

COMPLIANCE: DATA DICTIONARY

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Document Summary

Property	Value
Document Title	Compliance: Data Dictionary
Date Created	11/15/2019
Sections	2
Entries	30
Document Filename	dictionary_compliance.111519.rtf

Compliance: Data Dictionary

Section 1: Identifiers

Class	Variable	Label	Description	Format Text
01. Principal	Accession	Participant Assignment	Participant Assignment	numeric
01. Principal	Form	Form	Form. CDE: 3008882 1.0 Released	"Compliance"="Compliance"
01. Principal	Institution	Institution	Institution. CDE: 2551737 1.0 Released	"Brigham and Women's Hospital"="Brigham and Women's Hospital" "M. D. Anderson Cancer Center"="M. D. Anderson Cancer Center" "University of Michigan Comprehensive Cancer Center"="University of Michigan Comprehensive Cancer Center" "University of Utah Health System - Huntsman Cancer Institute"="University of Utah Health System - Huntsman Cancer Institute"
01. Principal	MRNO	Participant ID (MRNO)	Participant ID (MRNO). CDE: 2003301 4.0 Released	numeric
01. Principal	Reg_Date	Registration Date	Registration Date. CDE: 2171 4.0 Released	sasdate
01. Principal	Trial	Trial	Trial. CDE: 977 3.0 Released	"MDA2013-01-02"="MDA2013-01-02"

Section 2: Compliance

Class	Variable	Label	Description	Format Text
01. Principal	_3451_10000_Was_agent_interrupted	Was agent interrupted during this period?	Was agent interrupted during this period? CDE: 2182793 1.0 Released	"N/A"="N/A" "No"="No" "Yes"="Yes"
01. Principal	_3451_10001_If_Yes_indicate_number	If yes, indicate number of interruptions this period	If yes, indicate number of interruptions this period. CDE: 2480316 1.0 Released	numeric .="Missing"
01. Principal	_3451_10002_Was_agent_regimen_modified	Was agent regimen modified during this period?	Was agent regimen modified during this period? CDE: 2182601 2.0 Released	" "="Not Applicable" "N/A"="N/A" "No"="No" "Yes"="Yes"
01. Principal	_3451_10003_Amount_of_agent_provided	Amount of agent provided at last visit	Amount of agent provided at last visit. CDE: 2182819 1.0 Released	numeric .="Missing"
01. Principal	_3451_10004_Amount_of_agent_returned	Amount of agent returned this visit	Amount of agent returned this visit. CDE: 2182824 1.0 Released	numeric .="Missing"
01. Principal	_3451_10005_Amount_of_agent_taken	Amount of agent taken during this period	Amount of agent taken during this period. CDE: 2182826 2.0 Released	char, 7 " "="Not Applicable"
01. Principal	_3451_10006_Amount_of_agent_missing	Amount of agent missing/not accounted for this period	Amount of agent missing/not accounted for this period. CDE: 2182828 1.0 Released	char, 7 " "="Not Applicable"
01. Principal	_3451_10007_Is_the_participant_compliant	Is the participant compliant with protocol intervention?	Is the participant compliant with protocol intervention? CDE: 2202007 1.0 Released	"No"="No" "Yes"="Yes"
01. Principal	_3451_10008_If_No_specify_reason	If No, specify reason for noncompliance	If No, specify reason for noncompliance. CDE: 2182832 1.0 Released	char, 96 " "="Not Applicable"
01. Principal	_3451_10009_Was_agent_provided_at	Was agent provided at this visit?	Was agent provided at this visit? CDE: 2182836 1.0 Released	" "="Not Applicable" "No"="No" "Yes"="Yes"
01. Principal	_3451_10010_Amount_of_agent_provided_at	Amount of agent provided at this visit	Amount of agent provided at this visit. CDE: 2182836 1.0 Released	" "="Not Applicable" "N/A"="N/A"
01. Principal	_3451_10220_Amount_of_agent_provided	Any agent provided at this visit	Any agent provided at this visit	"False"="False"

Class	Variable	Label	Description	Format Text
01. Principal	_3451_9997_Visit_Date	Visit date	Visit date. CDE: 2182871 1.0 Released	sasdate
01. Principal	_3451_9998_First_Dose_taken_thi_s	First Dose taken this period	First Dose taken this period. CDE: 2182785 1.0 Released & 2182789 1.0 Released	char, 19 " "="Not Applicable"
01. Principal	_3451_9999_Last_Dose_taken_thi_s_	Last Dose taken this period	Last Dose taken this period. CDE: 2182675 1.0 Released	char, 20 " "="Not Applicable"
01. Principal	_3452_10012_Ag ent	Agent	Agent. CDE: 2798176 1.0 Released	char, 1 " "="Not Applicable"
01. Principal	_3452_10013_Do se_Units	Agent Units	Agent Units. CDE: 3028750 1.0 Released	"Capsule"="Capsule"
01. Principal	_3452_10014_Fre quency	Agent Frequency	Agent Frequency. CDE: 2003322 4.0 Released	"QD"="QD"
01. Principal	_3452_10015_Do se	Agent Dose	Agent Dose. CDE: 2182728 2.0 Released	numeric
01. Principal	_3452_10016_Ag ent_Placebo	Agent Name	Agent Name. CDE: 10 4.0 Released	"Naproxen 440mg/220mg/ Placebo"="Naproxen 440mg/220mg/ Placebo"
01. Principal	VAR11	Was agent interrupted during this period?	Was agent interrupted during this period? CDE: 2182793 1.0 Released	"N/A"="N/A" "No"="No" "Yes"="Yes"
01. Principal	VAR14	Was agent regimen modified during this period?	Was agent regimen modified during this period? CDE: 2182601 2.0 Released	" "="Not Applicable" "N/A"="N/A" "No"="No" "Yes"="Yes"
01. Principal	VAR20	Is the participant compliant with protocol intervention?	Is the participant compliant with protocol intervention? CDE: 2202007 1.0 Released	"No"="No" "Yes"="Yes"
01. Principal	VAR23	Was agent provided at this visit?	Was agent provided at this visit? CDE: 2182836 1.0 Released	" "="Not Applicable" "No"="No" "Yes"="Yes"