

## 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 AGEU Type Character Length 5 Format . Label Age Units

Variable Number 6 Variable AGEGR1 Type Character Length 14 Format . Label Pooled Age Group 1

Variable Number 7 Variable AGEGR1N Type Numeric Length 8 Format . Label Pooled Age Group 1 (N)

Variable Number 8 Variable SEX Type Character Length 1 Format . Label Sex

Variable Number 9 Variable SEXN Type Numeric Length 8 Format . Label Sex (N)

Variable Number 10 Variable WEIGHTBL Type Numeric Length 8 Format . Label Weight at Baseline (kg)

Variable Number 11 Variable HEIGHTBL Type Numeric Length 8 Format . Label Height at Baseline (cm)

Variable Number 12 Variable BMIBL Type Numeric Length 8 Format . Label BMI at Baseline (kg/m<sup>2</sup>)

Variable Number 13 Variable RACE Type Character Length 25 Format . Label Race

Variable Number 14 Variable RACEN Type Numeric Length 8 Format . Label Race (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 RANDFL Type Character Length 1 Format . Label Randomized Population Flag

Variable Number 23 Variable RANDFN Type Numeric Length 8 Format . Label Randomized 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 ITTFL Type Character Length 1 Format . Label Intent-To-Treat Population Flag

Variable Number 27 Variable ITTFN Type Numeric Length 8 Format . Label Intent-To-Treat Population Flag (N)

Variable Number 28 Variable MITTFL Type Character Length 1 Format . Label Modified ITT Population Flag

Variable Number 29 Variable MITTFN Type Numeric Length 8 Format . Label Modified ITT Population Flag (N)

Variable Number 30 Variable PPROTFL Type Character Length 1 Format . Label Per-Protocol Population Flag

Variable Number 31 Variable PPROTFN Type Numeric Length 8 Format . Label Per-Protocol Population Flag (N)

Variable Number 32 Variable STABLEFL Type Character Length 1 Format . Label Dosed at Stable Dosing Period Flag

Variable Number 33 Variable STABLEFN Type Numeric Length 8 Format . Label Dosed at Stable Dosing Period Flag (N)

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

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

Variable Number 36 Variable EXTENFL Type Character Length 1 Format . Label Entered into LUM001-305 Extension Study

Variable Number 37 Variable EXTENFN Type Numeric Length 8 Format . Label Entered into LUM001-305 Extension (N)

Variable Number 38 Variable LOWDOSFL Type Character Length 1 Format . Label Recd. Lower Dose Due to Tolerability

Variable Number 39 Variable LOWDOSFN Type Numeric Length 8 Format . Label Recd. Lower Dose Due to Tolerability (N)

Variable Number 40 Variable HIDOSEFL Type Character Length 1 Format . Label Two Highest Tolerated Doses Flag

Variable Number 41 Variable HIDOSEFN Type Numeric Length 8 Format . Label Two Highest Tolerated Doses Flag (N)

Variable Number 42 Variable DOSINTFL Type Character Length 1 Format . Label Drug Interrupted for >14 Days Flag

Variable Number 43 Variable DOSINTFN Type Numeric Length 8 Format . Label Drug Interrupted for >14 Days Flag (N)

Variable Number 44 Variable ARM Type Character Length 20 Format . Label Description of Planned Arm

Variable Number 45 Variable ARMCD Type Character Length 1 Format . Label Description Code of Planned Arm

Variable Number 46 Variable ACTARM Type Character Length 20 Format . Label Description of Actual Arm

Variable Number 47 Variable ACTARMCD Type Character Length 1 Format . Label Description Code of Actual Arm

Variable Number 48 Variable TRT01P Type Character Length 20 Format . Label Planned Treatment for Period 01

Variable Number 49 Variable TRT01PN Type Numeric Length 8 Format . Label Planned Treatment for Period 01 (N)

Variable Number 50 Variable TRT01A Type Character Length 20 Format . Label Actual Treatment for Period 01

Variable Number 51 Variable TRT01AN Type Numeric Length 8 Format . Label Actual Treatment for Period 01 (N)

Variable Number 52 Variable TR01PG1 Type Character Length 13 Format . Label Planned Pooled Treatment 1 for Period 01

Variable Number 53 Variable TR01PG1N Type Numeric Length 8 Format . Label Planned Pooled Trt 1 for Period 01 (N)

Variable Number 54 Variable TR01PG2 Type Character Length 32 Format . Label Planned Pooled Treatment 1 for Period 02

Variable Number 55 Variable TR01PG2N Type Numeric Length 8 Format . Label Planned Pooled Trt 1 for Period 02 (N)

Variable Number 56 Variable TR01AG1 Type Character Length 13 Format . Label Actual Pooled Treatment 1 for Period 01

Variable Number 57 Variable TR01AG1N Type Numeric Length 8 Format . Label Actual Pooled Trt 1 for Period 01 (N)

Variable Number 58 Variable TRT02P Type Character Length 20 Format . Label Planned Treatment for Period 02

Variable Number 59 Variable TRT02PN Type Numeric Length 8 Format . Label Planned Treatment for Period 02 (N)

Variable Number 60 Variable TRT02A Type Character Length 20 Format . Label Actual Treatment for Period 02

Variable Number 61 Variable TRT02AN Type Numeric Length 8 Format . Label Actual Treatment for Period 02 (N)

Variable Number 62 Variable TR02PG1 Type Character Length 13 Format . Label Planned Pooled Treatment 1 for Period 02

Variable Number 63 Variable TR02PG1N Type Numeric Length 8 Format . Label Planned Pooled Trt 1 for Period 02 (N)

Variable Number 64 Variable TR02AG1 Type Character Length 13 Format . Label Actual Pooled Treatment 1 for Period 02

Variable Number 65 Variable TR02AG1N Type Numeric Length 8 Format . Label Actual Pooled Trt 1 for Period 02 (N)

Variable Number 66 Variable TRTP Type Character Length 20 Format . Label Planned Treatment

Variable Number 67 Variable TRTPN Type Numeric Length 8 Format . Label Planned Treatment (N)

Variable Number 68 Variable TRTA Type Character Length 20 Format . Label Actual Treatment

Variable Number 69 Variable TRTAN Type Numeric Length 8 Format . Label Actual Treatment (N)

Variable Number 70 Variable TRTPG1 Type Character Length 13 Format . Label Planned Pooled Treatment 1

Variable Number 71 Variable TRTPG1N Type Numeric Length 8 Format . Label Planned Pooled Treatment 1 (N)

Variable Number 72 Variable TRTPG2 Type Character Length 32 Format . Label Planned Pooled Treatment 2

Variable Number 73 Variable TRTPG2N Type Numeric Length 8 Format . Label Planned Pooled Treatment 2 (N)

Variable Number 74 Variable TRTAG1 Type Character Length 13 Format . Label Actual Pooled Treatment 1

Variable Number 75 Variable TRTAG1N Type Numeric Length 8 Format . Label Actual Pooled Treatment 1 (N)

Variable Number 76 Variable AESEQ Type Numeric Length 8 Format . Label Sequence Number

Variable Number 77 Variable AESPID Type Character Length 3 Format . Label Sponsor-Defined Identifier

Variable Number 78 Variable AEGRPID Type Character Length 9 Format . Label Group ID

Variable Number 79 Variable AETERM Type Character Length 69 Format . Label Reported Term for the Adverse Event

Variable Number 80 Variable AELLT Type Character Length 36 Format . Label Lowest Level Term

Variable Number 81 Variable AELLTCD Type Numeric Length 8 Format . Label Lowest Level Term Code

Variable Number 82 Variable AEDECOD Type Character Length 40 Format . Label Dictionary-Derived Term

Variable Number 83 Variable AEPTCD Type Numeric Length 8 Format . Label Preferred Term Code

Variable Number 84 Variable AEHLT Type Character Length 59 Format . Label High Level Term

Variable Number 85 Variable AEHLTCD Type Numeric Length 8 Format . Label High Level Term Code

Variable Number 86 Variable AEHLGT Type Character Length 59 Format . Label High Level Group Term

Variable Number 87 Variable AEHLGTC Type Numeric Length 8 Format . Label High Level Group Term Code

Variable Number 88 Variable AEBODSYS Type Character Length 52 Format . Label Body System or Organ Class

Variable Number 89 Variable AEBDSYCD Type Numeric Length 8 Format . Label Body System or Organ Class Code

Variable Number 90 Variable AESOC Type Character Length 52 Format . Label Primary System Organ Class

Variable Number 91 Variable AESOCCD Type Numeric Length 8 Format . Label Primary System Organ Class Code

Variable Number 92 Variable AESIGI Type Character Length 26 Format . Label AEs of Special Interest GI Disorders

Variable Number 93 Variable AESIGIFL Type Character Length 1 Format . Label AEs of Special Interest GI Dis. Flag

Variable Number 94 Variable AESILD Type Character Length 19 Format . Label AEs of Special Interest Liver Det.

Variable Number 95 Variable AESILDFL Type Character Length 1 Format . Label AEs of Special Interest Liver Det. Flag

Variable Number 96 Variable AESITF Type Character Length 1 Format . Label AEs of Special Interest Thyroid Fn.

Variable Number 97 Variable AESITFFL Type Character Length 1 Format . Label AEs of Special Interest Thyroid Fn. Flag

Variable Number 98 Variable AESIFS Type Character Length 30 Format . Label AEs of Special Interest Fat Sl. Vit

Variable Number 99 Variable AESIFSFL Type Character Length 1 Format . Label AEs of Special Interest Fat Sl. Vit Flag

Variable Number 100 Variable AESIGR Type Character Length 1 Format . Label AEs of Special Interest Growth Ret.

Variable Number 101 Variable AESIGRFL Type Character Length 1 Format . Label AEs of Special Interest Growth Ret. Flag

Variable Number 102 Variable AESER Type Character Length 1 Format . Label Serious Event

Variable Number 103 Variable AESERN Type Numeric Length 8 Format . Label Serious Event (N)

Variable Number 104 Variable AETOXGR Type Character Length 1 Format . Label Standard Toxicity Grade

Variable Number 105 Variable AETOXGRN Type Numeric Length 8 Format . Label Standard Toxicity Grade (N)

Variable Number 106 Variable ATOXGR Type Character Length 18 Format . Label Analysis Toxicity Grade

Variable Number 107 Variable ATOXGRN Type Numeric Length 8 Format . Label Analysis Toxicity Grade (N)

Variable Number 108 Variable AEACN Type Character Length 16 Format . Label Action Taken with Study Treatment

Variable Number 109 Variable AEACNN Type Numeric Length 8 Format . Label Action Taken with Study Treatment (N)

Variable Number 110 Variable AEACNOTH Type Character Length 31 Format . Label Other Action Taken

Variable Number 111 Variable AEREL Type Character Length 25 Format . Label Causality

Variable Number 112 Variable AERELN Type Numeric Length 8 Format . Label Causality (N)

Variable Number 113 Variable AREL Type Character Length 25 Format . Label Analysis Causality

Variable Number 114 Variable ARELN Type Numeric Length 8 Format . Label Analysis Causality (N)

Variable Number 115 Variable RELGR1 Type Character Length 19 Format . Label Pooled Causality Group 1

Variable Number 116 Variable RELGR1N Type Numeric Length 8 Format . Label Pooled Causality Group 1 (N)

Variable Number 117 Variable AEOUT Type Character Length 26 Format . Label Outcome of Adverse Event

Variable Number 118 Variable AEOUTN Type Numeric Length 8 Format . Label Outcome of Adverse Event (N)

Variable Number 119 Variable AESDTH Type Character Length 1 Format . Label Results in Death

Variable Number 120 Variable AESHOSP Type Character Length 1 Format . Label Requires or Prolongs Hospitalization

Variable Number 121 Variable AESLIFE Type Character Length 1 Format . Label Is Life Threatening

Variable Number 122 Variable AECONTRT Type Character Length 1 Format . Label Concomitant or Additional Trtmnt Given

Variable Number 123 Variable AETRT Type Character Length 41 Format . Label Treatment Required

Variable Number 124 Variable AEDIS Type Character Length 1 Format . Label AE Caused Discontinuation from Study

Variable Number 125 Variable ASTDTF Type Character Length 1 Format . Label Analysis Start Date Imputation Flag

Variable Number 126 Variable AENDTF Type Character Length 1 Format . Label Analysis End Date Imputation Flag

Variable Number 127 Variable ASTDY Type Numeric Length 8 Format . Label Analysis Start Relative Day (from first treatment date)

Variable Number 128 Variable AESTDY Type Numeric Length 8 Format . Label Study Day of Start of Adverse Event (from first treatment date)

Variable Number 129 Variable AENDY Type Numeric Length 8 Format . Label Analysis End Relative Day (from first treatment date)

Variable Number 130 Variable AEENDY Type Numeric Length 8 Format . Label Study Day of End of Adverse Event (from first treatment date)

Variable Number 131 Variable ADURN Type Numeric Length 8 Format . Label AE Duration (N)

Variable Number 132 Variable ADURU Type Character Length 4 Format . Label AE Duration Units

Variable Number 133 Variable AEENRF Type Character Length 7 Format . Label End Relative to Reference Period

Variable Number 134 Variable APERIOD Type Numeric Length 8 Format . Label Period

Variable Number 135 Variable APERIODC Type Character Length 15 Format . Label Period (C)

Variable Number 136 Variable DOSEAEON Type Character Length 8 Format . Label Study Drug Dose at AE Onset

Variable Number 137 Variable DOSAEONU Type Character Length 9 Format . Label Study Drug Dose at AE Onset Units

Variable Number 138 Variable TRTEMFL Type Character Length 1 Format . Label Treatment Emergent Analysis Flag

Variable Number 139 Variable AOCCFL Type Character Length 1 Format . Label 1st Occurrence of Any AE Flag

Variable Number 140 Variable AOCCSFL Type Character Length 1 Format . Label 1st Occurrence of SOC Flag

Variable Number 141 Variable AOCCPFL Type Character Length 1 Format . Label 1st Occurrence of Preferred Term Flag

Variable Number 142 Variable AOC01FL Type Character Length 1 Format . Label 1st Occurrence of Any AE Flag 01

Variable Number 143 Variable AOCS01FL Type Character Length 1 Format . Label 1st Occurrence of SOC Flag 01

Variable Number 144 Variable AOCP01FL Type Character Length 1 Format . Label 1st Occurrence of Preferred Term Flag 01

Variable Number 145 Variable AOC02FL Type Character Length 1 Format . Label 1st Occurrence of Any AE Flag 02

Variable Number 146 Variable AOCS02FL Type Character Length 1 Format . Label 1st Occurrence of SOC Flag 02

Variable Number 147 Variable AOCP02FL Type Character Length 1 Format . Label 1st Occurrence of Preferred Term Flag 02

Variable Number 148 Variable AOCCIFL Type Character Length 1 Format . Label 1st Max Sev./Int. Occurrence Flag

Variable Number 149 Variable AOCCSIFL Type Character Length 1 Format . Label 1st Max Sev./Int. Occur Within SOC Flag

Variable Number 150 Variable AOCCPIFL Type Character Length 1 Format . Label 1st Max Sev./Int. Occur Within PT Flag

Variable Number 151 Variable AOI01FL Type Character Length 1 Format . Label 1st Max Sev./Int. Occur Flag 01

Variable Number 152 Variable AOSI01FL Type Character Length 1 Format . Label 1st Max Sev/Int Occur Within SOC Flag 01

Variable Number 153 Variable AOPI01FL Type Character Length 1 Format . Label 1st Max Sev/Int Occur Within PT Flag 01

Variable Number 154 Variable AOI02FL Type Character Length 1 Format . Label 1st Max Sev./Int. Occur Flag 02

Variable Number 155 Variable AOSI02FL Type Character Length 1 Format . Label 1st Max Sev/Int Occur Within SOC Flag 02

Variable Number 156 Variable AOPI02FL Type Character Length 1 Format . Label 1st Max Sev/Int Occur Within PT Flag 02

Variable Number 157 Variable AOCCTFL Type Character Length 1 Format . Label 1st Occurrence of Any Trt Rel AE Flag

Variable Number 158 Variable AOCCTSFL Type Character Length 1 Format . Label 1st Occurrence of Trt Rel SOC Flag



Variable Number 159 Variable AOCCTPFL Type Character Length 1 Format . Label 1st Occurrence of Trt Rel PT Flag

Variable Number 160 Variable AOT01FL Type Character Length 1 Format . Label 1st Occurrence of Any Trt Rel AE Flag 01

