Pilot OCE/OOD Safety Team Standard Data Requests

- As part of your NDA/BLA submission, we ask that you prepare the datasets and conduct the safety analyses with the assumptions and dataset variables as below.
- Please provide define files (PDF and .xml with stylesheet) and a reviewer's guide for submitted datasets.

ADSL - Subject level Analysis Dataset (adsl.xpt):

Structure: One record per subject

- In addition to the CDISC required variables for adsl and variables necessary for analyses for the submitted trials, the dataset should include the variables listed below important for the analyses with identifiers for each trial period/drug as applicable (not an all-inclusive list):

ADSL Variable Name	Variable Label	Type	Codelist/Controlled Terms	CDISC Core	OCE/OOD Core	Source (ADaMIG v1.1 or SDTM v3.2 or OCE/OOD v1.3=FDA)	OCE/OOD Additional Information
USUBJID	Unique Subject Identifier	Char		Req	Req	STDM	
SUBJID	Subject Identifier for the Study	Char		Req	Req	STDM	
STUDYID	Study Identifier	Char		Req	Req	STDM	
AGE	Age	Num		Req	Req	STDM	
AGEU	Age Units	Char	(AGEU)	Req	Req	SDTM	
AGEGRy	Pooled Age Group y	Char		Perm	Req	ADaM	Age <65 and ≥ 65 should be presented; Other groupings may also be presented as discussed with review team or deemed relevant by applicant.
AGEGRyN	Pooled Age Group y (N)	Num		Perm	Req	ADaM	
SEX	Sex	Char	(SEX)	Req	Req	SDTM	
RACE	Race	Char	(RACE)	Req	Req	SDTM	

ADSL Variable Name	Variable Label	Type	Codelist/Controlled Terms	CDISC Core	OCE/OOD Core	Source (ADaMIG v1.1 or SDTM v3.2 or OCE/OOD v1.3=FDA)	OCE/OOD Additional Information
RACEGRy	Pooled Race Group y	Char		Perm	Perm	ADaM	Asian, Black or African American, White, Other should be presented; Other groupings may also be presented as discussed with review team or deemed relevant by applicant.
RACEGRyN	Pooled Race Group y (N)	Num		Perm	Perm	ADaM	
ETHNIC	Ethnicity	Char			Perm	SDTM	Hispanic or Latino, not Hispanic or Latino, not reported, unknown
ETHNICN	Ethnicity (N)	Num			Perm	AdaM	
COUNTRY	Country	Char			Req	SDTM	
COUNTRYN	Country (N)	Num			Req	ADaM	
REGIONy	Geographic Region y	Char		Perm	Req	ADaM	North America, Western Europe, Rest of the World should be presented; Other groupings may also be presented as discussed with review team or deemed relevant by applicant.
REGIONyN	Geographic Region y (N)	Num		Perm	Req	ADaM	
TRT01P	Planned Treatment for Period 01	Char		Req	Req	ADaM	
TRT01A	Actual Treatment for Period 01	Char		Cond	Req	ADaM	There must be one TRTxxA for each value of TRTxxP
TR01SDT	Date of First Exposure in Period 01	Num		Req	Req	ADaM	

ADSL Variable Name	Variable Label	Type	Codelist/Controlled Terms	CDISC Core	OCE/OOD Core	Source (ADaMIG v1.1 or SDTM v3.2 or OCE/OOD v1.3=FDA)	OCE/OOD Additional Information
TR01EDT	Date of Last Exposure in Period 01	Num		Req	Req	ADaM	
TRTxxP	Planned Treatment for Period xx	Char		Cond	Cond	ADaM	Required if there are multiple treatment periods
TRTxxA	Actual Treatment for Period xx	Char		Cond	Cond	ADaM	Required if there are multiple treatment periods
TRxxSDT	Date of First Exposure in Period xx	Num		Cond	Cond	ADaM	Required if there are multiple treatment periods
TRxxEDT	Date of Last Exposure in Period xx	Num		Cond	Cond	ADaM	Required if there are multiple treatment periods
TRTSDT	Date of First Exposure to Treatment	Num		Cond	Req	ADaM	
TRTEDT	Date of Last Exposure to Treatment	Num		Cond	Req	ADaM	
TRTEDY	Study day of Last Exposure to Treatment	Num		N/A	Req	FDA	Study day of last exposure to treatment
SAFFL	Safety Population Flag	Char	Y, Null	Cond	Req	ADaM	Safety population = patients who received at least one dose of study drug
TRTFL	Treated Population Flag	Char	Y, Null	N/A	Perm	FDA	Treated population = patients who received at least one dose of all drugs in a combination regimen
ADTHFL	Analysis Subject Death Flag	Char	Y, Null	Exp	Req	ADaM	Flag indicating if subject died before end of study (or data cutoff, if applicable).

ADSL Variable Name	Variable Label	Type	Codelist/Controlled Terms	CDISC Core	OCE/OOD Core	Source (ADaMIG v1.1 or SDTM v3.2 or OCE/OOD v1.3=FDA)	OCE/OOD Additional Information
DTH30TFL	Death Within 30 Days of Last Treatment	Char	Y, Null	N/A	Req	FDA	Flag indicating if subject died within 30 days of last treatment
DTHA30FL	Death After 30 Days of Last Treatment	Char	Y, Null	N/A	Req	FDA	Flag indicating if subject died after 30 days of last treatment
DTHB30FL	Death Within 30 Days of First Treatment	Char	Y, Null	N/A	Req	FDA	Death within 30 days of starting treatment
DTHDT	Date of Death	Num		Perm	Req	ADaM	
DTHDY	Study Day of Death	Num		N/A	Req	ADaM	
DTHCAUS	Cause of Death	Char	See OCE/OOD additional information	Perm	Req	ADaM	Cause of death as listed by investigator on CRF; recommended codelist values include “progressive disease”, “adverse event”, “other”; further describe “other” in DTHCAUSP
DTHCAUSS	Cause of Death Sponsor	Char		N/A	Perm	FDA	Cause of death as determined by sponsor if different than the investigator
DTHCAUSP	Cause Spec for Death	Char		N/A	Req	FDA	Specify “other” as listed in DTHCAUS
LSTALVDT	Date Last Known Alive	Num		Perm	Req	ADaM	
DCSREAS	Reason for Discontinuation from Study	Char		Perm	Req	ADaM	
DCSREASP	Reason Specify for Discont from Study	Char		Perm	Cond	ADaM	Specify “other” as listed in DCSREAS

