion instructions:	Please indicate if <specific condition> has occurred /is occurring by checking “Yes” or “No”.					
Info. for Sponsors:	MHOCCUR should only be used if the condition pre-printed on the CRF elicits a “Yes” or “No” response. MHOCCUR should not be used if the conditions are collected on the CRF in a manner that requires a free-flow text response.					
MH_13_2011-10-24	Start Date	HBP.MHSTDAT		MH	Optional	MHSTDTC*
Description:	Start date of Medical History event.					
Question:	Start Date					
Completion instructions:	Record the start date using this format (DD-MON-YYYY).					
Info. for Sponsors:	The sponsor may choose to capture a complete date or any variation thereof (e.g., month & year or year, etc.). For the SDTM-based dataset, the SDTM IG variable MHSTDTC is derived from the CDASH Start Date (MHSTDAT) using the ISO 8601 format. For more details see Best Practice Recommendations. This field does not map directly to an SDTM variable.					
MH_14_2011-10-24	End Date	HBP.MHENDAT		MH	Optional	MHENDTC*
Description:	End date of Medical History event.					
Question:	End Date					
Completion instructions:	Record the end date using this format (DD-MON-YYYY).					
Info. for Sponsors:	The sponsor may choose to capture a complete date or any variation thereof (month & year or year, etc.). For the SDTM-based dataset, the SDTM IG variable MHENDTC is derived from the CDASH End Date (MHENDAT) using the ISO 8601 format. For more details see Best Practice Recommendations. This field does not map directly to an SDTM variable.					
MH_15_2011-10-24	Ongoing	HBP.MHONGO	No Yes Response	MH	Optional	MHENRF*
Description:	Indicates medical history event is ongoing when no End Date is provided. {NY} (See Section 2.2.)					
Question:	Ongoing					
Completion instructions:	Select the most appropriate response.					
Info. for Sponsors:	This field will be completed to indicate that the condition has not resolved at the time of data collection. It is expected that every reported condition should have either an End					

	Date or the Ongoing field marked “yes” (or checked), but not both. The purpose of collecting this field is to help with data cleaning and monitoring, since this field provides further confirmation that the End Date was deliberately left blank. As described in Section 3.4.1, Best Practices, this is a special use case of “Yes/No” where the question is usually presented as a single possible response of “Yes” in conjunction with an end date. In this case, if the box is checked, the field will contain “Yes” and if it is blank and there is an end date present, it can be mapped to “No”.’ The date of data collection in conjunction with a collected time point anchor Date and the MHONGO CDASH fields would determine how the SDTM IG variables would be populated. Reference Section 2.1.3 for more information. This field does not map directly to an SDTM variable.					
MH_16_2011-10-24	Appendectomy	APPENDECTOMY.MHOCCUR	No Yes Response	MH	Optional	MHOCCUR
Description:	A response to a pre-printed term used to indicate whether or not a medical condition has occurred. {NY} (See Section 2.2.)					
Question:	Appendectomy					
Completion instructions:	Please indicate if <specific condition> has occurred /is occurring by checking “Yes” or “No”.					
Info. for Sponsors:	MHOCCUR should only be used if the condition pre-printed on the CRF elicits a “Yes” or “No” response. MHOCCUR should not be used if the conditions are collected on the CRF in a manner that requires a free-flow text response.					
MH_17_2011-10-24	Start Date	APPENDECTOMY.MHSTDAT		MH	Optional	MHSTDTC*
Description:	Start date of Medical History event.					
Question:	Start Date					
Completion instructions:	Record the start date using this format (DD-MON-YYYY).					
Info. for Sponsors:	The sponsor may choose to capture a complete date or any variation thereof (e.g., month & year or year, etc.). For the SDTM-based dataset, the SDTM IG variable MHSTDTC is derived from the CDASH Start Date (MHSTDAT) using the ISO 8601 format. For more details see Best Practice Recommendations. This field does not map directly to an SDTM variable.					
VS_1_2011-10-24	Vital signs collected?	VSPERF	No Yes Response	VS	Optional	-
Description:	General prompt question regarding whether or not any VS were collected during the study. This provides verification that all other fields on the CRF were deliberately left blank. {NY} (See Section 2.2.)					
Question:	Vital signs collected?					
Completion instructions:	Indicate if the vital signs were collected. If yes, include the appropriate details where indicated on the CRF.					
Info. for Sponsors:	The intent/purpose of collecting this field is to help with data cleaning and monitoring. For the SDTM-based dataset, the SDTMIG variable VSSTAT is derived from a no value in VSPERF when a specific vital signs observation is not done. Not an SDTM variable, may be submitted in SDTM VSSTAT when VSTESCD = VSALL.					
VS_2_2011-10-24	Date	VSDAT		VS	Recommended/ Conditional	VSSTDTC*
Description:	Date of measurements					
Question:	Date					
Completion instructions:	Record date of measurements using the CDASH-recommended date format (e.g., 08-AUG-2008). For more detail see the Best Practice section.					
Info. for Sponsors:	The date of measurement can usually be derived from the date of visit and in such cases a separate measurement date field is not required. For the SDTM-based dataset, the SDTMIG variable VSDTC is derived by concatenating CDASH Date (VSDAT) and Time (VSTIM) of Vital Sign Measurements (if time is collected) into VSDTC using the ISO 8601 format.					
VS_3_2011-10-24	Time	VSTIM		VS	Recommended/ Conditional	VSSTDTC*
Description:	Time of measurements.					
Question:	Time					
Completion instructions:	Record time of measurement (as complete as possible). For more detail see the Best Practice section.					
Info. for Sponsors:	For the SDTM-based dataset, the SDTMIG variable VSDTC is derived by concatenating CDASH Date (VSDT) and Time (VSTIM) of Vital Sign Measurements (if time is					

	collected) into VSDTC using the ISO 8601 format.					
VS_4_2011-10-24	Date and Time	VSDTC		VS	Recommended/ Conditional	VSDTC
Description:	Date and time of measurements.					
Question:	Date and Time					
Completion instructions:	See VSDAT/VSTIM					
Info. for Sponsors:	See VSDAT/VSTIM					
VS_5_2011-10-24	ID	VSSPID		VS	Optional	VSSPID
Description:	A sponsor-defined identifier which can be used for pre-printed numbers on the CRF.					
Question:	ID					
Completion instructions:	Not applicable.					
Info. for Sponsors:	It can be beneficial to use an identifying number in a data query to clearly communicate to the site the specific record in question or to reconcile with other domains as needed.					
VS_6_2011-10-24	Planned Time Point	VSTPT		VS	Recommended/ Conditional	VSTPT
Description:	Text description of time when measurement should be taken					
Question:	Planned Time Point					
Completion instructions:	Not applicable.					
Info. for Sponsors:	If applicable, this will be pre-printed on CRF when measurements are required at multiple time points within a visit day.					
VS_7_2011-10-24	Test	VSTEST	Vital Signs Test Name	VS	Highly Recommended	VSTEST
Description:	Verbatim name of the test or examination used to obtain the measurement or finding. {VSTEST} (See Section 2.2.)					
Question:	Test					
Completion instructions:	Record the name of the vital sign test if not pre-printed on the CRF.					
Info. for Sponsors:	It is recommended that the test names be pre-printed on the CRF.					
VS_8_2011-10-24	Result	VSORRES-VSORRESU		VS	Highly Recommended	VSORRES
Description:	Result of the vital signs measurement as originally received or collected.					
Question:	Result					
Completion instructions:	Record vital sign results.					
Info. for Sponsors:	None.					
VS_9_2011-10-24	Units	VSORRESU	Units for Vital Signs Results	VS	Recommended/ Conditional	VSORRESU
Description:	Original units in which the data were collected. {VSRESU) (See Section 2.2.)					
Question:	Units					
Completion instructions:	Record or select the unit of measure associated with the test, if not pre-printed on the CRF.					
Info. for Sponsors:	It is recommended that the units be sponsor-defined are pre-printed on the CRF when possible.					
VS_10_2011-10-24	Clinically Significant	VSCLSIG	No Yes Response	VS	Optional	SUPPVS.QNAM
Description:	Whether vital sign result was clinically significant.					
Question:	Clinically Significant					
Completion instructions:	Record whether vital sign result was clinically significant.					
Info. for Sponsors:	If this level of information is needed, it may be added to the CRF.					
VS_11_2011-10-24	Location	VSLOC	Anatomical Location	VS	Optional	VSLOC
Description:	Location relevant to the collection of Vital Signs measurement. Example: LEFT ARM for blood pressure. {LOC) (See Section 2.2.)					
Question:	Location					
Completion instructions:	Record or select location on body where measurement was performed, if not pre-printed on CRF.					

Info. for Sponsors:	Location may be pre-defined as part of CRF label.					
VS_12_2011-10-24	Position	VSPOS	Vital Sign Positions	VS	Recommended/ Conditional	VSPOS
Description:	Position of the subject during a measurement or examination. {POSITION} (See Section 2.2.)					
Question:	Position					
Completion instructions:	Record the position of subject at time of test. (e.g. SITTING).					
Info. for Sponsors:	Position may be pre-defined as part of CRF label or site may be given one or more options to select from.					
VS_13_2011-10-24	Height collected?	HEIGHT.VSPERF	No Yes Response	VS	Optional	-
Description:	General prompt question regarding whether or not any VS were collected during the study. This provides verification that all other fields on the CRF were deliberately left blank. {NY} (See Section 2.2.)					
Question:	Height collected?					
Completion instructions:	Indicate if the vital signs were collected. If yes, include the appropriate details where indicated on the CRF.					
Info. for Sponsors:	The intent/purpose of collecting this field is to help with data cleaning and monitoring. For the SDTM-based dataset, the SDTMIG variable VSSTAT is derived from a no value in VSPERF when a specific vital signs observation is not done. Not an SDTM variable, may be submitted in SDTM VSSTAT when VSTESCD = VSALL.					
VS_14_2011-10-24	Height	HEIGHT.VSORRES		VS	Highly Recommended	VSORRES+VSORRESU
Description:	Result of the vital signs measurement as originally received or collected.					
Question:	Height					
Measurement Units:	cm, IN					
Completion instructions:	Record vital sign results.					
Info. for Sponsors:	None.					
VS_15_2011-10-24	Clinically Significant	HEIGHT.VSCLSIG	No Yes Response	VS	Optional	SUPPVS.QNAM
Description:	Whether vital sign result was clinically significant.					
Question:	Clinically Significant					
Completion instructions:	Record whether vital sign result was clinically significant.					
Info. for Sponsors:	If this level of information is needed, it may be added to the CRF.					
VS_16_2011-10-24	Weight collected?	WEIGHT.VSPERF	No Yes Response	VS	Optional	-
Description:	General prompt question regarding whether or not any VS were collected during the study. This provides verification that all other fields on the CRF were deliberately left blank. {NY} (See Section 2.2.)					
Question:	Weight collected?					
Completion instructions:	Indicate if the vital signs were collected. If yes, include the appropriate details where indicated on the CRF.					
Info. for Sponsors:	The intent/purpose of collecting this field is to help with data cleaning and monitoring. For the SDTM-based dataset, the SDTMIG variable VSSTAT is derived from a no value in VSPERF when a specific vital signs observation is not done. Not an SDTM variable, may be submitted in SDTM VSSTAT when VSTESCD = VSALL.					
VS_17_2011-10-24	Weight	WEIGHT.VSORRES		VS	Highly Recommended	VSORRES+VSORRESU
Description:	Result of the vital signs measurement as originally received or collected.					
Question:	Weight					
Measurement Units:	kg, LB					
Completion instructions:	Record vital sign results.					
Info. for Sponsors:	None.					
VS_18_2011-10-24	Clinically Significant	WEIGHT.VSCLSIG	No Yes Response	VS	Optional	SUPPVS.QNAM
Description:	Whether vital sign result was clinically significant.					
Question:	Clinically Significant					
Completion instructions:	Record whether vital sign result was clinically significant.					

Info. for Sponsors:	If this level of information is needed, it may be added to the CRF.					
VS_19_2011-10-24	BP collected?	BP.VSPERF	No Yes Response	VS	Optional	-
Description:	General prompt question regarding whether or not any VS were collected during the study. This provides verification that all other fields on the CRF were deliberately left blank. {NY} (See Section 2.2.)					
Question:	BP collected?					
Completion instructions:	Indicate if the vital signs were collected. If yes, include the appropriate details where indicated on the CRF.					
Info. for Sponsors:	The intent/purpose of collecting this field is to help with data cleaning and monitoring. For the SDTM-based dataset, the SDTMIG variable VSSTAT is derived from a no value in VSPERF when a specific vital signs observation is not done. Not an SDTM variable, may be submitted in SDTM VSSTAT when VSTESCD = VSALL.					
VS_20_2011-10-24	Systolic	BP.SYSBP.VSORRES		VS	Highly Recommended	VSORRES+VSORRESU
Description:	Result of the vital signs measurement as originally received or collected.					
Question:	Systolic					
Measurement Units:	mmHg					
Completion instructions:	Record vital sign results.					
Info. for Sponsors:	None.					
VS_21_2011-10-24	Diastolic	BP.DIABP.VSORRES		VS	Highly Recommended	VSORRES+VSORRESU
Description:	Result of the vital signs measurement as originally received or collected.					
Question:	Diastolic					
Measurement Units:	mmHg					
Completion instructions:	Record vital sign results.					
Info. for Sponsors:	None.					
VS_22_2011-10-24	BP Location	BP.VSLOC	Anatomical Location	VS	Optional	VSLOC
Description:	Location relevant to the collection of Vital Signs measurement. Example: LEFT ARM for blood pressure. {LOC} (See Section 2.2.)					
Question:	BP Location					
Completion instructions:	Record or select location on body where measurement was performed, if not pre-printed on CRF.					
Info. for Sponsors:	Location may be pre-defined as part of CRF label.					
VS_23_2011-10-24	BP Position	BP.VSPOS	Vital Sign Positions	VS	Recommended/ Conditional	VSPOS
Description:	Position of the subject during a measurement or examination. {POSITION} (See Section 2.2.)					
Question:	BP Position					
Completion instructions:	Record the position of subject at time of test. (e.g. SITTING).					
Info. for Sponsors:	Position may be pre-defined as part of CRF label or site may be given one or more options to select from.					
VS_24_2011-10-24	BP Clinically Significant	BP.VSCLSIG	No Yes Response	VS	Optional	SUPPVS.QNAM
Description:	Whether vital sign result was clinically significant.					
Question:	BP Clinically Significant					
Completion instructions:	Record whether vital sign result was clinically significant.					
Info. for Sponsors:	If this level of information is needed, it may be added to the CRF.					
VS_25_2011-10-24	Time	BP.VSTIM		VS	Recommended/ Conditional	VSSTDTC*
Description:	Time of measurements.					
Question:	Time					
Completion instructions:	Record time of measurement (as complete as possible). For more detail see the Best Practice section.					
Info. for Sponsors:	For the SDTM-based dataset, the SDTMIG variable VSDTC is derived by concatenating CDASH Date (VSDT) and Time (VSTIM) of Vital Sign Measurements (if time is					

	collected) into VSDTC using the ISO 8601 format.					
VS_26_2011-10-24	Pulse collected?	PULSE.VSPERF	No Yes Response	VS	Optional	-
Description:	General prompt question regarding whether or not any VS were collected during the study. This provides verification that all other fields on the CRF were deliberately left blank. {NY} (See Section 2.2.)					
Question:	Pulse collected?					
Completion instructions:	Indicate if the vital signs were collected. If yes, include the appropriate details where indicated on the CRF.					
Info. for Sponsors:	The intent/purpose of collecting this field is to help with data cleaning and monitoring. For the SDTM-based dataset, the SDTMIG variable VSSTAT is derived from a no value in VSPERF when a specific vital signs observation is not done. Not an SDTM variable, may be submitted in SDTM VSSTAT when VSTESCD = VSALL.					
VS_27_2011-10-24	Pulse	PULSE.VSORRES		VS	Highly Recommended	VSORRES+VSORRESU
Description:	Result of the vital signs measurement as originally received or collected.					
Question:	Pulse					
Measurement Units:	BEATS/MIN					
Completion instructions:	Record vital sign results.					
Info. for Sponsors:	None.					
VS_28_2011-10-24	Pulse Location	PULSE.VSLOC	Anatomical Location	VS	Optional	VSLOC
Description:	Location relevant to the collection of Vital Signs measurement. Example: LEFT ARM for blood pressure. {LOC} (See Section 2.2.)					
Question:	Pulse Location					
Completion instructions:	Record or select location on body where measurement was performed, if not pre-printed on CRF.					
Info. for Sponsors:	Location may be pre-defined as part of CRF label.					
VS_29_2011-10-24	Pulse Position	PULSE.VSPOS	Vital Sign Positions	VS	Recommended/ Conditional	VSPOS
Description:	Position of the subject during a measurement or examination. {POSITION} (See Section 2.2.)					
Question:	Pulse Position					
Completion instructions:	Record the position of subject at time of test. (e.g. SITTING).					
Info. for Sponsors:	Position may be pre-defined as part of CRF label or site may be given one or more options to select from.					
VS_30_2011-10-24	Clinically Significant	PULSE.VSCLSIG	No Yes Response	VS	Optional	SUPPVS.QNAM
Description:	Whether vital sign result was clinically significant.					
Question:	Clinically Significant					
Completion instructions:	Record whether vital sign result was clinically significant.					
Info. for Sponsors:	If this level of information is needed, it may be added to the CRF.					
VS_31_2011-10-24	Temperature collected?	TEMP.VSPERF	No Yes Response	VS	Optional	-
Description:	General prompt question regarding whether or not any VS were collected during the study. This provides verification that all other fields on the CRF were deliberately left blank. {NY} (See Section 2.2.)					
Question:	Temperature collected?					
Completion instructions:	Indicate if the vital signs were collected. If yes, include the appropriate details where indicated on the CRF.					
Info. for Sponsors:	The intent/purpose of collecting this field is to help with data cleaning and monitoring. For the SDTM-based dataset, the SDTMIG variable VSSTAT is derived from a no value in VSPERF when a specific vital signs observation is not done. Not an SDTM variable, may be submitted in SDTM VSSTAT when VSTESCD = VSALL.					
VS_32_2011-10-24	Temperature	TEMP.VSORRES		VS	Highly Recommended	VSORRES+VSORRESU
Description:	Result of the vital signs measurement as originally received or collected.					
Question:	Temperature					
Measurement Units:	C, F					

