

## Data Set Name: adae.sas7bdat

Variable Number 1 Variable SubjRandID Type Numeric Length 8 Format . Label Subject Identifier (randomly assigned)

Variable Number 2 Variable STUDYID Type Character Length 10 Format . Label Study Identifier

Variable Number 3 Variable AGE Type Numeric Length 8 Format . Label Age

Variable Number 4 Variable AGE1 Type Numeric Length 8 Format . Label Age at Baseline

Variable Number 5 Variable AGEM Type Numeric Length 8 Format . Label Age at Baseline (Months)

Variable Number 6 Variable AGEU Type Character Length 5 Format . Label Age Units

Variable Number 7 Variable AGEGR1 Type Character Length 14 Format . Label Pooled Age Group 1

Variable Number 8 Variable AGEGR1N Type Numeric Length 8 Format . Label Pooled Age Group 1 (N)

Variable Number 9 Variable RACE Type Character Length 25 Format . Label Race

Variable Number 10 Variable RACE1 Type Character Length 25 Format . Label Race 1

Variable Number 11 Variable RACE2 Type Character Length 5 Format . Label Race 2

Variable Number 12 Variable RACEN Type Numeric Length 8 Format . Label Race (N)

Variable Number 13 Variable SEX Type Character Length 1 Format . Label Sex

Variable Number 14 Variable SEXN Type Numeric Length 8 Format . Label Sex (N)

Variable Number 15 Variable ETHNIC Type Character Length 22 Format . Label Ethnicity

Variable Number 16 Variable ETHNICN Type Numeric Length 8 Format . Label Ethnicity (N)

Variable Number 17 Variable COUNTRY Type Character Length 3 Format . Label Country

Variable Number 18 Variable SCRNFL Type Character Length 1 Format . Label Screened Population Flag

Variable Number 19 Variable SCRNFN Type Numeric Length 8 Format . Label Screened Population Flag (N)

Variable Number 20 Variable ENRFL Type Character Length 1 Format . Label Enrolled Population Flag

Variable Number 21 Variable ENRFLN Type Numeric Length 8 Format . Label Enrolled Population Flag (N)

Variable Number 22 Variable SAFFL Type Character Length 1 Format . Label Safety Population Flag

Variable Number 23 Variable SAFFN Type Numeric Length 8 Format . Label Safety Population Flag (N)

Variable Number 24 Variable SAFOPFL Type Character Length 1 Format . Label Safety Population Flag Core Trt

Variable Number 25 Variable SAFOPFN Type Numeric Length 8 Format . Label Safety Population Flag Core Trt (N)

Variable Number 26 Variable SAFPA4FL Type Character Length 1 Format . Label Safety Population Flag PA4

Variable Number 27 Variable SAFPA4FN Type Numeric Length 8 Format . Label Safety Population Flag PA4 (N)

Variable Number 28 Variable SAFPA5FL Type Character Length 1 Format . Label Safety Population Flag PA5

Variable Number 29 Variable SAFPA5FN Type Numeric Length 8 Format . Label Safety Population Flag PA5 (N)

Variable Number 30 Variable SAFPA6FL Type Character Length 1 Format . Label Safety Population Flag PA6

Variable Number 31 Variable SAFPA6FN Type Numeric Length 8 Format . Label Safety Population Flag PA6 (N)

Variable Number 32 Variable COMPLFL Type Character Length 1 Format . Label Completers Population Flag

Variable Number 33 Variable COMPLFN Type Numeric Length 8 Format . Label Completers Population Flag (N)

Variable Number 34 Variable COMPL2FL Type Character Length 1 Format . Label Completers Population Flag 02

Variable Number 35 Variable COMPL2FN Type Numeric Length 8 Format . Label Completers Population Flag 02 (N)

Variable Number 36 Variable COMPL3FL Type Character Length 1 Format . Label Completers Population Flag 03

Variable Number 37 Variable COMPL3FN Type Numeric Length 8 Format . Label Completers Population Flag 03 (N)

Variable Number 38 Variable COMPL4FL Type Character Length 1 Format . Label Completers Population Flag 04

Variable Number 39 Variable COMPL4FN Type Numeric Length 8 Format . Label Completers Population Flag 04 (N)

Variable Number 40 Variable DOSINTFL Type Character Length 1 Format . Label Drug Interrupted for >28 Days Flag

Variable Number 41 Variable DOSINTFN Type Numeric Length 8 Format . Label Drug Interrupted for >28 Days Flag (N)

Variable Number 42 Variable ARM Type Character Length 11 Format . Label Description of Planned Arm

Variable Number 43 Variable ACTARM Type Character Length 11 Format . Label Description of Actual Arm

Variable Number 44 Variable TRT01P Type Character Length 3 Format . Label Planned Treatment for Period 01

Variable Number 45 Variable TRT01PN Type Numeric Length 8 Format . Label Planned Treatment for Period 01 (N)

Variable Number 46 Variable TRT01A Type Character Length 3 Format . Label Actual Treatment for Period 01

Variable Number 47 Variable TRT01AN Type Numeric Length 8 Format . Label Actual Treatment for Period 01 (N)

Variable Number 48 Variable TRTSEQP Type Character Length 7 Format . Label Planned Sequence of Treatments

Variable Number 49 Variable TRTSEQPN Type Numeric Length 8 Format . Label Planned Sequence of Treatments (N)

Variable Number 50 Variable TRTSEQA Type Character Length 7 Format . Label Actual Sequence of Treatments

Variable Number 51 Variable TRTSEQAN Type Numeric Length 8 Format . Label Actual Sequence of Treatments (N)

Variable Number 52 Variable TRTP Type Character Length 7 Format . Label Planned Treatment

Variable Number 53 Variable TRTPN Type Numeric Length 8 Format . Label Planned Treatment (N)

Variable Number 54 Variable TRTA Type Character Length 7 Format . Label Actual Treatment

Variable Number 55 Variable TRTAN Type Numeric Length 8 Format . Label Actual Treatment (N)

Variable Number 56 Variable AESEQ Type Numeric Length 8 Format . Label Sequence Number

Variable Number 57 Variable AESPID Type Character Length 3 Format . Label Sponsor-Defined Identifier

Variable Number 58 Variable AEGRPID Type Character Length 9 Format . Label Group ID

Variable Number 59 Variable AETERM Type Character Length 108 Format . Label Reported Term for the Adverse Event

Variable Number 60 Variable AELLT Type Character Length 39 Format . Label Lowest Level Term

Variable Number 61 Variable AELLTCD Type Numeric Length 8 Format . Label Lowest Level Term Code

Variable Number 62 Variable AEDECOD Type Character Length 47 Format . Label Dictionary-Derived Term

Variable Number 63 Variable AEPTCD Type Numeric Length 8 Format . Label Preferred Term Code

Variable Number 64 Variable AEHLT Type Character Length 63 Format . Label High Level Term

Variable Number 65 Variable AEHLTCD Type Numeric Length 8 Format . Label High Level Term Code

Variable Number 66 Variable AEHLGT Type Character Length 59 Format . Label High Level Group Term

Variable Number 67 Variable AEHLGTCD Type Numeric Length 8 Format . Label High Level Group Term Code

Variable Number 68 Variable AEBODSYS Type Character Length 67 Format . Label Body System or Organ Class

Variable Number 69 Variable AEBDSYCD Type Numeric Length 8 Format . Label Body System or Organ Class Code

Variable Number 70 Variable AESOC Type Character Length 67 Format . Label Primary System Organ Class

Variable Number 71 Variable AESOCCD Type Numeric Length 8 Format . Label Primary System Organ Class Code

Variable Number 72 Variable AESIDI Type Character Length 16 Format . Label AEs of Special Interest Diarrhoea

Variable Number 73 Variable AESIDIFL Type Character Length 1 Format . Label AEs of Special Interest Diarrhoea Flag

Variable Number 74 Variable AESIFS Type Character Length 37 Format . Label AEs of Special Interest Fat Sl. Vit

Variable Number 75 Variable AESIFSFL Type Character Length 1 Format . Label AEs of Special Interest Fat Sl. Vit Flag

Variable Number 76 Variable AESIET Type Character Length 29 Format . Label AEs of Special Interest Elv transaminase

Variable Number 77 Variable AESIETFL Type Character Length 1 Format . Label AEs of Special Interest Elv transam Flag

Variable Number 78 Variable AESIEB Type Character Length 25 Format . Label AEs of Special Interest Elevat Bilirubin

Variable Number 79 Variable AESIEBFL Type Character Length 1 Format . Label AEs of Special Interest Elevat Bili Flag

Variable Number 80 Variable AESER Type Character Length 1 Format . Label Serious Event

Variable Number 81 Variable AESERN Type Numeric Length 8 Format . Label Serious Event (N)

Variable Number 82 Variable AETOXGR Type Character Length 1 Format . Label Standard Toxicity Grade

Variable Number 83 Variable AETOXGRN Type Numeric Length 8 Format . Label Standard Toxicity Grade (N)

Variable Number 84 Variable ATOXGR Type Character Length 18 Format . Label Analysis Toxicity Grade

Variable Number 85 Variable ATOXGRN Type Numeric Length 8 Format . Label Analysis Toxicity Grade (N)

Variable Number 86 Variable AEACN Type Character Length 16 Format . Label Action Taken with Study Treatment

Variable Number 87 Variable AEACNN Type Numeric Length 8 Format . Label Action Taken with Study Treatment (N)

Variable Number 88 Variable AEACNOTH Type Character Length 99 Format . Label Other Action Taken

Variable Number 89 Variable AEREL Type Character Length 25 Format . Label Causality

Variable Number 90 Variable AERELN Type Numeric Length 8 Format . Label Causality (N)

Variable Number 91 Variable AREL Type Character Length 25 Format . Label Analysis Causality

Variable Number 92 Variable ARELN Type Numeric Length 8 Format . Label Analysis Causality (N)

Variable Number 93 Variable RELGR1 Type Character Length 19 Format . Label Pooled Causality Group 1

Variable Number 94 Variable RELGR1N Type Numeric Length 8 Format . Label Pooled Causality Group 1 (N)

Variable Number 95 Variable AEOUT Type Character Length 32 Format . Label Outcome of Adverse Event

Variable Number 96 Variable AEOUTN Type Numeric Length 8 Format . Label Outcome of Adverse Event (N)

Variable Number 97 Variable AESDTH Type Character Length 1 Format . Label Results in Death

Variable Number 98 Variable AESHOSP Type Character Length 1 Format . Label Requires or Prolongs Hospitalization

Variable Number 99 Variable AESLIFE Type Character Length 1 Format . Label Is Life Threatening

Variable Number 100 Variable AECONTRT Type Character Length 1 Format . Label Concomitant or Additional Trtmnt Given

Variable Number 101 Variable AETRRT Type Character Length 106 Format . Label Treatment Required

Variable Number 102 Variable AEDIS Type Character Length 1 Format . Label AE Caused Discontinuation from Study

Variable Number 103 Variable ASTDTF Type Character Length 1 Format . Label Analysis Start Date Imputation Flag

Variable Number 104 Variable AENDTF Type Character Length 1 Format . Label Analysis End Date Imputation Flag

Variable Number 105 Variable ASTDY Type Numeric Length 8 Format . Label Analysis Start Relative Day (from first treatment date)

Variable Number 106 Variable AESTDY Type Numeric Length 8 Format . Label Study Day of Start of Adverse Event (from first treatment date)

Variable Number 107 Variable AENDY Type Numeric Length 8 Format . Label Analysis End Relative Day (from first treatment date)

Variable Number 108 Variable AEENDY Type Numeric Length 8 Format . Label Study Day of End of Adverse Event (from first treatment date)

Variable Number 109 Variable ADURN Type Numeric Length 8 Format . Label AE Duration (N)

Variable Number 110 Variable ADURU Type Character Length 4 Format . Label AE Duration Units

Variable Number 111 Variable AEENRF Type Character Length 7 Format . Label End Relative to Reference Period

Variable Number 112 Variable DOSEAEON Type Character Length 8 Format . Label Study Drug Dose at AE Onset

Variable Number 113 Variable DOSAEONU Type Character Length 9 Format . Label Study Drug Dose at AE Onset Units

Variable Number 114 Variable TRTEMFL Type Character Length 1 Format . Label Treatment Emergent Analysis Flag

Variable Number 115 Variable AOCCFL Type Character Length 1 Format . Label 1st Occurrence of Any AE Flag

Variable Number 116 Variable AOCCSFL Type Character Length 1 Format . Label 1st Occurrence of SOC Flag

Variable Number 117 Variable AOCCPFL Type Character Length 1 Format . Label 1st Occurrence of Preferred Term Flag

Variable Number 118 Variable AOCCIFL Type Character Length 1 Format . Label 1st Max Sev./Int. Occurrence Flag

Variable Number 119 Variable AOCCSIFL Type Character Length 1 Format . Label 1st Max Sev./Int. Occur Within SOC Flag

Variable Number 120 Variable AOCCPIFL Type Character Length 1 Format . Label 1st Max Sev./Int. Occur Within PT Flag

Variable Number 121 Variable AOCSFL Type Character Length 1 Format . Label Ser. 1st Occurrence of Any AE Flag

Variable Number 122 Variable AOCSSFL Type Character Length 1 Format . Label Ser. 1st Occurrence of SOC Flag

Variable Number 123 Variable AOCSPFL Type Character Length 1 Format . Label Ser. 1st Occurrence of PT Flag

Variable Number 124 Variable AOSTRFL Type Character Length 1 Format . Label Ser. 1st Occ. of Any TRT Rel AE Flag

Variable Number 125 Variable AOSTRSFL Type Character Length 1 Format . Label Ser. 1st Occ. of TRT Rel SOC Flag

Variable Number 126 Variable AOSTRPFL Type Character Length 1 Format . Label Ser. 1st Occ. of TRT Rel PT Flag

Variable Number 127 Variable AOCD CFL Type Character Length 1 Format . Label 1st AE Leading to Discontinuation Flag

Variable Number 128 Variable AOCD CSFL Type Character Length 1 Format . Label 1st AE Leading to Discon. SOC Flag

Variable Number 129 Variable AOCD CPFL Type Character Length 1 Format . Label 1st AE Leading to Discon. PT Flag

Variable Number 130 Variable AOCCTFL Type Character Length 1 Format . Label 1st Occurrence of Any Trt Rel AE Flag

Variable Number 131 Variable AOCCTSFL Type Character Length 1 Format . Label 1st Occurrence of Trt Rel SOC Flag

Variable Number 132 Variable AOCCTPFL Type Character Length 1 Format . Label 1st Occurrence of Trt Rel PT Flag

Variable Number 133 Variable AOCTIFL Type Character Length 1 Format . Label 1st Max Sev Trt Rel Occur Flag

Variable Number 134 Variable AOCTSIFL Type Character Length 1 Format . Label 1st Max Sev Trt Rel Occur W/I SOC Flag

Variable Number 135 Variable AOCTPIFL Type Character Length 1 Format . Label 1st Max Sev Trt Rel Occur W/I PT Flag

Variable Number 136 Variable AOTEDIFL Type Character Length 1 Format . Label 1st TEAE for Diarrhoea Events Flag

Variable Number 137 Variable AOTEDSFL Type Character Length 1 Format . Label 1st TEAE for Diarrhoea Event in SOC Flag

Variable Number 138 Variable AOTEDPFL Type Character Length 1 Format . Label 1st TEAE for Diarrhoea Events in PT Flag

Variable Number 139 Variable AOTEVTFL Type Character Length 1 Format . Label 1st TEAE for Vitamin Def Events Flag

Variable Number 140 Variable AOTEVSFL Type Character Length 1 Format . Label 1st TEAE for Vitamin Events in SOC Flag

Variable Number 141 Variable AOTEVPFL Type Character Length 1 Format . Label 1st TEAE for Vitamin Events in PT Flag

Variable Number 142 Variable AOTEETFL Type Character Length 1 Format . Label 1st TEAE for Elevated Transaminases Flag

Variable Number 143 Variable AOTETSFL Type Character Length 1 Format . Label 1st TEAE for Elevated Transa in SOC Flag

Variable Number 144 Variable AOTETPFL Type Character Length 1 Format . Label 1st TEAE for Elevated Transam in PT Flag

Variable Number 145 Variable AOTEEBFL Type Character Length 1 Format . Label 1st TEAE for Elevated Bilirubin Flag

Variable Number 146 Variable AOTEBSFL Type Character Length 1 Format . Label 1st TEAE for Elevated Bili in SOC Flag

Variable Number 147 Variable AOTEBPFL Type Character Length 1 Format . Label 1st TEAE for Elevated Bili in PT Flag

## Data Set Name: [adcm.sas7bdat](#)

Variable Number 1 Variable SubjRandID Type Numeric Length 8 Format . Label Subject Identifier (randomly assigned)

Variable Number 2 Variable STUDYID Type Character Length 10 Format . Label Study Identifier

Variable Number 3 Variable AGE Type Numeric Length 8 Format . Label Age

Variable Number 4 Variable AGE1 Type Numeric Length 8 Format . Label Age at Baseline

Variable Number 5 Variable AGEM Type Numeric Length 8 Format . Label Age at Baseline (Months)

Variable Number 6 Variable AGEU Type Character Length 5 Format . Label Age Units



Variable Number 7 Variable AGEGR1 Type Character Length 14 Format . Label Pooled Age Group 1