Variable Number 161 Variable AOTS01FL Type Character Length 1 Format . Label 1st Occurrence of Trt Rel SOC Flag 01

Variable Number 162 Variable AOTP01FL Type Character Length 1 Format . Label 1st Occurrence of Trt Rel PT Flag 01

Variable Number 163 Variable AOT02FL Type Character Length 1 Format . Label 1st Occurrence of Any Trt Rel AE Flag 02

Variable Number 164 Variable AOTS02FL Type Character Length 1 Format . Label 1st Occurrence of Trt Rel SOC Flag 02

Variable Number 165 Variable AOTP02FL Type Character Length 1 Format . Label 1st Occurrence of Trt Rel PT Flag 02

Variable Number 166 Variable AOCTIFL Type Character Length 1 Format . Label 1st Max Sev Trt Rel Occur Flag

Variable Number 167 Variable AOCTSIFL Type Character Length 1 Format . Label 1st Max Sev Trt Rel Occur W/I SOC Flag

Variable Number 168 Variable AOCTPIFL Type Character Length 1 Format . Label 1st Max Sev Trt Rel Occur W/I PT Flag

Variable Number 169 Variable ATI01FL Type Character Length 1 Format . Label 1st Max Sev Trt Rel Occur Flag 01

Variable Number 170 Variable ATSI01FL Type Character Length 1 Format . Label 1st Max Sev Trt Rel Occ. W/I SOC Flag 01

Variable Number 171 Variable ATPI01FL Type Character Length 1 Format . Label 1st Max Sev Trt Rel Occur W/I PT Flag 01

Variable Number 172 Variable ATI02FL Type Character Length 1 Format . Label 1st Max Sev Trt Rel Occur Flag 02

Variable Number 173 Variable ATSI02FL Type Character Length 1 Format . Label 1st Max Sev Trt Rel Occ. W/I SOC Flag 02

Variable Number 174 Variable ATPI02FL Type Character Length 1 Format . Label 1st Max Sev Trt Rel Occur W/I PT Flag 02

Variable Number 175 Variable AOCSFL Type Character Length 1 Format . Label Ser. 1st Occurrence of Any AE Flag

Variable Number 176 Variable AOCSSFL Type Character Length 1 Format . Label Ser. 1st Occurrence of SOC Flag

Variable Number 177 Variable AOCSPFL Type Character Length 1 Format . Label Ser. 1st Occurrence of PT Flag

Variable Number 178 Variable AOS01FL Type Character Length 1 Format . Label Ser. 1st Occurrence of Any AE Flag 01

Variable Number 179 Variable AOSS01FL Type Character Length 1 Format . Label Ser. 1st Occurrence of SOC Flag 01

Variable Number 180 Variable AOSP01FL Type Character Length 1 Format . Label Ser. 1st Occurrence of PT Flag 01

Variable Number 181 Variable AOS02FL Type Character Length 1 Format . Label Ser. 1st Occurrence of Any AE Flag 02

Variable Number 182 Variable AOSS02FL Type Character Length 1 Format . Label Ser. 1st Occurrence of SOC Flag 02

Variable Number 183 Variable AOSP02FL Type Character Length 1 Format . Label Ser. 1st Occurrence of PT Flag 02

Variable Number 184 Variable AOSTRFL Type Character Length 1 Format . Label Ser. 1st Occ. of Any TRT Rel AE Flag

Variable Number 185 Variable AOSTRSFL Type Character Length 1 Format . Label Ser. 1st Occurrence of TRT Rel SOC Flag

Variable Number 186 Variable AOSTRPFL Type Character Length 1 Format . Label Ser. 1st Occurrence of TRT Rel PT Flag

Variable Number 187 Variable ASR01FL Type Character Length 1 Format . Label Ser. 1st Occ. of Any TRT Rel AE Flag 01

Variable Number 188 Variable ASRS01FL Type Character Length 1 Format . Label Ser. 1st Occ. of TRT Rel SOC Flag 01

Variable Number 189 Variable ASRP01FL Type Character Length 1 Format . Label Ser. 1st Occ. of TRT Rel PT Flag 01

Variable Number 190 Variable ASR02FL Type Character Length 1 Format . Label Ser. 1st Occ. of Any TRT Rel AE Flag 02

Variable Number 191 Variable ASRS02FL Type Character Length 1 Format . Label Ser. 1st Occ. of TRT Rel SOC Flag 02

Variable Number 192 Variable ASRP02FL Type Character Length 1 Format . Label Ser. 1st Occ. of TRT Rel PT Flag 02

Variable Number 193 Variable AOCD CFL Type Character Length 1 Format . Label 1st AE Leading to Discontinuation Flag

Variable Number 194 Variable AOCD CSFL Type Character Length 1 Format . Label 1st AE Leading to Discon. in SOC Flag

Variable Number 195 Variable AOCD CPFL Type Character Length 1 Format . Label 1st AE Leading to Discon. in PT Flag

Variable Number 196 Variable ADC01FL Type Character Length 1 Format . Label 1st AE Leading to Discon. Flag 01

Variable Number 197 Variable ADCS01FL Type Character Length 1 Format . Label 1st AE Leading to Discon. in SOC Flag 01

Variable Number 198 Variable ADCP01FL Type Character Length 1 Format . Label 1st AE Leading to Discon. in PT Flag 01

Variable Number 199 Variable ADC02FL Type Character Length 1 Format . Label 1st AE Leading to Discon. Flag 02

Variable Number 200 Variable ADCS02FL Type Character Length 1 Format . Label 1st AE Leading to Discon. in SOC Flag 02

Variable Number 201 Variable ADCP02FL Type Character Length 1 Format . Label 1st AE Leading to Discon. in PT Flag 02

Variable Number 202 Variable AOTEGIFL Type Character Length 1 Format . Label 1st TEAE for GI Events Flag

Variable Number 203 Variable AOTEGSFL Type Character Length 1 Format . Label 1st TEAE for GI Events in SOC Flag

Variable Number 204 Variable AOTEGPFL Type Character Length 1 Format . Label 1st TEAE for GI Events in PT Flag

Variable Number 205 Variable ATGI01FL Type Character Length 1 Format . Label 1st TEAE for GI Events Flag 01

Variable Number 206 Variable ATGS01FL Type Character Length 1 Format . Label 1st TEAE for GI Events in SOC Flag 01

Variable Number 207 Variable ATGP01FL Type Character Length 1 Format . Label 1st TEAE for GI Events in PT Flag 01

Variable Number 208 Variable ATGI02FL Type Character Length 1 Format . Label 1st TEAE for GI Events Flag 02

Variable Number 209 Variable ATGS02FL Type Character Length 1 Format . Label 1st TEAE for GI Events in SOC Flag 02

Variable Number 210 Variable ATGP02FL Type Character Length 1 Format . Label 1st TEAE for GI Events in PT Flag 02

Variable Number 211 Variable AOTELDFL Type Character Length 1 Format . Label 1st TEAE for Liver Det. Events Flag

Variable Number 212 Variable AOTEFLSFL Type Character Length 1 Format . Label 1st TEAE for Liver Events in SOC Flag

Variable Number 213 Variable AOTELPFL Type Character Length 1 Format . Label 1st TEAE for Liver Events in PT Flag

Variable Number 214 Variable ATLD01FL Type Character Length 1 Format . Label 1st TEAE for Liver Det. Events Flag 01

Variable Number 215 Variable ATLS01FL Type Character Length 1 Format . Label 1st TEAE for Liver Events in SOC Flag 01

Variable Number 216 Variable ATLP01FL Type Character Length 1 Format . Label 1st TEAE for Liver Events in PT Flag 01

Variable Number 217 Variable ATLD02FL Type Character Length 1 Format . Label 1st TEAE for Liver Det. Events Flag 02

Variable Number 218 Variable ATLS02FL Type Character Length 1 Format . Label 1st TEAE for Liver Events in SOC Flag 02

Variable Number 219 Variable ATLP02FL Type Character Length 1 Format . Label 1st TEAE for Liver Events in PT Flag 02

Variable Number 220 Variable AOTETHFL Type Character Length 1 Format . Label 1st TEAE for Thyroid Events Flag

Variable Number 221 Variable AOTETSFL Type Character Length 1 Format . Label 1st TEAE for Thyroid Events in SOC Flag

Variable Number 222 Variable AOTETPFL Type Character Length 1 Format . Label 1st TEAE for Thyroid Events in PT Flag

Variable Number 223 Variable ATTH01FL Type Character Length 1 Format . Label 1st TEAE for Thyroid Events Flag 01

Variable Number 224 Variable ATTS01FL Type Character Length 1 Format . Label 1st TEAE for Thy. Events in SOC Flag 01

Variable Number 225 Variable ATTP01FL Type Character Length 1 Format . Label 1st TEAE for Thy. Events in PT Flag 01

Variable Number 226 Variable ATTH02FL Type Character Length 1 Format . Label 1st TEAE for Thyroid Events Flag 02

Variable Number 227 Variable ATTS02FL Type Character Length 1 Format . Label 1st TEAE for Thy. Events in SOC Flag 02

Variable Number 228 Variable ATTP02FL Type Character Length 1 Format . Label 1st TEAE for Thy. Events in PT Flag 02

Variable Number 229 Variable AOTEVTFL Type Character Length 1 Format . Label 1st TEAE for Vit. Def Events Flag

Variable Number 230 Variable AOTEVSFL Type Character Length 1 Format . Label 1st TEAE for Vitamin Events in SOC Flag

Variable Number 231 Variable AOTEVPFL Type Character Length 1 Format . Label 1st TEAE for Vitamin Events in PT Flag

Variable Number 232 Variable ATVT01FL Type Character Length 1 Format . Label 1st TEAE for Vitamin Events Flag 01

Variable Number 233 Variable ATVS01FL Type Character Length 1 Format . Label 1st TEAE for Vit. Events in SOC Flag 01

Variable Number 234 Variable ATVP01FL Type Character Length 1 Format . Label 1st TEAE for Vit. Events in PT Flag 01

Variable Number 235 Variable ATVT02FL Type Character Length 1 Format . Label 1st TEAE for Vitamin Events Flag 02

Variable Number 236 Variable ATVS02FL Type Character Length 1 Format . Label 1st TEAE for Vit. Events in SOC Flag 02

Variable Number 237 Variable ATVP02FL Type Character Length 1 Format . Label 1st TEAE for Vit. Events in PT Flag 02

Variable Number 238 Variable AOTEGRFL Type Character Length 1 Format . Label 1st TEAE for Growth Ret. Events Flag

Variable Number 239 Variable AOTERSFL Type Character Length 1 Format . Label 1st TEAE for Growth Events in SOC Flag

Variable Number 240 Variable AOTERPFL Type Character Length 1 Format . Label 1st TEAE for Growth Events in PT Flag

Variable Number 241 Variable ATGR01FL Type Character Length 1 Format . Label 1st TEAE for Growth Events Flag 01

Variable Number 242 Variable ATRS01FL Type Character Length 1 Format . Label 1st TEAE for Grth. Events in SOC Flag 01

Variable Number 243 Variable ATRP01FL Type Character Length 1 Format . Label 1st TEAE for Grth. Events in PT Flag 01

Variable Number 244 Variable ATGR02FL Type Character Length 1 Format . Label 1st TEAE for Growth Events Flag 02

Variable Number 245 Variable ATRS02FL Type Character Length 1 Format . Label 1st TEAE for Grth. Events in SOC Flag 02

Variable Number 246 Variable ATRP02FL Type Character Length 1 Format . Label 1st TEAE for Grth. Events in PT Flag 02

Variable Number 247 Variable AOCCDFL Type Character Length 1 Format . Label 1st Occurrence of Any AE Death Flag

Variable Number 248 Variable CRIT1 Type Character Length 45 Format . Label Analysis Criterion 1

Variable Number 249 Variable CRIT1FL Type Character Length 1 Format . Label Criterion 1 Evaluation Result 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 AGEU Type Character Length 5 Format . Label Age Units

Variable Number 6 Variable AGEGR1 Type Character Length 14 Format . Label Pooled Age Group 1

Variable Number 7 Variable AGEGR1N Type Numeric Length 8 Format . Label Pooled Age Group 1 (N)

Variable Number 8 Variable SEX Type Character Length 1 Format . Label Sex

Variable Number 9 Variable SEXN Type Numeric Length 8 Format . Label Sex (N)

Variable Number 10 Variable WEIGHTBL Type Numeric Length 8 Format . Label Weight at Baseline (kg)

Variable Number 11 Variable HEIGHTBL Type Numeric Length 8 Format . Label Height at Baseline (cm)

Variable Number 12 Variable BMIBL Type Numeric Length 8 Format . Label BMI at Baseline (kg/m<sup>2</sup>)

Variable Number 13 Variable RACE Type Character Length 25 Format . Label Race

Variable Number 14 Variable RACEN Type Numeric Length 8 Format . Label Race (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 RANDFL Type Character Length 1 Format . Label Randomized Population Flag

Variable Number 23 Variable RANDFN Type Numeric Length 8 Format . Label Randomized 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 ITTFL Type Character Length 1 Format . Label Intent-To-Treat Population Flag

Variable Number 27 Variable ITTFN Type Numeric Length 8 Format . Label Intent-To-Treat Population Flag (N)

Variable Number 28 Variable MITTFL Type Character Length 1 Format . Label Modified ITT Population Flag

Variable Number 29 Variable MITTFN Type Numeric Length 8 Format . Label Modified ITT Population Flag (N)

Variable Number 30 Variable PPROTFL Type Character Length 1 Format . Label Per-Protocol Population Flag

Variable Number 31 Variable PPROTFN Type Numeric Length 8 Format . Label Per-Protocol Population Flag (N)

Variable Number 32 Variable STABLEFL Type Character Length 1 Format . Label Dosed at Stable Dosing Period Flag

Variable Number 33 Variable STABLEFN Type Numeric Length 8 Format . Label Dosed at Stable Dosing Period Flag (N)

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

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

Variable Number 36 Variable EXTENFL Type Character Length 1 Format . Label Entered into LUM001-305 Extension Study

Variable Number 37 Variable EXTENFN Type Numeric Length 8 Format . Label Entered into LUM001-305 Extension (N)

Variable Number 38 Variable LOWDOSFL Type Character Length 1 Format . Label Recd. Lower Dose Due to Tolerability

Variable Number 39 Variable LOWDOSFN Type Numeric Length 8 Format . Label Recd. Lower Dose Due to Tolerability (N)

Variable Number 40 Variable HIDOSEFL Type Character Length 1 Format . Label Two Highest Tolerated Doses Flag

Variable Number 41 Variable HIDOSEFN Type Numeric Length 8 Format . Label Two Highest Tolerated Doses Flag (N)

Variable Number 42 Variable DOSINTFL Type Character Length 1 Format . Label Drug Interrupted for >14 Days Flag

Variable Number 43 Variable DOSINTFN Type Numeric Length 8 Format . Label Drug Interrupted for >14 Days Flag (N)

Variable Number 44 Variable ARM Type Character Length 20 Format . Label Description of Planned Arm

Variable Number 45 Variable ARMCD Type Character Length 1 Format . Label Description Code of Planned Arm

Variable Number 46 Variable ACTARM Type Character Length 20 Format . Label Description of Actual Arm

Variable Number 47 Variable ACTARMCD Type Character Length 1 Format . Label Description Code of Actual Arm

Variable Number 48 Variable TRT01P Type Character Length 20 Format . Label Planned Treatment for Period 01

Variable Number 49 Variable TRT01PN Type Numeric Length 8 Format . Label Planned Treatment for Period 01 (N)

Variable Number 50 Variable TRT01A Type Character Length 20 Format . Label Actual Treatment for Period 01

Variable Number 51 Variable TRT01AN Type Numeric Length 8 Format . Label Actual Treatment for Period 01 (N)

Variable Number 52 Variable TR01PG1 Type Character Length 13 Format . Label Planned Pooled Treatment 1 for Period 01

Variable Number 53 Variable TR01PG1N Type Numeric Length 8 Format . Label Planned Pooled Trt 1 for Period 01 (N)

Variable Number 54 Variable TR01PG2 Type Character Length 32 Format . Label Planned Pooled Treatment 1 for Period 02



Variable Number 55 Variable TR01PG2N Type Numeric Length 8 Format . Label Planned Pooled Trt 1 for Period 02 (N)

Variable Number 56 Variable TR01AG1 Type Character Length 13 Format . Label Actual Pooled Treatment 1 for Period 01