Completion instructions:	Record vital sign results.					
Info. for Sponsors:	None.					
VS_33_2011-10-24	Temperature Location	TEMP.VSLOC	Anatomical Location	VS	Optional	VSLOC
Description:	Location relevant to the collection of Vital Signs measurement. Example: LEFT ARM for blood pressure. {LOC) (See Section 2.2.)					
Question:	Temperature Location					
Completion instructions:	Record or select location on body where measurement was performed, if not pre-printed on CRF.					
Info. for Sponsors:	Location may be pre-defined as part of CRF label.					
VS_34_2011-10-24	Clinically Significant	TEMP.VSCLSIG	No Yes Response	VS	Optional	SUPPVS.QNAM
Description:	Whether vital sign result was clinically significant.					
Question:	Clinically Significant					
Completion instructions:	Record whether vital sign result was clinically significant.					
Info. for Sponsors:	If this level of information is needed, it may be added to the CRF.					
VS_35_2011-10-24	Frame Size collected?	FRMSIZE.VSPERF	No Yes Response	VS	Optional	-
Description:	General prompt question regarding whether or not any VS were collected during the study. This provides verification that all other fields on the CRF were deliberately left blank. {NY} (See Section 2.2.)					
Question:	Frame Size collected?					
Completion instructions:	Indicate if the vital signs were collected. If yes, include the appropriate details where indicated on the CRF.					
Info. for Sponsors:	The intent/purpose of collecting this field is to help with data cleaning and monitoring. For the SDTM-based dataset, the SDTMIG variable VSSTAT is derived from a no value in VSPERF when a specific vital signs observation is not done. Not an SDTM variable, may be submitted in SDTM VSSTAT when VSTESCD = VSALL.					
VS_36_2011-10-24	Frame Size	FRMSIZE.VSORRES	Vital Sign frame size	VS	Highly Recommended	VSORRES+VSORRESU
Description:	Result of the vital signs measurement as originally received or collected.					
Question:	Frame Size					
Completion instructions:	Record vital sign results.					
Info. for Sponsors:	None.					
SU_1_2011-10-24	<Type of Substance>	SUTRT		SU	Highly Recommended	SUTRT
Description:	The type of substance (e.g., TOBACCO, ALCOHOL, CAFFEINE or CIGARETTES, CIGARS, COFFEE).					
Question:	<Type of Substance>					
Completion instructions:	Not applicable.					
Info. for Sponsors:	Sponsors may require different types of substance use data (e.g., illicit drug use, cigarettes, etc.); the value for category may be pre-printed on the CRF as a label for the prompt for Substance Use. If a more detailed type of substance appears on the CRF (e.g., CIGARETTES, CIGARS, rather than TOBACCO), SUCAT should be “TOBACCO” and SUTRT should be “CIGARETTES”. If the sponsor does not specify a type of tobacco on the CRF, SUTRT should be “TOBACCO”.					
SU_2_2011-10-24	Usage	SUNCF	Substance use	SU	Highly Recommended	-
Description:	Substance Use Occurrence. {NCF} See Section 2.2					
Question:	Usage					
Completion instructions:	Check the appropriate box to indicate if the subject has ever used/consumed tobacco/alcohol/caffeine, currently consumes tobacco/alcohol/caffeine, or formerly used/consumed tobacco/alcohol/caffeine.					
Info. for Sponsors:	The three options, “NEVER”, “CURRENT” and “FORMER” should be sponsor-defined in relation to the protocol. If the sponsor has specific definitions for the three, these definitions should be detailed in the instructions to the site. As this type of response does not correspond exactly to an SDTM IG variable, CDASH recommends using SUNCF as the variable name in the clinical database. The SDTM variable SUOCCUR may be determined from SUNCF. See SDTM IG v3.1.2 Section 6.1.3.2 for more details.					

	This field does not map directly to an SDTM variable.					
SU_3_2011-10-24	<Substance Category>	SUCAT		SU	Optional	SUCAT
Description:	Used to define a category of related records (e.g., TOBACCO, ALCOHOL, CAFFEINE, etc.).					
Question:	<Substance Category>					
Completion instructions:	Not applicable.					
Info. for Sponsors:	Sponsors may require different types of substance use data (e.g., illicit drug use, cigarettes, etc.); the value for category may be pre-printed on the CRF as a label for the Prompt for Substance Use. If a more detailed type of substance appears on the CRF (e.g., CIGARETTES, CIGARS, rather than TOBACCO), SUCAT should be “TOBACCO” and SUTRT should be “CIGARETTES”. If the sponsor does not specify a type of tobacco on the CRF, SUTRT should be “TOBACCO”.					
SU_4_2011-10-24	Amount	SUDSTXT		SU	Optional	SUDOSTXT or SUDOSE**
Description:	The amount of substance used [e.g., 1-2 (packs), 8 (ounces)].					
Question:	Amount					
Completion instructions:	Check the appropriate box to indicate the amount of tobacco/alcohol/caffeine the subject consumes on a regular basis.					
Info. for Sponsors:	Where possible, the options for dose/amount should be pre-printed on the CRF. In the example given in the Definition, “(packs)” and “(ounces)” have been included as a point of reference. They would, of course, be submitted as SUDOSU. Care should be taken to map each record to the appropriate SDTM variable SUDOSTXT (text results that can't be represented in a numeric field) and SUDOSE (numeric results). This field does not map directly to an SDTM variable.					
SU_5_2011-10-24	Unit	SUDOSU		SU	Optional	SUDOSU
Description:	Units for SUDOSTXT (e.g., PACKS, OUNCES, etc.). {UNIT} See Section 2.2.					
Question:	Unit					
Completion instructions:	Not applicable.					
Info. for Sponsors:	Where possible, the options for dose/amount units should be pre-printed on the CRF.					
SU_6_2011-10-24	Frequency	SUDOSFRQ	Frequency	SU	Optional	SUDOSFRQ
Description:	Usually expressed as the number of uses consumed per a specific interval (e.g., PER DAY, PER WEEK, OCCASIONAL).					
Question:	Frequency					
Completion instructions:	Not applicable.					
Info. for Sponsors:	Where possible, the options for dose/amount frequency should be pre-printed on the CRF.					
SU_7_2011-10-24	Start Date	SUSTDAT		SU	Optional	SUSTDTC*
Description:	Date substance use started.					
Question:	Start Date					
Completion instructions:	Record the start date using this format (DD-MON-YYYY).					
Info. for Sponsors:	The sponsor may choose to capture a complete date or any variation thereof (e.g., month & year or year, etc.). For the SDTM-based dataset, the SDTM IG variable SUSTDTC is derived by concatenating CDASH Start Date (SUSTDAT) into SUSTDTC using the ISO 8601 format. For more details see Best Practice Recommendations. This field does not map directly to an SDTM variable.					
SU_8_2011-10-24	End date	SUENDAT		SU	Optional	SUENDTC*
Description:	Date substance use ended.					
Question:	End date					
Completion instructions:	Record the end date using this format (DD-MON-YYYY).					
Info. for Sponsors:	The sponsor may choose to capture a complete date or any variation thereof (e.g., month & year or year, etc.).					

	For more details see Best Practice Recommendations. This field does not map directly to an SDTM variable.					
SU_9_2011-10-24	Duration	SUCDUR+SUCDURU		SU	Optional	SUDUR*
Description:	The duration of the substance use.					
Question:	Duration					
Completion instructions:	Provide the duration of the Substance Abuse (e.g., Record how long the subject has smoked).					
Info. for Sponsors:	This should only be collected on the CRF if this level of detail is needed and if SUSTDAT & SUENDAT are not collected on the CRF. The sponsor-defined options (e.g., weeks, months, years, etc.) should be pre-printed on the CRF to avoid making this a free text field. This will allow the response to be translated into ISO 8601 format. For the SDTM-based dataset, the SDTMIG variable SUDUR can be derived by concatenating the CDASH duration and duration unit's variables.					
SU_10_2011-10-24	Usage	TOBACCO.CIGARETTES.SUNCF	Substance use	SU	Highly Recommended	-
Description:	Substance Use Occurrence. {NCF} See Section 2.2					
Question:	Usage					
Completion instructions:	Check the appropriate box to indicate if the subject has ever used/consumed tobacco/alcohol/caffeine, currently consumes tobacco/alcohol/caffeine, or formerly used/consumed tobacco/alcohol/caffeine.					
Info. for Sponsors:	The three options, "NEVER", "CURRENT" and "FORMER" should be sponsor-defined in relation to the protocol. If the sponsor has specific definitions for the three, these definitions should be detailed in the instructions to the site. As this type of response does not correspond exactly to an SDTMIG variable. CDASH recommends using SUNCF as the variable name in the clinical database. SUNCF is not defined in the SDTM and, generally, should be dropped prior to submission. If submitted, it should be submitd in SUPPSU. "NEVER" maps to SDTM SUOCCUR as "N". "CURRENT" and "FORMER" map to SUOCCUR as "Y".					
SU_11_2011-10-24	Amount	TOBACCO.CIGARETTES.SUDSTXT	Cigarette Usage Amount	SU	Optional	SUDOSTXT
Description:	Substance use consumption amounts or a range of consumption information collected in text form [e.g., 1-2 (packs), 8 (ounces), etc].					
Question:	Amount					
Completion instructions:	Check the appropriate box to indicate the amount of tobacco/alcohol/caffeine the subject consumes on a regular basis.					
Info. for Sponsors:	Where possible, the options for dose/amount should be pre-printed on the CRF. In the example given in the Definition, "(packs)" and "(ounces)" have been included as a point of reference. They would, of course, be submitted as SUDOSU. Care should be taken to map each record to the appropriate SDTM variable SUDOSTXT (text results that can't be represented in a numeric field) and SUDOSE (numeric results)					
SU_12_2011-10-24	Start Date	TOBACCO.CIGARETTES.SUSTDAT		SU	Optional	SUSTDTC*
Description:	Date substance use started.					
Question:	Start Date					
Completion instructions:	Record the start date using the CDASH-recommended date format (e.g., 22-AUG-2008). For more details see Best Practice Recommendations.					
Info. for Sponsors:	The sponsor may choose to capture a complete date or any variation thereof (e.g., month & year or year, etc.). For the SDTM-based dataset, the SDTMIG variable SUSTDTC is derived by concatenating CDASH Start Date (SUSTDAT) into SUSTDTC using the ISO 8601 format.					
SU_13_2011-10-24	End date	TOBACCO.CIGARETTES.SUENDAT		SU	Optional	SUENDTC*
Description:	Date substance use ended.					
Question:	End date					
Completion instructions:	Record the end date using the CDASH-recommended date format (e.g., 22-AUG-2008). For more details see Best Practice Recommendations.					
Info. for Sponsors:	The sponsor may choose to capture a complete date or any variation thereof (e.g., month & year or year, etc.). For the SDTM-based dataset, the SDTMIG variable SUENDTC is derived by concatenating CDASH Start Date (SUENDAT) into SUENDTC using the ISO 8601 format.					
SU_14_2011-10-24	Duration	TOBACCO.CIGARETTES.SUCDUR		SU	Optional	SUDUR*
Description:	The duration of the substance use.					
Question:	Duration					
Completion instructions:	Provide the duration of the Substance Abuse (e.g., Record how long the subject has smoked).					
Info. for Sponsors:	This should only be collected on the CRF if this level of detail is needed and if SUSTDAT & SUENDAT are not collected on the CRF. The sponsor-defined options (e.g., weeks, months, years, etc.) should be pre-printed on the CRF to avoid making this a free text field. This will allow the response to be					

	translated into ISO 8601 format. For the SDTM-based dataset, the SDTMIG variable SUDUR can be derived by concatenating the CDASH duration and duration unit's variables.					
SU_15_2011-10-24	Usage	TOBACCO.CIGARS.SUNCF	Substance use	SU	Highly Recommended	-
Description:	Substance Use Occurrence. {NCF} See Section 2.2					
Question:	Usage					
Completion instructions:	Check the appropriate box to indicate if the subject has ever used/consumed tobacco/alcohol/caffeine, currently consumes tobacco/alcohol/caffeine, or formerly used/consumed tobacco/alcohol/caffeine.					
Info. for Sponsors:	The three options, "NEVER", "CURRENT" and "FORMER" should be sponsor-defined in relation to the protocol. If the sponsor has specific definitions for the three, these definitions should be detailed in the instructions to the site. As this type of response does not correspond exactly to an SDTMIG variable. CDASH recommends using SUNCF as the variable name in the clinical database. SUNCF is not defined in the SDTM and, generally, should be dropped prior to submission. If submitted, it should be submitd in SUPPSU. "NEVER" maps to SDTM SUOCCUR as "N". "CURRENT" and "FORMER" map to SUOCCUR as "Y".					
SU_16_2011-10-24	Amount	TOBACCO.CIGARS.SUDSTXT	Cigar Usage Amount	SU	Optional	SUDOSTXT
Description:	Substance use consumption amounts or a range of consumption information collected in text form [e.g., 1-2 (packs), 8 (ounces), etc].					
Question:	Amount					
Completion instructions:	Check the appropriate box to indicate the amount of tobacco/alcohol/caffeine the subject consumes on a regular basis.					
Info. for Sponsors:	Where possible, the options for dose/amount should be pre-printed on the CRF. In the example given in the Definition, "(packs)" and "(ounces)" have been included as a point of reference. They would, of course, be submitted as SUDOSU. Care should be taken to map each record to the appropriate SDTM variable SUDOSTXT (text results that can't be represented in a numeric field) and SUDOSE (numeric results)					
SU_17_2011-10-24	Start Date	TOBACCO.CIGARS.SUSTDAT		SU	Optional	SUSTDTC*
Description:	Date substance use started.					
Question:	Start Date					
Completion instructions:	Record the start date using the CDASH-recommended date format (e.g., 22-AUG-2008). For more details see Best Practice Recommendations.					
Info. for Sponsors:	The sponsor may choose to capture a complete date or any variation thereof (e.g., month & year or year, etc.). For the SDTM-based dataset, the SDTMIG variable SUSTDTC is derived by concatenating CDASH Start Date (SUSTDAT) into SUSTDTC using the ISO 8601 format.					
SU_18_2011-10-24	End date	TOBACCO.CIGARS.SUENDAT		SU	Optional	SUENDTC*
Description:	Date substance use ended.					
Question:	End date					
Completion instructions:	Record the end date using the CDASH-recommended date format (e.g., 22-AUG-2008). For more details see Best Practice Recommendations.					
Info. for Sponsors:	The sponsor may choose to capture a complete date or any variation thereof (e.g., month & year or year, etc.). For the SDTM-based dataset, the SDTMIG variable SUENDTC is derived by concatenating CDASH Start Date (SUENDAT) into SUENDTC using the ISO 8601 format.					
SU_19_2011-10-24	Duration	TOBACCO.CIGARS.SUCDUR		SU	Optional	SUDUR*
Description:	The duration of the substance use.					
Question:	Duration					
Completion instructions:	Provide the duration of the Substance Abuse (e.g., Record how long the subject has smoked).					
Info. for Sponsors:	This should only be collected on the CRF if this level of detail is needed and if SUSTDAT & SUENDAT are not collected on the CRF. The sponsor-defined options (e.g., weeks, months, years, etc.) should be pre-printed on the CRF to avoid making this a free text field. This will allow the response to be translated into ISO 8601 format. For the SDTM-based dataset, the SDTMIG variable SUDUR can be derived by concatenating the CDASH duration and duration unit's variables.					
SU_20_2011-10-24	Usage	ALCOHOL.SUNCF	Substance use	SU	Highly Recommended	-
Description:	Substance Use Occurrence. {NCF} See Section 2.2					
Question:	Usage					
Completion instructions:	Check the appropriate box to indicate if the subject has ever used/consumed tobacco/alcohol/caffeine, currently consumes tobacco/alcohol/caffeine, or formerly used/consumed tobacco/alcohol/caffeine.					
Info. for Sponsors:	The three options, "NEVER", "CURRENT" and "FORMER" should be sponsor-defined in relation to the protocol. If the sponsor has specific definitions for the three, these definitions should be detailed in the instructions to the site. As this type of response does not correspond exactly to an SDTMIG variable. CDASH recommends using SUNCF as the variable name in the clinical database.					

