

Design ADSL and ADBASE in Cell Therapy

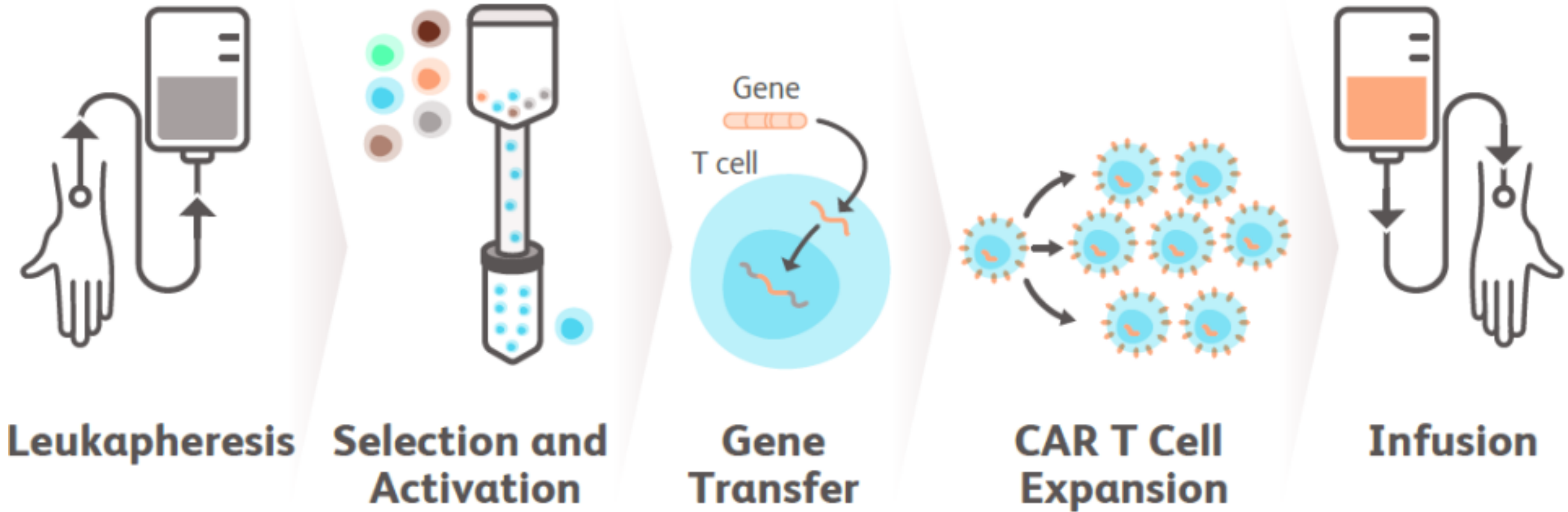
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Cell Therapy

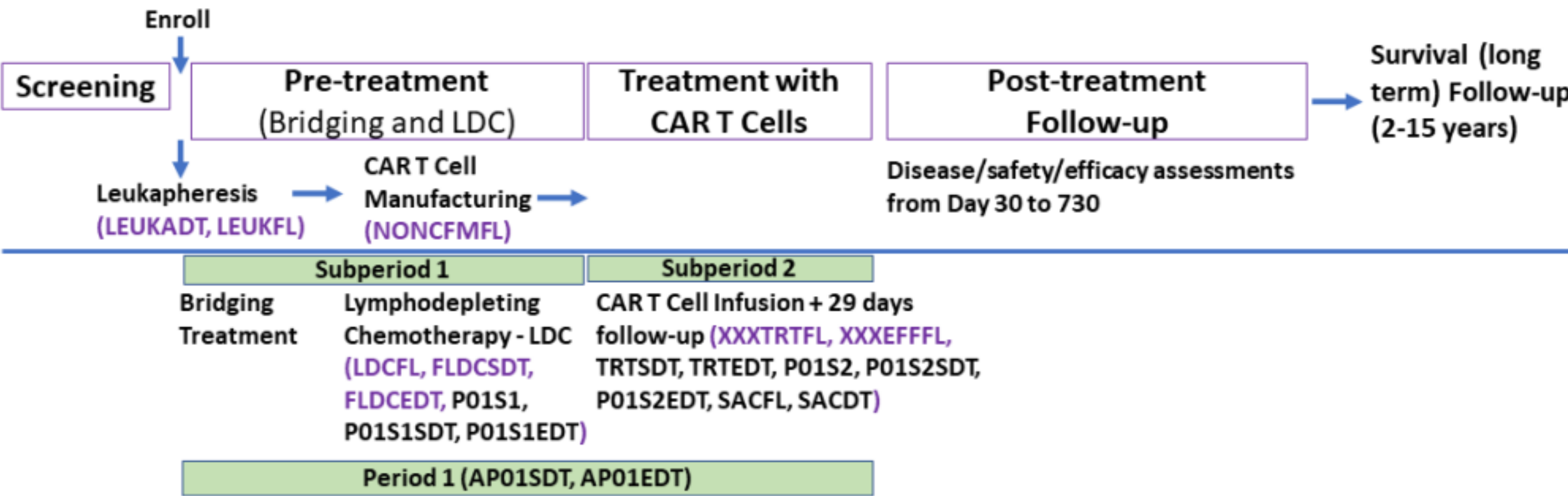
- Use a person's own cells to unlock new potential in the fight against some of the most difficult-to-treat cancers.
- Autologous **chimeric antigen receptor (CAR)** T cell therapy is a type of immunotherapy that works with a patient's immune system by reprogramming their T cells to recognize and bind to antigens found on the surface of certain cells, including cancerous and/or healthy cells that may also express the tumor-associated antigen.
- Unlike traditional anti-cancer treatments which usually involve repeated drug cycles, the CAR T cells can continue to multiply in the patient's body after being administered either **once** or over **multiple** infusions.