Variable Number 8 Variable AGEGR1N Type Numeric Length 8 Format . Label Pooled Age Group 1 (N)

Variable Number 9 Variable RACE Type Character Length 25 Format . Label Race

Variable Number 10 Variable RACE1 Type Character Length 25 Format . Label Race 1

Variable Number 11 Variable RACE2 Type Character Length 5 Format . Label Race 2

Variable Number 12 Variable RACEN Type Numeric Length 8 Format . Label Race (N)

Variable Number 13 Variable SEX Type Character Length 1 Format . Label Sex

Variable Number 14 Variable SEXN Type Numeric Length 8 Format . Label Sex (N)

Variable Number 15 Variable ETHNIC Type Character Length 22 Format . Label Ethnicity

Variable Number 16 Variable ETHNICN Type Numeric Length 8 Format . Label Ethnicity (N)

Variable Number 17 Variable COUNTRY Type Character Length 3 Format . Label Country

Variable Number 18 Variable SCRNFL Type Character Length 1 Format . Label Screened Population Flag

Variable Number 19 Variable SCRNFN Type Numeric Length 8 Format . Label Screened Population Flag (N)

Variable Number 20 Variable ENRFL Type Character Length 1 Format . Label Enrolled Population Flag

Variable Number 21 Variable ENRFLN Type Numeric Length 8 Format . Label Enrolled Population Flag (N)

Variable Number 22 Variable SAFFL Type Character Length 1 Format . Label Safety Population Flag

Variable Number 23 Variable SAFFN Type Numeric Length 8 Format . Label Safety Population Flag (N)

Variable Number 24 Variable SAFOPFL Type Character Length 1 Format . Label Safety Population Flag Core Trt

Variable Number 25 Variable SAFOPFN Type Numeric Length 8 Format . Label Safety Population Flag Core Trt (N)

Variable Number 26 Variable SAFPA4FL Type Character Length 1 Format . Label Safety Population Flag PA4

Variable Number 27 Variable SAFPA4FN Type Numeric Length 8 Format . Label Safety Population Flag PA4 (N)

Variable Number 28 Variable SAFPA5FL Type Character Length 1 Format . Label Safety Population Flag PA5

Variable Number 29 Variable SAFPA5FN Type Numeric Length 8 Format . Label Safety Population Flag PA5 (N)

Variable Number 30 Variable SAFPA6FL Type Character Length 1 Format . Label Safety Population Flag PA6

Variable Number 31 Variable SAFPA6FN Type Numeric Length 8 Format . Label Safety Population Flag PA6 (N)

Variable Number 32 Variable COMPLFL Type Character Length 1 Format . Label Completers Population Flag

Variable Number 33 Variable COMPLFN Type Numeric Length 8 Format . Label Completers Population Flag (N)

Variable Number 34 Variable COMPL2FL Type Character Length 1 Format . Label Completers Population Flag 02

Variable Number 35 Variable COMPL2FN Type Numeric Length 8 Format . Label Completers Population Flag 02 (N)

Variable Number 36 Variable COMPL3FL Type Character Length 1 Format . Label Completers Population Flag 03

Variable Number 37 Variable COMPL3FN Type Numeric Length 8 Format . Label Completers Population Flag 03 (N)

Variable Number 38 Variable COMPL4FL Type Character Length 1 Format . Label Completers Population Flag 04

Variable Number 39 Variable COMPL4FN Type Numeric Length 8 Format . Label Completers Population Flag 04 (N)

Variable Number 40 Variable DOSINTFL Type Character Length 1 Format . Label Drug Interrupted for >28 Days Flag

Variable Number 41 Variable DOSINTFN Type Numeric Length 8 Format . Label Drug Interrupted for >28 Days Flag (N)

Variable Number 42 Variable ARM Type Character Length 11 Format . Label Description of Planned Arm

Variable Number 43 Variable ACTARM Type Character Length 11 Format . Label Description of Actual Arm

Variable Number 44 Variable TRT01P Type Character Length 3 Format . Label Planned Treatment for Period 01

Variable Number 45 Variable TRT01PN Type Numeric Length 8 Format . Label Planned Treatment for Period 01 (N)

Variable Number 46 Variable TRT01A Type Character Length 3 Format . Label Actual Treatment for Period 01

Variable Number 47 Variable TRT01AN Type Numeric Length 8 Format . Label Actual Treatment for Period 01 (N)

Variable Number 48 Variable TRTSEQP Type Character Length 7 Format . Label Planned Sequence of Treatments

Variable Number 49 Variable TRTSEQPN Type Numeric Length 8 Format . Label Planned Sequence of Treatments (N)

Variable Number 50 Variable TRTSEQA Type Character Length 7 Format . Label Actual Sequence of Treatments

Variable Number 51 Variable TRTSEQAN Type Numeric Length 8 Format . Label Actual Sequence of Treatments (N)

Variable Number 52 Variable TRTP Type Character Length 7 Format . Label Planned Treatment

Variable Number 53 Variable TRTPN Type Numeric Length 8 Format . Label Planned Treatment (N)

Variable Number 54 Variable TRTA Type Character Length 7 Format . Label Actual Treatment

Variable Number 55 Variable TRTAN Type Numeric Length 8 Format . Label Actual Treatment (N)

Variable Number 56 Variable ASTDTF Type Character Length 1 Format . Label Analysis Start Date Imputation Flag

Variable Number 57 Variable AENDTF Type Character Length 1 Format . Label Analysis End Date Imputation Flag

Variable Number 58 Variable ASTDY Type Numeric Length 8 Format . Label Analysis Start Relative Day (from first treatment date)

Variable Number 59 Variable CMSTDY Type Numeric Length 8 Format . Label Study Day of Start of Medication (from first treatment date)

Variable Number 60 Variable AENDY Type Numeric Length 8 Format . Label Analysis End Relative Day (from first treatment date)

Variable Number 61 Variable CMENDY Type Numeric Length 8 Format . Label Study Day of End of Medication (from first treatment date)

Variable Number 62 Variable CMENRTPT Type Character Length 7 Format . Label End Relative to Reference Time Point

Variable Number 63 Variable CMSEQ Type Numeric Length 8 Format . Label Sequence Number

Variable Number 64 Variable CMSPID Type Character Length 3 Format . Label Sponsor-Defined Identifier

Variable Number 65 Variable CMTRT Type Character Length 174 Format . Label Reported Name of Drug, Med, or Therapy

Variable Number 66 Variable CMDECOD Type Character Length 199 Format . Label Standardized Medication Name

Variable Number 67 Variable CMDECOD2 Type Character Length 36 Format . Label Standardized Medication Name 2

Variable Number 68 Variable CMCAT Type Character Length 5 Format . Label Category for Medication

Variable Number 69 Variable CMINDC Type Character Length 104 Format . Label Indication

Variable Number 70 Variable CMCLAS Type Character Length 64 Format . Label Medication Class

Variable Number 71 Variable CMDOSE Type Numeric Length 8 Format . Label Dose per Administration

Variable Number 72 Variable CMDOSTXT Type Character Length 7 Format . Label Dose Description

Variable Number 73 Variable CMDOSU Type Character Length 12 Format . Label Dose Units

Variable Number 74 Variable CMDOSFRQ Type Character Length 45 Format . Label Dosing Frequency per Interval

Variable Number 75 Variable CMROUTE Type Character Length 24 Format . Label Route of Administration

Variable Number 76 Variable CMEDFL Type Character Length 1 Format . Label Concomitant Medication Flag

Variable Number 77 Variable CMEDFN Type Numeric Length 8 Format . Label Concomitant Medication Flag (N)

Variable Number 78 Variable PRURMDFL Type Character Length 1 Format . Label Pruritus Therapy Medications Flag

Variable Number 79 Variable PRURMDFN Type Numeric Length 8 Format . Label Pruritus Therapy Medications Flag (N)

Variable Number 80 Variable PRURMD Type Numeric Length 8 Format . Label No. Prior Pruritus Therapy Meds

Variable Number 81 Variable PRURMCAT Type Character Length 22 Format . Label Prior Pruritus only Category

Variable Number 82 Variable PRURMCAN Type Numeric Length 8 Format . Label Prior Pruritus only Category (N)

Variable Number 83 Variable NPRURMD Type Numeric Length 8 Format . Label No. Prior Non-Pruritus Therapy Meds

Variable Number 84 Variable NPRURMCT Type Character Length 22 Format . Label Prior Non-Pruritus only Category

Variable Number 85 Variable NPRURMCN Type Numeric Length 8 Format . Label Prior Non-Pruritus only Category (N)

## Data Set Name: adef.sas7bdat

Variable Number 1 Variable SubjRandID Type Numeric Length 8 Format . Label Subject Identifier (randomly assigned)

Variable Number 2 Variable STUDYID Type Character Length 10 Format . Label Study Identifier

Variable Number 3 Variable AGE Type Numeric Length 8 Format . Label Age

Variable Number 4 Variable AGE1 Type Numeric Length 8 Format . Label Age at Baseline

Variable Number 5 Variable AGEM Type Numeric Length 8 Format . Label Age at Baseline (Months)

Variable Number 6 Variable AGEU Type Character Length 5 Format . Label Age Units

Variable Number 7 Variable AGEGR1 Type Character Length 14 Format . Label Pooled Age Group 1

Variable Number 8 Variable AGEGR1N Type Numeric Length 8 Format . Label Pooled Age Group 1 (N)

Variable Number 9 Variable RACE Type Character Length 25 Format . Label Race

Variable Number 10 Variable RACE1 Type Character Length 25 Format . Label Race 1

Variable Number 11 Variable RACE2 Type Character Length 5 Format . Label Race 2

Variable Number 12 Variable RACEN Type Numeric Length 8 Format . Label Race (N)

Variable Number 13 Variable SEX Type Character Length 1 Format . Label Sex

Variable Number 14 Variable SEXN Type Numeric Length 8 Format . Label Sex (N)

Variable Number 15 Variable ETHNIC Type Character Length 22 Format . Label Ethnicity

Variable Number 16 Variable ETHNICN Type Numeric Length 8 Format . Label Ethnicity (N)

Variable Number 17 Variable COUNTRY Type Character Length 3 Format . Label Country

Variable Number 18 Variable SCRNFL Type Character Length 1 Format . Label Screened Population Flag

Variable Number 19 Variable SCRNFN Type Numeric Length 8 Format . Label Screened Population Flag (N)

Variable Number 20 Variable ENRFL Type Character Length 1 Format . Label Enrolled Population Flag

Variable Number 21 Variable ENRFLN Type Numeric Length 8 Format . Label Enrolled Population Flag (N)

Variable Number 22 Variable SAFFL Type Character Length 1 Format . Label Safety Population Flag

Variable Number 23 Variable SAFFN Type Numeric Length 8 Format . Label Safety Population Flag (N)

Variable Number 24 Variable SAFOPFL Type Character Length 1 Format . Label Safety Population Flag Core Trt

Variable Number 25 Variable SAFOPFN Type Numeric Length 8 Format . Label Safety Population Flag Core Trt (N)

Variable Number 26 Variable SAFPA4FL Type Character Length 1 Format . Label Safety Population Flag PA4

Variable Number 27 Variable SAFPA4FN Type Numeric Length 8 Format . Label Safety Population Flag PA4 (N)

Variable Number 28 Variable SAFPA5FL Type Character Length 1 Format . Label Safety Population Flag PA5

Variable Number 29 Variable SAFPA5FN Type Numeric Length 8 Format . Label Safety Population Flag PA5 (N)

Variable Number 30 Variable SAFPA6FL Type Character Length 1 Format . Label Safety Population Flag PA6

Variable Number 31 Variable SAFPA6FN Type Numeric Length 8 Format . Label Safety Population Flag PA6 (N)

Variable Number 32 Variable COMPLFL Type Character Length 1 Format . Label Completers Population Flag

Variable Number 33 Variable COMPLFN Type Numeric Length 8 Format . Label Completers Population Flag (N)

Variable Number 34 Variable COMPL2FL Type Character Length 1 Format . Label Completers Population Flag 02

Variable Number 35 Variable COMPL2FN Type Numeric Length 8 Format . Label Completers Population Flag 02 (N)

Variable Number 36 Variable COMPL3FL Type Character Length 1 Format . Label Completers Population Flag 03

Variable Number 37 Variable COMPL3FN Type Numeric Length 8 Format . Label Completers Population Flag 03 (N)

Variable Number 38 Variable COMPL4FL Type Character Length 1 Format . Label Completers Population Flag 04

Variable Number 39 Variable COMPL4FN Type Numeric Length 8 Format . Label Completers Population Flag 04 (N)

Variable Number 40 Variable DOSINTFL Type Character Length 1 Format . Label Drug Interrupted for >28 Days Flag

Variable Number 41 Variable DOSINTFN Type Numeric Length 8 Format . Label Drug Interrupted for >28 Days Flag (N)

Variable Number 42 Variable ARM Type Character Length 11 Format . Label Description of Planned Arm

Variable Number 43 Variable ARMCD Type Character Length 2 Format . Label Description Code of Planned Arm

Variable Number 44 Variable ACTARM Type Character Length 11 Format . Label Description of Actual Arm

Variable Number 45 Variable ACTARMCD Type Character Length 2 Format . Label Description Code of Actual Arm

Variable Number 46 Variable TRT01P Type Character Length 3 Format . Label Planned Treatment for Period 01

Variable Number 47 Variable TRT01PN Type Numeric Length 8 Format . Label Planned Treatment for Period 01 (N)

Variable Number 48 Variable TRT01A Type Character Length 3 Format . Label Actual Treatment for Period 01

Variable Number 49 Variable TRT01AN Type Numeric Length 8 Format . Label Actual Treatment for Period 01 (N)

Variable Number 50 Variable TRTSEQP Type Character Length 7 Format . Label Planned Sequence of Treatments

Variable Number 51 Variable TRTSEQPN Type Numeric Length 8 Format . Label Planned Sequence of Treatments (N)

Variable Number 52 Variable TRTSEQA Type Character Length 7 Format . Label Actual Sequence of Treatments

Variable Number 53 Variable TRTSEQAN Type Numeric Length 8 Format . Label Actual Sequence of Treatments (N)

Variable Number 54 Variable TRTP Type Character Length 7 Format . Label Planned Treatment

Variable Number 55 Variable TRTPN Type Numeric Length 8 Format . Label Planned Treatment (N)

Variable Number 56 Variable TRTA Type Character Length 7 Format . Label Actual Treatment

Variable Number 57 Variable TRTAN Type Numeric Length 8 Format . Label Actual Treatment (N)

Variable Number 58 Variable APERIOD Type Numeric Length 8 Format . Label Period

Variable Number 59 Variable APERIODC Type Character Length 46 Format . Label Period (C)

Variable Number 60 Variable LBSEQ Type Numeric Length 8 Format . Label Sequence Number

Variable Number 61 Variable VISIT Type Character Length 28 Format . Label Visit Name

Variable Number 62 Variable VISITNUM Type Numeric Length 8 Format . Label Visit Number

Variable Number 63 Variable LBDY Type Numeric Length 8 Format . Label Study Day of Specimen Collection

Variable Number 64 Variable AVISITN Type Numeric Length 8 Format . Label Analysis Visit (N)

Variable Number 65 Variable AVISIT Type Character Length 13 Format . Label Analysis Visit

Variable Number 66 Variable DTYPE Type Character Length 23 Format . Label Derivation Type

Variable Number 67 Variable ADY Type Numeric Length 8 Format . Label Analysis Relative Day (from first treatment date)

Variable Number 68 Variable PARAM Type Character Length 46 Format . Label Parameter

Variable Number 69 Variable PARAMCD Type Character Length 6 Format . Label Parameter Code

Variable Number 70 Variable PARAMN Type Numeric Length 8 Format . Label Parameter (N)

Variable Number 71 Variable PARCAT1 Type Character Length 9 Format . Label Parameter Category 1

Variable Number 72 Variable PARCAT2 Type Character Length 22 Format . Label Parameter Category 2

Variable Number 73 Variable AVAL Type Numeric Length 8 Format . Label Analysis Value

Variable Number 74 Variable AVALC Type Character Length 8 Format . Label Analysis Value (C)

Variable Number 75 Variable BASE Type Numeric Length 8 Format . Label Baseline Value

Variable Number 76 Variable BASEC Type Character Length 8 Format . Label Baseline Value (C)

Variable Number 77 Variable CHG Type Numeric Length 8 Format . Label Change from Baseline

Variable Number 78 Variable PCHG Type Numeric Length 8 Format . Label Percent Change from Baseline

Variable Number 79 Variable ABLFL Type Character Length 1 Format . Label Baseline Record Flag

Variable Number 80 Variable ABLFN Type Numeric Length 8 Format . Label Baseline Record Flag (N)

Variable Number 81 Variable ANRLO Type Character Length 3 Format . Label Analysis Normal Range Lower Limit



Variable Number 82 Variable ANRHI Type Character Length 3 Format . Label Analysis Normal Range Upper Limit

Variable Number 83 Variable ANRIND Type Character Length 6 Format . Label Analysis Reference Range Indicator

Variable Number 84 Variable BNRIND Type Character Length 6 Format . Label Baseline Reference Range Indicator

Variable Number 85 Variable SHIFT1 Type Character Length 16 Format . Label Shift 1

