Pilot OOD Standard Safety Data Requests v1.1

Pilot Office of Oncologic Diseases (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

- 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):

<table>
<thead>
<tr>
<th>ADSL Variable Name</th>
<th>Variable Label</th>
<th>Type</th>
<th>Codelist/Controlled Terms</th>
<th>CDISC Core</th>
<th>OHOP Core</th>
<th>Source (ADaM v1.1 or SDTM v3.2 or OHOP v1.0=FDA)</th>
<th>OHOP Additional Information</th>
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</thead>
<tbody>
<tr>
<td>TRT01P</td>
<td>Planned Treatment for Period 01</td>
<td>Char</td>
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<td>Req</td>
<td>Req</td>
<td>ADaM</td>
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<td>TRT01A</td>
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<td>Char</td>
<td></td>
<td>Cond</td>
<td>Req</td>
<td>ADaM</td>
<td>There must be one TRTxxA for each value of TRTxxP</td>
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<tr>
<td>TR01SDT</td>
<td>Date of First Exposure in Period 01</td>
<td>Num</td>
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<td>Cond</td>
<td>ADaM</td>
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<td>Cond</td>
<td>Cond</td>
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<td>Cond</td>
<td>Cond</td>
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<td>Study day of last exposure to treatment</td>
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<td>SAFFL</td>
<td>Safety Population Flag</td>
<td>Char</td>
<td>Y, N</td>
<td>Cond</td>
<td>ADaM</td>
<td>Safety population = patients who received at least one dose of study drug</td>
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<td>TRTFL</td>
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<td>Char</td>
<td>Y, N</td>
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<td>Perm</td>
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<td>Treated population = patients who received at least one dose of all drugs in a combination regimen</td>
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<td>FDA</td>
<td>Flag indicating if subject died before end of study (or data cutoff, if applicable)</td>
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<td>Y, N</td>
<td>N/A</td>
<td>Req</td>
<td>FDA</td>
<td>Flag indicating if subject died within 30 days of last treatment</td>
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<td>N/A</td>
<td>Req</td>
<td>FDA</td>
<td>Flag indicating if subject died after 30 days of last treatment</td>
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<td>Codelist/Controlled Terms</td>
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<td>OHOP Core</td>
<td>Source (ADaMIG v1.1 or SDTM v3.2 or OHOP v1.0=FDA)</td>
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<td>N/A</td>
<td>Req</td>
<td>FDA</td>
<td>Death within 30 days of starting treatment</td>
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<td>Req</td>
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<td>Req</td>
<td>ADaM</td>
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<tr>
<td>DTHCAUS</td>
<td>Cause of Death</td>
<td>Char</td>
<td>Perm</td>
<td>Req</td>
<td>ADaM</td>
<td>Cause of death as listed by investigator on CRF</td>
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<td>DTHCAUSS</td>
<td>Cause of Death Sponsor</td>
<td>Char</td>
<td>N/A</td>
<td>Cond</td>
<td>FDA</td>
<td>Cause of death as determined by sponsor</td>
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<td>Req</td>
<td>ADaM</td>
<td>Specify “other” as listed in DCSREAS</td>
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<tr>
<td>DCSREASP</td>
<td>Reason Spec for Discont from Study</td>
<td>Char</td>
<td>Perm</td>
<td>Cond</td>
<td>ADaM</td>
<td>Repeat DCTREAS, DCTREA, DCTFL, DCTDT, DCTAESP, DCTADY for each drug in a combination therapy regimen</td>
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<td>Reason for Discontinuation of Treatment</td>
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<td>Perm</td>
<td>Req</td>
<td>ADaM</td>
<td>Repeat DCTREAS, DCTREA, DCTFL, DCTDT, DCTAESP, DCTADY for each drug in a combination therapy regimen</td>
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<td>DCTREASP</td>
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<td>Req</td>
<td>FDA</td>
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<td>N/A</td>
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<td>FDA</td>
<td>Date of treatment discontinuation</td>
<td></td>
</tr>
</tbody>
</table>
### 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
---|---|---|---|---|---|---|---
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 | 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:
  - **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).
    - 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):**
<table>
<thead>
<tr>
<th>ADAE Variable Name</th>
<th>Variable Label</th>
<th>Type</th>
<th>Codelist/Controlled Terms</th>
<th>CDISC Core (SDTM or ADaM)</th>
<th>OHOP Core</th>
<th>Source (ADaMIG v1.1 or SDTM v3.3 or OHOP v1.0=FDA)</th>
<th>OHOP Additional Information</th>
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<tr>
<td>SAFFL</td>
<td>Safety Population Flag</td>
<td>Char</td>
<td>Y, N</td>
<td>Cond</td>
<td>Req</td>
<td>ADaM</td>
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<td>TRTFL</td>
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<td>Char</td>
<td>Y, N</td>
<td>N/A</td>
<td>Perm</td>
<td>FDA</td>
