Roworder	variable_name	variable_label	derivation
001	STUDYID	Study Identifier	Equals to the value from raw.demog.STUDY
002	DOMAIN	Domain Abbreviation	Assign as 'DM'
003	USUBJID	Unique Subject Identifier	Derive by concatenating raw.demog.STUDY and raw.demog.PT variable values, separated with a hyphen in between.
004	SUBJID	Subject Identifier for the Study	Equals to the value from raw.demog.PT
005	RFSTDTC	Subject Reference Start Date/Time	For the subjects with non-missing sdtm.dm.RFXSTDTC, Equals to the date component of sdtm.dm.RFXSTDTC. Else if a subject is randomized, then assign the value of raw.enrlment.RANDDT_RAW after converting to ISO 8601 format. Else assign the value of sdtm.dm.RFICDTC

Roworder	variable_name	variable_label	derivation
006	RFENDTC	Subject Reference End Date/Time	Derive the date value in ISO 8601 format by obtaining the value from raw.eos.EOSTDT_RAW where raw.eos.EOSCAT="End of Study"
007	RFXSTDTC	Date/Time of First Study Treatment	Derive the datetime value in ISO 8601 format by obtaining the earliest non-missing raw.ipadmin.IPSTDT_RAW and raw.ipadmin.IPSTTM_RAW for each subject where raw.ipadmin.IPQTY_RAW is greater than 0.
008	RFXENDTC	Date/Time of Last Study Treatment	Derive the datetime value in ISO 8601 format by obtaining the latest non-missing raw.ipadmin.IPSTDT_RAW and raw.ipadmin.IPSTTM_RAW for each subject where raw.ipadmin.IPQTY_RAW is greater than 0.
009	RFICDTC	Date/Time of Informed Consent	Derive the date value in ISO 8601 format by obtaining the value from raw.enrlment.ICDT_RAW.

Roworder	variable_name	variable_label	derivation
010	RFPENDTC	Date/Time of End of Participation	Derive the date value in ISO 8601 format by obtaining the latest date value from all raw datasets. Date variables in a dataset can be identified with the suffix of 'DT_RAW'.
011	DTHDTC	Date/Time of Death	Derive the date value in ISO 8601 format by obtaining the value from raw.eos.EOSDT_RAW where raw.eos.EOSCAT="End of Study" and raw.eos.EOSTERM="Death"
012	DTHFL	Subject Death Flag	Assign as "Y" on the records where sdtm.dm.DTHDTC is not null.
013	SITEID	Study Site Identifier	Equals to the first 2 characters from raw.demog.PT
014	AGE	Age	Equals to the value from raw.demog.AGE_RAW
015	AGEU	Age Units	Equals to the value from raw.demog.AGE_RAWU
016	SEX	Sex	Equals to the value from raw.demog.SEX after converting to standard controlled terminology.

Roworder	variable_name	variable_label	derivation
017	RACE	Race	Derive sdtm.dm.RACE based on the values from raw.demog.RACE, raw.demog.RACE2, raw.demog.RACE3 and raw.demog.RACE4. If more than one of the above 4 variables is populated then assign a value of 'MULTIPLE', else assign the value from the populated variable after converting to standard controlled terminology.
018	ETHNIC	Ethnicity	Equals to the value from raw.demog.ETHNIC after converting to standard controlled terminology.
019	ARMCD	Planned Arm Code	Derive sdtm.dm.ARMCD based on the information present in raw.enrlment and raw.rand datasets. Part A) 1) Fetch the randomization number for each subject from raw.enrlment.RANDNO. 2) Fetch the raw.rand.TX_CD as ARMCD by joining the datasets based on RANDNO and raw.rand.RAND_ID.

Roworder	variable_name	variable_label	derivation
			Part B) For the subjects with raw.enrlment.ICDT_RAW not null and raw.enrlment.ENRLDT_RAW is null, assign as 'SCRNFAIL'. Part C) For the subjects with raw.enrlment.ENRLDT_RAW not null and raw.enrlment.RANDDT_RAW is null, assign as 'NOTASSGN'.
020	ARM	Description of Planned Arm	Assign as 'Active' when sdtm.dm.ARMCD is equal to 'ACTIVE'. Else assign as 'Placebo' when sdtm.dm.ARMCD is equal to 'PBO'. Else assign as 'Screen Failure' when sdtm.dm.ARMCD="SCRNFAIL". Else assign as 'Not Assigned' when sdtm.dm.ARMCD="NOTASSGN"
021	ACTARMCD	Actual Arm Code	Derive sdtm.dm.ACTARMCD based on the information present in raw.ipadmin and raw.box datasets. Part A) 1) Fetch the raw.ipadmin.IPBOXID from the earliest record with non-

Roworder	variable_name	variable_label	derivation
			missing IPQTY_RAW for each subject. 2) Fetch the raw.box.CONTENT as ACTARMCD by joining the datasets based on IPBOXID and raw.box.KITID. Part B) For subjects with sdtm.dm.ARMCD in ("SCRNFAIL" "NOTASSGN") assign the value of sdtm.dm.ARMCD. Part C) For the subjects with raw.rand.RANDDT_RAW not null and sdtm.dm.RFXSTDTC is null, assign as 'NOTTRT'.
022	ACTARM	Description of Actual Arm	Assign as 'Active' when sdtm.dm.ACTARMCD is equal to 'ACTIVE'. Else assign as 'Placebo' when sdtm.dm.ACTARMCD is equal to 'PBO'. Else assign as 'Screen Failure' when sdtm.dm.ACTARMCD="SCRNFAIL". Else assign as 'Not Assigned' when sdtm.dm.ACTARMCD="NOTASSGN".

Roworder	variable_name	variable_label	derivation
			Else assign as 'Not Treated' when sdtm.dm.ACTARMCD="NOTTRT".
023	COUNTRY	Country	Equals to the value from raw.demog.COUNTRY
024	RACE1	Race 1	Equals to the value from raw.demog.RACE when sdtm.dm.RACE is 'MULTIPLE' after converting to standard controlled terminology.
025	RACE2	Race 2	Equals to the value from raw.demog.RACE2 when sdtm.dm.RACE is 'MULTIPLE' after converting to standard controlled terminology.
026	RACE3	Race 3	Equals to the value from raw.demog.RACE3 when sdtm.dm.RACE is 'MULTIPLE' after converting to standard controlled terminology.

Roworder	variable_name	variable_label	derivation
027	RACE4	Race 4	Equals to the value from raw.demog.RACE4 when sdtm.dm.RACE is 'MULTIPLE' after converting to standard controlled terminology.
028	RACESP	Race Other Specify	Equals to the value form raw.demog.RACESP.