ADSL Variable Name	Variable Label	Type	Codelist/Controlled Terms	CDISC Core	OCE/OOD Core	Source (ADaMIG v1.1 or SDTM v3.2 or OCE/OOD v1.3=FDA)	OCE/OOD Additional Information
DCTREAS	Reason for Discontinuation of Treatment	Char	See OCE/OOD additional information	Perm	Req	ADaM	Recommended codelist values of “adverse event” or “other”; further describe “other” in DCTREASP; differentiate DCTREAS, DCTREASP, DCTFL, DCTDT, DCTAESP, DCTADY for each drug in a combination therapy regimen
DCTREASP	Reason Specify for Discont of Treatment	Char		Perm	Cond	ADaM	Specify “other” as listed in DCTREAS
DCTFL	Subject Discontinued Treatment Flag	Char	Y, Null	N/A	Req	FDA	Flag indicating if subject discontinued treatment
DCTDT	Treatment Discontinuation Date	Num		N/A	Req	FDA	Date of treatment discontinuation
DCTADY	Study day of Treatment discontinuation	Num		N/A	Req	FDA	Study day defn: date of first drug = day 1
DCUTDT	Data Cutoff Date	Num		N/A	Cond	FDA	Cutoff date for current analysis if different than end of study date
NCTXSDT	Start Date of New Anti-Cancer Therapy	Num		N/A	Req	FDA	Start date of first subsequent anti-cancer treatment.
ECOGBL	Baseline ECOG	Num	0, 1, 2, 3, 4	N/A	Req	FDA	ECOG performance status at baseline (study enrollment)

ADAE – Adverse Events Analysis Dataset (adae.xpt)

Structure: One record per subject per adverse event per start date

- Safety analyses should be completed on the safety population evaluating treatment-emergent adverse events using the definitions below. If sponsors choose to use alternative definitions, they should discuss this with the relevant review division prior to submission of the application.
  - Safety population: patients who received at least one dose of study drug, even if randomized to comparator arm and dosed in error. (Patients dosed with the wrong medication for safety purposes should be analyzed in the arm of the treatment they actually received.)
  - Treatment-emergent adverse events (TEAE): new or worsening events occurring in the safety population at or after the first drug treatment up to and including 30 days after last dose of study drug or the day prior to start of subsequent therapy (whichever comes first). AEs starting more than 30 days after last dose of study drug that were determined by the sponsor to be related to the study drug should also be considered TEAEs.
    - AE records describing the same event should be linked (e.g. if a subject's pancreatitis started at Grade 4 on Day 25 after last dose of study drug and on Day 35 after the last dose of study drug the subject had Grade 5 pancreatitis, these records should be linked, and both should be flagged as TEAEs.)

- **Dataset should include the variables listed below important for the analyses (not an all-inclusive list):**

ADAE Variable Name	Variable Label	Type	Codelist/ Controlled Terms	CDISC Core (SDTM or ADaM)	OCE/OOD Core	Source (ADaMIG v1.1 or SDTM v3.3 or OCE/OOD v1.3=FDA)	OCE/OOD Additional Information
USUBJID	Unique Subject Identifier	Char		Req	Req	STDM	
SAFFL	Safety Population Flag	Char	Y, Null	Cond	Req	ADaM	
TRTFL	Treated Population Flag	Char	Y, Null	N/A	Perm	FDA	Patients who received at least one dose of all drugs in a combination regimen; only relevant for multi-drug regimens
DTHFL	Subject Death Flag	Char	Y, Null	Exp	Req	STDM	Flag indicating if subject died before end of study (or data cutoff, if applicable)
DTHDT	Date of Death	Num		Perm	Req	ADaM	

ADAE Variable Name	Variable Label	Type	Codelist/ Controlled Terms	CDISC Core (SDTM or ADaM)	OCE/OOD Core	Source (ADaMIG v1.1 or SDTM v3.3 or OCE/OOD v1.3=FDA)	OCE/OOD Additional Information
TRT01A	Actual Treatment for Period 01	Char		Cond	Req	ADaM	
TR01SDT	Date of First Exposure in Period 01	Num		Perm	Req	ADaM	
TR01EDT	Date of Last Exposure in Period 01	Num		Perm	Req	ADaM	
TRTxxA	Actual Treatment for Period xx	Char		Perm	Cond	ADaM	Required if there are multiple treatment periods; Use TRTA if only one treatment period is relevant for the analyses
TRxxSDT	Date of First Exposure in Period xx	Num		Perm	Cond	ADaM	Required if there are multiple treatment periods
TRxxEDT	Date of Last Exposure in Period xx	Num		Perm	Cond	ADaM	Required if there are multiple treatment periods
TRTSDT	Date of First Exposure to Treatment	Num		Perm	Req	ADaM	
TRTEDT	Date of Last Exposure to Treatment	Num		Perm	Req	ADaM	
TRTEDY	Study Day of Last Exposure to Treatment	Num		N/A	Req	FDA	Study day of last exposure to treatment
APERIOD	Period	Num		Perm	Cond	ADaM	Required if there are multiple treatment periods
AESEQ	Sequence Number	Num		Req	Req	SDTM	
AETERM	Reported Term for the Adverse Event	Char		Req	Req	SDTM	
AEDECOD	Dictionary-Derived Term	Char	MedDRA	Cond	Req	SDTM	
AEBODSYS	Body System or Organ Class	Char	MedDRA	Cond	Req	SDTM	
AEHLT	High Level Term	Char	MedDRA	Cond	Req	SDTM	