	SUNCF is not defined in the SDTM and, generally, should be dropped prior to submission. If submitted, it should be submitd in SUPPSU. “NEVER” maps to SDTM SUOCCUR as “N”. “CURRENT” and “FORMER” map to SUOCCUR as “Y”.					
SU_21_2011-10-24	Amount Beer	ALCOHOL.BEER.SUDSTXT		SU	Optional	SUDOSTXT
Description:	Substance use consumption amounts or a range of consumption information collected in text form [e.g., 1-2 (packs), 8 (ounces), etc].					
Question:	Amount Beer					
Measurement Units:	BEER UNIT					
Completion instructions:	Check the appropriate box to indicate the amount of tobacco/alcohol/caffeine the subject consumes on a regular basis.					
Info. for Sponsors:	Where possible, the options for dose/amount should be pre-printed on the CRF. In the example given in the Definition, “(packs)” and “(ounces)” have been included as a point of reference. They would, of course, be submitted as SUDOSU. Care should be taken to map each record to the appropriate SDTM variable SUDOSTXT (text results that can't be represented in a numeric field) and SUDOSE (numeric results)					
SU_22_2011-10-24	Frequency Beer	ALCOHOL.BEER.SUDOSFRQ	Frequency	SU	Optional	SUDOSFRQ
Description:	Usually expressed as the number of uses consumed per a specific interval (e.g., PER DAY, PER WEEK, OCCASIONAL).					
Question:	Frequency Beer					
Completion instructions:	Not applicable.					
Info. for Sponsors:	Where possible, the options for dose/amount frequency should be pre-printed on the CRF.					
SU_23_2011-10-24	Amount Wine	ALCOHOL.WINE.SUDSTXT		SU	Optional	SUDOSTXT
Description:	Substance use consumption amounts or a range of consumption information collected in text form [e.g., 1-2 (packs), 8 (ounces), etc].					
Question:	Amount Wine					
Measurement Units:	WINE UNIT					
Completion instructions:	Check the appropriate box to indicate the amount of tobacco/alcohol/caffeine the subject consumes on a regular basis.					
Info. for Sponsors:	Where possible, the options for dose/amount should be pre-printed on the CRF. In the example given in the Definition, “(packs)” and “(ounces)” have been included as a point of reference. They would, of course, be submitted as SUDOSU. Care should be taken to map each record to the appropriate SDTM variable SUDOSTXT (text results that can't be represented in a numeric field) and SUDOSE (numeric results)					
SU_24_2011-10-24	Frequency Wine	ALCOHOL.WINE.SUDOSFRQ	Frequency	SU	Optional	SUDOSFRQ
Description:	Usually expressed as the number of uses consumed per a specific interval (e.g., PER DAY, PER WEEK, OCCASIONAL).					
Question:	Frequency Wine					
Completion instructions:	Not applicable.					
Info. for Sponsors:	Where possible, the options for dose/amount frequency should be pre-printed on the CRF.					
SU_25_2011-10-24	Amount Spirits	ALCOHOL.SPIRITS.SUDSTXT		SU	Optional	SUDOSTXT
Description:	Substance use consumption amounts or a range of consumption information collected in text form [e.g., 1-2 (packs), 8 (ounces), etc].					
Question:	Amount Spirits					
Measurement Units:	SPIRIT UNIT					
Completion instructions:	Check the appropriate box to indicate the amount of tobacco/alcohol/caffeine the subject consumes on a regular basis.					
Info. for Sponsors:	Where possible, the options for dose/amount should be pre-printed on the CRF. In the example given in the Definition, “(packs)” and “(ounces)” have been included as a point of reference. They would, of course, be submitted as SUDOSU. Care should be taken to map each record to the appropriate SDTM variable SUDOSTXT (text results that can't be represented in a numeric field) and SUDOSE (numeric results)					
SU_26_2011-10-24	Frequency Spirits	ALCOHOL.SPIRITS.SUDOSFRQ	Frequency	SU	Optional	SUDOSFRQ
Description:	Usually expressed as the number of uses consumed per a specific interval (e.g., PER DAY, PER WEEK, OCCASIONAL).					
Question:	Frequency Spirits					
Completion instructions:	Not applicable.					
Info. for Sponsors:	Where possible, the options for dose/amount frequency should be pre-printed on the CRF.					
SU_27_2011-10-24	Start Date	ALCOHOL.SUSTDAT		SU	Optional	SUSTDTC*
Description:	Date substance use started.					
Question:	Start Date					

Completion instructions:	Record the start date using the CDASH-recommended date format (e.g., 22-AUG-2008). For more details see Best Practice Recommendations.					
Info. for Sponsors:	The sponsor may choose to capture a complete date or any variation thereof (e.g., month & year or year, etc.). For the SDTM-based dataset, the SDTMIG variable SUSTDTC is derived by concatenating CDASH Start Date (SUSTDAT) into SUSTDTC using the ISO 8601 format.					
SU_28_2011-10-24	End date	ALCOHOL.SUENDAT		SU	Optional	SUENDTC*
Description:	Date substance use ended.					
Question:	End date					
Completion instructions:	Record the end date using the CDASH-recommended date format (e.g., 22-AUG-2008). For more details see Best Practice Recommendations.					
Info. for Sponsors:	The sponsor may choose to capture a complete date or any variation thereof (e.g., month & year or year, etc.). For the SDTM-based dataset, the SDTMIG variable SUENDTC is derived by concatenating CDASH Start Date (SUENDAT) into SUENDTC using the ISO 8601 format.					
SU_29_2011-10-24	Duration	ALCOHOL.SUCDUR		SU	Optional	SUDUR
Description:	The duration of the substance use.					
Question:	Duration					
Completion instructions:	Provide the duration of the Substance Abuse (e.g., Record how long the subject has smoked).					
Info. for Sponsors:	This should only be collected on the CRF if this level of detail is needed and if SUSTDAT & SUENDAT are not collected on the CRF. The sponsor-defined options (e.g., weeks, months, years, etc.) should be pre-printed on the CRF to avoid making this a free text field. This will allow the response to be translated into ISO 8601 format. For the SDTM-based dataset, the SDTMIG variable SUDUR can be derived by concatenating the CDASH duration and duration unit's variables.					
EG_1_2011-10-24	ECG Performed	EGPERF	No Yes Response	EG	Highly Recommended	EGSTAT
Description:	Status of whether or not ECG or a specific ECG test was done. {NY} (See Section 2.2.)					
Question:	ECG Performed					
Completion instructions:	Indicate whether or not ECG or specific ECG test was done.					
Info. for Sponsors:	This may be collected for an entire ECG, or for a specific ECG test. This is intended to be used as a data management tool to verify that missing results are confirmed missing. See Best Practice Section 3.4, FAQ #6. For the SDTM-based dataset, the SDTM IG variable EGSTAT can be derived from EGPERF. This field does not map directly to an SDTM variable.					
EG_2_2011-10-24	Reference ID	EGREFID		EG	Optional	EGREFID
Description:	Identifier of the ECG (e.g. waveform number).					
Question:	Reference ID					
Completion instructions:	Record the identifier number assigned.					
Info. for Sponsors:	This can be used to confirm that the appropriate data record is present in the electronic transfer if this reference ID happens to be available to the site at the time of collection (e.g., Universally Unique Identifier (UUID) for external waveform file, session number automatically generated by electronic equipment). This can also be used to link records.					
EG_3_2011-10-24	Method	EGMETHOD	ECG Test Method	EG	Optional	EGMETHOD
Description:	Method used to measure ECG. {EGMETHOD} (See Section 2.2.)					
Question:	Method					
Completion instructions:	Record the method used to measure ECG.					
Info. for Sponsors:	Results may be affected by whether conditions for ECG as specified in the protocol were properly met. One possible condition is the method used to collect or calculate the ECG data. If the protocol requires this type of information, then this question may be included to confirm that the method used matches the protocol. The following are examples of when it is not necessary to collect these data on the CRF: Method of ECG is provided as part of the electronic data, or Method of ECG is not pertinent to the protocol, or The protocol specifies only one possible method for collecting ECG measurements and the sponsor does not feel there is significant risk of the sites performing the ECG using the incorrect method. *See the BRIDG model for complete path.					
EG_4_2011-10-24	Subject Position	EGPOS	Position	EG	Optional	EGPOS
Description:	Position of the subject during the ECG measurement. {POSITION} (See Section 2.2.)					
Question:	Subject Position					
Completion instructions:	Record the position of the subject during the ECG.					
Info. for Sponsors:	Results may be affected by whether conditions for ECG as specified in the protocol were properly met.					

	One common condition is the subject's position (e.g., Supine, Standing). If the protocol requires this type of information, then this question may be included to confirm that the subject's position matches the protocol. The following are examples of when it is not necessary to collect these data on the CRF: - Position of the subject is provided as part of the electronic data, or - Position of the subject is not pertinent to the protocol, or - The protocol specifies only one possible position and the sponsor does not feel there is significant risk of the sites performing the ECG with the subject in the wrong position *See the BRIDG model for complete path.					
EG_5_2011-10-24	ECG Date	EGDAT		EG	Recommended / Conditional	EGDTC*
Description:	Date of ECG.					
Question:	ECG Date					
Completion instructions:	Record the date ECG was done using this format (DD-MON-YYYY).					
Info. for Sponsors:	A complete date is expected. The date of collection may be derived from the date of visit and if so, a separate assessment date field is not required. Intended for reconciliation purposes. If electronic data are being supplied continuously and in real time to the sites, then collecting the date on the CRF for reconciliation may not be needed. Likewise, if a sponsor's process considers the date electronically created by the ECG equipment as the source data then collecting this field is not necessary. If Date of ECG is not collected, it is still recommended to confirm that the electronic data contain measurements for each visit where an ECG was done. For the SDTM-based dataset, the SDTMIG variable EGDTC is derived by putting CDASH Date of ECG (EGDAT) into EGDTC using the ISO 8601 format. For more detail see the Best Practice section. This field does not map directly to an SDTM variable. *See the BRIDG model for complete path.					
EG_6_2011-10-24	<Planned Time Point>	EGTPT		EG	Recommended / Conditional	EGTPT
Description:	Text description of planned time point when measurements should be taken for use when multiple sequential assessments are done.					
Question:	<Planned Time Point>					
Completion instructions:	Record the time point labels for when the ECG test should be taken, if not pre-printed on the CRF.					
Info. for Sponsors:	Planned time point would be needed to differentiate multiple sequential assessments. It is recommended that time points be pre-printed on the CRF rather than collected in a field that requires the site to enter text. If the form is laid out as a grid, then words such as “Planned Time Point” can be included as the column header. If ECG is not being done at multiple time points within a visit, do not include this item on the CRF.					
EG_7_2011-10-24	ECG Time	EGTIM		EG	Recommended / Conditional	EGDTC*
Description:	Time of ECG.					
Question:	ECG Time					
Completion instructions:	Record the time the ECG was done (as complete as possible).					
Info. for Sponsors:	Especially important when multiple assessments are done on one day. Intended for reconciliation purposes. If electronic data are being supplied continuously and in real time to the sites, then collecting the time on the CRF for reconciliation may not be needed. Likewise, if a sponsor's process considers the time electronically created by the ECG equipment as the source data then collecting this field is not necessary. If time of ECG is not collected, on the CRF it is still recommended to confirm that the electronic data contain measurements for each time point where an ECG was done. For the SDTM-based dataset, the SDTMIG variable EGDTC is derived by concatenating CDASH Date of ECG (EGDAT) and Time of ECG (EGTIM) into EGDTC using the ISO 8601 format. For more detail see the Best Practice section. This field does not map directly to an SDTM variable. *See the BRIDG model for complete path.					
EG_8_2011-10-24	ECG Date and Time	EGDTC		EG	Recommended / Conditional	EGDTC
Description:	Date and Time of ECG.					
Question:	ECG Date and Time					
Completion instructions:	See EGDAT/EGTIM					
Info. for Sponsors:	See EGDAT/EGTIM					
EG_9_2011-10-24	<Test name>	EGTEST	ECG Test Code	EG	Highly Recommended	EGTEST

Description:	Descriptive name of the measurement or finding. {EGTEST} (See Section 2.2.)					
Question:	<Test name>					
Completion instructions:	Record the name of the ECG measurement or finding, if not pre-printed on the CRF.					
Info. for Sponsors:	Required to identify which ECG test the result is for. If specific tests are required, these should be pre-printed on the CRF rather than collected in a field that requires the site to enter text. If the form is laid out as a grid, then words such as "Test" can be included as the column header. *See the BRIDG model for complete path.					
EG_10_2011-10-24	Result	EGORRES		EG	Highly Recommended	EGORRES
Description:	Result of the measurement or finding as originally received or collected.					
Question:	Result					
Completion instructions:	Record test results, interpretations or findings.					
Info. for Sponsors:	Both quantitative results and interpretive findings or summaries may be recorded here. *See the BRIDG model for complete path.					
EG_12_2011-10-24	Clinically significant	EGCLSIG	No Yes Response	EG	Optional	SUPPEG.QNAM
Description:	Whether ECG results were clinically significant. {NY} (See Section 2.2.)					
Question:	Clinically significant					
Completion instructions:	Record whether ECG results were clinically significant.					
Info. for Sponsors:	Could apply to specific measurements or to overall interpretation. This field does not map directly to an SDTM variable.					
EG_13_2011-10-24	Summary (Mean) Ventricular Rate	VRMEAN.EGORRES		EG	Highly Recommended	EGORRES+EGORRESU
Description:	Result of the measurement or finding as originally received or collected.					
Question:	Summary (Mean) Ventricular Rate					
Measurement Units:	BEATS/MIN					
Completion instructions:	Record test results, interpretations or findings.					
Info. for Sponsors:	Both quantitative results and interpretive findings or summaries may be recorded here.					
EG_14_2011-10-24	Summary (Mean) Ventricular Rate Clinically Significant	VRMEAN.EGCLSIG	No Yes Response	EG	Optional	SUPPEG.QNAM
Description:	Whether ECG results were clinically significant. {NY} (See Section 2.2.)					
Question:	Summary (Mean) Ventricular Rate Clinically Significant					
Completion instructions:	Record whether ECG results were clinically significant.					
Info. for Sponsors:	Could apply to specific measurements or to overall interpretation.					
EG_15_2011-10-24	PR	PRMEAN.EGORRES		EG	Highly Recommended	EGORRES+EGORRESU
Description:	Result of the measurement or finding as originally received or collected.					
Question:	PR					
Measurement Units:	msec					
Completion instructions:	Record test results, interpretations or findings.					
Info. for Sponsors:	Both quantitative results and interpretive findings or summaries may be recorded here.					
EG_16_2011-10-24	PR Clinically Significant	PRMEAN.EGCLSIG	No Yes Response	EG	Optional	SUPPEG.QNAM
Description:	Whether ECG results were clinically significant. {NY} (See Section 2.2.)					
Question:	PR Clinically Significant					
Completion instructions:	Record whether ECG results were clinically significant.					
Info. for Sponsors:	Could apply to specific measurements or to overall interpretation.					
EG_17_2011-10-24	QRS	QRSDUR.EGORRES		EG	Highly Recommended	EGORRES+EGORRESU

Description:	Result of the measurement or finding as originally received or collected.					
Question:	QRS					
Measurement Units:	msec					
Completion instructions:	Record test results, interpretations or findings.					
Info. for Sponsors:	Both quantitative results and interpretive findings or summaries may be recorded here.					
EG_18_2011-10-24	QRS Clinically Significant	QRSDUR.EGCLSIG	No Yes Response	EG	Optional	SUPPEG.QNAM
Description:	Whether ECG results were clinically significant. {NY} (See Section 2.2.)					
Question:	QRS Clinically Significant					
Completion instructions:	Record whether ECG results were clinically significant.					
Info. for Sponsors:	Could apply to specific measurements or to overall interpretation.					
EG_19_2011-10-24	QT	QTMEAN.EGORRES		EG	Highly Recommended	EGORRES+EGORRESU
Description:	Result of the measurement or finding as originally received or collected.					
Question:	QT					
Measurement Units:	msec					
Completion instructions:	Record test results, interpretations or findings.					
Info. for Sponsors:	Both quantitative results and interpretive findings or summaries may be recorded here.					
EG_20_2011-10-24	QT Clinically Significant	QTMEAN.EGCLSIG	No Yes Response	EG	Optional	SUPPEG.QNAM
Description:	Whether ECG results were clinically significant. {NY} (See Section 2.2.)					
Question:	QT Clinically Significant					
Completion instructions:	Record whether ECG results were clinically significant.					
Info. for Sponsors:	Could apply to specific measurements or to overall interpretation.					
EG_21_2011-10-24	QTc - Bazett's	QTCB.EGORRES		EG	Highly Recommended	EGORRES+EGORRESU
Description:	Result of the measurement or finding as originally received or collected.					
Question:	QTc - Bazett's					
Measurement Units:	msec					
Completion instructions:	Record test results, interpretations or findings.					
Info. for Sponsors:	Both quantitative results and interpretive findings or summaries may be recorded here.					
EG_22_2011-10-24	QTc - Bazett's Clinically Significant	QTCB.EGCLSIG	No Yes Response	EG	Optional	SUPPEG.QNAM
Description:	Whether ECG results were clinically significant. {NY} (See Section 2.2.)					
Question:	QTc - Bazett's Clinically Significant					
Completion instructions:	Record whether ECG results were clinically significant.					
Info. for Sponsors:	Could apply to specific measurements or to overall interpretation.					
EG_23_2011-10-24	Interpretation	INTRP.EGORRES		EG	Highly Recommended	EGORRES+EGORRESU
Description:	Result of the measurement or finding as originally received or collected.					
Question:	Interpretation					
Completion instructions:	Record test results, interpretations or findings.					
Info. for Sponsors:	Both quantitative results and interpretive findings or summaries may be recorded here.					
EG_24_2011-10-24	Interpretation Clinically Significant	INTRP.EGCLSIG	No Yes Response	EG	Optional	SUPPEG.QNAM
Description:	Whether ECG results were clinically significant. {NY} (See Section 2.2.)					
Question:	Interpretation Clinically Significant					
Completion instructions:	Record whether ECG results were clinically significant.					

