ROWORDER	VARIABLE_NAME	VARIABLE_LABEL	TYPE	GENERAL_COMMENT
001	STUDYID	Study Identifier	Char	DM.STUDYID
002	USUBJID	Unique Subject Identifier	Char	DM.USUBJID
003	SUBJID	Subject Identifier for the Study	Char	DM.SUBJID
004	SITEID	Study Site Identifier	Char	DM.SITEID
005	AGE	Age	Num	DM.AGE
006	AGEU	Age Units	Char	DM.AGEU
007	AGEGR1	Pooled Age Group 1	Char	Populate using DM.AGE. If AGE<60 then set to "< 60 Years". Else if AGE>=60 then set to ">= 60 Years".
008	AGEGR1N	Pooled Age Group 1 (N)	Num	Populate using ADSL.AGEGR1. If AGEGR1="< 60 Years" then set to 1. Else if AGEGR1=">= 60 Years" then set to 2.
009	SEX	Sex	Char	DM.SEX
010	RACE	Race	Char	DM.RACE

ROWORDER	VARIABLE_NAME	VARIABLE_LABEL	TYPE	GENERAL_COMMENT
011	RACE1	Race 1	Char	Populate using QVAL where SUPPDM.QNAM="RACE1"
012	RACE2	Race 2	Char	Populate using QVAL where SUPPDM.QNAM="RACE2"
013	RACESP	Race Other Specify	Char	Populate using QVAL where SUPPDM.QNAM="RACESP"
014	SAFFL	Safety Population Flag	Char	Populate as "Y" for the subjects with non missing treatment start date (ADSL.TRTSDT). Else populate as "N".
015	COMPLFL	Completers Population Flag	Char	Populate as "Y" for the subjects who completed the study (DS.DSSCAT="END OF STUDY" and DS.DSDECOD="COMPLETED"). Else populate as "N".
016	RANDFL	Randomized Population Flag	Char	Populate as "Y" for the subjects with non missing randomization date (ADSL.RANDDT). Else populate as "N".

ROWORDER	VARIABLE_NAME	VARIABLE_LABEL	TYPE	GENERAL_COMMENT
017	ENRLFL	Enrolled Population Flag	Char	Populate as "Y" for the subjects with non missing enrollment date (ADSL.ENRLDT). Else populate as "N".
018	ARM	Description of Planned Arm	Char	DM.ARM
019	ACTARM	Description of Actual Arm	Char	DM.ACTARM
020	TRT01P	Planned Treatment for Period 01	Char	Populate using DM.ARM. If ARM="Placebo" then "Placebo". Else if ARM="Active" then "Active". Else set to null.
021	TRT01PN	Planned Treatment for Period 01 (N)	Num	Populate using ADSL.TRT01P. If TRT01P="Placebo" then set to 1. Else if TRT01P="Active" then set to 2..
022	TRT01A	Actual Treatment for Period 01	Char	Populate using DM.ACTARM. If ARM="Placebo" then "Placebo". Else if ACTARM="Active" then "Active". Else set to null.

ROWORDER	VARIABLE_NAME	VARIABLE_LABEL	TYPE	GENERAL_COMMENT
023	TRT01AN	Actual Treatment for Period 01 (N)	Num	Populate using ADSL.TRT01A. If TRT01P="Placebo" then set to 1. Else if TRT01A="Active" then set to 2..
024	TRTSDT	Date of First Exposure to Treatment	Num	ADSL.TR01SDT
025	TRTEDT	Date of Last Exposure to Treatment	Num	ADSL.TR01EDT
026	TR01SDT	Date of First Exposure in Period 01	Num	Populate using DM.RFXSTDTC
027	TR01EDT	Date of Last Exposure in Period 01	Num	Populate using DM.RFXENDTC
028	EOSSTT	End of Study Status	Char	Populate using the end of study status record in disposition data (DS.DSSCAT="END OF STUDY"). If DSDECOD="COMPLETED" then set to "COMPLETED".

ROWORDER	VARIABLE_NAME	VARIABLE_LABEL	TYPE	GENERAL_COMMENT
				Else if DSDECOD is not null then set to "DISONTINUED". Else if no record exists in disposition for end of study status and subject is not screen failure (ADSL.ARM is not "Screen Failure"), then set to "ONGOING".
029	EOSDT	End of Study Date	Num	Populate using DS.DSSTDTC from the record where DS.DSSCAT="END OF STUDY".
030	DCSREAS	Reason for Discontinuation from Study	Char	Populate using DS.DSDECOD form the end of study status record in disposition data (DS.DSSCAT="END OF STUDY" and DS.DSDECOD is not "COMPLETED").
031	EOTSTT	End of Treatment Status	Char	Populate using the end of study treatment record in disposition data (DS.DSSCAT="END OF TREATMENT"). If DSDECOD="COMPLETED" then set to "COMPLETED".

ROWORDER	VARIABLE_NAME	VARIABLE_LABEL	TYPE	GENERAL_COMMENT
				Else if DSDECOD is not null then set to "DISONTINUED". Else if no record exists in disposition for end of treatment status and subject is a safety subject (ADSL.SAFFL="Y"), then set to "ONGOING".
032	DCTREAS	Reason for Discontinuation of Treatment	Char	Populate using DS.DSDECOD form the end of study status record in disposition data (DS.DSSCAT="END OF TREATMENT" and DS.DSDECOD is not "COMPLETED").
033	RFICDT	Date of Informed Consent	Num	Populate using DM.RFICDTC, after converting the date portion to numeric version.
034	ENRLDT	Date of Enrollment	Num	Populate using DS.DSSTDTC on the record where DSTERM="ENROLLED"
035	RANDDT	Date of Randomization	Num	Populate using DS.DSSTDTC on the record where DSDECOD="RANDOMIZED"

ROWORDER	VARIABLE_NAME	VARIABLE_LABEL	TYPE	GENERAL_COMMENT
036	LSTALVDT	Date Last Known Alive	Num	Populate using DM.RFPENDTC
037	TRTDURD	Total Treatment Duration (Days)	Num	Populate as the difference between TRTEDT-TRTSDT+1.
038	DTHDT	Date of Death	Num	Populate using DM.DTHDTC.
039	HEIGHTBL	Baseline Height (cm)	Num	Populate using VS.VSSTRESN where VS.VSTESTCD="HEIGHT" and VS.VSBLFL="Y".
040	WEIGHTBL	Baseline Weight (kg)	Num	Populate using VS.VSSTRESN where VS.VSTESTCD="WEIGHT" and VS.VSBLFL="Y".