Variable Number 86 Variable CRIT1 Type Character Length 36 Format . Label Analysis Criterion 1

Variable Number 87 Variable CRIT1FL Type Character Length 1 Format . Label Criterion 1 Evaluation Result Flag

Variable Number 88 Variable CRIT2 Type Character Length 9 Format . Label Analysis Criterion 2

Variable Number 89 Variable CRIT2FL Type Character Length 1 Format . Label Criterion 2 Evaluation Result Flag

Variable Number 90 Variable CRIT3 Type Character Length 10 Format . Label Analysis Criterion 3

Variable Number 91 Variable CRIT3FL Type Character Length 1 Format . Label Criterion 3 Evaluation Result Flag

Variable Number 92 Variable CRIT4 Type Character Length 10 Format . Label Analysis Criterion 4

Variable Number 93 Variable CRIT4FL Type Character Length 1 Format . Label Criterion 4 Evaluation Result Flag

## Data Set Name: adex.sas7bdat

Variable Number 1 Variable SubjRandID Type Numeric Length 8 Format . Label Subject Identifier (randomly assigned)

Variable Number 2 Variable STUDYID Type Character Length 10 Format . Label Study Identifier

Variable Number 3 Variable AGE Type Numeric Length 8 Format . Label Age

Variable Number 4 Variable AGE1 Type Numeric Length 8 Format . Label Age at Baseline

Variable Number 5 Variable AGEM Type Numeric Length 8 Format . Label Age at Baseline (Months)

Variable Number 6 Variable AGEU Type Character Length 5 Format . Label Age Units

Variable Number 7 Variable AGEGR1 Type Character Length 14 Format . Label Pooled Age Group 1

Variable Number 8 Variable AGEGR1N Type Numeric Length 8 Format . Label Pooled Age Group 1 (N)

Variable Number 9 Variable RACE Type Character Length 25 Format . Label Race

Variable Number 10 Variable RACE1 Type Character Length 25 Format . Label Race 1

Variable Number 11 Variable RACE2 Type Character Length 5 Format . Label Race 2

Variable Number 12 Variable RACEN Type Numeric Length 8 Format . Label Race (N)

Variable Number 13 Variable SEX Type Character Length 1 Format . Label Sex

Variable Number 14 Variable SEXN Type Numeric Length 8 Format . Label Sex (N)

Variable Number 15 Variable ETHNIC Type Character Length 22 Format . Label Ethnicity

Variable Number 16 Variable ETHNICN Type Numeric Length 8 Format . Label Ethnicity (N)

Variable Number 17 Variable COUNTRY Type Character Length 3 Format . Label Country

Variable Number 18 Variable SCRNFL Type Character Length 1 Format . Label Screened Population Flag

Variable Number 19 Variable SCRNFN Type Numeric Length 8 Format . Label Screened Population Flag (N)

Variable Number 20 Variable ENRFL Type Character Length 1 Format . Label Enrolled Population Flag

Variable Number 21 Variable ENRFLN Type Numeric Length 8 Format . Label Enrolled Population Flag (N)

Variable Number 22 Variable SAFFL Type Character Length 1 Format . Label Safety Population Flag

Variable Number 23 Variable SAFFN Type Numeric Length 8 Format . Label Safety Population Flag (N)

Variable Number 24 Variable SAFOPFL Type Character Length 1 Format . Label Safety Population Flag Core Trt

Variable Number 25 Variable SAFOPFN Type Numeric Length 8 Format . Label Safety Population Flag Core Trt (N)

Variable Number 26 Variable SAFPA4FL Type Character Length 1 Format . Label Safety Population Flag PA4

Variable Number 27 Variable SAFPA4FN Type Numeric Length 8 Format . Label Safety Population Flag PA4 (N)

Variable Number 28 Variable SAFPA5FL Type Character Length 1 Format . Label Safety Population Flag PA5

Variable Number 29 Variable SAFPA5FN Type Numeric Length 8 Format . Label Safety Population Flag PA5 (N)

Variable Number 30 Variable SAFPA6FL Type Character Length 1 Format . Label Safety Population Flag PA6

Variable Number 31 Variable SAFPA6FN Type Numeric Length 8 Format . Label Safety Population Flag PA6 (N)

Variable Number 32 Variable COMPLFL Type Character Length 1 Format . Label Completers Population Flag

Variable Number 33 Variable COMPLFN Type Numeric Length 8 Format . Label Completers Population Flag (N)

Variable Number 34 Variable COMPL2FL Type Character Length 1 Format . Label Completers Population Flag 02

Variable Number 35 Variable COMPL2FN Type Numeric Length 8 Format . Label Completers Population Flag 02 (N)

Variable Number 36 Variable COMPL3FL Type Character Length 1 Format . Label Completers Population Flag 03

Variable Number 37 Variable COMPL3FN Type Numeric Length 8 Format . Label Completers Population Flag 03 (N)

Variable Number 38 Variable COMPL4FL Type Character Length 1 Format . Label Completers Population Flag 04

Variable Number 39 Variable COMPL4FN Type Numeric Length 8 Format . Label Completers Population Flag 04 (N)

Variable Number 40 Variable DOSINTFL Type Character Length 1 Format . Label Drug Interrupted for >28 Days Flag

Variable Number 41 Variable DOSINTFN Type Numeric Length 8 Format . Label Drug Interrupted for >28 Days Flag (N)

Variable Number 42 Variable ARM Type Character Length 11 Format . Label Description of Planned Arm

Variable Number 43 Variable ARMCD Type Character Length 2 Format . Label Description Code of Planned Arm

Variable Number 44 Variable ACTARM Type Character Length 11 Format . Label Description of Actual Arm

Variable Number 45 Variable ACTARMCD Type Character Length 2 Format . Label Description Code of Actual Arm

Variable Number 46 Variable TRT01P Type Character Length 3 Format . Label Planned Treatment for Period 01

Variable Number 47 Variable TRT01PN Type Numeric Length 8 Format . Label Planned Treatment for Period 01 (N)

Variable Number 48 Variable TRT01A Type Character Length 3 Format . Label Actual Treatment for Period 01

Variable Number 49 Variable TRT01AN Type Numeric Length 8 Format . Label Actual Treatment for Period 01 (N)

Variable Number 50 Variable TRTSEQP Type Character Length 7 Format . Label Planned Sequence of Treatments

Variable Number 51 Variable TRTSEQPN Type Numeric Length 8 Format . Label Planned Sequence of Treatments (N)

Variable Number 52 Variable TRTSEQA Type Character Length 7 Format . Label Actual Sequence of Treatments

Variable Number 53 Variable TRTSEQAN Type Numeric Length 8 Format . Label Actual Sequence of Treatments (N)

Variable Number 54 Variable TRTP Type Character Length 7 Format . Label Planned Treatment

Variable Number 55 Variable TRTPN Type Numeric Length 8 Format . Label Planned Treatment (N)

Variable Number 56 Variable TRTA Type Character Length 7 Format . Label Actual Treatment

Variable Number 57 Variable TRTAN Type Numeric Length 8 Format . Label Actual Treatment (N)

Variable Number 58 Variable AVISIT Type Character Length 46 Format . Label Analysis Visit

Variable Number 59 Variable AVISITN Type Numeric Length 8 Format . Label Analysis Visit (N)

Variable Number 60 Variable PARAM Type Character Length 30 Format . Label Parameter

Variable Number 61 Variable PARAMCD Type Character Length 8 Format . Label Parameter Code

Variable Number 62 Variable PARAMN Type Numeric Length 8 Format . Label Parameter (N)

Variable Number 63 Variable PARAMTYP Type Character Length 7 Format . Label Parameter Type

Variable Number 64 Variable AVAL Type Numeric Length 8 Format . Label Analysis Value

Variable Number 65 Variable CRIT1 Type Character Length 30 Format . Label Analysis Criterion 1

Variable Number 66 Variable CRIT1FL Type Character Length 1 Format . Label Criterion 1 Evaluation Result Flag

Variable Number 67 Variable CRIT2 Type Character Length 35 Format . Label Analysis Criterion 2

Variable Number 68 Variable CRIT2FL Type Character Length 1 Format . Label Criterion 2 Evaluation Result Flag

Variable Number 69 Variable CRIT3 Type Character Length 35 Format . Label Analysis Criterion 3

Variable Number 70 Variable CRIT3FL Type Character Length 1 Format . Label Criterion 3 Evaluation Result Flag

Variable Number 71 Variable CRIT4 Type Character Length 36 Format . Label Analysis Criterion 4

Variable Number 72 Variable CRIT4FL Type Character Length 1 Format . Label Criterion 4 Evaluation Result Flag

Variable Number 73 Variable CRIT5 Type Character Length 37 Format . Label Analysis Criterion 5

Variable Number 74 Variable CRIT5FL Type Character Length 1 Format . Label Criterion 5 Evaluation Result Flag

Variable Number 75 Variable CRIT6 Type Character Length 37 Format . Label Analysis Criterion 6

Variable Number 76 Variable CRIT6FL Type Character Length 1 Format . Label Criterion 6 Evaluation Result Flag

Variable Number 77 Variable CRIT7 Type Character Length 30 Format . Label Analysis Criterion 7

Variable Number 78 Variable CRIT7FL Type Character Length 1 Format . Label Criterion 7 Evaluation Result Flag

Variable Number 79 Variable SDFIRRX Type Numeric Length 8 Format . Label Study Day of First Exposure to Treatment (from first treatment date)

Variable Number 80 Variable SDLASRX Type Numeric Length 8 Format . Label Study Day of Last Exposure to Treatment (from first treatment date)

Variable Number 81 Variable SDSTP1 Type Numeric Length 8 Format . Label Study Day of Period 01 Start (from first treatment date)

Variable Number 82 Variable SDENP1 Type Numeric Length 8 Format . Label Study Day of Period 01 End (from first treatment date)

Variable Number 83 Variable SDSTP2 Type Numeric Length 8 Format . Label Study Day of Period 02 Start (from first treatment date)

Variable Number 84 Variable SDENP2 Type Numeric Length 8 Format . Label Study Day of Period 02 End (from first treatment date)

Variable Number 85 Variable SDSTP3 Type Numeric Length 8 Format . Label Study Day of Period 03 Start (from first treatment date)

Variable Number 86 Variable SDENP3 Type Numeric Length 8 Format . Label Study Day of Period 03 End (from first treatment date)

Variable Number 87 Variable SDSTP4 Type Numeric Length 8 Format . Label Study Day of Period 04 Start (from first treatment date)

Variable Number 88 Variable SDENP4 Type Numeric Length 8 Format . Label Study Day of Period 04 End (from first treatment date)

Variable Number 89 Variable SDILASRX1 Type Numeric Length 8 Format . Label Study Day of Initial Last Exposure 01 (from first treatment date)

Variable Number 90 Variable SDRXAFLEX1 Type Numeric Length 8 Format . Label Study Day of Drug After Last Exposure 01 (from first treatment date)

Variable Number 91 Variable SDILASRX2 Type Numeric Length 8 Format . Label Study Day of Initial Last Exposure 02 (from first treatment date)

Variable Number 92 Variable SDRXAFLEX2 Type Numeric Length 8 Format . Label Study Day of Drug After Last Exposure 02 (from first treatment date)

## Data Set Name: `adlb.sas7bdat`

Variable Number 1 Variable SubjRandID Type Numeric Length 8 Format . Label Subject Identifier (randomly assigned)

Variable Number 2 Variable STUDYID Type Character Length 10 Format . Label Study Identifier

Variable Number 3 Variable AGE Type Numeric Length 8 Format . Label Age

Variable Number 4 Variable AGE1 Type Numeric Length 8 Format . Label Age at Baseline

Variable Number 5 Variable AGEM Type Numeric Length 8 Format . Label Age at Baseline (Months)

Variable Number 6 Variable AGEU Type Character Length 5 Format . Label Age Units

Variable Number 7 Variable AGEGR1 Type Character Length 14 Format . Label Pooled Age Group 1

Variable Number 8 Variable AGEGR1N Type Numeric Length 8 Format . Label Pooled Age Group 1 (N)

Variable Number 9 Variable RACE Type Character Length 25 Format . Label Race

Variable Number 10 Variable RACE1 Type Character Length 25 Format . Label Race 1

Variable Number 11 Variable RACE2 Type Character Length 5 Format . Label Race 2

Variable Number 12 Variable RACEN Type Numeric Length 8 Format . Label Race (N)

Variable Number 13 Variable SEX Type Character Length 1 Format . Label Sex

Variable Number 14 Variable SEXN Type Numeric Length 8 Format . Label Sex (N)

Variable Number 15 Variable ETHNIC Type Character Length 22 Format . Label Ethnicity

Variable Number 16 Variable ETHNICN Type Numeric Length 8 Format . Label Ethnicity (N)

Variable Number 17 Variable COUNTRY Type Character Length 3 Format . Label Country

Variable Number 18 Variable SCRNFL Type Character Length 1 Format . Label Screened Population Flag

Variable Number 19 Variable SCRNFN Type Numeric Length 8 Format . Label Screened Population Flag (N)

Variable Number 20 Variable ENRFL Type Character Length 1 Format . Label Enrolled Population Flag

Variable Number 21 Variable ENRFLN Type Numeric Length 8 Format . Label Enrolled Population Flag (N)

Variable Number 22 Variable SAFFL Type Character Length 1 Format . Label Safety Population Flag

Variable Number 23 Variable SAFFN Type Numeric Length 8 Format . Label Safety Population Flag (N)

Variable Number 24 Variable SAFOPFL Type Character Length 1 Format . Label Safety Population Flag Core Trt

Variable Number 25 Variable SAFOPFN Type Numeric Length 8 Format . Label Safety Population Flag Core Trt (N)

Variable Number 26 Variable SAFPA4FL Type Character Length 1 Format . Label Safety Population Flag PA4

Variable Number 27 Variable SAFPA4FN Type Numeric Length 8 Format . Label Safety Population Flag PA4 (N)

Variable Number 28 Variable SAFPA5FL Type Character Length 1 Format . Label Safety Population Flag PA5

Variable Number 29 Variable SAFPA5FN Type Numeric Length 8 Format . Label Safety Population Flag PA5 (N)

Variable Number 30 Variable SAFPA6FL Type Character Length 1 Format . Label Safety Population Flag PA6

Variable Number 31 Variable SAFPA6FN Type Numeric Length 8 Format . Label Safety Population Flag PA6 (N)

Variable Number 32 Variable COMPLFL Type Character Length 1 Format . Label Completers Population Flag

Variable Number 33 Variable COMPLFN Type Numeric Length 8 Format . Label Completers Population Flag (N)

Variable Number 34 Variable COMPL2FL Type Character Length 1 Format . Label Completers Population Flag 02

Variable Number 35 Variable COMPL2FN Type Numeric Length 8 Format . Label Completers Population Flag 02 (N)

Variable Number 36 Variable COMPL3FL Type Character Length 1 Format . Label Completers Population Flag 03

Variable Number 37 Variable COMPL3FN Type Numeric Length 8 Format . Label Completers Population Flag 03 (N)

Variable Number 38 Variable COMPL4FL Type Character Length 1 Format . Label Completers Population Flag 04

Variable Number 39 Variable COMPL4FN Type Numeric Length 8 Format . Label Completers Population Flag 04 (N)

Variable Number 40 Variable DOSINTFL Type Character Length 1 Format . Label Drug Interrupted for >28 Days Flag

Variable Number 41 Variable DOSINTFN Type Numeric Length 8 Format . Label Drug Interrupted for >28 Days Flag (N)

Variable Number 42 Variable ARM Type Character Length 11 Format . Label Description of Planned Arm

Variable Number 43 Variable ARMCD Type Character Length 2 Format . Label Description Code of Planned Arm

Variable Number 44 Variable ACTARM Type Character Length 11 Format . Label Description of Actual Arm

Variable Number 45 Variable ACTARMCD Type Character Length 2 Format . Label Description Code of Actual Arm

Variable Number 46 Variable TRT01P Type Character Length 3 Format . Label Planned Treatment for Period 01

Variable Number 47 Variable TRT01PN Type Numeric Length 8 Format . Label Planned Treatment for Period 01 (N)

Variable Number 48 Variable TRT01A Type Character Length 3 Format . Label Actual Treatment for Period 01

Variable Number 49 Variable TRT01AN Type Numeric Length 8 Format . Label Actual Treatment for Period 01 (N)

Variable Number 50 Variable TRTSEQP Type Character Length 7 Format . Label Planned Sequence of Treatments

Variable Number 51 Variable TRTSEQPN Type Numeric Length 8 Format . Label Planned Sequence of Treatments (N)

Variable Number 52 Variable TRTSEQA Type Character Length 7 Format . Label Actual Sequence of Treatments



Variable Number 53 Variable TRTSEQAN Type Numeric Length 8 Format . Label Actual Sequence of Treatments (N)

Variable Number 54 Variable TRTP Type Character Length 7 Format . Label Planned Treatment

Variable Number 55 Variable TRTPN Type Numeric Length 8 Format . Label Planned Treatment (N)

Variable Number 56 Variable TRTA Type Character Length 7 Format . Label Actual Treatment

Variable Number 57 Variable TRTAN Type Numeric Length 8 Format . Label Actual Treatment (N)