ADAE Variable Name	Variable Label	Type	Codelist/ Controlled Terms	CDISC Core (SDTM or ADaM)	OCE/OOD Core	Source (ADaMIG v1.1 or SDTM v3.3 or OCE/OOD v1.3=FDA)	OCE/OOD Additional Information
AEHLGT	High Level Group Term	Char	MedDRA	Cond	Req	SDTM	
TRTEMFL	Treatment Emergent Analysis Flag	Char	Y	Cond	Req	ADaM	See information above about the definition of treatment emergent adverse events.
TREMzzFL	Treatment Emergent Analysis zz Flag	Char	Y	N/A	Cond	FDA	If there is a significant change in regimen or treatment across periods (e.g., cross-over or open-label extension for subject who was on placebo), include a treatment emergent flag for each new regimen or treatment.
AEACN	Action Taken with Study Treatment	Char	(ACN)	Perm	Req	SDTM	
AACNSD01	Analysis Action Taken with Study Drug 01	Char	(ACN)	N/A	Cond	FDA	Create one analysis action taken variable for each action taken with study drug collected in AEACN and / or SUPPAE.
AACNSDzz	Analysis Action Taken with Study Drug zz	Char	(ACN)	N/A	Cond	FDA	Required if action taken with study treatment was captured for more than one study drug. See AACNSD01.
AEACNOTH	Other Action Taken	Char		Perm	Cond	SDTM	Describe “other” from AEACN
AETOXGR	Standard Toxicity Grade	Char	1, 2, 3, 4, 5, null	Perm	Req	SDTM	Use CTCAE toxicity grade if applicable; if using other grading system for certain events, specify this in Reviewer’s guide
AETOXGRN	Standard Toxicity Grade (N)	Num	1, 2, 3, 4, 5, null	N/A	Req	FDA	Numeric indicator for AETOXGR

ADAE Variable Name	Variable Label	Type	Codelist/ Controlled Terms	CDISC Core (SDTM or ADaM)	OCE/OOD Core	Source (ADaMIG v1.1 or SDTM v3.3 or OCE/OOD v1.3=FDA)	OCE/OOD Additional Information
ATOXGR	Analysis Toxicity Grade	Char	1, 2, 3, 4, 5, null		Req	ADaM	Toxicity grade used in the analyses
ATOXGRN	Analysis Toxicity Grade (N)	Num	1, 2, 3, 4, 5, null		Req	ADaM	Numeric indicator for ATOXGR
AESER	Serious Event	Char	Y, N	Exp	Req	SDTM	
AEOSIxxFL	AEOSI Category Flag	Char	Y		Perm	ADaM	Create separate variable for each adverse event of special interest category
AEOUT	Outcome of Adverse Event	Char	(OUT)	Perm	Req	SDTM	
AEREL	Causality	Char		Exp	Cond	SDTM	Investigator-assessed causality as noted on CRF. If relationship to more than one study drug was captured, provide separate variables
AERELS	Sponsor assessment of relatedness	Char		N/A	Cond	ADaM	Sponsor assessment of relatedness if applicable for the application
AESTDTC	Start Date/Time of Adverse Event	Char	ISO 8601	Exp	Req	SDTM	
AEENDTC	End Date/Time of Adverse Event	Char	ISO 8601	Exp	Req	SDTM	
ASTDT	Analysis Start Date	Num		Cond	Req	ADaM	
AENDT	Analysis End Date	Num		Cond	Req	ADaM	
AEDUR	Duration of Adverse Event	Char	ISO 8601	Perm	Perm	SDTM	

ADAE Variable Name	Variable Label	Type	Codelist/ Controlled Terms	CDISC Core (SDTM or ADaM)	OCE/OOD Core	Source (ADaMIG v1.1 or SDTM v3.3 or OCE/OOD v1.3=FDA)	OCE/OOD Additional Information
ADURN	Analysis Duration (N)	Num		Perm	Req	ADaM	
ADURU	Analysis Duration Units	Char		Cond	Req	ADaM	
AESTDY	Study Day of Start of Adverse Event	Num		Perm	Req	SDTM	RFSTDTC should be first day of treatment =
AEENDY	Study Day of End of Adverse Event	Num		Perm	Req	SDTM	RFSTDTC should be first day of treatment = day 1
AECONTRT	Concomitant or Additional Trtmnt Given	Char	Y,null	Perm	Cond	SDTM	If concomitant treatments are linked to AEs
CONTRSP	Specific CMED or Additional Trtmnt Given	Char		N/A	Cond	FDA	Specify treatment if AECONTRT = "Y"
AESDTH	Results in Death	Char	Y, null	Perm	Req	SDTM	
GRPID	Group ID	Char			Req	FDA	Used to tie together a block of records for a subject that belong to the same adverse event; e.g., grade 1 pyrexia which progresses to grade 2 should be identified with the same GRPID

Values in parenthesis are the names of CDISC Controlled Terminology codelists

ADLB: Laboratory Analysis Dataset (adlb.xpt):

Structure: One record per subject per visit per parameter

- The standard in OCE/OOD for analyses reported in the laboratory abnormalities table in product labeling is to use patients with a baseline and at least one post-baseline laboratory evaluation as the denominator for each test. The denominator will vary from test to test. This is to ensure that all patients who had laboratory evaluations done both pre and post-drug exposure for each test are captured.
- Two columns for toxicity grade should be populated for consistency in evaluation to account for labs with bidirectional grading (e.g. potassium)

- A flag, EVLLBFL, should be included to identify all on-study values for those lab parameters where a subject has both a baseline and at least one on-study value for a specified laboratory test that occur during the period defined for the Treatment Emergent adverse event flag (TRTEMFL) for the adverse event dataset to define all evaluable laboratory values to be included in the safety analyses
- The FDA algorithm generally considers all lab values with an associated analysis toxicity grade (ATOXGRN), for patients with a baseline value (ABLFL = "Y") and at least one post-baseline value, defined labs designated with an evaluable lab flag (EVLLBFL). Laboratory values are considered to be worsening if the maximum toxicity grade is greater than the toxicity grade at baseline for the specific laboratory measurement and patient. Patients who move from a baseline low grade to a high grade, or from a baseline high grade to a low grade, are also considered worsening for any tox grade > 0. ATOXGRL/N and ATOXGRH/N columns will be used to determine high and low grades.
- Laboratory values should be graded as per CTCAE if applicable. Analyses for non-CTCAE gradable laboratory values should be clearly described in the reviewer's guide
- For each type of lab test, only one standard unit should be used, which is defined in LBSTRESU. LBSTRESN (lab test value in standard unit), LBSTNRLO (lower limit of normal in standard unit), and LBSTNRHI (higher limit of normal in standard unit) should be consistent with LBSTRESU.
- **Datasets should include the variables listed below important for the analyses (not an all-inclusive list):**