The process of a typical CAR T cell therapy



1). Leukapheresis; 2). CAR T cell manufacture; 3). CAR T cell infusion; 4). Survival (Long term) follow-up

The design of a sample CAR T hematological malignancy with its related ADSL variables in purple



How we design ADSL/ADBASE specification

- Compliant to all current CDISC/ADaM standards (ADaMIG v1.1, v1.2 and v1.3);
- Implement complicated study design of CAR T studies and ADaMIG instructions;
- Two types of variables: a). variables that are marked **purple** are some of the key CAR T specific features to address CT study needs; b). variables that are not marked are the common CDISC-compliant variables;
- **One-stop shop** to cover these variables when a new study is initiated in CAR T cell therapy. The variables and sources/derivations in this paper are **practical examples** for your information; study/programming team need to closely check the study specifics and **modify** them accordingly.

ADSL: IDENTIFIER AND SUBJECT DEMOGRAPHICS VARIABLES

Variable	Label	Source/Derivation
STUDYID	Study Identifier	SDTM.DM.STUDYID
USUBJID	Unique Subject Identifier	SDTM.DM.USUBJID
SUBJID	Subject Identifier for the Study	SDTM.DM.SUBJID;
SITEID	Study Site Identifier	SDTM.DM.SITEID
INVNAM	Investigator Name	SDTM.DM.INVNAM
COUNTRY	Country	SDTM.DM.COUNTRY
BRTHDTC	Date/Time of Birth	SDTM.DM.BRTHDTC
BRTHDT	Date of Birth	Numeric version of ADSL.BRTHDTC; no imputation needed
AGE	Age	SDTM.DM.AGE
AGEU	Age Units	SDTM.DM.AGEU
AAGE	Analysis Age	From SAP, AAGE = Integer of (ADSL.TRSTDT – ADSL.BRTHDT + 1) / 365.25; If ADSL.TRSTDT is missing then AAGE = AGE
AGEGR1	Pooled Age Group 1	Derived from AAGE. AGEGR1 = '< 65 years' if $z < AAGE < 65$; AGEGR1 = '>= 65 and < 75 years' if $65 \leq AAGE < 75$; AGEGR1 = '>= 75 years' if $AAGE \geq 75$.
AGEGR1N	Pooled Age Group 1 (N)	The numeric code of ADSL.AGEGR1. If AGEGR1 = '< 65 years' then AGEGR1N = 1; If AGEGR1 = '>= 65 and < 75 years' then AGEGR1N = 2; If AGEGR1 = '>= 75 years' then AGEGR1N = 3.
SEX	Sex	SDTM.DM.SEX
SEXN	Sex (N)	The numeric code of ADSL.SEX. If SEX = 'F' then SEXN = 1; If SEX = 'M' then SEXN = 2; If SEX = '' then SEXN = .