Info. for Sponsors:	Could apply to specific measurements or to overall interpretation.					
LB_1_2011-10-24	Lab Status	LBPERF	No Yes Response	LB	Highly Recommended	LBSTAT
Description:	Status of whether or not lab specimen was collected or measurement performed. {NY} (See Section 2.2.)					
Question:	Lab Status					
Completion instructions:	Indicate whether or not lab specimen was collected or measurement performed.					
Info. for Sponsors:	This may be implemented for an entire panel, or on a specific test basis. This is intended to be used as a data management tool to verify that missing results are confirmed missing. See Best Practice Section 3.4, FAQ #6. For the SDTM-based dataset, the SDTM IG variable LBSTAT is derived from LBPERF when an entire panel or a specific is not done. The question text used might be reflected in the reason not done (LBREASND). This field does not map directly to an SDTM variable.					
LB_2_2011-10-24	Collection Date	LBDAT		LB	Highly Recommended	LBDTC*
Description:	Date of specimen collection.					
Question:	Collection Date					
Completion instructions:	Record the date when specimen collection occurred using this format (DD-MON-YYYY).					
Info. for Sponsors:	A complete date is expected. The date of collection may be derived from the date of visit and if so, a separate assessment date field is not required. For the SDTM-based dataset, the SDTMIG variable LBDTC is derived by concatenating CDASH Date (LBDAT) and Time (LBTIM) of collection (if time is collected) into LBDTC using the ISO 8601 format. For more details see Best Practice Recommendations. This field does not map directly to an SDTM variable.					
LB_3_2011-10-24	Collection Time	LBTIM		LB	Recommended/ Conditional	LBDTC*
Description:	Time of specimen collection.					
Question:	Collection Time					
Completion instructions:	Record time of collection (as complete as possible).					
Info. for Sponsors:	Especially important when multiple assessments are done on one day. For the SDTM-based dataset, the SDTMIG variable LBDTC is derived by concatenating CDASH Date (LBDAT) and Time (LBTIM) of collection (if time is collected) into LBDTC using the ISO 8601 format. For more details see Best Practice Recommendations. This field does not map directly to an SDTM variable.					
LB_4_2011-10-24	Collection Date and Time	LBDTC		LB	Highly Recommended	LBDTC
Description:	Date and Time of specimen collection.					
Question:	Collection Date and Time					
Completion instructions:	See LBDAT/LBTIM					
Info. for Sponsors:	See LBDAT/LBTIM					
LB_5_2011-10-24	<Panel Name>	LBCAT		LB	Recommended/ Conditional	LBCAT
Description:	Used to define a category of related laboratory records (e.g. HEMATOLOGY, CHEMISTRY, URINALYSIS).					
Question:	<Panel Name>					
Completion instructions:	Record the lab test category, if not pre-printed on the CRF.					
Info. for Sponsors:	To be included if lab status is collected for each panel (e.g., HEMATOLOGY, URINALYSIS, CHEMISTRY). If specific panels are required, these should be pre-printed on the CRF rather than collected in a field that requires the site to enter text.					
LB_6_2011-10-24	<Sub-Panel Name>	LBSCAT		LB	Recommended/ Conditional	LBSCAT
Description:	Used to define a category of related laboratory records (e.g. HEMATOLOGY, CHEMISTRY, URINALYSIS).					
Question:	<Sub-Panel Name>					
Completion instructions:	Record the lab test category, if not pre-printed on the CRF.					

Info. for Sponsors:	To be included if lab status is collected for each panel (e.g., HEMATOLOGY, URINALYSIS, CHEMISTRY). If specific panels are required, these should be pre-printed on the CRF rather than collected in a field that requires the site to enter text.					
LB_7_2011-10-24	<Planned Time Point>	LBTPT		LB	Recommended/ Conditional	LBTPT
Description:	Text description of planned time point when measurements should be taken for use when multiple sequential assessments are done.					
Question:	<Planned Time Point>					
Completion instructions:	Record the planned time point labels for the lab test, if not pre-printed on the CRF.					
Info. for Sponsors:	Planned time point would be needed to differentiate for multiple sequential assessments. It is recommended that time points should be pre-printed on the CRF rather than collected in a field that requires the site to enter text. If the form is laid out as a grid, then words such as “Planned Time Point” can be included as the column header.					
LB_8_2011-10-24	<protocol-defined testing condition>	LBCOND	No Yes Response	LB	Recommended/ Conditional	-
Description:	Confirmation that the protocol defined condition imposed on the subject when testing (e.g., FASTING, HYDRATION, EXERCISE) was met. If collecting this as a Yes/No, use {NY}(See Section 2.2.)					
Question:	<protocol-defined testing condition>					
Completion instructions:	Record whether protocol defined testing conditions were met.					
Info. for Sponsors:	This information is collected when the test results may be affected by whether conditions for testing were properly met. This may not be relevant for all tests. This information may be collected using the {NY} codelist, or sponsors may develop and use controlled terminology for this field if the value being collected is the testing condition. This field does not map directly to an SDTM variable.					
LB_9_2011-10-24	Fasting ?	FASTING.LBCOND	No Yes Response	LB	Recommended/ Conditional	-
Description:	Confirmation that the protocol defined condition imposed on the subject when testing (e.g., FASTING, HYDRATION, EXERCISE) was met. If collecting this as a Yes/No, use {NY}(See Section 2.2.)					
Question:	Fasting ?					
Completion instructions:	Record whether protocol defined testing conditions were met.					
Info. for Sponsors:	This information is collected when the test results may be affected by whether conditions for testing were properly met. This may not be relevant for all tests. This information may be collected using the {NY} codelist, or sponsors may develop and use controlled terminology for this field if the value being collected is the testing condition. This field does not map directly to an SDTM variable.					
LB_10_2011-10-24	Accession Number	LBREFID		LB	Recommended/ Conditional	LBREFID
Description:	Internal or external specimen identifier.					
Question:	Accession Number					
Completion instructions:	Record the specimen or accession number assigned.					
Info. for Sponsors:	This can be used to reconcile CRF data with the electronic transfer (e.g., Specimen ID).					
LB_11_2011-10-24	Specimen Condition	LBSPCCND		LB	Recommended/ Conditional	LBSPCCND
Description:	Free or standardized text describing the condition of the specimen.					
Question:	Specimen Condition					
Completion instructions:	Record condition of specimen.					
Info. for Sponsors:	Results may be affected by whether conditions for specimen were properly met (e.g., HEMOLYZED, ICTERIC, LIPEMIC).					

LB_12_2011-10-24	<Test Name>	LBTEST		LB	Highly Recommended	LBTEST
Description:	Verbatim name of the test or examination used to obtain the measurement or finding. Any test normally performed by a clinical laboratory is considered a lab test. {LBTEST} (See Section 2.2.)					
Question:	<Test Name>					
Completion instructions:	Record the type or name of the lab test, if not pre-printed on the CRF.					
Info. for Sponsors:	Required to identify the test. It is recommended that the test names be pre-printed on the CRF. If the form is laid out as a grid, then words such as “Test” can be included as the column header.					
LB_13_2011-10-24	Result	LBORRES		LB	Highly Recommended	LBORRES
Description:	Result of the measurement or finding as originally received or collected.					
Question:	Result					
Completion instructions:	Record test results.					
Info. for Sponsors:	Key data collected.					
LB_14_2011-10-24	Units	LBORRESU		LB	Recommended/ Conditional	LBORRESU
Description:	Original units in which the data were collected.					
Question:	Units					
Completion instructions:	Record the units of the lab test, if not pre-printed on the CRF or captured in an external “lab normal” file.					
Info. for Sponsors:	Should be included if applicable and not available elsewhere. For some lab tests the units may not be applicable (e.g., urine color).					
LB_15_2011-10-24	Units	LBORRESU.LB_UNIT_x10E9/L	Lab Codelist for x10E9/L	LB	Recommended/ Conditional	LBORRESU
Description:	Original units in which the data were collected.					
Question:	Units					
Completion instructions:	Record the units of the lab test, if not pre-printed on the CRF or captured in an external “lab normal” file.					
Info. for Sponsors:	Should be included if applicable and not available elsewhere. For some lab tests the units may not be applicable (e.g., urine color).					
LB_16_2011-10-24	Units	LBORRESU.LB_UNIT_x10E12/L	Lab Codelist for x10E12/L	LB	Recommended/ Conditional	LBORRESU
Description:	Original units in which the data were collected.					
Question:	Units					
Completion instructions:	Record the units of the lab test, if not pre-printed on the CRF or captured in an external “lab normal” file.					
Info. for Sponsors:	Should be included if applicable and not available elsewhere. For some lab tests the units may not be applicable (e.g., urine color).					
LB_17_2011-10-24	Units	LBORRESU.LB_UNIT_nmol/L	Lab Codelist for nmol/L	LB	Recommended/ Conditional	LBORRESU
Description:	Original units in which the data were collected.					
Question:	Units					
Completion instructions:	Record the units of the lab test, if not pre-printed on the CRF or captured in an external “lab normal” file.					
Info. for Sponsors:	Should be included if applicable and not available elsewhere. For some lab tests the units may not be applicable (e.g., urine color).					
LB_18_2011-10-24	Units	LBORRESU.LB_UNIT_mmol/L	Lab Codelist for mmol/L	LB	Recommended/ Conditional	LBORRESU
Description:	Original units in which the data were collected.					
Question:	Units					
Completion instructions:	Record the units of the lab test, if not pre-printed on the CRF or captured in an external “lab normal” file.					
Info. for Sponsors:	Should be included if applicable and not available elsewhere. For some lab tests the units may not be applicable (e.g., urine color).					

LB_19_2011-10-24	Units	LBORRESU.LB_UNIT_fmol	Lab Codelist for fmol	LB	Recommended/ Conditional	LBORRESU
Description:	Original units in which the data were collected.					
Question:	Units					
Completion instructions:	Record the units of the lab test, if not pre-printed on the CRF or captured in an external “lab normal” file.					
Info. for Sponsors:	Should be included if applicable and not available elsewhere. For some lab tests the units may not be applicable (e.g., urine color).					
LB_20_2011-10-24	Units	LBORRESU.LB_UNIT_%	Lab Codelist for %	LB	Recommended/ Conditional	LBORRESU
Description:	Original units in which the data were collected.					
Question:	Units					
Completion instructions:	Record the units of the lab test, if not pre-printed on the CRF or captured in an external “lab normal” file.					
Info. for Sponsors:	Should be included if applicable and not available elsewhere. For some lab tests the units may not be applicable (e.g., urine color).					
LB_21_2011-10-24	Units	LBORRESU.LB_UNIT_fL	Lab Codelist for fL	LB	Recommended/ Conditional	LBORRESU
Description:	Original units in which the data were collected.					
Question:	Units					
Completion instructions:	Record the units of the lab test, if not pre-printed on the CRF or captured in an external “lab normal” file.					
Info. for Sponsors:	Should be included if applicable and not available elsewhere. For some lab tests the units may not be applicable (e.g., urine color).					
LB_22_2011-10-24	Low Normal	LBORNRLO		LB	Recommended/ Conditional	LBORNRLO
Description:	The lowest continuous numeric value of a given lab result expected in the population of interest.					
Question:	Low Normal					
Completion instructions:	Record the lower limit of the reference range of the lab test.					
Info. for Sponsors:	LBORNRLO and LBORNRHI should be populated only for continuous results; LBSTNRC should be populated only for non-continuous results. These data may be obtained from the lab or the electronic equipment. These data could be derived from a site or lab specific set of normal ranges stored in a look up table. See SDTMIG for details on mapping on selecting the proper variable name.					
LB_23_2011-10-24	High Normal	LBORNRHI		LB	Recommended/ Conditional	LBORNRHI
Description:	The highest continuous numeric value of a given lab result expected in the population of interest.					
Question:	High Normal					
Completion instructions:	Record the upper limit of the reference range of the lab test.					
Info. for Sponsors:	LBORNRLO and LBORNRHI should be populated only for continuous results; LBSTNRC should be populated only for non-continuous results. These data may be obtained from the lab or the electronic equipment. These data could be derived from a site or lab specific set of normal ranges stored in a look up table. See SDTMIG for details on mapping on selecting the proper variable name.					
LB_24_2011-10-24	Abnormal	LBNRIND	Reference Range Indicator	LB	Recommended/ Conditional	LBNRIND
Description:	Reference Range Indicator Indicates where value falls with respect to reference range defined by high and low ranges. {NRIND} (See Section 2.2.)					
Question:	Abnormal					
Completion instructions:	Record where the specimen fell with respect to the reference range (e.g. HIGH, LOW, ABNORMAL).					
Info. for Sponsors:	Abnormal flags may be included if not derived or determined programmatically after data collection.					
LB_25_2011-10-24	Clinically Significant	LBCLSIG	No Yes Response	LB	Recommended/ Conditional	SUPPLB.QNAM
Description:	Whether lab test results were clinically significant.					