Variable Number 57 Variable TR01AG1N Type Numeric Length 8 Format . Label Actual Pooled Trt 1 for Period 01 (N)

Variable Number 58 Variable TRT02P Type Character Length 20 Format . Label Planned Treatment for Period 02

Variable Number 59 Variable TRT02PN Type Numeric Length 8 Format . Label Planned Treatment for Period 02 (N)

Variable Number 60 Variable TRT02A Type Character Length 20 Format . Label Actual Treatment for Period 02

Variable Number 61 Variable TRT02AN Type Numeric Length 8 Format . Label Actual Treatment for Period 02 (N)

Variable Number 62 Variable TR02PG1 Type Character Length 13 Format . Label Planned Pooled Treatment 1 for Period 02

Variable Number 63 Variable TR02PG1N Type Numeric Length 8 Format . Label Planned Pooled Trt 1 for Period 02 (N)

Variable Number 64 Variable TR02AG1 Type Character Length 13 Format . Label Actual Pooled Treatment 1 for Period 02

Variable Number 65 Variable TR02AG1N Type Numeric Length 8 Format . Label Actual Pooled Trt 1 for Period 02 (N)

Variable Number 66 Variable TRTP Type Character Length 20 Format . Label Planned Treatment

Variable Number 67 Variable TRTPN Type Numeric Length 8 Format . Label Planned Treatment (N)

Variable Number 68 Variable TRTA Type Character Length 20 Format . Label Actual Treatment

Variable Number 69 Variable TRTAN Type Numeric Length 8 Format . Label Actual Treatment (N)

Variable Number 70 Variable TRTPG1 Type Character Length 13 Format . Label Planned Pooled Treatment 1

Variable Number 71 Variable TRTPG1N Type Numeric Length 8 Format . Label Planned Pooled Treatment 1 (N)

Variable Number 72 Variable TRTPG2 Type Character Length 32 Format . Label Planned Pooled Treatment 2

Variable Number 73 Variable TRTPG2N Type Numeric Length 8 Format . Label Planned Pooled Treatment 2 (N)

Variable Number 74 Variable TRTAG1 Type Character Length 13 Format . Label Actual Pooled Treatment 1

Variable Number 75 Variable TRTAG1N Type Numeric Length 8 Format . Label Actual Pooled Treatment 1 (N)

Variable Number 76 Variable ASTDTF Type Character Length 1 Format . Label Analysis Start Date Imputation Flag

Variable Number 77 Variable AENDTF Type Character Length 1 Format . Label Analysis End Date Imputation Flag

Variable Number 78 Variable ASTDY Type Numeric Length 8 Format . Label Analysis Start Relative Day (from first treatment date)

Variable Number 79 Variable CMSTDY Type Numeric Length 8 Format . Label Study Day of Start of Medication (from first treatment date)

Variable Number 80 Variable AENDY Type Numeric Length 8 Format . Label Analysis End Relative Day (from first treatment date)

Variable Number 81 Variable CMENDY Type Numeric Length 8 Format . Label Study Day of End of Medication (from first treatment date)

Variable Number 82 Variable CMENRF Type Character Length 7 Format . Label End Relative to Reference Period

Variable Number 83 Variable CMSEQ Type Numeric Length 8 Format . Label Sequence Number

Variable Number 84 Variable CMSPID Type Character Length 3 Format . Label Sponsor-Defined Identifier

Variable Number 85 Variable CMTRT Type Character Length 104 Format . Label Reported Name of Drug, Med, or Therapy

Variable Number 86 Variable CMDECOD Type Character Length 193 Format . Label Standardized Medication Name

Variable Number 87 Variable CMCAT Type Character Length 5 Format . Label Category for Medication

Variable Number 88 Variable CMINDC Type Character Length 89 Format . Label Indication

Variable Number 89 Variable CMCLAS Type Character Length 64 Format . Label Medication Class

Variable Number 90 Variable CMDOSE Type Numeric Length 8 Format . Label Dose per Administration

Variable Number 91 Variable CMDOSTXT Type Character Length 7 Format . Label Dose Description

Variable Number 92 Variable CMDOSU Type Character Length 11 Format . Label Dose Units

Variable Number 93 Variable CMDOSFRQ Type Character Length 16 Format . Label Dosing Frequency per Interval

Variable Number 94 Variable CMROUTE Type Character Length 24 Format . Label Route of Administration

Variable Number 95 Variable CMEDFL Type Character Length 11 Format . Label Prior/Concomitant Medication Flag

Variable Number 96 Variable CMEDFN Type Numeric Length 8 Format . Label Prior/Concomitant Medication Flag (N)

Variable Number 97 Variable PRDISFL Type Character Length 1 Format . Label Prior Disease Medications Flag

Variable Number 98 Variable PRDISFN Type Numeric Length 8 Format . Label Prior Disease Medications Flag (N)

Variable Number 99 Variable PRURMDFL Type Character Length 1 Format . Label Prior Pruritus Therapy Medications Flag

Variable Number 100 Variable PRURMDFN Type Numeric Length 8 Format . Label Prior Pruritus Therapy Meds Flag (N)

Variable Number 101 Variable PDPRUR Type Numeric Length 8 Format . Label No. Prior Disease and/or Pruritus Meds

Variable Number 102 Variable PDPRCAT Type Character Length 22 Format . Label Prior Disease and Pruritus Category

Variable Number 103 Variable PDPRCATN Type Numeric Length 8 Format . Label Prior Disease and Pruritus Category (N)

Variable Number 104 Variable PRURMD Type Numeric Length 8 Format . Label No. Prior Pruritus Therapy Meds

Variable Number 105 Variable PRURMCAT Type Character Length 22 Format . Label Prior Pruritus only Category

Variable Number 106 Variable PRURMCAN Type Numeric Length 8 Format . Label Prior Pruritus only Category (N)

## Data Set Name: [adeff.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 AGEU Type Character Length 5 Format . Label Age Units

Variable Number 6 Variable AGEGR1 Type Character Length 14 Format . Label Pooled Age Group 1

Variable Number 7 Variable AGEGR1N Type Numeric Length 8 Format . Label Pooled Age Group 1 (N)

Variable Number 8 Variable SEX Type Character Length 1 Format . Label Sex

Variable Number 9 Variable SEXN Type Numeric Length 8 Format . Label Sex (N)

Variable Number 10 Variable WEIGHTBL Type Numeric Length 8 Format . Label Weight at Baseline (kg)

Variable Number 11 Variable HEIGHTBL Type Numeric Length 8 Format . Label Height at Baseline (cm)

Variable Number 12 Variable BMIBL Type Numeric Length 8 Format . Label BMI at Baseline (kg/m2)

Variable Number 13 Variable RACE Type Character Length 25 Format . Label Race

Variable Number 14 Variable RACEN Type Numeric Length 8 Format . Label Race (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 RANDFL Type Character Length 1 Format . Label Randomized Population Flag

Variable Number 23 Variable RANDFN Type Numeric Length 8 Format . Label Randomized 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 ITTFL Type Character Length 1 Format . Label Intent-To-Treat Population Flag

Variable Number 27 Variable ITTFN Type Numeric Length 8 Format . Label Intent-To-Treat Population Flag (N)

Variable Number 28 Variable MITTFL Type Character Length 1 Format . Label Modified ITT Population Flag

Variable Number 29 Variable MITTFN Type Numeric Length 8 Format . Label Modified ITT Population Flag (N)

Variable Number 30 Variable PPROTFL Type Character Length 1 Format . Label Per-Protocol Population Flag

Variable Number 31 Variable PPROTFN Type Numeric Length 8 Format . Label Per-Protocol Population Flag (N)

Variable Number 32 Variable STABLEFL Type Character Length 1 Format . Label Dosed at Stable Dosing Period Flag

Variable Number 33 Variable STABLEFN Type Numeric Length 8 Format . Label Dosed at Stable Dosing Period Flag (N)

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

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

Variable Number 36 Variable EXTENFL Type Character Length 1 Format . Label Entered into LUM001-305 Extension Study

Variable Number 37 Variable EXTENFN Type Numeric Length 8 Format . Label Entered into LUM001-305 Extension (N)

Variable Number 38 Variable LOWDOSFL Type Character Length 1 Format . Label Recd. Lower Dose Due to Tolerability

Variable Number 39 Variable LOWDOSFN Type Numeric Length 8 Format . Label Recd. Lower Dose Due to Tolerability (N)

Variable Number 40 Variable HIDOSEFL Type Character Length 1 Format . Label Two Highest Tolerated Doses Flag

Variable Number 41 Variable HIDOSEFN Type Numeric Length 8 Format . Label Two Highest Tolerated Doses Flag (N)

Variable Number 42 Variable DOSINTFL Type Character Length 1 Format . Label Drug Interrupted for >14 Days Flag

Variable Number 43 Variable DOSINTFN Type Numeric Length 8 Format . Label Drug Interrupted for >14 Days Flag (N)

Variable Number 44 Variable ARM Type Character Length 20 Format . Label Description of Planned Arm

Variable Number 45 Variable ARMCD Type Character Length 1 Format . Label Description Code of Planned Arm

Variable Number 46 Variable ACTARM Type Character Length 20 Format . Label Description of Actual Arm

Variable Number 47 Variable ACTARMCD Type Character Length 1 Format . Label Description Code of Actual Arm

Variable Number 48 Variable TRT01P Type Character Length 20 Format . Label Planned Treatment for Period 01

Variable Number 49 Variable TRT01PN Type Numeric Length 8 Format . Label Planned Treatment for Period 01 (N)

Variable Number 50 Variable TRT01A Type Character Length 20 Format . Label Actual Treatment for Period 01

Variable Number 51 Variable TRT01AN Type Numeric Length 8 Format . Label Actual Treatment for Period 01 (N)

Variable Number 52 Variable TR01PG1 Type Character Length 13 Format . Label Planned Pooled Treatment 1 for Period 01

Variable Number 53 Variable TR01PG1N Type Numeric Length 8 Format . Label Planned Pooled Trt 1 for Period 01 (N)

Variable Number 54 Variable TR01PG2 Type Character Length 32 Format . Label Planned Pooled Treatment 1 for Period 02

Variable Number 55 Variable TR01PG2N Type Numeric Length 8 Format . Label Planned Pooled Trt 1 for Period 02 (N)

Variable Number 56 Variable TR01AG1 Type Character Length 13 Format . Label Actual Pooled Treatment 1 for Period 01

Variable Number 57 Variable TR01AG1N Type Numeric Length 8 Format . Label Actual Pooled Trt 1 for Period 01 (N)

Variable Number 58 Variable TRT02P Type Character Length 20 Format . Label Planned Treatment for Period 02

Variable Number 59 Variable TRT02PN Type Numeric Length 8 Format . Label Planned Treatment for Period 02 (N)

Variable Number 60 Variable TRT02A Type Character Length 20 Format . Label Actual Treatment for Period 02

Variable Number 61 Variable TRT02AN Type Numeric Length 8 Format . Label Actual Treatment for Period 02 (N)

Variable Number 62 Variable TR02PG1 Type Character Length 13 Format . Label Planned Pooled Treatment 1 for Period 02

Variable Number 63 Variable TR02PG1N Type Numeric Length 8 Format . Label Planned Pooled Trt 1 for Period 02 (N)

Variable Number 64 Variable TR02AG1 Type Character Length 13 Format . Label Actual Pooled Treatment 1 for Period 02

Variable Number 65 Variable TR02AG1N Type Numeric Length 8 Format . Label Actual Pooled Trt 1 for Period 02 (N)

Variable Number 66 Variable TRTP Type Character Length 20 Format . Label Planned Treatment

Variable Number 67 Variable TRTPN Type Numeric Length 8 Format . Label Planned Treatment (N)

Variable Number 68 Variable TRTA Type Character Length 20 Format . Label Actual Treatment

Variable Number 69 Variable TRTAN Type Numeric Length 8 Format . Label Actual Treatment (N)

Variable Number 70 Variable TRTPG1 Type Character Length 13 Format . Label Planned Pooled Treatment 1

Variable Number 71 Variable TRTPG1N Type Numeric Length 8 Format . Label Planned Pooled Treatment 1 (N)

Variable Number 72 Variable TRTPG2 Type Character Length 32 Format . Label Planned Pooled Treatment 2

Variable Number 73 Variable TRTPG2N Type Numeric Length 8 Format . Label Planned Pooled Treatment 2 (N)

Variable Number 74 Variable TRTAG1 Type Character Length 13 Format . Label Actual Pooled Treatment 1

Variable Number 75 Variable TRTAG1N Type Numeric Length 8 Format . Label Actual Pooled Treatment 1 (N)

Variable Number 76 Variable ADY Type Numeric Length 8 Format . Label Analysis Relative Day (from first treatment date)

Variable Number 77 Variable AVISITN Type Numeric Length 8 Format . Label Analysis Visit (N)

Variable Number 78 Variable AVISIT Type Character Length 21 Format . Label Analysis Visit

Variable Number 79 Variable VISIT Type Character Length 10 Format . Label Visit Name

Variable Number 80 Variable VISITNUM Type Numeric Length 8 Format . Label Visit Number

Variable Number 81 Variable LBSEQ Type Numeric Length 8 Format . Label Sequence Number

Variable Number 82 Variable PARAM Type Character Length 46 Format . Label Parameter

Variable Number 83 Variable PARAMCD Type Character Length 6 Format . Label Parameter Code

Variable Number 84 Variable PARAMN Type Numeric Length 8 Format . Label Parameter (N)

Variable Number 85 Variable PARCAT1 Type Character Length 9 Format . Label Parameter Category 1

Variable Number 86 Variable PARCAT2 Type Character Length 22 Format . Label Parameter Category 2

Variable Number 87 Variable AVAL Type Numeric Length 8 Format . Label Analysis Value

Variable Number 88 Variable BASE Type Numeric Length 8 Format . Label Baseline Value

Variable Number 89 Variable CHG Type Numeric Length 8 Format . Label Change from Baseline

Variable Number 90 Variable PCHG Type Numeric Length 8 Format . Label Percent Change from Baseline

Variable Number 91 Variable CRIT1 Type Character Length 41 Format . Label Analysis Criterion 1

Variable Number 92 Variable CRIT1FL Type Character Length 1 Format . Label Criterion 1 Evaluation Result Flag

Variable Number 93 Variable CRIT1FN Type Numeric Length 8 Format . Label Criterion 1 Evaluation Result Flag (N)

Variable Number 94 Variable CRIT2 Type Character Length 16 Format . Label Analysis Criterion 2 sBA <= - 50

Variable Number 95 Variable CRIT2FL Type Character Length 1 Format . Label Criterion 2 Evaluation Result Flag

Variable Number 96 Variable CRIT3 Type Character Length 16 Format . Label Analysis Criterion 3 sBA <= - 70

Variable Number 97 Variable CRIT3FL Type Character Length 1 Format . Label Criterion 3 Evaluation Result Flag

Variable Number 98 Variable CRIT4 Type Character Length 16 Format . Label Analysis Criterion 4 sBA <= - 80

Variable Number 99 Variable CRIT4FL Type Character Length 1 Format . Label Criterion 4 Evaluation Result Flag

Variable Number 100 Variable CRIT5 Type Character Length 17 Format . Label Analysis Criterion 5 sBA <= 8.5 umol/L

Variable Number 101 Variable CRIT5FL Type Character Length 1 Format . Label Criterion 5 Evaluation Result Flag

Variable Number 102 Variable CRIT6 Type Character Length 15 Format . Label Analysis Criterion 6 C4 >= 100

Variable Number 103 Variable CRIT6FL Type Character Length 1 Format . Label Criterion 6 Evaluation Result Flag

Variable Number 104 Variable CRIT7 Type Character Length 38 Format . Label Analysis Criterion 7 Shift in AST

Variable Number 105 Variable CRIT7FL Type Character Length 1 Format . Label Criterion 7 Evaluation Result Flag

Variable Number 106 Variable CRIT8 Type Character Length 38 Format . Label Analysis Criterion 8 Shift in ALT

Variable Number 107 Variable CRIT8FL Type Character Length 1 Format . Label Criterion 8 Evaluation Result Flag

Variable Number 108 Variable CRIT9 Type Character Length 50 Format . Label Analysis Criterion 9 Shift in Total Bili



Variable Number 109 Variable CRIT9FL Type Character Length 1 Format . Label Criterion 9 Evaluation Result Flag

Variable Number 110 Variable CRIT10 Type Character Length 22 Format . Label Analysis Criterion 10 -70 < sBA <= -50

Variable Number 111 Variable CRIT10FL Type Character Length 1 Format . Label Criterion 10 Evaluation Result Flag