RACE	Race	SDTM.DM.RACE
RACEN	Race (N)	Numeric version of ADSL.RACE. 1="AMERICAN INDIAN OR ALASKA NATIVE" 2="ASIAN" 3="BLACK OR AFRICAN AMERICAN" 4="NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER" 5="WHITE" 96="NOT COLLECTED OR UNKNOWN" 97="OTHER" .= " "
RACEGR1	Pooled Race Group 1	If SDTM.DM.RACE = 'WHITE' then RACEGR1 = 'White'; If SDTM.DM.RACE is NOT in (' ', 'NOT REPORTED OR UNKNOWN') then RACEGR1 = 'Other'; Else RACEGR1 = 'Unknown'.
RACEGR1N	Pooled Race Group 1 (N)	The numeric code of ADSL.RACEGR1. If RACEGR1 = 'White' then RACEGR1N = 1. If RACEGR1 = 'Other' then RACEGR1N = 2. If RACEGR1 = 'Unknown' then RACEGR1N = 3.
ETHNIC	Ethnicity	SDTM.DM.ETHNIC
ETHNICN	Ethnicity (N)	Numeric version of ADSL.ETHNIC. 1='HISPANIC OR LATINO' 2='NOT HISPANIC OR LATINO' 97='NOT REPORTED' 98='UNKNOWN' .= " "
ETHNGR1	Pooled Ethnicity Group 1	If SDTM.DM.ETHNIC = 'HISPANIC OR LATINO' then ETHNGR1 = 'Hispanic or Latino'; If SDTM.DM.ETHNIC = 'NOT HISPANIC OR LATINO' then ETHNGR1 = 'Not Hispanic or Latino'; If SDTM.DM.ETHNIC = 'NOT REPORTED' then ETHNGR1 = 'Not Reported'; Else ETHNGR1 = 'Unknown/Missing'.
ETHNGR1N	Pooled Ethnicity Group 1 (N)	The numeric code of ADSL.ETHNGR1. If ETHNGR1 = 'Hispanic or Latino' then ETHNGR1N = 1; If ETHNGR1 = 'Not Hispanic or Latino' then ETHNGR1N = 2; If ETHNGR1 = 'Not Reported' then ETHNGR1N = 3; If ETHNGR1 = 'Unknown/Missing' then ETHNGR1N = 4.



ADSL: POPULATION INDICATOR AND TREATMENT VARIABLES

Variable	Label	Source/Derivation
SCRNFL	Screened Set Population Flag	'Y' if ADSL.RFICDT is not missing; 'N' otherwise.
ELIGFL	Eligible Set Population Flag	'Y' for subjects who met all eligibility criteria in SDTM.IE at the 'Screening' visit (IE.VISIT='SCREENING') AND [(IE.IECAT='EXCLUSION' & IE.IESTRESC = 'N') OR (IE.IECAT='INCLUSION' & IE.IESTRESC = 'Y')]; 'N' otherwise.
LEUKAFL	Leukapheresed Set Population Flag	'Y' for subjects who signed informed consent, who meet all inclusion/exclusion criteria, and underwent leukapheresis (SDTM.PR.PRTRT = "LEUKAPHERESIS" and SDTM.PR.PROCCUR='Y'); in case of protocol deviations where subjects undergo leukapheresis without meeting all inclusion/exclusion criteria, the subjects will still be included in the Leukapheresed Set. 'N' otherwise.
LDCFL	Lymphodepleting Chemo Population Flag	'Y' for subjects who signed informed consent, underwent leukapheresis, and received at least one dose of lymphodepletion chemotherapy (LDC); 'N' otherwise.
NONCFMFL	Non-conforming Product Population Flag	'N' for subjects who received conforming products or had non-missing ADSL.TRTSMT. Otherwise 'Y'

ADSL: POPULATION INDICATOR AND TREATMENT VARIABLES

XXXTRTFL	XXX Treated Set Population Flag	'Y' for subjects who received conforming products (ADSL.NONCFMFL='N') with non-missing XXX cell infusion date. 'N' otherwise.
XXXEFFFL	XXX Treated Efficacy Set Flag	'Y' for subjects in the XXX-treated Analysis Set (ADSL.XXXTRTFL='Y') who have positive disease present before XXX cell infusion (ADSL.TRTSDT) based on IRC assessment. 'N' for subjects who do not have baseline assessment repeated after anticancer therapy (ADSL.SACTDT) for disease control AND before XXX cell infusion (ADSL.TRTSDT). Otherwise 'N'
ARM	Description of Planned Arm	SDTM.DM.ARM
ARMCD	Planned Arm Code	SDTM.DM.ARMCD
ACTARM	Description of Actual Arm	SDTM.DM.ACTARM
ACTARMCD	Actual Arm Code	SDTM.DM.ACTARMCD
TRT01P	Planned Treatment for Period 01	Upper case of SDTM.DM.ARM)
TRT01A	Actual Treatment for Period 01	Upper case of SDTM.DM.ACTARM