ADLB Variable Name	Variable Label	Type	Codelist/ Controlled Terms	CDISC Core	OCE/OOD Core (SDTM or ADaM)	CDISC Variable (ADaMIG v1.1 or SDTM v3.3 or OCE/OOD v1.3=FDA)	OCE/OOD Additional Information
USUBJID	Unique Subject Identifier	Char		Req	Req	SDTM	
SAFFL	Safety Population Flag	Char	Y, Null	Cond	Req	ADaM	
TRTFL	Treated Population Flag	Char	Y, Null	N/A	Perm	FDA	Patients who received at least one dose of all drugs in a combination regimen
DTHFL	Subject Death Flag	Char	Y, Null	Exp	Req	SDTM	Flag indicating if subject died before end of study (or data cutoff, if applicable)
TRT01A	Actual Treatment for Period 01	Char		Cond	Req	ADaM	
TR01SDT	Date of First Exposure in Period 01	Num		Req	Req	ADaM	
TR01EDT	Date of Last Exposure in Period 01	Num		Cond	Req	ADaM	
TRTxxA	Actual Treatment for Period xx	Char		Cond	Cond	ADaM	Required if there are multiple treatment periods

ADLB Variable Name	Variable Label	Type	Codelist/ Controlled Terms	CDISC Core	OCE/OOD Core (SDTM or ADaM)	CDISC Variable (ADaMIG v1.1 or SDTM v3.3 or OCE/OOD v1.3=FDA)	OCE/OOD Additional Information
TRxxSDT	Date of First Exposure in Period xx	Num		Cond	Cond	ADaM	Required if there are multiple treatment periods
TRxxEDT	Date of Last Exposure in Period xx	Num		Cond	Cond	ADaM	Required if there are multiple treatment periods
AVISIT	Analysis Visit	Char		Cond	Cond	ADaM	Required if there are multiple treatment periods
ADT	Analysis Date	Num		Perm	Req	ADaM	
ADY	Analysis Relative Day	Num		Perm	Req	ADaM	
APERIOD	Period	Num		Perm	Req	ADaM	
PARAM	Parameter	Char		Req	Req	ADaM	
PARAMCD	Parameter Code	Char		Req	Req	ADaM	
AVAL	Analysis Value	Num		Cond	Req	ADaM	
AVALC	Analysis Value (C)	Char		Cond	Cond	ADaM	
AVALU	Analysis Value Unit	Char		N/A	Req	FDA	Include even if unit is included in PARAM description.
BASE	Baseline Value	Num		Cond	Cond	ADaM	
CHG	Change from Baseline	Num		Perm	Perm	ADaM	
PCHG	Percent Change from Baseline	Num		Perm	Perm	ADaM	
ABLFL	Baseline Record Flag	Char	Y, N	Cond	Req	ADaM	
ANRLO	Analysis Normal Range Lower Limit	Num		Perm	Req	ADaM	
ANRHI	Analysis Normal Range Upper Limit	Num		Perm	Req	ADaM	

ADLB Variable Name	Variable Label	Type	Codelist/ Controlled Terms	CDISC Core	OCE/OOD Core (SDTM or ADaM)	CDISC Variable (ADaMIG v1.1 or SDTM v3.3 or OCE/OOD v1.3=FDA)	OCE/OOD Additional Information
ANRIND	Analysis Reference Range Indicator	Char	High, low, normal, abnormal	Perm	Req	ADaM	Use high, low, normal values
BNRIND	Baseline Range Indicator	Char	High, low, normal, abnormal	N/A	Req	FDA	Equal to ANRIND at ABLFL==Y; Use high, low, normal
ATOXGRL	Analysis Toxicity Grade Low	Char	0, 1, 2, 3, 4, Null	Perm	Req	ADaM	CTCAE grade (if applicable) if the toxicity grade is a low grade; if another grading system is used, provide details of this grading system in Study Data Reviewers Guide
ATOXGRLN	Analysis Toxicity Grade Low (N)	Num	0, 1, 2, 3, 4, Null	Perm	Req	ADaM	Numeric version of ATOXGRL
ATOXGRH	Analysis Toxicity Grade High	Char	0, 1, 2, 3, 4, Null	Perm	Req	ADaM	CTCAE grade (if applicable) if the toxicity grade is a high grade; if another grading system is used, provide details of this grading system in Study Data Reviewers Guide
ATOXGRHN	Analysis Toxicity Grade High (N)	Num	0, 1, 2, 3, 4, Null	Perm	Req	ADaM	Numeric version of ATOXGRH
BTOXGRL	Baseline Toxicity Grade Low	Char	0, 1, 2, 3, 4, Null	Perm	Req	ADaM	CTCAE grade (if applicable); if another grading system is used, provide details of this grading system in Study Data Reviewers Guide
BTOXGRLN	Baseline Toxicity Grade Low (N)	Num	0, 1, 2, 3, 4, Null	Perm	Req	ADaM	Numeric version of BTOXGRL
BTOXGRH	Baseline Toxicity Grade High	Char	0, 1, 2, 3, 4, Null	Perm	Req	ADaM	CTCAE grade (if applicable); if another grading system is used, provide details of this grading system in Study Data Reviewers Guide

ADLB Variable Name	Variable Label	Type	Codelist/ Controlled Terms	CDISC Core	OCE/OOD Core (SDTM or ADaM)	CDISC Variable (ADaMIG v1.1 or SDTM v3.3 or OCE/OOD v1.3=FDA)	OCE/OOD Additional Information
BTOXGRHN	Baseline Toxicity Grade High (N)	Num	0, 1, 2, 3, 4, Null	Perm	Req	ADaM	Numeric version of BTOXGRH
EVLLBFL	Evaluable Lab Flag	Char	Y, N	N/A	Req	FDA	Flag baseline and all on-study values for those lab parameters where a subject has both a baseline and at least one on-study value for a specified laboratory test. Only include laboratory values that occur during the period defined for the Treatment Emergent adverse event flag (TRTEMFL) for the adverse event dataset
LBSEQ	Sequence Number	Num		Req	Req	SDTM	
LBTESTCD	Lab Test or Examination Short Name	Char		Req	Req	SDTM	
LBTEST	Lab Test or Examination Name	Char		Req	Req	SDTM	
LBSTRESN	Numeric Result/Finding in Standard Units	Num		Exp	Req	SDTM	
LBSTRESC	Character Result/Finding in Std Format	Char	(LBSTRESC)	Exp	Req	SDTM	
LBSTRESU	Standard Units	Char	(UNIT)	Exp	Req	SDTM	

ADEX: Exposure Analysis Dataset (adex.xpt)

Structure: One record per subject per treatment (EXTRT) per start date.