<td>Patients who received at least one dose of all drugs in a combination regimen</td>
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<td>DTHFL</td>
<td>Subject Death Flag</td>
<td>Char</td>
<td>Y, N</td>
<td>N/A</td>
<td>Req</td>
<td>FDA</td>
<td>Flag indicating if subject died before end of study (or data cutoff, if applicable)</td>
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<tr>
<td>DTHDT</td>
<td>Date of Death</td>
<td>Num</td>
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<td>Perm</td>
<td>Req</td>
<td>ADaM</td>
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<td>Char</td>
<td></td>
<td>Cond</td>
<td>Req</td>
<td>ADaM</td>
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<td>Perm</td>
<td>Cond</td>
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<td>TRxxSDT</td>
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<td>TRxxEDT</td>
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<td>Num</td>
<td></td>
<td>Perm</td>
<td>Cond</td>
<td>ADaM</td>
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<td>Num</td>
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<td>Perm</td>
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<td>ADaM</td>
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<td>FDA</td>
<td>Study day of last exposure to treatment</td>
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<td>Codelist/Controlled Terms</td>
<td>CDISC Core (SDTM or ADaM)</td>
<td>OHOP Core</td>
<td>Source (ADaMIG v1.1 or SDTM v3.3 or OHOP v1.0=FDA)</td>
<td>OHOP Additional Information</td>
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<td>AETERM</td>
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<td>Char</td>
<td>MedDRA</td>
<td>Req</td>
<td>Req</td>
<td>SDTM</td>
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<td>Dictionary-Derived Term</td>
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<td>MedDRA</td>
<td>Cond</td>
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<td>SDTM</td>
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<td>Body System or Organ Class</td>
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<td>MedDRA</td>
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<td>Y, N</td>
<td>Cond</td>
<td>Req</td>
<td>ADaM</td>
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<td>Treatment Emergent Analysis zz Flag</td>
<td>Char</td>
<td>N/A</td>
<td>Cond</td>
<td>FDA</td>
<td>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.</td>
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</tr>
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<td>Fatal On-study AE in FUP Flag</td>
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<td>Y, N</td>
<td>N/A</td>
<td>Req</td>
<td>FDA</td>
<td>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)</td>
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<td>N/A</td>
<td>Req</td>
<td>FDA</td>
<td>Indicates and AE present at baseline that worsened by at least one grade during the study</td>
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<td>(ACN)</td>
<td>Perm</td>
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<td>SDTM</td>
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<td>Codelist/Controlled Terms</td>
<td>CDISC Core (SDTM or ADaM)</td>
<td>OHOP Core</td>
<td>Source (ADaMIG v1.1 or SDTM v3.3 or OHOP v1.0=FDA)</td>
<td>OHOP Additional Information</td>
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<tr>
<td>AACNSD01</td>
<td>Analysis Action Taken with Study Drug 01</td>
<td>Char</td>
<td>N/A</td>
<td>Cond</td>
<td>FDA</td>
<td>Create one analysis action taken variable for each action taken with study drug collected in AEACN and / or SUPPAE.</td>
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<td>Analysis Action Taken with Study Drug zz</td>
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<td>N/A</td>
<td>Cond</td>
<td>FDA</td>
<td>Required if action taken with study treatment was captured for more than one study drug. See AACNSD01.</td>
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<td>AEACN0TH</td>
<td>Other Action Taken</td>
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<td>Perm</td>
<td>Cond</td>
<td>SDTM</td>
<td>Describe “other” from AEACN</td>
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<td>Dose Reduced Study Drug 01 Flag</td>
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<td>Y, N</td>
<td>N/A</td>
<td>Cond</td>
<td>Flag records where the action taken in AACNSD01 is dose reduced.</td>
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<td>DOSR01DT</td>
<td>Dose Reduced Study Drug 01 Date</td>
<td>Num</td>
<td>N/A</td>
<td>Cond</td>
<td>FDA</td>
<td>Date that dose referenced in DOSR01FL was reduced.</td>
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<td>Char</td>
<td>Y, N</td>
<td>N/A</td>
<td>Cond</td>
<td>If action taken was captured for more than one study drug, flag records where the action taken for the corresponding AACNSDzz is dose reduced.</td>
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<td>FDA</td>
<td>Date that dose referenced in DOSRzzFL was reduced.</td>
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<td>Cond</td>
<td>Dose re-escalation flag zz, if relevant.</td>
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<td>DOSEzzDT</td>
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<td>Cond</td>
<td>FDA</td>
<td>Dose re-escalation date zz, if relevant.</td>
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<td>FDA</td>
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Pilot OOD Standard Safety Data Requests v1.1