ADSL: TREATMENT AND OTHER TIMING VARIABLES

Variable	Label	Source/Derivation
RFICDT	Date of Informed Consent	Numeric version of SDTM.DM.RFICDTC
TRTSDT	Date of First Exposure to Treatment	Numeric date part of first SDTM.EC.ECSTDTC where SDTM.EC.VISIT = 'XXX DAY 1' and SDTM.EC.ECDOSE >0 and SDTM.EC.ECMOOD='PERFORMED'.
TRTEDT	Date of Last Exposure to Treatment	Numeric date part of last SDTM.EC.ECENDTC where SDTM.EC.VISIT = 'XXX DAY 1' and SDTM.EC.ECDOSE >0 and SDTM.EC.ECMOOD='PERFORMED'.
LEUKADT	Leukapheresis Date	Date of first leukapheresis; If ADSL.LEUKAFL='Y', then LEUKADT= date part of earliest SDTM.PR.PRSTDTC where SDTM.PR.PRCAT='LEUKAPHERESIS' and SDTM.PR.PROCCUR='Y'.
SACFL	Subsequent Anti-cancer Therapy Flag	Use the same criteria from ADSL.SACTDT below, if a subject has any record, then set to "Y". else "N".
SACTDT	Date of Subsequent Anti-cancer Therapy	SACTDT is the earliest date of (stem cell transplant, radiation therapy and systematic anti-cancer therapy).
FLDCSDT	First Lymphodepletion Start Date	Start date of the first lymphodepleting chemotherapy from SDTM.EC where ECCAT="GENERAL DRUG EXPOSURE" and ECMOOD='PERFORMED' and ECDOSE >0 and index(VISIT, 'LD CHEMOTHERAPHY') >0
FLDCEDT	First Lymphodepletion End Date	End date of the first lymphodepleting chemotherapy from SDTM.EC where ECCAT="GENERAL DRUG EXPOSURE" and ECMOOD='PERFORMED' and ECDOSE >0 and index(VISIT, 'LD CHEMOTHERAPHY') >0

ADSL: TREATMENT AND OTHER TIMING VARIABLES

AP01SDT	Period 01 Start Date	The earliest of non-missing ADSL.P01S1SDT and ADSL.P01S2SDT
AP01EDT	Period 01 End Date	The maximum of non-missing ADSL.P01S1EDT and ADSL.P01S2EDT
P01S1	Description of Period 01 Subperiod 1	If subject received any LDC then P01S1='LYMPHODEPLETION CHEMOTHERAPY'.
P01S1SDT	Period 01 Subperiod 1 Start Date	Start date of the last lymphodepleting chemotherapy
P01S1EDT	Period 01 Subperiod 1 End Date	End date of last lymphodepletion chemotherapy
P01S2	Description of Period 01 Subperiod 2	If subject received XXX or non-conforming product (i.e. not missing ADSL.TRTSDT) then P01S2 = 'XXX TREATMENT'.
P01S2SDT	Period 01 Subperiod 2 Start Date	Start date of first XXX or non-conforming product infusion; this is the same as ADSL.TRTSDT.
P01S2EDT	Period 01 Subperiod 2 End Date	Only populated for subjects who received a XXX or non-conforming product infusion, i.e. non-missing XXX infusion start date + 29 (ADSL.P01S2SDT + 29)

ADSL: SUBJECT-LEVEL TRIAL EXPERIENCE AND OTHER VARIABLES

Variable	Label	Source/Derivation
STRATAR	Strata Used for Randomization	STRATAR contains the combination of values of the individual stratification factors used for randomization. e.g. ">-50, Treatment experienced, N"
STRATARN	Strata Used for Randomization (N)	Numeric one-to-one map of ADSL.STRARAR
STRATwD	Description of Stratification Factor w	A full description of the stratification factor 'w'. This text description will remain constant for all subjects. e.g. STRAT3D="Hypertension"
STRATwR	Strat Factor w Value Used for Rand	The subject-level value of the "w'th" stratification factor is used for randomization. e.g. STRAT3R="N"
STRATwRN	Strat Factor w Value Used for Rand (N)	Numeric one-to-one map of ADSL. STRATwR
STRATAV	Strata from Verification Source	STRATAV contains the entire string value represents the combination of values of the individual stratification factors that should have been used and represents the "as verified" value.
STRATAVN	Strata from Verification Source (N)	Numeric one-to-one map of ADSL.STRARAR
STRATwV	Strata Factor w Value from Verif Source	STRATWV is the "as verified" subject-level value of the "With" stratification factor. If the value based on randomization was correct, then STRATWV will equal STRATWR. e.g. STRAT3V="Y"
STRATwVN	Strata Factor w Value from Verif Source (N)	Numeric one-to-one map of ADSL. STRATwV

