Analysis Results Metadata (Summary) for Study CDISCPILOT01
Table_14-1.01Summary of Populations
Table_14-1.02Summary of End of Study Data (ITT population)
Table_14-2.01Summary of Demographic and Baseline Characteristics (ITT population) treatment group comparison for continuous variables treatment group comparison for categorical variables
Table_14-3.01Primary Endpoint Analysis: ADAS-Cog - Summary at Week 24 - LOCF (Efficacy Population) dose response analysis for ADAS-Cog changes from baseline pairwise comparisons to placebo for ADAS-Cog changes from baseline
Table_14-3.02Primary Endpoint Analysis: CIBIC+ - Summary at Week 24 - LOCF (Efficacy Population) dose response analysis for CIBIC+ values pairwise comparisons to placebo for CIBIC+ values
Table_14-3.12Mean NPI-X total score from Weeks 4 through Week 24 - Windowed (Efficacy Population) Descriptive statistics (n, mean, standard deviation, median, min, and max) p-values, difference of LS means , their standard error and 95% confidence intervals
Table_14-5.02Incidence of Treatment Emergent Serious Adverse Events by Treatment Group
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Table_14-6.04Shifts of Laboratory Values During Treatment, Categorized Based on Threshold Ranges, by Visit (Safety Population) Frequency counts of change in threshold ranges by visit and treatment
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Table_14-6.06Shifts of Hy's Law Values During Treatment (Safety Population) Frequency counts of change in Hy's Law abnormalities by treatment including comparison of treatment with Fisher's Exact test
Figure_14-1Time to Dermatologic Event by Treatment Group treatment group comparison for time to event variables

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Analysis Results Metadata (Detail) for Study CDISCPILOT01

Table_14-1.01

Display	Table 14-1.01 Summary of Populations
AnalysisResult	
Analysis Parameter(s)	
Analysis Variable(s)	ITTFL SAFFL EFFFL COMP24FL DISCONFL
Reason	pre-specified in SAP
Data References (incl. Selection Criteria)	ADSL
Documentation	SAP Section 9.1

Programming Statements	`proc freq data = pilot.adsl;`
	`  tables (ittfl saffl efffl comp24fl disconfl)*trt01pn / missing;`
	`run;`

Table_14-1.02

Display	Table 14-1.02 Summary of End of Study Data (ITT population)
AnalysisResult	
Analysis Parameter(s)	
Analysis Variable(s)	COMP24FL DCREASCD
Reason	pre-specified in SAP
Data References (incl. Selection Criteria)	ADSL[ITTFL="Y"]
Documentation	SAP Section 9.1Reasons for discontinuation are summarized for subjects discontinuing before Week 24 (visit 12) (i.e. COMP24FL ne ="Y" and VISNUMEN less than 12)

Programming Statements	`proc freq data=adsl;`
	`  table COMP24FL*TRT01P/chisq fisher exact;`
	`run;`
	
	`proc freq data=adsl;`
	`  where COMP24FL="N";`
	`  table DCREASCD* TRT01P/ chisq fisher exact;`
	`run;`

Table_14-2.01

Display	Table 14-2.01 Summary of Demographic and Baseline Characteristics (ITT population)
AnalysisResult	**treatment group comparison for continuous variables**
Analysis Parameter(s)	
Analysis Variable(s)	AGE MMSETOT DURDIS EDUCLVL WEIGHTBL HEIGHTBL BMIBL
Reason	pre-specified in protocol
Data References (incl. Selection Criteria)	ADSL[ITTFL="Y"]
Documentation	ANOVA treatment group comparison
AnalysisResult	**treatment group comparison for categorical variables**
Analysis Parameter(s)	
Analysis Variable(s)	AGEGR1 SEX RACE DURDSGR1 BMIBLGR1
Reason	pre-specified in protocol

Data References (incl. Selection Criteria)	ADSL[ITTFL="Y"]
Documentation	Pearson s chisquare test

Table_14-3.01

Display	Table 14-3.01 Primary Endpoint Analysis: ADAS-Cog - Summary at Week 24 - LOCF (Efficacy Population)
AnalysisResult	**dose response analysis for ADAS-Cog changes from baseline**
Analysis Parameter(s)	ACTOT=Adas-Cog(11) Subscore
Analysis Variable(s)	CHG
Reason	Primary Endpoint Analysis; pre-specified in SAP
Data References (incl. Selection Criteria)	ADQSADAS[EFFFL="Y" and ANL01FL="Y" and AVISIT="Week 24" and PARAMCD="ATOT"]
Documentation	SAP Section 10.1.1Linear model analysis of CHG for dose response; using randomized dose (0 for placebo; 54 for low dose; 81 for high dose) and site group in model. Used PROC GLM in SAS to produce p-value (from Type III SS for treatment dose).

Programming Statements	`proc glm data = ADQSADAS;`
	`  where EFFFL='Y' and ANL01FL='Y' and AVISIT='Week 24' and PARAMCD="ATOT";`
	`  class sitegr1;`
	`  model CHG = trtpn sitegr1;`
	`run;`

AnalysisResult	**pairwise comparisons to placebo for ADAS-Cog changes from baseline**
Analysis Parameter(s)	ACTOT=Adas-Cog(11) Subscore
Analysis Variable(s)	CHG
Reason	Primary Endpoint Analysis; pre-specified in SAP
Data References (incl. Selection Criteria)	ADQSADAS[EFFFL="Y" and ANL01FL="Y" and AVISIT="Week 24" and PARAMCD="ATOT"]
Documentation	SAP Section 10.1.1ANCOVA analysis of CHG performed to provide pairwise comparisons among treatment groups and adjusted means; using randomized treatment as class variable and site group as class variable in

	model and the baseline value as a covariate.

Programming Statements	`proc glm data = ADQSADAS;`
	`  where EFFFL='Y' and ANL01FL='Y' and AVISIT='Week 24' and PARAMCD="ATOT";`
	`  class trtpn sitegr1;`
	`  model CHG = trtpn sitegr1 base;`
	`  means trtpn;`
	`  lsmeans trtpn / OM STDERR PDIFF CL;`
	`run;`

Table_14-3.02

Display	Table 14-3.02 Primary Endpoint Analysis: CIBIC+ - Summary at Week 24 - LOCF (Efficacy Population)
AnalysisResult	**dose response analysis for CIBIC+ values**
Analysis Parameter(s)	CIBICVAL=CIBIC Score
Analysis Variable(s)	AVAL
Reason	Primary Endpoint Analysis; pre-specified in SAP
Data References (incl. Selection Criteria)	ADQSCIBC[EFFFL="Y" and ANL01FL="Y" and AVISIT="Week 24" and PARAMCD="CIBICVAL"]
Documentation	SAP Section 10.1.1Summary statistics of AVAL at Week 24. Linear model analysis of AVAL for dose response; using randomized dose (0 for placebo; 54 for low dose; 81 for high dose) and site group in model. Used PROC GLM in SAS to produce p-value (from Type III SS for treatment dose);

Programming Statements	`proc glm data = ADQSCIBC;`
	`  where EFFFL='Y' and ANL01FL='Y' and AVISIT='Week 24' and PARAMCD="CIBICVAL";`
	`  class sitegr1;`
	`  model AVAL = trtpn sitegr1;`
	`run;`

AnalysisResult	**pairwise comparisons to placebo for CIBIC+ values**
Analysis Parameter(s)	CIBICVAL=CIBIC Score
Analysis Variable(s)	AVAL
Reason	Primary Endpoint Analysis; pre-specified in SAP
Data References (incl. Selection Criteria)	ADQSCIBC[EFFFL="Y" and ANL01FL="Y" and AVISIT="Week 24" and PARAMCD="CIBICVAL"]
Documentation	SAP Section 10.1.1ANCOVA analysis of AVAL performed to provide pairwise comparisons among treatment groups and adjusted means; using randomized treatment as class variable and site group as class variable in

	model and the baseline value as a covariate.

Programming Statements	`proc glm data = ADQSCIBC;`
	`  where EFFFL='Y' and ANL01FL='Y' and AVISIT='Week 24' and PARAMCD="CIBICVAL";`
	`  class trtpn sitegr1;`
	`  model AVAL = trtpn sitegr1;`
	`  means trtpn;`
	`  lsmeans trtpn / OM STDERR PDIFF CL;`
	`run;`

Table_14-3.12

Display	Table 14-3.12 Mean NPI-X total score from Weeks 4 through Week 24 - Windowed (Efficacy Population)
AnalysisResult	**Descriptive statistics (n, mean, standard deviation, median, min, and max)**
Analysis Parameter(s)	NPTOTMN=Mean NPI-X (9) Total (Week 4 to 24)
Analysis Variable(s)	AVAL BASE
Reason	pre-specified in SAP
Data References (incl. Selection Criteria)	ADQSNPIX[EFFFL="Y" and PARAMCD="NPTOTMN" and AVISIT="Weeks 4-24" and ANL01FL="Y"]
Documentation	SAP Section 10.2

Programming Statements	`PROC UNIVARIATE data= ADQSNPIX (where =(EFFFL = 'Y' and PARAMCD = 'NPTOTMN' and AVISIT='Weeks 4-24' and ANL01FL= 'Y'));`
	` Var BASE AVAL;`
	` By TRTPN;`
	`Run;`

AnalysisResult	**p-values, difference of LS means , their standard error and 95% confidence intervals**
Analysis Parameter(s)	NPTOTMN=Mean NPI-X (9) Total (Week 4 to 24)
Analysis Variable(s)	AVAL
Reason	pre-specified in SAP
Data References (incl. Selection Criteria)	ADQSNPIX[EFFFL="Y" and PARAMCD="NPTOTMN" and AVISIT="Weeks 4-24" and ANL01FL="Y"]
Documentation	SAP Section 10.2
Programming	`PROC MIXED data= ADQSNPIX (where =(EFFFL = 'Y' and PARAMCD = 'NPTOTMN' and AVISIT = 'Weeks 4-`

Statements	24' and ANL01FL= 'Y'));
	  class sitegr1 trtpn;
	  model aval = trtpn sitegr1 base;
	  lsmeans trtpn / diff pdiff cl;
	Run;

Table_14-5.02

Display	Table 14-5.02 Incidence of Treatment Emergent Serious Adverse Events by Treatment Group
AnalysisResult	
Analysis Parameter(s)	
Analysis Variable(s)	TRTA AEBODSYS AEDECOD
Reason	pre-specified in SAP
Data References (incl. Selection Criteria)	ADAE[TRTEMFL="Y" and AESER="Y"] ADSL[SAFFL="Y"]
Documentation	SAP Section 11.2Unique count of subjects that experienced an Adverse Event by Preferred Term, System Organ Class, and Treatment Group and percentages based on the number of subjects in the safety population within each treatment group. The total number of times an event occurred was recorded by Preferred Term, System Organ Class, and Treatment Group. Fisher's exact test was used for treatment comparison.
Programming Statements	at14-5-02.sas

Table_14-6.01

Display	Table 14-6.01 Summary Statistics for Continuous Laboratory Values (Safety Population)
AnalysisResult	**Summary statistics for each laboratory parameter (numeric results) and change from baseline, provided for each scheduled visit**
Analysis Parameter(s)	ALB=Albumin (g/L) ALP=Alkaline Phosphatase (U/L) ALT=Alanine Aminotransferase (U/L) AST=Aspartate Aminotransferase (U/L) BILI=Bilirubin (umol/L) BUN=Blood Urea Nitrogen (mmol/L) CA=Calcium (mmol/L) CHOL=Cholesterol (mmol/L) CK=Creatine Kinase (U/L) CL=Chloride (mmol/L) CREAT=Creatinine (umol/L) GGT=Gamma Glutamyl Transferase (U/L) GLUC=Glucose (mmol/L) K=Potassium (mmol/L) PHOS=Phosphate (mmol/L) PROT=Protein (g/L) SODIUM=Sodium (mmol/L) URATE=Urate (umol/L) ANISO=Anisocytes BASO=Basophils (GI/L) EOS=Eosinophils (GI/L) HCT=Hematocrit HGB=Hemoglobin (mmol/L)

	LYM=Lymphocytes (GI/L) MACROCY=Macrocytes MCH=Ery. Mean Corpuscular Hemoglobin (fmol(Fe)) MCHC=Ery. Mean Corpuscular HGB Concentration(mmol/L) MCV=Ery. Mean Corpuscular Volume (fL) MICROCY=Microcytes MONO=Monocytes (GI/L) PLAT=Platelet (GI/L) POIKILO=Poikilocytes POLICHR=Polychromasia RBC=Erythrocytes (TI/L) WBC=Leukocytes (GI/L)
Analysis Variable(s)	AVAL CHG
Reason	pre-specified in SAP
Data References (incl. Selection Criteria)	ADLBC[PARAMCD not contains "_"] ADLBH[PARAMCD not contains "_"] ADSL[SAFFL="Y"]
Documentation	SAP Section 11.5

Table_14-6.02

Display	Table 14-6.02 Frequency of Normal and Abnormal (Beyond Normal Range) Laboratory Values During Treatment (Safety Population)
AnalysisResult	**Frequency counts of normal and abnormal lab values including treatment comparisons using Fisher's Exact tests**
Analysis Parameter(s)	ALB=Albumin (g/L) ALP=Alkaline Phosphatase (U/L) ALT=Alanine Aminotransferase (U/L) AST=Aspartate Aminotransferase (U/L) BILI=Bilirubin (umol/L) BUN=Blood Urea Nitrogen (mmol/L) CA=Calcium (mmol/L) CHOL=Cholesterol (mmol/L) CK=Creatine Kinase (U/L) CL=Chloride (mmol/L) CREAT=Creatinine (umol/L) GGT=Gamma Glutamyl Transferase (U/L) GLUC=Glucose (mmol/L) K=Potassium (mmol/L) PHOS=Phosphate (mmol/L) PROT=Protein (g/L) SODIUM=Sodium (mmol/L) URATE=Urate (umol/L) ANISO=Anisocytes BASO=Basophils (GI/L) EOS=Eosinophils (GI/L) HCT=Hematocrit

	HGB=Hemoglobin (mmol/L) LYM=Lymphocytes (GI/L) MACROCY=Macrocytes MCH=Ery. Mean Corpuscular Hemoglobin (fmol(Fe)) MCHC=Ery. Mean Corpuscular HGB Concentration(mmol/L) MCV=Ery. Mean Corpuscular Volume (fL) MICROCY=Microcytes MONO=Monocytes (GI/L) PLAT=Platelet (GI/L) POIKILO=Poikilocytes POLICHR=Polychromasia RBC=Erythrocytes (TI/L) WBC=Leukocytes (GI/L)
Analysis Variable(s)	LBNRIND
Reason	pre-specified in SAP
Data References (incl. Selection Criteria)	ADLBC[ANL01FL="Y" and PARAMCD not contains "_"] ADLBH[ANL01FL="Y" and PARAMCD not contains "_"] ADSL[SAFFL="Y"]
Documentation	SAP Section 11.5

Programming Statements	`PROC FREQ (WHERE=(SAFFL="Y" and ANL01FL ="Y" and index(PARAMCD,"_")=0));`
	`  BY PARCAT1 PARAMCD;`
	`  TABLES TRTPN*LBNRIND/ALL FISHER;`
	`run;`

Table_14-6.03

Display	Table 14-6.03 Frequency of Normal and Abnormal (Clinically Significant Change from Previous Observation) Laboratory Values During Treatment (Safety Population)
AnalysisResult	**Frequency counts of clinically significant lab values including treatment comparisons using Fisher's Exact tests**
Analysis Parameter(s)	_ALB=Albumin (g/L) change from previous visit, relative to normal range _ALP=Alkaline Phosphatase (U/L) change from previous visit, relative to normal range _ALT=Alanine Aminotransferase (U/L) change from previous visit, relative to normal range _AST=Aspartate Aminotransferase (U/L) change from previous visit, relative to normal range _BILI=Bilirubin (umol/L) change from previous visit, relative to normal range _BUN=Blood Urea Nitrogen (mmol/L) change from previous visit, relative to normal range _CA=Calcium (mmol/L) change from previous visit, relative to normal range _CHOL=Cholesterol (mmol/L) change from previous visit, relative to normal range _CK=Creatine Kinase (U/L) change from previous visit, relative to normal range _CL=Chloride (mmol/L) change from previous visit, relative to normal range _CREAT=Creatinine (umol/L) change from previous visit, relative to normal range _GGT=Gamma Glutamyl Transferase (U/L) change from previous visit, relative to normal range _GLUC=Glucose (mmol/L) change from previous visit, relative to normal range _K=Potassium (mmol/L) change from previous visit, relative to normal range _PHOS=Phosphate (mmol/L) change from previous visit, relative to normal range _PROT=Protein (g/L) change from previous visit, relative to normal range _SODIUM=Sodium (mmol/L) change from previous visit, relative to normal range _URATE=Urate (umol/L) change from previous visit, relative to normal range _ANISO=Anisocytes change from previous visit, relative to normal range _BASO=Basophils (GI/L) change from previous visit, relative to normal range _EOS=Eosinophils (GI/L) change from previous visit, relative to normal range _HCT=Hematocrit change from previous visit, relative to normal range