Variable Number 58 Variable APERIOD Type Numeric Length 8 Format . Label Period

Variable Number 59 Variable APERIODC Type Character Length 46 Format . Label Period (C)

Variable Number 60 Variable LBSEQ Type Numeric Length 8 Format . Label Sequence Number

Variable Number 61 Variable VISIT Type Character Length 28 Format . Label Visit Name

Variable Number 62 Variable VISITNUM Type Numeric Length 8 Format . Label Visit Number

Variable Number 63 Variable LBDY Type Numeric Length 8 Format . Label Study Day of Specimen Collection (from first treatment date)

Variable Number 64 Variable AVISITN Type Numeric Length 8 Format . Label Analysis Visit (N)

Variable Number 65 Variable AVISIT Type Character Length 13 Format . Label Analysis Visit

Variable Number 66 Variable DTYPE Type Character Length 23 Format . Label Derivation Type

Variable Number 67 Variable ADY Type Numeric Length 8 Format . Label Analysis Relative Day (from first treatment date)

Variable Number 68 Variable PARAM Type Character Length 46 Format . Label Parameter

Variable Number 69 Variable PARAMCD Type Character Length 8 Format . Label Parameter Code

Variable Number 70 Variable PARAMN Type Numeric Length 8 Format . Label Parameter (N)

Variable Number 71 Variable PARAMTYP Type Character Length 7 Format . Label Parameter Type

Variable Number 72 Variable PARCAT1 Type Character Length 11 Format . Label Parameter Category 1

Variable Number 73 Variable PARCAT2 Type Character Length 20 Format . Label Parameter Category 2

Variable Number 74 Variable AVAL Type Numeric Length 8 Format . Label Analysis Value

Variable Number 75 Variable AVALC Type Character Length 13 Format . Label Analysis Value (C)

Variable Number 76 Variable BASETYPE Type Character Length 11 Format . Label Baseline Type

Variable Number 77 Variable BASE Type Numeric Length 8 Format . Label Baseline Value

Variable Number 78 Variable BASEC Type Character Length 13 Format . Label Baseline Value (C)

Variable Number 79 Variable CHG Type Numeric Length 8 Format . Label Change from Baseline

Variable Number 80 Variable PCHG Type Numeric Length 8 Format . Label Percent Change from Baseline

Variable Number 81 Variable ABLFL Type Character Length 1 Format . Label Baseline Record Flag

Variable Number 82 Variable ABLFN Type Numeric Length 8 Format . Label Baseline Record Flag (N)

Variable Number 83 Variable ANRLO Type Character Length 5 Format . Label Analysis Normal Range Lower Limit

Variable Number 84 Variable ANRHI Type Character Length 4 Format . Label Analysis Normal Range Upper Limit

Variable Number 85 Variable ANRIND Type Character Length 6 Format . Label Analysis Reference Range Indicator

Variable Number 86 Variable BNRIND Type Character Length 6 Format . Label Baseline Reference Range Indicator

Variable Number 87 Variable SHIFT1 Type Character Length 16 Format . Label Shift 1

Variable Number 88 Variable CRIT1 Type Character Length 32 Format . Label Analysis Criterion 1

Variable Number 89 Variable CRIT1FL Type Character Length 1 Format . Label Criterion 1 Evaluation Result Flag

Variable Number 90 Variable CRIT2 Type Character Length 29 Format . Label Analysis Criterion 2

Variable Number 91 Variable CRIT2FL Type Character Length 1 Format . Label Criterion 2 Evaluation Result Flag

Variable Number 92 Variable CRIT3 Type Character Length 29 Format . Label Analysis Criterion 3

Variable Number 93 Variable CRIT3FL Type Character Length 1 Format . Label Criterion 3 Evaluation Result Flag

## Data Set Name: adpc.sas7bdat

Variable Number 1 Variable SubjRandID Type Numeric Length 8 Format . Label Subject Identifier (randomly assigned)

Variable Number 2 Variable STUDYID Type Character Length 10 Format . Label Study Identifier

Variable Number 3 Variable AGE Type Numeric Length 8 Format . Label Age

Variable Number 4 Variable AGE1 Type Numeric Length 8 Format . Label Age at Baseline

Variable Number 5 Variable AGEM Type Numeric Length 8 Format . Label Age at Baseline (Months)

Variable Number 6 Variable AGEU Type Character Length 5 Format . Label Age Units

Variable Number 7 Variable AGEGR1 Type Character Length 14 Format . Label Pooled Age Group 1

Variable Number 8 Variable AGEGR1N Type Numeric Length 8 Format . Label Pooled Age Group 1 (N)

Variable Number 9 Variable RACE Type Character Length 25 Format . Label Race

Variable Number 10 Variable RACE1 Type Character Length 25 Format . Label Race 1

Variable Number 11 Variable RACE2 Type Character Length 5 Format . Label Race 2

Variable Number 12 Variable RACEN Type Numeric Length 8 Format . Label Race (N)

Variable Number 13 Variable SEX Type Character Length 1 Format . Label Sex

Variable Number 14 Variable SEXN Type Numeric Length 8 Format . Label Sex (N)

Variable Number 15 Variable ETHNIC Type Character Length 22 Format . Label Ethnicity

Variable Number 16 Variable ETHNICN Type Numeric Length 8 Format . Label Ethnicity (N)

Variable Number 17 Variable COUNTRY Type Character Length 3 Format . Label Country

Variable Number 18 Variable SCRNFL Type Character Length 1 Format . Label Screened Population Flag

Variable Number 19 Variable SCRNFN Type Numeric Length 8 Format . Label Screened Population Flag (N)

Variable Number 20 Variable ENRFL Type Character Length 1 Format . Label Enrolled Population Flag

Variable Number 21 Variable ENRFLN Type Numeric Length 8 Format . Label Enrolled Population Flag (N)

Variable Number 22 Variable SAFFL Type Character Length 1 Format . Label Safety Population Flag

Variable Number 23 Variable SAFFN Type Numeric Length 8 Format . Label Safety Population Flag (N)

Variable Number 24 Variable SAFOPFL Type Character Length 1 Format . Label Safety  
Population Flag Core Trt

Variable Number 25 Variable SAFOPFN Type Numeric Length 8 Format . Label Safety  
Population Flag Core Trt (N)

Variable Number 26 Variable SAFPA4FL Type Character Length 1 Format . Label Safety  
Population Flag PA4

Variable Number 27 Variable SAFPA4FN Type Numeric Length 8 Format . Label Safety  
Population Flag PA4 (N)

Variable Number 28 Variable SAFPA5FL Type Character Length 1 Format . Label Safety  
Population Flag PA5

Variable Number 29 Variable SAFPA5FN Type Numeric Length 8 Format . Label Safety  
Population Flag PA5 (N)

Variable Number 30 Variable SAFPA6FL Type Character Length 1 Format . Label Safety  
Population Flag PA6

Variable Number 31 Variable SAFPA6FN Type Numeric Length 8 Format . Label Safety  
Population Flag PA6 (N)

Variable Number 32 Variable COMPLFL Type Character Length 1 Format . Label Completers  
Population Flag

Variable Number 33 Variable COMPLFN Type Numeric Length 8 Format . Label Completers  
Population Flag (N)

Variable Number 34 Variable COMPL2FL Type Character Length 1 Format . Label Completers  
Population Flag 02

Variable Number 35 Variable COMPL2FN Type Numeric Length 8 Format . Label Completers  
Population Flag 02 (N)

Variable Number 36 Variable COMPL3FL Type Character Length 1 Format . Label Completers  
Population Flag 03

Variable Number 37 Variable COMPL3FN Type Numeric Length 8 Format . Label Completers  
Population Flag 03 (N)

Variable Number 38 Variable COMPL4FL Type Character Length 1 Format . Label Completers  
Population Flag 04

Variable Number 39 Variable COMPL4FN Type Numeric Length 8 Format . Label Completers  
Population Flag 04 (N)

Variable Number 40 Variable DOSINTFL Type Character Length 1 Format . Label Drug  
Interrupted for >28 Days Flag

Variable Number 41 Variable DOSINTFN Type Numeric Length 8 Format . Label Drug  
Interrupted for >28 Days Flag (N)

Variable Number 42 Variable ARM Type Character Length 11 Format . Label Description of Planned Arm

Variable Number 43 Variable ARMCD Type Character Length 2 Format . Label Description Code of Planned Arm

Variable Number 44 Variable ACTARM Type Character Length 11 Format . Label Description of Actual Arm

Variable Number 45 Variable ACTARMCD Type Character Length 2 Format . Label Description Code of Actual Arm

Variable Number 46 Variable TRT01P Type Character Length 3 Format . Label Planned Treatment for Period 01

Variable Number 47 Variable TRT01PN Type Numeric Length 8 Format . Label Planned Treatment for Period 01 (N)

Variable Number 48 Variable TRT01A Type Character Length 3 Format . Label Actual Treatment for Period 01

Variable Number 49 Variable TRT01AN Type Numeric Length 8 Format . Label Actual Treatment for Period 01 (N)

Variable Number 50 Variable TRTSEQP Type Character Length 7 Format . Label Planned Sequence of Treatments

Variable Number 51 Variable TRTSEQPN Type Numeric Length 8 Format . Label Planned Sequence of Treatments (N)

Variable Number 52 Variable TRTSEQA Type Character Length 7 Format . Label Actual Sequence of Treatments

Variable Number 53 Variable TRTSEQAN Type Numeric Length 8 Format . Label Actual Sequence of Treatments (N)

Variable Number 54 Variable TRTP Type Character Length 7 Format . Label Planned Treatment

Variable Number 55 Variable TRTPN Type Numeric Length 8 Format . Label Planned Treatment (N)

Variable Number 56 Variable TRTA Type Character Length 7 Format . Label Actual Treatment

Variable Number 57 Variable TRTAN Type Numeric Length 8 Format . Label Actual Treatment (N)

Variable Number 58 Variable APERIOD Type Numeric Length 8 Format . Label Period

Variable Number 59 Variable APERIODC Type Character Length 46 Format . Label Period (C)

Variable Number 60 Variable PCSEQ Type Numeric Length 8 Format . Label Sequence Number

Variable Number 61 Variable VISIT Type Character Length 28 Format . Label Visit Name

Variable Number 62 Variable VISITNUM Type Numeric Length 8 Format . Label Visit Number

Variable Number 63 Variable PCDY Type Numeric Length 8 Format . Label Actual Study Day of Specimen Collection (from first treatment date)

Variable Number 64 Variable AVISITN Type Numeric Length 8 Format . Label Analysis Visit (N)

Variable Number 65 Variable AVISIT Type Character Length 12 Format . Label Analysis Visit

Variable Number 66 Variable DTYPE Type Character Length 3 Format . Label Derivation Type

Variable Number 67 Variable ADY Type Numeric Length 8 Format . Label Analysis Relative Day (from first treatment date)

Variable Number 68 Variable PARCAT1 Type Character Length 7 Format . Label Parameter Category 1

Variable Number 69 Variable PARAM Type Character Length 11 Format . Label Parameter

Variable Number 70 Variable PARAMCD Type Character Length 3 Format . Label Parameter Code

Variable Number 71 Variable PARAMN Type Numeric Length 8 Format . Label Parameter (N)

Variable Number 72 Variable AVAL Type Numeric Length 8 Format . Label Analysis Value

Variable Number 73 Variable AVALC Type Character Length 5 Format . Label Analysis Value (C)

Variable Number 74 Variable ABLFL Type Character Length 1 Format . Label Baseline Record Flag

Variable Number 75 Variable ABLFN Type Numeric Length 8 Format . Label Baseline Record Flag (N)

Variable Number 76 Variable BASE Type Numeric Length 8 Format . Label Baseline Value

Variable Number 77 Variable CHG Type Numeric Length 8 Format . Label Change from Baseline

Variable Number 78 Variable DOSEON Type Character Length 8 Format . Label Study Drug Dose at Onset

Variable Number 79 Variable DOSEONU Type Character Length 9 Format . Label Study Drug Dose at Onset Units

## Data Set Name: [adqs.sas7bdat](#)

Variable Number 1 Variable SubjRandID Type Numeric Length 8 Format . Label Subject Identifier (randomly assigned)

Variable Number 2 Variable STUDYID Type Character Length 10 Format . Label Study Identifier

Variable Number 3 Variable AGE Type Numeric Length 8 Format . Label Age

Variable Number 4 Variable AGE1 Type Numeric Length 8 Format . Label Age at Baseline

Variable Number 5 Variable AGEM Type Numeric Length 8 Format . Label Age at Baseline (Months)

Variable Number 6 Variable AGEU Type Character Length 5 Format . Label Age Units

Variable Number 7 Variable AGEGR1 Type Character Length 14 Format . Label Pooled Age Group 1

Variable Number 8 Variable AGEGR1N Type Numeric Length 8 Format . Label Pooled Age Group 1 (N)

Variable Number 9 Variable RACE Type Character Length 25 Format . Label Race

Variable Number 10 Variable RACE1 Type Character Length 25 Format . Label Race 1

Variable Number 11 Variable RACE2 Type Character Length 5 Format . Label Race 2

Variable Number 12 Variable RACEN Type Numeric Length 8 Format . Label Race (N)

Variable Number 13 Variable SEX Type Character Length 1 Format . Label Sex

Variable Number 14 Variable SEXN Type Numeric Length 8 Format . Label Sex (N)

Variable Number 15 Variable ETHNIC Type Character Length 22 Format . Label Ethnicity

Variable Number 16 Variable ETHNICN Type Numeric Length 8 Format . Label Ethnicity (N)

Variable Number 17 Variable COUNTRY Type Character Length 3 Format . Label Country

Variable Number 18 Variable SCRNFL Type Character Length 1 Format . Label Screened Population Flag

Variable Number 19 Variable SCRNFN Type Numeric Length 8 Format . Label Screened Population Flag (N)

Variable Number 20 Variable ENRFL Type Character Length 1 Format . Label Enrolled Population Flag

Variable Number 21 Variable ENRFLN Type Numeric Length 8 Format . Label Enrolled Population Flag (N)

Variable Number 22 Variable SAFFL Type Character Length 1 Format . Label Safety Population Flag

Variable Number 23 Variable SAFFN Type Numeric Length 8 Format . Label Safety Population Flag (N)

Variable Number 24 Variable SAFOPFL Type Character Length 1 Format . Label Safety Population Flag Core Trt

Variable Number 25 Variable SAFOPFN Type Numeric Length 8 Format . Label Safety Population Flag Core Trt (N)

Variable Number 26 Variable SAFPA4FL Type Character Length 1 Format . Label Safety Population Flag PA4

Variable Number 27 Variable SAFPA4FN Type Numeric Length 8 Format . Label Safety Population Flag PA4 (N)

Variable Number 28 Variable SAFPA5FL Type Character Length 1 Format . Label Safety Population Flag PA5

Variable Number 29 Variable SAFPA5FN Type Numeric Length 8 Format . Label Safety Population Flag PA5 (N)

Variable Number 30 Variable SAFPA6FL Type Character Length 1 Format . Label Safety Population Flag PA6

Variable Number 31 Variable SAFPA6FN Type Numeric Length 8 Format . Label Safety Population Flag PA6 (N)

Variable Number 32 Variable COMPLFL Type Character Length 1 Format . Label Completers Population Flag

Variable Number 33 Variable COMPLFN Type Numeric Length 8 Format . Label Completers Population Flag (N)

Variable Number 34 Variable COMPL2FL Type Character Length 1 Format . Label Completers Population Flag 02

Variable Number 35 Variable COMPL2FN Type Numeric Length 8 Format . Label Completers Population Flag 02 (N)

Variable Number 36 Variable COMPL3FL Type Character Length 1 Format . Label Completers Population Flag 03

Variable Number 37 Variable COMPL3FN Type Numeric Length 8 Format . Label Completers Population Flag 03 (N)

Variable Number 38 Variable COMPL4FL Type Character Length 1 Format . Label Completers Population Flag 04

Variable Number 39 Variable COMPL4FN Type Numeric Length 8 Format . Label Completers Population Flag 04 (N)

Variable Number 40 Variable DOSINTFL Type Character Length 1 Format . Label Drug Interrupted for >28 Days Flag

Variable Number 41 Variable DOSINTFN Type Numeric Length 8 Format . Label Drug Interrupted for >28 Days Flag (N)

Variable Number 42 Variable ARM Type Character Length 11 Format . Label Description of Planned Arm

Variable Number 43 Variable ARMCD Type Character Length 2 Format . Label Description Code of Planned Arm

Variable Number 44 Variable ACTARM Type Character Length 11 Format . Label Description of Actual Arm

Variable Number 45 Variable ACTARMCD Type Character Length 2 Format . Label Description Code of Actual Arm



Variable Number 46 Variable TRTSEQP Type Character Length 7 Format . Label Planned Sequence of Treatments

Variable Number 47 Variable TRTSEQPN Type Numeric Length 8 Format . Label Planned Sequence of Treatments (N)

Variable Number 48 Variable TRTSEQA Type Character Length 7 Format . Label Actual Sequence of Treatments

Variable Number 49 Variable TRTSEQAN Type Numeric Length 8 Format . Label Actual Sequence of Treatments (N)

Variable Number 50 Variable TRTP Type Character Length 7 Format . Label Planned Treatment