ADSL: SUBJECT-LEVEL TRIAL EXPERIENCE AND OTHER VARIABLES

EOSDT	End of Study Date	Date subject ended the study – either date of completion or date of discontinuation or data cutoff date
DCSREAS	Reason for Discontinuation from Study	Reason for subject's discontinuation from study. The source would most likely be the SDTM DS dataset. Null for subjects who completed the study.
DCSREASP	Reason Spec for Discont from Study	Additional detail regarding subject's discontinuation from study (e.g., description of "other").
EOTSTT	End of Treatment Status	The status of end of treatment or data cutoff. Examples: COMPLETED, DISCONTINUED, ONGOING.
DCTREAS	Reason for Discontinuation of Treatment	If a subject discontinued treatment in the study, then this variable indicates the reason for discontinuation. This is for discontinuation of treatment in the overall study and not to be used for discontinuation reason within individual treatment periods.
DCTREASP	Reason Specify for Discont of Treatment	Additional detail regarding subject's discontinuation from treatment (e.g., description of "other").
TRTDURD	Total Treatment Duration (Days)	Total treatment duration, as measured in days. More than one of TRTDURD, TRTDURM, and TRTDURY can be populated, but each represents the entire duration in its respective units.
TRTDURM	Total Treatment Duration (Months)	Total treatment duration, as measured in months. More than one of TRTDURD, TRTDURM, and TRTDURY can be populated, but each represents the entire duration in its respective units.
TRTDURY	Total Treatment Duration (Years)	Total treatment duration, as measured in years. More than one of TRTDURD, TRTDURM, and TRTDURY can be populated, but each represents the entire duration in its respective units.
DTHDT	Date of Death	Numeric version of SDTM.DS.DSSTDTC when DSDECOD='DEATH'.
DTHFL	Subject Death Flag	'Y' if ADSL.DTHDT is not missing.
DTHCAUS	Cause of Death	Cause of Death.
DSDT	Date of Discon Study	Date part of SDTM.DS.DSSTDTC for discontinuation from study.

ADBASE: baseline demographics and disease characteristics

Variable	Label	Source/Derivation
CHILDPOT	Reproductive Status	1) If SDTM.DM.SEX='F' and SDTM.RP.RPSTRESC='Y' when STD.M.RP.RPTESTCD="CHILDPOT" and SDTM.RP.EPOCH='SCREENING' then CHILDPOT = "Female of Childbearing Potential". 2) If SDTM.DM.SEX='F' and SDTM.RP.RPSTRESC='N' when STD.M.RP.RPTESTCD="CHILDPOT" and SDTM.RP.EPOCH='SCREENING' then CHILDPOT = "Female of Nonchildbearing Potential". 3) SDTM.DM.SEX='M' then CHILDPOT = "Male" 4) Otherwise CHILDPOT = "Missing".
HEIGHTBL	Baseline Height (cm)	The last available non-missing SDTM.VS.VSSTRESN value (in cm) where SDTM.VS.VSTESTCD='HEIGHT' on or before the date (and time if collected) of the first dose of XXX or non-conforming product is administered (ADSL.TRTSDT). For subjects who were not treated, the baseline will be the latest non-missing value. If there are multiple records with the same date meeting the criteria, get the average of SDTM.VS.VSSTRESN values from the multiple records meeting the date criteria.

ADBASE: baseline demographics and disease characteristics

WEIGHTBL	Baseline Weight (kg)	The last available non-missing SDTM.VS.VSSTRESN value (in kg) where SDTM.VS.VSTESTCD='WEIGHT' on or before the date (and time if collected) of the first dose of XXX or non-conforming product is administered (ADSL.TRTSDT). For subjects who were not treated, the baseline will be the latest non-missing value. If there are multiple records with the same date meeting the criteria, get the average of SDTM.VS.VSSTRESN values from the multiple records meeting the date criteria.
BMIBL	Baseline BMI (kg/m^2)	BMIBL = Weight (kg) / [Height (m)] ² ; use ADBASE.WEIGHTBL and ADBASE.HEIGHTBL to derive; ADBASE.HEIGHTBL is in cm so it needs to be converted firstly to meter (m) before using the formula above.
BSABL	Baseline Body Surface Area (m^2)	Square root of (ADBASE.HEIGHTBL*ADBASE.WEIGHTBL/3600)
BCELNHL	B-Cell NHL Type	SDTM.MH.MHTERM where SDTM.MH.MHCAT = 'DISEASE DIAGNOSIS' and SDTM.MH.MHOCCUR='Y' and SDTM.MH.MHPRESP='Y'.
DIAGDTC	Date/Time of Diagnosis	SDTM.MH.MHSTDTC where MHCAT = 'DISEASE DIAGNOSIS' and MHOCCUR='Y' and MHPRESP='Y'.
DIAGDT	Date of Diagnosis	Numeric date part of ADBASE.DIAGDTC; imputation may apply for partial dates
.....	Disease Related Variables	Multiple variables related to disease diagnose and characteristics should be listed here such as Lymphoma cells, Ann Arbor Stage, Risk categories.