- Include variables and parameters where applicable for trial design.
- The timing for ADEX is based on start date, but VISIT and VISITNUM should be added if present in EX.
- The timing for ADEXSUM is AEVLINT, Analysis Interval for Evaluation. AVISIT should not be present. ADT should be included if there are any sponsor-defined parameter that flag a specific value over an evaluation interval (e.g., first value or highest value) to indicate the date that the value in AVAL was observed.

ADEX Variable Name	Variable Label	Type	Codelist/ Controlled Terms	CDISC Core (SDTM or ADaM	OCE/OOD Core	CDISC Variable (ADaMIG v1.1 or SDTM v3.3 or OCE/OOD v1.3=FDA)	OCE/OOD Additional Information
USUBJID	Unique Subject Identifier	Char		Req	Req	SDTM	
SAFFL	Safety Population Flag	Char	Y, Null	Cond	Req	ADaM	
TRTFL	Treated Population Flag	Char	Y, Null	N/A	Perm	FDA	Patients who received at least one dose of all drugs in a combination regimen
DTHFL	Subject Death Flag	Char	Y, Null	Exp	Req	SDTM	Flag indicating if subject died before end of study (or data cutoff, if applicable)
TRT01A	Actual Treatment for Period 01	Char		Cond	Req	ADaM	
TR01SDT	Date of First Exposure in Period 01	Num		Req	Req	ADaM	
TR01EDT	Date of Last Exposure in Period 01	Num		Req	Req	ADaM	
TR01STM	Time of First Exposure in Period 01	Num		Cond	Cond	ADaM	
TR01ETM	Time of Last Exposure in Period 01	Num		Cond	Cond	ADaM	
TRTxxA	Actual Treatment for Period xx	Char		Cond	Cond	ADaM	
TRxxSDT	Date of First Exposure in Period xx	Num		Cond	Cond	ADaM	
TRxxEDT	Date of Last Exposure in Period xx	Num		Cond	Cond	ADaM	

ADEX Variable Name	Variable Label	Type	Codelist/ Controlled Terms	CDISC Core (SDTM or ADaM	OCE/OOD Core	CDISC Variable (ADaMIG v1.1 or SDTM v3.3 or OCE/OOD v1.3=FDA)	OCE/OOD Additional Information
TRxxSTM	Time of First Exposure in Period xx	Num		Cond	Cond	ADaM	
TRxxETM	Time of Last Exposure in Period xx	Num		Cond	Cond	ADaM	
TRTSDT	Date of First Exposure to Treatment	Num		Cond	Cond	ADaM	
TRTEDT	Date of Last Exposure to Treatment	Num		Cond	Cond	ADaM	
TRTEDY	Study Day of Last Exposure to Treatment	Num		N/A	Req	FDA	Study Day of Last Exposure to Treatment
EXTRT	Name of Treatment	Char		Req	Req	SDTM	
EXDOSE	Dose	Num					
EXDOSEU	Dose Units	Char	(UNIT)	Exp	Req	SDTM	
EXDOSFRM	Dose Form	Char	(FRM)	Exp	Cond	SDTM	
EXDOSFRQ	Dosing Frequency Per Interval	Char	(FREQ)	Exp	Cond	SDTM	
EXDOSRGM	Intended Dose Regimen	Char		Perm	Cond	SDTM	
EXROUTE	Route of Administration	Char	(ROUTE)	Perm	Req	SDTM	
EXADJ	Reason for Dose Adjustment	Char		Perm	Req	SDTM	
EXADJOTH	Reason for Dose Adjustment Other	Char		N/A	Cond	FDA	Specify “other” as listed in EXADJ
EPOCH	Epoch	Char	(EPOCH)	Perm	Cond	SDTM	Sponsors should discuss definition of Epoch with review team ahead of submission.
EXSTDTC	Start Date/Time of Treatment	Char	ISO 8601	Ex	Req	SDTM	

ADEX Variable Name	Variable Label	Type	Codelist/ Controlled Terms	CDISC Core (SDTM or ADaM	OCE/OOD Core	CDISC Variable (ADaMIG v1.1 or SDTM v3.3 or OCE/OOD v1.3=FDA)	OCE/OOD Additional Information
EXENDTC	End Date/Time of Treatment	Char	ISO 8601	Ex	Req	SDTM	
EXSTDY	Study Day of Start of Treatment	Num		Perm	Req	SDTM	
EXENDY	Study Day of End of Treatment	Num		Perm	Req	SDTM	
EXSEQ	Sequence Number	Num		Req	Req	SDTM	
ASTDT	Analysis Start Date	Num		Perm	Req	ADaM	
AENDT	Analysis End Date	Num		Perm	Req	ADaM	
ASTM	Analysis Start Time	Num		Perm	Cond	ADaM	For infusions
AETM	Analysis End Time	Num		Perm	Cond	ADaM	For infusions
EXDUR	Duration of Treatment	Char	ISO 8601	Perm	Cond	SDTM	
EXDURD	Duration of Treatment (days)	Num		N/A	Cond	FDA	Derived treatment duration (days)
DOSREDFL	Dose Reduced Flag	Char	Y, N	N/A	Cond	FDA	Indicates dose was changed from intended dose
DOSINTFL	Dose Interrupted Flag	Char	Y, N	N/A	Cond	FDA	Indicates dosing was interrupted
DOSDELFL	Dose Delay Flag	Char	Y, N	N/A	Cond	FDA	Indicates dose was delayed

ADEXSUM: Exposure Summary Analysis Dataset (adexsum.xpt)