Variable Number 51 Variable TRTPN Type Numeric Length 8 Format . Label Planned Treatment (N)

Variable Number 52 Variable TRTA Type Character Length 7 Format . Label Actual Treatment

Variable Number 53 Variable TRTAN Type Numeric Length 8 Format . Label Actual Treatment (N)

Variable Number 54 Variable APERIOD Type Numeric Length 8 Format . Label Period

Variable Number 55 Variable APERIODC Type Character Length 46 Format . Label Period (C)

Variable Number 56 Variable ADY Type Numeric Length 8 Format . Label Analysis Relative Day (from first treatment date)

Variable Number 57 Variable MRXADY Type Numeric Length 8 Format . Label MRX Analysis Relative Day

Variable Number 58 Variable AVISITN Type Numeric Length 8 Format . Label Analysis Visit (N)

Variable Number 59 Variable AVISIT Type Character Length 13 Format . Label Analysis Visit

Variable Number 60 Variable VISIT Type Character Length 28 Format . Label Visit Name

Variable Number 61 Variable VISITNUM Type Numeric Length 8 Format . Label Visit Number

Variable Number 62 Variable QSSEQ Type Numeric Length 8 Format . Label Sequence Number

Variable Number 63 Variable PARAM Type Character Length 47 Format . Label Parameter

Variable Number 64 Variable PARAMCD Type Character Length 8 Format . Label Parameter Code

Variable Number 65 Variable PARAMN Type Numeric Length 8 Format . Label Parameter (N)

Variable Number 66 Variable PARAMTYP Type Character Length 7 Format . Label Parameter Type

Variable Number 67 Variable PARCAT1 Type Character Length 30 Format . Label Parameter Category 1

Variable Number 68 Variable PARCAT2 Type Character Length 26 Format . Label Parameter Category 2

Variable Number 69 Variable AVAL Type Numeric Length 8 Format . Label Analysis Value

Variable Number 70 Variable ABLFL Type Character Length 1 Format . Label Baseline Record Flag

Variable Number 71 Variable ABLFN Type Numeric Length 8 Format . Label Baseline Record Flag (N)

Variable Number 72 Variable BASE Type Numeric Length 8 Format . Label Baseline Value

Variable Number 73 Variable CHG Type Numeric Length 8 Format . Label Change from Baseline

Variable Number 74 Variable PCHG Type Numeric Length 8 Format . Label Percent Change from Baseline

Variable Number 75 Variable CRIT1 Type Character Length 33 Format . Label Analysis Criterion 1

Variable Number 76 Variable CRIT1FL Type Character Length 1 Format . Label Criterion 1 Evaluation Result Flag

Variable Number 77 Variable CRIT2 Type Character Length 33 Format . Label Analysis Criterion 2

Variable Number 78 Variable CRIT2FL Type Character Length 1 Format . Label Criterion 2 Evaluation Result Flag

Variable Number 79 Variable CRIT3 Type Character Length 22 Format . Label Analysis Criterion 3

Variable Number 80 Variable CRIT3FL Type Character Length 1 Format . Label Criterion 3 Evaluation Result Flag

Variable Number 81 Variable DTYPE Type Character Length 14 Format . Label Derivation Type

Variable Number 82 Variable ANL01FL Type Character Length 1 Format . Label Analysis Record Flag 01

## Data Set Name: [adsl.sas7bdat](#)

Variable Number 1 Variable SubjRandID Type Numeric Length 8 Format . Label Subject Identifier (randomly assigned)

Variable Number 2 Variable STUDYID Type Character Length 10 Format . Label Study Identifier

Variable Number 3 Variable AGE Type Numeric Length 8 Format . Label Age

Variable Number 4 Variable AGE1 Type Numeric Length 8 Format . Label Age at Baseline

Variable Number 5 Variable AGEM Type Numeric Length 8 Format . Label Age at Baseline (Months)

Variable Number 6 Variable AGESCRN Type Numeric Length 8 Format . Label Age at 301 Screening

Variable Number 7 Variable AGEMRX Type Numeric Length 8 Format . Label Age at First MRX Dose

Variable Number 8 Variable AGEU Type Character Length 5 Format . Label Age Units

Variable Number 9 Variable AGEGR1 Type Character Length 14 Format . Label Pooled Age Group 1

Variable Number 10 Variable AGEGR1N Type Numeric Length 8 Format . Label Pooled Age Group 1 (N)

Variable Number 11 Variable RACE Type Character Length 25 Format . Label Race

Variable Number 12 Variable RACE1 Type Character Length 25 Format . Label Race 1

Variable Number 13 Variable RACE2 Type Character Length 5 Format . Label Race 2

Variable Number 14 Variable RACEN Type Numeric Length 8 Format . Label Race (N)

Variable Number 15 Variable SEX Type Character Length 1 Format . Label Sex

Variable Number 16 Variable SEXN Type Numeric Length 8 Format . Label Sex (N)

Variable Number 17 Variable ETHNIC Type Character Length 22 Format . Label Ethnicity

Variable Number 18 Variable ETHNICN Type Numeric Length 8 Format . Label Ethnicity (N)

Variable Number 19 Variable COUNTRY Type Character Length 3 Format . Label Country

Variable Number 20 Variable SCRNFL Type Character Length 1 Format . Label Screened Population Flag

Variable Number 21 Variable SCRNFN Type Numeric Length 8 Format . Label Screened Population Flag (N)

Variable Number 22 Variable ENRFL Type Character Length 1 Format . Label Enrolled Population Flag

Variable Number 23 Variable ENRFLN Type Numeric Length 8 Format . Label Enrolled Population Flag (N)

Variable Number 24 Variable SAFFL Type Character Length 1 Format . Label Safety Population Flag

Variable Number 25 Variable SAFFN Type Numeric Length 8 Format . Label Safety Population Flag (N)

Variable Number 26 Variable SAFOPFL Type Character Length 1 Format . Label Safety Population Flag Core Trt

Variable Number 27 Variable SAFOPFN Type Numeric Length 8 Format . Label Safety Population Flag Core Trt (N)

Variable Number 28 Variable SAFPA4FL Type Character Length 1 Format . Label Safety Population Flag PA4

Variable Number 29 Variable SAFPA4FN Type Numeric Length 8 Format . Label Safety Population Flag PA4 (N)

Variable Number 30 Variable SAFPA5FL Type Character Length 1 Format . Label Safety Population Flag PA5

Variable Number 31 Variable SAFPA5FN Type Numeric Length 8 Format . Label Safety Population Flag PA5 (N)

Variable Number 32 Variable SAFPA6FL Type Character Length 1 Format . Label Safety Population Flag PA6

Variable Number 33 Variable SAFPA6FN Type Numeric Length 8 Format . Label Safety Population Flag PA6 (N)

Variable Number 34 Variable LWDOPFL Type Character Length 1 Format . Label Recd. Lower Dose Flag Core Trt

Variable Number 35 Variable LWDOPFN Type Numeric Length 8 Format . Label Recd. Lower Dose Flag Core Trt (N)

Variable Number 36 Variable LWDP4FL Type Character Length 1 Format . Label Recd. Lower Dose Flag PA4

Variable Number 37 Variable LWDP4FN Type Numeric Length 8 Format . Label Recd. Lower Dose Flag PA4 (N)

Variable Number 38 Variable LWDP5FL Type Character Length 1 Format . Label Recd. Lower Dose Flag PA5

Variable Number 39 Variable LWDP5FN Type Numeric Length 8 Format . Label Recd. Lower Dose Flag PA5 (N)

Variable Number 40 Variable LWDP6FL Type Character Length 1 Format . Label Recd. Lower Dose Flag PA6

Variable Number 41 Variable LWDP6FN Type Numeric Length 8 Format . Label Recd. Lower Dose Flag PA6 (N)

Variable Number 42 Variable COMPLFL Type Character Length 1 Format . Label Completers Population Flag

Variable Number 43 Variable COMPLFN Type Numeric Length 8 Format . Label Completers Population Flag (N)

Variable Number 44 Variable COMPL2FL Type Character Length 1 Format . Label Completers Population Flag 02

Variable Number 45 Variable COMPL2FN Type Numeric Length 8 Format . Label Completers Population Flag 02 (N)

Variable Number 46 Variable COMPL3FL Type Character Length 1 Format . Label Completers Population Flag 03

Variable Number 47 Variable COMPL3FN Type Numeric Length 8 Format . Label Completers Population Flag 03 (N)

Variable Number 48 Variable COMPL4FL Type Character Length 1 Format . Label Completers Population Flag 04

Variable Number 49 Variable COMPL4FN Type Numeric Length 8 Format . Label Completers Population Flag 04 (N)

Variable Number 50 Variable DOSINTFL Type Character Length 1 Format . Label Drug Interrupted for >28 Days Flag

Variable Number 51 Variable DOSINTFN Type Numeric Length 8 Format . Label Drug Interrupted for >28 Days Flag (N)

Variable Number 52 Variable ARM Type Character Length 11 Format . Label Description of Planned Arm

Variable Number 53 Variable ARMCD Type Character Length 2 Format . Label Description Code of Planned Arm

Variable Number 54 Variable ACTARM Type Character Length 11 Format . Label Description of Actual Arm

Variable Number 55 Variable ACTARMCD Type Character Length 2 Format . Label Description Code of Actual Arm

Variable Number 56 Variable TRT01P Type Character Length 3 Format . Label Planned Treatment for Period 01

Variable Number 57 Variable TRT01PN Type Numeric Length 8 Format . Label Planned Treatment for Period 01 (N)

Variable Number 58 Variable TRT01A Type Character Length 3 Format . Label Actual Treatment for Period 01

Variable Number 59 Variable TRT01AN Type Numeric Length 8 Format . Label Actual Treatment for Period 01 (N)

Variable Number 60 Variable TRTSEQP Type Character Length 7 Format . Label Planned Sequence of Treatments

Variable Number 61 Variable TRTSEQPN Type Numeric Length 8 Format . Label Planned Sequence of Treatments (N)

Variable Number 62 Variable TRTSEQA Type Character Length 7 Format . Label Actual Sequence of Treatments

Variable Number 63 Variable TRTSEQAN Type Numeric Length 8 Format . Label Actual Sequence of Treatments (N)

Variable Number 64 Variable DSTERM Type Character Length 23 Format . Label Reported Term for the Disposition Event

Variable Number 65 Variable DSTERMN Type Numeric Length 8 Format . Label Rep. Term for the Disposition Event (N)

Variable Number 66 Variable DSTERMSP Type Character Length 200 Format . Label Disposition Event Other, Specify

Variable Number 67 Variable DSTERM2 Type Character Length 30 Format . Label Reported Term for the Disp. Event 02

Variable Number 68 Variable DSTERMN2 Type Numeric Length 8 Format . Label Rep. Term for the Disp. Event 02 (N)

Variable Number 69 Variable DSTERMS2 Type Character Length 1 Format . Label Disposition Event Other, Specify 02

Variable Number 70 Variable DSTERM3 Type Character Length 19 Format . Label Reported Term for the Disp. Event 03

Variable Number 71 Variable DSTERMN3 Type Numeric Length 8 Format . Label Rep. Term for the Disp. Event 03 (N)

Variable Number 72 Variable DSTERMS3 Type Character Length 45 Format . Label Disposition Event Other, Specify 03

Variable Number 73 Variable DSTERM4 Type Character Length 21 Format . Label Reported Term for the Disp. Event 04

Variable Number 74 Variable DSTERMN4 Type Numeric Length 8 Format . Label Rep. Term for the Disp. Event 04 (N)

Variable Number 75 Variable DSTERMS4 Type Character Length 55 Format . Label Disposition Event Other, Specify 04

Variable Number 76 Variable PAICSTAT Type Character Length 22 Format . Label PA4/PA5/PA6 Informed Consent Status

Variable Number 77 Variable ALGSDN Type Numeric Length 8 Format . Label Time Since Diagnosis of ALGS (Months)

Variable Number 78 Variable ALGSHX Type Character Length 1 Format . Label Family History of ALGS

Variable Number 79 Variable PAUCITY Type Character Length 1 Format . Label Presence of Paucity

Variable Number 80 Variable MUTATION Type Character Length 7 Format . Label Mutation Present

Variable Number 81 Variable CHOLEST Type Character Length 1 Format . Label Chronic Cholestasis

Variable Number 82 Variable CARDIAC Type Character Length 1 Format . Label Cardiac Disease

Variable Number 83 Variable RENAL Type Character Length 1 Format . Label Renal Abnormalities

Variable Number 84 Variable VASCULAR Type Character Length 1 Format . Label Vascular Abnormalities

Variable Number 85 Variable SKELETAL Type Character Length 1 Format . Label Skeletal Abnormalities

Variable Number 86 Variable OCULAR Type Character Length 1 Format . Label Ocular Abnormalities

Variable Number 87 Variable FACIAL Type Character Length 1 Format . Label Characteristic Facial Features

Variable Number 88 Variable ALGSCRT Type Numeric Length 8 Format . Label No. Clinical Criteria/Features of ALGS

Variable Number 89 Variable ALGSCAT Type Character Length 6 Format . Label Critical Criteria of ALGS Category

Variable Number 90 Variable ALGSCATN Type Numeric Length 8 Format . Label Critical Criteria of ALGS Category (N)

Variable Number 91 Variable ITCHTRT Type Character Length 1 Format . Label Used Anything to Treat Itch in the Past

Variable Number 92 Variable TCORTICO Type Character Length 1 Format . Label Topical Corticosteroids

Variable Number 93 Variable TCALCIN Type Character Length 1 Format . Label Topical Calcineurin Inhibitors

Variable Number 94 Variable TANTIHIS Type Character Length 1 Format . Label Topical Antihistamines

Variable Number 95 Variable TMENTHOL Type Character Length 1 Format . Label Topical Menthol

Variable Number 96 Variable TCAPSAIS Type Character Length 1 Format . Label Topical Capsaicin

Variable Number 97 Variable TSALICYL Type Character Length 1 Format . Label Topical Salicylic Acid

Variable Number 98 Variable TLOCAL Type Character Length 1 Format . Label Topical Local Anesthetics

Variable Number 99 Variable OANDROG Type Character Length 1 Format . Label Oral Androgens

Variable Number 100 Variable OANTICHO Type Character Length 1 Format . Label Oral  
Anticholestatic Agents

Variable Number 101 Variable OANTICON Type Character Length 1 Format . Label Oral  
Anticonvulsants

Variable Number 102 Variable OANTIDEP Type Character Length 1 Format . Label Oral  
Antidepressants

Variable Number 103 Variable OANTIHIS Type Character Length 1 Format . Label Oral  
Antihistamines

Variable Number 104 Variable OANTIOX Type Character Length 1 Format . Label Oral Anti-  
Oxidants

Variable Number 105 Variable OBINDING Type Character Length 1 Format . Label Oral Binding  
Resins

Variable Number 106 Variable OCOLCHIC Type Character Length 1 Format . Label Oral  
Colchicine

Variable Number 107 Variable OCANNABI Type Character Length 1 Format . Label Oral  
Cannabinoid Agonist

Variable Number 108 Variable OENZYMEI Type Character Length 1 Format . Label Oral  
Enzyme Inducers

Variable Number 109 Variable OIMMUNO Type Character Length 1 Format . Label Oral  
Immunosuppressants

Variable Number 110 Variable OOOPIATE Type Character Length 1 Format . Label Oral Opiate  
Antagonists

Variable Number 111 Variable OSEROTON Type Character Length 1 Format . Label Oral  
Serotonin Antagonists

Variable Number 112 Variable OUDCA Type Character Length 1 Format . Label Oral Ursodiol  
(UDCA)

Variable Number 113 Variable PHOTO Type Character Length 1 Format . Label Other  
Phototherapy

Variable Number 114 Variable HEMOFILT Type Character Length 1 Format . Label Other  
Hemofiltration (MARS)

Variable Number 115 Variable PLASMAPH Type Character Length 1 Format . Label Other  
Plasmapheresis

Variable Number 116 Variable NASALBIL Type Character Length 1 Format . Label Other Nasal  
Biliary Drainage

Variable Number 117 Variable SPECIFY Type Character Length 51 Format . Label Other  
Specify



Variable Number 118 Variable PRURTHER Type Numeric Length 8 Format . Label No. Prior Pruritus Therapies Per Patient

Variable Number 119 Variable PRURCAT Type Character Length 20 Format . Label Prior Pruritus Therapy Category

Variable Number 120 Variable PRURCATN Type Numeric Length 8 Format . Label Prior Pruritus Therapy Category (N)

Variable Number 121 Variable HEIGHTBL Type Numeric Length 8 Format . Label Height at Baseline (cm)

Variable Number 122 Variable WEIGHTBL Type Numeric Length 8 Format . Label Weight at Baseline (kg)

Variable Number 123 Variable BMIBL Type Numeric Length 8 Format . Label BMI at Baseline (kg/m<sup>2</sup>)

Variable Number 124 Variable ZHGTBL Type Numeric Length 8 Format . Label Height Z-Score at Baseline

Variable Number 125 Variable ZWGTBL Type Numeric Length 8 Format . Label Weight Z-Score at Baseline

Variable Number 126 Variable ZBMIBL Type Numeric Length 8 Format . Label BMI Z-Score at Baseline

Variable Number 127 Variable SDSTDISP Type Numeric Length 8 Format . Label Study Day of Disposition Event from Infomed Consent Date