ADBASE: baseline demographics and disease characteristics

TDIA2XXX	Time Since Diagnosis to XXX Infusion (months)	Months from diagnosis date to first XXX or non-conforming product infusion, i.e. $(ADSL.TRTSDT - ADBASE.DIAGDT + 1) / 30.4375$
PD1SDT	First Progression Date	Numeric date of SDTM.RS.RSDTC where the first SDTM.RS.RSSTRESC='PD'
TDIA2PD	Time Since Diagnosis to First Progression (months)	Months from diagnosis date to first progression date, i.e. $(ADBASE.PD1SDT - ADBASE.DIAGDT + 1) / 30.4375$.
TINIT2PD	Time Since Initial Treatment to First Progression (months)	Months from initial treatment date (ADSL.P01S1SDT) to first progression date (ADBASE.PD1SDT), i.e. $(ADBASE.PD1SDT - ADSL.P01S1SDT + 1) / 30.4375$
TSYS2PD	Time from Last Systemic Regimen to First Progression (months)	Months from most recent systemic regimen date (SYSDT) to first progression date (ADBASE.PD1SDT), i.e. $(ADBASE.PD1SDT - SYSDT + 1) / 30.4375$. To get SYSDT, get records from SDTM.CM and SDTM.PR as follows (imputation rules for partial dates may apply): a). for records from SDTM.CM: $SYSDT = SDTM.CM.CMSTDTC$ where $index(SDTM.CM.CMCAT, 'SYSTEMIC ANTI-CANCER THERAPIES FOR DISEASE UNDER STUDY') > 0$ and $(SDTM.CM.CMSTRF = 'BEFORE' \text{ and } SDTM.CM.CMSTDTC \leq ADSL.LEUKADT)$. b). for records from SDTM.PR: $SYSDT = SDTM.PR.PRSTDTC$ where $index(SDTM.PR.PRCAT, 'STEM CELL TRANSPLANTS FOR DISEASE UNDER STUDY') > 0$ and $(SDTM.PR.PRSTRTPT = 'BEFORE' \text{ and } SDTM.PR.PRSTDTC \leq ADSL.LEUKADT)$. Finally, SYSDT is the most recent date from the above selected records in a) and b).

ADBASE: baseline demographics and disease characteristics

SPDLDC	Sum of Prod of Diam (cm^2) Prior to LDC	The last available non-missing sum of products of the perpendicular diameters on or before the first date of the lymphodepletion chemotherapy regimen (ADSL.P01S1SDT). 1). select records where SDTM.TR.TREVAL='INVESTIGATOR', SDTM.TR.TRTESTCD in ('LDIAM', 'LPERP') and SDTM.TR.TRSTRESU = 'cm'. Multiply the values for LDIAM and LPERP per subject, date, and lesion (SDTM.TR.TRLNKID). 2). if any measurement (LDIAM or LPERP) of a lesion is missing for a date, the date will not be considered for SPD. 3). sum the product values (SPD) for the records from the latest date on or before LDC (SDTM.TR.TRDTC <= ADSL.P01S1SDT). Note: for subjects who did not receive LDC, use the latest non-missing SPD; if there are multiple records for a lesion with the same date meeting the criteria, use the average of the product values for the lesions when calculating the SPD value for the date.
ECOGSCR	ECOG Score at Screening	SDTM.QS.QSSTRESN where SDTM.QS.QSTESTCD='ECOG101' and SDTM.QS.VISIT='SCREENING'.
ECOGLDC	ECOG prior Lympho Chemotherapy status	The last available non-missing SDTM.QS.QSSTRESN where SDTM.QS.QSTESTCD= 'ECOG101' on or before the first date of the lymphodepletion chemotherapy (ADSL.P01S1DT) given immediately prior to the initial XXX or non-conforming product infusion. For subjects who did not receive lymphodepletion chemotherapy, use the latest non-missing value of SDTM.QS.QSSTRESN; If there are multiple records with the same date meeting the criteria, get the lowest severity (1 is less severe than 2) from the multiple records meeting the date criteria.

