Pilot OHOP 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

- Ensure variables used in adsl.xpt are the same as in other datasets
- In addition to the CDISC required variables for adsl and variables necessary for analyses for the submitted trials, the dataset should include the key variables listed below 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	OHOP Core	Source (ADaMIG v1.1 or SDTM v3.2 or OHOP v1.0=FDA)	OHOP Additional Information
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	
TR01EDT	Date of Last Exposure in Period 01	Num		Req	Req	ADaM	
TRTxxP	Planned Treatment for Period xx	Char		Cond	Cond	ADaM	

ADSL Variable Name	Variable Label	Type	Codelist/Controlled Terms	CDISC Core	OHOP Core	Source (ADaMIG v1.1 or SDTM v3.2 or OHOP v1.0=FDA)	OHOP Additional Information
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	
TRTSDT	Date of First Exposure to Treatment	Num		Cond	Req	ADaM	
TRTEDT	Date of Last Exposure to Treatment	Num		Cond	Req	ADaM	
TRTEDY	Day of Last Exposure to Treatment	Num		N/A	Req	FDA	
SAFFL	Safety Population Flag	Char	Y, N	Cond	Req	ADaM	Safety population = patients who received at least one dose of study drug
TRTFL	Treated Population Flag	Char	Y, N	N/A	Perm	FDA	Treated population = patients who received at least one dose of all drugs in a combination regimen
DTHFL	Subject Death Flag	Char	Y, N	N/A	Req	FDA	
DTH30TFL	Death Within 30 Days of Last	Char	Y, N	N/A	Req	FDA	

ADSL Variable Name	Variable Label	Type	Codelist/Controlled Terms	CDISC Core	OHOP Core	Source (ADaMIG v1.1 or SDTM v3.2 or OHOP v1.0=FDA)	OHOP Additional Information
	Treatment						
DTHA30TFL	Death After 30 Days of Last Treatment	Char	Y, N	N/A	Req	FDA	
DTHB30TFL	Death Within 30 Days of First Treatment	Char	Y, N	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		Perm	Req	ADaM	Cause of death as listed by investigator on CRF
DTHCAUSS	Cause of Death Sponsor	Char		N/A	Cond	FDA	Cause of death as determined by sponsor
LSTALVDT	Date Last Known Alive	Num		Perm	Req	ADaM	
DCSREAS	Reason for Discontinuation from Study	Char		Perm	Req	ADaM	
DCSREASP	Reason Spec for Discont from Study	Char		Perm	Cond	ADaM	Specify “other” as listed in DCSREAS
DCTREAS	Reason for Discontinuation of Treatment	Char		Perm	Req	ADaM	Repeat DCTREAS, DCTREA, DCTFL, DCTDT, DCTAESP, DCTADY for each drug in a combination therapy regimen
DCTREASP	Reason Spec for Discont of Treatment	Char		Perm	Cond	ADaM	Specify “other” as listed in DCTREAS

ADSL Variable Name	Variable Label	Type	Codelist/Controlled Terms	CDISC Core	OHOP Core	Source (ADaMIG v1.1 or SDTM v3.2 or OHOP v1.0=FDA)	OHOP Additional Information
DCTFL	Subject Discontinued Treatment Flag	Char	Y, N	N/A	Req	FDA	
DCTDT	Treatment Discontinuation Date	Num		N/A	Req	FDA	
DCTAE	Specific AE Leading to Treat. Discont.	Char		N/A	Req	FDA	If treatment was discontinued due to toxicity, DCTAE should contain the specific Adverse Event PT
DCTADY	Study day of discontinuation	Num		N/A	Req	FDA	Study day defn: date of first drug = day 1
CUTOFFDT	Data Cutoff Date	Num		N/A	Cond	FDA	Cutoff date for current analysis
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	

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:
  - 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.

- The following scenarios should be considered, and sponsors should clearly note in the reviewer's guide if any AEs with the following criteria are included in the sponsor's AE analyses in the application:
  - Any worsening beyond day 30 after the last dose of study drug of an AE that was considered treatment-emergent (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, this event should be included in the definition of TEAE used in the safety analyses.)
  - AEs starting more than 30 days after last dose if that AE was determined by the sponsor to be related to any of the study drugs.