Variable Number 128 Variable SEALGDIAG Type Numeric Length 8 Format . Label Study Day of Diagnosis of ALGS from Infomed Consent Date

Variable Number 129 Variable SDRXST Type Numeric Length 8 Format . Label Study Day of RX First Exposure from Infomed Consent Date

Variable Number 130 Variable SDRXEN Type Numeric Length 8 Format . Label Study Day of RX Last Exposure from Infomed Consent Date

Variable Number 131 Variable SDWK48DT Type Numeric Length 8 Format . Label Study Day of Week 48 Date from Infomed Consent Date

Variable Number 132 Variable SDWK96DT Type Numeric Length 8 Format . Label Study Day of Week 96/ET Date from Infomed Consent Date

Variable Number 133 Variable SDWK144DT Type Numeric Length 8 Format . Label Study Day of Week 144/ET Date from Infomed Consent Date

Variable Number 134 Variable SDWK216DT Type Numeric Length 8 Format . Label Study Day of Week 216/ET Date from Infomed Consent Date

## Data Set Name: advs.sas7bdat

Variable Number 1 Variable SubjRandID Type Numeric Length 8 Format . Label Subject Identifier (randomly assigned)

Variable Number 2 Variable STUDYID Type Character Length 10 Format . Label Study Identifier

Variable Number 3 Variable AGE Type Numeric Length 8 Format . Label Age

Variable Number 4 Variable AGE1 Type Numeric Length 8 Format . Label Age at Baseline

Variable Number 5 Variable AGEM Type Numeric Length 8 Format . Label Age at Baseline (Months)

Variable Number 6 Variable AGEU Type Character Length 5 Format . Label Age Units

Variable Number 7 Variable AGEGR1 Type Character Length 14 Format . Label Pooled Age Group 1

Variable Number 8 Variable AGEGR1N Type Numeric Length 8 Format . Label Pooled Age Group 1 (N)

Variable Number 9 Variable RACE Type Character Length 25 Format . Label Race

Variable Number 10 Variable RACE1 Type Character Length 25 Format . Label Race 1

Variable Number 11 Variable RACE2 Type Character Length 5 Format . Label Race 2

Variable Number 12 Variable RACEN Type Numeric Length 8 Format . Label Race (N)

Variable Number 13 Variable SEX Type Character Length 1 Format . Label Sex

Variable Number 14 Variable SEXN Type Numeric Length 8 Format . Label Sex (N)

Variable Number 15 Variable ETHNIC Type Character Length 22 Format . Label Ethnicity

Variable Number 16 Variable ETHNICN Type Numeric Length 8 Format . Label Ethnicity (N)

Variable Number 17 Variable COUNTRY Type Character Length 3 Format . Label Country

Variable Number 18 Variable SCRNFL Type Character Length 1 Format . Label Screened Population Flag

Variable Number 19 Variable SCRNFN Type Numeric Length 8 Format . Label Screened Population Flag (N)

Variable Number 20 Variable ENRFL Type Character Length 1 Format . Label Enrolled Population Flag

Variable Number 21 Variable ENRFLN Type Numeric Length 8 Format . Label Enrolled Population Flag (N)

Variable Number 22 Variable SAFFL Type Character Length 1 Format . Label Safety Population Flag

Variable Number 23 Variable SAFFN Type Numeric Length 8 Format . Label Safety Population Flag (N)

Variable Number 24 Variable SAFOPFL Type Character Length 1 Format . Label Safety  
Population Flag Core Trt

Variable Number 25 Variable SAFOPFN Type Numeric Length 8 Format . Label Safety  
Population Flag Core Trt (N)

Variable Number 26 Variable SAFPA4FL Type Character Length 1 Format . Label Safety  
Population Flag PA4

Variable Number 27 Variable SAFPA4FN Type Numeric Length 8 Format . Label Safety  
Population Flag PA4 (N)

Variable Number 28 Variable SAFPA5FL Type Character Length 1 Format . Label Safety  
Population Flag PA5

Variable Number 29 Variable SAFPA5FN Type Numeric Length 8 Format . Label Safety  
Population Flag PA5 (N)

Variable Number 30 Variable SAFPA6FL Type Character Length 1 Format . Label Safety  
Population Flag PA6

Variable Number 31 Variable SAFPA6FN Type Numeric Length 8 Format . Label Safety  
Population Flag PA6 (N)

Variable Number 32 Variable COMPLFL Type Character Length 1 Format . Label Completers  
Population Flag

Variable Number 33 Variable COMPLFN Type Numeric Length 8 Format . Label Completers  
Population Flag (N)

Variable Number 34 Variable COMPL2FL Type Character Length 1 Format . Label Completers  
Population Flag 02

Variable Number 35 Variable COMPL2FN Type Numeric Length 8 Format . Label Completers  
Population Flag 02 (N)

Variable Number 36 Variable COMPL3FL Type Character Length 1 Format . Label Completers  
Population Flag 03

Variable Number 37 Variable COMPL3FN Type Numeric Length 8 Format . Label Completers  
Population Flag 03 (N)

Variable Number 38 Variable COMPL4FL Type Character Length 1 Format . Label Completers  
Population Flag 04

Variable Number 39 Variable COMPL4FN Type Numeric Length 8 Format . Label Completers  
Population Flag 04 (N)

Variable Number 40 Variable DOSINTFL Type Character Length 1 Format . Label Drug  
Interrupted for >28 Days Flag

Variable Number 41 Variable DOSINTFN Type Numeric Length 8 Format . Label Drug  
Interrupted for >28 Days Flag (N)

Variable Number 42 Variable ARM Type Character Length 11 Format . Label Description of Planned Arm

Variable Number 43 Variable ARMCD Type Character Length 2 Format . Label Description Code of Planned Arm

Variable Number 44 Variable ACTARM Type Character Length 11 Format . Label Description of Actual Arm

Variable Number 45 Variable ACTARMCD Type Character Length 2 Format . Label Description Code of Actual Arm

Variable Number 46 Variable TRT01P Type Character Length 3 Format . Label Planned Treatment for Period 01

Variable Number 47 Variable TRT01PN Type Numeric Length 8 Format . Label Planned Treatment for Period 01 (N)

Variable Number 48 Variable TRT01A Type Character Length 3 Format . Label Actual Treatment for Period 01

Variable Number 49 Variable TRT01AN Type Numeric Length 8 Format . Label Actual Treatment for Period 01 (N)

Variable Number 50 Variable TRTSEQP Type Character Length 7 Format . Label Planned Sequence of Treatments

Variable Number 51 Variable TRTSEQPN Type Numeric Length 8 Format . Label Planned Sequence of Treatments (N)

Variable Number 52 Variable TRTSEQA Type Character Length 7 Format . Label Actual Sequence of Treatments

Variable Number 53 Variable TRTSEQAN Type Numeric Length 8 Format . Label Actual Sequence of Treatments (N)

Variable Number 54 Variable TRTPN Type Numeric Length 8 Format . Label Planned Treatment (N)

Variable Number 55 Variable TRTP Type Character Length 7 Format . Label Planned Treatment

Variable Number 56 Variable TRTAN Type Numeric Length 8 Format . Label Actual Treatment (N)

Variable Number 57 Variable TRTA Type Character Length 7 Format . Label Actual Treatment

Variable Number 58 Variable APERIOD Type Numeric Length 8 Format . Label Period

Variable Number 59 Variable APERIODC Type Character Length 46 Format . Label Period (C)

Variable Number 60 Variable VSSEQ Type Numeric Length 8 Format . Label Sequence Number

Variable Number 61 Variable VISIT Type Character Length 28 Format . Label Visit Name

Variable Number 62 Variable VISITNUM Type Numeric Length 8 Format . Label Visit Number

Variable Number 63 Variable VSDY Type Numeric Length 8 Format . Label Study Day of Vital Signs (from first treatment date)

Variable Number 64 Variable AVISITN Type Numeric Length 8 Format . Label Analysis Visit (N)

Variable Number 65 Variable AVISIT Type Character Length 13 Format . Label Analysis Visit

Variable Number 66 Variable DTYPE Type Character Length 13 Format . Label Derivation Type

Variable Number 67 Variable ADY Type Numeric Length 8 Format . Label Analysis Relative Day (from first treatment date)

Variable Number 68 Variable PARAM Type Character Length 31 Format . Label Parameter

Variable Number 69 Variable PARAMCD Type Character Length 7 Format . Label Parameter Code

Variable Number 70 Variable PARAMN Type Numeric Length 8 Format . Label Parameter (N)

Variable Number 71 Variable PARAMTYP Type Character Length 7 Format . Label Parameter Type

Variable Number 72 Variable AVAL Type Numeric Length 8 Format . Label Analysis Value

Variable Number 73 Variable ABLFL Type Character Length 1 Format . Label Baseline Record Flag

Variable Number 74 Variable ABLFN Type Numeric Length 8 Format . Label Baseline Record Flag (N)

Variable Number 75 Variable BASE Type Numeric Length 8 Format . Label Baseline Value

Variable Number 76 Variable BASETYPE Type Character Length 11 Format . Label Baseline Type

Variable Number 77 Variable CHG Type Numeric Length 8 Format . Label Change from Baseline

Variable Number 78 Variable PCHG Type Numeric Length 8 Format . Label Percent Change from Baseline

Variable Number 79 Variable ANRLO Type Numeric Length 8 Format . Label Analysis Normal Range Lower Limit

Variable Number 80 Variable ANRHI Type Numeric Length 8 Format . Label Analysis Normal Range Upper Limit

Variable Number 81 Variable ANRIND Type Character Length 6 Format . Label Analysis Reference Range Indicator

Variable Number 82 Variable BNRIND Type Character Length 6 Format . Label Baseline Reference Range Indicator

## Data Set Name: ae.sas7bdat

Variable Number 1 Variable SubjRandID Type Numeric Length 8 Format . Label Subject Identifier (randomly assigned)

Variable Number 2 Variable STUDYID Type Character Length 10 Format . Label Study Identifier

Variable Number 3 Variable DOMAIN Type Character Length 2 Format . Label Domain Abbreviation

Variable Number 4 Variable AESEQ Type Numeric Length 8 Format . Label Sequence Number

Variable Number 5 Variable AEGRPID Type Character Length 9 Format . Label Group ID

Variable Number 6 Variable AESPID Type Character Length 3 Format . Label Sponsor-Defined Identifier

Variable Number 7 Variable AETERM Type Character Length 108 Format . Label Reported Term for the Adverse Event

Variable Number 8 Variable AELLT Type Character Length 39 Format . Label Lowest Level Term

Variable Number 9 Variable AELLTCD Type Numeric Length 8 Format . Label Lowest Level Term Code

Variable Number 10 Variable AEDECOD Type Character Length 47 Format . Label Dictionary-Derived Term

Variable Number 11 Variable AEPTCD Type Numeric Length 8 Format . Label Preferred Term Code

Variable Number 12 Variable AEHLT Type Character Length 63 Format . Label High Level Term

Variable Number 13 Variable AEHLTCD Type Numeric Length 8 Format . Label High Level Term Code

Variable Number 14 Variable AEHLGT Type Character Length 59 Format . Label High Level Group Term

Variable Number 15 Variable AEHLGTCD Type Numeric Length 8 Format . Label High Level Group Term Code

Variable Number 16 Variable AEBODSYS Type Character Length 67 Format . Label Body System or Organ Class

Variable Number 17 Variable AEBDSYCD Type Numeric Length 8 Format . Label Body System or Organ Class Code

Variable Number 18 Variable AESOC Type Character Length 67 Format . Label Primary System Organ Class

Variable Number 19 Variable AESOCCD Type Numeric Length 8 Format . Label Primary System Organ Class Code

Variable Number 20 Variable AESER Type Character Length 1 Format . Label Serious Event

Variable Number 21 Variable AEACN Type Character Length 16 Format . Label Action Taken with Study Treatment

Variable Number 22 Variable AEACNOTH Type Character Length 99 Format . Label Other Action Taken

Variable Number 23 Variable AEREL Type Character Length 25 Format . Label Causality

Variable Number 24 Variable AEOU Type Character Length 32 Format . Label Outcome of Adverse Event

Variable Number 25 Variable AESDTH Type Character Length 1 Format . Label Results in Death

Variable Number 26 Variable AESHOSP Type Character Length 1 Format . Label Requires or Prolongs Hospitalization

Variable Number 27 Variable AESLIFE Type Character Length 1 Format . Label Is Life Threatening

Variable Number 28 Variable AECONTRT Type Character Length 1 Format . Label Concomitant or Additional Trtmnt Given

Variable Number 29 Variable AETOXGR Type Character Length 1 Format . Label Standard Toxicity Grade

Variable Number 30 Variable EPOCH Type Character Length 45 Format . Label Epoch

Variable Number 31 Variable AESTDY Type Numeric Length 8 Format . Label Study Day of Start of Adverse Event (from first treatment date)

Variable Number 32 Variable AEENDY Type Numeric Length 8 Format . Label Study Day of End of Adverse Event (from first treatment date)

Variable Number 33 Variable AEENRF Type Character Length 7 Format . Label End Relative to Reference Period

## Data Set Name: [cm.sas7bdat](#)

Variable Number 1 Variable SubjRandID Type Numeric Length 8 Format . Label Subject Identifier (randomly assigned)

Variable Number 2 Variable STUDYID Type Character Length 10 Format . Label Study Identifier

Variable Number 3 Variable DOMAIN Type Character Length 2 Format . Label Domain Abbreviation

Variable Number 4 Variable CMSEQ Type Numeric Length 8 Format . Label Sequence Number

Variable Number 5 Variable CMSPID Type Character Length 3 Format . Label Sponsor-Defined Identifier

Variable Number 6 Variable CMTRT Type Character Length 174 Format . Label Reported Name of Drug, Med, or Therapy

Variable Number 7 Variable CMDECOD Type Character Length 199 Format . Label Standardized Medication Name

Variable Number 8 Variable CMCAT Type Character Length 5 Format . Label Category for Medication

Variable Number 9 Variable CMINDC Type Character Length 104 Format . Label Indication

Variable Number 10 Variable CMCLAS Type Character Length 64 Format . Label Medication Class

Variable Number 11 Variable CMCLASCD Type Character Length 3 Format . Label Medication Class Code

Variable Number 12 Variable CMDOSE Type Numeric Length 8 Format . Label Dose per Administration

Variable Number 13 Variable CMDOSTXT Type Character Length 7 Format . Label Dose Description

Variable Number 14 Variable CMDOSU Type Character Length 12 Format . Label Dose Units

Variable Number 15 Variable CMDOSFRQ Type Character Length 45 Format . Label Dosing Frequency per Interval

Variable Number 16 Variable CMROUTE Type Character Length 24 Format . Label Route of Administration

Variable Number 17 Variable EPOCH Type Character Length 45 Format . Label Epoch

Variable Number 18 Variable CMSTDY Type Numeric Length 8 Format . Label Study Day of Start of Medication (from first treatment date)

Variable Number 19 Variable CMENDY Type Numeric Length 8 Format . Label Study Day of End of Medication (from first treatment date)

Variable Number 20 Variable CMENRTPT Type Character Length 7 Format . Label End Relative to Reference Time Point

## Data Set Name: [co.sas7bdat](#)

Variable Number 1 Variable SubjRandID Type Numeric Length 8 Format . Label Subject Identifier (randomly assigned)

Variable Number 2 Variable STUDYID Type Character Length 10 Format . Label Study Identifier

Variable Number 3 Variable DOMAIN Type Character Length 2 Format . Label Domain Abbreviation

Variable Number 4 Variable RDOMAIN Type Character Length 2 Format . Label Related Domain Abbreviation

Variable Number 5 Variable COSEQ Type Numeric Length 8 Format . Label Sequence Number

Variable Number 6 Variable IDVAR Type Character Length 5 Format . Label Identifying Variable



Variable Number 7 Variable IDVARVAL Type Character Length 4 Format . Label Identifying Variable Value

Variable Number 8 Variable COREF Type Character Length 20 Format . Label Comment Reference

Variable Number 9 Variable COVAL Type Character Length 200 Format . Label Comment

Variable Number 10 Variable COVAL1 Type Character Length 198 Format . Label Comment 1

Variable Number 11 Variable COVAL2 Type Character Length 200 Format . Label Comment 2

Variable Number 12 Variable COVAL3 Type Character Length 166 Format . Label Comment 3

## Data Set Name: da.sas7bdat

Variable Number 1 Variable SubjRandID Type Numeric Length 8 Format . Label Subject Identifier (randomly assigned)

Variable Number 2 Variable STUDYID Type Character Length 10 Format . Label Study Identifier

Variable Number 3 Variable DOMAIN Type Character Length 2 Format . Label Domain Abbreviation

Variable Number 4 Variable DASEQ Type Numeric Length 8 Format . Label Sequence Number

Variable Number 5 Variable DAGRPID Type Character Length 7 Format . Label Group ID

Variable Number 6 Variable DAREFID Type Character Length 3 Format . Label Reference ID

Variable Number 7 Variable DATESTCD Type Character Length 7 Format . Label Short Name of Accountability Assessment

Variable Number 8 Variable DATEST Type Character Length 16 Format . Label Name of Accountability Assessment

Variable Number 9 Variable DAORRES Type Character Length 1 Format . Label Assessment Result in Original Units

