UWI2016-07-01 - Minimum Data Dictionary

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UWI2016-07-01 - Minimum: Data Dictionary

Section 1: Identifiers

Class	Variable	Label	Description	Format Text
01. Principal	**SEQUENCE_NO_**	Patient ID		Numeric

Section 2: Study-wide

Class	Variable	Label	Description	Format Text
01. Principal	**ARM**	Arm		Char
01. Principal	**CYCLE**	Cycle		Char
01. Principal	**DAY_1**	Day		Numeric
01. Principal	**FORM**	Form		"CP_DCP_Minimum_Data_Set V2"="CP_DCP_Minimum_Data_Set V2"
01. Principal	**FORM_DESC_**	Form Description		"Minimum Data Set Built for UW16110"="Minimum Data Set Built for UW16110"
01. Principal	**FORM_STATUS**	Form Status		"Amended"="Amended" "Completed"="Completed"
01. Principal	**LEVEL**	Level		Char
01. Principal	**MDS_DCPProtocolNumber**	DCP Protocol Number	Unique alphanumeric identifier assigned to a protocol by the National Cancer Institute for reporting of data.	"UWI2016-07-01"="UWI2016-07-01"
01. Principal	**MDS_RegisteringInstitution**	Registering Institution	Code that uniquely identifies the institution where the research participant was registered in the clinical trial	"MD017"="MD017" "MN022"="MN022" "WI020"="WI020"
01. Principal	**NOT_APPLICABLE_OR_MISSING**	Not Applicable Or Missing		Char
01. Principal	**PHASE**	Phase		"Treatment"="Treatment"
01. Principal	**SEGMENT**	Segment		"Screening/Baseline"="Screening/Baseline"
01. Principal	**VISIT_DATE**	Visit Date		SAS Date

Section 3: Minimum

Class	Variable	Label	Description	Format Text
01. Principal	**MDS_EnrollDate**	Participant Enrollment Date	The date the Participant is accepted into the study. The study site may also be notified of the treatment arm and Study Participant Identifier on this date.	SAS Date
01. Principal	**MDS_Participant CountryCode**	Participant Country Code	The code that represents the country where the addressee is located.	"USA"="USA"
01. Principal	**MDS_ParticipantI dentifier**	Participant Identifier	The unique numeric or alphanumeric identification assigned to a participant in a clinical trial or research study.	Numeric
01. Principal	**MDS_Participant ZipCode**	Participant Zip Code	The string of characters used to identify the five-digit Zone Improvement Plan (ZIP) code and the four-digit extension code (if available) that represents the geographic segment that is a subunit of the ZIPcode, assigned by the U.S. Postal Service to a geographic location to facilitate mail delivery; or the postal zone specific to the country, other than the U.S., where the mail is delivered.	"XXXXX"="XXXXX"
01. Principal	**MDS_Registering Consortium**	Registering Consortium	The designation of a consortium that will be officially recorded as the registering consortium for the study.	"WI020"="WI020"
01. Principal	**MDS_TreatmentA ssignmentCodeT AC**	Treatment Assignment Code (TAC)	A coded value representing a treatment assigned to be uniformly administered to a group of study subjects for separate statistical analysis.	"TAC-0"="TAC-0" "TAC1"="TAC1"

Class	Variable	Label	Description	Format Text
01. Principal	**ParticipantMethodofPayment**	Participant Method Of Payment	Text term for an entity, organization, government, corporation, health plan sponsor, or any other financial agent who pays a healthcare provider for the healthcare service rendered to a person or reimburses the cost of the healthcare service.	"Managed Care/Medicare"="Managed Care/Medicare" "Medicare and Private Insurance"="Medicare and Private Insurance" "Medicare"="Medicare" "Military Sponsored (including CHAMPUS & TriCare)"="Military Sponsored (including CHAMPUS & TriCare)" "Private Insurance"="Private Insurance" "Self-Pay (No insurance)"="Self-Pay (No insurance)" "State Supplemental Health Insurance"="State Supplemental Health Insurance"
01. Principal	**Screen2Date**	Screen 2 Date	Date of applicable patient's second screening visit.	Char
01. Principal	**Screen2DateYN**	Screen 2 Date Applicable Or Not Applicable?	Indicator representing if a patient screened for the study a second time	"Not Applicable"="Not Applicable"