Variable Number 112 Variable CRIT11 Type Character Length 22 Format . Label Analysis Criterion 11 -80 < sBA <= -70

Variable Number 113 Variable CRIT11FL Type Character Length 1 Format . Label Criterion 11 Evaluation Result Flag

Variable Number 114 Variable DTYPE Type Character Length 18 Format . Label Derivation Type

Variable Number 115 Variable ANRIND Type Character Length 6 Format . Label Analysis Reference Range Indicator

Variable Number 116 Variable BNRIND Type Character Length 6 Format . Label Baseline Reference Range Indicator

Variable Number 117 Variable ANRLO Type Character Length 3 Format . Label Analysis Normal Range Lower Limit

Variable Number 118 Variable ANRHI Type Character Length 3 Format . Label Analysis Normal Range Upper Limit

Variable Number 119 Variable ABLFL Type Character Length 1 Format . Label Baseline Record Flag

Variable Number 120 Variable ABLFN Type Numeric Length 8 Format . Label Baseline Record Flag (N)

## Data Set Name: [adeg.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 AGEU Type Character Length 5 Format . Label Age Units

Variable Number 6 Variable AGEGR1 Type Character Length 14 Format . Label Pooled Age Group 1

Variable Number 7 Variable AGEGR1N Type Numeric Length 8 Format . Label Pooled Age Group 1 (N)

Variable Number 8 Variable SEX Type Character Length 1 Format . Label Sex

Variable Number 9 Variable SEXN Type Numeric Length 8 Format . Label Sex (N)

Variable Number 10 Variable WEIGHTBL Type Numeric Length 8 Format . Label Weight at Baseline (kg)

Variable Number 11 Variable HEIGHTBL Type Numeric Length 8 Format . Label Height at Baseline (cm)

Variable Number 12 Variable BMIBL Type Numeric Length 8 Format . Label BMI at Baseline (kg/m2)

Variable Number 13 Variable RACE Type Character Length 25 Format . Label Race

Variable Number 14 Variable RACEN Type Numeric Length 8 Format . Label Race (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 RANDFL Type Character Length 1 Format . Label Randomized Population Flag

Variable Number 23 Variable RANDFN Type Numeric Length 8 Format . Label Randomized 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 ITTFL Type Character Length 1 Format . Label Intent-To-Treat Population Flag

Variable Number 27 Variable ITTFN Type Numeric Length 8 Format . Label Intent-To-Treat Population Flag (N)

Variable Number 28 Variable MITTFL Type Character Length 1 Format . Label Modified ITT Population Flag

Variable Number 29 Variable MITTFN Type Numeric Length 8 Format . Label Modified ITT Population Flag (N)

Variable Number 30 Variable PPROTFL Type Character Length 1 Format . Label Per-Protocol Population Flag

Variable Number 31 Variable PPROTFN Type Numeric Length 8 Format . Label Per-Protocol Population Flag (N)

Variable Number 32 Variable STABLEFL Type Character Length 1 Format . Label Dosed at Stable Dosing Period Flag

Variable Number 33 Variable STABLEFN Type Numeric Length 8 Format . Label Dosed at Stable Dosing Period Flag (N)

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

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

Variable Number 36 Variable EXTENFL Type Character Length 1 Format . Label Entered into LUM001-305 Extension Study

Variable Number 37 Variable EXTENFN Type Numeric Length 8 Format . Label Entered into LUM001-305 Extension (N)

Variable Number 38 Variable LOWDOSFL Type Character Length 1 Format . Label Recd. Lower Dose Due to Tolerability

Variable Number 39 Variable LOWDOSFN Type Numeric Length 8 Format . Label Recd. Lower Dose Due to Tolerability (N)

Variable Number 40 Variable HIDOSEFL Type Character Length 1 Format . Label Two Highest Tolerated Doses Flag

Variable Number 41 Variable HIDOSEFN Type Numeric Length 8 Format . Label Two Highest Tolerated Doses Flag (N)

Variable Number 42 Variable DOSINTFL Type Character Length 1 Format . Label Drug Interrupted for >14 Days Flag

Variable Number 43 Variable DOSINTFN Type Numeric Length 8 Format . Label Drug Interrupted for >14 Days Flag (N)

Variable Number 44 Variable ARM Type Character Length 20 Format . Label Description of Planned Arm

Variable Number 45 Variable ARMCD Type Character Length 1 Format . Label Description Code of Planned Arm

Variable Number 46 Variable ACTARM Type Character Length 20 Format . Label Description of Actual Arm

Variable Number 47 Variable ACTARMCD Type Character Length 1 Format . Label Description Code of Actual Arm

Variable Number 48 Variable TRT01P Type Character Length 20 Format . Label Planned Treatment for Period 01

Variable Number 49 Variable TRT01PN Type Numeric Length 8 Format . Label Planned Treatment for Period 01 (N)

Variable Number 50 Variable TRT01A Type Character Length 20 Format . Label Actual Treatment for Period 01

Variable Number 51 Variable TRT01AN Type Numeric Length 8 Format . Label Actual Treatment for Period 01 (N)

Variable Number 52 Variable TR01PG1 Type Character Length 13 Format . Label Planned Pooled Treatment 1 for Period 01

Variable Number 53 Variable TR01PG1N Type Numeric Length 8 Format . Label Planned Pooled Trt 1 for Period 01 (N)

Variable Number 54 Variable TR01PG2 Type Character Length 32 Format . Label Planned Pooled Treatment 1 for Period 02

Variable Number 55 Variable TR01PG2N Type Numeric Length 8 Format . Label Planned Pooled Trt 1 for Period 02 (N)

Variable Number 56 Variable TR01AG1 Type Character Length 13 Format . Label Actual Pooled Treatment 1 for Period 01

Variable Number 57 Variable TR01AG1N Type Numeric Length 8 Format . Label Actual Pooled Trt 1 for Period 01 (N)

Variable Number 58 Variable TRT02P Type Character Length 20 Format . Label Planned Treatment for Period 02

Variable Number 59 Variable TRT02PN Type Numeric Length 8 Format . Label Planned Treatment for Period 02 (N)

Variable Number 60 Variable TRT02A Type Character Length 20 Format . Label Actual Treatment for Period 02

Variable Number 61 Variable TRT02AN Type Numeric Length 8 Format . Label Actual Treatment for Period 02 (N)

Variable Number 62 Variable TR02PG1 Type Character Length 13 Format . Label Planned Pooled Treatment 1 for Period 02

Variable Number 63 Variable TR02PG1N Type Numeric Length 8 Format . Label Planned Pooled Trt 1 for Period 02 (N)

Variable Number 64 Variable TR02AG1 Type Character Length 13 Format . Label Actual Pooled Treatment 1 for Period 02

Variable Number 65 Variable TR02AG1N Type Numeric Length 8 Format . Label Actual Pooled Trt 1 for Period 02 (N)

Variable Number 66 Variable TRTP Type Character Length 20 Format . Label Planned Treatment

Variable Number 67 Variable TRTPN Type Numeric Length 8 Format . Label Planned Treatment (N)

Variable Number 68 Variable TRTA Type Character Length 20 Format . Label Actual Treatment

Variable Number 69 Variable TRTAN Type Numeric Length 8 Format . Label Actual Treatment (N)

Variable Number 70 Variable TRTPG1 Type Character Length 13 Format . Label Planned Pooled Treatment 1

Variable Number 71 Variable TRTPG1N Type Numeric Length 8 Format . Label Planned Pooled Treatment 1 (N)

Variable Number 72 Variable TRTPG2 Type Character Length 32 Format . Label Planned Pooled Treatment 2

Variable Number 73 Variable TRTPG2N Type Numeric Length 8 Format . Label Planned Pooled Treatment 2 (N)

Variable Number 74 Variable TRTAG1 Type Character Length 13 Format . Label Actual Pooled Treatment 1

Variable Number 75 Variable TRTAG1N Type Numeric Length 8 Format . Label Actual Pooled Treatment 1 (N)

Variable Number 76 Variable EGSEQ Type Numeric Length 8 Format . Label Sequence Number

Variable Number 77 Variable VISIT Type Character Length 10 Format . Label Visit Name

Variable Number 78 Variable VISITNUM Type Numeric Length 8 Format . Label Visit Number

Variable Number 79 Variable EGDY Type Numeric Length 8 Format . Label Study Day of ECG (from first treatment date)

Variable Number 80 Variable AVISITN Type Numeric Length 8 Format . Label Analysis Visit (N)

Variable Number 81 Variable AVISIT Type Character Length 21 Format . Label Analysis Visit

Variable Number 82 Variable DTYPE Type Character Length 8 Format . Label Derivation Type

Variable Number 83 Variable ADY Type Numeric Length 8 Format . Label Analysis Relative Day (from first treatment date)

Variable Number 84 Variable PARAM Type Character Length 14 Format . Label Parameter

Variable Number 85 Variable PARAMCD Type Character Length 4 Format . Label Parameter Code

Variable Number 86 Variable PARAMN Type Numeric Length 8 Format . Label Parameter (N)

Variable Number 87 Variable AVALC Type Character Length 8 Format . Label Analysis Value (C)

Variable Number 88 Variable ABLFL Type Character Length 1 Format . Label Baseline Record Flag

Variable Number 89 Variable ABLFN Type Numeric Length 8 Format . Label Baseline Record Flag (N)

Variable Number 90 Variable BASEC Type Character Length 8 Format . Label Baseline Value (C)

Variable Number 91 Variable EGSTAT Type Character Length 1 Format . Label Completion Status

## 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 AGEU Type Character Length 5 Format . Label Age Units

Variable Number 6 Variable AGEGR1 Type Character Length 14 Format . Label Pooled Age Group 1

Variable Number 7 Variable AGEGR1N Type Numeric Length 8 Format . Label Pooled Age Group 1 (N)

Variable Number 8 Variable SEX Type Character Length 1 Format . Label Sex

Variable Number 9 Variable SEXN Type Numeric Length 8 Format . Label Sex (N)

Variable Number 10 Variable WEIGHTBL Type Numeric Length 8 Format . Label Weight at Baseline (kg)

Variable Number 11 Variable HEIGHTBL Type Numeric Length 8 Format . Label Height at Baseline (cm)

Variable Number 12 Variable BMIBL Type Numeric Length 8 Format . Label BMI at Baseline (kg/m<sup>2</sup>)

Variable Number 13 Variable RACE Type Character Length 25 Format . Label Race

Variable Number 14 Variable RACEN Type Numeric Length 8 Format . Label Race (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 AOUNTRY Type Character Length 13 Format . Label Analysis Country

Variable Number 19 Variable SCRNFL Type Character Length 1 Format . Label Screened Population Flag

Variable Number 20 Variable SCRNFN Type Numeric Length 8 Format . Label Screened Population Flag (N)

Variable Number 21 Variable ENRFL Type Character Length 1 Format . Label Enrolled Population Flag

Variable Number 22 Variable ENRFLN Type Numeric Length 8 Format . Label Enrolled Population Flag (N)

Variable Number 23 Variable RANDFL Type Character Length 1 Format . Label Randomized Population Flag

Variable Number 24 Variable RANDFN Type Numeric Length 8 Format . Label Randomized Population Flag (N)

Variable Number 25 Variable SAFFL Type Character Length 1 Format . Label Safety Population Flag

Variable Number 26 Variable SAFFN Type Numeric Length 8 Format . Label Safety Population Flag (N)

Variable Number 27 Variable ITTFL Type Character Length 1 Format . Label Intent-To-Treat Population Flag

Variable Number 28 Variable ITTFN Type Numeric Length 8 Format . Label Intent-To-Treat Population Flag (N)

Variable Number 29 Variable MITTFL Type Character Length 1 Format . Label Modified ITT Population Flag

Variable Number 30 Variable MITTFN Type Numeric Length 8 Format . Label Modified ITT Population Flag (N)

Variable Number 31 Variable STABLEFL Type Character Length 1 Format . Label Dosed at Stable Dosing Period Flag

Variable Number 32 Variable STABLEFN Type Numeric Length 8 Format . Label Dosed at Stable Dosing Period Flag (N)

Variable Number 33 Variable COMPLFL Type Character Length 1 Format . Label Completers Population Flag

Variable Number 34 Variable COMPLFN Type Numeric Length 8 Format . Label Completers Population Flag (N)

Variable Number 35 Variable EXTENFL Type Character Length 1 Format . Label Entered into LUM001-305 Extension Study

Variable Number 36 Variable EXTENFN Type Numeric Length 8 Format . Label Entered into LUM001-305 Extension (N)

Variable Number 37 Variable LOWDOSFL Type Character Length 1 Format . Label Recd. Lower Dose Due to Tolerability

Variable Number 38 Variable LOWDOSFN Type Numeric Length 8 Format . Label Recd. Lower Dose Due to Tolerability (N)

Variable Number 39 Variable HIDOSEFL Type Character Length 1 Format . Label Two Highest Tolerated Doses Flag

Variable Number 40 Variable HIDOSEFN Type Numeric Length 8 Format . Label Two Highest Tolerated Doses Flag (N)

Variable Number 41 Variable DOSINTFL Type Character Length 1 Format . Label Drug Interrupted for >14 Days Flag

Variable Number 42 Variable DOSINTFN Type Numeric Length 8 Format . Label Drug Interrupted for >14 Days Flag (N)

Variable Number 43 Variable ARM Type Character Length 20 Format . Label Description of Planned Arm

Variable Number 44 Variable ARMCD Type Character Length 1 Format . Label Description Code of Planned Arm

Variable Number 45 Variable ACTARM Type Character Length 20 Format . Label Description of Actual Arm

Variable Number 46 Variable ACTARMCD Type Character Length 1 Format . Label Description Code of Actual Arm

Variable Number 47 Variable TRTP Type Character Length 20 Format . Label Planned Treatment

Variable Number 48 Variable TRTPN Type Numeric Length 8 Format . Label Planned Treatment (N)

Variable Number 49 Variable TRTA Type Character Length 20 Format . Label Actual Treatment

Variable Number 50 Variable TRTAN Type Numeric Length 8 Format . Label Actual Treatment (N)

Variable Number 51 Variable TRT01P Type Character Length 20 Format . Label Planned Treatment for Period 01

Variable Number 52 Variable TRT01PN Type Numeric Length 8 Format . Label Planned Treatment for Period 01 (N)

Variable Number 53 Variable TRT01A Type Character Length 20 Format . Label Actual Treatment for Period 01

Variable Number 54 Variable TRT01AN Type Numeric Length 8 Format . Label Actual Treatment for Period 01 (N)

Variable Number 55 Variable TR01PG1 Type Character Length 13 Format . Label Planned Pooled Treatment 1 for Period 01

Variable Number 56 Variable TR01PG1N Type Numeric Length 8 Format . Label Planned Pooled Trt 1 for Period 01 (N)

Variable Number 57 Variable TR01PG2 Type Character Length 32 Format . Label Planned Pooled Treatment 1 for Period 02

Variable Number 58 Variable TR01PG2N Type Numeric Length 8 Format . Label Planned Pooled Trt 1 for Period 02 (N)

Variable Number 59 Variable TR01AG1 Type Character Length 13 Format . Label Actual Pooled Treatment 1 for Period 01

Variable Number 60 Variable TR01AG1N Type Numeric Length 8 Format . Label Actual Pooled Trt 1 for Period 01 (N)

Variable Number 61 Variable TRT02P Type Character Length 20 Format . Label Planned Treatment for Period 02

Variable Number 62 Variable TRT02PN Type Numeric Length 8 Format . Label Planned Treatment for Period 02 (N)



Variable Number 63 Variable TRT02A Type Character Length 20 Format . Label Actual Treatment for Period 02

Variable Number 64 Variable TRT02AN Type Numeric Length 8 Format . Label Actual Treatment for Period 02 (N)

Variable Number 65 Variable TR02PG1 Type Character Length 13 Format . Label Planned Pooled Treatment 1 for Period 02

Variable Number 66 Variable TR02PG1N Type Numeric Length 8 Format . Label Planned Pooled Trt 1 for Period 02 (N)

Variable Number 67 Variable TR02AG1 Type Character Length 13 Format . Label Actual Pooled Treatment 1 for Period 02

Variable Number 68 Variable TR02AG1N Type Numeric Length 8 Format . Label Actual Pooled Trt 1 for Period 02 (N)

Variable Number 69 Variable AVISIT Type Character Length 22 Format . Label Analysis Visit

Variable Number 70 Variable AVISITN Type Numeric Length 8 Format . Label Analysis Visit (N)