Variable Number 10 Variable DAORRESU Type Character Length 4 Format . Label Original Units

Variable Number 11 Variable DASTRESC Type Character Length 1 Format . Label Assessment Result in Std Format

Variable Number 12 Variable DASTRESN Type Numeric Length 8 Format . Label Numeric Result/Finding in Standard Units

Variable Number 13 Variable DASTRESU Type Character Length 4 Format . Label Assessment Standard Units

Variable Number 14 Variable EPOCH Type Character Length 45 Format . Label Epoch

Variable Number 15 Variable DADY Type Numeric Length 8 Format . Label Study Day of Accountability Assessment

Variable Number 16 Variable SDaccass Type Numeric Length 8 Format . Label Study Day from Infomed Consent of Accountability Assessment

## Data Set Name: dm.sas7bdat

Variable Number 1 Variable SubjRandID Type Numeric Length 8 Format . Label Subject Identifier (randomly assigned)

Variable Number 2 Variable STUDYID Type Character Length 10 Format . Label Study Identifier

Variable Number 3 Variable DOMAIN Type Character Length 2 Format . Label Domain Abbreviation

Variable Number 4 Variable DTHFL Type Character Length 1 Format . Label Subject Death Flag

Variable Number 5 Variable AGE Type Numeric Length 8 Format . Label Age

Variable Number 6 Variable AGEU Type Character Length 5 Format . Label Age Units

Variable Number 7 Variable SEX Type Character Length 1 Format . Label Sex

Variable Number 8 Variable RACE Type Character Length 25 Format . Label Race

Variable Number 9 Variable ETHNIC Type Character Length 22 Format . Label Ethnicity

Variable Number 10 Variable ARMCD Type Character Length 2 Format . Label Planned Arm Code

Variable Number 11 Variable ARM Type Character Length 11 Format . Label Description of Planned Arm

Variable Number 12 Variable ACTARMCD Type Character Length 2 Format . Label Actual Arm Code

Variable Number 13 Variable ACTARM Type Character Length 11 Format . Label Description of Actual Arm

Variable Number 14 Variable COUNTRY Type Character Length 3 Format . Label Country

Variable Number 15 Variable SDmedst Type Numeric Length 8 Format . Label Med Start Study Day from Infomed Consent

Variable Number 16 Variable SDmedsp Type Numeric Length 8 Format . Label Med Stop Study Day from Infomed Consent

Variable Number 17 Variable SDlastp Type Numeric Length 8 Format . Label Study Day of last participation from Infomed Consent

## Data Set Name: ds.sas7bdat

Variable Number 1 Variable SubjRandID Type Numeric Length 8 Format . Label Subject Identifier (randomly assigned)

Variable Number 2 Variable STUDYID Type Character Length 10 Format . Label Study Identifier

Variable Number 3 Variable DOMAIN Type Character Length 2 Format . Label Domain Abbreviation

Variable Number 4 Variable DSSEQ Type Numeric Length 8 Format . Label Sequence Number

Variable Number 5 Variable DSTERM Type Character Length 200 Format . Label Reported Term for the Disposition Event

Variable Number 6 Variable DSDECOD Type Character Length 36 Format . Label Standardized Disposition Term

Variable Number 7 Variable DSCAT Type Character Length 18 Format . Label Category for Disposition Event

Variable Number 8 Variable EPOCH Type Character Length 45 Format . Label Epoch

Variable Number 9 Variable DSSTDY Type Numeric Length 8 Format . Label Study Day of Start of Disposition Event (from first treatment date)

### Data Set Name: dv.sas7bdat

Variable Number 1 Variable SubjRandID Type Numeric Length 8 Format . Label Subject Identifier (randomly assigned)

Variable Number 2 Variable STUDYID Type Character Length 10 Format . Label Study Identifier

Variable Number 3 Variable DOMAIN Type Character Length 2 Format . Label Domain Abbreviation

Variable Number 4 Variable DVSEQ Type Numeric Length 8 Format . Label Sequence Number

Variable Number 5 Variable DVTERM Type Character Length 200 Format . Label Protocol Deviation Term

Variable Number 6 Variable DVDECOD Type Character Length 38 Format . Label Protocol Deviation Coded Term

Variable Number 7 Variable DVCAT Type Character Length 5 Format . Label Category for Protocol Deviation

Variable Number 8 Variable EPOCH Type Character Length 45 Format . Label Epoch

Variable Number 9 Variable DVDY Type Numeric Length 8 Format . Label Study Day of Collection (from first treatment date)

Variable Number 10 Variable DVSTDY Type Numeric Length 8 Format . Label Study Day of Start of Deviation (from first treatment date)

### Data Set Name: ec.sas7bdat

Variable Number 1 Variable SubjRandID Type Numeric Length 8 Format . Label Subject Identifier (randomly assigned)

Variable Number 2 Variable STUDYID Type Character Length 10 Format . Label Study Identifier

Variable Number 3 Variable DOMAIN Type Character Length 2 Format . Label Domain Abbreviation

Variable Number 4 Variable ECSEQ Type Numeric Length 8 Format . Label Sequence Number

Variable Number 5 Variable ECGRPID Type Character Length 12 Format . Label Group ID

Variable Number 6 Variable ECREFID Type Character Length 8 Format . Label Reference ID

Variable Number 7 Variable ECTRT Type Character Length 3 Format . Label Name of Treatment

Variable Number 8 Variable ECDOSE Type Numeric Length 8 Format . Label Dose

Variable Number 9 Variable ECDOSU Type Character Length 2 Format . Label Dose Units

Variable Number 10 Variable ECDOSFRM Type Character Length 20 Format . Label Dose Form

Variable Number 11 Variable ECDOSFRQ Type Character Length 2 Format . Label Dosing Frequency per Interval

Variable Number 12 Variable ECROUTE Type Character Length 4 Format . Label Route of Administration

Variable Number 13 Variable ECPSTRG Type Numeric Length 8 Format . Label Pharmaceutical Strength

Variable Number 14 Variable ECPSTRGU Type Character Length 9 Format . Label Pharmaceutical Strength Units

Variable Number 15 Variable EPOCH Type Character Length 45 Format . Label Epoch

Variable Number 16 Variable ECSTDY Type Numeric Length 8 Format . Label Study Day of Start of Treatment

Variable Number 17 Variable ECENDY Type Numeric Length 8 Format . Label Study Day of End of Treatment (from first treatment date)

## Data Set Name: ex.sas7bdat

Variable Number 1 Variable SubjRandID Type Numeric Length 8 Format . Label Subject Identifier (randomly assigned)

Variable Number 2 Variable STUDYID Type Character Length 10 Format . Label Study Identifier

Variable Number 3 Variable DOMAIN Type Character Length 2 Format . Label Domain Abbreviation

Variable Number 4 Variable EXSEQ Type Numeric Length 8 Format . Label Sequence Number

Variable Number 5 Variable EXTRT Type Character Length 3 Format . Label Name of Treatment

Variable Number 6 Variable EXDOSE Type Numeric Length 8 Format . Label Dose

Variable Number 7 Variable EXDOSU Type Character Length 9 Format . Label Dose Units

Variable Number 8 Variable EXDOSFRM Type Character Length 20 Format . Label Dose Form

Variable Number 9 Variable EXDOSFRQ Type Character Length 2 Format . Label Dosing Frequency per Interval

Variable Number 10 Variable EXROUTE Type Character Length 4 Format . Label Route of Administration

Variable Number 11 Variable EPOCH Type Character Length 43 Format . Label Epoch

Variable Number 12 Variable EXSTDY Type Numeric Length 8 Format . Label Study Day of Start of Treatment (from first treatment date)

Variable Number 13 Variable EXENDY Type Numeric Length 8 Format . Label Study Day of End of Treatment (from first treatment date)

## Data Set Name: fa.sas7bdat

Variable Number 1 Variable SubjRandID Type Numeric Length 8 Format . Label Subject Identifier (randomly assigned)

Variable Number 2 Variable STUDYID Type Character Length 10 Format . Label Study Identifier

Variable Number 3 Variable DOMAIN Type Character Length 2 Format . Label Domain Abbreviation

Variable Number 4 Variable FASEQ Type Numeric Length 8 Format . Label Sequence Number

Variable Number 5 Variable FAGRPID Type Character Length 5 Format . Label Group ID

Variable Number 6 Variable FASPID Type Character Length 2 Format . Label Sponsor-Defined Identifier

Variable Number 7 Variable FATESTCD Type Character Length 8 Format . Label Findings About Test Short Name

Variable Number 8 Variable FATEST Type Character Length 20 Format . Label Findings About Test Name

Variable Number 9 Variable FAOBJ Type Character Length 23 Format . Label Object of the Observation

Variable Number 10 Variable FACAT Type Character Length 21 Format . Label Category for Findings About

Variable Number 11 Variable FAORRES Type Character Length 9 Format . Label Result or Finding in Original Units

Variable Number 12 Variable FASTRESC Type Character Length 9 Format . Label Character Result/Finding in Std Format

Variable Number 13 Variable VISITNUM Type Numeric Length 8 Format . Label Visit Number

Variable Number 14 Variable VISIT Type Character Length 28 Format . Label Visit Name

Variable Number 15 Variable EPOCH Type Character Length 45 Format . Label Epoch

Variable Number 16 Variable FADY Type Numeric Length 8 Format . Label Study Day of Collection (from first treatment date)

### Data Set Name: ie.sas7bdat

Variable Number 1 Variable SubjRandID Type Numeric Length 8 Format . Label Subject Identifier (randomly assigned)

Variable Number 2 Variable STUDYID Type Character Length 10 Format . Label Study Identifier

Variable Number 3 Variable DOMAIN Type Character Length 2 Format . Label Domain Abbreviation

Variable Number 4 Variable IESEQ Type Numeric Length 8 Format . Label Sequence Number

Variable Number 5 Variable IETESTCD Type Character Length 8 Format . Label Inclusion/Exclusion Criterion Short Name

Variable Number 6 Variable IETEST Type Character Length 50 Format . Label Inclusion/Exclusion Criterion

Variable Number 7 Variable IECAT Type Character Length 9 Format . Label Inclusion/Exclusion Category

Variable Number 8 Variable IEORRES Type Character Length 1 Format . Label I/E Criterion Original Result

Variable Number 9 Variable IESTRESC Type Character Length 1 Format . Label I/E Criterion Result in Std Format

### Data Set Name: lb.sas7bdat

Variable Number 1 Variable SubjRandID Type Numeric Length 8 Format . Label Subject Identifier (randomly assigned)

Variable Number 2 Variable STUDYID Type Character Length 10 Format . Label Study Identifier

Variable Number 3 Variable DOMAIN Type Character Length 2 Format . Label Domain Abbreviation

Variable Number 4 Variable LBSEQ Type Numeric Length 8 Format . Label Sequence Number

Variable Number 5 Variable LBGRPID Type Character Length 11 Format . Label Group ID

Variable Number 6 Variable LBREFID Type Character Length 8 Format . Label Specimen ID

Variable Number 7 Variable LBTESTCD Type Character Length 8 Format . Label Lab Test or Examination Short Name

Variable Number 8 Variable LBTEST Type Character Length 39 Format . Label Lab Test or Examination Name

Variable Number 9 Variable LBCAT Type Character Length 11 Format . Label Category for Lab Test

Variable Number 10 Variable LBSCAT Type Character Length 22 Format . Label Subcategory for Lab Test

Variable Number 11 Variable LBORRES Type Character Length 9 Format . Label Result or Finding in Original Units

Variable Number 12 Variable LBORRESU Type Character Length 8 Format . Label Original Units

Variable Number 13 Variable LBORNRL0 Type Character Length 5 Format . Label Reference Range Lower Limit in Orig Unit

Variable Number 14 Variable LBORNRLHI Type Character Length 5 Format . Label Reference Range Upper Limit in Orig Unit

Variable Number 15 Variable LBSTRESC Type Character Length 13 Format . Label Character Result/Finding in Std Format

Variable Number 16 Variable LBSTRESN Type Numeric Length 8 Format . Label Numeric Result/Finding in Standard Units

Variable Number 17 Variable LBSTRESU Type Character Length 8 Format . Label Standard Units

Variable Number 18 Variable LBSTNRLO Type Numeric Length 8 Format . Label Reference Range Lower Limit-Std Units

Variable Number 19 Variable LBSTNRHI Type Numeric Length 8 Format . Label Reference Range Upper Limit-Std Units

Variable Number 20 Variable LBNRIND Type Character Length 6 Format . Label Reference Range Indicator

Variable Number 21 Variable LBSTAT Type Character Length 8 Format . Label Completion Status

Variable Number 22 Variable LBREASND Type Character Length 154 Format . Label Reason Test Not Done

Variable Number 23 Variable LBNAM Type Character Length 30 Format . Label Vendor Name

Variable Number 24 Variable LBSPEC Type Character Length 6 Format . Label Specimen Type

Variable Number 25 Variable LBBLFL Type Character Length 1 Format . Label Baseline Flag

Variable Number 26 Variable LBFAST Type Character Length 1 Format . Label Fasting Status

Variable Number 27 Variable VISITNUM Type Numeric Length 8 Format . Label Visit Number

Variable Number 28 Variable VISIT Type Character Length 28 Format . Label Visit Name

Variable Number 29 Variable EPOCH Type Character Length 45 Format . Label Epoch

Variable Number 30 Variable LBDY Type Numeric Length 8 Format . Label Study Day of Specimen Collection (from first treatment date)

## Data Set Name: mh.sas7bdat

Variable Number 1 Variable SubjRandID Type Numeric Length 8 Format . Label Subject Identifier (randomly assigned)

Variable Number 2 Variable STUDYID Type Character Length 10 Format . Label Study Identifier

Variable Number 3 Variable DOMAIN Type Character Length 2 Format . Label Domain Abbreviation

Variable Number 4 Variable MHSEQ Type Numeric Length 8 Format . Label Sequence Number

Variable Number 5 Variable MHSPID Type Character Length 3 Format . Label Sponsor-Defined Identifier

Variable Number 6 Variable MHTERM Type Character Length 32 Format . Label Reported Term for the Medical History

Variable Number 7 Variable MHLLT Type Character Length 20 Format . Label Lowest Level Term

Variable Number 8 Variable MHLLTCD Type Numeric Length 8 Format . Label Lowest Level Term Code

Variable Number 9 Variable MHDECOD Type Character Length 29 Format . Label Dictionary-Derived Term

Variable Number 10 Variable MHPTCD Type Numeric Length 8 Format . Label Preferred Term Code

Variable Number 11 Variable MHHLT Type Character Length 54 Format . Label High Level Term

Variable Number 12 Variable MHHLTCD Type Numeric Length 8 Format . Label High Level Term Code

Variable Number 13 Variable MHHLGT Type Character Length 52 Format . Label High Level Group Term

Variable Number 14 Variable MHHLGTCD Type Numeric Length 8 Format . Label High Level Group Term Code

Variable Number 15 Variable MHCAT Type Character Length 43 Format . Label Category for Medical History

Variable Number 16 Variable MHBODSYS Type Character Length 47 Format . Label Body System or Organ Class

Variable Number 17 Variable MHBDSYCD Type Numeric Length 8 Format . Label Body System or Organ Class Code

Variable Number 18 Variable MHSOC Type Character Length 47 Format . Label Primary System Organ Class

Variable Number 19 Variable MHSOCCD Type Numeric Length 8 Format . Label Primary System Organ Class Code



Variable Number 20 Variable MHSTDY Type Numeric Length 8 Format . Label Study Day of Start of Observation (from first treatment date)

Variable Number 21 Variable MHENDY Type Numeric Length 8 Format . Label Study Day of End of Observation (from first treatment date)

Variable Number 22 Variable MHENRTPT Type Character Length 7 Format . Label End Relative to Reference Time Point

## Data Set Name: pc.sas7bdat

Variable Number 1 Variable SubjRandID Type Numeric Length 8 Format . Label Subject Identifier (randomly assigned)

Variable Number 2 Variable STUDYID Type Character Length 10 Format . Label Study Identifier

Variable Number 3 Variable DOMAIN Type Character Length 2 Format . Label Domain Abbreviation

Variable Number 4 Variable PCSEQ Type Numeric Length 8 Format . Label Sequence Number

Variable Number 5 Variable PCREFID Type Character Length 12 Format . Label Reference ID

Variable Number 6 Variable PCTESTCD Type Character Length 3 Format . Label Pharmacokinetic Test Short Name

Variable Number 7 Variable PCTEST Type Character Length 3 Format . Label Pharmacokinetic Test Name

Variable Number 8 Variable PCCAT Type Character Length 7 Format . Label Test Category

Variable Number 9 Variable PCORRES Type Character Length 11 Format . Label Result or Finding in Original Units

Variable Number 10 Variable PCORRESU Type Character Length 5 Format . Label Original Units

Variable Number 11 Variable PCSTRESC Type Character Length 11 Format . Label Character Result/Finding Standard Format

Variable Number 12 Variable PCSTRESN Type Numeric Length 8 Format . Label Numeric Result/Finding in Standard Units

Variable Number 13 Variable PCSTRESU Type Character Length 5 Format . Label Standard Units

Variable Number 14 Variable PCSTAT Type Character Length 8 Format . Label Completion Status