	_HGB=Hemoglobin (mmol/L) change from previous visit, relative to normal range _LYM=Lymphocytes (GI/L) change from previous visit, relative to normal range _MACROCY=Macrocytes change from previous visit, relative to normal range _MCH=Ery. Mean Corpuscular Hemoglobin (fmol(Fe)) change from previous visit, relative to normal range _MCHC=Ery. Mean Corpuscular HGB Concentration(mmol/L) change from previous visit, relative to normal rang _MCV=Ery. Mean Corpuscular Volume (fL) change from previous visit, relative to normal range _MICROCY=Microcytes change from previous visit, relative to normal range _MONO=Monocytes (GI/L) change from previous visit, relative to normal range _PLAT=Platelet (GI/L) change from previous visit, relative to normal range _POIKILO=Poikilocytes change from previous visit, relative to normal range _POLICHR=Polychromasia change from previous visit, relative to normal range _RBC=Erythrocytes (TI/L) change from previous visit, relative to normal range _WBC=Leukocytes (GI/L) change from previous visit, relative to normal range
Analysis Variable(s)	ANRIND
Reason	pre-specified in SAP
Data References (incl. Selection Criteria)	ADLBC[ANL01FL="Y" and PARAMCD contains "_"] ADLBH[ANL01FL="Y" and PARAMCD contains "_"] ADSL[SAFFL="Y"]
Documentation	SAP Section 11.5

Programming Statements	`PROC  FREQ(WHERE=(SAFFL="Y" and ANL01FL ="Y" and index(PARAMCD,"_")));`
	`  BY PARCAT1 PARAMCD;`
	`  TABLES TRTPN*ANRIND/ALL FISHER;`
	`RUN;`

Table_14-6.04

Display	Table 14-6.04 Shifts of Laboratory Values During Treatment, Categorized Based on Threshold Ranges, by Visit (Safety Population)
AnalysisResult	**Frequency counts of change in threshold ranges by visit and treatment**
Analysis Parameter(s)	ALB=Albumin (g/L) ALP=Alkaline Phosphatase (U/L) ALT=Alanine Aminotransferase (U/L) AST=Aspartate Aminotransferase (U/L) BILI=Bilirubin (umol/L) BUN=Blood Urea Nitrogen (mmol/L) CA=Calcium (mmol/L) CHOL=Cholesterol (mmol/L) CK=Creatine Kinase (U/L) CL=Chloride (mmol/L) CREAT=Creatinine (umol/L) GGT=Gamma Glutamyl Transferase (U/L) GLUC=Glucose (mmol/L) K=Potassium (mmol/L) PHOS=Phosphate (mmol/L) PROT=Protein (g/L) SODIUM=Sodium (mmol/L) URATE=Urate (umol/L) ANISO=Anisocytes BASO=Basophils (GI/L) EOS=Eosinophils (GI/L) HCT=Hematocrit HGB=Hemoglobin (mmol/L)

	LYM=Lymphocytes (GI/L) MACROCY=Macrocytes MCH=Ery. Mean Corpuscular Hemoglobin (fmol(Fe)) MCHC=Ery. Mean Corpuscular HGB Concentration(mmol/L) MCV=Ery. Mean Corpuscular Volume (fL) MICROCY=Microcytes MONO=Monocytes (GI/L) PLAT=Platelet (GI/L) POIKILO=Poikilocytes POLICHR=Polychromasia RBC=Erythrocytes (TI/L) WBC=Leukocytes (GI/L)
Analysis Variable(s)	ANRIND BNRIND
Reason	pre-specified in SAP
Data References (incl. Selection Criteria)	ADLBC[PARAMCD not contains "_"] ADLBH[PARAMCD not contains "_"] ADSL[SAFFL="Y"]
Documentation	SAP Section 11.5

Programming Statements	`PROC FREQ (WHERE=(SAFFL="Y" and index(PARAMCD,"_")=0));`
	`  TABLES PARCAT1*PARAMCD*AVISITN*TRTPN*BNRIND*ANRIND;`
	`RUN;`

Table_14-6.05

Display	Table 14-6.05 Shifts of Laboratory Values During Treatment, Categorized Based on Threshold Ranges (Safety Population)
AnalysisResult	**Frequency counts of change in threshold ranges by treatment including comparison of treatment with Fisher's Exact test**
Analysis Parameter(s)	ALB=Albumin (g/L) ALP=Alkaline Phosphatase (U/L) ALT=Alanine Aminotransferase (U/L) AST=Aspartate Aminotransferase (U/L) BILI=Bilirubin (umol/L) BUN=Blood Urea Nitrogen (mmol/L) CA=Calcium (mmol/L) CHOL=Cholesterol (mmol/L) CK=Creatine Kinase (U/L) CL=Chloride (mmol/L) CREAT=Creatinine (umol/L) GGT=Gamma Glutamyl Transferase (U/L) GLUC=Glucose (mmol/L) K=Potassium (mmol/L) PHOS=Phosphate (mmol/L) PROT=Protein (g/L) SODIUM=Sodium (mmol/L) URATE=Urate (umol/L) ANISO=Anisocytes BASO=Basophils (GI/L) EOS=Eosinophils (GI/L) HCT=Hematocrit

	HGB=Hemoglobin (mmol/L) LYM=Lymphocytes (GI/L) MACROCY=Macrocytes MCH=Ery. Mean Corpuscular Hemoglobin (fmol(Fe)) MCHC=Ery. Mean Corpuscular HGB Concentration(mmol/L) MCV=Ery. Mean Corpuscular Volume (fL) MICROCY=Microcytes MONO=Monocytes (GI/L) PLAT=Platelet (GI/L) POIKILO=Poikilocytes POLICHR=Polychromasia RBC=Erythrocytes (TI/L) WBC=Leukocytes (GI/L)
Analysis Variable(s)	ANRIND BNRIND
Reason	pre-specified in SAP
Data References (incl. Selection Criteria)	ADLBC[ANL01FL="Y" and PARAMCD not contains "_"] ADLBH[ANL01FL="Y" and PARAMCD not contains "_"] ADSL[SAFFL="Y"]
Documentation	SAP Section 11.5

Programming Statements	`PROC  FREQ(WHERE=(SAFFL="Y" and ANL01FL="Y" and index(PARAMCD,"_")=0)) t;`
	`  BY PARCAT1 PARAMCD;`
	` TABLES BNRIND*TRTPN*ANRIND / cmh ;`
	`RUN;`

Table_14-6.06

Display	Table 14-6.06 Shifts of Hy's Law Values During Treatment (Safety Population)
AnalysisResult	**Frequency counts of change in Hy's Law abnormalities by treatment including comparison of treatment with Fisher's Exact test**
Analysis Parameter(s)	TRANSHY=Transaminase 1.5 x ULN HYLAW=Total Bili 1.5 x ULN and Transaminase 1.5 x ULN
Analysis Variable(s)	AVAL
Reason	pre-specified in SAP
Data References (incl. Selection Criteria)	ADLBHY[PARAMCD in("TRANSHY","HYLAW")] ADSL[SAFFL="Y"]
Documentation	SAP Section 11.5Take the maximum AVAL per patient when patients were on treatment (AVISITN in (2,4,6,8,12,16,20,24,26)) for the Hy's Law parameters then perform a frequency count by treatment with Fisher's Exact test.

Figure_14-1

Display	Figure 14-1 Time to Dermatologic Event by Treatment Group
AnalysisResult	**treatment group comparison for time to event variables**
Analysis Parameter(s)	TTDE=Time to First Dermatological Event
Analysis Variable(s)	AVAL CNSR
Reason	pre-specified in SAP
Data References (incl. Selection Criteria)	ADTTE[SAFFL="Y"]
Documentation	SAP Section 11.2Kaplan-Meier estimates and log-rank analysis of time to first dermatological adverse event, safety population

Programming Statements	`proc lifetest data = adtte (where=(saffl="Y"))  plots=s;`
	` id usubjid;`
	` strata trtan;`
	` time aval*cnsr(1);`
	` test trtan;`
	`run;`

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ADaM Datasets for Study CDISCPILOT01

Dataset	Description	Class	Structure	Keys	Location	Documentation
ADSL	Subject-Level Analysis	ADSL	one record per subject	USUBJID	adsl.xpt	
ADAE	Adverse Events Analysis Dataset	ADAE	one record per subject per adverse event	USUBJID, AETERM, ASTDT, AESEQ	adae.xpt	see program ..\programs\adae.sas
ADLBC	Analysis Dataset Lab Blood Chemistry	BDS	one record per subject per parameter per analysis visit	USUBJID, PARAMCD, AVISIT, LBSEQ	adlbc.xpt	
ADLBH	Analysis Dataset Lab Hematology	BDS	one record per subject per parameter per analysis visit	USUBJID, PARAMCD, AVISIT, LBSEQ	adlbh.xpt	
ADLBHY	Analysis Dataset Lab Hy's Law	BDS	one record per subject per parameter per analysis visit	USUBJID, PARAMCD, AVISIT, LBSEQ	adlbhy.xpt	
ADQSADAS	ADAS-Cog Analysis	BDS	one record per subject per parameter per analysis visit per analysis date	USUBJID, PARAMCD, AVISIT, ADT	adqsadas.xpt	
ADQSCIBC	CIBIC+ Analysis	BDS	one record per subject per parameter per analysis visit per analysis date	USUBJID, PARAMCD, AVISIT, ADT	adqscibc.xpt	
ADQSNPIX	NPI-X Item Analysis Data	BDS	one record per subject per parameter per analysis visit per analysis date	USUBJID, PARAMCD, AVISIT, ADT	adqsnpix.xpt	

Dataset	Description	Class	Structure	Keys	Location	Documentation
ADTTE	AE Time To 1st Derm. Event Analysis	BDS	one record per subject per parameter	USUBJID, PARAMCD	adtte.xpt	
ADVS	Vital Signs Analysis Dataset	BDS	one record per subject per parameter per analysis visit per analysis timepoint	USUBJID, PARAMCD, AVISIT, ATPT	advs.xpt	

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Subject-Level Analysis (ADSL) adsl.xpt

Variable	Label	Type	Length	Display Format	Code List / Controlled Terms	Source/Derivation/Comments
STUDYID	Study Identifier	text	12			DM.STUDYID
USUBJID	Unique Subject Identifier	text	11			DM.USUBJID
SUBJID	Subject Identifier for the Study	text	4			DM.SUBJID
SITEID	Study Site Identifier	text	3			DM.SITEID

Variable	Label	Type	Length	Display Format	Code List / Controlled Terms	Source/Derivation/Comments
SITEGR1	Pooled Site Group 1	text	3			refer to SAP, Section 7.1 - if not pooled then SITEGR1=SITEID. If pooled, SITEGR1 will be 900
ARM	Description of Planned Arm	text	20		ARM	DM.ARM
TRT01P	Planned Treatment for Period 01	text	20		ARM	DM.ARM
TRT01PN	Planned Treatment for Period 01 (N)	integer	8		ARMN	Numeric code for TRT01P which corresponds to the randomized dose
TRT01A	Actual Treatment for Period 01	text	20		ARM	TRT01A=TRT01P, i.e., no difference between actual and randomized treatment in this study.
TRT01AN	Actual Treatment for Period 01 (N)	integer	8		ARMN	Numeric code for TRT01A which corresponds to the randomized dose
TRTSDT	Date of First Exposure to Treatment	integer	8	DATE9.		SV.SVSTDTC when SV.VISITNUM=3, converted to SAS date
TRTEDT	Date of Last Exposure to Treatment	integer	8	DATE9.		The date of final dose (from the CRF) is EX.EXENDTC on the subject's last EX record. If the date of final dose is missing for the subject and the subject discontinued after visit 3, use the date of discontinuation as the date of last dose. Convert the date to a SAS date.
TRTDUR	Duration of Treatment (days)	integer	8			TRTEDT-TRTSDT+1

Variable	Label	Type	Length	Display Format	Code List / Controlled Terms	Source/Derivation/Comments
AVGDD	Avg Daily Dose (as planned)	float	8			CUMDOSE/TRTDUR
CUMDOSE	Cumulative Dose (as planned)	float	8			For ARMN=0 or 1: CUMDOSE=TRT01PN*TRTDUR. --- For ARMN=2: CUMDOSE will be based on 54mg per day for the # of days subj was in 1st dosing interval (i.e., visit4date-TRTSTDT+1 if 1st interval completed, TRTEDT-TRTSTDT+1 if subj discontinued <=visit 4 and > visit 3), 81mg per day for the # of days subj was in 2nd dosing interval (i.e., visit12date-visit4date if 2nd interval completed, TRTEDT-visit4date if subj discontinued <= visit 12 and > visit 4), and 54mg per day for the # of days subj was in 3rd dosing interval (i.e., TRTEDT - visit12date if subj continued after visit 12).
AGE	Age	integer	8			DM.AGE
AGEGR1	Pooled Age Group 1	text	5		AGEGR1	Character variable derived from ADSL.AGEGR1N
AGEGR1N	Pooled Age Group 1 (N)	integer	8		AGEGR1N	AGEGR1 = 1 if AGE <65. AGEGR1 = 2 if AGE 65-80. AGEGR1 = 3 if AGE >80.
AGEU	Age Units	text	5		AGEU	DM.AGEU
RACE	Race	text	32		RACE	DM.RACE
RACEN	Race (N)	integer	8		RACEN	Numeric code for RACE

Variable	Label	Type	Length	Display Format	Code List / Controlled Terms	Source/Derivation/Comments
SEX	Sex	text	1		SEX	DM.SEX
ETHNIC	Ethnicity	text	22		ETHNIC	DM.ETHNIC
SAFFL	Safety Population Flag	text	1		YN	Y if ITTFL='Y' and TRTSDT ne missing. N otherwise
ITTFL	Intent-To-Treat Population Flag	text	1		YN	Y if ARMCD ne ' '. N otherwise
EFFFL	Efficacy Population Flag	text	1		YN	Y if SAFFL='Y AND subject has at least one record in QS for ADAS-Cog with VISITNUM>3 AND at least one record in QS for CIBIC+ with VISITNUM>3, N otherwise
COMP8FL	Completers of Week 8 Population Flag	text	1		YN	Y if subject has a SV.VISITNUM=8 and ENDDT >= date of visit 8, N otherwise
COMP16FL	Completers of Week 16 Population Flag	text	1		YN	Y if subject has a SV.VISITNUM=10 and ENDDT>=date of visit 10, N otherwise
COMP24FL	Completers of Week 24 Population Flag	text	1		YN	Y if subject has a SV.VISITNUM=12 and ENDDT>= date of visit 12 , N otherwise
DISCONFL	Did the Subject Discontinue the Study?	text	1		Y_BLANK	Y if DCREASCD ^= 'Completed'. Null otherwise
DSRAEFL	Discontinued due to AE?	text	1		Y_BLANK	Y if DCREASCD='Adverse Event'. Null otherwise
DTHFL	Subject Died?	text	1		Y_BLANK	DM.DTHFL

Variable	Label	Type	Length	Display Format	Code List / Controlled Terms	Source/Derivation/Comments
BMIBL	Baseline BMI (kg/m^2)	float	8			WEIGHTBL / ((HEIGHTBL*100)**2)
BMIBLGR1	Pooled Baseline BMI Group 1	text	6		BMICAT	BMIBLGR1=Normal if . < BMIBL <25. BMIBLGR1=Overweight if 25 <=BMIBL <30. BMIBLGR1=Obese if BMIBL >=30
HEIGHTBL	Baseline Height (cm)	float	8			VSSTRESN when VS.VSTESTCD='HEIGHT' and VS.VISITNUM=1
WEIGHTBL	Baseline Weight (kg)	float	8			VSSTRESN when VS.VSTESTCD='WEIGHT' and VS.VISITNUM=3
EDUCLVL	Years of Education	integer	8			SC.SCSTRESN where SC.SCTESTCD=YEARSEDU
DISONSDT	Date of Onset of Disease	integer	8	DATE9.		MH.MHSTDTC where MHCAT='PRIMARY DIAGNOSIS' converted to SAS date
DURDIS	Duration of Disease (Months)	float	8			number of months between VISIT1DT and DISONSET
DURDSGR1	Pooled Disease Duration Group 1	text	4		DURDISC	grouping DURDIS values as <12 and >=12
VISIT1DT	Date of Visit 1	integer	8	DATE9.		SV.SVSTDTC when SV.VISITNUM=1, converted to SAS date
RFSTDTC	Subject Reference Start Date/Time	datetime	20		ISO8601	DM.RFSTDTC

Variable	Label	Type	Length	Display Format	Code List / Controlled Terms	Source/Derivation/Comments
RFENDTC	Subject Reference End Date/Time	datetime	20		ISO8601	DM.RFENDTC
VISNUMEN	End of Trt Visit (Vis 12 or Early Term.)	integer	8			if DS.VISITNUM=13 where DSTERM='PROTCOL COMPLETED' then VISNUMEN=12, otherwise VISNUMEN=DS.VISITNUM where DSTERM='PROTCOL COMPLETED'
RFENDT	Date of Discontinuation/Completion	integer	8	DATE9.		RFENDTC converted to SAS date
DCDECOD	Standardized Disposition Term	text	27		DISCCD	DS.DSDECOD where DSCAT='DISPOSITION EVENT'
DCREASCD	Reason for Discontinuation	text	18		DISCREAS	Grouping of DCDECOD values to support summarizing study completion status and reason for discontinuation
MMSETOT	MMSE Total	integer	8			sum of QS.QSORRES values for the subject

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Adverse Events Analysis Dataset (ADAE) adae.xpt