ADBASE: baseline demographics and disease characteristics

ECOGXXX	ECOG prior XXX Infusion status	The last available non-missing SDTM.QS.QSSTRESN where SDTM.QS.QSTESTCD = 'ECOG101' on or before the date of initial XXX or non-conforming product infusion (ADSL.TRTSDT). For subjects who did not receive XXX, use the latest non-missing value of SDTM.QS.QSSTRESN; If there are multiple records with the same date meeting the criteria, get the lowest severity (1 is less severe than 2) from the multiple records meeting the date criteria.
CRPBL	C-Reactive Protein (CRP)	The last available non-missing SDTM.LB.LBSTRESN value (in mg/L) for SDTM.LB.LBTESTCD='CRP' and SDTM.LB.LBCAT='CHEMISTRY' on or before the date (and time if collected) of the first dose of XXX or non-conforming product is administered (ADSL.TRTSDT). For subjects who were not treated, the baseline will be the latest non-missing value. If there are multiple records with the same date meeting the criteria, get the average of the SDTM.LB.LBSTRESN values from the multiple records meeting the date criteria.
LDHLDC	Lactate dehydrogenase (LDH) (U/L) Prior to LDC	The last available non-missing SDTM.LB.LBSTRESN where SDTM.LB.LBCAT = 'CHEMISTRY' and SDTM.LB.LBTESTCD = 'LDH' and SDTM.LB.LBSTRESU = 'U/L' on or before the first date of the lymphodepletion chemotherapy given immediately prior to the initial XXX or nonconforming product infusion (ADSL.P01S1SDT). For subjects who did not receive lymphodepletion chemotherapy, use the latest non-missing value of SDTM.LB.LBSTRESN. If there are multiple records with the same date meeting the criteria, get the average of the SDTM.LB.LBSTRESN values from the multiple records meeting the date criteria.

ADBASE: baseline demographics and disease characteristics

HSCTFL	Prior Hematopoietic Stem Cell Transplant	'Y' for subjects who there is prior hematopoietic stem cell transplant on or before XXX infusion (SDTM.PR.PRCAT = "STEM CELL TRANSPLANTS FOR DISEASE UNDER STUDY" and SDTM.PR.PRTRT = "STEM CELL TRANSPLANT" and SDTM.PR.PRSTRTPPT = "BEFORE" and SDTM.PR.PRSTDTC <= ADSL.TRTSDT). Otherwise 'N'
BESTRESP	Best Response to Last Prior Systemic Regimen	Get the best response records from SDTM.CM and SDTM.PR datasets as follows (imputation rules for partial dates may apply): a). for records from SDTM.CM: CM.BESTRESP where index(CM.CMCAT, 'SYSTEMIC ANTI-CANCER THERAPIES FOR DISEASE UNDER STUDY') >0 and (CM.CMSTRF = 'BEFORE' and CM.CMSTDTC <= ADSL.LEUKADT). b). for records from SDTM.PR: PR.BESTRESP where index(PR.PRCAT, 'STEM CELL TRANSPLANTS FOR DISEASE UNDER STUDY') >0 and (PR.PRSTRTPPT = 'BEFORE' and PR.PRSTDTC <= ADSL.LEUKADT). BESTRESP is the best response from the above selected records in a) and b).

ADBASE: baseline demographics and disease characteristics

NPRT	Number of All Prior Therapies	NPRT is derived as the sum of number of prior radiation therapy and prior systemic therapy (imputation rules for partial dates may apply). Number of prior radiation therapy: Count distinct start dates (SDTM.PR.PRSTDTC) where PR.PRSTRTP = "BEFORE" and PR.PRTRT is not missing and index(PR.PRCAT, "ANTI-CANCER PROCEDURES - PRIOR RADIATION THERAPIES") >0 and PR.PRSTDTC <= ADSL.LEUKADT. Number of prior systemic therapy: For records from SDTM.CM: count distinct regimes (CM.CMGRPID) where index(CM.CMCAT, 'SYSTEMIC ANTI-CANCER THERAPIES FOR DISEASE UNDER STUDY') >0 and (CM.CMSTRF = 'BEFORE' and CM.CMSTDTC <= ADSL.LEUKADT). For records from SDTM.PR: count distinct start dates (PR.PRSTDTC) where index(PR.PRCAT, 'STEM CELL TRANSPLANTS FOR DISEASE UNDER STUDY') >0 and (PR.PRSTRTP = 'BEFORE' and PR.PRSTDTC <= ADSL.LEUKADT).
NPRAD	Number of Prior Radiation Therapies	If SDTM.PR.PRSTRTP = "BEFORE" and SDTM.PR.PRTRT is not missing and index(SDTM.PR.PRCAT, "ANTI-CANCER PROCEDURES - PRIOR RADIATION THERAPIES") >0 and SDTM.PR.PRSTDTC <= ADSL.TRTSDT then count distinct start dates (SDTM.PR.PRSTDTC) received by each subject. If no radiation therapies for a subject, then NPRAD=0 .