Structure: One record per subject per parameter per analysis interval

ADEXSUM Variable Name	Variable Label	Type	Codelist/ Controlled Terms	CDISC Core (SDTM or ADaM)	OCE/OOD Core	CDISC Variable (ADaMIG v1.1 or SDTM v3.3 or OCE/OOD v1.3=FDA)	OCE/OOD Additional Information
USUBJID	Unique Subject Identifier	Char		Req	Req	SDTM	
SAFFL	Safety Population Flag	Char	Y, Null	Cond	Req	ADaM	
TRTFL	Treated Population Flag	Char	Y, Null	N/A	Perm	FDA	Patients who received at least one dose of all drugs in a combination regimen
DTHFL	Subject Death Flag	Char	Y, Null	Exp	Req	SDTM	Flag indicating if subject died before end of study (or data cutoff, if applicable)
TRT01P	Planned Treatment for Period 01	Char		Perm	Req	ADaM	
TRTxxP	Planned Treatment for Period xx	Char		Perm	Cond	ADaM	
TRT01A	Actual Treatment for Period 01	Char		Perm	Req	ADaM	
TRTxxA	Actual Treatment for Period xx	Char		Perm	Cond	ADaM	
TR01SDT	Date of First Exposure in Period 01	Num		Perm	Req	ADaM	
TR01EDT	Date of Last Exposure in Period 01	Num		Perm	Req	ADaM	
TRxxSDT	Date of First Exposure in Period xx	Num		Perm	Cond	ADaM	
TRxxEDT	Date of Last Exposure in Period xx	Num		Perm	Cond	ADaM	
AEVLINT	Analysis Interval for Evaluation	Char		N/A	Req	FDA	Describes the interval of time that was evaluated to derive AVAL, e.g., Overall, Cycle X, etc.
PARQUAL	Parameter Qualifier	Char		N/A	Req	FDA	Description of the treatment summarized on each record. Equal to EXTRT for summaries/ evaluations of individual treatments, or 'All' for summaries / evaluations across all treatments.

ADEXSUM Variable Name	Variable Label	Type	Codelist/ Controlled Terms	CDISC Core (SDTM or ADaM)	OCE/OOD Core	CDISC Variable (ADaMIG v1.1 or SDTM v3.3 or OCE/OOD v1.3=FDA)	OCE/OOD Additional Information
PARAM	Parameter	Char		Req	Req	ADaM	
PARAMCD	Parameter Code	Char		Req	Req	ADaM	
AVAL	Analysis Value	Num		Cond	Req	ADaM	Populated only when PARAM analysis value is numeric
AVALC	Analysis Value (C)	Char		Cond	Req	ADaM	Populated only when PARAM analysis value is a character
AVALU	Analysis Value Unit	Char		N/A	Req	FDA	Unit of AVAL

ADEXSUM: Value-level Metadata

ADEXSUM AVAL/AVALC	AEVLINT	PARQUAL	PARAMCD	PARAM	OCE/OOD Notes
AVAL	Overall	All	TRTDURD	Treatment Duration Actual in Days	Total duration of treatment over all values of EXTRT for each subject. AVALU should be days.
AVAL	Overall	All	TRTPDURD	Treatment Duration Planned in Days	
AVAL	Overall	All	NADMIN	Nr of Actual Study Drug Administrations	Number of treatment administrations for all values of EXTRT combined per subject
AVAL	Overall	All	NUMCYC	Number of Actual Cycles	Total number of cycles across all treatments for each subject. Sponsors should discuss definition of cycles with review team ahead of submission, if applicable.
AVAL	Overall	All	NUMPCYC	Number of Planned Cycles	
AVAL	Overall and <by cycle>	<each value of EXTRT>	CUMPLDOS	Cumulative Planned Dose	Cumulative planned dose for each treatment for each subject over each evaluation interval (AEVLINT). Unit should be captured in AVALU.
AVAL	Overall and <by cycle>	<each value of EXTRT>	CUMACDOS	Cumulative Actual Dose	Cumulative actual dose for each treatment for each subject over each evaluation interval (AEVLINT). Unit should be captured in AVALU.

ADEXSUM AVAL/AVALC	AEVLINT	PARQUAL	PARAMCD	PARAM	OCE/OOD Notes
AVAL	Overall and <by cycle>	<each value of EXTRT>	TOTPLDOS	Total Planned Dose	Total planned dose for each treatment for each subject over each evaluation interval. Unit should be captured in AVALU.
AVAL	Overall and <by cycle>	<each value of EXTRT>	TOTACDOS	Total Actual Dose	Total actual dose for each treatment for each subject over each evaluation interval. Unit should be captured in AVALU.
AVAL	Overall and <by cycle>	< each value of EXTRT>	RDOSINT	Relative Dose Intensity (%)	Ratio of actual to planned dose expressed as percentage for each subject over each evaluation interval.
AVALC	Overall	<each value of EXTRT>	DELAY	Any Dose Delays	Y if there were any dose delays over each evaluation interval.
AVAL	Overall	<each value of EXTRT>	NDELAY	Number of Dose Delays	Total number of dose delays over each evaluation interval.
AVAL	Overall	<each value of EXTRT>	DURDLAY	Total Duration of Delays	Total duration of delays. Unit should be in AVALU.
AVALC	Overall	ALL	CYCDLAY	Any Cycle Delays	Y if there were any cycle delays.
AVAL	Overall	ALL	NCYCDLAY	Number of Cycle Delays	Number of Cycle Delays.
AVALC	Overall	<each value of EXTRT>	DOSDCTS	Any Dose Discontinuations	Y if there were any dose discontinuations.
AVAL	Overall	<each value of EXTRT>	NDOSDCTS	Number of Dose Discontinuations	Total number of dose discontinuations.

ADEXSUM AVAL/AVALC	AEVLINT	PARQUAL	PARAMCD	PARAM	OCE/OOD Notes
AVALC	Overall	<each value of EXTRT>	DOSRED	Any Dose Reductions	Y if there were any dose reductions
AVALC	Overall	<each value of EXTRT>	NDOSRED	Number of Dose Reductions	Number of dose reductions
AVALC	Overall	<each value of EXTRT>	DOSINT	Any Dose Interruptions	Y if there were any dose interruptions
AVALC	Overall	<each value of EXTRT>	NDOSINT	Number of Dose Interruptions	Number of dose interruptions
AVALC	Overall	ALL	TRTDCT	Treatment Discontinued	Y if treatment permanently discontinued for all drugs.