Variable	Label	Type	Length	Display Format	Code List / Controlled Terms	Source/Derivation/Comments
STUDYID	Study Identifier	text	12			ADSL.STUDYID
SITEID	Study Site Identifier	text	3			ADSL.SITEID
USUBJID	Unique Subject Identifier	text	11			ADSL.USUBJID
TRTA	Actual Treatment	text	20		ARM	ADSL.TRT01A
TRTAN	Actual Treatment (N)	integer	8		ARMN	ADSL.TRT01AN
AGE	Age	integer	8			ADSL.AGE
AGEGR1	Pooled Age Group 1	text	5		AGEGR1	ADSL.AGEGR1
AGEGR1N	Pooled Age Group 1 (N)	integer	8		AGEGR1N	ADSL.AGEGR1N
RACE	Race	text	32		RACE	ADSL.RACE
RACEN	Race (N)	integer	8		RACEN	ADSL.RACEN
SEX	Sex	text	1		SEX	ADSL.SEX
SAFFL	Safety Population Flag	text	1		YN	ADSL.SAFFL

Variable	Label	Type	Length	Display Format	Code List / Controlled Terms	Source/Derivation/Comments
TRTSDT	Date of First Exposure to Treatment	integer	8	DATE9.		ADSL.TRTSDT
TRTEDT	Date of Last Exposure to Treatment	integer	8	DATE9.		ADSL.TRTEDT
ASTDT	Analysis Start Date	integer	8	DATE9.		AE.AESTDTC, converted to a numeric SAS date. Some events with partial dates are imputed in a conservative manner. If the day component is missing, a value of '01' is used. If both the month and day are missing no imputation is performed as these dates clearly indicate a start prior to the beginning of treatment. There are no events with completely missing start dates.
ASTDTF	Analysis Start Date Imputation Flag	text	1		DMY	ASTDTF='D' if the day value within the character date is imputed. Note that only day values needed to be imputed for this study.
ASTDY	Analysis Start Relative Day	integer	8			IF ASTDT>=TRTSDT>MISSING then ASTDY=ASTDT-TRTSDT+1 Else if TRTSDT>ASTDT>MISSING then ASTDY=ASTDT-TRTSDT
AENDT	Analysis End Date	integer	8	DATE9.		AE.AEENDTC, converted to a numeric SAS date
AENDY	Analysis End Relative Day	integer	8			IF AENDT>=TRTSDT>MISSING then AENDY=AENDT-TRTSDT+1 Else if TRTSDT>AENDT>MISSING then AENDY=AENDT-TRTSDT

Variable	Label	Type	Length	Display Format	Code List / Controlled Terms	Source/Derivation/Comments
ADURN	AE Duration (N)	integer	8			ADURN=AENDT-ASTDT+1
ADURU	AE Duration Units	text	3			If ADURN is not missing then ADURU='DAY'
AETERM	Reported Term for the Adverse Event	text	46			AE.AETERM
AELLT	Lowest Level Term	text	46		ADVERSE EVENT DICTIONARY	AE.AELLT
AELLTCD	Lowest Level Term Code	integer	8			AE.AELLTCD
AEDECOD	Dictionary-Derived Term	text	46		ADVERSE EVENT DICTIONARY	AE.AEDECOD
AEPTCD	Preferred Term Code	integer	8			AE.AEPTCD
AEHLT	High Level Term	text	8		ADVERSE EVENT DICTIONARY	AE.AEHLT
AEHLTCD	High Level Term Code	integer	8			AE.AEHLTCD

Variable	Label	Type	Length	Display Format	Code List / Controlled Terms	Source/Derivation/Comments
AEHLGT	High Level Group Term	text	9		ADVERSE EVENT DICTIONARY	AE.AEHLGT
AEHLGTCD	High Level Group Term Code	integer	8			AE.AEHLGTCD
AEBODSYS	Body System or Organ Class	text	67		ADVERSE EVENT DICTIONARY	AE.AEBODSYS
AESOC	Primary System Organ Class	text	67		ADVERSE EVENT DICTIONARY	AE.AESOC
AESOCCD	Primary System Organ Class Code	integer	8			AE.AESOCCD
AESEV	Severity/Intensity	text	8		SEV	AE.AESEV
AESER	Serious Event	text	1		YN	AE.AESER
AESCAN	Involves Cancer	text	1		YN	AE.AESCAN
AESCONG	Congenital Anomaly or Birth Defect	text	1		YN	AE.AESCONG
AESDISAB	Persist or Signif Disability/Incapacity	text	1		YN	AE.AESDISAB

Variable	Label	Type	Length	Display Format	Code List / Controlled Terms	Source/Derivation/Comments
AESDTH	Results in Death	text	1		YN	AE.AESDTH
AESHOSP	Requires or Prolongs Hospitalization	text	1		YN	AE.AESHOSP
AESLIFE	Is Life Threatening	text	1		YN	AE.AESLIFE
AESOD	Occurred with Overdose	text	1		YN	AE.AESOD
AEREL	Causality	text	8		AECAUS	AE.AEREL
AEACN	Action Taken with Study Treatment	text	1			AE.AEACN
AEOUT	Outcome of Adverse Event	text	26		OUT	AE.AEOUT
AESEQ	Sequence Number	integer	8			AE.AESEQ
TRTEMFL	Treatment Emergent Analysis Flag	text	1		YN	If ASTDT >= TRTSDT > . then TRTEMFL='Y'. Otherwise TRTEMFL='N'
AOCCFL	1st Occurrence of Any AE Flag	text	1		Y_BLANK	Subset to TRTEMFL='Y' and sort by Subject (USUBJID), Start Date (ASTDT), and Sequence Number (AESEQ) and flag the first record (set AOCCFL='Y') within each Subject

Variable	Label	Type	Length	Display Format	Code List / Controlled Terms	Source/Derivation/Comments
AOCCSFL	1st Occurrence of SOC Flag	text	1		Y_BLANK	Subset to TRTEMFL='Y' and sort by Subject (USUBJID), System Organ Class (AEBODSYS), Start Date (ASTDT), and Sequence Number (AESEQ) and flag the first record (set AOCCSFL='Y') within each Subject and SOC
AOCCPFL	1st Occurrence of Preferred Term Flag	text	1		Y_BLANK	Subset to TRTEMFL='Y' and sort by Subject (USUBJID), System Organ Class (AEBODSYS), Preferred Term (AEDECOD), Start Date (ASTDT), and Sequence Number (AESEQ) and flag the first record (set AOCCPFL='Y') within each Subject, SOC, and PT
AOCC02FL	1st Occurrence 02 Flag for Serious	text	1		Y_BLANK	Subset to TRTEMFL='Y' and AESER='Y' and sort by Subject (USUBJID), Start Date (ASTDT), and Sequence Number (AESEQ) and flag the first record (set AOCC02FL='Y') within each Subject
AOCC03FL	1st Occurrence 03 Flag for Serious SOC	text	1		Y_BLANK	Subset to TRTEMFL='Y' and AESER='Y' and sort by Subject (USUBJID), System Organ Class (AEBODSYS), Start Date (ASTDT), and Sequence Number (AESEQ) and flag the first record (set AOCC03FL='Y') within each Subject and SOC
AOCC04FL	1st Occurrence 04 Flag for Serious PT	text	1		Y_BLANK	Subset to TRTEMFL='Y' and AESER='Y' and sort by Subject (USUBJID), System Organ Class (AEBODSYS), Preferred Term (AEDECOD), Start Date (ASTDT), and Sequence Number (AESEQ) and flag the first record (set AOCC04FL='Y') within each Subject, SOC, and PT

Variable	Label	Type	Length	Display Format	Code List / Controlled Terms	Source/Derivation/Comments
CQ01NAM	Customized Query 01 Name	text	19			If AEDECOD contains any of the character strings of ('APPLICATION', 'DERMATITIS', 'ERYTHEMA', 'BLISTER') OR if AEBODSYS='SKIN AND SUBC UTANEOUS TISSUE DISORDERS' but AEDECOD is not in ('COLD SWEAT', 'HYPERHIDROSIS', 'ALOPECIA') then CQ01NAM='DERMATOLOGIC EVENTS' Otherwise CQ01NAM=NULL
AOCC01FL	1st Occurrence 01 Flag for CQ01	text	1		Y_BLANK	Subset to CQ01NAM='' and TRTEMFL='Y' and sort by Subject (USUBJID), Start Date (ASTDT), and Sequence Number (AESEQ) and flag the first record (set AOCC01FL='Y') within each Subject (Flag First Treatment Emergent Dermatological Event for Time to Event Analysis)

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Analysis Dataset Lab Blood Chemistry (ADLBC) adlbc.xpt

Variable	Label	Type	Length	Display Format	Code List / Controlled Terms	Source/Derivation/Comments
STUDYID	Study Identifier	text	12			ADSL.STUDYID
SUBJID	Subject Identifier for the Study	text	4			ADSL.SUBJID
USUBJID	Unique Subject Identifier	text	11			ADSL.USUBJID
TRTP	Planned Treatment	text	20		ARM	ADSL.TRT01P
TRTPN	Planned Treatment (N)	integer	8		ARMN	ADSL.TRT01PN
TRTA	Actual Treatment	text	20		ARM	ADSL.TRT01A
TRTAN	Actual Treatment (N)	integer	8		ARMN	ADSL.TRT01AN
TRTSDT	Date of First Exposure to Treatment	integer	8	DATE9.		ADSL.TRTSDT
TRTEDT	Date of Last Exposure to Treatment	integer	8	DATE9.		ADSL.TRTEDT
AGE	Age	integer	8			ADSL.AGE

Variable	Label	Type	Length	Display Format	Code List / Controlled Terms	Source/Derivation/Comments
AGEGR1	Pooled Age Group 1	text	5		AGEGR1	ADSL.AGEGR1
AGEGR1N	Pooled Age Group 1 (N)	integer	8		AGEGR1N	ADSL.AGEGR1N
RACE	Race	text	32		RACE	ADSL.RACE
RACEN	Race (N)	integer	8		RACEN	ADSL.RACEN
SEX	Sex	text	1		SEX	ADSL.SEX
COMP24FL	Completers of Week 24 Population Flag	text	1		YN	ADSL.COMP24FL
DSRAEFL	Discontinued due to AE?	text	1		YN	ADSL.DSRAEFL
SAFFL	Safety Population Flag	text	1		YN	ADSL.SAFFL
AVISIT	Analysis Visit	text	16		AVISIT	Analysis Visit
AVISITN	Analysis Visit (N)	integer	8		AVISITN	Numeric code for AVISIT
ADY	Analysis Relative Day	integer	8			LB.LBDY

Variable	Label	Type	Length	Display Format	Code List / Controlled Terms	Source/Derivation/Comments
ADT	Analysis Date	integer	8	DATE9.		LB.LBDTC converted to SAS date
VISIT	Visit Name	text	19		VISIT	LB.VISIT
VISITNUM	Visit Number	float	8		VISITNUM	LB.VISITNUM
PARAM	Parameter	text	100		PARAM_ADLBC	For PARAMN<100: same as LB.LBTEST concatenated with LB.LBSTRESU. For PARAMN>100: LB.LBTEST concatenated with LB.LBSTRESU concatenated with " change from previous visit, relative to normal range"
PARAMCD	Parameter Code	text	8		PARAMCD_ADLBC	For PARAMN<100: same as LBTESTCD, For PARAMN>100: _ + LBTESTCD
PARAMN	Parameter (N)	integer	8		PARAMN_ADLBC	Numeric code for Parameter
PARCAT1	Parameter Category 1	text	5		ADLBCAT	harcoded to 'CHEM'
AVAL	Analysis Value	float	8			
BASE	Baseline Value	float	8			
CHG	Change from Baseline	float	8			
A1LO	Analysis Range 1 Lower Limit	float	8			LB.LBSTNRLO

Variable	Label	Type	Length	Display Format	Code List / Controlled Terms	Source/Derivation/Comments
A1HI	Analysis Range 1 Upper Limit	float	8			LB.LBSTNRHI
R2A1LO	Ratio to Analysis Range 1 Lower Limit	float	8			AVAL / A1HI
R2A1HI	Ratio to Analysis Range 1 Upper Limit	float	8			AVAL / A1LO
BR2A1LO	Base Ratio to Analysis Range 1 Lower Lim	float	8			AVAL / A1HI at baseline
BR2A1HI	Base Ratio to Analysis Range 1 Upper Lim	float	8			AVAL / A1LO at baseline
ANL01FL	Analysis Record Flag 1	text	1		Y_BLANK	
ALBTRVAL	Amount Threshold Range	float	8			Maximum of [LBSTRESN-(1.5*ULN)] and [(.5*LLN) - LBSTRESN]
ANRIND	Analysis Reference Range Indicator	text	1		LNH	

Variable	Label	Type	Length	Display Format	Code List / Controlled Terms	Source/Derivation/Comments
BNRIND	Baseline Reference Range Indicator	text	1		LNH	
ABLFL	Baseline Record Flag	text	1		Y_BLANK	
AENTMTFL	Last value in treatment visit	text	1		Y_BLANK	Last observed value for this lab parameter during treatment phase: 'Y' if VISITNUM=12, if subject discontinues prior to VISIT 12, then this variable is set to 'Y' if this is the last assessment of this analyte for the subject
LBSEQ	Sequence Number	integer	8			LB.LBSEQ
LBNRIND	Reference Range Indicator	text	8		LBNRIND	LB.LBNRIND
LBSTRESN	Numeric Result/Finding in Standard Units	float	8			LB.LBSTRESN

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Analysis Dataset Lab Hematology (ADLBH) adlbh.xpt

Variable	Label	Type	Length	Display Format	Code List / Controlled Terms	Source/Derivation/Comments
STUDYID	Study Identifier	text	12			ADSL.STUDYID
SUBJID	Subject Identifier for the Study	text	4			ADSL.SUBJID
USUBJID	Unique Subject Identifier	text	11			ADSL.USUBJID
TRTP	Planned Treatment	text	20		ARM	ADSL.TRT01P
TRTPN	Planned Treatment (N)	integer	8		ARMN	ADSL.TRT01PN
TRTA	Actual Treatment	text	20		ARM	ADSL.TRT01A
TRTAN	Actual Treatment (N)	integer	8		ARMN	ADSL.TRT01AN
TRTSDT	Date of First Exposure to Treatment	integer	8	DATE9.		ADSL.TRTSDT
TRTEDT	Date of Last Exposure to Treatment	integer	8	DATE9.		ADSL.TRTEDT
AGE	Age	integer	8			ADSL.AGE

Variable	Label	Type	Length	Display Format	Code List / Controlled Terms	Source/Derivation/Comments
AGEGR1	Pooled Age Group 1	text	5		AGEGR1	ADSL.AGEGR1
AGEGR1N	Pooled Age Group 1 (N)	integer	8		AGEGR1N	ADSL.AGEGR1N
RACE	Race	text	32		RACE	ADSL.RACE
RACEN	Race (N)	integer	8		RACEN	ADSL.RACEN
SEX	Sex	text	1		SEX	ADSL.SEX
COMP24FL	Completers of Week 24 Population Flag	text	1		YN	ADSL.COMP24FL
DSRAEFL	Discontinued due to AE?	text	1		YN	ADSL.DSRAEFL
SAFFL	Safety Population Flag	text	1		YN	ADSL.SAFFL
AVISIT	Analysis Visit	text	16		AVISIT	Analysis Visit
AVISITN	Analysis Visit (N)	integer	8		AVISITN	Numeric code for AVISIT
ADY	Analysis Relative Day	integer	8			LB.LBDY

Variable	Label	Type	Length	Display Format	Code List / Controlled Terms	Source/Derivation/Comments
ADT	Analysis Date	integer	8	DATE9.		LB.LBDTC converted to SAS date
VISIT	Visit Name	text	19		VISIT	LB.VISIT
VISITNUM	Visit Number	float	8		VISITNUM	LB.VISITNUM
PARAM	Parameter	text	100		PARAM_ADLBH	For PARAMN<100: same as LBTEST concatenated with LBSTRESU For PARAMN>100: LBTEST concatenated with LB.LBSTRESU concatenated with "change from previous visit, relative to normal range"
PARAMCD	Parameter Code	text	8		PARAMCD_ADLBH	For PARAMN<100: same as LBTESTCD For PARAMN>100: _ + LBTESTCD
PARAMN	Parameter (N)	integer	8		PARAMN_ADLBH	Numeric code for Parameter
PARCAT1	Parameter Category 1	text	5		ADLBCAT	harcoded to 'HEM'
AVAL	Analysis Value	float	8			
BASE	Baseline Value	float	8			
CHG	Change from Baseline	float	8			
A1LO	Analysis Range 1 Lower Limit	float	8			

Variable	Label	Type	Length	Display Format	Code List / Controlled Terms	Source/Derivation/Comments
A1HI	Analysis Range 1 Upper Limit	float	8			LB.LBSTNRHI
R2A1LO	Ratio to Analysis Range 1 Lower Limit	float	8			AVAL / A1HI
R2A1HI	Ratio to Analysis Range 1 Upper Limit	float	8			AVAL / A1LO
BR2A1LO	Base Ratio to Analysis Range 1 Lower Lim	float	8			AVAL / A1HI at baseline
BR2A1HI	Base Ratio to Analysis Range 1 Upper Lim	float	8			AVAL / A1LO at baseline
ANL01FL	Analysis Record Flag 1	text	1		Y_BLANK	
ALBTRVAL	Amount Threshold Range	float	8			Maximum of [LBSTRESN-(1.5*ULN)] and [(.5*LLN) - LBSTRESN]
ANRIND	Analysis Reference Range Indicator	text	1		LNH	

Variable	Label	Type	Length	Display Format	Code List / Controlled Terms	Source/Derivation/Comments
BNRIND	Baseline Reference Range Indicator	text	1		LNH	
ABLFL	Baseline Record Flag	text	1		Y_BLANK	
AENTMTFL	Last value in treatment visit	text	1		Y_BLANK	Last observed value for this lab test during treatment phase: 'Y' if VISITNUM=12, if subject discontinues prior to VISIT 12, then this variable is set to 'Y' if this is the last assessment of this analyte for the subject
LBSEQ	Sequence Number	integer	8			LB.LBSEQ
LBNRIND	Reference Range Indicator	text	8		LBNRIND	LB.LBNRIND
LBSTRESN	Numeric Result/Finding in Standard Units	float	8			LB.LBSTRESN