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

ADAE Variable Name	Variable Label	Type	Codelist/ Controlled Terms	CDISC Core (SDTM or ADaM)	OHOP Core	Source (ADaMIG v1.1 or SDTM v3.3 or OHOP v1.0=FDA)	OHOP Additional Information
SAFFL	Safety Population Flag	Char	Y, N	Cond	Req	ADaM	
TRTFL	Treated Population Flag	Char	Y, N	N/A	Perm	FDA	Patients who received at least one dose of all drugs in a combination regimen
DTHFL	Subject Death Flag	Char	Y, N	N/A	Req	FDA	
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	

ADAE Variable Name	Variable Label	Type	Codelist/ Controlled Terms	CDISC Core (SDTM or ADaM)	OHOP Core	Source (ADaMIG v1.1 or SDTM v3.3 or OHOP v1.0=FDA)	OHOP Additional Information
TRxxSDT	Date of First Exposure in Period xx	Num		Perm	Cond	ADaM	
TRxxEDT	Date of Last Exposure in Period xx	Num		Perm	Cond	ADaM	
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	
APERIOD	Period	Num		Cond	Cond	ADaM	
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	
AEHLGT	High Level Group Term	Char	MedDRA	Cond	Req	SDTM	
TRTEMFL	Treatment Emergent Analysis Flag	Char	Y, N	Cond	Req	ADaM	See information above about the definition of treatment emergent adverse events.

ADAE Variable Name	Variable Label	Type	Codelist/ Controlled Terms	CDISC Core (SDTM or ADaM)	OHOP Core	Source (ADaMIG v1.1 or SDTM v3.3 or OHOP v1.0=FDA)	OHOP Additional Information
TREMzzFL	Treatment Emergent Analysis zz Flag	Char		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.
FUPWRSFL	Fatal On-study AE in FUP Flag	Char	Y, N	N/A	Req	FDA	Indicates an adverse event with a start date during the treatment-emergent time-frame that became fatal in the follow-up period (e.g. patient had grade 3 pancreatitis on day 28 after the last dose of drug, treatment emergent period is 30 days after the last dose of drug, and pancreatitis increased to grade 5 on day 32 after the last dose of study drug)
WRSBLFL	Worsening Of Baseline AE Flag	Char	Y, N	N/A	Req	FDA	Indicates and AE present at baseline that worsened by at least one grade during the study
AEACN	Action Taken with Study Treatment	Char	(ACN)	Perm	Req	SDTM	
AACNSD01	Analysis Action Taken with Study Drug 01	Char		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		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
DOSR01FL	Dose Reduced Study Drug 01 Flag	Char	Y, N	N/A	Cond	FDA	Flag records where the action taken in AACNSD01 is dose reduced.

ADAE Variable Name	Variable Label	Type	Codelist/ Controlled Terms	CDISC Core (SDTM or ADaM)	OHOP Core	Source (ADaMIG v1.1 or SDTM v3.3 or OHOP v1.0=FDA)	OHOP Additional Information
DOSR01DT	Dose Reduced Study Drug 01 Date	Num		N/A	Cond	FDA	Date that dose referenced in DOSR01FL was reduced.
DOSRzzFL	Dose Reduced Study Drug zz Flag	Char	Y, N	N/A	Cond	FDA	If action taken was captured for more than one study drug, flag records where the action taken for the corresponding AACNSDzz is dose reduced.
DOSRzzDT	Dose Reduced Study Drug zz Date	Num		N/A	Cond	FDA	Date that dose referenced in DOSRzzFL was reduced.
DOSEzzFL	Dose Re-escalation zz Flag	Char	Y, N	N/A	Cond	FDA	Dose re-escalation flag zz, if relevant.
DOSEzzDT	Dose Re-escalation zz Date	Num		N/A	Cond	FDA	Dose re-escalation date zz, if relevant.
DOSISDTM	Dose Interruption Start Datetime	Num		N/A	Cond	FDA	Infusions only
DOSIEDTM	Dose Interruption End Datetime	Num		N/A	Cond	FDA	Infusions only
AETOXGR	Standard Toxicity Grade	Char	0, 1, 2, 3, 4, 5	Perm	Req	SDTM	
AETOXGRN	Standard Toxicity Grade (N)	Num	0, 1, 2, 3, 4, 5	N/A	Req	FDA	
AESER	Serious Event	Char	Y, N	Exp	Req	SDTM	
AEOUT	Outcome of Adverse Event	Char	(OUT)	Perm	Req	SDTM	
AEREL	Causality	Char		Exp	Cond	SDTM	If relationship to more than one study drug was captured, provide separate variables using values of QNAM.
AESTDTC	Start Date/Time of Adverse Event	Char	ISO 8601	Exp	Req	SDTM	
AESTDTC	End Date/Time of Adverse Event	Char	ISO 8601	Exp	Req	SDTM	