Variable Number 15 Variable PCREASND Type Character Length 59 Format . Label Reason Test Not Done

Variable Number 16 Variable PCNAM Type Character Length 7 Format . Label Vendor Name

Variable Number 17 Variable PCSPEC Type Character Length 6 Format . Label Specimen Material Type

Variable Number 18 Variable PCMETHOD Type Character Length 21 Format . Label Method of Test or Examination

Variable Number 19 Variable PCBLFL Type Character Length 1 Format . Label Baseline Flag

Variable Number 20 Variable PCFAST Type Character Length 1 Format . Label Fasting Status

Variable Number 21 Variable PCLLOQ Type Numeric Length 8 Format . Label Lower Limit of Quantitation

Variable Number 22 Variable VISITNUM Type Numeric Length 8 Format . Label Visit Number

Variable Number 23 Variable VISIT Type Character Length 28 Format . Label Visit Name

Variable Number 24 Variable EPOCH Type Character Length 45 Format . Label Epoch

Variable Number 25 Variable PCDY Type Numeric Length 8 Format . Label Actual Study Day of Specimen Collection (from first treatment date)

## Data Set Name: pe.sas7bdat

Variable Number 1 Variable SubjRandID Type Numeric Length 8 Format . Label Subject Identifier (randomly assigned)

Variable Number 2 Variable STUDYID Type Character Length 10 Format . Label Study Identifier

Variable Number 3 Variable DOMAIN Type Character Length 2 Format . Label Domain Abbreviation

Variable Number 4 Variable PESEQ Type Numeric Length 8 Format . Label Sequence Number

Variable Number 5 Variable PETESTCD Type Character Length 5 Format . Label Body System Examined Short Name

Variable Number 6 Variable PETEST Type Character Length 20 Format . Label Body System Examined

Variable Number 7 Variable PECAT Type Character Length 30 Format . Label Category for Examination

Variable Number 8 Variable PEORRES Type Character Length 8 Format . Label Verbatim Examination Finding

Variable Number 9 Variable PESTRESC Type Character Length 8 Format . Label Character Result/Finding Standard Format

Variable Number 10 Variable PESTAT Type Character Length 8 Format . Label Completion Status

Variable Number 11 Variable PEBLFL Type Character Length 1 Format . Label Baseline Flag

Variable Number 12 Variable VISITNUM Type Numeric Length 8 Format . Label Visit Number

Variable Number 13 Variable VISIT Type Character Length 28 Format . Label Visit Name

Variable Number 14 Variable EPOCH Type Character Length 45 Format . Label Epoch

Variable Number 15 Variable PEDY Type Numeric Length 8 Format . Label Study Day of Examination (from first treatment date)

## Data Set Name: qs.sas7bdat

Variable Number 1 Variable SubjRandID Type Numeric Length 8 Format . Label Subject Identifier (randomly assigned)

Variable Number 2 Variable STUDYID Type Character Length 10 Format . Label Study Identifier

Variable Number 3 Variable DOMAIN Type Character Length 2 Format . Label Domain Abbreviation

Variable Number 4 Variable QSSEQ Type Numeric Length 8 Format . Label Sequence Number

Variable Number 5 Variable QSGRPID Type Character Length 8 Format . Label Group ID

Variable Number 6 Variable QSSPID Type Character Length 3 Format . Label Sponsor-Defined Identifier

Variable Number 7 Variable QSTESTCD Type Character Length 8 Format . Label Question Short Name

Variable Number 8 Variable QSTEST Type Character Length 40 Format . Label Question Name

Variable Number 9 Variable QSCAT Type Character Length 52 Format . Label Category of Question

Variable Number 10 Variable QSSCAT Type Character Length 26 Format . Label Subcategory for Question

Variable Number 11 Variable QSORRES Type Character Length 54 Format . Label Finding in Original Units

Variable Number 12 Variable QSSTRESC Type Character Length 25 Format . Label Character Result/Finding Standard Format

Variable Number 13 Variable QSSTRESN Type Numeric Length 8 Format . Label Numeric Finding in Standard Units

Variable Number 14 Variable QSSTAT Type Character Length 8 Format . Label Completion Status

Variable Number 15 Variable QSREASND Type Character Length 14 Format . Label Reason Not Performed

Variable Number 16 Variable QSBLFL Type Character Length 1 Format . Label Baseline Flag

Variable Number 17 Variable VISITNUM Type Numeric Length 8 Format . Label Visit Number

Variable Number 18 Variable VISIT Type Character Length 28 Format . Label Visit Name

Variable Number 19 Variable EPOCH Type Character Length 45 Format . Label Epoch

Variable Number 20 Variable QSDY Type Numeric Length 8 Format . Label Study Day of Finding (from first treatment date)

### Data Set Name: se.sas7bdat

Variable Number 1 Variable SubjRandID Type Numeric Length 8 Format . Label Subject Identifier (randomly assigned)

Variable Number 2 Variable STUDYID Type Character Length 10 Format . Label Study Identifier

Variable Number 3 Variable DOMAIN Type Character Length 2 Format . Label Domain Abbreviation

Variable Number 4 Variable SESEQ Type Numeric Length 8 Format . Label Sequence Number

Variable Number 5 Variable ETCD Type Character Length 8 Format . Label Element Code

Variable Number 6 Variable ELEMENT Type Character Length 19 Format . Label Description of Element

Variable Number 7 Variable TAETORD Type Numeric Length 8 Format . Label Planned Order of Element within Arm

Variable Number 8 Variable EPOCH Type Character Length 45 Format . Label Epoch

Variable Number 9 Variable SESTDY Type Numeric Length 8 Format . Label Study Day of Start of Element (from first treatment date)

Variable Number 10 Variable SEENDY Type Numeric Length 8 Format . Label Study Day of End of Element (from first treatment date)

### Data Set Name: suppa.e.sas7bdat

Variable Number 1 Variable SubjRandID Type Numeric Length 8 Format . Label Subject Identifier (randomly assigned)

Variable Number 2 Variable STUDYID Type Character Length 10 Format . Label Study Identifier

Variable Number 3 Variable RDOMAIN Type Character Length 2 Format . Label Related Domain Abbreviation

Variable Number 4 Variable IDVAR Type Character Length 5 Format . Label Identifying Variable

Variable Number 5 Variable IDVARVAL Type Character Length 3 Format . Label Identifying Variable Value

Variable Number 6 Variable QNAM Type Character Length 7 Format . Label Qualifier Variable Name

Variable Number 7 Variable QLABEL Type Character Length 31 Format . Label Qualifier Variable Label

Variable Number 8 Variable QVAL Type Character Length 1 Format . Label Data Value

Variable Number 9 Variable QORIG Type Character Length 3 Format . Label Origin

Variable Number 10 Variable QEVAL Type Character Length 1 Format . Label Evaluator

### Data Set Name: [suppcm.sas7bdat](#)

Variable Number 1 Variable SubjRandID Type Numeric Length 8 Format . Label Subject Identifier (randomly assigned)

Variable Number 2 Variable STUDYID Type Character Length 10 Format . Label Study Identifier

Variable Number 3 Variable RDOMAIN Type Character Length 2 Format . Label Related Domain Abbreviation

Variable Number 4 Variable IDVAR Type Character Length 5 Format . Label Identifying Variable

Variable Number 5 Variable IDVARVAL Type Character Length 2 Format . Label Identifying Variable Value

Variable Number 6 Variable QNAM Type Character Length 8 Format . Label Qualifier Variable Name

Variable Number 7 Variable QLABEL Type Character Length 30 Format . Label Qualifier Variable Label

Variable Number 8 Variable QVAL Type Character Length 36 Format . Label Data Value

Variable Number 9 Variable QORIG Type Character Length 3 Format . Label Origin

Variable Number 10 Variable QEVAL Type Character Length 1 Format . Label Evaluator

### Data Set Name: [suppdm.sas7bdat](#)

Variable Number 1 Variable SubjRandID Type Numeric Length 8 Format . Label Subject Identifier (randomly assigned)

Variable Number 2 Variable STUDYID Type Character Length 10 Format . Label Study Identifier

Variable Number 3 Variable RDOMAIN Type Character Length 2 Format . Label Related Domain Abbreviation

Variable Number 4 Variable IDVAR Type Character Length 1 Format . Label Identifying Variable

Variable Number 5 Variable IDVARVAL Type Character Length 1 Format . Label Identifying Variable Value

Variable Number 6 Variable QNAM Type Character Length 8 Format . Label Qualifier Variable Name

Variable Number 7 Variable QLABEL Type Character Length 40 Format . Label Qualifier Variable Label

Variable Number 8 Variable QVAL Type Character Length 25 Format . Label Data Value

Variable Number 9 Variable QORIG Type Character Length 3 Format . Label Origin

Variable Number 10 Variable QEVAL Type Character Length 1 Format . Label Evaluator

## Data Set Name: suppds.sas7bdat

Variable Number 1 Variable SubjRandID Type Numeric Length 8 Format . Label Subject Identifier (randomly assigned)

Variable Number 2 Variable STUDYID Type Character Length 10 Format . Label Study Identifier

Variable Number 3 Variable RDOMAIN Type Character Length 2 Format . Label Related Domain Abbreviation

Variable Number 4 Variable IDVAR Type Character Length 5 Format . Label Identifying Variable

Variable Number 5 Variable IDVARVAL Type Character Length 1 Format . Label Identifying Variable Value

Variable Number 6 Variable QNAM Type Character Length 8 Format . Label Qualifier Variable Name

Variable Number 7 Variable QLABEL Type Character Length 34 Format . Label Qualifier Variable Label

Variable Number 8 Variable QVAL Type Character Length 14 Format . Label Data Value

Variable Number 9 Variable QORIG Type Character Length 3 Format . Label Origin

Variable Number 10 Variable QEVAL Type Character Length 1 Format . Label Evaluator

## Data Set Name: suppdv.sas7bdat

Variable Number 1 Variable SubjRandID Type Numeric Length 8 Format . Label Subject Identifier (randomly assigned)

Variable Number 2 Variable STUDYID Type Character Length 10 Format . Label Study Identifier

Variable Number 3 Variable RDOMAIN Type Character Length 2 Format . Label Related Domain Abbreviation

Variable Number 4 Variable IDVAR Type Character Length 5 Format . Label Identifying Variable

Variable Number 5 Variable IDVARVAL Type Character Length 2 Format . Label Identifying Variable Value

Variable Number 6 Variable QNAM Type Character Length 7 Format . Label Qualifier Variable Name

Variable Number 7 Variable QLABEL Type Character Length 25 Format . Label Qualifier Variable Label

Variable Number 8 Variable QVAL Type Character Length 200 Format . Label Data Value

Variable Number 9 Variable QORIG Type Character Length 3 Format . Label Origin

Variable Number 10 Variable QEVAL Type Character Length 12 Format . Label Evaluator

## Data Set Name: [suppfa.sas7bdat](#)

Variable Number 1 Variable SubjRandID Type Numeric Length 8 Format . Label Subject Identifier (randomly assigned)

Variable Number 2 Variable STUDYID Type Character Length 10 Format . Label Study Identifier

Variable Number 3 Variable RDOMAIN Type Character Length 2 Format . Label Related Domain Abbreviation

Variable Number 4 Variable IDVAR Type Character Length 5 Format . Label Identifying Variable

Variable Number 5 Variable IDVARVAL Type Character Length 2 Format . Label Identifying Variable Value

Variable Number 6 Variable QNAM Type Character Length 8 Format . Label Qualifier Variable Name

Variable Number 7 Variable QLABEL Type Character Length 24 Format . Label Qualifier Variable Label

Variable Number 8 Variable QVAL Type Character Length 192 Format . Label Data Value

Variable Number 9 Variable QORIG Type Character Length 3 Format . Label Origin

Variable Number 10 Variable QEVAL Type Character Length 1 Format . Label Evaluator

## Data Set Name: [supplb.sas7bdat](#)

Variable Number 1 Variable SubjRandID Type Numeric Length 8 Format . Label Subject Identifier (randomly assigned)

Variable Number 2 Variable STUDYID Type Character Length 10 Format . Label Study Identifier

Variable Number 3 Variable RDOMAIN Type Character Length 2 Format . Label Related Domain Abbreviation

Variable Number 4 Variable IDVAR Type Character Length 8 Format . Label Identifying Variable

Variable Number 5 Variable IDVARVAL Type Character Length 4 Format . Label Identifying Variable Value

Variable Number 6 Variable QNAM Type Character Length 5 Format . Label Qualifier Variable Name

Variable Number 7 Variable QLABEL Type Character Length 17 Format . Label Qualifier Variable Label

Variable Number 8 Variable QVAL Type Character Length 10 Format . Label Data Value

Variable Number 9 Variable QORIG Type Character Length 3 Format . Label Origin

Variable Number 10 Variable QEVAL Type Character Length 1 Format . Label Evaluator

Variable Number 11 Variable SDQval Type Numeric Length 8 Format . Label Study Day of QVAL from date of consent

## Data Set Name: suppqs.sas7bdat

Variable Number 1 Variable SubjRandID Type Numeric Length 8 Format . Label Subject Identifier (randomly assigned)

Variable Number 2 Variable STUDYID Type Character Length 10 Format . Label Study Identifier

Variable Number 3 Variable RDOMAIN Type Character Length 2 Format . Label Related Domain Abbreviation

Variable Number 4 Variable IDVAR Type Character Length 5 Format . Label Identifying Variable

Variable Number 5 Variable IDVARVAL Type Character Length 4 Format . Label Identifying Variable Value

Variable Number 6 Variable QNAM Type Character Length 8 Format . Label Qualifier Variable Name

Variable Number 7 Variable QLABEL Type Character Length 34 Format . Label Qualifier Variable Label

Variable Number 8 Variable QVAL Type Character Length 27 Format . Label Data Value

Variable Number 9 Variable QORIG Type Character Length 3 Format . Label Origin

Variable Number 10 Variable QEVAL Type Character Length 1 Format . Label Evaluator

## Data Set Name: sv.sas7bdat

Variable Number 1 Variable SubjRandID Type Numeric Length 8 Format . Label Subject Identifier (randomly assigned)

Variable Number 2 Variable STUDYID Type Character Length 10 Format . Label Study Identifier

Variable Number 3 Variable DOMAIN Type Character Length 2 Format . Label Domain Abbreviation

Variable Number 4 Variable VISITNUM Type Numeric Length 8 Format . Label Visit Number

Variable Number 5 Variable VISIT Type Character Length 28 Format . Label Visit Name

Variable Number 6 Variable VISITDY Type Numeric Length 8 Format . Label Planned Study Day of Visit (from first treatment date)

Variable Number 7 Variable EPOCH Type Character Length 45 Format . Label Epoch

Variable Number 8 Variable SVSTDY Type Numeric Length 8 Format . Label Study Day of Start of Visit (from first treatment date)

Variable Number 9 Variable SVENDY Type Numeric Length 8 Format . Label Study Day of End of Visit (from first treatment date)

## Data Set Name: vs.sas7bdat

Variable Number 1 Variable SubjRandID Type Numeric Length 8 Format . Label Subject Identifier (randomly assigned)



Variable Number 2 Variable STUDYID Type Character Length 10 Format . Label Study Identifier

Variable Number 3 Variable DOMAIN Type Character Length 2 Format . Label Domain Abbreviation

Variable Number 4 Variable VSSEQ Type Numeric Length 8 Format . Label Sequence Number

Variable Number 5 Variable VSTESTCD Type Character Length 6 Format . Label Vital Signs Test Short Name

Variable Number 6 Variable VSTEST Type Character Length 24 Format . Label Vital Signs Test Name

Variable Number 7 Variable VSORRES Type Character Length 4 Format . Label Result or Finding in Original Units

Variable Number 8 Variable VSORRESU Type Character Length 11 Format . Label Original Units

Variable Number 9 Variable VSORNRL0 Type Character Length 3 Format . Label Normal Range Lower Limit-Original Units

Variable Number 10 Variable VSORNRLHI Type Character Length 3 Format . Label Normal Range Upper Limit-Original Units

Variable Number 11 Variable VSSTRESC Type Character Length 4 Format . Label Character Result/Finding in Std Format

Variable Number 12 Variable VSSTRESN Type Numeric Length 8 Format . Label Numeric Result/Finding in Standard Units

Variable Number 13 Variable VSSTRESU Type Character Length 11 Format . Label Standard Units

Variable Number 14 Variable VSSTNRLO Type Numeric Length 8 Format . Label Normal Range Lower Limit-Standard Units

Variable Number 15 Variable VSSTNRHI Type Numeric Length 8 Format . Label Normal Range Upper Limit-Standard Units

Variable Number 16 Variable VSNRIND Type Character Length 6 Format . Label Normal/Reference Range Indicator

Variable Number 17 Variable VSSTAT Type Character Length 8 Format . Label Completion Status

Variable Number 18 Variable VSBLFL Type Character Length 1 Format . Label Baseline Flag

Variable Number 19 Variable VISITNUM Type Numeric Length 8 Format . Label Visit Number

Variable Number 20 Variable VISIT Type Character Length 28 Format . Label Visit Name

Variable Number 21 Variable EPOCH Type Character Length 45 Format . Label Epoch

Variable Number 22 Variable VSDY Type Numeric Length 8 Format . Label Study Day of Vital Signs (from first treatment date)