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Analysis Dataset Lab Hy's Law (ADLBHY) adlbhy.xpt

Variable	Label	Type	Length	Display Format	Code List / Controlled Terms	Source/Derivation/Comments
STUDYID	Study Identifier	text	12			ADSL.STUDYID
SUBJID	Subject Identifier for the Study	text	4			ADSL.SUBJID
USUBJID	Unique Subject Identifier	text	11			ADSL.USUBJID
TRTP	Planned Treatment	text	20		ARM	ADSL.TRT01P
TRTPN	Planned Treatment (N)	integer	8		ARMN	ADSL.TRT01PN
TRTA	Actual Treatment	text	20		ARM	ADSL.TRT01A
TRTAN	Actual Treatment (N)	integer	8		ARMN	ADSL.TRT01AN
TRTSDT	Date of First Exposure to Treatment	integer	8	DATE9.		ADSL.TRTSDT
TRTEDT	Date of Last Exposure to Treatment	integer	8	DATE9.		ADSL.TRTEDT
AGE	Age	integer	8			ADSL.AGE
AGEGR1	Pooled Age Group 1	text	5		AGEGR1	ADSL.AGEGR1

Variable	Label	Type	Length	Display Format	Code List / Controlled Terms	Source/Derivation/Comments
AGEGR1N	Pooled Age Group 1 (N)	integer	8		AGEGR1N	ADSL.AGEGR1N
RACE	Race	text	32		RACE	ADSL.RACE
RACEN	Race (N)	integer	8		RACEN	ADSL.RACEN
SEX	Sex	text	1		SEX	ADSL.SEX
COMP24FL	Completers of Week 24 Population Flag	text	1		YN	ADSL.COMP24FL
DSRAEFL	Discontinued due to AE?	text	1		YN	ADSL.DSRAEFL
SAFFL	Safety Population Flag	text	1		YN	ADSL.SAFFL
AVISIT	Analysis Visit	text	16		AVISIT	Analysis Visit
AVISITN	Analysis Visit (N)	integer	8		AVISITN	Numeric code for AVISIT
ADY	Analysis Relative Day	integer	8			LB.LBDY
ADT	Analysis Date	integer	8	DATE9.		LB.LBDTC converted to SAS date
VISIT	Visit Name	text	19		VISIT	LB.VISIT
VISITNUM	Visit Number	float	8		VISITNUM	LB.VISITNUM

Variable	Label	Type	Length	Display Format	Code List / Controlled Terms	Source/Derivation/Comments
PARAMTYP	Parameter Type	text	7		PARAMTYP	
PARAM	Parameter	text	100		PARAM_ADLBHY	same as LBTEST concatenated with LBSTRESU except for hylaw params
PARAMCD	Parameter Code	text	8		PARAMCD_ADLBHY	
PARAMN	Parameter (N)	integer	8		PARAMN_ADLBHY	Numeric code for Parameter
PARCAT1	Parameter Category 1	text	5		ADLBCAT	
AVAL	Analysis Value	float	8			
BASE	Baseline Value	float	8			
A1LO	Analysis Range 1 Lower Limit	float	8			
A1HI	Analysis Range 1 Upper Limit	float	8			
R2A1LO	Ratio to Analysis Range 1 Lower Limit	float	8			
R2A1HI	Ratio to Analysis Range 1 Upper Limit	float	8			
BR2A1LO	Base Ratio to Analysis Range 1 Lower Lim	float	8			

Variable	Label	Type	Length	Display Format	Code List / Controlled Terms	Source/Derivation/Comments
BR2A1HI	Base Ratio to Analysis Range 1 Upper Lim	float	8			
ABLFL	Baseline Record Flag	text	1		Y_BLANK	ADLBC.ABLFL
SHIFT1	Shift 1	text	16		SHIFT	
SHIFT1N	Shift 1 (N)	integer	8		SHIFTN	Numeric code for SHIFT1
CRIT1	Analysis Criterion 1	text	12			
CRIT1FL	Criterion 1 Evaluation Result Flag	text	1		YN	
CRIT1FN	Criterion 1 Evaluation Result Flag (N)	integer	8		YNN	Numeric Code for CRIT1FL

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ADAS-Cog Analysis (ADQSADAS) adqsadas.xpt

Variable	Label	Type	Length	Display Format	Code List / Controlled Terms	Source/Derivation/Comments
STUDYID	Study Identifier	text	12			ADSL.STUDYID
SITEID	Study Site Identifier	text	3			ADSL.SITEID
SITEGR1	Pooled Site Group 1	text	3			ADSL.SITEGR1
USUBJID	Unique Subject Identifier	text	11			ADSL.USUBJID
TRTSDT	Date of First Exposure to Treatment	integer	8	DATE9.		ADSL.TRTSDT
TRTEDT	Date of Last Exposure to Treatment	integer	8	DATE9.		ADSL.TRTEDT
TRTP	Planned Treatment	text	20		ARM	ADSL.TRT01P
TRTPN	Planned Treatment (N)	integer	8		ARMN	ADSL.TRT01PN
AGE	Age	integer	8			ADSL.AGE
AGEGR1	Pooled Age Group 1	text	5		AGEGR1	ADSL.AGEGR1

Variable	Label	Type	Length	Display Format	Code List / Controlled Terms	Source/Derivation/Comments
AGEGR1N	Pooled Age Group 1 (N)	integer	8		AGEGR1N	ADSL.AGEGR1N
RACE	Race	text	32		RACE	ADSL.RACE
RACEN	Race (N)	integer	8		RACEN	ADSL.RACEN
SEX	Sex	text	1		SEX	ADSL.SEX
ITTFL	Intent-to-Treat Population Flag	text	1		YN	ADSL.ITTFL
EFFFL	Efficacy Population Flag	text	1		YN	ADSL.FASFL
COMP24FL	Completers of Week 24 Population Flag	text	1		YN	ADSL.COMP24FL
AVISIT	Analysis Visit	text	16		AVISIT	Derived based on windowing algorithm described in SAP, Section 8.2
AVISITN	Analysis Visit (N)	integer	8		AVISITN	Numeric code for AVISIT
VISIT	Visit Name	text	19		VISIT	QS.VISIT
VISITNUM	Visit Number	float	8		VISITNUM	QS.VISITNUM

Variable	Label	Type	Length	Display Format	Code List / Controlled Terms	Source/Derivation/Comments
ADY	Analysis Relative Day	integer	8			ADY = ADT - TRTSDT + 1, if ADT>=TRTSDT. ADY = ADT - TRTSDT, if ADT<TRTSDT.
ADT	Analysis Date	integer	8	DATE9.		SAS date from QS.QSDTC
PARAM	Parameter	text	100		PARAM_ADQSADAS	
PARAMCD	Parameter Code	text	8		PARAMCD_ADQSADAS	
PARAMN	Parameter (N)	integer	8		PARAMN_ADQSADAS	Assign a numeric code for each value of PARAMCD (see codelistPARAMN_ADQSADAS)
AVAL	Analysis Value	integer	8			
BASE	Baseline Value	integer	8			QS.QSSTRESN when QS.QSBLFL=Y (QS.VISITNUM=3)
CHG	Baseline Value	integer	8			AVAL - BASE
PCHG	Percent Change from Baseline	integer	8			100* (CHG/BASE)
ABLFL	ABLFL	text	1		Y_BLANK	QS.QSBLFL
ANL01FL	Analysis Record Flag 01	text	1		Y_BLANK	If multiple visits fall into the same visit window, then the one closest to the target date is chosen for analysis. These are flagged with ANL01FL="Y".
DTYPE	Derivation Type	text	7		DTYPE	

Variable	Label	Type	Length	Display Format	Code List / Controlled Terms	Source/Derivation/Comments
AWRANGE	Analysis Window Valid Relative Range	text	9			Window range, specified in the SAP.
AWTARGET	Analysis Window Target	integer	8			Target day within the window, specified in the SAP.
AWTDIFF	Analysis Window Diff from Target	integer	8			Absolute difference between AWTARGET and ADY
AWLO	Analysis Window Beginning Timepoint	integer	8			Start day of the window, specified in the SAP.
AWHI	Analysis Window Ending Timepoint	integer	8			End day of the window, specified in the SAP.
AWU	Analysis Window Unit	text	4		AWU	Assigned as "DAYS".
QSSEQ	Sequence Number	integer	8			

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CIBIC+ Analysis (ADQSCIBC) adqscibc.xpt

Variable	Label	Type	Length	Display Format	Code List / Controlled Terms	Source/Derivation/Comments
STUDYID	Study Identifier	text	12			ADSL.STUDYID
SITEID	Study Site Identifier	text	3			ADSL.SITEID
SITEGR1	Pooled Site Group 1	text	3			ADSL.SITEGR1
USUBJID	Unique Subject Identifier	text	11			ADSL.USUBJID
TRTSDT	Date of First Exposure to Treatment	integer	8	DATE9.		ADSL.TRTSDT
TRTEDT	Date of Last Exposure to Treatment	integer	8	DATE9.		ADSL.TRTEDT
TRTP	Planned Treatment	text	20		ARM	ADSL.TRT01P
TRTPN	Planned Treatment (N)	integer	8		ARMN	ADSL.TRT01PN
AGE	Age	integer	8			ADSL.AGE
AGEGR1	Pooled Age Group 1	text	5		AGEGR1	ADSL.AGEGR1

Variable	Label	Type	Length	Display Format	Code List / Controlled Terms	Source/Derivation/Comments
AGEGR1N	Pooled Age Group 1 (N)	integer	8		AGEGR1N	ADSL.AGEGR1N
RACE	Race	text	32		RACE	ADSL.RACE
RACEN	Race (N)	integer	8		RACEN	ADSL.RACEN
SEX	Sex	text	1		SEX	ADSL.SEX
ITTFL	Intent-to-Treat Population Flag	text	1		YN	ADSL.ITTFL
EFFFL	Efficacy Population Flag	text	1		YN	ADSL.FASFL
COMP24FL	Completers of Week 24 Population Flag	text	1		YN	ADSL.COMP24FL
AVISIT	Analysis Visit	text	16		AVISIT	Character version of the visit.
AVISITN	Analysis Visit (N)	integer	8		AVISITN	Using window method in SAP Page 10 to determine AVISITN value based on ADY.
VISIT	Visit Name	text	19		VISIT	QS.VISIT
VISITNUM	Visit Number	float	8		VISITNUM	QS.VISITNUM

Variable	Label	Type	Length	Display Format	Code List / Controlled Terms	Source/Derivation/Comments
ADY	Analysis Relative Day	integer	8			ADY = ADT - TRTSDT + 1, if ADT>=TRTSDT. ADY = ADT - TRTSDT, if ADT<TRTSDT.
ADT	Analysis Date	integer	8	DATE9.		SAS date from QS.QSDTC
PARAMCD	Parameter Code	text	8		PARAMCD_ADQSCIBC	Value: CIBICVAL
PARAM	Parameter	text	100		PARAM_ADQSCIBC	Value: CIBIC Score
PARAMN	Parameter (N)	integer	8		PARAMN_ADQSCIBC	Numeric code for Parameter
AVAL	Analysis Value	integer	8			QS.QSSTRESN, where QS.QSTESTCD = CIBIC
ANL01FL	Analysis Record Flag 01	text	1		Y_BLANK	Set ANL01FL=Y based on SAP Page 10 analysis windows.
DTYPE	Derivation Type	text	7		DTYPE	Value: LOCF denotes that the LOCF imputation method was used to impute the value for the given parameter and analysis visit.
AWRANGE	Analysis Window Valid Relative Range	text	9			Window range, specified in the SAP.
AWTARGET	Analysis Window Target	integer	8			Target day within the window, specified in the SAP.
AWTDIFF	Analysis Window Diff from Target	integer	8			Absolute difference between AWTARGET and ADY

Variable	Label	Type	Length	Display Format	Code List / Controlled Terms	Source/Derivation/Comments
AWLO	Analysis Window Beginning Timepoint	integer	8			Start day of the window, specified in the SAP.
AWHI	Analysis Window Ending Timepoint	integer	8			End day of the window, specified in the SAP.
AWU	Analysis Window Unit	text	4		AWU	Assigned as "DAYS".
QSSEQ	Sequence Number	integer	8			QS.QSSEQ

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NPI-X Item Analysis Data (ADQSNPIX) adqsnpix.xpt

Variable	Label	Type	Length	Display Format	Code List / Controlled Terms	Source/Derivation/Comments
STUDYID	Study Identifier	text	12			ADSL.STUDYID
SITEID	Study Site Identifier	text	3			ADSL.SITEID
SITEGR1	Pooled Site Group 1	text	3			ADSL.SITEGR1
USUBJID	Unique Subject Identifier	text	11			ADSL.USUBJID
TRTSDT	Date of First Exposure to Treatment	integer	8	DATE9.		ADSL.TRTSDT
TRTEDT	Date of Last Exposure to Treatment	integer	8	DATE9.		ADSL.TRTEDT
TRTP	Planned Treatment	text	20		ARM	ADSL.TRT01P
TRTPN	Planned Treatment (N)	integer	8		ARMN	ADSL.TRT01PN
AGE	Age	integer	8			ADSL.AGE
AGEGR1	Pooled Age Group 1	text	5		AGEGR1	ADSL.AGEGR1

Variable	Label	Type	Length	Display Format	Code List / Controlled Terms	Source/Derivation/Comments
AGEGR1N	Pooled Age Group 1 (N)	integer	8		AGEGR1N	ADSL.AGEGR1N
RACE	Race	text	32		RACE	ADSL.RACE
RACEN	Race (N)	integer	8		RACEN	ADSL.RACEN
SEX	Sex	text	1		SEX	ADSL.SEX
ITTFL	Intent-to-Treat Population Flag	text	1		YN	ADSL.ITTFL
EFFFL	Efficacy Population Flag	text	1		YN	ADSL.FASFL
COMP24FL	Completers of Week 24 Population Flag	text	1		YN	ADSL.COMP24FL
AVISIT	Analysis Visit	text	16		AVISIT	Character version of the visit.
AVISITN	Analysis Visit (N)	integer	8		AVISITN	Using window method in SAP Page 10 to determine AVISITN value based on ADY.
ADY	Analysis Relative Day	integer	8			ADY = ADT - TRTSDT + 1, if ADT>=TRTSDT. ADY = ADT - TRTSDT, if ADT<TRTSDT.
ADT	Analysis Date	integer	8	DATE9.		SAS date from QS.QSDTC

Variable	Label	Type	Length	Display Format	Code List / Controlled Terms	Source/Derivation/Comments
VISITNUM	Visit Number	float	8		VISITNUM	QS.VISITNUM
VISIT	Visit Name	text	19		VISIT	QS.VISIT
PARAM	Parameter	text	100		PARAM_ADQSNPIX	
PARAMCD	Parameter Code	text	8		PARAMCD_ADQSNPIX	
PARAMN	Parameter (N)	integer	8		PARAMN_ADQSNPIX	Assign a numeric code for each value of PARAMCD (see codelist PRMNNPIX)
PARAMTYP	Parameter Type	text	7		PARAMTYP	
AVAL	Analysis Value	integer	8			
BASE	Baseline Value	integer	8			
CHG	Change from Baseline	integer	8			
PCHG	Percent Change from Baseline	integer	8			
ABLFL	Analysis Baseline Flag	text	1		Y_BLANK	
ANL01FL	Analysis Record Flag 01	text	1		Y_BLANK	

Variable	Label	Type	Length	Display Format	Code List / Controlled Terms	Source/Derivation/Comments
DTYPE	Derivation Type	text	7		DTYPE	
AWRANGE	Analysis Window Valid Relative Range	text	9			Window range, specified in the SAP Page 10.
AWTARGET	Analysis Window Target	integer	8			Target day within the window, specified in the SAP Page 10.
AWTDIFF	Analysis Window Diff from Target	integer	8			Absolute difference between AWTARGET and ADY
AWLO	Analysis Window Beginning Timepoint	integer	8			Start day of the window, specified in the SAP Page 10.
AWHI	Analysis Window Ending Timepoint	integer	8			End day of the window, specified in the SAP Page 10.
AWU	Analysis Window Unit	text	4		AWU	Assigned as "DAYS".
QSSEQ	Sequence Number	integer	8			

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AE Time To 1st Derm. Event Analysis (ADTTE) adtte.xpt

Variable	Label	Type	Length	Display Format	Code List / Controlled Terms	Source/Derivation/Comments
STUDYID	Study Identifier	text	12			ADSL.STUDYID
SITEID	Study Site Identifier	text	3			ADSL.SITEID
USUBJID	Unique Subject Identifier	text	11			ADSL.USUBJID
AGE	Age	integer	8			ADSL.AGE
AGEGR1	Pooled Age Group 1	text	5		AGEGR1	ADSL.AGEGR1
AGEGR1N	Pooled Age Group 1 (N)	integer	8		AGEGR1N	ADSL.AGEGR1N
RACE	Race	text	32		RACE	ADSL.RACE
RACEN	Race (N)	integer	8		RACEN	ADSL.RACEN
SEX	Sex	text	1		SEX	ADSL.SEX
TRTSDT	Date of First Exposure to Treatment	integer	8	DATE9.		ADSL.TRTSDT