Variable Number 71 Variable PARAM Type Character Length 30 Format . Label Parameter

Variable Number 72 Variable PARAMCD Type Character Length 8 Format . Label Parameter Code

Variable Number 73 Variable PARAMN Type Numeric Length 8 Format . Label Parameter (N)

Variable Number 74 Variable PARAMTYP Type Character Length 7 Format . Label Parameter Type

Variable Number 75 Variable AVAL Type Numeric Length 8 Format . Label Analysis Value

Variable Number 76 Variable WGTSCRN Type Numeric Length 8 Format . Label Weight at Screening (kg)

Variable Number 77 Variable SDFIRRX Type Numeric Length 8 Format . Label Study Day of First Exposure to Treatment (from first treatment date)

Variable Number 78 Variable SDFIRRX1 Type Numeric Length 8 Format . Label Study Day of First Exposure in Period 01 (from first treatment date)

Variable Number 79 Variable SDLASRX1 Type Numeric Length 8 Format . Label Study Day of Last Exposure in Period 01 (from first treatment date)

Variable Number 80 Variable SDFIRRX2 Type Numeric Length 8 Format . Label Study Day of First Exposure in Period 02 (from first treatment date)

Variable Number 81 Variable SDLASRX2 Type Numeric Length 8 Format . Label Study Day of Last Exposure in Period 02 (from first treatment date)

Variable Number 82 Variable SDLASRX Type Numeric Length 8 Format . Label Study Day of Last Exposure to Treatment (from first treatment date)

Variable Number 83 Variable SDSTP1 Type Numeric Length 8 Format . Label Study Day of Period 01 Start (from first treatment date)

Variable Number 84 Variable SDENP1 Type Numeric Length 8 Format . Label Study Day of Period 01 End (from first treatment date)

Variable Number 85 Variable SDSTP2 Type Numeric Length 8 Format . Label Study Day of Period 02 Start (from first treatment date)

Variable Number 86 Variable SDENP2 Type Numeric Length 8 Format . Label Study Day of Period 02 End (from first treatment date)

Variable Number 87 Variable SDILASRX Type Numeric Length 8 Format . Label Study Day of Initial Last Exposure 01 (from first treatment date)

Variable Number 88 Variable SDRXAFLEX Type Numeric Length 8 Format . Label Study Day of Drug After Last Exposure 01 (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 AGEU Type Character Length 5 Format . Label Age Units

Variable Number 6 Variable AGEGR1 Type Character Length 14 Format . Label Pooled Age Group 1

Variable Number 7 Variable AGEGR1N Type Numeric Length 8 Format . Label Pooled Age Group 1 (N)

Variable Number 8 Variable SEX Type Character Length 1 Format . Label Sex

Variable Number 9 Variable SEXN Type Numeric Length 8 Format . Label Sex (N)

Variable Number 10 Variable WEIGHTBL Type Numeric Length 8 Format . Label Weight at Baseline (kg)

Variable Number 11 Variable HEIGHTBL Type Numeric Length 8 Format . Label Height at Baseline (cm)

Variable Number 12 Variable BMIBL Type Numeric Length 8 Format . Label BMI at Baseline (kg/m<sup>2</sup>)

Variable Number 13 Variable RACE Type Character Length 25 Format . Label Race

Variable Number 14 Variable RACEN Type Numeric Length 8 Format . Label Race (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 ENRNFN Type Numeric Length 8 Format . Label Enrolled Population Flag (N)

Variable Number 22 Variable RANDFL Type Character Length 1 Format . Label Randomized Population Flag

Variable Number 23 Variable RANDFN Type Numeric Length 8 Format . Label Randomized 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 ITTFL Type Character Length 1 Format . Label Intent-To-Treat Population Flag

Variable Number 27 Variable ITTFN Type Numeric Length 8 Format . Label Intent-To-Treat Population Flag (N)

Variable Number 28 Variable MITTFL Type Character Length 1 Format . Label Modified ITT Population Flag

Variable Number 29 Variable MITTFN Type Numeric Length 8 Format . Label Modified ITT Population Flag (N)

Variable Number 30 Variable PPROTFL Type Character Length 1 Format . Label Per-Protocol Population Flag

Variable Number 31 Variable PPROTFN Type Numeric Length 8 Format . Label Per-Protocol Population Flag (N)

Variable Number 32 Variable STABLEFL Type Character Length 1 Format . Label Dosed at Stable Dosing Period Flag

Variable Number 33 Variable STABLEFN Type Numeric Length 8 Format . Label Dosed at Stable Dosing Period Flag (N)

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

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

Variable Number 36 Variable EXTENFL Type Character Length 1 Format . Label Entered into LUM001-305 Extension Study

Variable Number 37 Variable EXTENFN Type Numeric Length 8 Format . Label Entered into LUM001-305 Extension (N)

Variable Number 38 Variable LOWDOSFL Type Character Length 1 Format . Label Recd. Lower Dose Due to Tolerability

Variable Number 39 Variable LOWDOSFN Type Numeric Length 8 Format . Label Recd. Lower Dose Due to Tolerability (N)

Variable Number 40 Variable HIDOSEFL Type Character Length 1 Format . Label Two Highest Tolerated Doses Flag

Variable Number 41 Variable HIDOSEFN Type Numeric Length 8 Format . Label Two Highest Tolerated Doses Flag (N)

Variable Number 42 Variable DOSINTFL Type Character Length 1 Format . Label Drug Interrupted for >14 Days Flag

Variable Number 43 Variable DOSINTFN Type Numeric Length 8 Format . Label Drug Interrupted for >14 Days Flag (N)

Variable Number 44 Variable ARM Type Character Length 20 Format . Label Description of Planned Arm

Variable Number 45 Variable ARMCD Type Character Length 1 Format . Label Description Code of Planned Arm

Variable Number 46 Variable ACTARM Type Character Length 20 Format . Label Description of Actual Arm

Variable Number 47 Variable ACTARMCD Type Character Length 1 Format . Label Description Code of Actual Arm

Variable Number 48 Variable TRT01P Type Character Length 20 Format . Label Planned Treatment for Period 01

Variable Number 49 Variable TRT01PN Type Numeric Length 8 Format . Label Planned Treatment for Period 01 (N)

Variable Number 50 Variable TRT01A Type Character Length 20 Format . Label Actual Treatment for Period 01

Variable Number 51 Variable TRT01AN Type Numeric Length 8 Format . Label Actual Treatment for Period 01 (N)

Variable Number 52 Variable TR01PG1 Type Character Length 13 Format . Label Planned Pooled Treatment 1 for Period 01

Variable Number 53 Variable TR01PG1N Type Numeric Length 8 Format . Label Planned Pooled Trt 1 for Period 01 (N)

Variable Number 54 Variable TR01PG2 Type Character Length 32 Format . Label Planned Pooled Treatment 1 for Period 02

Variable Number 55 Variable TR01PG2N Type Numeric Length 8 Format . Label Planned Pooled Trt 1 for Period 02 (N)

Variable Number 56 Variable TR01AG1 Type Character Length 13 Format . Label Actual Pooled Treatment 1 for Period 01

Variable Number 57 Variable TR01AG1N Type Numeric Length 8 Format . Label Actual Pooled Trt 1 for Period 01 (N)

Variable Number 58 Variable TRT02P Type Character Length 20 Format . Label Planned Treatment for Period 02

Variable Number 59 Variable TRT02PN Type Numeric Length 8 Format . Label Planned Treatment for Period 02 (N)

Variable Number 60 Variable TRT02A Type Character Length 20 Format . Label Actual Treatment for Period 02

Variable Number 61 Variable TRT02AN Type Numeric Length 8 Format . Label Actual Treatment for Period 02 (N)

Variable Number 62 Variable TR02PG1 Type Character Length 13 Format . Label Planned Pooled Treatment 1 for Period 02

Variable Number 63 Variable TR02PG1N Type Numeric Length 8 Format . Label Planned Pooled Trt 1 for Period 02 (N)

Variable Number 64 Variable TR02AG1 Type Character Length 13 Format . Label Actual Pooled Treatment 1 for Period 02

Variable Number 65 Variable TR02AG1N Type Numeric Length 8 Format . Label Actual Pooled Trt 1 for Period 02 (N)

Variable Number 66 Variable TRTP Type Character Length 20 Format . Label Planned Treatment

Variable Number 67 Variable TRTPN Type Numeric Length 8 Format . Label Planned Treatment (N)

Variable Number 68 Variable TRTA Type Character Length 20 Format . Label Actual Treatment

Variable Number 69 Variable TRTAN Type Numeric Length 8 Format . Label Actual Treatment (N)

Variable Number 70 Variable TRTPG1 Type Character Length 13 Format . Label Planned Pooled Treatment 1

Variable Number 71 Variable TRTPG1N Type Numeric Length 8 Format . Label Planned Pooled Treatment 1 (N)

Variable Number 72 Variable TRTPG2 Type Character Length 32 Format . Label Planned Pooled Treatment 2

Variable Number 73 Variable TRTPG2N Type Numeric Length 8 Format . Label Planned Pooled Treatment 2 (N)

Variable Number 74 Variable TRTAG1 Type Character Length 13 Format . Label Actual Pooled Treatment 1

Variable Number 75 Variable TRTAG1N Type Numeric Length 8 Format . Label Actual Pooled Treatment 1 (N)

Variable Number 76 Variable VISIT Type Character Length 11 Format . Label Visit Name

Variable Number 77 Variable VISITNUM Type Numeric Length 8 Format . Label Visit Number

Variable Number 78 Variable LBDY Type Numeric Length 8 Format . Label Study Day of Specimen Collection (from first treatment date)

Variable Number 79 Variable AVISITN Type Numeric Length 8 Format . Label Analysis Visit (N)

Variable Number 80 Variable AVISIT Type Character Length 21 Format . Label Analysis Visit

Variable Number 81 Variable LBSEQ Type Numeric Length 8 Format . Label Sequence Number

Variable Number 82 Variable DTYPE Type Character Length 18 Format . Label Derivation Type

Variable Number 83 Variable ADY Type Numeric Length 8 Format . Label Analysis Relative Day (from first treatment date)

Variable Number 84 Variable PARAM Type Character Length 46 Format . Label Parameter

Variable Number 85 Variable PARAMCD Type Character Length 8 Format . Label Parameter Code

Variable Number 86 Variable PARAMN Type Numeric Length 8 Format . Label Parameter (N)

Variable Number 87 Variable PARAMTYP Type Character Length 7 Format . Label Parameter Type

Variable Number 88 Variable PARCAT1 Type Character Length 11 Format . Label Parameter Category 1

Variable Number 89 Variable PARCAT2 Type Character Length 22 Format . Label Parameter Category 2

Variable Number 90 Variable LBSPEC Type Character Length 6 Format . Label Specimen Type

Variable Number 91 Variable LBFAS Type Character Length 1 Format . Label Fasting Status

Variable Number 92 Variable AVAL Type Numeric Length 8 Format . Label Analysis Value

Variable Number 93 Variable AVALC Type Character Length 13 Format . Label Analysis Value (C)

Variable Number 94 Variable BASE Type Numeric Length 8 Format . Label Baseline Value

Variable Number 95 Variable BASEC Type Character Length 13 Format . Label Baseline Value (C)

Variable Number 96 Variable CHG Type Numeric Length 8 Format . Label Change from Baseline

Variable Number 97 Variable PCHG Type Numeric Length 8 Format . Label Percent Change from Baseline

Variable Number 98 Variable ABLFL Type Character Length 1 Format . Label Baseline Record Flag

Variable Number 99 Variable ABLFN Type Numeric Length 8 Format . Label Baseline Record Flag (N)

Variable Number 100 Variable ANRLO Type Character Length 5 Format . Label Analysis Normal Range Lower Limit

Variable Number 101 Variable ANRHI Type Character Length 4 Format . Label Analysis Normal Range Upper Limit

Variable Number 102 Variable ANRIND Type Character Length 6 Format . Label Analysis Reference Range Indicator

Variable Number 103 Variable BNRIND Type Character Length 6 Format . Label Baseline Reference Range Indicator

Variable Number 104 Variable SHIFT1 Type Character Length 16 Format . Label Shift 1

Variable Number 105 Variable CRIT1 Type Character Length 98 Format . Label Analysis Criterion 1

Variable Number 106 Variable CRIT1FL Type Character Length 1 Format . Label Criterion 1 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 AGEU Type Character Length 5 Format . Label Age Units

Variable Number 6 Variable AGEGR1 Type Character Length 14 Format . Label Pooled Age Group 1

Variable Number 7 Variable AGEGR1N Type Numeric Length 8 Format . Label Pooled Age Group 1 (N)

Variable Number 8 Variable SEX Type Character Length 1 Format . Label Sex

Variable Number 9 Variable SEXN Type Numeric Length 8 Format . Label Sex (N)

Variable Number 10 Variable WEIGHTBL Type Numeric Length 8 Format . Label Weight at Baseline (kg)

Variable Number 11 Variable HEIGHTBL Type Numeric Length 8 Format . Label Height at Baseline (cm)

Variable Number 12 Variable BMIBL Type Numeric Length 8 Format . Label BMI at Baseline (kg/m<sup>2</sup>)

Variable Number 13 Variable RACE Type Character Length 25 Format . Label Race

Variable Number 14 Variable RACEN Type Numeric Length 8 Format . Label Race (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 RANDFL Type Character Length 1 Format . Label Randomized Population Flag

Variable Number 23 Variable RANDFN Type Numeric Length 8 Format . Label Randomized 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 ITTFL Type Character Length 1 Format . Label Intent-To-Treat Population Flag

Variable Number 27 Variable ITTFN Type Numeric Length 8 Format . Label Intent-To-Treat Population Flag (N)

Variable Number 28 Variable MITTFL Type Character Length 1 Format . Label Modified ITT Population Flag

Variable Number 29 Variable MITTFN Type Numeric Length 8 Format . Label Modified ITT Population Flag (N)

Variable Number 30 Variable PPROTFL Type Character Length 1 Format . Label Per-Protocol Population Flag

Variable Number 31 Variable PPROTFN Type Numeric Length 8 Format . Label Per-Protocol Population Flag (N)

Variable Number 32 Variable STABLEFL Type Character Length 1 Format . Label Dosed at Stable Dosing Period Flag

Variable Number 33 Variable STABLEFN Type Numeric Length 8 Format . Label Dosed at Stable Dosing Period Flag (N)

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

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

Variable Number 36 Variable EXTENFL Type Character Length 1 Format . Label Entered into LUM001-305 Extension Study



Variable Number 37 Variable EXTENFN Type Numeric Length 8 Format . Label Entered into LUM001-305 Extension (N)

Variable Number 38 Variable LOWDOSFL Type Character Length 1 Format . Label Recd. Lower Dose Due to Tolerability

Variable Number 39 Variable LOWDOSFN Type Numeric Length 8 Format . Label Recd. Lower Dose Due to Tolerability (N)

Variable Number 40 Variable HIDOSEFL Type Character Length 1 Format . Label Two Highest Tolerated Doses Flag

Variable Number 41 Variable HIDOSEFN Type Numeric Length 8 Format . Label Two Highest Tolerated Doses Flag (N)

Variable Number 42 Variable DOSINTFL Type Character Length 1 Format . Label Drug Interrupted for >14 Days Flag

Variable Number 43 Variable DOSINTFN Type Numeric Length 8 Format . Label Drug Interrupted for >14 Days Flag (N)

Variable Number 44 Variable ARM Type Character Length 20 Format . Label Description of Planned Arm

Variable Number 45 Variable ARMCD Type Character Length 1 Format . Label Description Code of Planned Arm

Variable Number 46 Variable ACTARM Type Character Length 20 Format . Label Description of Actual Arm

Variable Number 47 Variable ACTARMCD Type Character Length 1 Format . Label Description Code of Actual Arm

Variable Number 48 Variable TRT01P Type Character Length 20 Format . Label Planned Treatment for Period 01

Variable Number 49 Variable TRT01PN Type Numeric Length 8 Format . Label Planned Treatment for Period 01 (N)

Variable Number 50 Variable TRT01A Type Character Length 20 Format . Label Actual Treatment for Period 01

Variable Number 51 Variable TRT01AN Type Numeric Length 8 Format . Label Actual Treatment for Period 01 (N)

Variable Number 52 Variable TR01PG1 Type Character Length 13 Format . Label Planned Pooled Treatment 1 for Period 01

Variable Number 53 Variable TR01PG1N Type Numeric Length 8 Format . Label Planned Pooled Trt 1 for Period 01 (N)