ADBASE: baseline demographics and disease characteristics

NPSYS	Number of Prior Systemic Therapies	For records from SDTM.CM: count distinct regimes (CM.CMGRPID) where $\text{index}(\text{CM.CMCAT}, \text{'SYSTEMIC ANTI-CANCER THERAPIES FOR DISEASE UNDER STUDY'}) > 0$ and $(\text{CM.CMSTRF} = \text{'BEFORE'})$ and $\text{CM.CMSTDTC} \leq \text{ADSL.LEUKADT}$). For records from SDTM.PR: count distinct start dates (PR.PRSTDTC) where $\text{index}(\text{PR.PRCAT}, \text{'STEM CELL TRANSPLANTS FOR DISEASE UNDER STUDY'}) > 0$ and $(\text{PR.PRSTRTP} = \text{'BEFORE'})$ and $\text{PR.PRSTDTC} \leq \text{ADSL.LEUKADT}$). Add number of distinct records above; if no distinct systemic therapy for a subject, then NPSYS=0.
NPSURG	Number of Prior Surgeries	If $\text{SDTM.PR.PRSTRTP} = \text{'BEFORE'}$ and $\text{index}(\text{SDTM.PR.PRCAT}, \text{'ANTI-CANCER PROCEDURES - PRIOR CANCER SURGERIES'}) > 0$ and $\text{SDTM.PR.PRSTDTC} \leq \text{ADSL.LEUKADT}$, then count the number of the distinct surgeries (distinct start dates SDTM.PR.PRSTDTC) received by each subject. If no distinct surgeries for a subject, then NPSURG=0.
TEMPBL	Baseline Temperature (C)	The last available non-missing SDTM.VS.VSSTRESN value in C for $\text{SDTM.VS.VSTESTCD} = \text{'TEMP'}$ on or before the date (and time if collected) of the first dose of XXX or non-conforming product is administered (ADSL.TRSTDTC). For subjects who were not treated, the baseline will be the latest non-missing value. If there are multiple records with the same date meeting the criteria, get the average of the SDTM.VS.VSSTRESN values from the multiple records meeting the date criteria.

ADBASE: baseline demographics and disease characteristics

SYSBPBL	Baseline Systolic Blood Pressure (mmHg)	The last available non-missing SDTM.VS.VSSTRESN value in mmHg for SDTM.VS.VSTESTCD='SYSBP' on or before the date (and time if collected) of the first dose of XXX or non-conforming product is administered (ADSL.TRTSDT). For subjects who were not treated, the baseline will be the latest non-missing value. If there are multiple records with the same date meeting the criteria, get the average of the SDTM.VS.VSSTRESN values from the multiple records meeting the date criteria.
DIABPBL	Baseline Diastolic Blood Pressure (mmHg)	The last available non-missing SDTM.VS.VSSTRESN value in mmHg for SDTM.VS.VSTESTCD='DIABP' on or before the date (and time if collected) of the first dose of XXX or non-conforming product is administered (ADSL.TRTSDT). For subjects who were not treated, the baseline will be the latest non-missing value. If there are multiple records with the same date meeting the criteria, get the average of the SDTM.VS.VSSTRESN values from the multiple records meeting the date criteria. For subjects who underwent leukapheresis but did not receive lymphodepletion chemotherapy, the baseline will be the last assessment value taken on or before leukapheresis.
PULSEBL	Baseline Pulse (beats/min)	The last available non-missing SDTM.VS.VSSTRESN value in BEATS/MIN for SDTM.VS.VSTESTCD='PULSE' on or before the date (and time if collected) of the first dose of XXX or non-conforming product is administered (ADSL.TRTSDT). For subjects who were not treated, the baseline will be the latest non-missing value. If there are multiple records with the same date meeting the criteria, get the average of the SDTM.VS.VSSTRESN values from the multiple records meeting the date criteria.

ADBASE: baseline demographics and disease characteristics

RESPBL	Respiratory Rate (breaths/min)	The last available non-missing SDTM.VS.VSSTRESN value in BREATHS/MIN for SDTM.VS.VSTESTCD='RESP' on or before the date (and time if collected) of the first dose of XXX or non-conforming product is administered (ADSL.TRTSDT). For subjects who were not treated, the baseline will be the latest non-missing value. If there are multiple records with the same date meeting the criteria, get the average of the SDTM.VS.VSSTRESN values from the multiple records meeting the date criteria. For subjects who underwent leukapheresis but did not receive lymphodepletion chemotherapy, the baseline will be the last assessment value taken on or before leukapheresis.
OXYSATBL	Oxygen Saturation (%)	The last available non-missing SDTM.VS.VSSTRESN value in % for SDTM.VS.VSTESTCD='OXYSAT' on or before the date (and time if collected) of the first dose of XXX or non-conforming product is administered (ADSL.TRTSDT). For subjects who were not treated, the baseline will be the latest non-missing value. If there are multiple records with the same date meeting the criteria, get the average of the SDTM.VS.VSSTRESN values from the multiple records meeting the date criteria.



Thank you

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