Variable	Label	Type	Length	Display Format	Code List / Controlled Terms	Source/Derivation/Comments
TRTEDT	Date of Last Exposure to Treatment	integer	8	DATE9.		ADSL.TRTEDT
TRTDUR	Duration of treatment (days)	integer	8			ADSL.TRTDUR
TRTP	Planned Treatment	text	20		ARM	ADSL.TRT01P
TRTA	Actual Treatment	text	20		ARM	ADSL.TRT01A
TRTAN	Actual Treatment (N)	integer	8		ARMN	ADSL.TRT01AN
PARAM	Parameter Description	text	100		PARAM_ADTTE	PARAM="Time to First Dermatologic Event"
PARAMCD	Parameter Code	text	8		PARAMCD_ADTTE	PARAMCD="TTDE"
AVAL	Analysis Value	integer	8			ADT-STARTDT+1
STARTDT	Time to Event Origin Date for Subject	integer	8	DATE9.		ADSL.RFSTDTC
ADT	Analysis Date	integer	8	DATE9.		if ADAE.ASTDT is not missing and occurred after TRTSDT then ADAE.ASTDT else convert ADSL.RFENDTC to a SAS numeric date

Variable	Label	Type	Length	Display Format	Code List / Controlled Terms	Source/Derivation/Comments
CNSR	Censor	integer	8		CENSOR	if ADAE.TRTEMFL ="Y" then CNSR=0, else CNSR=1
EVNTDESC	Event or Censoring Description	text	25			if ADTTE.CNSR = 0 then "Dematologic Event Occured", else if ADTTE.CNSR =1 then "Study Completion Date"
SRCDOM	Source Domain	text	4			The Source domain referred to in order to populate ADT (either ADAE or ADSL)
SRCVAR	Source Variable	text	6			The Source variable referred to in order to populate ADT (either ASTDT or RFENDT)
SRCSEQ	Source Sequence Number	integer	8			The value of ADAE.AESEQ if SRCDOM=ADAE, otherwise null.
SAFFL	Safety Population Flag	text	1		YN	ADSL.SAFFL

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Vital Signs Analysis Dataset (ADVS) advs.xpt

Variable	Label	Type	Length	Display Format	Code List / Controlled Terms	Source/Derivation/Comments
STUDYID	Study Identifier	text	12			ADSL.STUDYID
SITEID	Study Site Identifier	text	3			ADSL.SITEID
USUBJID	Unique Subject Identifier	text	11			ADSL.USUBJID
AGE	Age	integer	8			ADSL.AGE
AGEGR1	Pooled Age Group 1	text	5		AGEGR1	ADSL.AGEGR1
AGEGR1N	Pooled Age Group 1 (N)	integer	8		AGEGR1N	ADSL.AGEGR1N
RACE	Race	text	32		RACE	ADSL.RACE
RACEN	Race (N)	integer	8		RACEN	ADSL.RACEN
SEX	Sex	text	1		SEX	ADSL.SEX
SAFFL	Safety Population Flag	text	1		YN	ADSL.SAFFL

Variable	Label	Type	Length	Display Format	Code List / Controlled Terms	Source/Derivation/Comments
TRTSDT	Date of First Exposure to Treatment	integer	8	DATE9.		ADSL.TRTSDT
TRTEDT	Date of Last Exposure to Treatment	integer	8	DATE9.		ADSL.TRTEDT
TRTP	Planned Treatment	text	20		ARM	ADSL.TRT01P
TRTPN	Planned Treatment (N)	integer	8		ARMN	ADSL.TRT01PN
TRTA	Actual Treatment	text	20		ARM	ADSL.TRT01AN
TRTAN	Actual Treatment (N)	integer	8		ARMN	ADSL.TRT01AN
PARAMCD	Parameter Code	text	8		PARAMCD_ADVS	VS.VSTESTCD
PARAM	Parameter	text	100		PARAM_ADVS	
PARAMN	Parameter Number	integer	8		PARAMN_ADVS	Numeric code for Parameter

Variable	Label	Type	Length	Display Format	Code List / Controlled Terms	Source/Derivation/Comments
ADT	Analysis Date	integer	8	DATE9.		the date part of VS.VSDTC converted to a SAS date
ADY	Analysis Relative Day	integer	8			VS.VSDY
ATPTN	Analysis Timepoint (N)	integer	8			Numeric code for ATPT
ATPT	Analysis Timepoint	text	30		ATPT	VS.VSTPT
AVISIT	Analysis Visit	text	16		AVISIT	Derived from VS.VISIT for values to be included in a per visit analysis. AVISIT is missing for values from SDTM screening visits, unscheduled visits, and event related visits, e.g. "AMBUL ECG REMOVAL", which are not included in a per visit analysis.
AVISITN	Analysis Visit (N)	integer	8		AVISITN	Numeric code for AVISIT
AVAL	Analysis Value	float	8			VS.VSSTRESN
BASE	Baseline Value	float	8			VS.VSSTRESN where VSBLFL="Y"
CHG	Change from Baseline	float	8			AVAL-BASE

Variable	Label	Type	Length	Display Format	Code List / Controlled Terms	Source/Derivation/Comments
PCHG	Percent Change from Baseline	float	8			100* (CHG/BASE)
VISITNUM	Visit Number	float	8		VISITNUM	VS.VISITNUM
VISIT	Visit Name	text	19		VISIT	VS.VISIT
VSSEQ	Sequence Number	integer	8			VS.VSSEQ
ANL01FL	Analysis Record Flag 01	text	1		Y_BLANK	ANL01FL="Y" if the value is to be included in a per visit analysis. ANL01FL is missing for values from SDTM screening visits, unscheduled visits, and event related visits, e.g. "AMBUL ECG REMOVAL"
ABLFL	Baseline Record Flag	text	1		Y_BLANK	VS.VSBLFL

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Parameter Value List - ADLBC [A1HI]

Source Variable	Where PARAMCD=	Where PARAM=	Type	Length	Display Format	Code List / Controlled Term	Source/Derivation/Comments
A1HI	ALB	Albumin (g/L)	integer	8			LB.LBSTNRHI
A1HI	ALP	Alkaline Phosphatase (U/L)	integer	8			LB.LBSTNRHI
A1HI	ALT	Alanine Aminotransferase (U/L)	integer	8			LB.LBSTNRHI
A1HI	AST	Aspartate Aminotransferase (U/L)	integer	8			LB.LBSTNRHI
A1HI	BILI	Bilirubin (umol/L)	float	8	6.2		LB.LBSTNRHI
A1HI	BUN	Blood Urea Nitrogen (mmol/L)	float	8	7.3		LB.LBSTNRHI
A1HI	CA	Calcium (mmol/L)	float	8	8.5		LB.LBSTNRHI
A1HI	CHOL	Cholesterol (mmol/L)	float	8	8.5		LB.LBSTNRHI
A1HI	CK	Creatine Kinase (U/L)	integer	8			LB.LBSTNRHI
A1HI	CL	Chloride (mmol/L)	integer	8			LB.LBSTNRHI
A1HI	CREAT	Creatinine (umol/L)	float	8	6.2		LB.LBSTNRHI
A1HI	GGT	Gamma Glutamyl Transferase (U/L)	integer	8			LB.LBSTNRHI

Source Variable	Where PARAMCD=	Where PARAM=	Type	Length	Display Format	Code List / Controlled Term	Source/Derivation/Comments
A1HI	GLUC	Glucose (mmol/L)	float	8	8.5		LB.LBSTNRHI
A1HI	K	Potassium (mmol/L)	float	8	4.1		LB.LBSTNRHI
A1HI	PHOS	Phosphate (mmol/L)	float	8	7.5		LB.LBSTNRHI
A1HI	PROT	Protein (g/L)	integer	8			LB.LBSTNRHI
A1HI	SODIUM	Sodium (mmol/L)	integer	8			LB.LBSTNRHI
A1HI	URATE	Urate (umol/L)	float	8	7.3		LB.LBSTNRHI
A1HI	_ALB	Albumin (g/L) change from previous visit, relative to normal range	integer	8			Set to missing
A1HI	_ALP	Alkaline Phosphatase (U/L) change from previous visit, relative to normal range	integer	8			Set to missing
A1HI	_ALT	Alanine Aminotransferase (U/L) change from previous visit, relative to normal range	integer	8			Set to missing
A1HI	_AST	Aspartate Aminotransferase (U/L) change from previous visit, relative to normal range	integer	8			Set to missing

Source Variable	Where PARAMCD=	Where PARAM=	Type	Length	Display Format	Code List / Controlled Term	Source/Derivation/Comments
A1HI	_BILI	Bilirubin (umol/L) change from previous visit, relative to normal range	integer	8			Set to missing
A1HI	_BUN	Blood Urea Nitrogen (mmol/L) change from previous visit, relative to normal range	integer	8			Set to missing
A1HI	_CA	Calcium (mmol/L) change from previous visit, relative to normal range	integer	8			Set to missing
A1HI	_CHOL	Cholesterol (mmol/L) change from previous visit, relative to normal range	integer	8			Set to missing
A1HI	_CK	Creatine Kinase (U/L) change from previous visit, relative to normal range	integer	8			Set to missing
A1HI	_CL	Chloride (mmol/L) change from previous visit, relative to normal range	integer	8			Set to missing
A1HI	_CREAT	Creatinine (umol/L) change from previous visit, relative to normal range	integer	8			Set to missing

Source Variable	Where PARAMCD=	Where PARAM=	Type	Length	Display Format	Code List / Controlled Term	Source/Derivation/Comments
A1HI	_GGT	Gamma Glutamyl Transferase (U/L) change from previous visit, relative to normal range	integer	8			Set to missing
A1HI	_GLUC	Glucose (mmol/L) change from previous visit, relative to normal range	integer	8			Set to missing
A1HI	_K	Potassium (mmol/L) change from previous visit, relative to normal range	integer	8			Set to missing
A1HI	_PHOS	Phosphate (mmol/L) change from previous visit, relative to normal range	integer	8			Set to missing
A1HI	_PROT	Protein (g/L) change from previous visit, relative to normal range	integer	8			Set to missing
A1HI	_SODIUM	Sodium (mmol/L) change from previous visit, relative to normal range	integer	8			Set to missing
A1HI	_URATE	Urate (umol/L) change from previous visit, relative to normal range	integer	8			Set to missing

Parameter Value List - ADLBC [A1LO]

Source Variable	Where PARAMCD=	Where PARAM=	Type	Length	Display Format	Code List / Controlled Term	Source/Derivation/Comments
A1LO	ALB	Albumin (g/L)	integer	8			LB.LBSTNRLO
A1LO	ALP	Alkaline Phosphatase (U/L)	integer	8			LB.LBSTNRLO
A1LO	ALT	Alanine Aminotransferase (U/L)	integer	8			LB.LBSTNRLO
A1LO	AST	Aspartate Aminotransferase (U/L)	integer	8			LB.LBSTNRLO
A1LO	BILI	Bilirubin (umol/L)	float	8	6.2		LB.LBSTNRLO
A1LO	BUN	Blood Urea Nitrogen (mmol/L)	float	8	7.3		LB.LBSTNRLO
A1LO	CA	Calcium (mmol/L)	float	8	8.5		LB.LBSTNRLO
A1LO	CHOL	Cholesterol (mmol/L)	float	8	8.5		LB.LBSTNRLO
A1LO	CK	Creatine Kinase (U/L)	integer	8			LB.LBSTNRLO
A1LO	CL	Chloride (mmol/L)	integer	8			LB.LBSTNRLO
A1LO	CREAT	Creatinine (umol/L)	float	8	6.2		LB.LBSTNRLO
A1LO	GGT	Gamma Glutamyl Transferase (U/L)	integer	8			LB.LBSTNRLO

Source Variable	Where PARAMCD=	Where PARAM=	Type	Length	Display Format	Code List / Controlled Term	Source/Derivation/Comments
A1LO	GLUC	Glucose (mmol/L)	float	8	8.5		LB.LBSTNRLO
A1LO	K	Potassium (mmol/L)	float	8	4.1		LB.LBSTNRLO
A1LO	PHOS	Phosphate (mmol/L)	float	8	7.5		LB.LBSTNRLO
A1LO	PROT	Protein (g/L)	integer	8			LB.LBSTNRLO
A1LO	SODIUM	Sodium (mmol/L)	integer	8			LB.LBSTNRLO
A1LO	URATE	Urate (umol/L)	float	8	7.3		LB.LBSTNRLO
A1LO	_ALB	Albumin (g/L) change from previous visit, relative to normal range	integer	8			Set to missing
A1LO	_ALP	Alkaline Phosphatase (U/L) change from previous visit, relative to normal range	integer	8			Set to missing
A1LO	_ALT	Alanine Aminotransferase (U/L) change from previous visit, relative to normal range	integer	8			Set to missing
A1LO	_AST	Aspartate Aminotransferase (U/L) change from previous visit, relative to normal range	integer	8			Set to missing

Source Variable	Where PARAMCD=	Where PARAM=	Type	Length	Display Format	Code List / Controlled Term	Source/Derivation/Comments
A1LO	_BILI	Bilirubin (umol/L) change from previous visit, relative to normal range	integer	8			Set to missing
A1LO	_BUN	Blood Urea Nitrogen (mmol/L) change from previous visit, relative to normal range	integer	8			Set to missing
A1LO	_CA	Calcium (mmol/L) change from previous visit, relative to normal range	integer	8			Set to missing
A1LO	_CHOL	Cholesterol (mmol/L) change from previous visit, relative to normal range	integer	8			Set to missing
A1LO	_CK	Creatine Kinase (U/L) change from previous visit, relative to normal range	integer	8			Set to missing
A1LO	_CL	Chloride (mmol/L) change from previous visit, relative to normal range	integer	8			Set to missing
A1LO	_CREAT	Creatinine (umol/L) change from previous visit, relative to normal range	integer	8			Set to missing

Source Variable	Where PARAMCD=	Where PARAM=	Type	Length	Display Format	Code List / Controlled Term	Source/Derivation/Comments
A1LO	_GGT	Gamma Glutamyl Transferase (U/L) change from previous visit, relative to normal range	integer	8			Set to missing
A1LO	_GLUC	Glucose (mmol/L) change from previous visit, relative to normal range	integer	8			Set to missing
A1LO	_K	Potassium (mmol/L) change from previous visit, relative to normal range	integer	8			Set to missing
A1LO	_PHOS	Phosphate (mmol/L) change from previous visit, relative to normal range	integer	8			Set to missing
A1LO	_PROT	Protein (g/L) change from previous visit, relative to normal range	integer	8			Set to missing
A1LO	_SODIUM	Sodium (mmol/L) change from previous visit, relative to normal range	integer	8			Set to missing
A1LO	_URATE	Urate (umol/L) change from previous visit, relative to normal range	integer	8			Set to missing

Parameter Value List - ADLBC [ABLFL]

Source Variable	Where PARAMCD=	Where PARAM=	Type	Length	Display Format	Code List / Controlled Term	Source/Derivation/Comments
ABLFL	ALB	Albumin (g/L)	text	1		Y_BLANK	Y if VISITNUM=1, null otherwise
ABLFL	ALP	Alkaline Phosphatase (U/L)	text	1		Y_BLANK	Y if VISITNUM=1, null otherwise
ABLFL	ALT	Alanine Aminotransferase (U/L)	text	1		Y_BLANK	Y if VISITNUM=1, null otherwise
ABLFL	AST	Aspartate Aminotransferase (U/L)	text	1		Y_BLANK	Y if VISITNUM=1, null otherwise
ABLFL	BILI	Bilirubin (umol/L)	text	1		Y_BLANK	Y if VISITNUM=1, null otherwise
ABLFL	BUN	Blood Urea Nitrogen (mmol/L)	text	1		Y_BLANK	Y if VISITNUM=1, null otherwise
ABLFL	CA	Calcium (mmol/L)	text	1		Y_BLANK	Y if VISITNUM=1, null otherwise
ABLFL	CHOL	Cholesterol (mmol/L)	text	1		Y_BLANK	Y if VISITNUM=1, null otherwise
ABLFL	CK	Creatine Kinase (U/L)	text	1		Y_BLANK	Y if VISITNUM=1, null otherwise
ABLFL	CL	Chloride (mmol/L)	text	1		Y_BLANK	Y if VISITNUM=1, null otherwise
ABLFL	CREAT	Creatinine (umol/L)	text	1		Y_BLANK	Y if VISITNUM=1, null otherwise
ABLFL	GGT	Gamma Glutamyl Transferase (U/L)	text	1		Y_BLANK	Y if VISITNUM=1, null otherwise

Source Variable	Where PARAMCD=	Where PARAM=	Type	Length	Display Format	Code List / Controlled Term	Source/Derivation/Comments
ABLFL	GLUC	Glucose (mmol/L)	text	1		Y_BLANK	Y if VISITNUM=1, null otherwise
ABLFL	K	Potassium (mmol/L)	text	1		Y_BLANK	Y if VISITNUM=1, null otherwise
ABLFL	PHOS	Phosphate (mmol/L)	text	1		Y_BLANK	Y if VISITNUM=1, null otherwise
ABLFL	PROT	Protein (g/L)	text	1		Y_BLANK	Y if VISITNUM=1, null otherwise
ABLFL	SODIUM	Sodium (mmol/L)	text	1		Y_BLANK	Y if VISITNUM=1, null otherwise
ABLFL	URATE	Urate (umol/L)	text	1		Y_BLANK	Y if VISITNUM=1, null otherwise
ABLFL	_ALB	Albumin (g/L) change from previous visit, relative to normal range	text	1			Set to missing
ABLFL	_ALP	Alkaline Phosphatase (U/L) change from previous visit, relative to normal range	text	1			Set to missing
ABLFL	_ALT	Alanine Aminotransferase (U/L) change from previous visit, relative to normal range	text	1			Set to missing
ABLFL	_AST	Aspartate Aminotransferase (U/L) change from previous visit, relative to normal range	text	1			Set to missing