ADCRSNT – Adverse Events Analysis Dataset for Cytokine Release Syndrome (CRS) and Neurotoxicity (NT) (adcrsnt.xpt)

Structure: One record per subject per adverse event per start date

- **Dataset should include the variables listed below important for the analyses (not an all-inclusive list):**

ADCRSNT Variable Name	Variable Label	Type	Codelist/ Controlled Terms	CDISC Core (SDTM or ADaM)	FDA Core	Source (ADaMIG v1.1 or SDTM v3.3 or FDA)	FDA Additional Information
USUBJID	Unique Subject Identifier	Char		Req	Req	STDM	
SAFFL	Safety Population Flag	Char	Y, Null	Cond	Req	ADaM	
TRTFL	Treated Population Flag	Char	Y, Null	N/A	Perm	FDA	Patients who received at least one dose of all drugs in a combination regimen
DTHFL	Subject Death Flag	Char	Y, Null	Exp	Req	STDM	Flag indicating if subject died before end of study (or data cutoff, if applicable)
DTHDT	Date of Death	Num		Perm	Req	ADaM	
TRT01A	Actual Treatment for Period 01	Char		Cond	Req	ADaM	
TR01SDT	Date of First Exposure in Period 01	Num		Perm	Req	ADaM	
TR01EDT	Date of Last Exposure in Period 01	Num		Perm	Req	ADaM	
TRTxxA	Actual Treatment for Period xx	Char		Perm	Cond	ADaM	Required if there are multiple treatment periods; Use TRTA if only one treatment period is relevant for the analyses
TRxxSDT	Date of First Exposure in Period xx	Num		Perm	Cond	ADaM	Required if there are multiple treatment periods
TRxxEDT	Date of Last Exposure in Period xx	Num		Perm	Cond	ADaM	Required if there are multiple treatment periods
TRTSDT	Date of First Exposure to Treatment	Num		Perm	Req	ADaM	

ADCRSNT Variable Name	Variable Label	Type	Codelist/ Controlled Terms	CDISC Core (SDTM or ADaM)	FDA Core	Source (ADaMIG v1.1 or SDTM v3.3 or FDA)	FDA Additional Information
TRTEDT	Date of Last Exposure to Treatment	Num		Perm	Req	ADaM	
TRTEDY	Study Day of Last Exposure to Treatment	Num		N/A	Req	FDA	Study day of last exposure to treatment
APERIOD	Period	Num		Perm	Cond	ADaM	Required if there are multiple treatment periods
APERSDY	Analysis Period Start Day	Num				FDA	Study day of Start date of APERIOD
APEREDY	Analysis Period End Day	NUM				FDA	Study day of End date of APERIOD
AESEQ	Sequence Number	Num		Req	Req	SDTM	
AETERM	Reported Term for the Adverse Event	Char		Req	Req	SDTM	
AEDECOD	Dictionary-Derived Term	Char	MedDRA	Cond	Req	SDTM	
AEBODSYS	Body System or Organ Class	Char	MedDRA	Cond	Req	SDTM	
FDAGT	FDA Grouped Term	Char	CRS, NT			FDA	FDA-defined composite grouping of MedDRA Preferred Terms for CRS and NT
TRTEMFL	Treatment Emergent Analysis Flag	Char	Y, Null	Cond	Req	ADaM	See information above about the definition of treatment emergent adverse events.
AEACN	Action Taken with Study Treatment	Char	(ACN)	Perm	Req	SDTM	
AETOXGR	Standard Toxicity Grade	Char	0, 1, 2, 3, 4, 5	Perm	Req	SDTM	Use CTCAE toxicity grade if applicable; if using other grading system for certain events, specify this in Reviewer's guide
AETOXGRN	Standard Toxicity Grade (N)	Num	0, 1, 2, 3, 4, 5	N/A	Req	FDA	Numeric indicator for AETOXGR

ADCRSNT Variable Name	Variable Label	Type	Codelist/ Controlled Terms	CDISC Core (SDTM or ADaM)	FDA Core	Source (ADaMIG v1.1 or SDTM v3.3 or FDA)	FDA Additional Information
ATOXGR	Analysis Toxicity Grade						Toxicity grade used in the analyses
ATOXGRN	Analysis Toxicity Grade (N)						Numeric indicator for ATOXGR
AEOUT	Outcome of Adverse Event	Char	(OUT)	Perm	Req	SDTM	
AESTDTC	Start Date/Time of Adverse Event	Char	ISO 8601	Exp	Req	SDTM	
AEENDTC	End Date/Time of Adverse Event	Char	ISO 8601	Exp	Req	SDTM	
ASTDT	Analysis Start Date	Num		Cond	Req	ADaM	
AENDT	Analysis End Date	Num		Cond	Req	ADaM	
AEDUR	Duration of Adverse Event	Char	ISO 8601	Perm	Perm	SDTM	
ADURN	Analysis Duration (N)	Num		Perm	Req	ADaM	
ADURU	Analysis Duration Units	Char		Cond	Req	ADaM	
AESTDY	Study Day of Start of Adverse Event	Num		Perm	Req	SDTM	RFSTDTC should be first day of treatment = day 1
AEENDY	Study Day of End of Adverse Event	Num		Perm	Req	SDTM	RFSTDTC should be first day of treatment = day 1
AESDTH	Results in Death	Char	Y, N	Perm	Req	SDTM	
CRSFLR	Record level CRS flag	Char	Y,N			FDA	Indicates if the record is a CRS event as defined in FDAGT
NTFLR	Record level NT flag	Char	Y, N			FDA	Indicates if the record is a NT event as defined in FDAGT
CRSFLS	Subject level CRS flag by Period	Char	Y, N			FDA	Indicates if the subject experienced a CRS event during treatment period specified in APERIOD