Question:	Clinically Significant					
Completion instructions:	Record whether lab results were clinically significant.					
Info. for Sponsors:	May be included if required by the protocol. This field does not map directly to an SDTM variable.					
LB_26_2011-10-24	Laboratory Name	LBNAM		LB	Recommended/ Conditional	LBNAM
Description:	Name of lab analyzing specimen.					
Question:	Laboratory Name					
Completion instructions:	Record the laboratory name.					
Info. for Sponsors:	Recommended to collect on the CRF if lab names not collected at the site / study level or if multiple labs are used by a site.					
SC_1_2011-10-24	Any Subject Characteristics?	SCPERF	No Yes Response	SC	Optional	-
Description:	General prompt question to aid in monitoring and data cleaning. {NY} (See Section 2.2.)					
Question:	Any Subject Characteristics?					
Completion instructions:	Indicate if subject characteristics information was collected If “Yes”, include the appropriate details.					
Info. for Sponsors:	This is intended to be used as a data management tool to verify that missing results are confirmed missing. See Best Practice Section 3.4, FAQ #6. For the SDTM-based dataset, the SDTM IG variable SCSTAT is derived from SCPERF when the assessment is not done. This field does not map directly to an SDTM variable.					
SC_2_2011-10-24	<subject characteristic>	SCTEST		SC	Highly Recommended	SCTEST
Description:	The name of the subject characteristic being queried. {SCCD} (See Section 2.2.)					
Question:	<subject characteristic>					
Completion instructions:	Not applicable.					
Info. for Sponsors:	CRF completion instructions are not applicable as the subject characteristic is usually pre-printed on the CRF as a field prompt. If the form is laid out as a grid, then words such as “Test” can be included as the column header.					
SC_3_2011-10-24	<subject characteristic>	SCORRES		SC	Highly Recommended	SCORRES
Description:	Answer/result of the subject characteristic question as originally received or collected.					
Question:	<subject characteristic>					
Completion instructions:	Record the answer to the question.					
Info. for Sponsors:	Not applicable					
SC_4_2011-10-24	Gestational Age at Birth	GESTAGEB.SCORRES		SC	Highly Recommended	SCORRES+SCORRESU
Description:	The age (in weeks) of the newborn infant, counted from the woman's last menstrual period (LMP) or health status indicators/Clinical Estimate (CE).					
Question:	Gestational Age at Birth					
Measurement Units:	WEEKS					
Completion instructions:	Not applicable.					
Info. for Sponsors:	A constant that may be useful for analysis in pediatric or neonatal study analyses.					
SC_5_2011-10-24	Childbearing Potential	CHBEARP.SCORRES	No Yes Response	SC	Highly Recommended	SCORRES
Description:	Subject’s childbearing potential.					
Question:	Childbearing Potential					
Completion instructions:	Check the correct box to indicate the subject’s childbearing potential, or postmenopausal or sterilized as required for the form.					
Info. for Sponsors:	Not applicable.					
SC_6_2011-10-24	Education	EDLEVEL.SCORRES		SC	Highly Recommended	SCORRES

Description:	Education level achieved at start of study (Reference date).					
Question:	Education					
Completion instructions:	Not applicable.					
Info. for Sponsors:	Not applicable.					
SC_7_2011-10-24	Skin Classification	SKINCLAS.SCORRES	Skin Classification	SC	Highly Recommended	SCORRES
Description:	A classification system used to categorize the sensitivity of a subject's skin to sunlight.					
Question:	Skin Classification					
Completion instructions:	Skin Classification					
Info. for Sponsors:	Skin type rating in the Fitzpatrick Skin Type classification system.					
SC_8_2011-10-24	Marital Status	MARISTAT.SCORRES	Marital Status	SC	Highly Recommended	SCORRES
Description:	A demographic parameter indicating a person's current conjugal status.					
Question:	Marital Status					
Completion instructions:	Current Marital Status					
Info. for Sponsors:	Not applicable					
IE_1_2011-10-24	Met Criteria	IEYN	No Yes Response	IE	Highly Recommended	-
Description:	Response for whether the subject met all the eligibility requirements for this study at the time the subject was enrolled. Did subject meet all eligibility criteria? {NY} (See Section 2.2.)					
Question:	Met Criteria					
Completion instructions:	Record “Yes” if all eligibility criteria were met for the study. Record “No” if subject did not meet all criteria at the time the subject was enrolled.					
Info. for Sponsors:	This is a Yes/No question that is intended to be used primarily as a monitoring and/or data management tool to verify that the investigator/site recorded any entry criteria that were not met. Must be recorded on the CRF. This field does not map directly to an SDTM variable. *See the BRIDG model for complete path.					
IE_2_2011-10-24	Criterion Type	IECAT		IE	Optional	IECAT
Description:	Specifies whether the criterion is inclusion or exclusion.					
Question:	Criterion Type					
Completion instructions:	Record whether the criterion that this subject did not meet was “Inclusion” or “Exclusion”. Checkbox: Check “Inclusion” or “Exclusion”.					
Info. for Sponsors:	Only records for criteria that are not met appear in the IE SDTM IG domain .and for those records IECAT must also be populated. This criterion category may be collected on the CRF in a checkbox format, or, it may be included as part of the Criterion Identifier (e.g., I01, E01), or derived from the inclusion/exclusion criteria in the Trial Inclusion (TI) trial dataset, or other protocol definitions external to the clinical database when a unique criterion identifier is recorded in the IETESTCD field. *See the BRIDG model for complete path.					
IE_3_2011-10-24	Criterion ID Not Met	IETESTCD		IE	Highly Recommended	IESTESTCD
Description:	The identifier associated with the criterion that the subject did not meet. This must be a unique identifier that corresponds to a specific entry criterion.					
Question:	Criterion ID Not Met					
Completion instructions:	If “No”, enter the identifying code for each criterion not met. Record this only for the criterion/criteria that this subject did not meet Paper: Record the criterion identifier from the list of inclusion/ exclusion criteria provided by the sponsor. EDC: Select the criterion from the pick-list.					
Info. for Sponsors:	This field is required to appear on the CRF, but may be null if all criteria are met. Multiple responses should be allowed on CRF. See SDTM IG V3.1.2 Section 7.5.2 for Assumptions regarding protocol versioning. *See the BRIDG model for complete path.					
IE_4_2011-10-24	Criterion Description	IETEST		IE	Optional	IETEST
Description:	The wording of an inclusion or exclusion criterion.					
Question:	Criterion Description					

Completion instructions:	EDC: Verify the wording of this criterion.					
Info. for Sponsors:	EDC: The primary use of this field would be on an eCRF in an EDC system. This field could be automatically populated when the Criterion Identifier is populated, and then be verified by the PI to ensure the right Identifier was selected. Paper: The monitoring process should include a cross-verification of entry criteria codes against the medical records. *See the BRIDG model for complete path.					
DS_1_2011-10-24	Trial Period	EPOCH		DS	Recommended/ Conditional	EPOCH
Description:	Trial epoch (e.g., DOUBLE BLIND, SINGLE BLIND, TREATMENT, SCREENING, RUN IN, etc.) for which subject disposition is being collected.					
Question:	Trial Period					
Completion instructions:	Check the <epoch, or insert more appropriate wording> for which disposition is being recorded.					
Info. for Sponsors:	Typically, the trial epoch will be pre-printed on the CRF as the title of the page; however, some companies have a standard CRF module that includes a “pick-list” of epochs. See SDTMIG for further information regarding EPOCH.					
DS_2_2011-10-24	Status	DSDECOD	Completion/Reason for Non-Completion	DS	Highly Recommended	DSDECOD
Description:	Describes whether a subject completed the study or a portion of a study (epoch) or the reason they did not complete. DSDECOD is the Standardized Disposition Term {NCOMPLT} (See Section 2.2.)					
Question:	Status					
Completion instructions:	Document the subject’s status at <insert text corresponding to the selected trial epoch>. If the subject discontinued prematurely, record the primary reason for discontinuation.					
Info. for Sponsors:	DSTERM The verbatim term for completion or reason discontinuation. DSDECOD holds the corresponding code or control terminology. DSDECODE can be used as the pre-printed coded list with DSTERM used to capture “other specify”, or DSDECODE can be used on its own. For Sponsor- and/or study-specific reasons for discontinuation, it is recommended that these reasons be pre-printed on the CRF, with check boxes for completion wherever possible, as sub-categories of the appropriate DSDECOD item. However, it is recommended to limiting the use of sponsor- and study-specific reasons in order to promote consistent use of terminology and hence permit the combination of data across multiple sponsors.					
DS_3_2011-10-24	Specify Status	DSTERM		DS	Highly Recommended	DSTERM
Description:	Describes whether a subject completed the study or a portion of a study (epoch) or the reason they did not complete. DSDECOD is the Standardized Disposition Term {NCOMPLT} (See Section 2.2.)					
Question:	Specify Status					
Completion instructions:	Document the subject’s status at <insert text corresponding to the selected trial epoch>. If the subject discontinued prematurely, record the primary reason for discontinuation.					
Info. for Sponsors:	DSTERM The verbatim term for completion or reason discontinuation. DSDECOD holds the corresponding code or control terminology. DSDECODE can be used as the pre-printed coded list with DSTERM used to capture “other specify”, or DSDECODE can be used on its own. For Sponsor- and/or study-specific reasons for discontinuation, it is recommended that these reasons be pre-printed on the CRF, with check boxes for completion wherever possible, as sub-categories of the appropriate DSDECOD item. However, it is recommended to limiting the use of sponsor- and study-specific reasons in order to promote consistent use of terminology and hence permit the combination of data across multiple sponsors.					
DS_4_2011-10-24	Completion or Discontinuation Date	DSSTDAT		DS	Recommended / Conditional	DSSTDTC*
Description:	The date that the subject completed the study or portion of the study, or the date that the subject discontinued from the selected trial epoch.					
Question:	Completion or Discontinuation Date					
Completion instructions:	Record the date that the subject completed the <insert text corresponding to the selected trial epoch> as defined in the protocol and/or CRF Completion Instructions using the CDASH recommended collection date format. If the subject did not complete the <insert text corresponding to the selected trial epoch>, record the date as defined in the protocol and/or CRF Completion Instructions using the CDASH-recommended date format (e.g., 08-AUG-2008). For more detail see the Best Practice section.					
Info. for Sponsors:	Define in the protocol and/or CRF Completion Instructions the criteria for completion of each epoch for which a disposition CRF will be provided. Define also the date of completion or discontinuation. Only collect the date of completion or discontinuation on the disposition CRF module if the same information is not being collected on another CRF module. For example, if the date of the last dose is defined to mark the end of the Treatment Phase epoch, and is collected on the Exposure form, then this field would not be collected on the Disposition CRF module. If not collected elsewhere, this variable should be collected on the Disposition CRF module. For the SDTM-based dataset, the SDTMIG variable DSSTDTC is derived by concatenating CDASH Date (DSSTDAT) and Time of Completion or Discontinuation ((DSSTTIM if time is collected) and converting into ISO 8601 format.					
DS_5_2011-10-24	Completion or Discontinuation Time	DSSTTIM		DS	Optional	DSSTDTC*
Description:	The time that the subject completed the study or portion of the study or the date that the subject discontinued.					
Question:	Completion or Discontinuation Time					

Completion instructions:	Record the time (as complete as possible) that the subject completed the study or portion of the study as defined in the protocol and/or CRF Completion Instructions. If the subject did not complete the study or portion of the study, record the time (as complete as possible) as defined in the protocol and/or CRF Completion Instructions. For more detail see the Best Practice section.					
Info. for Sponsors:	Define in the protocol and/or CRF Completion Instructions the criteria for completion of each epoch for which a disposition CRF will be provided. Define also the date of completion or discontinuation. Collecting the time of completion or discontinuation is only appropriate if it can be realistically determined and if there is a scientific reason for needing to know this level of detail. Typically, it is not recommended that a time be collected unless the subject is under the direct care of the site at the time of the event. Only collect the time of completion or discontinuation on the disposition CRF module if the same information is not being collected on another CRF module. For example, if the time of the last dose is defined to mark the end of the Treatment Phase epoch, and is collected on the Drug Exposure form, then this field would not be collected on the Disposition CRF module. For the SDTM-based dataset, the SDTMIG variable DSSTDTC is derived by concatenating CDASH Date (DSSTDAT) and Time of Completion or Discontinuation (DSSTTIM) if time is collected) and converting into ISO 8601 format.					
DS_6_2011-10-24	Completion or Discontinuation Date and Time	DSSTDTC		DS	Recommended / Conditional	DSSTDTC
Description:	The date and time that the subject completed the study or portion of the study or the date that the subject discontinued.					
Question:	Completion or Discontinuation Date and Time					
Completion instructions:	See DSSTDAT/DSSTTIM					
Info. for Sponsors:	See DSSTDAT/DSSTTIM					
DS_7_2011-10-24	Unblinded	DSUNBLND	No Yes Response	DS	Optional	-
Description:	Identifies in a blinded trial whether or not the subject's blind was broken by the site. {NY} (See Section 2.2.)					
Question:	Unblinded					
Completion instructions:	Was the subject's treatment assignment unblinded by the site?					
Info. for Sponsors:	Not an SDTM variable.					
DS_8_2011-10-24	Subject Continue	DSCONT	No Yes Response	DS	Optional	-
Description:	Plan for subject continuation to the next phase of the study or another study at the time of completion of the CRF. {NY} (See Section 2.2.)					
Question:	Subject Continue					
Completion instructions:	To the best of your knowledge, record if the subject will be continuing to <the next phase of this study or another related study> (sponsor to specify as appropriate).					
Info. for Sponsors:	Sponsor should specify the next phase of the study or the related study. Not an SDTM variable.					
DS_9_2011-10-24	Next Period	DSNEXT		DS	Optional	-
Description:	Identifies the study epoch or new study in which the subject will participate.					
Question:	Next Period					
Completion instructions:	Record the study <epoch or study identifier> (sponsor to specify as appropriate) if the subject is continuing.					
Info. for Sponsors:	Sponsor should specify the next phase of the study or the related study. Not an SDTM variable.					
DS_10_2011-10-24	Completion or Discontinuation Date	ENDOFSTUDY.DSSTDAT		DS	Recommended / Conditional	DSSTDTC*
Description:	The date that the subject completed the study or portion of the study, or the date that the subject discontinued from the selected trial epoch.					
Question:	Completion or Discontinuation Date					
Completion instructions:	Record the date that the subject completed the <insert text corresponding to the selected trial epoch> as defined in the protocol and/or CRF Completion Instructions using the CDASH recommended collection date format. If the subject did not complete the <insert text corresponding to the selected trial epoch>, record the date as defined in the protocol and/or CRF Completion Instructions using the CDASH-recommended date format (e.g., 08-AUG-2008). For more detail see the Best Practice section.					
Info. for Sponsors:	Define in the protocol and/or CRF Completion Instructions the criteria for completion of each epoch for which a disposition CRF will be provided. Define also the date of completion or discontinuation. Only collect the date of completion or discontinuation on the disposition CRF module if the same information is not being collected on another CRF module. For example, if the date of the last dose is defined to mark the end of the Treatment Phase epoch, and is collected on the Exposure form, then this field would not be collected on the Disposition CRF module. If not collected elsewhere, this variable should be collected on the Disposition CRF module. For the SDTM-based dataset, the SDTMIG variable DSSTDTC is derived by concatenating CDASH Date (DSSTDAT) and Time of Completion or Discontinuation ((DSSTTIM					

	if time is collected) and converting into ISO 8601 format.					
DS_11_2011-10-24	Completion or Discontinuation Time	ENDOFSTUDY.DSSTTIM		DS	Optional	DSSTDTC*
Description:	The time that the subject completed the study or portion of the study or the date that the subject discontinued.					
Question:	Completion or Discontinuation Time					
Completion instructions:	Record the time (as complete as possible) that the subject completed the study or portion of the study as defined in the protocol and/or CRF Completion Instructions. If the subject did not complete the study or portion of the study, record the time (as complete as possible) as defined in the protocol and/or CRF Completion Instructions. For more detail see the Best Practice section.					
Info. for Sponsors:	Define in the protocol and/or CRF Completion Instructions the criteria for completion of each epoch for which a disposition CRF will be provided. Define also the date of completion or discontinuation. Collecting the time of completion or discontinuation is only appropriate if it can be realistically determined and if there is a scientific reason for needing to know this level of detail. Typically, it is not recommended that a time be collected unless the subject is under the direct care of the site at the time of the event. Only collect the time of completion or discontinuation on the disposition CRF module if the same information is not being collected on another CRF module. For example, if the time of the last dose is defined to mark the end of the Treatment Phase epoch, and is collected on the Drug Exposure form, then this field would not be collected on the Disposition CRF module. For the SDTM-based dataset, the SDTMIG variable DSSTDTC is derived by concatenating CDASH Date (DSSTDAT) and Time of Completion or Discontinuation (DSSTTIM) if time is collected) and converting into ISO 8601 format.					
DS_12_2011-10-24	Status	ENDOFSTUDY.DSDECODE	Completion/Reason for Non-Completion	DS	Highly Recommended	DSDECOD
Description:	Describes whether a subject completed the study or a portion of a study (epoch) or the reason they did not complete. DSDECOD is the Standardized Disposition Term {NCOMPLT} (See Section 2.2.)					
Question:	Status					
Completion instructions:	Document the subject's status at <insert text corresponding to the selected trial epoch>. If the subject discontinued prematurely, record the primary reason for discontinuation.					
Info. for Sponsors:	DSTERM The verbatim term for completion or reason discontinuation. DSDECOD holds the corresponding code or control terminology. DSDECODE can be used as the pre-printed coded list with DSTERM used to capture "other specify", or DSDECODE can be used on its own. For Sponsor- and/or study-specific reasons for discontinuation, it is recommended that these reasons be pre-printed on the CRF, with check boxes for completion wherever possible, as sub-categories of the appropriate DSDECOD item. However, it is recommended to limiting the use of sponsor- and study-specific reasons in order to promote consistent use of terminology and hence permit the combination of data across multiple sponsors.					
DS_13_2011-10-24	Specify Status	ENDOFSTUDY.DSTERM		DS	Highly Recommended	DSTERM
Description:	Describes whether a subject completed the study or a portion of a study (epoch) or the reason they did not complete. DSDECOD is the Standardized Disposition Term {NCOMPLT} (See Section 2.2.)					
Question:	Specify Status					
Completion instructions:	Document the subject's status at <insert text corresponding to the selected trial epoch>. If the subject discontinued prematurely, record the primary reason for discontinuation.					
Info. for Sponsors:	DSTERM The verbatim term for completion or reason discontinuation. DSDECOD holds the corresponding code or control terminology. DSDECODE can be used as the pre-printed coded list with DSTERM used to capture "other specify", or DSDECODE can be used on its own. For Sponsor- and/or study-specific reasons for discontinuation, it is recommended that these reasons be pre-printed on the CRF, with check boxes for completion wherever possible, as sub-categories of the appropriate DSDECOD item. However, it is recommended to limiting the use of sponsor- and study-specific reasons in order to promote consistent use of terminology and hence permit the combination of data across multiple sponsors.					
DA_1_2011-10-24	DA Performed?	DAPERF	No Yes Response	DA	Optional	DASTAT
Description:	Status of whether or not drug accountability was done. {NY} (See Section 2.2.)					
Question:	DA Performed?					
Completion instructions:	Indicate whether or not drug accountability was done.					
Info. for Sponsors:	This may be implemented for an entire Drug accountability on a visit-by-visit basis This is intended to be used as a data management tool to verify that results missing from the electronic transfer were intentional. For the SDTM-based dataset, the SDTMIG variable DASTAT can be derived from DAPERF.					
DA_2_2011-10-24	Treatment Type	DACAT		DA	Optional	DACAT
Description:	Used to define a categorization level for a group of related records.					
Question:	Treatment Type					
Completion instructions:	Record the type of study treatment dispensed/returned (i.e., Study Medication, Comparator, Placebo).					
Info. for Sponsors:	Not applicable.					
DA_3_2011-10-24	Treatment Name	DASCAT		DA	Optional	DASCAT