Source Variable	Where PARAMCD=	Where PARAM=	Type	Length	Display Format	Code List / Controlled Term	Source/Derivation/Comments
ABLFL	_BILI	Bilirubin (umol/L) change from previous visit, relative to normal range	text	1			Set to missing
ABLFL	_BUN	Blood Urea Nitrogen (mmol/L) change from previous visit, relative to normal range	text	1			Set to missing
ABLFL	_CA	Calcium (mmol/L) change from previous visit, relative to normal range	text	1			Set to missing
ABLFL	_CHOL	Cholesterol (mmol/L) change from previous visit, relative to normal range	text	1			Set to missing
ABLFL	_CK	Creatine Kinase (U/L) change from previous visit, relative to normal range	text	1			Set to missing
ABLFL	_CL	Chloride (mmol/L) change from previous visit, relative to normal range	text	1			Set to missing
ABLFL	_CREAT	Creatinine (umol/L) change from previous visit, relative to normal range	text	1			Set to missing

Source Variable	Where PARAMCD=	Where PARAM=	Type	Length	Display Format	Code List / Controlled Term	Source/Derivation/Comments
ABLFL	_GGT	Gamma Glutamyl Transferase (U/L) change from previous visit, relative to normal range	text	1			Set to missing
ABLFL	_GLUC	Glucose (mmol/L) change from previous visit, relative to normal range	text	1			Set to missing
ABLFL	_K	Potassium (mmol/L) change from previous visit, relative to normal range	text	1			Set to missing
ABLFL	_PHOS	Phosphate (mmol/L) change from previous visit, relative to normal range	text	1			Set to missing
ABLFL	_PROT	Protein (g/L) change from previous visit, relative to normal range	text	1			Set to missing
ABLFL	_SODIUM	Sodium (mmol/L) change from previous visit, relative to normal range	text	1			Set to missing
ABLFL	_URATE	Urate (umol/L) change from previous visit, relative to normal range	text	1			Set to missing

Parameter Value List - ADLBC [ANL01FL]

Source Variable	Where PARAMCD=	Where PARAM=	Type	Length	Display Format	Code List / Controlled Term	Source/Derivation/Comments
ANL01FL	ALB	Albumin (g/L)	text	1		Y_BLANK	Y if this ALBTRVAL is the largest for the subject in Visits 4-12 inclusive, null otherwise (if this value of ALBTRVAL occurs more than once, the first one is flagged).
ANL01FL	ALP	Alkaline Phosphatase (U/L)	text	1		Y_BLANK	Y if this ALBTRVAL is the largest for the subject in Visits 4-12 inclusive, null otherwise (if this value of ALBTRVAL occurs more than once, the first one is flagged).
ANL01FL	ALT	Alanine Aminotransferase (U/L)	text	1		Y_BLANK	Y if this ALBTRVAL is the largest for the subject in Visits 4-12 inclusive, null otherwise (if this value of ALBTRVAL occurs more than once, the first one is flagged).
ANL01FL	AST	Aspartate Aminotransferase (U/L)	text	1		Y_BLANK	Y if this ALBTRVAL is the largest for the subject in Visits 4-12 inclusive, null otherwise (if this value of ALBTRVAL occurs more than once, the first one is flagged).
ANL01FL	BILI	Bilirubin (umol/L)	text	1		Y_BLANK	Y if this ALBTRVAL is the largest for the subject in Visits 4-12 inclusive, null otherwise (if this value of ALBTRVAL occurs more than once, the first one is flagged).
ANL01FL	BUN	Blood Urea Nitrogen (mmol/L)	text	1		Y_BLANK	Y if this ALBTRVAL is the largest for the subject in Visits 4-12 inclusive, null otherwise (if this value of ALBTRVAL occurs more than once, the first one is flagged).

Source Variable	Where PARAMCD=	Where PARAM=	Type	Length	Display Format	Code List / Controlled Term	Source/Derivation/Comments
ANL01FL	CA	Calcium (mmol/L)	text	1		Y_BLANK	Y if this ALBTRVAL is the largest for the subject in Visits 4-12 inclusive, null otherwise (if this value of ALBTRVAL occurs more than once, the first one is flagged).
ANL01FL	CHOL	Cholesterol (mmol/L)	text	1		Y_BLANK	Y if this ALBTRVAL is the largest for the subject in Visits 4-12 inclusive, null otherwise (if this value of ALBTRVAL occurs more than once, the first one is flagged).
ANL01FL	CK	Creatine Kinase (U/L)	text	1		Y_BLANK	Y if this ALBTRVAL is the largest for the subject in Visits 4-12 inclusive, null otherwise (if this value of ALBTRVAL occurs more than once, the first one is flagged).
ANL01FL	CL	Chloride (mmol/L)	text	1		Y_BLANK	Y if this ALBTRVAL is the largest for the subject in Visits 4-12 inclusive, null otherwise (if this value of ALBTRVAL occurs more than once, the first one is flagged).
ANL01FL	CREAT	Creatinine (umol/L)	text	1		Y_BLANK	Y if this ALBTRVAL is the largest for the subject in Visits 4-12 inclusive, null otherwise (if this value of ALBTRVAL occurs more than once, the first one is flagged).
ANL01FL	GGT	Gamma Glutamyl Transferase (U/L)	text	1		Y_BLANK	Y if this ALBTRVAL is the largest for the subject in Visits 4-12 inclusive, null otherwise (if this value of ALBTRVAL occurs more than once, the first one is flagged).

Source Variable	Where PARAMCD=	Where PARAM=	Type	Length	Display Format	Code List / Controlled Term	Source/Derivation/Comments
ANL01FL	GLUC	Glucose (mmol/L)	text	1		Y_BLANK	Y if this ALBTRVAL is the largest for the subject in Visits 4-12 inclusive, null otherwise (if this value of ALBTRVAL occurs more than once, the first one is flagged).
ANL01FL	K	Potassium (mmol/L)	text	1		Y_BLANK	Y if this ALBTRVAL is the largest for the subject in Visits 4-12 inclusive, null otherwise (if this value of ALBTRVAL occurs more than once, the first one is flagged).
ANL01FL	PHOS	Phosphate (mmol/L)	text	1		Y_BLANK	Y if this ALBTRVAL is the largest for the subject in Visits 4-12 inclusive, null otherwise (if this value of ALBTRVAL occurs more than once, the first one is flagged).
ANL01FL	PROT	Protein (g/L)	text	1		Y_BLANK	Y if this ALBTRVAL is the largest for the subject in Visits 4-12 inclusive, null otherwise (if this value of ALBTRVAL occurs more than once, the first one is flagged).
ANL01FL	SODIUM	Sodium (mmol/L)	text	1		Y_BLANK	Y if this ALBTRVAL is the largest for the subject in Visits 4-12 inclusive, null otherwise (if this value of ALBTRVAL occurs more than once, the first one is flagged).
ANL01FL	URATE	Urate (umol/L)	text	1		Y_BLANK	Y if this ALBTRVAL is the largest for the subject in Visits 4-12 inclusive, null otherwise (if this value of ALBTRVAL occurs more than once, the first one is flagged).

Source Variable	Where PARAMCD=	Where PARAM=	Type	Length	Display Format	Code List / Controlled Term	Source/Derivation/Comments
ANL01FL	_ALB	Albumin (g/L) change from previous visit, relative to normal range	text	1		Y_BLANK	Y if the absolute value of this AVAL is the largest for the subject for VISITS 4-12 inclusive, null otherwise; only the first on-treatment AVAL that has absolute val equal to the max is flagged.
ANL01FL	_ALP	Alkaline Phosphatase (U/L) change from previous visit, relative to normal range	text	1		Y_BLANK	Y if the absolute value of this AVAL is the largest for the subject for VISITS 4-12 inclusive, null otherwise; only the first on-treatment AVAL that has absolute val equal to the max is flagged.
ANL01FL	_ALT	Alanine Aminotransferase (U/L) change from previous visit, relative to normal range	text	1		Y_BLANK	Y if the absolute value of this AVAL is the largest for the subject for VISITS 4-12 inclusive, null otherwise; only the first on-treatment AVAL that has absolute val equal to the max is flagged.
ANL01FL	_AST	Aspartate Aminotransferase (U/L) change from previous visit, relative to normal range	text	1		Y_BLANK	Y if the absolute value of this AVAL is the largest for the subject for VISITS 4-12 inclusive, null otherwise; only the first on-treatment AVAL that has absolute val equal to the max is flagged.
ANL01FL	_BILI	Bilirubin (umol/L) change from previous visit, relative to normal range	text	1		Y_BLANK	Y if the absolute value of this AVAL is the largest for the subject for VISITS 4-12 inclusive, null otherwise; only the first on-treatment AVAL that has absolute val equal to the max is flagged.

Source Variable	Where PARAMCD=	Where PARAM=	Type	Length	Display Format	Code List / Controlled Term	Source/Derivation/Comments
ANL01FL	_BUN	Blood Urea Nitrogen (mmol/L) change from previous visit, relative to normal range	text	1		Y_BLANK	Y if the absolute value of this AVAL is the largest for the subject for VISITS 4-12 inclusive, null otherwise; only the first on-treatment AVAL that has absolute val equal to the max is flagged.
ANL01FL	_CA	Calcium (mmol/L) change from previous visit, relative to normal range	text	1		Y_BLANK	Y if the absolute value of this AVAL is the largest for the subject for VISITS 4-12 inclusive, null otherwise; only the first on-treatment AVAL that has absolute val equal to the max is flagged.
ANL01FL	_CHOL	Cholesterol (mmol/L) change from previous visit, relative to normal range	text	1		Y_BLANK	Y if the absolute value of this AVAL is the largest for the subject for VISITS 4-12 inclusive, null otherwise; only the first on-treatment AVAL that has absolute val equal to the max is flagged.
ANL01FL	_CK	Creatine Kinase (U/L) change from previous visit, relative to normal range	text	1		Y_BLANK	Y if the absolute value of this AVAL is the largest for the subject for VISITS 4-12 inclusive, null otherwise; only the first on-treatment AVAL that has absolute val equal to the max is flagged.
ANL01FL	_CL	Chloride (mmol/L) change from previous visit, relative to normal range	text	1		Y_BLANK	Y if the absolute value of this AVAL is the largest for the subject for VISITS 4-12 inclusive, null otherwise; only the first on-treatment AVAL that has absolute val equal to the max is flagged.

Source Variable	Where PARAMCD=	Where PARAM=	Type	Length	Display Format	Code List / Controlled Term	Source/Derivation/Comments
ANL01FL	_CREAT	Creatinine (umol/L) change from previous visit, relative to normal range	text	1		Y_BLANK	Y if the absolute value of this AVAL is the largest for the subject for VISITS 4-12 inclusive, null otherwise; only the first on-treatment AVAL that has absolute val equal to the max is flagged.
ANL01FL	_GGT	Gamma Glutamyl Transferase (U/L) change from previous visit, relative to normal range	text	1		Y_BLANK	Y if the absolute value of this AVAL is the largest for the subject for VISITS 4-12 inclusive, null otherwise; only the first on-treatment AVAL that has absolute val equal to the max is flagged.
ANL01FL	_GLUC	Glucose (mmol/L) change from previous visit, relative to normal range	text	1		Y_BLANK	Y if the absolute value of this AVAL is the largest for the subject for VISITS 4-12 inclusive, null otherwise; only the first on-treatment AVAL that has absolute val equal to the max is flagged.
ANL01FL	_K	Potassium (mmol/L) change from previous visit, relative to normal range	text	1		Y_BLANK	Y if the absolute value of this AVAL is the largest for the subject for VISITS 4-12 inclusive, null otherwise; only the first on-treatment AVAL that has absolute val equal to the max is flagged.
ANL01FL	_PHOS	Phosphate (mmol/L) change from previous visit, relative to normal range	text	1		Y_BLANK	Y if the absolute value of this AVAL is the largest for the subject for VISITS 4-12 inclusive, null otherwise; only the first on-treatment AVAL that has absolute val equal to the max is flagged.

Source Variable	Where PARAMCD=	Where PARAM=	Type	Length	Display Format	Code List / Controlled Term	Source/Derivation/Comments
ANL01FL	_PROT	Protein (g/L) change from previous visit, relative to normal range	text	1		Y_BLANK	Y if the absolute value of this AVAL is the largest for the subject for VISITS 4-12 inclusive, null otherwise; only the first on-treatment AVAL that has absolute val equal to the max is flagged.
ANL01FL	_SODIUM	Sodium (mmol/L) change from previous visit, relative to normal range	text	1		Y_BLANK	Y if the absolute value of this AVAL is the largest for the subject for VISITS 4-12 inclusive, null otherwise; only the first on-treatment AVAL that has absolute val equal to the max is flagged.
ANL01FL	_URATE	Urate (umol/L) change from previous visit, relative to normal range	text	1		Y_BLANK	Y if the absolute value of this AVAL is the largest for the subject for VISITS 4-12 inclusive, null otherwise; only the first on-treatment AVAL that has absolute val equal to the max is flagged.

Parameter Value List - ADLBC [ANRIND]

Source Variable	Where PARAMCD=	Where PARAM=	Type	Length	Display Format	Code List / Controlled Term	Source/Derivation/Comments
ANRIND	ALB	Albumin (g/L)	text	1		LNH	if AVAL < (0.5*LBSTNRLO) then ANRIND='L'; if LAVAL > 1.5* LBSTNRHI then ANRIND='H'; ANRIND='N' otherwise. Used for shift tables

Source Variable	Where PARAMCD=	Where PARAM=	Type	Length	Display Format	Code List / Controlled Term	Source/Derivation/Comments
ANRIND	ALP	Alkaline Phosphatase (U/L)	text	1		LNH	if AVAL < (0.5*LBSTNRLO) then ANRIND='L'; if LAVAL > 1.5* LBSTNRHI then ANRIND='H'; ANRIND='N' otherwise. Used for shift tables
ANRIND	ALT	Alanine Aminotransferase (U/L)	text	1		LNH	if AVAL < (0.5*LBSTNRLO) then ANRIND='L'; if LAVAL > 1.5* LBSTNRHI then ANRIND='H'; ANRIND='N' otherwise. Used for shift tables
ANRIND	AST	Aspartate Aminotransferase (U/L)	text	1		LNH	if AVAL < (0.5*LBSTNRLO) then ANRIND='L'; if LAVAL > 1.5* LBSTNRHI then ANRIND='H'; ANRIND='N' otherwise. Used for shift tables
ANRIND	BILI	Bilirubin (umol/L)	text	1		LNH	if AVAL < (0.5*LBSTNRLO) then ANRIND='L'; if LAVAL > 1.5* LBSTNRHI then ANRIND='H'; ANRIND='N' otherwise. Used for shift tables
ANRIND	BUN	Blood Urea Nitrogen (mmol/L)	text	1		LNH	if AVAL < (0.5*LBSTNRLO) then ANRIND='L'; if LAVAL > 1.5* LBSTNRHI then ANRIND='H'; ANRIND='N' otherwise. Used for shift tables
ANRIND	CA	Calcium (mmol/L)	text	1		LNH	if AVAL < (0.5*LBSTNRLO) then ANRIND='L'; if LAVAL > 1.5* LBSTNRHI then ANRIND='H'; ANRIND='N' otherwise. Used for shift tables

Source Variable	Where PARAMCD=	Where PARAM=	Type	Length	Display Format	Code List / Controlled Term	Source/Derivation/Comments
ANRIND	CHOL	Cholesterol (mmol/L)	text	1		LNH	if AVAL < (0.5*LBSTNRLO) then ANRIND='L'; if LAVAL > 1.5* LBSTNRHI then ANRIND='H'; ANRIND='N' otherwise. Used for shift tables
ANRIND	CK	Creatine Kinase (U/L)	text	1		LNH	if AVAL < (0.5*LBSTNRLO) then ANRIND='L'; if LAVAL > 1.5* LBSTNRHI then ANRIND='H'; ANRIND='N' otherwise. Used for shift tables
ANRIND	CL	Chloride (mmol/L)	text	1		LNH	if AVAL < (0.5*LBSTNRLO) then ANRIND='L'; if LAVAL > 1.5* LBSTNRHI then ANRIND='H'; ANRIND='N' otherwise. Used for shift tables
ANRIND	CREAT	Creatinine (umol/L)	text	1		LNH	if AVAL < (0.5*LBSTNRLO) then ANRIND='L'; if LAVAL > 1.5* LBSTNRHI then ANRIND='H'; ANRIND='N' otherwise. Used for shift tables
ANRIND	GGT	Gamma Glutamyl Transferase (U/L)	text	1		LNH	if AVAL < (0.5*LBSTNRLO) then ANRIND='L'; if LAVAL > 1.5* LBSTNRHI then ANRIND='H'; ANRIND='N' otherwise. Used for shift tables
ANRIND	GLUC	Glucose (mmol/L)	text	1		LNH	if AVAL < (0.5*LBSTNRLO) then ANRIND='L'; if LAVAL > 1.5* LBSTNRHI then ANRIND='H'; ANRIND='N' otherwise. Used for shift tables

