

UWI2013-00-01 - COMPLIANCE: DATA DICTIONARY

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Document Summary

Property	Value
Document Title	UWI2013-00-01 - Compliance: Data Dictionary
Date Created	04/29/2020
Sections	3
Entries	32
Document Filename	dictionary_compliance.rtf

UWI2013-00-01 - Compliance: Data Dictionary

Section 1: Identifiers

Variable	Label	Description	Format Text
Sequence_No_	Patient ID		Numeric

Section 2: Study-wide

Variable	Label	Description	Format Text
Arm	Arm		"POMx 1000mg/Placebo daily"="POMx 1000mg/Placebo daily"
Cycle	Cycle		Char, 1
Day	Day		Numeric
Form	Form		"CP DCP Compliance(CO11378) V2"="CP DCP Compliance(CO11378) V2"
Form_Desc_	Form Description		"CP DCP Compliance(CO11378)"="CP DCP Compliance(CO11378)"
Form_Status	Form Status		"Amended"="Amended" "Completed"="Completed" "Validated"="Validated"
Institution_Code	Institution Code		"MA017"="MA017" "MN022"="MN022" "TX273"="TX273" "WI020"="WI020"
Level	Level		Char, 1
Not_Applicable_or_Missing	Not Applicable Or Missing		Char, 1
Phase	Phase		"Treatment"="Treatment"
Segment	Segment		"End of Study"="End of Study" "Week 13"="Week 13" "Week 26"="Week 26" "Week 39"="Week 39"
Visit_Date	Visit Date		SAS Date
Visit_Type	Visit Type		"End of Study"="End of Study" "Week 13"="Week 13" "Week 26"="Week 26" "Week 39"="Week 39" "Week 52"="Week 52"

Section 3: Compliance

Variable	Label	Description	Format Text
Amount_of_agent_missing_not_acc	Amount Of Agent Missing/Not Accounted For This Period		Numeric
Amount_of_agent_provided_at_last	Amount Of Agent Provided At Last Visit		Numeric .="Missing"
Amount_of_agent_provided_at_this	Amount Of Agent Provided At This Visit		Numeric .="Missing"
Amount_of_agent_returned_this_visit	Amount Of Agent Returned This Visit		Numeric
Amount_of_agent_taken_during_this_visit	Amount Of Agent Taken During This Visit		Numeric
First_Dose_taken_this_period_Date	First Dose Taken This Period Time		SAS Date
First_Dose_taken_this_period_Time	First Dose Taken This Period Time		Numeric
If_No_specify_reason_for_noncompliance	If No, Specify Reason For Noncompliance		Char, 612
If_Yes_indicate_the_number_of_interruptions	If Yes, Indicate The Number Of Interruptions This Period		Numeric .="Missing"
Is_the_participant_compliant_with_the_protocol_intervention	Is The Participant Compliant With The Protocol Intervention		"Yes"="Yes"
Last_Dose_taken_this_period_Date	Last Dose Taken This Period Date		SAS Date
Last_Dose_taken_this_period_Time	Last Dose Taken This Period Time		Numeric
N_A	N/A		Char, 1
VAR16	Var16		"Day"="Day"
VAR19	Var19		"Day"="Day"
Was_agent_interrupted_this_period?	Was Agent Interruption This Period?		"No"="No" "Unknown"="Unknown" "Yes"="Yes"
Was_agent_provided_at_this_visit?	Was Agent Provided At This Visit		"No"="No" "Yes"="Yes"
Was_agent_regimen_modified_during_this_period?	Was Agent Regimen Modified During This Period?		"No"="No"