Variable Number 54 Variable TR01PG2 Type Character Length 32 Format . Label Planned Pooled Treatment 1 for Period 02

Variable Number 55 Variable TR01PG2N Type Numeric Length 8 Format . Label Planned Pooled Trt 1 for Period 02 (N)

Variable Number 56 Variable TR01AG1 Type Character Length 13 Format . Label Actual Pooled Treatment 1 for Period 01

Variable Number 57 Variable TR01AG1N Type Numeric Length 8 Format . Label Actual Pooled Trt 1 for Period 01 (N)

Variable Number 58 Variable TRT02P Type Character Length 20 Format . Label Planned Treatment for Period 02

Variable Number 59 Variable TRT02PN Type Numeric Length 8 Format . Label Planned Treatment for Period 02 (N)

Variable Number 60 Variable TRT02A Type Character Length 20 Format . Label Actual Treatment for Period 02

Variable Number 61 Variable TRT02AN Type Numeric Length 8 Format . Label Actual Treatment for Period 02 (N)

Variable Number 62 Variable TR02PG1 Type Character Length 13 Format . Label Planned Pooled Treatment 1 for Period 02

Variable Number 63 Variable TR02PG1N Type Numeric Length 8 Format . Label Planned Pooled Trt 1 for Period 02 (N)

Variable Number 64 Variable TR02AG1 Type Character Length 13 Format . Label Actual Pooled Treatment 1 for Period 02

Variable Number 65 Variable TR02AG1N Type Numeric Length 8 Format . Label Actual Pooled Trt 1 for Period 02 (N)

Variable Number 66 Variable TRTP Type Character Length 20 Format . Label Planned Treatment

Variable Number 67 Variable TRTPN Type Numeric Length 8 Format . Label Planned Treatment (N)

Variable Number 68 Variable TRTA Type Character Length 20 Format . Label Actual Treatment

Variable Number 69 Variable TRTAN Type Numeric Length 8 Format . Label Actual Treatment (N)

Variable Number 70 Variable TRTPG1 Type Character Length 13 Format . Label Planned Pooled Treatment 1

Variable Number 71 Variable TRTPG1N Type Numeric Length 8 Format . Label Planned Pooled Treatment 1 (N)

Variable Number 72 Variable TRTPG2 Type Character Length 32 Format . Label Planned Pooled Treatment 2

Variable Number 73 Variable TRTPG2N Type Numeric Length 8 Format . Label Planned Pooled Treatment 2 (N)

Variable Number 74 Variable TRTAG1 Type Character Length 13 Format . Label Actual Pooled Treatment 1

Variable Number 75 Variable TRTAG1N Type Numeric Length 8 Format . Label Actual Pooled Treatment 1 (N)

Variable Number 76 Variable PCSEQ Type Numeric Length 8 Format . Label Sequence Number

Variable Number 77 Variable VISIT Type Character Length 10 Format . Label Visit Name

Variable Number 78 Variable VISITNUM Type Numeric Length 8 Format . Label Visit Number

Variable Number 79 Variable PCDY Type Numeric Length 8 Format . Label Actual Study Day of Specimen Collection (from first treatment date)

Variable Number 80 Variable AVISITN Type Numeric Length 8 Format . Label Analysis Visit (N)

Variable Number 81 Variable AVISIT Type Character Length 21 Format . Label Analysis Visit

Variable Number 82 Variable DTYPE Type Character Length 13 Format . Label Derivation Type

Variable Number 83 Variable ADY Type Numeric Length 8 Format . Label Analysis Relative Day (from first treatment date)

Variable Number 84 Variable PARCAT1 Type Character Length 7 Format . Label Parameter Category 1

Variable Number 85 Variable PARAM Type Character Length 14 Format . Label Parameter

Variable Number 86 Variable PARAMCD Type Character Length 6 Format . Label Parameter Code

Variable Number 87 Variable PARAMN Type Numeric Length 8 Format . Label Parameter (N)

Variable Number 88 Variable AVAL Type Numeric Length 8 Format . Label Analysis Value

Variable Number 89 Variable AVALC Type Character Length 5 Format . Label Analysis Value (C)

Variable Number 90 Variable ABLFL Type Character Length 1 Format . Label Baseline Record Flag

Variable Number 91 Variable ABLFN Type Numeric Length 8 Format . Label Baseline Record Flag (N)

Variable Number 92 Variable BASE Type Numeric Length 8 Format . Label Baseline Value

Variable Number 93 Variable CHG Type Numeric Length 8 Format . Label Change from Baseline

### 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 AGEU Type Character Length 5 Format . Label Age Units

Variable Number 6 Variable AGEGR1 Type Character Length 14 Format . Label Pooled Age Group 1

Variable Number 7 Variable AGEGR1N Type Numeric Length 8 Format . Label Pooled Age Group 1 (N)

Variable Number 8 Variable SEX Type Character Length 1 Format . Label Sex

Variable Number 9 Variable SEXN Type Numeric Length 8 Format . Label Sex (N)

Variable Number 10 Variable WEIGHTBL Type Numeric Length 8 Format . Label Weight at Baseline (kg)

Variable Number 11 Variable HEIGHTBL Type Numeric Length 8 Format . Label Height at Baseline (cm)

Variable Number 12 Variable BMIBL Type Numeric Length 8 Format . Label BMI at Baseline (kg/m2)

Variable Number 13 Variable RACE Type Character Length 25 Format . Label Race

Variable Number 14 Variable RACEN Type Numeric Length 8 Format . Label Race (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 RANDFL Type Character Length 1 Format . Label Randomized Population Flag

Variable Number 23 Variable RANDFN Type Numeric Length 8 Format . Label Randomized 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 ITTFL Type Character Length 1 Format . Label Intent-To-Treat Population Flag

Variable Number 27 Variable ITTFN Type Numeric Length 8 Format . Label Intent-To-Treat Population Flag (N)

Variable Number 28 Variable MITTFL Type Character Length 1 Format . Label Modified ITT Population Flag

Variable Number 29 Variable MITTFN Type Numeric Length 8 Format . Label Modified ITT Population Flag (N)

Variable Number 30 Variable PPROTFN Type Character Length 1 Format . Label Per-Protocol Population Flag

Variable Number 31 Variable PPROTFN Type Numeric Length 8 Format . Label Per-Protocol Population Flag (N)

Variable Number 32 Variable STABLEFL Type Character Length 1 Format . Label Dosed at Stable Dosing Period Flag

Variable Number 33 Variable STABLEFN Type Numeric Length 8 Format . Label Dosed at Stable Dosing Period Flag (N)

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

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

Variable Number 36 Variable EXTENFL Type Character Length 1 Format . Label Entered into LUM001-305 Extension Study

Variable Number 37 Variable EXTENFN Type Numeric Length 8 Format . Label Entered into LUM001-305 Extension (N)

Variable Number 38 Variable LOWDOSFL Type Character Length 1 Format . Label Recd. Lower Dose Due to Tolerability

Variable Number 39 Variable LOWDOSFN Type Numeric Length 8 Format . Label Recd. Lower Dose Due to Tolerability (N)

Variable Number 40 Variable HIDOSEFL Type Character Length 1 Format . Label Two Highest Tolerated Doses Flag

Variable Number 41 Variable HIDOSEFN Type Numeric Length 8 Format . Label Two Highest Tolerated Doses Flag (N)

Variable Number 42 Variable DOSINTFL Type Character Length 1 Format . Label Drug Interrupted for >14 Days Flag

Variable Number 43 Variable DOSINTFN Type Numeric Length 8 Format . Label Drug Interrupted for >14 Days Flag (N)

Variable Number 44 Variable ARM Type Character Length 20 Format . Label Description of Planned Arm

Variable Number 45 Variable ARMCD Type Character Length 1 Format . Label Description Code of Planned Arm

Variable Number 46 Variable ACTARM Type Character Length 20 Format . Label Description of Actual Arm

Variable Number 47 Variable ACTARMCD Type Character Length 1 Format . Label Description Code of Actual Arm

Variable Number 48 Variable TRT01P Type Character Length 20 Format . Label Planned Treatment for Period 01

Variable Number 49 Variable TRT01PN Type Numeric Length 8 Format . Label Planned Treatment for Period 01 (N)

Variable Number 50 Variable TRT01A Type Character Length 20 Format . Label Actual Treatment for Period 01

Variable Number 51 Variable TRT01AN Type Numeric Length 8 Format . Label Actual Treatment for Period 01 (N)

Variable Number 52 Variable TR01PG1 Type Character Length 13 Format . Label Planned Pooled Treatment 1 for Period 01

Variable Number 53 Variable TR01PG1N Type Numeric Length 8 Format . Label Planned Pooled Trt 1 for Period 01 (N)

Variable Number 54 Variable TR01PG2 Type Character Length 32 Format . Label Planned Pooled Treatment 1 for Period 02

Variable Number 55 Variable TR01PG2N Type Numeric Length 8 Format . Label Planned Pooled Trt 1 for Period 02 (N)

Variable Number 56 Variable TR01AG1 Type Character Length 13 Format . Label Actual Pooled Treatment 1 for Period 01

Variable Number 57 Variable TR01AG1N Type Numeric Length 8 Format . Label Actual Pooled Trt 1 for Period 01 (N)

Variable Number 58 Variable TRT02P Type Character Length 20 Format . Label Planned Treatment for Period 02

Variable Number 59 Variable TRT02PN Type Numeric Length 8 Format . Label Planned Treatment for Period 02 (N)

Variable Number 60 Variable TRT02A Type Character Length 20 Format . Label Actual Treatment for Period 02

Variable Number 61 Variable TRT02AN Type Numeric Length 8 Format . Label Actual Treatment for Period 02 (N)

Variable Number 62 Variable TR02PG1 Type Character Length 13 Format . Label Planned Pooled Treatment 1 for Period 02

Variable Number 63 Variable TR02PG1N Type Numeric Length 8 Format . Label Planned Pooled Trt 1 for Period 02 (N)

Variable Number 64 Variable TR02AG1 Type Character Length 13 Format . Label Actual Pooled Treatment 1 for Period 02

Variable Number 65 Variable TR02AG1N Type Numeric Length 8 Format . Label Actual Pooled Trt 1 for Period 02 (N)

Variable Number 66 Variable TRTP Type Character Length 20 Format . Label Planned Treatment

Variable Number 67 Variable TRTPN Type Numeric Length 8 Format . Label Planned Treatment (N)

Variable Number 68 Variable TRTA Type Character Length 20 Format . Label Actual Treatment

Variable Number 69 Variable TRTAN Type Numeric Length 8 Format . Label Actual Treatment (N)

Variable Number 70 Variable TRTPG1 Type Character Length 13 Format . Label Planned Pooled Treatment 1

Variable Number 71 Variable TRTPG1N Type Numeric Length 8 Format . Label Planned Pooled Treatment 1 (N)

Variable Number 72 Variable TRTPG2 Type Character Length 32 Format . Label Planned Pooled Treatment 2

Variable Number 73 Variable TRTPG2N Type Numeric Length 8 Format . Label Planned Pooled Treatment 2 (N)

Variable Number 74 Variable TRTAG1 Type Character Length 13 Format . Label Actual Pooled Treatment 1

Variable Number 75 Variable TRTAG1N Type Numeric Length 8 Format . Label Actual Pooled Treatment 1 (N)

Variable Number 76 Variable ADY Type Numeric Length 8 Format . Label Analysis Relative Day (from first treatment date)

Variable Number 77 Variable AVISITN Type Numeric Length 8 Format . Label Analysis Visit (N)

Variable Number 78 Variable AVISIT Type Character Length 21 Format . Label Analysis Visit

Variable Number 79 Variable VISIT Type Character Length 10 Format . Label Visit Name

Variable Number 80 Variable VISITNUM Type Numeric Length 8 Format . Label Visit Number

Variable Number 81 Variable QSSEQ Type Numeric Length 8 Format . Label Sequence Number

Variable Number 82 Variable PARAM Type Character Length 47 Format . Label Parameter

Variable Number 83 Variable PARAMCD Type Character Length 8 Format . Label Parameter Code

Variable Number 84 Variable PARAMN Type Numeric Length 8 Format . Label Parameter (N)

Variable Number 85 Variable PARAMTYP Type Character Length 7 Format . Label Parameter Type

Variable Number 86 Variable PARCAT1 Type Character Length 36 Format . Label Parameter Category 1

Variable Number 87 Variable PARCAT2 Type Character Length 26 Format . Label Parameter Category 2

Variable Number 88 Variable AVAL Type Numeric Length 8 Format . Label Analysis Value

Variable Number 89 Variable ABLFL Type Character Length 1 Format . Label Baseline Record Flag

Variable Number 90 Variable ABLFN Type Numeric Length 8 Format . Label Baseline Record Flag (N)

Variable Number 91 Variable BASE Type Numeric Length 8 Format . Label Baseline Value

Variable Number 92 Variable CHG Type Numeric Length 8 Format . Label Change from Baseline

Variable Number 93 Variable PCHG Type Numeric Length 8 Format . Label Percent Change from Baseline

Variable Number 94 Variable CRIT1 Type Character Length 21 Format . Label Analysis Criterion 1

Variable Number 95 Variable CRIT1FL Type Character Length 1 Format . Label Criterion 1 Evaluation Result Flag

Variable Number 96 Variable CRIT2 Type Character Length 21 Format . Label Analysis Criterion 2

Variable Number 97 Variable CRIT2FL Type Character Length 1 Format . Label Criterion 2 Evaluation Result Flag

Variable Number 98 Variable CRIT3 Type Character Length 11 Format . Label Analysis Criterion 3

Variable Number 99 Variable CRIT3FL Type Character Length 1 Format . Label Criterion 3 Evaluation Result Flag

Variable Number 100 Variable CRIT4 Type Character Length 11 Format . Label Analysis Criterion 4

Variable Number 101 Variable CRIT4FL Type Character Length 1 Format . Label Criterion 4 Evaluation Result Flag

Variable Number 102 Variable CRIT5 Type Character Length 11 Format . Label Analysis Criterion 5

Variable Number 103 Variable CRIT5FL Type Character Length 1 Format . Label Criterion 5 Evaluation Result Flag

Variable Number 104 Variable CRIT6 Type Character Length 18 Format . Label Analysis Criterion 6

Variable Number 105 Variable CRIT6FL Type Character Length 1 Format . Label Criterion 6 Evaluation Result Flag

Variable Number 106 Variable CRIT7 Type Character Length 19 Format . Label Analysis Criterion 7

Variable Number 107 Variable CRIT7FL Type Character Length 1 Format . Label Criterion 7 Evaluation Result Flag

Variable Number 108 Variable CRIT8 Type Character Length 12 Format . Label Analysis Criterion 8

Variable Number 109 Variable CRIT8FL Type Character Length 1 Format . Label Criterion 8 Evaluation Result Flag

Variable Number 110 Variable DTYPE Type Character Length 8 Format . Label Derivation Type



## 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 AGEU Type Character Length 5 Format . Label Age Units

Variable Number 6 Variable AGEGR1 Type Character Length 14 Format . Label Pooled Age Group 1

Variable Number 7 Variable AGEGR1N Type Numeric Length 8 Format . Label Pooled Age Group 1 (N)

Variable Number 8 Variable SEX Type Character Length 1 Format . Label Sex

Variable Number 9 Variable SEXN Type Numeric Length 8 Format . Label Sex (N)

Variable Number 10 Variable WEIGHTBL Type Numeric Length 8 Format . Label Weight at Baseline (kg)

Variable Number 11 Variable HEIGHTBL Type Numeric Length 8 Format . Label Height at Baseline (cm)

Variable Number 12 Variable BMIBL Type Numeric Length 8 Format . Label BMI at Baseline (kg/m2)

Variable Number 13 Variable RACE Type Character Length 25 Format . Label Race

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

Variable Number 15 Variable ARACE Type Character Length 25 Format . Label Analysis Race

Variable Number 16 Variable ARACEN Type Numeric Length 8 Format . Label Analysis Race (N)

Variable Number 17 Variable RACE1 Type Character Length 41 Format . Label Race 1

Variable Number 18 Variable RACE2 Type Character Length 5 Format . Label Race 2

Variable Number 19 Variable RACE3 Type Character Length 1 Format . Label Race 3

Variable Number 20 Variable RACE4 Type Character Length 1 Format . Label Race 4

Variable Number 21 Variable RACE5 Type Character Length 1 Format . Label Race 5

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

Variable Number 23 Variable ETHNICN Type Numeric Length 8 Format . Label Ethnicity (N)