Source Variable	Where PARAMCD=	Where PARAM=	Type	Length	Display Format	Code List / Controlled Term	Source/Derivation/Comments
ANRIND	K	Potassium (mmol/L)	text	1		LNH	if AVAL < (0.5*LBSTNRLO) then ANRIND='L'; if LAVAL > 1.5* LBSTNRHI then ANRIND='H'; ANRIND='N' otherwise. Used for shift tables
ANRIND	PHOS	Phosphate (mmol/L)	text	1		LNH	if AVAL < (0.5*LBSTNRLO) then ANRIND='L'; if LAVAL > 1.5* LBSTNRHI then ANRIND='H'; ANRIND='N' otherwise. Used for shift tables
ANRIND	PROT	Protein (g/L)	text	1		LNH	if AVAL < (0.5*LBSTNRLO) then ANRIND='L'; if LAVAL > 1.5* LBSTNRHI then ANRIND='H'; ANRIND='N' otherwise. Used for shift tables
ANRIND	SODIUM	Sodium (mmol/L)	text	1		LNH	if AVAL < (0.5*LBSTNRLO) then ANRIND='L'; if LAVAL > 1.5* LBSTNRHI then ANRIND='H'; ANRIND='N' otherwise. Used for shift tables
ANRIND	URATE	Urate (umol/L)	text	1		LNH	if AVAL < (0.5*LBSTNRLO) then ANRIND='L'; if LAVAL > 1.5* LBSTNRHI then ANRIND='H'; ANRIND='N' otherwise. Used for shift tables
ANRIND	_ALB	Albumin (g/L) change from previous visit, relative to normal range	text	1		LNH	if AVAL < -1 then ANRIND='L'; if AVAL > 1 then ANRIND='H'; ANRIND='N' otherwise; null if LBBLFL=Y or AVAL=null

Source Variable	Where PARAMCD=	Where PARAM=	Type	Length	Display Format	Code List / Controlled Term	Source/Derivation/Comments
ANRIND	_ALP	Alkaline Phosphatase (U/L) change from previous visit, relative to normal range	text	1		LNH	if AVAL < -1 then ANRIND='L'; if AVAL > 1 then ANRIND='H'; ANRIND='N' otherwise; null if LBBLFL=Y or AVAL=null
ANRIND	_ALT	Alanine Aminotransferase (U/L) change from previous visit, relative to normal range	text	1		LNH	if AVAL < -1 then ANRIND='L'; if AVAL > 1 then ANRIND='H'; ANRIND='N' otherwise; null if LBBLFL=Y or AVAL=null
ANRIND	_AST	Aspartate Aminotransferase (U/L) change from previous visit, relative to normal range	text	1		LNH	if AVAL < -1 then ANRIND='L'; if AVAL > 1 then ANRIND='H'; ANRIND='N' otherwise; null if LBBLFL=Y or AVAL=null
ANRIND	_BILI	Bilirubin (umol/L) change from previous visit, relative to normal range	text	1		LNH	if AVAL < -1 then ANRIND='L'; if AVAL > 1 then ANRIND='H'; ANRIND='N' otherwise; null if LBBLFL=Y or AVAL=null
ANRIND	_BUN	Blood Urea Nitrogen (mmol/L) change from previous visit, relative to normal range	text	1		LNH	if AVAL < -1 then ANRIND='L'; if AVAL > 1 then ANRIND='H'; ANRIND='N' otherwise; null if LBBLFL=Y or AVAL=null
ANRIND	_CA	Calcium (mmol/L) change from previous visit, relative to normal range	text	1		LNH	if AVAL < -1 then ANRIND='L'; if AVAL > 1 then ANRIND='H'; ANRIND='N' otherwise; null if LBBLFL=Y or AVAL=null

Source Variable	Where PARAMCD=	Where PARAM=	Type	Length	Display Format	Code List / Controlled Term	Source/Derivation/Comments
ANRIND	_CHOL	Cholesterol (mmol/L) change from previous visit, relative to normal range	text	1		LNH	if AVAL < -1 then ANRIND='L'; if AVAL > 1 then ANRIND='H'; ANRIND='N' otherwise; null if LBBLFL=Y or AVAL=null
ANRIND	_CK	Creatine Kinase (U/L) change from previous visit, relative to normal range	text	1		LNH	if AVAL < -1 then ANRIND='L'; if AVAL > 1 then ANRIND='H'; ANRIND='N' otherwise; null if LBBLFL=Y or AVAL=null
ANRIND	_CL	Chloride (mmol/L) change from previous visit, relative to normal range	text	1		LNH	if AVAL < -1 then ANRIND='L'; if AVAL > 1 then ANRIND='H'; ANRIND='N' otherwise; null if LBBLFL=Y or AVAL=null
ANRIND	_CREAT	Creatinine (umol/L) change from previous visit, relative to normal range	text	1		LNH	if AVAL < -1 then ANRIND='L'; if AVAL > 1 then ANRIND='H'; ANRIND='N' otherwise; null if LBBLFL=Y or AVAL=null
ANRIND	_GGT	Gamma Glutamyl Transferase (U/L) change from previous visit, relative to normal range	text	1		LNH	if AVAL < -1 then ANRIND='L'; if AVAL > 1 then ANRIND='H'; ANRIND='N' otherwise; null if LBBLFL=Y or AVAL=null
ANRIND	_GLUC	Glucose (mmol/L) change from previous visit, relative to normal range	text	1		LNH	if AVAL < -1 then ANRIND='L'; if AVAL > 1 then ANRIND='H'; ANRIND='N' otherwise; null if LBBLFL=Y or AVAL=null

Source Variable	Where PARAMCD=	Where PARAM=	Type	Length	Display Format	Code List / Controlled Term	Source/Derivation/Comments
ANRIND	_K	Potassium (mmol/L) change from previous visit, relative to normal range	text	1		LNH	if AVAL < -1 then ANRIND='L'; if AVAL > 1 then ANRIND='H'; ANRIND='N' otherwise; null if LBBLFL=Y or AVAL=null
ANRIND	_PHOS	Phosphate (mmol/L) change from previous visit, relative to normal range	text	1		LNH	if AVAL < -1 then ANRIND='L'; if AVAL > 1 then ANRIND='H'; ANRIND='N' otherwise; null if LBBLFL=Y or AVAL=null
ANRIND	_PROT	Protein (g/L) change from previous visit, relative to normal range	text	1		LNH	if AVAL < -1 then ANRIND='L'; if AVAL > 1 then ANRIND='H'; ANRIND='N' otherwise; null if LBBLFL=Y or AVAL=null
ANRIND	_SODIUM	Sodium (mmol/L) change from previous visit, relative to normal range	text	1		LNH	if AVAL < -1 then ANRIND='L'; if AVAL > 1 then ANRIND='H'; ANRIND='N' otherwise; null if LBBLFL=Y or AVAL=null
ANRIND	_URATE	Urate (umol/L) change from previous visit, relative to normal range	text	1		LNH	if AVAL < -1 then ANRIND='L'; if AVAL > 1 then ANRIND='H'; ANRIND='N' otherwise; null if LBBLFL=Y or AVAL=null

Parameter Value List - ADLBC [AVAL]

Source Variable	Where PARAMCD=	Where PARAM=	Type	Length	Display Format	Code List / Controlled Term	Source/Derivation/Comments
AVAL	ALB	Albumin (g/L)	integer	8			LB.LBSTRESN
AVAL	ALP	Alkaline Phosphatase (U/L)	integer	8			LB.LBSTRESN
AVAL	ALT	Alanine Aminotransferase (U/L)	integer	8			LB.LBSTRESN
AVAL	AST	Aspartate Aminotransferase (U/L)	integer	8			LB.LBSTRESN
AVAL	BILI	Bilirubin (umol/L)	float	8	6.2		LB.LBSTRESN
AVAL	BUN	Blood Urea Nitrogen (mmol/L)	float	8	7.3		LB.LBSTRESN
AVAL	CA	Calcium (mmol/L)	float	8	8.5		LB.LBSTRESN
AVAL	CHOL	Cholesterol (mmol/L)	float	8	8.5		LB.LBSTRESN
AVAL	CK	Creatine Kinase (U/L)	integer	8			LB.LBSTRESN
AVAL	CL	Chloride (mmol/L)	integer	8			LB.LBSTRESN
AVAL	CREAT	Creatinine (umol/L)	float	8	6.2		LB.LBSTRESN

Source Variable	Where PARAMCD=	Where PARAM=	Type	Length	Display Format	Code List / Controlled Term	Source/Derivation/Comments
AVAL	GGT	Gamma Glutamyl Transferase (U/L)	integer	8			LB.LBSTRESN
AVAL	GLUC	Glucose (mmol/L)	float	8	8.5		LB.LBSTRESN
AVAL	K	Potassium (mmol/L)	float	8	4.1		LB.LBSTRESN
AVAL	PHOS	Phosphate (mmol/L)	float	8	7.5		LB.LBSTRESN
AVAL	PROT	Protein (g/L)	integer	8			LB.LBSTRESN
AVAL	SODIUM	Sodium (mmol/L)	integer	8			LB.LBSTRESN
AVAL	URATE	Urate (umol/L)	float	8	7.3		LB.LBSTRESN
AVAL	_ALB	Albumin (g/L) change from previous visit, relative to normal range	float	8	4.1		(LBSTRESN - previous LBSTRESN)/(.5*(LBSTNRHI-LBSTNRLO)); null if LBBLFL=Y
AVAL	_ALP	Alkaline Phosphatase (U/L) change from previous visit, relative to normal range	float	8	4.1		(LBSTRESN - previous LBSTRESN)/(.5*(LBSTNRHI-LBSTNRLO)); null if LBBLFL=Y
AVAL	_ALT	Alanine Aminotransferase (U/L) change from previous visit, relative to normal range	float	8	4.1		(LBSTRESN - previous LBSTRESN)/(.5*(LBSTNRHI-LBSTNRLO)); null if LBBLFL=Y

Source Variable	Where PARAMCD=	Where PARAM=	Type	Length	Display Format	Code List / Controlled Term	Source/Derivation/Comments
AVAL	_AST	Aspartate Aminotransferase (U/L) change from previous visit, relative to normal range	float	8	4.1		(LBSTRESN - previous LBSTRESN)/(.5*(LBSTNRHI-LBSTNRLO)); null if LBBLFL=Y
AVAL	_BILI	Bilirubin (umol/L) change from previous visit, relative to normal range	float	8	4.1		(LBSTRESN - previous LBSTRESN)/(.5*(LBSTNRHI-LBSTNRLO)); null if LBBLFL=Y
AVAL	_BUN	Blood Urea Nitrogen (mmol/L) change from previous visit, relative to normal range	float	8	4.1		(LBSTRESN - previous LBSTRESN)/(.5*(LBSTNRHI-LBSTNRLO)); null if LBBLFL=Y
AVAL	_CA	Calcium (mmol/L) change from previous visit, relative to normal range	float	8	4.1		(LBSTRESN - previous LBSTRESN)/(.5*(LBSTNRHI-LBSTNRLO)); null if LBBLFL=Y
AVAL	_CHOL	Cholesterol (mmol/L) change from previous visit, relative to normal range	float	8	4.1		(LBSTRESN - previous LBSTRESN)/(.5*(LBSTNRHI-LBSTNRLO)); null if LBBLFL=Y
AVAL	_CK	Creatine Kinase (U/L) change from previous visit, relative to normal range	float	8	4.1		(LBSTRESN - previous LBSTRESN)/(.5*(LBSTNRHI-LBSTNRLO)); null if LBBLFL=Y

Source Variable	Where PARAMCD=	Where PARAM=	Type	Length	Display Format	Code List / Controlled Term	Source/Derivation/Comments
AVAL	_CL	Chloride (mmol/L) change from previous visit, relative to normal range	float	8	4.1		(LBSTRESN - previous LBSTRESN)/(.5*(LBSTNRHI-LBSTNRLO)); null if LBBLFL=Y
AVAL	_CREAT	Creatinine (umol/L) change from previous visit, relative to normal range	float	8	4.1		(LBSTRESN - previous LBSTRESN)/(.5*(LBSTNRHI-LBSTNRLO)); null if LBBLFL=Y
AVAL	_GGT	Gamma Glutamyl Transferase (U/L) change from previous visit, relative to normal range	float	8	4.1		(LBSTRESN - previous LBSTRESN)/(.5*(LBSTNRHI-LBSTNRLO)); null if LBBLFL=Y
AVAL	_GLUC	Glucose (mmol/L) change from previous visit, relative to normal range	float	8	4.1		(LBSTRESN - previous LBSTRESN)/(.5*(LBSTNRHI-LBSTNRLO)); null if LBBLFL=Y
AVAL	_K	Potassium (mmol/L) change from previous visit, relative to normal range	float	8	4.1		(LBSTRESN - previous LBSTRESN)/(.5*(LBSTNRHI-LBSTNRLO)); null if LBBLFL=Y
AVAL	_PHOS	Phosphate (mmol/L) change from previous visit, relative to normal range	float	8	4.1		(LBSTRESN - previous LBSTRESN)/(.5*(LBSTNRHI-LBSTNRLO)); null if LBBLFL=Y

Source Variable	Where PARAMCD=	Where PARAM=	Type	Length	Display Format	Code List / Controlled Term	Source/Derivation/Comments
AVAL	_PROT	Protein (g/L) change from previous visit, relative to normal range	float	8	4.1		(LBSTRESN - previous LBSTRESN)/(.5*(LBSTNRHI-LBSTNRLO)); null if LBBLFL=Y
AVAL	_SODIUM	Sodium (mmol/L) change from previous visit, relative to normal range	float	8	4.1		(LBSTRESN - previous LBSTRESN)/(.5*(LBSTNRHI-LBSTNRLO)); null if LBBLFL=Y
AVAL	_URATE	Urate (umol/L) change from previous visit, relative to normal range	float	8	4.1		(LBSTRESN - previous LBSTRESN)/(.5*(LBSTNRHI-LBSTNRLO)); null if LBBLFL=Y

Parameter Value List - ADLBC [BASE]

Source Variable	Where PARAMCD=	Where PARAM=	Type	Length	Display Format	Code List / Controlled Term	Source/Derivation/Comments
BASE	ALB	Albumin (g/L)	integer	8			ADLBC.LBSTRESN when ADLBC.ABLFL=Y
BASE	ALP	Alkaline Phosphatase (U/L)	integer	8			ADLBC.LBSTRESN when ADLBC.ABLFL=Y
BASE	ALT	Alanine Aminotransferase (U/L)	integer	8			ADLBC.LBSTRESN when ADLBC.ABLFL=Y
BASE	AST	Aspartate Aminotransferase (U/L)	integer	8			ADLBC.LBSTRESN when ADLBC.ABLFL=Y
BASE	BILI	Bilirubin (umol/L)	float	8	6.2		ADLBC.LBSTRESN when ADLBC.ABLFL=Y
BASE	BUN	Blood Urea Nitrogen (mmol/L)	float	8	7.3		ADLBC.LBSTRESN when ADLBC.ABLFL=Y
BASE	CA	Calcium (mmol/L)	float	8	8.5		ADLBC.LBSTRESN when ADLBC.ABLFL=Y
BASE	CHOL	Cholesterol (mmol/L)	float	8	8.5		ADLBC.LBSTRESN when ADLBC.ABLFL=Y
BASE	CK	Creatine Kinase (U/L)	integer	8			ADLBC.LBSTRESN when ADLBC.ABLFL=Y

Source Variable	Where PARAMCD=	Where PARAM=	Type	Length	Display Format	Code List / Controlled Term	Source/Derivation/Comments
BASE	CL	Chloride (mmol/L)	integer	8			ADLBC.LBSTRESN when ADLBC.ABLFL=Y
BASE	CREAT	Creatinine (umol/L)	float	8	6.2		ADLBC.LBSTRESN when ADLBC.ABLFL=Y
BASE	GGT	Gamma Glutamyl Transferase (U/L)	integer	8			ADLBC.LBSTRESN when ADLBC.ABLFL=Y
BASE	GLUC	Glucose (mmol/L)	float	8	8.5		ADLBC.LBSTRESN when ADLBC.ABLFL=Y
BASE	K	Potassium (mmol/L)	float	8	4.1		ADLBC.LBSTRESN when ADLBC.ABLFL=Y
BASE	PHOS	Phosphate (mmol/L)	float	8	7.5		ADLBC.LBSTRESN when ADLBC.ABLFL=Y
BASE	PROT	Protein (g/L)	integer	8			ADLBC.LBSTRESN when ADLBC.ABLFL=Y
BASE	SODIUM	Sodium (mmol/L)	integer	8			ADLBC.LBSTRESN when ADLBC.ABLFL=Y
BASE	URATE	Urate (umol/L)	float	8	7.3		ADLBC.LBSTRESN when ADLBC.ABLFL=Y

Source Variable	Where PARAMCD=	Where PARAM=	Type	Length	Display Format	Code List / Controlled Term	Source/Derivation/Comments
BASE	_ALB	Albumin (g/L) change from previous visit, relative to normal range	integer	8			Set to missing
BASE	_ALP	Alkaline Phosphatase (U/L) change from previous visit, relative to normal range	integer	8			Set to missing
BASE	_ALT	Alanine Aminotransferase (U/L) change from previous visit, relative to normal range	integer	8			Set to missing
BASE	_AST	Aspartate Aminotransferase (U/L) change from previous visit, relative to normal range	integer	8			Set to missing
BASE	_BILI	Bilirubin (umol/L) change from previous visit, relative to normal range	integer	8			Set to missing
BASE	_BUN	Blood Urea Nitrogen (mmol/L) change from previous visit, relative to normal range	integer	8			Set to missing
BASE	_CA	Calcium (mmol/L) change from previous visit, relative to normal range	integer	8			Set to missing