ADAE Variable Name	Variable Label	Type	Codelist/ Controlled Terms	CDISC Core (SDTM or ADaM)	OHOP Core	Source (ADaMIG v1.1 or SDTM v3.3 or OHOP v1.0=FDA)	OHOP Additional Information
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	Cond	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
AECONTRT	Concomitant or Additional Trtmnt Given	Char	Y, N	Perm	Cond	SDTM	
CONTRSP	Specific CMED or Additional Trtmnt Given	Char		N/A	Cond	FDA	Specify treatment if AECONTRT = "Y"
AESDTH	Results in Death	Char	Y, N	Perm	Req	SDTM	

Values in parenthesis are the names of CDISC Controlled Terminology codelists

ADLB: Laboratory Analysis Dataset (adlb.xpt):

Example structure: One record per subject per visit per parameter

- Analyses should be completed using evaluable laboratory values
  - Evaluable laboratory values = values from patients with a baseline and at least one on-study value (denominators used to calculate percentages in incidence tables will vary)
- Only results that worsened by at least one grade from baseline should be displayed in the sponsor's safety tables in the CSR and safety summaries

- Laboratory values should be graded as per CTCAE if applicable (do not grade if CTCAE grade does not exist). 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 key variables listed below (not an all-inclusive list):**

ADLB Variable Name	Variable Label	Type	Codelist/ Controlled Terms	CDISC Core	OHOP Core (SDTM or ADaM)	CDISC Variable (ADaMIG v1.1 or SDTM v3.3 or OHOP v1.0=FDA)	OHOP Additional Information
SAFFL	Safety Population Flag	Char	Y, N	Cond	Req	ADaM	
TRTFL	Treated Population Flag	Char	Y, N	N/A	Perm	FDA	Patients who received at least one dose of all drugs in a combination regimen
DTHFL	Subject Death Flag	Char	Y, N	N/A	Req	FDA	
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	
TRxxSDT	Date of First Exposure in Period xx	Num		Cond	Cond	ADaM	
TRxxEDT	Date of Last Exposure in Period xx	Num		Cond	Cond	ADaM	
AVISIT	Analysis Visit	Char		Cond	Cond	ADaM	
ADT	Analysis Date	Num		Perm	Req	ADaM	
ADY	Analysis Relative Day	Num		Perm	Req	ADaM	
APERIOD	Period	Num		Perm	Req	ADaM	

ADLB Variable Name	Variable Label	Type	Codelist/ Controlled Terms	CDISC Core	OHOP Core (SDTM or ADaM)	CDISC Variable (ADaMIG v1.1 or SDTM v3.3 or OHOP v1.0=FDA)	OHOP Additional Information
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	Cond	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	
ANRIND	Analysis Reference Range Indicator	Char		Perm	Req	ADaM	
ATOXGR	Analysis Toxicity Grade	Char	0, 1 ,2, 3, 4, NA	Perm	Req	ADaM	
ATOXGRN	Analysis Toxicity Grade (N)	Num	0, 1, 2, 3, 4	Perm	Req	ADaM	Leave blank if ATOXGR is NA
ATOXGRL	Analysis Toxicity Grade Low	Char	0, 1, 2, 3, 4, NA	Perm	Req	ADaM	
ATOXGRLN	Analysis Toxicity Grade Low (N)	Num	0, 1, 2, 3, 4	Perm	Req	ADaM	Leave blank if ATOXGRL is NA
ATOXGRH	Analysis Toxicity Grade High	Char	0, 1, 2, 3, 4, NA	Perm	Req	ADaM	