Description:	Used to define a further categorization level for a group of related records.					
Question:	Treatment Name					
Completion instructions:	Record the name of the study treatment dispensed/returned (i.e., Drug A, Drug B, Placebo).					
Info. for Sponsors:	Not applicable.					
DA_4_2011-10-24	Date (dispensed or returned)	DADAT		DA	Recommended/Conditional	DADTC*
Description:	Date the study treatment was dispensed or returned					
Question:	Date (dispensed or returned)					
Completion instructions:	Record the exact date the study treatment was (dispensed or returned), using the CDASH-recommended date format (e.g., 08-AUG-2008). For more detail see the Best Practice section.					
Info. for Sponsors:	The date study treatment dispensed / returned should be recorded for each dispensation for a study with multiple periods or multiple products dispensed. For the SDTM-based dataset, the SDTMIG variable DADTC is derived by putting the CDASH Date study treatment dispensed or returned (DADAT) into DADTC using the ISO 8601 format.					
DA_5_2011-10-24	Treatment label ID	DAREFID		DA	Optional	DAREFID
Description:	Treatment label identifier (e.g. kit number, bottle label, vial identifier).					
Question:	Treatment label ID					
Completion instructions:	Record treatment label identifier.					
Info. for Sponsors:	This information may be collected in many ways (e.g. affixing label onto CRF or scanning a bar code), this is an optional variable to store returned treatment label identification information (e.g. kit number, bottle label, vial identifier).					
DA_6_2011-10-24	Dispensed or returned	DATEST	Drug Accountability Test Name	DA	Highly Recommended	DATEST
Description:	Verbatim name, corresponding to the topic variable, of the test or examination used to obtain the drug accountability assessment (e.g., dispensed, returned). {DATEST and DATESTCD} (See Section 2.2.)					
Question:	Dispensed or returned					
Completion instructions:	Not applicable.					
Info. for Sponsors:	DATEST must be used in concert with DAORRES and DAORRESU to describe these distinct pieces of data.					
DA_7_2011-10-24	Amount	DAORRES		DA	Highly Recommended	DAORRES+DAORRESU
Description:	Result of the Drug Accountability assessment as originally dispensed or returned (i.e., actual amount).					
Question:	Amount					
Measurement Units:	TABLET					
Completion instructions:	Record the actual amount of study treatment dispensed or returned.					
Info. for Sponsors:	For a study with multiple periods or multiple products dispensed, drug accountability should be assessed for each dispensation. In this case, a sequence number or a group ID should be used to tie together a block of related records and to link dispensed product to returned product.					
DA_8_2011-10-24	Date	RETAMT.DADAT		DA	Recommended/Conditional	DADTC*
Description:	Date the study treatment was dispensed or returned					
Question:	Date					
Completion instructions:	Record the exact date the study treatment was (dispensed or returned), using the CDASH-recommended date format (e.g., 08-AUG-2008). For more detail see the Best Practice section.					
Info. for Sponsors:	The date study treatment dispensed / returned should be recorded for each dispensation for a study with multiple periods or multiple products dispensed. For the SDTM-based dataset, the SDTMIG variable DADTC is derived by putting the CDASH Date study treatment dispensed or returned (DADAT) into DADTC using the ISO 8601 format.					
DA_9_2011-10-24	Treatment label ID	RETAMT.DAREFID		DA	Optional	DAREFID
Description:	Treatment label identifier (e.g. kit number, bottle label, vial identifier).					
Question:	Treatment label ID					
Completion instructions:	Record treatment label identifier.					
Info. for Sponsors:	This information may be collected in many ways (e.g. affixing label onto CRF or scanning a bar code), this is an optional variable to store returned treatment label identification information (e.g. kit number, bottle label, vial identifier).					

DA_10_2011-10-24	DA Performed?	RETAMT.DAPERF	No Yes Response	DA	Optional	DASTAT
Description:	Status of whether or not drug accountability was done. {NY} (See Section 2.2.)					
Question:	DA Performed?					
Completion instructions:	Indicate whether or not drug accountability was done.					
Info. for Sponsors:	This may be implemented for an entire Drug accountability on a visit-by-visit basis This is intended to be used as a data management tool to verify that results missing from the electronic transfer were intentional. For the SDTM-based dataset, the SDTMIG variable DASTAT can be derived from DAPERF.					
DA_11_2011-10-24	Amount	RETAMT.DAORRES		DA	Highly Recommended	DAORRES+DAORRESU
Description:	Result of the Drug Accountability assessment as originally dispensed or returned (i.e., actual amount).					
Question:	Amount					
Measurement Units:	TABLET					
Completion instructions:	Record the actual amount of study treatment dispensed or returned.					
Info. for Sponsors:	For a study with multiple periods or multiple products dispensed, drug accountability should be assessed for each dispensation. In this case, a sequence number or a group ID should be used to tie together a block of related records and to link dispensed product to returned product.					
DA_12_2011-10-24	Date	DISPAMT.DADAT		DA	Recommended/Conditional	DADTC*
Description:	Date the study treatment was dispensed or returned					
Question:	Date					
Completion instructions:	Record the exact date the study treatment was (dispensed or returned), using the CDASH-recommended date format (e.g., 08-AUG-2008). For more detail see the Best Practice section.					
Info. for Sponsors:	The date study treatment dispensed / returned should be recorded for each dispensation for a study with multiple periods or multiple products dispensed. For the SDTM-based dataset, the SDTMIG variable DADTC is derived by putting the CDASH Date study treatment dispensed or returned (DADAT) into DADTC using the ISO 8601 format.					
DA_13_2011-10-24	Treatment label ID	DISPAMT.DAREFID		DA	Optional	DAREFID
Description:	Treatment label identifier (e.g. kit number, bottle label, vial identifier).					
Question:	Treatment label ID					
Completion instructions:	Record treatment label identifier.					
Info. for Sponsors:	This information may be collected in many ways (e.g. affixing label onto CRF or scanning a bar code), this is an optional variable to store returned treatment label identification information (e.g. kit number, bottle label, vial identifier).					
DA_14_2011-10-24	DA Performed?	DISPAMT.DAPERF	No Yes Response	DA	Optional	DASTAT
Description:	Status of whether or not drug accountability was done. {NY} (See Section 2.2.)					
Question:	DA Performed?					
Completion instructions:	Indicate whether or not drug accountability was done.					
Info. for Sponsors:	This may be implemented for an entire Drug accountability on a visit-by-visit basis This is intended to be used as a data management tool to verify that results missing from the electronic transfer were intentional. For the SDTM-based dataset, the SDTMIG variable DASTAT can be derived from DAPERF.					
DA_15_2011-10-24	Amount	DISPAMT.DAORRES		DA	Highly Recommended	DAORRES+DAORRESU
Description:	Result of the Drug Accountability assessment as originally dispensed or returned (i.e., actual amount).					
Question:	Amount					
Measurement Units:	TABLET					
Completion instructions:	Record the actual amount of study treatment dispensed or returned.					
Info. for Sponsors:	For a study with multiple periods or multiple products dispensed, drug accountability should be assessed for each dispensation. In this case, a sequence number or a group ID should be used to tie together a block of related records and to link dispensed product to returned product.					
EX_1_2011-10-24	Dosed?	EXYN	No Yes Response	EX	Optional	EXOCCUR
Description:	General prompt question to aid in monitoring and data cleaning. {NY} (See Section 2.2.)					
Question:	Dosed?					
Completion instructions:	Indicate if the subject took any medications. If “Yes”, include the appropriate details where indicated.					
Info. for Sponsors:	The intent/purpose of collecting this field is to help with data cleaning and monitoring.					

	EXYN will not be included as part of the SDTMIG EX Domain for submission.					
EX_2_2011-10-24	Start Date	EXSTDAT		EX	Highly Recommended	EXSTDTC*
Description:	Start date of treatment.					
Question:	Start Date					
Completion instructions:	Record the start date of the study treatment administration using the CDASH-recommended date format (e.g., 08-AUG-2008). For more detail see the Best Practice section.					
Info. for Sponsors:	Date when constant dosing interval of the study treatment started or single administration occurred. For the SDTM-based dataset, the SDTMIG variable EXSTDTC is derived by concatenating CDASH Start Date (EXSTDAT) and Time (EXSTTIM) of treatment (if time is collected) into EXSTDTC using the ISO 8601 format.					
EX_3_2011-10-24	Start Time	EXSTTIM		EX	Recommended/Conditional	EXSTDTC*
Description:	Start time of treatment.					
Question:	Start Time					
Completion instructions:	Record the start time (as complete as possible) when administration of study treatment started. For more detail see the Best Practice section.					
Info. for Sponsors:	Time when study treatment period started. For the SDTM-based dataset, the SDTMIG variable EXSTDTC is derived by concatenating CDASH Start Date (EXSTDAT) and Time (EXSTTIM) of treatment (if time is collected) into EXSTDTC using the ISO 8601 format.					
EX_4_2011-10-24	Start Date and Time	EXSTDTC		EX	Recommended/Conditional	EXSTDTC*
Description:	Start date and time of treatment.					
Question:	Start Date and Time					
Completion instructions:	See EXSTDAT/EXSTTIM					
Info. for Sponsors:	See EXSTDAT/EXSTTIM					
EX_5_2011-10-24	Treatment label ID	EXREFID		EX	Recommended/Conditional	EXREFID
Description:	Treatment label identifier (e.g. kit number, bottle label, vial identifier).					
Question:	Treatment label ID					
Completion instructions:	Record treatment label identifier.					
Info. for Sponsors:	This information may be collected in many ways (e.g. affixing label onto CRF or scanning a bar code), this is an optional variable to store returned treatment label identification information (e.g. kit number, bottle label, vial identifier).					
EX_6_2011-10-24	End Date	EXENDAT		EX	Recommended/Conditional	EXENDTC*
Description:	End date of treatment.					
Question:	End Date					
Completion instructions:	Record the end date or last date of administration of study treatment using the CDASH-recommended date format (e.g., 08-AUG-2008). For more detail see the Best Practice section.					
Info. for Sponsors:	Date when study treatment period stopped. If start date and end date are not expected to be on the same date, the end date is required. If the study design indicates that the start and end date are on the same day, the end date is not required since it can be assigned to be equal to the start date. For the SDTM-based dataset, the SDTMIG variable EXENDTC is derived by concatenating CDASH End Date (EXENDAT) and Time (EXENTIM) of treatment (if time is collected) into EXENDTC using the ISO 8601 format.					
EX_7_2011-10-24	End Time	EXENTIM		EX	Recommended/Conditional	EXENDTC*
Description:	End time of treatment.					
Question:	End Time					
Completion instructions:	Record the time, (as complete as possible) when study treatment administration stopped (e.g., for infusions this is the time when the infusion ended). For more detail see the Best Practice section.					
Info. for Sponsors:	Time when study treatment “constant dosing interval” ended. assigned to be equal to the start date. For the SDTM-based dataset, the SDTMIG variable EXENDTC is derived by concatenating CDASH End Date (EXENDAT) and Time (EXENTIM) of treatment (if time is collected) into EXENDTC using the ISO 8601 format.					
EX_8_2011-10-24	End Date and Time	EXENDTC		EX	Recommended/Conditional	EXENDTC*
Description:	End date and time of treatment.					
Question:	End Date and Time					

Completion instructions:	See EXENDAT/EXENTIM					
Info. for Sponsors:	See EXENDAT/EXENTIM					
EX_9_2011-10-24	Dose	EXDSTXT		EX	Recommended/Conditional	EXDOSE or EXDOSTXT**
Description:	Dose per administration.					
Question:	Dose					
Measurement Units:	mg, ug, mL, g, IU					
Completion instructions:	Record the dose or amount of study treatment that was administered to/taken by the subject in the period recorded; from the start date/time to the end date/time inclusive.					
Info. for Sponsors:	Dose or amount taken for single administration of study treatment or per constant dosing interval recorded. Dose must be collected if it cannot be derived via other methods (e.g., derived from diary data, drug accountability data, protocol etc.). Care should be taken when mapping EXDSTXT to the appropriate SDTMIG variable EXDOSE or EXDOSTXT. The data collected in this dose text-format field need to be separated or mapped to either SDTMIG EXDOSE if numeric or EXDOSTXT if text.					
EX_12_2011-10-24	Lot Number	EXLOT		EX	Optional	EXLOT
Description:	EXLOT = Lot Number of the EXTRT product.					
Question:	Lot Number					
Completion instructions:	Record the lot number that appears on the container holding the study treatment.					
Info. for Sponsors:	Reference number that appears on the container holding the study treatment. The Lot Number identifies the batch or bottle number of the study treatment. , and may map to the randomization schema. In open label studies, the reference number on the study treatment container could represent an actual Lot Number and should be submitd using EXLOT.					
EX_13_2011-10-24	Kit Number	EXKIT		EX	Optional	-
Description:	EXKIT= Kit number of the EXKIT product.					
Question:	Kit Number					
Completion instructions:	Record the kit number that appears on the container holding the study treatment.					
Info. for Sponsors:	Reference number that appears on the kit holding the study treatment. The Kit Number identifies the batch or bottle number of the study treatment, and may map to the randomization schema. In open label studies, the reference number on the study treatment container could represent an actual Lot Number and could be stored using EXKIT. Not an SDTM variable.					
EX_14_2011-10-24	Treatment Name	EXTRT		EX	Recommended/Conditional	EXTRT
Description:	Name of the study treatment or intervention given per single administration or during the “constant dosing interval” for the observation.					
Question:	Treatment Name					
Completion instructions:	Record the name of study treatment.					
Info. for Sponsors:	Name of study treatment that was administered to the subject. This is collected for open label studies and derived for blinded studies. This variable must be populated in the SDTM whether it is collected or derived.					
EX_15_2011-10-24	Adjusted	EXDOSADJ	No Yes Response	EX	Optional	-
Description:	Confirmation of dose adjustment. {NY} (See Section 2.2.)					
Question:	Adjusted					
Completion instructions:	Select either “Yes” or “No” to indicate whether there was a change in dosing.					
Info. for Sponsors:	Provides a definitive response regarding dose changes. Not and SDTM variable.					
EX_16_2011-10-24	Reason adjusted	EXADJ		EX	Optional	EXADJ
Description:	Describes reason or explanation of why a dose is adjusted – used only when an adjustment is represented in EXPOSURE dataset. May be used for variations from protocol-specified doses, or changes from expected doses.					
Question:	Reason adjusted					
Completion instructions:	If there was a change in dosing, record the reason for change.					
Info. for Sponsors:	Captures reason dose was changed/modified. The reason may be chosen from a select list (for example, adverse event, insufficient response, etc.) or entered as free text.					
EX_17_2011-10-24	Frequency	EXDOSFRQ	Frequency	EX	Optional	EXDOSFRQ

Description:	Number of doses given per a specific interval. {FREQ} (See Section 2.2.)					
Question:	Frequency					
Completion instructions:	Record the frequency the study treatment was administered for a defined period of time (e.g., BID, QID, TID).					
Info. for Sponsors:	Usually expressed as the number of doses given per a specific interval.					
EX_18_2011-10-24	Route	EXROUTE	Route of Administration	EX	Recommended/Conditional	EXROUTE
Description:	Route of administration for EXTRT. {ROUTE} (See Section 2.2.)					
Question:	Route					
Completion instructions:	Record the route of administration (e.g., IV, ORAL or TRANSDERMAL) or enter the appropriate code from the code list.					
Info. for Sponsors:	This can be pre-printed on the CRF or derived from the protocol.					
EX_19_2011-10-24	Formulation	EXDOSFRM		EX	Recommended/Conditional	EXDOSFRM
Description:	Dose form for EXTRT. {FRM} (See Section 2.2.)					
Question:	Formulation					
Completion instructions:	Record the formulation (e.g., SOLUTION, TABLET, and LOTION) or enter the appropriate code from the code list.					
Info. for Sponsors:	This must be collected if it can not be derived.					
EX_20_2011-10-24	Interruption Duration	EXINTRP		EX	Optional	-
Description:	Duration of the treatment interruption.					
Question:	Interruption Duration					
Completion instructions:	Record the duration of treatment interruption.					
Info. for Sponsors:	In some situations, the duration of the interruption may be calculated from the administration start and end times recorded elsewhere in the CRF. Not and SDTM variable.					
EX_22_2011-10-24	Anatomical Location	EXLOC	Anatomical Location	EX	Optional	EXLOC
Description:	Specifies anatomical location of administration. {LOC} (See Section 2.2.)					
Question:	Anatomical Location					
Completion instructions:	Record the body location where the study treatment was administered (e.g., SHOULDER, HIP, ARM).					
Info. for Sponsors:	Location where the study treatment was administered. This may be pre-printed or collected.					
EX_23_2011-10-24	Total Amount	EXVAMT		EX	Optional	-
Description:	Total amount of study treatment (drug + vehicle) administered or given to the subject.					
Question:	Total Amount					
Measurement Units:	mg, ug, mL, g, IU					
Completion instructions:	Record the total amount that was administered/given to the subject.					
Info. for Sponsors:	Administration amount that was given to the subject.					
EX_25_2011-10-24	Infusion Rate	EXFLRT		EX	Optional	-
Description:	Rate of infusion.					
Question:	Infusion Rate					
Measurement Units:	mg, ug, mL, g, IU					
Completion instructions:	Record the Rate of Infusion (e.g., 10 mL/min. Record “10”as the infusion rate).					
Info. for Sponsors:	Infusion rate can be used to derive dose. Not an SDTM variable.					
EX_27_2011-10-24	Planned Time Point	EXTPT		EX	Optional	EXTPT
Description:	Planned time point name.					
Question:	Planned Time Point					
Completion instructions:	Record the planned time point of study treatment administration (e.g., 5 minutes post dose).					