Variable Number 24 Variable COUNTRY Type Character Length 3 Format . Label Country

Variable Number 25 Variable ACOUNTRY Type Character Length 13 Format . Label Analysis Country

Variable Number 26 Variable SCRNFL Type Character Length 1 Format . Label Screened Population Flag

Variable Number 27 Variable SCRNFN Type Numeric Length 8 Format . Label Screened Population Flag (N)

Variable Number 28 Variable ENRFL Type Character Length 1 Format . Label Enrolled Population Flag

Variable Number 29 Variable ENRFLN Type Numeric Length 8 Format . Label Enrolled Population Flag (N)

Variable Number 30 Variable RANDFL Type Character Length 1 Format . Label Randomized Population Flag

Variable Number 31 Variable RANDFN Type Numeric Length 8 Format . Label Randomized Population Flag (N)

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

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

Variable Number 34 Variable ITTFL Type Character Length 1 Format . Label Intent-To-Treat Population Flag

Variable Number 35 Variable ITTFN Type Numeric Length 8 Format . Label Intent-To-Treat Population Flag (N)

Variable Number 36 Variable MITTFL Type Character Length 1 Format . Label Modified ITT Population Flag

Variable Number 37 Variable MITTFN Type Numeric Length 8 Format . Label Modified ITT Population Flag (N)

Variable Number 38 Variable PPROTFN Type Character Length 1 Format . Label Per-Protocol Population Flag

Variable Number 39 Variable PPROTFN Type Numeric Length 8 Format . Label Per-Protocol Population Flag (N)

Variable Number 40 Variable STABLEFL Type Character Length 1 Format . Label Dosed at Stable Dosing Period Flag

Variable Number 41 Variable STABLEFN Type Numeric Length 8 Format . Label Dosed at Stable Dosing Period Flag (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 EOSSTT Type Character Length 12 Format . Label End of Study Status

Variable Number 45 Variable EXTENFL Type Character Length 1 Format . Label Entered into LUM001-305 Extension Study

Variable Number 46 Variable EXTENFN Type Numeric Length 8 Format . Label Entered into LUM001-305 Extension (N)

Variable Number 47 Variable LOWDOSFL Type Character Length 1 Format . Label Recd. Lower Dose Due to Tolerability

Variable Number 48 Variable LOWDOSFN Type Numeric Length 8 Format . Label Recd. Lower Dose Due to Tolerability (N)

Variable Number 49 Variable HIDOSEFL Type Character Length 1 Format . Label Two Highest Tolerated Doses Flag

Variable Number 50 Variable HIDOSEFN Type Numeric Length 8 Format . Label Two Highest Tolerated Doses Flag (N)

Variable Number 51 Variable DOSINTFL Type Character Length 1 Format . Label Drug Interrupted for >14 Days Flag

Variable Number 52 Variable DOSINTFN Type Numeric Length 8 Format . Label Drug Interrupted for >14 Days Flag (N)

Variable Number 53 Variable ARM Type Character Length 20 Format . Label Description of Planned Arm

Variable Number 54 Variable ARMCD Type Character Length 8 Format . Label Description Code of Planned Arm

Variable Number 55 Variable ACTARM Type Character Length 20 Format . Label Description of Actual Arm

Variable Number 56 Variable ACTARMCD Type Character Length 8 Format . Label Description Code of Actual Arm

Variable Number 57 Variable TRT01P Type Character Length 20 Format . Label Planned Treatment for Period 01

Variable Number 58 Variable TRT01PN Type Numeric Length 8 Format . Label Planned Treatment for Period 01 (N)

Variable Number 59 Variable TRT01A Type Character Length 20 Format . Label Actual Treatment for Period 01

Variable Number 60 Variable TRT01AN Type Numeric Length 8 Format . Label Actual Treatment for Period 01 (N)

Variable Number 61 Variable TR01PG1 Type Character Length 13 Format . Label Planned Pooled Treatment 1 for Period 01

Variable Number 62 Variable TR01PG1N Type Numeric Length 8 Format . Label Planned Pooled Trt 1 for Period 01 (N)

Variable Number 63 Variable TR01PG2 Type Character Length 32 Format . Label Planned Pooled Treatment 1 for Period 02

Variable Number 64 Variable TR01PG2N Type Numeric Length 8 Format . Label Planned Pooled Trt 1 for Period 02 (N)

Variable Number 65 Variable TR01AG1 Type Character Length 13 Format . Label Actual Pooled Treatment 1 for Period 01

Variable Number 66 Variable TR01AG1N Type Numeric Length 8 Format . Label Actual Pooled Trt 1 for Period 01 (N)

Variable Number 67 Variable TRT02P Type Character Length 20 Format . Label Planned Treatment for Period 02

Variable Number 68 Variable TRT02PN Type Numeric Length 8 Format . Label Planned Treatment for Period 02 (N)

Variable Number 69 Variable TRT02A Type Character Length 20 Format . Label Actual Treatment for Period 02

Variable Number 70 Variable TRT02AN Type Numeric Length 8 Format . Label Actual Treatment for Period 02 (N)

Variable Number 71 Variable TR02PG1 Type Character Length 13 Format . Label Planned Pooled Treatment 1 for Period 02

Variable Number 72 Variable TR02PG1N Type Numeric Length 8 Format . Label Planned Pooled Trt 1 for Period 02 (N)

Variable Number 73 Variable TR02AG1 Type Character Length 13 Format . Label Actual Pooled Treatment 1 for Period 02

Variable Number 74 Variable TR02AG1N Type Numeric Length 8 Format . Label Actual Pooled Trt 1 for Period 02 (N)

Variable Number 75 Variable SFREAS Type Character Length 35 Format . Label Reason for Screen Failure

Variable Number 76 Variable SFIECAT Type Character Length 9 Format . Label Screen Failure Criterion Type

Variable Number 77 Variable SFIECD Type Character Length 2 Format . Label Screen Failure Criterion Number

Variable Number 78 Variable DSREAS Type Character Length 17 Format . Label Reported Term for the Disposition Event

Variable Number 79 Variable DSREASN Type Numeric Length 8 Format . Label Reported Term for Disposition Event (N)

Variable Number 80 Variable ALGSDTF Type Character Length 1 Format . Label Date of Diagnosis of ALGS Input. Flag

Variable Number 81 Variable ALGSDN Type Numeric Length 8 Format . Label Time Since Diagnosis of ALGS (Months)

Variable Number 82 Variable ALGSHX Type Character Length 1 Format . Label Family History of ALGS

Variable Number 83 Variable PAUCITY Type Character Length 1 Format . Label Presence of Paucity

Variable Number 84 Variable MUTATION Type Character Length 7 Format . Label Mutation Present

Variable Number 85 Variable CHOLEST Type Character Length 1 Format . Label Chronic Cholestasis

Variable Number 86 Variable CARDIAC Type Character Length 1 Format . Label Cardiac Disease

Variable Number 87 Variable RENAL Type Character Length 1 Format . Label Renal Abnormalities

Variable Number 88 Variable VASCULAR Type Character Length 1 Format . Label Vascular Abnormalities

Variable Number 89 Variable SKELETAL Type Character Length 1 Format . Label Skeletal Abnormalities

Variable Number 90 Variable OCULAR Type Character Length 1 Format . Label Ocular Abnormalities

Variable Number 91 Variable FACIAL Type Character Length 1 Format . Label Characteristic Facial Features

Variable Number 92 Variable ALGSCRT Type Numeric Length 8 Format . Label No. Clinical Criteria/Features of ALGS

Variable Number 93 Variable ALGSCAT Type Character Length 6 Format . Label Critical Criteria of ALGS Category

Variable Number 94 Variable ALGSCATN Type Numeric Length 8 Format . Label Critical Criteria of ALGS Category (N)

Variable Number 95 Variable ITCHTRT Type Character Length 1 Format . Label Used Anything to Treat Itch in the Past

Variable Number 96 Variable TCORTICO Type Character Length 1 Format . Label Topical Corticosteroids

Variable Number 97 Variable TCALCIN Type Character Length 1 Format . Label Topical Calcineurin Inhibitors

Variable Number 98 Variable TANTIHS Type Character Length 1 Format . Label Topical Antihistamines

Variable Number 99 Variable TMENTHOL Type Character Length 1 Format . Label Topical Menthol

Variable Number 100 Variable TCAPSAIS Type Character Length 1 Format . Label Topical Capsaicin

Variable Number 101 Variable TSALICYL Type Character Length 1 Format . Label Topical Salicylic Acid

Variable Number 102 Variable TLOCAL Type Character Length 1 Format . Label Topical Local Anesthetics

Variable Number 103 Variable OANDROG Type Character Length 1 Format . Label Oral Androgens

Variable Number 104 Variable OANTICHO Type Character Length 1 Format . Label Oral Anticholestatic Agents

Variable Number 105 Variable OANTICON Type Character Length 1 Format . Label Oral Anticonvulsants

Variable Number 106 Variable OANTIDEP Type Character Length 1 Format . Label Oral Antidepressants

Variable Number 107 Variable OANTIHIIS Type Character Length 1 Format . Label Oral Antihistamines

Variable Number 108 Variable OANTIOX Type Character Length 1 Format . Label Oral Anti-Oxidants

Variable Number 109 Variable OBINDING Type Character Length 1 Format . Label Oral Binding Resins

Variable Number 110 Variable OCOLCHIC Type Character Length 1 Format . Label Oral Colchicine

Variable Number 111 Variable OCANNABI Type Character Length 1 Format . Label Oral Cannabinoid Agonist

Variable Number 112 Variable OENZYMEI Type Character Length 1 Format . Label Oral Enzyme Inducers

Variable Number 113 Variable OIMMUNO Type Character Length 1 Format . Label Oral Immunosuppressants

Variable Number 114 Variable OOPIATE Type Character Length 1 Format . Label Oral Opiate Antagonists

Variable Number 115 Variable OSEROTON Type Character Length 1 Format . Label Oral Serotonin Antagonists

Variable Number 116 Variable OUDCA Type Character Length 1 Format . Label Oral Ursodiol (UDCA)

Variable Number 117 Variable PHOTO Type Character Length 1 Format . Label Other Phototherapy

Variable Number 118 Variable HEMOFILT Type Character Length 1 Format . Label Other Hemofiltration (MARS)

Variable Number 119 Variable PLASMAPH Type Character Length 1 Format . Label Other Plasmapheresis

Variable Number 120 Variable NASALBIL Type Character Length 1 Format . Label Other Nasal Biliary Drainage

Variable Number 121 Variable SPECIFY Type Character Length 51 Format . Label Other Specify

Variable Number 122 Variable PRURTHER Type Numeric Length 8 Format . Label No. Prior Pruritus Therapies Per Patient

Variable Number 123 Variable PRURCAT Type Character Length 20 Format . Label Prior Pruritus Therapy Category

Variable Number 124 Variable PRURCATN Type Numeric Length 8 Format . Label Prior Pruritus Therapy Category (N)

Variable Number 125 Variable SSCORBL Type Character Length 1 Format . Label Clinician Scratch Scale Score

Variable Number 126 Variable SSCORBLN Type Numeric Length 8 Format . Label Clinician Scratch Scale Score (N)

Variable Number 127 Variable CLXANBL Type Character Length 1 Format . Label Clinician Xanthoma Scale Score

Variable Number 128 Variable CLXANBLN Type Numeric Length 8 Format . Label Clinician Xanthoma Scale Score (N)

Variable Number 129 Variable ITCHOBBL Type Numeric Length 8 Format . Label ItchRO(Obs) Avg. Daily Score at Baseline

Variable Number 130 Variable ITCHPTBL Type Numeric Length 8 Format . Label ItchRO(Pt) Avg. Daily Score at Baseline

Variable Number 131 Variable BILEBL Type Numeric Length 8 Format . Label Serum Bile Acid (umol/L) at Baseline

Variable Number 132 Variable ALPBL Type Numeric Length 8 Format . Label Alkaline Phosphatase (U/L) at Baseline

Variable Number 133 Variable ASTBL Type Numeric Length 8 Format . Label Aspartate Aminotransferase (U/L) at BL

Variable Number 134 Variable ALTBL Type Numeric Length 8 Format . Label Alanine Aminotransferase (U/L) at BL

Variable Number 135 Variable GGTBL Type Numeric Length 8 Format . Label Gamma Glutamyl Transferase (U/L) at BL

Variable Number 136 Variable BILIBL Type Numeric Length 8 Format . Label Total Bilirubin (mg/dL) at Baseline

Variable Number 137 Variable BILDIRBL Type Numeric Length 8 Format . Label Direct Bilirubin (mg/dL) at Baseline

Variable Number 138 Variable TCHOLBL Type Numeric Length 8 Format . Label Cholesterol (mg/dL) at Baseline

Variable Number 139 Variable LDLCHBL Type Numeric Length 8 Format . Label LDL Cholesterol (mg/dL) at Baseline

Variable Number 140 Variable HYDRXBL Type Numeric Length 8 Format . Label 7 a-hydroxy-4-cholesten-3-one (ng/mL) BL

Variable Number 141 Variable VITDBL Type Numeric Length 8 Format . Label 25-Hydroxyvitamin D (ng/mL) at Baseline

Variable Number 142 Variable VITABL Type Numeric Length 8 Format . Label Vitamin A (ug/dL) at Baseline

Variable Number 143 Variable VITEBL Type Numeric Length 8 Format . Label Alpha Tocopherol (mg/dL) at Baseline

Variable Number 144 Variable INRBL Type Numeric Length 8 Format . Label Prothrombin Intl. Normalized Ratio at BL

Variable Number 145 Variable SDSTDISP Type Numeric Length 8 Format . Label Study Day of Disposition Event from Informed Consent Date

Variable Number 146 Variable SDENDPT Type Numeric Length 8 Format . Label Study Day of End of Participation from Informed Consent Date

Variable Number 147 Variable SEALGDIAG Type Numeric Length 8 Format . Label Study Day of Diagnosis of ALGS from Informed Consent Date

Variable Number 148 Variable SDRXST Type Numeric Length 8 Format . Label Study Day of RX First Exposure from Informed Consent Date

Variable Number 149 Variable SDRXEN Type Numeric Length 8 Format . Label Study Day of RX Last Exposure from Informed Consent Date

### Data Set Name: [adv.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 AGEU Type Character Length 5 Format . Label Age Units

Variable Number 6 Variable AGEGR1 Type Character Length 14 Format . Label Pooled Age Group 1

Variable Number 7 Variable AGEGR1N Type Numeric Length 8 Format . Label Pooled Age Group 1 (N)

Variable Number 8 Variable SEX Type Character Length 1 Format . Label Sex

Variable Number 9 Variable SEXN Type Numeric Length 8 Format . Label Sex (N)

Variable Number 10 Variable WEIGHTBL Type Numeric Length 8 Format . Label Weight at Baseline (kg)

Variable Number 11 Variable HEIGHTBL Type Numeric Length 8 Format . Label Height at Baseline (cm)

Variable Number 12 Variable BMIBL Type Numeric Length 8 Format . Label BMI at Baseline (kg/m<sup>2</sup>)

Variable Number 13 Variable RACE Type Character Length 25 Format . Label Race

Variable Number 14 Variable RACEN Type Numeric Length 8 Format . Label Race (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 RANDFL Type Character Length 1 Format . Label Randomized Population Flag

Variable Number 23 Variable RANDFN Type Numeric Length 8 Format . Label Randomized 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 ITTFL Type Character Length 1 Format . Label Intent-To-Treat Population Flag

Variable Number 27 Variable ITTFN Type Numeric Length 8 Format . Label Intent-To-Treat Population Flag (N)

Variable Number 28 Variable MITTFL Type Character Length 1 Format . Label Modified ITT Population Flag

Variable Number 29 Variable MITTFN Type Numeric Length 8 Format . Label Modified ITT Population Flag (N)

Variable Number 30 Variable PPROTFL Type Character Length 1 Format . Label Per-Protocol Population Flag

Variable Number 31 Variable PPROTFN Type Numeric Length 8 Format . Label Per-Protocol Population Flag (N)

Variable Number 32 Variable STABLEFL Type Character Length 1 Format . Label Dosed at Stable Dosing Period Flag

Variable Number 33 Variable STABLEFN Type Numeric Length 8 Format . Label Dosed at Stable Dosing Period Flag (N)

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

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

Variable Number 36 Variable EXTENFL Type Character Length 1 Format . Label Entered into LUM001-305 Extension Study