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<th>OHOP Core</th>
<th>Source (ADaMIG v1.1 or SDTM v3.3 or OHOP v1.0=FDA)</th>
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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):

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<th>ADLB Variable Name</th>
<th>Variable Label</th>
<th>Type</th>
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<th>OHOP Core</th>
<th>Source (ADaMIG v1.1 or SDTM v3.3 or OHOP v1.0=FDA)</th>
<th>OHOP Additional Information</th>
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<td>Cond</td>
<td>Req</td>
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<td>Patients who received at least one dose of all drugs in a combination regimen</td>
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<td>Req</td>
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<td>Flag indicating if subject died before end of study (or data cutoff, if applicable)</td>
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**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.

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<th>Variable Label</th>
<th>Type</th>
<th>Code List/Controlled Terms</th>
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<th>OHOP Core</th>
<th>CDISC Variable (ADaMIG v1.1 or SDTM v3.3 or OHOP v1.0=FDA)</th>
<th>OHOP Additional Information</th>
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<td>SAFFL</td>
<td>Safety Population Flag</td>
<td>Char</td>
<td>Y, N</td>
<td>Cond</td>
<td>Req</td>
<td>ADaM</td>
<td>Patients who received at least one dose of all drugs in a combination regimen</td>
</tr>
<tr>
<td>TRTFL</td>
<td>Treated Population Flag</td>
<td>Char</td>
<td>Y, N</td>
<td>N/A</td>
<td>Perm</td>
<td>FDA</td>
<td>Flag indicating if subject died before end of study (or data cutoff, if applicable)</td>
</tr>
<tr>
<td>DTHFL</td>
<td>Subject Death Flag</td>
<td>Char</td>
<td>Y, N</td>
<td>N/A</td>
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<td>CDISC Variable (ADaMIG v1.1 or SDTM v3.3 or OHOP v1.0=FDA)</td>
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<td>Derived treatment duration (days)</td>
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<td>Dose Reduced Flag</td>
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<td>Indicates dose was changed from intended dose</td>
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<td>FDA</td>
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<td>FDA</td>
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<td>Dose Discontinued Permanently Flag</td>
<td>Char</td>
<td>Y, N</td>
<td>N/A</td>
<td>FDA</td>
<td>Indicates dose was permanently discontinued</td>
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### ADEXSUM: Exposure Summary Analysis Dataset (adexsum.xpt)