Info. for Sponsors:	Indicates the planned time point of study treatment administration (e.g., 5 minutes post dose). This may be pre-printed or collected.					
EX_28_2011-10-24	Completed treatment	EXMEDCMP	No Yes Response	EX	Optional	-
Description:	Subject did not did not complete the intended regiment. {NY} (See Section 2.2.)					
Question:	Completed treatment					
Completion instructions:	Select either “Yes” or “No” to indicate whether subject has completed the full course of treatment.					
Info. for Sponsors:	Depending on how the study treatment details are collected via the CRF/ eCRF, it may be possible to derive those data if the regimen data are collected. Not an SDTM variable.					
EX_29_2011-10-24	Planned Dose	EXPDOSE		EX	Optional	-
Description:	Planned dose per administration.					
Question:	Planned Dose					
Measurement Units:	mg, ug, mL, g, IU					
Completion instructions:	Record the dose the subject was scheduled to receive.					
Info. for Sponsors:	Important: This field must be used in conjunction with “actual dose” EXDOSE since this field captures the planned dose rather than the dose the subject actually received. Not an SDTM variable.					
PE_1_2011-10-24	Exam performed	PEPERF	No Yes Response	PE	Optional	-
Description:	Used to indicate if the overall physical examination was performed as scheduled. Was the physical examination performed? {NY} (See Section 2.2.)					
Question:	Exam performed					
Completion instructions:	If physical examination was performed as planned then select “Yes”, otherwise, select “No”.					
Info. for Sponsors:	BASELINE: If examination is performed, CRF and CRF Instructions will direct site to report all abnormal findings/conditions on appropriate CRF (e.g., Medical History, Baseline Findings, Adverse Events). POST-BASELINE: If examination is performed and abnormality is new or worsened, CRF and CRF Instructions will direct site to capture all changes on appropriate CRF (e.g., Post-baseline Assessment, Adverse Events). The intent/purpose of collecting this field is to help with data cleaning and monitoring. For the SDTM-based dataset, the SDTMIG variable PESTAT is derived from a no value in PEPERF when a specific physical exam observation is not done.					
PE_2_2011-10-24	Exam Date	PEDAT		PE	Recommended/Conditional	PEDTC*
Description:	Date of examination.					
Question:	Exam Date					
Completion instructions:	Record complete date of examination, day, month and year using the CDASH-recommended date format (e.g., 08-AUG-2008). For more detail see the Best Practice section.					
Info. for Sponsors:	The date of examination may be derived from the date of visit and in that case a separate assessment date field may not be necessary. For the SDTM-based dataset, the SDTMIG variable PEDTC is derived by concatenating CDASH Date (PEDAT) and Time (PETIM) of Examination (if time is collected) into PEDTC using the ISO 8601 format.					
PE_3_2011-10-24	Exam Time	PETIM		PE	Optional	PEDTC*
Description:	Time of examination.					
Question:	Exam Time					
Completion instructions:	Record the time of examination (as complete as possible). For more detail see the Best Practice section.					
Info. for Sponsors:	For the SDTM-based dataset, the SDTMIG variable PEDTC is derived by concatenating CDASH Date (PEDAT) and Time (PETIM) of Examination (if time is collected) into PEDTC using the ISO 8601 format.					
PE_4_2011-10-24	Exam Date and Time	PEDTC		PE	Recommended/Conditional	PEDTC*
Description:	Date and Time of examination.					
Question:	Exam Date and Time					
Completion instructions:	See PEDAT/PETIM					
Info. for Sponsors:	See PEDAT/PETIM					
PE_5_2011-10-24	ID	PESPID		PE	Optional	PESPID
Description:	A sponsor-defined identifier which can be used for pre-printed numbers on the CRF.					
Question:	ID					
Completion instructions:	Not applicable.					

Info. for Sponsors:	It can be beneficial to use a sequence number in a data query to clearly communicate to the site the specific record in question or to reconcile physical exam findings with medical history records and/or Aes.					
PE_6_2011-10-24	Body system	PETEST		PE	Highly Recommended	PETEST
Description:	Name of the body system.					
Question:	Body system					
Completion instructions:	Per protocol, perform physical examinations of specified body systems.					
Info. for Sponsors:	Sponsor should pre-populate CRF with all body systems to be examined. The use of a complete list of body systems eliminates the need for an “other, specify” category as any abnormalities identified should fall under one of the pre-specified categories.					
PE_7_2011-10-24	Result	PERES		PE	Highly Recommended	PEORRES
Description:	Overall assessment of examined body system.					
Question:	Result					
Completion instructions:	For each body system listed, record the result of the examination (Normal or Abnormal). If the examination is not performed or not required select Not Done.					
Info. for Sponsors:	For each body system listed on the CRF, provide the following options for results: Normal, Abnormal and Not Done. Sites should be directed to complete overall assessment for each exam category/body system listed. In SDTMIG, if the examined body system is normal then the value in PEORRES should be NORMAL. If the body system is not examined, then the value in PEORRES should be Null and the value in PESTAT should be Not Done. If the examined body system is abnormal, then the value of PEORRES should contain the text of the abnormal findings. If the sponsor’s data collection system allows for up front recording of the abnormality and status using a single variable then the SDTMIG variable name PEORRES may be used in place of CDASH variable names PERES and PEDESC					
PE_8_2011-10-24	Abnormal Findings	PEDESC		PE	Highly Recommended	PEORRES
Description:	Text description of any abnormal findings.					
Question:	Abnormal Findings					
Completion instructions:	Record all abnormal findings for the given body system in the space provided.					
Info. for Sponsors:	Text entered under abnormal findings (PEDESC) should be mapped to SDTMIG PEORRES. If the sponsor’s data collection system allows for up front recording of the abnormality and status using a single variable then the SDTMIG variable name PEORRES may be used in place of CDASH variable names PERES and PEDESC					
PE_9_2011-10-24	Clinically significant	PECLSIG	No Yes Response	PE	Optional	-
Description:	Whether physical examination abnormality is clinically significant					
Question:	Clinically significant					
Completion instructions:	Record whether abnormality is clinically significant.					
Info. for Sponsors:	If this level of information is needed for reconciliation with adverse events, this field may be added to the CRF. PECLSIG is not defined in the SDTMIG PE domain. If collected, it should be submitted in the SUPPPE dataset.					
PE_10_2011-10-24	Evaluator	PEEVAL		PE	Optional	PEEVAL
Description:	Role of the person who provided the evaluation.					
Question:	Evaluator					
Completion instructions:	Enter the role of the person who provided the evaluation (e.g., investigator, adjudication committee, vendor).					
Info. for Sponsors:	Available for use if needed.					
DV_1_2011-10-24	Any Deviations?	DVYN	No Yes Response	DV	Optional	-
Description:	Indication of whether or not there was a protocol deviation. {NY} (See Section 2.2.)					
Question:	Any Deviations?					
Completion instructions:	Enter “Yes” if a protocol deviation occurred and “No” if none occurred. Ensure that any adverse event, concomitant medication use, newly discovered medical history, etc. which triggers a protocol deviation is noted in the respective CRF.					
Info. for Sponsors:	The intent/purpose of collecting this field is to help with data cleaning and monitoring. It provides verification that all other fields on the CRF were deliberately left blank. This field does not map directly to an SDTM variable.					
DV_2_2011-10-24	<Protocol Deviation>	DVDECOD		DV	Recommended / Conditional	DVDECOD
Description:	DVDECOD is the controlled terminology for the protocol deviation.					
Question:	<Protocol Deviation>					

Completion instructions:	Record protocol deviations identified and/or select the appropriate code from the list of protocol deviation terms.					
Info. for Sponsors:	DVTERM and DVDECOD may have the same value. If the CRF is collecting protocol deviations using a code list of responses, then DVDECOD should be used to store the code list response. Sponsors must use either DVDECOD or DVTERM on the CRF and in some cases, both may be used. For example, if the CRF collects “Other, Specify” or similar additional free text descriptions of code list items, then DVTERM should be used to store the detailed descriptive text. For the SDTM-based dataset, if no additional descriptive text is provided, then the code list response collected in DVDECOD should be used to populate DVTERM. *See the BRIDG model for complete path.					
DV_3_2011-10-24	Protocol Deviation or Other, Specify	DVTERM		DV	Recommended / Conditional	DVTERM
Description:	DVTERM is the verbatim text.					
Question:	Protocol Deviation or Other, Specify					
Completion instructions:	Record protocol the appropriate code from the list of protocol deviation terms.					
Info. for Sponsors:	DVTERM and DVDECOD may have the same value. If the CRF is collecting protocol deviations using a free text field, then DVTERM should be used to store the free text response. Sponsors must use either DVDECOD or DVTERM on the CRF, but a value in DVTERM is required for the SDTM submission data set. The value of DVTERM can be a duplicate of DVDECOD. *See the BRIDG model for complete path.					
DV_4_2011-10-24	Start Date	DVSTDAT		DV	Optional	DVSTDTC*
Description:	Start date of Deviation.					
Question:	Start Date					
Completion instructions:	Record complete date that the protocol deviation began using this format (DD-MON-YYYY). This should be the start or occurrence of the protocol deviation and not the date it was discovered or reported.					
Info. for Sponsors:	This may be derived if not collected on a CRF. For the SDTM-based dataset, the SDTM IG variable DVSTDTC is derived by concatenating CDASH Start Date (DVSTDAT) and Time (DVSTTIM) (if time is collected) into DVSTDTC using the ISO 8601 format. For more detail see the Best Practice section. This field does not map directly to an SDTM variable.					
DV_5_2011-10-24	Start Time	DVSTTIM		DV	Optional	DVSTDTC*
Description:	Start time of Deviation.					
Question:	Start Time					
Completion instructions:	If appropriate, record the time (as complete as possible) the protocol deviation began. For more detail see the Best Practice section. This should be the start or occurrence of the protocol deviation and not the time it was discovered or reported.					
Info. for Sponsors:	For the SDTM-based dataset, the SDTM IG variable DVSTDTC is derived by concatenating CDASH Start Date (DVSTDAT) and Time (DVSTTIM) (if time is collected) into DVSTDTC using the ISO 8601 format. For more detail see the Best Practice section. This field does not map directly to an SDTM variable.					
DV_6_2011-10-24	Start Date and Time	DVSTDTC		DV	Optional	DVSTDTC*
Description:	Start date and time of Deviation.					
Question:	Start Date and Time					
Completion instructions:	See DVSTDAT/DVSTTIM					
Info. for Sponsors:	See DVSTDAT/DVSTTIM					
DV_7_2011-10-24	End Date	DVENDAT		DV	Optional	DVENDTC*
Description:	End date of Deviation.					
Question:	End Date					
Completion instructions:	Record the date that the Protocol deviation ended using this format (DD-MON-YYYY). This should be the date the protocol deviation stopped and not the date it was discovered or reported.					
Info. for Sponsors:	For the SDTM-based dataset, the SDTM IG variable DVENDTC is derived by concatenating CDASH End Date (DVENDAT) and Time (DVENTIM) (if time is collected) into DVENDTC using the ISO 8601 format. For more detail see the Best Practice section. This field does not map directly to an SDTM variable.					

DV_8_2011-10-24	End Time	DVENTIM		DV	Optional	DVENDTC*
Description:	End time of Deviation.					
Question:	End Time					
Completion instructions:	If appropriate, record the time (as complete as possible) the protocol deviation ended. This should be the time the protocol deviation stopped and not the time it was discovered or reported.					
Info. for Sponsors:	For the SDTM-based dataset, the SDTM IG variable DVENDTC is derived by concatenating CDASH End Date (DVENDAT) and Time (DVENTIM) (if time is collected) into DVENDTC using the ISO 8601 format. For more detail see the Best Practice section. This field does not map directly to an SDTM variable.					
DV_9_2011-10-24	End Date and Time	DVENDTC		DV	Optional	DVENDTC*
Description:	End date and time of Deviation.					
Question:	End Date and Time					
Completion instructions:	See DVENDAT/DVENTIM					
Info. for Sponsors:	See DVENDAT/DVENTIM					
DV_10_2011-10-24	<line number> or <DV number>	DVSPID		DV	Optional	DVSPID
Description:	A sponsor-defined identifier which can be used for pre-printed numbers on the CRF.					
Question:	<line number> or <DV number>					
Completion instructions:	Not applicable.					
Info. for Sponsors:	It can be beneficial to use an identifier in a data query to communicate clearly to the site the specific record in question.					