ADCRSNT Variable Name	Variable Label	Type	Codelist/ Controlled Terms	CDISC Core (SDTM or ADaM)	FDA Core	Source (ADaMIG v1.1 or SDTM v3.3 or FDA)	FDA Additional Information
NTFLS	Subject level NT flag by Period	Char	Y, N			FDA	Indicates if the subject experience a NT event during treatment period specified in APERIOD
CRSONFL	Ongoing CRS flag	Char	Y, N			FDA	Indicates if CRS is ongoing at end of study or date last known alive
NTONFL	Ongoing NT flag	Char	Y, N			FDA	Indicates if NT is ongoing at end of study or date last known alive
CRSSTDY	Start day of CRS by subject and period	Char	Num			FDA	AESTDY of first CRS event for subject in APERIOD
CRSENDY	End day of CRS by subject and period	Char	Num			FDA	AEENDY of last CRS event for subject in APERIOD
NTSTDY	Start day of NT by subject and period	Char	Num			FDA	AESTDY of first NT event for subject in APERIOD
NTENDY	End day of NT by subject and period	Char	Num			FDA	AEENDY of last NT event for subject in APERIOD
CRSMAXTX	CRS max tox grade by subject-period	Char	Num			FDA	CRS max toxicity grade for subject in APERIOD
NTMAXTX	NT max tox grade by subject-period	Char	Num			FDA	NT max toxicity grade for subject in APERIOD
CRSMXSDY	Time to CRS max tox grade by subject-period	Char	Num			FDA	AESTDY of first CRS event with max toxicity grade (CRSMAXTX) for subject in APERIOD
NTMXSDY	Time to NT max tox grade by subject-period	Char	Num			FDA	AESTDY of first NT event with max toxicity grade (NTMAXTX) for subject in APERIOD
CRSDUR	Time to CRS resolution by subject-period	Char	Num			FDA	CRSENDY – CRSSTDY + 1
NTDUR	Time to NT resolution by subject-period	Char	Num			FDA	NTENDY – NTSTDY + 1

Values in parenthesis are the names of CDISC Controlled Terminology codelists

TS: Trial Summary Table (ts.xpt)

Structure: One record per trial summary parameter value

- In addition to the FDA desired elements from the current version of the Study Data Technical Conformance Guide, the dataset should include the variables listed below (not an all-inclusive list):

Trial Summary Codes

TSPARMCD	TSPARM	TSVAL (Codelist or Format)	Record with this Parameter	OCE/OOD Additional Information
TITLE	Trial Title	Char		
STUDYID	Study Identifier	Char		
REGID	Registry Identifier	Char		NCT number
STUDYIND	IND Where Trial Conducted	Char		IND number under which trial was conducted
SPONSOR	Clinical Study Sponsor	Char		
INDIC	Trial Disease/Condition Indication	Char		Use SnowMed terminology
INDICP	Proposed Indication	Char		Use proposed label indication
STYPE	Study Type	Char	Interventional, observational	
NARMS	Planned Number of Arms	Num		

TSPARMCD	TSPARM	TSVAL (Codelist or Format)	Record with this Parameter	OCE/OOD Additional Information
RANDOM	Trial is Randomized	Char	Y, N	
RANDQT	Randomization Quotient	Num		
ADDON	Added on to Existing Treatments	Char	Y, N	
STRATFCT	Stratification Factors	Char		Repeat as necessary
TBLIND	Trial Blinding Schema	Char	Single blind, double blind, open label	
INTMODEL	Intervention model	Char	Cross-over	
TCNTRL	Control Type	Char	Active, placebo, best supportive care, none	
TPHASE	Phase of Trial	Char	Phase 1, Phase 1/2, Phase 2/3, Phase 3, post-marketing	Generally, dose-finding=phase 1, therapeutic exploratory=phase 2, therapeutic confirmatory=phase 3
TPIVOTAL	Trial Pivotal	Char	Y, N	Is the trial the main trial supporting approval?
PLANSUB	Planned Number of Subjects	Num		
ACTSUB	Actual Number of Subjects	Num		
AGEMAX	Planned Maximum Age of Subjects	Char		
AGEMIN	Planned Minimum Age of Subjects	Char		
TRT	Investigational Therapy or Treatment	Char		Used established name (INN or USAN); repeat as necessary

TSPARMCD	TSPARM	TSVAL (Codelist or Format)	Record with this Parameter	OCE/OOD Additional Information
TRTUNII	Investigational Drug Number			Use UNII
PCLAS	Pharmacologic Class	NDF-RT		Use NDF-RT
PCLASATC	Pharmacologic Class ATC	WHO ATC		Use WHO ATC
ROUTE	Route of Administration			
DOSE	Dose per Administration			
DOSFRQ	Dosing Frequency			
DOSU	Dose Units			
TRTTGT	Drug Target			Select primary target for multi-targeted drugs
TRTBIO	Biomarker for patient selection			Name of biomarker(s)
TRTTST	Diagnostic Test			Type of test, name and, proposed to be companion or complementary
TRTTSTR	Diagnostic Test Result			
COMPTRT	Comparative Treatment Name			Use established names (INN, USAN) for comparator treatments
OBJPRIM	Trial Primary Objective			Use as many rows as needed
OBJSEC	Trial Secondary Objective			Use as many rows as needed
OBJEXP	Trial Exploratory Objective			Use as many rows as needed
PBJPRO	Trial PRO Objective			Trial Patient Reported Outcome Objective; Use as many rows as needed

TSPARMCD	TSPARM	TSVAL (Codelist or Format)	Record with this Parameter	OCE/OOD Additional Information
OUTMSPRI	Primary Outcome Measure			Overall survival, Progression free survivalUse as many rows as needed
OUTMSSEC	Secondary Outcome Measure			Use as many rows as needed
OUTMSEXP	Exploratory Outcome Measure			Use as many rows as needed
SSTDTC	Study Start Date			
SENDTC	Study End Date			
DCUTDESC	Data Cutoff Description			GRPID relates DCUTDTC to DCUTDESC.
DCUTDTC	Data Cutoff Date			GRPID relates DCUTDTC to DCUTDESC.

Major Revision History Table

Date	Version	Summary of Changes
7-2019	1.0	Initial Version
11-2019	1.1	Modified several variable names for CDISC compliance; added notes for some OOD-specific variables

2-2020	1.2	Added ts.xpt; Added some additional explanations and standard CDISC variables
2-2021	1.3	Modified several variable names for CDISC compliance; added notes for some OOD-specific variables