Variable Number 37 Variable EXTENFN Type Numeric Length 8 Format . Label Entered into LUM001-305 Extension (N)

Variable Number 38 Variable LOWDOSFL Type Character Length 1 Format . Label Recd. Lower Dose Due to Tolerability

Variable Number 39 Variable LOWDOSFN Type Numeric Length 8 Format . Label Recd. Lower Dose Due to Tolerability (N)

Variable Number 40 Variable HIDOSEFL Type Character Length 1 Format . Label Two Highest Tolerated Doses Flag

Variable Number 41 Variable HIDOSEFN Type Numeric Length 8 Format . Label Two Highest Tolerated Doses Flag (N)

Variable Number 42 Variable DOSINTFL Type Character Length 1 Format . Label Drug Interrupted for >14 Days Flag

Variable Number 43 Variable DOSINTFN Type Numeric Length 8 Format . Label Drug Interrupted for >14 Days Flag (N)

Variable Number 44 Variable ARM Type Character Length 20 Format . Label Description of Planned Arm

Variable Number 45 Variable ARMCD Type Character Length 1 Format . Label Description Code of Planned Arm

Variable Number 46 Variable ACTARM Type Character Length 20 Format . Label Description of Actual Arm

Variable Number 47 Variable ACTARMCD Type Character Length 1 Format . Label Description Code of Actual Arm

Variable Number 48 Variable TRT01P Type Character Length 20 Format . Label Planned Treatment for Period 01

Variable Number 49 Variable TRT01PN Type Numeric Length 8 Format . Label Planned Treatment for Period 01 (N)

Variable Number 50 Variable TRT01A Type Character Length 20 Format . Label Actual Treatment for Period 01

Variable Number 51 Variable TRT01AN Type Numeric Length 8 Format . Label Actual Treatment for Period 01 (N)

Variable Number 52 Variable TR01PG1 Type Character Length 13 Format . Label Planned Pooled Treatment 1 for Period 01

Variable Number 53 Variable TR01PG1N Type Numeric Length 8 Format . Label Planned Pooled Trt 1 for Period 01 (N)

Variable Number 54 Variable TR01PG2 Type Character Length 32 Format . Label Planned Pooled Treatment 1 for Period 02

Variable Number 55 Variable TR01PG2N Type Numeric Length 8 Format . Label Planned Pooled Trt 1 for Period 02 (N)

Variable Number 56 Variable TR01AG1 Type Character Length 13 Format . Label Actual Pooled Treatment 1 for Period 01

Variable Number 57 Variable TR01AG1N Type Numeric Length 8 Format . Label Actual Pooled Trt 1 for Period 01 (N)

Variable Number 58 Variable TRT02P Type Character Length 20 Format . Label Planned Treatment for Period 02

Variable Number 59 Variable TRT02PN Type Numeric Length 8 Format . Label Planned Treatment for Period 02 (N)

Variable Number 60 Variable TRT02A Type Character Length 20 Format . Label Actual Treatment for Period 02

Variable Number 61 Variable TRT02AN Type Numeric Length 8 Format . Label Actual Treatment for Period 02 (N)

Variable Number 62 Variable TR02PG1 Type Character Length 13 Format . Label Planned Pooled Treatment 1 for Period 02

Variable Number 63 Variable TR02PG1N Type Numeric Length 8 Format . Label Planned Pooled Trt 1 for Period 02 (N)

Variable Number 64 Variable TR02AG1 Type Character Length 13 Format . Label Actual Pooled Treatment 1 for Period 02

Variable Number 65 Variable TR02AG1N Type Numeric Length 8 Format . Label Actual Pooled Trt 1 for Period 02 (N)

Variable Number 66 Variable TRTP Type Character Length 20 Format . Label Planned Treatment

Variable Number 67 Variable TRTPN Type Numeric Length 8 Format . Label Planned Treatment (N)

Variable Number 68 Variable TRTA Type Character Length 20 Format . Label Actual Treatment

Variable Number 69 Variable TRTAN Type Numeric Length 8 Format . Label Actual Treatment (N)

Variable Number 70 Variable TRTPG1 Type Character Length 13 Format . Label Planned Pooled Treatment 1

Variable Number 71 Variable TRTPG1N Type Numeric Length 8 Format . Label Planned Pooled Treatment 1 (N)

Variable Number 72 Variable TRTPG2 Type Character Length 32 Format . Label Planned Pooled Treatment 2

Variable Number 73 Variable TRTPG2N Type Numeric Length 8 Format . Label Planned Pooled Treatment 2 (N)

Variable Number 74 Variable TRTAG1 Type Character Length 13 Format . Label Actual Pooled Treatment 1

Variable Number 75 Variable TRTAG1N Type Numeric Length 8 Format . Label Actual Pooled Treatment 1 (N)

Variable Number 76 Variable VSSEQ Type Numeric Length 8 Format . Label Sequence Number

Variable Number 77 Variable VISIT Type Character Length 10 Format . Label Visit Name

Variable Number 78 Variable VISITNUM Type Numeric Length 8 Format . Label Visit Number

Variable Number 79 Variable VSDY Type Numeric Length 8 Format . Label Study Day of Vital Signs (from first treatment date)

Variable Number 80 Variable AVISITN Type Numeric Length 8 Format . Label Analysis Visit (N)

Variable Number 81 Variable AVISIT Type Character Length 21 Format . Label Analysis Visit

Variable Number 82 Variable DTYPE Type Character Length 8 Format . Label Derivation Type

Variable Number 83 Variable ADY Type Numeric Length 8 Format . Label Analysis Relative Day (from first treatment date)

Variable Number 84 Variable PARAM Type Character Length 31 Format . Label Parameter

Variable Number 85 Variable PARAMCD Type Character Length 7 Format . Label Parameter Code

Variable Number 86 Variable PARAMN Type Numeric Length 8 Format . Label Parameter (N)

Variable Number 87 Variable PARAMTYP Type Character Length 7 Format . Label Parameter Type

Variable Number 88 Variable AVAL Type Numeric Length 8 Format . Label Analysis Value

Variable Number 89 Variable ANRLO Type Numeric Length 8 Format . Label Analysis Normal Range Lower Limit

Variable Number 90 Variable ANRHI Type Numeric Length 8 Format . Label Analysis Normal Range Upper Limit

Variable Number 91 Variable ANRIND Type Character Length 6 Format . Label Analysis Reference Range Indicator

Variable Number 92 Variable BASE Type Numeric Length 8 Format . Label Baseline Value

Variable Number 93 Variable BNRIND Type Character Length 6 Format . Label Baseline Reference Range Indicator

Variable Number 94 Variable CHG Type Numeric Length 8 Format . Label Change from Baseline

Variable Number 95 Variable ABLFL Type Character Length 1 Format . Label Baseline Record Flag

Variable Number 96 Variable ABLFN Type Numeric Length 8 Format . Label Baseline Record Flag (N)

Variable Number 97 Variable VSSTAT Type Character Length 1 Format . Label Completion Status

## 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 69 Format . Label Reported Term for the Adverse Event

Variable Number 8 Variable AELLT Type Character Length 36 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 40 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 59 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 52 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 52 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 31 Format . Label Other Action Taken

Variable Number 23 Variable AEREL Type Character Length 25 Format . Label Causality

Variable Number 24 Variable AEOUT Type Character Length 26 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 AESTDY Type Numeric Length 8 Format . Label Study Day of Start of Adverse Event (from first treatment date)

Variable Number 31 Variable AEENDY Type Numeric Length 8 Format . Label Study Day of End of Adverse Event (from first treatment date)

Variable Number 32 Variable AEENRF Type Character Length 7 Format . Label End Relative to Reference Period

### Data Set Name: ce.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 CESEQ Type Numeric Length 8 Format . Label Sequence Number

Variable Number 5 Variable CETERM Type Character Length 17 Format . Label Reported Term for the Clinical Event

Variable Number 6 Variable CEDECOD Type Character Length 17 Format . Label Dictionary-Derived Term

Variable Number 7 Variable CEDY Type Numeric Length 8 Format . Label Study Day of Event Collection (from first treatment date)

### 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 104 Format . Label Reported Name of Drug, Med, or Therapy

Variable Number 7 Variable CMDECOD Type Character Length 193 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 89 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 11 Format . Label Dose Units

Variable Number 15 Variable CMDOSFRQ Type Character Length 16 Format . Label Dosing Frequency per Interval

Variable Number 16 Variable CMROUTE Type Character Length 24 Format . Label Route of Administration

Variable Number 17 Variable CMSTDY Type Numeric Length 8 Format . Label Study Day of Start of Medication (from first treatment date)

Variable Number 18 Variable CMENDY Type Numeric Length 8 Format . Label Study Day of End of Medication (from first treatment date)

Variable Number 19 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 3 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 200 Format . Label Comment 1

Variable Number 11 Variable COVAL2 Type Character Length 21 Format . Label Comment 2

Variable Number 12 Variable CODY Type Numeric Length 8 Format . Label Study Day of Comment (from first treatment date)

### 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 8 Format . Label Planned Arm Code

Variable Number 11 Variable ARM Type Character Length 20 Format . Label Description of Planned Arm

Variable Number 12 Variable ACTARMCD Type Character Length 8 Format . Label Actual Arm Code

Variable Number 13 Variable ACTARM Type Character Length 20 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 Informed Consent

Variable Number 16 Variable SDmedsp Type Numeric Length 8 Format . Label Med Stop Study Day from Informed Consent

Variable Number 17 Variable SDlastp Type Numeric Length 8 Format . Label Study Day of last participation from Informed 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 49 Format . Label Reported Term for the Disposition Event

Variable Number 6 Variable DSDECOD Type Character Length 25 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 9 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 42 Format . Label Protocol Deviation Coded Term

Variable Number 7 Variable DVCAT Type Character Length 21 Format . Label Category for Protocol Deviation

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

Variable Number 9 Variable DVSTDY Type Numeric Length 8 Format . Label Study Day of Start of Deviation (from first treatment date)

## Data Set Name: eg.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 EGSEQ Type Numeric Length 8 Format . Label Sequence Number

Variable Number 5 Variable EGTESTCD Type Character Length 4 Format . Label ECG Test or Examination Short Name

Variable Number 6 Variable EGTEST Type Character Length 14 Format . Label ECG Test or Examination Name

Variable Number 7 Variable EGORRES Type Character Length 8 Format . Label Result or Finding in Original Units

Variable Number 8 Variable EGSTRESC Type Character Length 8 Format . Label Character Result/Finding in Std Format

Variable Number 9 Variable EGSTAT Type Character Length 8 Format . Label Completion Status

Variable Number 10 Variable EGBLFL Type Character Length 1 Format . Label Baseline Flag

Variable Number 11 Variable EGEVAL Type Character Length 12 Format . Label Evaluator

Variable Number 12 Variable VISITNUM Type Numeric Length 8 Format . Label Visit Number

Variable Number 13 Variable VISIT Type Character Length 10 Format . Label Visit Name

Variable Number 14 Variable EGDY Type Numeric Length 8 Format . Label Study Day of ECG (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 7 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 EXROUTE Type Character Length 4 Format . Label Route of Administration

Variable Number 10 Variable EXSTDY Type Numeric Length 8 Format . Label Study Day of Start of Treatment (from first treatment date)

Variable Number 11 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 38 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 FASCAT Type Character Length 28 Format . Label Subcategory for Findings About

Variable Number 12 Variable FAORRES Type Character Length 11 Format . Label Result or Finding in Original Units

Variable Number 13 Variable FASTRESC Type Character Length 11 Format . Label Character Result/Finding in Std Format

Variable Number 14 Variable VISITNUM Type Numeric Length 8 Format . Label Visit Number

Variable Number 15 Variable VISIT Type Character Length 17 Format . Label Visit Name

Variable Number 16 Variable FADY Type Numeric Length 8 Format . Label Study Day of Collection (from first treatment date)

### 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 9 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 LBFASST 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 11 Format . Label Visit Name

Variable Number 29 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 78 Format . Label Reported Term for the Medical History

Variable Number 7 Variable MHLLT Type Character Length 41 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 46 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 67 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 63 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 MHBODSYS Type Character Length 67 Format . Label Body System or Organ Class

Variable Number 16 Variable MHBDSYCD Type Numeric Length 8 Format . Label Body System or Organ Class Code

Variable Number 17 Variable MHSOC Type Character Length 67 Format . Label Primary System Organ Class

Variable Number 18 Variable MHSOCCD Type Numeric Length 8 Format . Label Primary System Organ Class Code

Variable Number 19 Variable MHSTDY Type Numeric Length 8 Format . Label Study Day of Start of Observation (from first treatment date)

Variable Number 20 Variable MHENDY Type Numeric Length 8 Format . Label Study Day of End of Observation (from first treatment date)

Variable Number 21 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 8 Format . Label Reference ID

Variable Number 6 Variable PCTESTCD Type Character Length 6 Format . Label Pharmacokinetic Test Short Name

Variable Number 7 Variable PCTEST Type Character Length 6 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 1 Format . Label Completion Status

Variable Number 15 Variable PCREASND Type Character Length 1 Format . Label Reason Test Not Done

Variable Number 16 Variable PCNAM Type Character Length 6 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 7 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 10 Format . Label Visit Name

Variable Number 24 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 8 Format . Label Body System Examined Short Name

Variable Number 6 Variable PETEST Type Character Length 30 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 180 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 10 Format . Label Visit Name

Variable Number 14 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 17 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 10 Format . Label Visit Name

Variable Number 19 Variable QSDY Type Numeric Length 8 Format . Label Study Day of Finding (from first treatment date)

## Data Set Name: qs\_raw\_data\_itchro.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 17 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 10 Format . Label Visit Name

Variable Number 19 Variable QSDY Type Numeric Length 8 Format . Label Study Day of Finding

### Data Set Name: [relrec.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 12 Format . Label Identifying Variable Value

Variable Number 6 Variable RELTYPE Type Character Length 1 Format . Label Relationship Type

Variable Number 7 Variable RELID Type Character Length 3 Format . Label Relationship Identifier

## 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 4 Format . Label Element Code

Variable Number 6 Variable ELEMENT Type Character Length 36 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 9 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: 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 17 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 SVSTDY Type Numeric Length 8 Format . Label Study Day of Start of Visit (from first treatment date)

Variable Number 8 Variable SVENDY Type Numeric Length 8 Format . Label Study Day of End of Visit (from first treatment date)

## Data Set Name: ta.sas7bdat

Variable Number 1 Variable STUDYID Type Character Length 10 Format . Label Study Identifier

Variable Number 2 Variable DOMAIN Type Character Length 2 Format . Label Domain Abbreviation

Variable Number 3 Variable ARMCD Type Character Length 1 Format . Label Planned Arm Code

Variable Number 4 Variable ARM Type Character Length 20 Format . Label Description of Planned Arm

Variable Number 5 Variable TAETORD Type Numeric Length 8 Format . Label Planned Order of Element within Arm

Variable Number 6 Variable ETCD Type Character Length 4 Format . Label Element Code

Variable Number 7 Variable ELEMENT Type Character Length 36 Format . Label Description of Element

Variable Number 8 Variable TABRANCH Type Character Length 34 Format . Label Branch

Variable Number 9 Variable TATRANS Type Character Length 1 Format . Label Transition Rule

Variable Number 10 Variable EPOCH Type Character Length 9 Format . Label Epoch

### Data Set Name: tv.sas7bdat

Variable Number 1 Variable STUDYID Type Character Length 10 Format . Label Study Identifier

Variable Number 2 Variable DOMAIN Type Character Length 2 Format . Label Domain Abbreviation

Variable Number 3 Variable VISITNUM Type Numeric Length 8 Format . Label Visit Number

Variable Number 4 Variable VISIT Type Character Length 17 Format . Label Visit Name

Variable Number 5 Variable VISITDY Type Numeric Length 8 Format . Label Planned Study Day of Visit

Variable Number 6 Variable ARMCD Type Character Length 1 Format . Label Planned Arm Code

Variable Number 7 Variable ARM Type Character Length 1 Format . Label Description of Planned Arm

Variable Number 8 Variable TVSTRL Type Character Length 39 Format . Label Visit Start Rule

Variable Number 9 Variable TVENRL Type Character Length 58 Format . Label Visit End Rule

### 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 VSORNRLO Type Character Length 3 Format . Label Normal Range Lower Limit-Original Units

Variable Number 10 Variable VSORNRHI 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 10 Format . Label Visit Name

Variable Number 21 Variable VSDY Type Numeric Length 8 Format . Label Study Day of Vital Signs (from first treatment date)