Structure: One record per subject per parameter per analysis interval

<table>
<thead>
<tr>
<th>ADEXSUM Variable Name</th>
<th>Variable Label</th>
<th>Type</th>
<th>Codelist/Controlled Terms</th>
<th>CDISC Core (SDTM or ADaM)</th>
<th>OHOP Core</th>
<th>CDISC Variable (ADaMIG v1.1 or SDTM v3.3 or OHOP v1.0=FDA)</th>
<th>OHOP Additional Information</th>
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<tbody>
<tr>
<td>SAFFL</td>
<td>Safety Population Flag</td>
<td>Char</td>
<td>Y, N</td>
<td>Cond</td>
<td>Req</td>
<td>ADaM</td>
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<tr>
<td>TRTFL</td>
<td>Treated Population Flag</td>
<td>Char</td>
<td>Y, N</td>
<td>N/A</td>
<td>Perm</td>
<td>FDA</td>
<td>Patients who received at least one dose of all drugs in a combination regimen</td>
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<tr>
<td>DTHFL</td>
<td>Subject Death Flag</td>
<td>Char</td>
<td>Y, N</td>
<td>N/A</td>
<td>Req</td>
<td>FDA</td>
<td>Flag indicating if subject died before end of study (or data cutoff, if applicable)</td>
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<td>TRT01P</td>
<td>Planned Treatment for Period 01</td>
<td>Char</td>
<td>Perm</td>
<td>Req</td>
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<td>Cond</td>
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<td>Perm</td>
<td>Cond</td>
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<td>Perm</td>
<td>Req</td>
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<td>ADaM</td>
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<td>TRxxSDT</td>
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<td>Num</td>
<td>Perm</td>
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<td>AEVLINT</td>
<td>Analysis Interval for Evaluation</td>
<td>Char</td>
<td>N/A</td>
<td>Req</td>
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<td>FDA</td>
<td>Describes the interval of time that was evaluated to derive AVAL, e.g., Overall, Cycle X, etc.</td>
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<td>PARQUAL</td>
<td>Parameter Qualifier</td>
<td>Char</td>
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<td>Req</td>
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<td>FDA</td>
<td>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.</td>
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<td>PARAM</td>
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<th>CDISC Variable (ADaMIG v1.1 or SDTM v3.3 or OHOP v1.0=FDA)</th>
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<td>All</td>
<td>TRTDURD</td>
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<td>Total duration of treatment over all values of EXTRT for each subject. AVALU should be days.</td>
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<td>Overall</td>
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<td>TRTPDURD</td>
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<td>Nr of Actual Study Drug Administrations</td>
<td>Number of treatment administrations for all values of EXTRT combined per subject</td>
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<td>AVAL</td>
<td>Overall</td>
<td>All</td>
<td>NUMCYC</td>
<td>Number of Actual Cycles</td>
<td>Total number of cycles across all treatments for each subject. Sponsors should discuss definition of cycles with review team ahead of submission, if applicable.</td>
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<td>Overall and &lt;by cycle&gt;</td>
<td>&lt;each value of EXTRT&gt;</td>
<td>CUMPLDOS</td>
<td>Cumulative Planned Dose</td>
<td>Cumulative planned dose for each treatment for each subject over each evaluation interval (AEVLINT). Unit should be captured in AVALU.</td>
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<td>&lt;each value of EXTRT&gt;</td>
<td>CUMACDOS</td>
<td>Cumulative Actual Dose</td>
<td>Cumulative actual dose for each treatment for each subject over each evaluation interval (AEVLINT). Unit should be captured in AVALU.</td>
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<td>AVAL</td>
<td>Overall and &lt;by cycle&gt;</td>
<td>&lt;each value of EXTRT&gt;</td>
<td>TOTPLDOS</td>
<td>Total Planned Dose</td>
<td>Total planned dose for each treatment for each subject over each evaluation interval. Unit should be captured in AVALU.</td>
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<td>&lt;each value of EXTRT&gt;</td>
<td>TOTACDOS</td>
<td>Total Actual Dose</td>
<td>Total actual dose for each treatment for each subject over each evaluation interval. Unit should be captured in AVALU.</td>
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<td>&lt;each value of EXTRT&gt;</td>
<td>RDOSINT</td>
<td>Relative Dose Intensity (%)</td>
<td>Ratio of actual to planned dose expressed as percentage for each subject over each evaluation interval.</td>
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<td>Any Dose Delays</td>
<td>Y if there were any dose delays over each evaluation interval.</td>
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<td>Total number of dose delays over each evaluation interval.</td>
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<td>ALL</td>
<td>NCYCDLAY</td>
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<td>Number of Cycle Delays.</td>
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## Revision History Table

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<th>Version</th>
<th>Summary of Changes</th>
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<td>7-2019</td>
<td>1.0</td>
<td>Initial Version</td>
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<tr>
<td>11-2019</td>
<td>1.1</td>
<td>Modified several variable names for CDISC compliance; added notes for some OOD-specific variables</td>
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