ADLB Variable Name	Variable Label	Type	Codelist/ Controlled Terms	CDISC Core	OHOP Core (SDTM or ADaM)	CDISC Variable (ADaMIG v1.1 or SDTM v3.3 or OHOP v1.0=FDA)	OHOP Additional Information
ATOXGRHN	Analysis Toxicity Grade High (N)	Num	0, 1, 2, 3, 4	Perm	Req	ADaM	Leave blank if ATOXGRH is NA
BTOXGRL	Baseline Toxicity Grade Low	Char	0, 1, 2, 3, 4	Perm	Req	ADaM	
BTOXGRLN	Baseline Toxicity Grade Low (N)	Num	0, 1, 2, 3, 4	Perm	Req	ADaM	
BTOXGRH	Baseline Toxicity Grade High	Char	0, 1, 2, 3, 4	Perm	Req	ADaM	
BTOXGRHN	Baseline Toxicity Grade High (N)	Num	0, 1, 2, 3, 4	Perm	Req	ADaM	
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 least one on-study value
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	OHOP Core	CDISC Variable (ADaMIG v1.1 or SDTM v3.3 or OHOP v1.0=FDA)	OHOP Additional Information
SAFFL	Safety Population Flag	Char	Y, N	Cond	Req	ADaM	
TRTFL	Treated Population Flag	Char	Y, N	N/A	Perm	FDA	Patients who received at least one dose of all drugs in a combination regimen
DTHFL	Subject Death Flag	Char	Y, N	N/A	Req	FDA	
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	
TRxxSTM	Time of First Exposure in Period xx	Num		Cond	Cond	ADaM	

ADEX Variable Name	Variable Label	Type	Codelist/ Controlled Terms	CDISC Core (SDTM or ADaM	OHOP Core	CDISC Variable (ADaMIG v1.1 or SDTM v3.3 or OHOP v1.0=FDA)	OHOP Additional Information
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	
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	
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	
EXENDTC	End Date/Time of Treatment	Char	ISO 8601	Ex	Req	SDTM	

ADEX Variable Name	Variable Label	Type	Codelist/ Controlled Terms	CDISC Core (SDTM or ADaM	OHOP Core	CDISC Variable (ADaMIG v1.1 or SDTM v3.3 or OHOP v1.0=FDA)	OHOP Additional Information
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.
DOSPDC	Dose Discontinued Permanently Flag	Char	Y, N	N/A	Cond	FDA	Indicates dose was permanently discontinued.

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)	OHOP Core	CDISC Variable (ADaMIG v1.1 or SDTM v3.3 or OHOP v1.0=FDA)	OHOP Additional Information
SAFFL	Safety Population Flag	Char	Y, N	Cond	Req	ADaM	
TRTFL	Treated Population Flag	Char	Y, N	N/A	Perm	FDA	Patients who received at least one dose of all drugs in a combination regimen
DTHFL	Subject Death Flag	Char	Y, N	N/A	Req	FDA	
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.
PARAM	Parameter	Char		Req	Req	ADaM	

ADEXSUM Variable Name	Variable Label	Type	Codelist/ Controlled Terms	CDISC Core (SDTM or ADaM)	OHOP Core	CDISC Variable (ADaMIG v1.1 or SDTM v3.3 or OHOP v1.0=FDA)	OHOP Additional Information
PARAMCD	Parameter Code	Char		Req	Req	ADaM	
AVAL	Analysis Value	Num		Cond	Req	ADaM	
AVALC	Analysis Value (C)	Char		Cond	Req	ADaM	
AVALU	Analysis Value Unit	Char		N/A	Req	FDA	

ADEXSUM: Value-level Metadata

ADEXSUM AVAL/AVALC	AEVLINT	PARQUAL	PARAMCD	PARAM	OHOP Notes

ADEXSUM AVAL/AVALC	AEVLINT	PARQUAL	PARAMCD	PARAM	OHOP 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	OHOP 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	OHOP 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.