Codelist Definitions

OID	Name	DataType	CodedValue	Decode	Term. Ref.	Extensible
CL.NY_SUB_Y_N_2011-10-24	No Yes Response	text			C66742	No
			N	NO	C49487	
			Y	YES	C49488	
CL.AESEV_2011-10-24	Severity/Intensity Scale for Adverse Events	text			C66769	No
			MILD	MILD	C41338	
			MODERATE	MODERATE	C41339	
			SEVERE	SEVERE	C41340	
CL.AEREL_2011-10-24	Relationship to Study Treatment	text				Yes
			NOT RELATED	NOT RELATED		
			UNLIKELY	UNLIKELY RELATED		
			POSSIBLY	POSSIBLY RELATED		
			RELATED	RELATED		
CL.ACN_2011-10-24	Action Taken with Study Treatment	text			C66767	No
			DOSE INCREASED	DOSE INCREASED	C49503	
			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	

CL.OUT_2011-10-24	Outcome of Event	text			C66768	No
			FATAL	FATAL	C48275	
			NOT RECOVERED/NOT RESOLVED	NOT RECOVERED/NOT RESOLVED	C49494	
			RECOVERED/RESOLVED	RECOVERED/RESOLVED	C49498	
			RECOVERED/RESOLVED WITH SEQUELAE	RECOVERED/RESOLVED WITH SEQUELAE	C49495	
			RECOVERING/RESOLVING	RECOVERING/RESOLVING	C49496	
			UNKNOWN	UNKNOWN	C17998	
CL.FRM.SUBSET.CMDOSFRM_2011-10-24	Pharmaceutical Dosage Form	text			C66726	Yes
			TABLET	TABLET	C42998	
			CAPSULE	CAPSULE	C25158	
			OINTMENT	OINTMENT	C42966	
			SUPPOSITORY	SUPPOSITORY	C42993	
			AEROSOL	AEROSOL	C42887	
			SPRAY	SPRAY	C42989	
			SUSPENSION	SUSPENSION	C42994	
			PATCH	PATCH	C42968	
			GAS	GAS	C42933	
			GEL	GEL	C42934	
			CREAM	CREAM	C28944	
			POWDER	POWDER	C42972	
CL.FREQ.SUBSET.CMDOSFRQ_2011-10-24	Frequency	text			C71113	Yes
			BID	BID	C64496	
			TID	TID	C64527	
			QID	QID	C64530	
			QOD	QOD	C64525	
			QM	QM	C64498	
			PRN	PRN	C64499	
			UNKNOWN	UNKNOWN	C17998	
CL.ROUTE.SUBSET.CMROUTE_2011-10-24	Route of Administration	text			C66729	Yes
			ORAL	ORAL	C38288	
			TOPICAL	TOPICAL	C38304	
			SUBCUTANEOUS	SUBCUTANEOUS	C38299	
			TRANSDERMAL	TRANSDERMAL	C38305	
			INTRAOCULAR	INTRAOCULAR	C38255	
			INTRAMUSCULAR	INTRAMUSCULAR	C28161	
			RESPIRATORY (INHALATION)	RESPIRATORY (INHALATION)	C38216	
			INTRALESIONAL	INTRALESIONAL	C38250	
			INTRAPERITONEAL	INTRAPERITONEAL	C38258	
			NASAL	NASAL	C38284	
			VAGINAL	VAGINAL	C38313	
			RECTAL	RECTAL	C38295	

CL.SEX_2011-10-24	Sex	text			C66731	No
			F	FEMALE	C16576	
			M	MALE	C20197	
CL.ETHNIC.SUBSET.ETHNIC_2011-10-24	Ethnic Group	text			C66790	Yes
			NOT HISPANIC OR LATINO	NOT HISPANIC OR LATINO	C41222	
			HISPANIC OR LATINO	HISPANIC OR LATINO	C17459	
			NOT REPORTED	NOT REPORTED	C43234	
			UNKNOWN	UNKNOWN	C17998	
CL.RACE_2011-10-24	Race	text			C74457	Yes
			BLACK OR AFRICAN AMERICAN	BLACK OR AFRICAN AMERICAN	C16352	
			AMERICAN INDIAN OR ALASKA NATIVE	AMERICAN INDIAN OR ALASKA NATIVE	C41259	
			ASIAN	ASIAN	C41260	
			NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER	NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER	C41219	
			WHITE	WHITE	C41261	
			OTHER	OTHER		
CL.VSTEST.SUBSET.VSTEST_2011-10-24	Vital Signs Test Name	text			C67153	Yes
			Diastolic Blood Pressure	DIABP	C25299	
			Body Frame Size	FRMSIZE	C49680	
			Height	HEIGHT	C25347	
			Pulse Rate	PULSE	C49676	
			Systolic Blood Pressure	SYSBP	C25298	
			Temperature	TEMP	C25206	
			Weight	WEIGHT	C25208	
CL.VSRESU_2011-10-24	Units for Vital Signs Results	text			C66770	Yes
			%	%	C25613	
			BEATS/MIN	BEATS/MIN	C49673	
			BREATHS/MIN	BREATHS/MIN	C49674	
			C	C	C42559	
			cm	cm	C49668	
			F	F	C44277	
			g	g	C48155	
			IN	IN	C48500	
			kg	kg	C28252	
			kg/m2	kg/m2	C49671	
			LB	LB	C48531	
			m2	m2	C42569	
			mmHg	mmHg	C49670	
			ohm	ohm	C42554	
CL.LOC.SUBSET.VSLOC_2011-10-24	Anatomical Location	text			C74456	Yes
			RADIAL ARTERY	RADIAL ARTERY	C12838	
			CAROTID ARTERY	CAROTID ARTERY	C12687	
			BRACHIAL ARTERY	BRACHIAL ARTERY	C12681	

			AXILLA	AXILLA	C12674	
			EAR	EAR	C12394	
CL.VSPOSITION_2011-10-24	Vital Sign Positions	text			C71148	Yes
			SITTING	SITTING	C62122	
			PRONE	PRONE	C62165	
			STANDING	STANDING	C62166	
			SUPINE	SUPINE	C62167	
CL.LOC_BP_2011-10-24	Anatomical Location	text			C74456	Yes
			BRACHIAL ARTERY	BRACHIAL ARTERY	C12681	
			ANKLE	ANKLE		
CL.LOC.SUBSET.PULSE.VSLOC_2011-10-24	Anatomical Location	text			C74456	Yes
			RADIAL ARTERY	RADIAL ARTERY	C12838	
			CAROTID ARTERY	CAROTID ARTERY	C12687	
			BRACHIAL ARTERY	BRACHIAL ARTERY	C12681	
CL.LOC.SUBSET.TEMP.VSLOC_2011-10-24	Anatomical Location	text			C74456	Yes
			AXILLA	AXILLA	C12674	
			EAR	EAR	C12394	
CL.FRMSIZE_2011-10-24	Vital Sign frame size	text				No
			SMALL	SMALL		
			MEDIUM	MEDIUM		
			LARGE	LARGE		
CL.SUNCF_2011-10-24	Substance use	text				Yes
			NEVER	NEVER		
			FORMER	FORMER		
			CURRENT	CURRENT		
CL.FREQ_2011-10-24	Frequency	text			C71113	Yes
			OTHER	OTHER	C17649	
			UNKNOWN	UNKNOWN	C17998	
			CONTINUOUS	CONTINUOUS	C53279	
			BID	BID	C64496	
			BIS	BIS	C64497	
			QM	QM	C64498	
			PRN	PRN	C64499	
			Q10H	Q10H	C64500	
			Q11H	Q11H	C64501	
			Q12H	Q12H	C64502	
			Q13H	Q13H	C64503	
			Q14H	Q14H	C64504	
			Q15H	Q15H	C64505	
			Q16H	Q16H	C64506	
			Q17H	Q17H	C64507	
			Q18H	Q18H	C64508	
			Q19H	Q19H	C64509	
			QH	QH	C64510	

			Q20H	Q20H	C64511	
			Q21H	Q21H	C64512	
			Q22H	Q22H	C64513	
			Q23H	Q23H	C64514	
			Q24H	Q24H	C64515	
			Q2H	Q2H	C64516	
			Q3H	Q3H	C64517	
			Q4H	Q4H	C64518	
			Q5H	Q5H	C64519	
			Q6H	Q6H	C64520	
			Q7H	Q7H	C64521	
			Q8H	Q8H	C64523	
			Q9H	Q9H	C64524	
			QOD	QOD	C64525	
			TID	TID	C64527	
			TIS	TIS	C64528	
			Q4S	Q4S	C64529	
			QID	QID	C64530	
			QIS	QIS	C64531	
			Q3D	Q3D	C64533	
			Q4D	Q4D	C64534	
			Q3S	Q3S	C64535	
			Q2M	Q2M	C64536	
			Q3M	Q3M	C64537	
			Q4M	Q4M	C64538	
			ONCE	ONCE	C64576	
			QS	QS	C67069	
			Q5D	Q5D	C71124	
			Q2S	Q2S	C71127	
			BIM	BIM	C71129	
			INTERMITTENT	INTERMITTENT	C71325	
			QD	QD	C25473	
CL.SUDOSTXT_CIGARETTES_2011-10-24	Cigarette Usage Amount	text				No
			LESS THAN 20 PER DAY	LESS THAN 20 PER DAY		
			20 TO 60 PER DAY	20 TO 60 PER DAY		
			MORE THAN 60 PER DAY	MORE THAN 60 PER DAY		
CL.SUDOSTXT_CIGARS_2011-10-24	Cigar Usage Amount	text				No
			LESS THAN 3 PER DAY	LESS THAN 3 PER DAY		
			3 TO 10 PER DAY	3 TO 10 PER DAY		
			MORE THAN 10 PER DAY	MORE THAN 10 PER DAY		
CL.FREQ.SUBSET.ALCOHOL.BEER.SUDOSFRQ_2011-10-24	Frequency	text			C71113	Yes
			Q24H	Q24H	C64515	
			QS	QS	C67069	

			QM	QM	C64498	
CL.FREQ.SUBSET.ALCOHOL.WINE.SUDOSFRQ_2011-10-24	Frequency	text			C71113	Yes
			Q24H	Q24H	C64515	
			QS	QS	C67069	
			QM	QM	C64498	
CL.FREQ.SUBSET.ALCOHOL.SPIRITS.SUDOSFRQ_2011-10-24	Frequency	text			C71113	Yes
			Q24H	Q24H	C64515	
			QS	QS	C67069	
			QM	QM	C64498	
CL.EGMETHOD_2011-10-24	ECG Test Method	text			C71151	Yes
			12 LEAD UNSPECIFIED	12 LEAD UNSPECIFIED	C71101	
			12 LEAD STANDARD	12 LEAD STANDARD	C71102	
			12 LEAD MASON LIKAR	12 LEAD MASON LIKAR	C71103	
			12 LEAD MODIFIED MASON LIKAR	12 LEAD MODIFIED MASON LIKAR	C71110	
			12 LEAD SINGLE PAD	12 LEAD SINGLE PAD	C71112	
			12 LEAD NON-STANDARD	12 LEAD NON-STANDARD	C71114	
			STANDARD LEADS FOR BICYCLE EXERCISE	STANDARD LEADS FOR BICYCLE EXERCISE	C71115	
			12 LEAD CABRERA	12 LEAD CABRERA	C71116	
			STANDARD LEADS ONE INTERCOSTAL SPACE HIGHER	STANDARD LEADS ONE INTERCOSTAL SPACE HIGHER	C71117	
			FRANK LEAD SYSTEM	FRANK LEAD SYSTEM	C71118	
			MCFEE-PARUNGAO LEAD SYSTEM	MCFEE-PARUNGAO LEAD SYSTEM	C71119	
			CUBE LEAD SYSTEM	CUBE LEAD SYSTEM	C71120	
			BIPOLAR UNCORRECTED XYZ LEAD SYSTEM	BIPOLAR UNCORRECTED XYZ LEAD SYSTEM	C71121	
			PSEUDO-ORTHOGONAL XYZ LEAD SYSTEM	PSEUDO-ORTHOGONAL XYZ LEAD SYSTEM	C71122	
			12 LEAD EASI DOWER TRANSFORMATION	12 LEAD EASI DOWER TRANSFORMATION	C71123	
			12 LEAD 1 LEAD MISSING	12 LEAD 1 LEAD MISSING	C71125	
			STANDARD 12-LEAD AND CM5-CC5-CH5	STANDARD 12-LEAD AND CM5-CC5-CH5	C71126	
			STANDARD 12-LEAD AND CC5-CM5-ML	STANDARD 12-LEAD AND CC5-CM5-ML	C71128	
			STANDARD 12-LEAD EXTENDED RIGHT	STANDARD 12-LEAD EXTENDED RIGHT	C71130	
			STANDARD 12-LEAD EXTENDED LEFT	STANDARD 12-LEAD EXTENDED LEFT	C71131	
			VECTORCARDIOGRAPH CORRECTED	VECTORCARDIOGRAPH CORRECTED	C71092	
			VECTORCARDIOGRAPH UNCORRECTED	VECTORCARDIOGRAPH UNCORRECTED	C71093	
CL.POSITION.SUBSET.EGPOS_2011-10-24	Position	text			C71148	Yes

			SITTING	SITTING	C62122	
			STANDING	STANDING	C62166	
			SUPINE	SUPINE	C62167	
CL.EGTESTCD.SUBSET.EGTEST_2011-10-24	ECG Test Code	text			C71153	Yes
			VRMEAN	VRMEAN	C62152	
			RRMEAN	RRMEAN	C62090	
			QRSDUR	QRSDUR	C62087	
			QTMEAN	QTMEAN	C62089	
			QTCB	QTCB	C62112	
CL.LB_UNIT_x10E9/L_2011-10-24	Lab Codelist for x10E9/L	text				Yes
			x10E9/L	x10E9/L		
CL.LB_UNIT_x10E12/L_2011-10-24	Lab Codelist for x10E12/L	text				Yes
			x10E12/L	x10E12/L		
CL.LB_UNIT_nmol/L_2011-10-24	Lab Codelist for nmol/L	text				Yes
			nmol/L	nmol/L		
CL.LB_UNIT_mmol/L_2011-10-24	Lab Codelist for mmol/L	text				Yes
			mmol/L	mmol/L		
CL.LB_UNIT_fmol_2011-10-24	Lab Codelist for fmol	text				Yes
			fmol	fmol		
CL.LB_UNIT_%_2011-10-24	Lab Codelist for %	text				Yes
			%	%		
CL.LB_UNIT_fL_2011-10-24	Lab Codelist for fL	text				Yes
			fL	fL		
CL.NRIND_2011-10-24	Reference Range Indicator	text			C78736	No
			NORMAL	NORMAL	C78727	
			HIGH	HIGH	C78800	
			LOW	LOW	C78801	
CL.SKINCLAS_2011-10-24	Skin Classification	text			C76351	Yes
			TYPE1	TYPE1	C74569	
			TYPE2	TYPE2	C74570	
			TYPE3	TYPE3	C74571	
			TYPE4	TYPE4	C74572	
			TYPE5	TYPE5	C74573	
			TYPE6	TYPE6	C74574	
CL.MARISTAT_2011-10-24	Marital Status	text			C76348	Yes
			ANNULLED	ANNULLED	C76240	
			DIVORCED	DIVORCED	C51776	
			INTERLOCUTORY	INTERLOCUTORY	C76241	
			LEGALLY SEPARATED	LEGALLY SEPARATED	C51777	
			MARRIED	MARRIED	C51773	
			NEVER MARRIED	NEVER MARRIED	C51774	
			WIDOWED	WIDOWED	C51775	

			POLYGAMOUS	POLYGAMOUS	C76242	
			DOMESTIC PARTNER	DOMESTIC PARTNER	C53262	
CL.NCOMPLT_2011-10-24	Completion/Reason for Non-Completion	text			C66727	Yes
			COMPLETED	COMPLETED	C25250	
			ADVERSE EVENT	ADVERSE EVENT	C41331	
			LOST TO FOLLOW-UP	LOST TO FOLLOW-UP	C48227	
			WITHDRAWAL BY SUBJECT	WITHDRAWAL BY SUBJECT	C49634	
			STUDY TERMINATED BY SPONSOR	STUDY TERMINATED BY SPONSOR	C49632	
			PHYSICIAN DECISION	PHYSICIAN DECISION	C48250	
			PROTOCOL VIOLATION	PROTOCOL VIOLATION	C48251	
			DEATH	DEATH	C28554	
			OTHER	OTHER	C17649	
CL.DATEST_2011-10-24	Drug Accountability Test Name	text			C78731	Yes
			Dispensed Amount	DISPAMT	C78721	
			Returned Amount	RETAMT	C78722	
CL.FREQ.SUBSET.EXDOSFRQ_2011-10-24	Frequency	text			C71113	Yes
			QID	QID	C64530	
			TID	TID	C64527	
			BID	BID	C64496	
			QOD	QOD	C64525	
			QM	QM	C64498	
			PRN	PRN	C64499	
CL.ROUTE.SUBSET.EXROUTE_2011-10-24	Route of Administration	text			C66729	Yes
			ORAL	ORAL	C38288	
			TOPICAL	TOPICAL	C38304	
			SUBCUTANEOUS	SUBCUTANEOUS	C38299	
			TRANSDERMAL	TRANSDERMAL	C38305	
			INTRAOCULAR	INTRAOCULAR	C38255	
			INTRAMUSCULAR	INTRAMUSCULAR	C28161	
CL.LOC.SUBSET.EXLOC_2011-10-24	Anatomical Location	text			C74456	Yes
			ARM	ARM	C32141	
			SHOULDER	SHOULDER	C25203	
			LEG	LEG	C32974	
			HIP	HIP	C64193	

Measurement Unit Definitions

OID	Name	Symbol	Term. Ref.
MU.mg_2011-10-24	mg	mg	C28253
MU.ug_2011-10-24	ug	ug	C48152
MU.mL_2011-10-24	mL	mL	C28254
MU.g_2011-10-24	g	g	C48155

MU.IU_2011-10-24	IU	IU	C48579
MU.DAYS_2011-10-24	DAYS	DAYS	C25301
MU.HOURS_2011-10-24	HOURS	HOURS	C25529
MU.MONTHS_2011-10-24	MONTHS	MONTHS	C29846
MU.WEEKS_2011-10-24	WEEKS	WEEKS	C29844
MU.YEARS_2011-10-24	YEARS	YEARS	C29848
MU.cm_2011-10-24	cm	cm	C49668
MU.IN_2011-10-24	IN	IN	C48500
MU.kg_2011-10-24	kg	kg	C28252
MU.LB_2011-10-24	LB	LB	C48531
MU.mmHg_2011-10-24	mmHg	mmHg	C49670
MU.BEATS/MIN_2011-10-24	BEATS/MIN	BEATS/MIN	C49673
MU.C_2011-10-24	C	C	C42559
MU.F_2011-10-24	F	F	C44277
MU.ALCOHOL_BEER_2011-10-24	BEER UNIT	GLASS/BOTTLE (0.5 l)	
MU.ALCOHOL_WINE_2011-10-24	WINE UNIT	GLASS (0.2 l)	
MU.ALCOHOL_SPIRIT_2011-10-24	SPIRIT UNIT	MEASURE (25mll)	
MU.msec_2011-10-24	msec	msec	C41140
MU.TABLET_2011-10-24	TABLET	TABLET	C48542