Source Variable	Where PARAMCD=	Where PARAM=	Type	Length	Display Format	Code List / Controlled Term	Source/Derivation/Comments
BASE	_CHOL	Cholesterol (mmol/L) change from previous visit, relative to normal range	integer	8			Set to missing
BASE	_CK	Creatine Kinase (U/L) change from previous visit, relative to normal range	integer	8			Set to missing
BASE	_CL	Chloride (mmol/L) change from previous visit, relative to normal range	integer	8			Set to missing
BASE	_CREAT	Creatinine (umol/L) change from previous visit, relative to normal range	integer	8			Set to missing
BASE	_GGT	Gamma Glutamyl Transferase (U/L) change from previous visit, relative to normal range	integer	8			Set to missing
BASE	_GLUC	Glucose (mmol/L) change from previous visit, relative to normal range	integer	8			Set to missing
BASE	_K	Potassium (mmol/L) change from previous visit, relative to normal range	integer	8			Set to missing

Source Variable	Where PARAMCD=	Where PARAM=	Type	Length	Display Format	Code List / Controlled Term	Source/Derivation/Comments
BASE	_PHOS	Phosphate (mmol/L) change from previous visit, relative to normal range	integer	8			Set to missing
BASE	_PROT	Protein (g/L) change from previous visit, relative to normal range	integer	8			Set to missing
BASE	_SODIUM	Sodium (mmol/L) change from previous visit, relative to normal range	integer	8			Set to missing
BASE	_URATE	Urate (umol/L) change from previous visit, relative to normal range	integer	8			Set to missing

Parameter Value List - ADLBC [BNRIND]

Source Variable	Where PARAMCD=	Where PARAM=	Type	Length	Display Format	Code List / Controlled Term	Source/Derivation/Comments
BNRIND	ALB	Albumin (g/L)	text	1		LNH	ADLBC.ANRIND when ADLBC.ABLFL=Y
BNRIND	ALP	Alkaline Phosphatase (U/L)	text	1		LNH	ADLBC.ANRIND when ADLBC.ABLFL=Y

Source Variable	Where PARAMCD=	Where PARAM=	Type	Length	Display Format	Code List / Controlled Term	Source/Derivation/Comments
BNRIND	ALT	Alanine Aminotransferase (U/L)	text	1		LNH	ADLBC.ANRIND when ADLBC.ABLFL=Y
BNRIND	AST	Aspartate Aminotransferase (U/L)	text	1		LNH	ADLBC.ANRIND when ADLBC.ABLFL=Y
BNRIND	BILI	Bilirubin (umol/L)	text	1		LNH	ADLBC.ANRIND when ADLBC.ABLFL=Y
BNRIND	BUN	Blood Urea Nitrogen (mmol/L)	text	1		LNH	ADLBC.ANRIND when ADLBC.ABLFL=Y
BNRIND	CA	Calcium (mmol/L)	text	1		LNH	ADLBC.ANRIND when ADLBC.ABLFL=Y
BNRIND	CHOL	Cholesterol (mmol/L)	text	1		LNH	ADLBC.ANRIND when ADLBC.ABLFL=Y
BNRIND	CK	Creatine Kinase (U/L)	text	1		LNH	ADLBC.ANRIND when ADLBC.ABLFL=Y
BNRIND	CL	Chloride (mmol/L)	text	1		LNH	ADLBC.ANRIND when ADLBC.ABLFL=Y
BNRIND	CREAT	Creatinine (umol/L)	text	1		LNH	ADLBC.ANRIND when ADLBC.ABLFL=Y
BNRIND	GGT	Gamma Glutamyl Transferase (U/L)	text	1		LNH	ADLBC.ANRIND when ADLBC.ABLFL=Y

Source Variable	Where PARAMCD=	Where PARAM=	Type	Length	Display Format	Code List / Controlled Term	Source/Derivation/Comments
BNRIND	GLUC	Glucose (mmol/L)	text	1		LNH	ADLBC.ANRIND when ADLBC.ABLFL=Y
BNRIND	K	Potassium (mmol/L)	text	1		LNH	ADLBC.ANRIND when ADLBC.ABLFL=Y
BNRIND	PHOS	Phosphate (mmol/L)	text	1		LNH	ADLBC.ANRIND when ADLBC.ABLFL=Y
BNRIND	PROT	Protein (g/L)	text	1		LNH	ADLBC.ANRIND when ADLBC.ABLFL=Y
BNRIND	SODIUM	Sodium (mmol/L)	text	1		LNH	ADLBC.ANRIND when ADLBC.ABLFL=Y
BNRIND	URATE	Urate (umol/L)	text	1		LNH	ADLBC.ANRIND when ADLBC.ABLFL=Y
BNRIND	_ALB	Albumin (g/L) change from previous visit, relative to normal range	text	1			Set to missing
BNRIND	_ALP	Alkaline Phosphatase (U/L) change from previous visit, relative to normal range	text	1			Set to missing
BNRIND	_ALT	Alanine Aminotransferase (U/L) change from previous visit, relative to normal range	text	1			Set to missing

Source Variable	Where PARAMCD=	Where PARAM=	Type	Length	Display Format	Code List / Controlled Term	Source/Derivation/Comments
BNRIND	_AST	Aspartate Aminotransferase (U/L) change from previous visit, relative to normal range	text	1			Set to missing
BNRIND	_BILI	Bilirubin (umol/L) change from previous visit, relative to normal range	text	1			Set to missing
BNRIND	_BUN	Blood Urea Nitrogen (mmol/L) change from previous visit, relative to normal range	text	1			Set to missing
BNRIND	_CA	Calcium (mmol/L) change from previous visit, relative to normal range	text	1			Set to missing
BNRIND	_CHOL	Cholesterol (mmol/L) change from previous visit, relative to normal range	text	1			Set to missing
BNRIND	_CK	Creatine Kinase (U/L) change from previous visit, relative to normal range	text	1			Set to missing
BNRIND	_CL	Chloride (mmol/L) change from previous visit, relative to normal range	text	1			Set to missing

Source Variable	Where PARAMCD=	Where PARAM=	Type	Length	Display Format	Code List / Controlled Term	Source/Derivation/Comments
BNRIND	_CREAT	Creatinine (umol/L) change from previous visit, relative to normal range	text	1			Set to missing
BNRIND	_GGT	Gamma Glutamyl Transferase (U/L) change from previous visit, relative to normal range	text	1			Set to missing
BNRIND	_GLUC	Glucose (mmol/L) change from previous visit, relative to normal range	text	1			Set to missing
BNRIND	_K	Potassium (mmol/L) change from previous visit, relative to normal range	text	1			Set to missing
BNRIND	_PHOS	Phosphate (mmol/L) change from previous visit, relative to normal range	text	1			Set to missing
BNRIND	_PROT	Protein (g/L) change from previous visit, relative to normal range	text	1			Set to missing
BNRIND	_SODIUM	Sodium (mmol/L) change from previous visit, relative to normal range	text	1			Set to missing

Source Variable	Where PARAMCD=	Where PARAM=	Type	Length	Display Format	Code List / Controlled Term	Source/Derivation/Comments
BNRIND	_URATE	Urate (umol/L) change from previous visit, relative to normal range	text	1			Set to missing

Parameter Value List - ADLBC [CHG]

Source Variable	Where PARAMCD=	Where PARAM=	Type	Length	Display Format	Code List / Controlled Term	Source/Derivation/Comments
CHG	ALB	Albumin (g/L)	integer	8			AVAL-BASE
CHG	ALP	Alkaline Phosphatase (U/L)	integer	8			AVAL-BASE
CHG	ALT	Alanine Aminotransferase (U/L)	integer	8			AVAL-BASE
CHG	AST	Aspartate Aminotransferase (U/L)	integer	8			AVAL-BASE
CHG	BILI	Bilirubin (umol/L)	float	8	6.2		AVAL-BASE
CHG	BUN	Blood Urea Nitrogen (mmol/L)	float	8	7.3		AVAL-BASE
CHG	CA	Calcium (mmol/L)	float	8	8.5		AVAL-BASE
CHG	CHOL	Cholesterol (mmol/L)	float	8	8.5		AVAL-BASE

Source Variable	Where PARAMCD=	Where PARAM=	Type	Length	Display Format	Code List / Controlled Term	Source/Derivation/Comments
CHG	CK	Creatine Kinase (U/L)	integer	8			AVAL-BASE
CHG	CL	Chloride (mmol/L)	integer	8			AVAL-BASE
CHG	CREAT	Creatinine (umol/L)	float	8	6.2		AVAL-BASE
CHG	GGT	Gamma Glutamyl Transferase (U/L)	integer	8			AVAL-BASE
CHG	GLUC	Glucose (mmol/L)	float	8	8.5		AVAL-BASE
CHG	K	Potassium (mmol/L)	float	8	4.1		AVAL-BASE
CHG	PHOS	Phosphate (mmol/L)	float	8	7.5		AVAL-BASE
CHG	PROT	Protein (g/L)	integer	8			AVAL-BASE
CHG	SODIUM	Sodium (mmol/L)	integer	8			AVAL-BASE
CHG	URATE	Urate (umol/L)	float	8	7.3		AVAL-BASE
CHG	_ALB	Albumin (g/L) change from previous visit, relative to normal range	integer	8			Set to missing
CHG	_ALP	Alkaline Phosphatase (U/L) change from previous visit, relative to normal range	integer	8			Set to missing

Source Variable	Where PARAMCD=	Where PARAM=	Type	Length	Display Format	Code List / Controlled Term	Source/Derivation/Comments
CHG	_ALT	Alanine Aminotransferase (U/L) change from previous visit, relative to normal range	integer	8			Set to missing
CHG	_AST	Aspartate Aminotransferase (U/L) change from previous visit, relative to normal range	integer	8			Set to missing
CHG	_BILI	Bilirubin (umol/L) change from previous visit, relative to normal range	integer	8			Set to missing
CHG	_BUN	Blood Urea Nitrogen (mmol/L) change from previous visit, relative to normal range	integer	8			Set to missing
CHG	_CA	Calcium (mmol/L) change from previous visit, relative to normal range	integer	8			Set to missing
CHG	_CHOL	Cholesterol (mmol/L) change from previous visit, relative to normal range	integer	8			Set to missing
CHG	_CK	Creatine Kinase (U/L) change from previous visit, relative to normal range	integer	8			Set to missing

Source Variable	Where PARAMCD=	Where PARAM=	Type	Length	Display Format	Code List / Controlled Term	Source/Derivation/Comments
CHG	_CL	Chloride (mmol/L) change from previous visit, relative to normal range	integer	8			Set to missing
CHG	_CREAT	Creatinine (umol/L) change from previous visit, relative to normal range	integer	8			Set to missing
CHG	_GGT	Gamma Glutamyl Transferase (U/L) change from previous visit, relative to normal range	integer	8			Set to missing
CHG	_GLUC	Glucose (mmol/L) change from previous visit, relative to normal range	integer	8			Set to missing
CHG	_K	Potassium (mmol/L) change from previous visit, relative to normal range	integer	8			Set to missing
CHG	_PHOS	Phosphate (mmol/L) change from previous visit, relative to normal range	integer	8			Set to missing
CHG	_PROT	Protein (g/L) change from previous visit, relative to normal range	integer	8			Set to missing

Source Variable	Where PARAMCD=	Where PARAM=	Type	Length	Display Format	Code List / Controlled Term	Source/Derivation/Comments
CHG	_SODIUM	Sodium (mmol/L) change from previous visit, relative to normal range	integer	8			Set to missing
CHG	_URATE	Urate (umol/L) change from previous visit, relative to normal range	integer	8			Set to missing

Parameter Value List - ADLBH [A1HI]

Source Variable	Where PARAMCD=	Where PARAM=	Type	Length	Display Format	Code List / Controlled Term	Source/Derivation/Comments
A1HI	ANISO	Anisocytes	integer	8			LB.LBSTNRHI
A1HI	BASO	Basophils (GI/L)	float	8	4.2		LB.LBSTNRHI
A1HI	EOS	Eosinophils (GI/L)	float	8	4.2		LB.LBSTNRHI
A1HI	MCHC	Ery. Mean Corpuscular HGB Concentration (mmol/L)	float	8	7.4		LB.LBSTNRHI
A1HI	MCH	Ery. Mean Corpuscular Hemoglobin (fmol(Fe))	float	8	7.5		LB.LBSTNRHI
A1HI	MCV	Ery. Mean Corpuscular Volume (fL)	integer	8			LB.LBSTNRHI

Source Variable	Where PARAMCD=	Where PARAM=	Type	Length	Display Format	Code List / Controlled Term	Source/Derivation/Comments
A1HI	RBC	Erythrocytes (TI/L)	float	8	3.1		LB.LBSTNRHI
A1HI	HCT	Hematocrit	float	8	4.2		LB.LBSTNRHI
A1HI	HGB	Hemoglobin (mmol/L)	float	8	8.5		LB.LBSTNRHI
A1HI	WBC	Leukocytes (GI/L)	float	8	5.2		LB.LBSTNRHI
A1HI	LYM	Lymphocytes (GI/L)	float	8	4.2		LB.LBSTNRHI
A1HI	MACROCY	Macrocytes	integer	8			LB.LBSTNRHI
A1HI	MICROCY	Microcytes	integer	8			LB.LBSTNRHI
A1HI	MONO	Monocytes (GI/L)	float	8	4.2		LB.LBSTNRHI
A1HI	PLAT	Platelet (GI/L)	integer	8			LB.LBSTNRHI
A1HI	POIKILO	Poikilocytes	integer	8			LB.LBSTNRHI
A1HI	POLYCHR	Polychromasia	integer	8			LB.LBSTNRHI
A1HI	_ANISO	Anisocytes change from previous visit, relative to normal range	integer	8			Set to missing

Source Variable	Where PARAMCD=	Where PARAM=	Type	Length	Display Format	Code List / Controlled Term	Source/Derivation/Comments
A1HI	_BASO	Basophils (GI/L) change from previous visit, relative to normal range	integer	8			Set to missing
A1HI	_EOS	Eosinophils (GI/L) change from previous visit, relative to normal range	integer	8			Set to missing
A1HI	_MCHC	Ery. Mean Corpuscular HGB Concentration (mmol/L) change from previous visit, relative to normal rang	integer	8			Set to missing
A1HI	_MCH	Ery. Mean Corpuscular Hemoglobin (fmol(Fe)) change from previous visit, relative to normal range	integer	8			Set to missing
A1HI	_MCV	Ery. Mean Corpuscular Volume (fL) change from previous visit, relative to normal range	integer	8			Set to missing
A1HI	_RBC	Erythrocytes (TI/L) change from previous visit, relative to normal range	integer	8			Set to missing
A1HI	_HCT	Hematocrit change from previous visit, relative to normal range	integer	8			Set to missing

Source Variable	Where PARAMCD=	Where PARAM=	Type	Length	Display Format	Code List / Controlled Term	Source/Derivation/Comments
A1HI	_HGB	Hemoglobin (mmol/L) change from previous visit, relative to normal range	integer	8			Set to missing
A1HI	_WBC	Leukocytes (GI/L) change from previous visit, relative to normal range	integer	8			Set to missing
A1HI	_LYM	Lymphocytes (GI/L) change from previous visit, relative to normal range	integer	8			Set to missing
A1HI	_MACROCY	Macrocytes change from previous visit, relative to normal range	integer	8			Set to missing
A1HI	_MICROCY	Microcytes change from previous visit, relative to normal range	integer	8			Set to missing
A1HI	_MONO	Monocytes (GI/L) change from previous visit, relative to normal range	integer	8			Set to missing
A1HI	_PLAT	Platelet (GI/L) change from previous visit, relative to normal range	integer	8			Set to missing

Source Variable	Where PARAMCD=	Where PARAM=	Type	Length	Display Format	Code List / Controlled Term	Source/Derivation/Comments
A1HI	_POIKILO	Poikilocytes change from previous visit, relative to normal range	integer	8			Set to missing
A1HI	_POLYCHR	Polychromasia change from previous visit, relative to normal range	integer	8			Set to missing

Parameter Value List - ADLBH [A1LO]

Source Variable	Where PARAMCD=	Where PARAM=	Type	Length	Display Format	Code List / Controlled Term	Source/Derivation/Comments
A1LO	ANISO	Anisocytes	integer	8			LB.LBSTNRLO
A1LO	BASO	Basophils (GI/L)	float	8	4.2		LB.LBSTNRLO
A1LO	EOS	Eosinophils (GI/L)	float	8	4.2		LB.LBSTNRLO
A1LO	MCHC	Ery. Mean Corpuscular HGB Concentration (mmol/L)	float	8	7.4		LB.LBSTNRLO
A1LO	MCH	Ery. Mean Corpuscular Hemoglobin (fmol(Fe))	float	8	7.5		LB.LBSTNRLO
A1LO	MCV	Ery. Mean Corpuscular Volume (fL)	integer	8			LB.LBSTNRLO

Source Variable	Where PARAMCD=	Where PARAM=	Type	Length	Display Format	Code List / Controlled Term	Source/Derivation/Comments
A1LO	RBC	Erythrocytes (TI/L)	float	8	3.1		LB.LBSTNRLO
A1LO	HCT	Hematocrit	float	8	4.2		LB.LBSTNRLO
A1LO	HGB	Hemoglobin (mmol/L)	float	8	8.5		LB.LBSTNRLO
A1LO	WBC	Leukocytes (GI/L)	float	8	5.2		LB.LBSTNRLO
A1LO	LYM	Lymphocytes (GI/L)	float	8	4.2		LB.LBSTNRLO
A1LO	MACROCY	Macrocytes	integer	8			LB.LBSTNRLO
A1LO	MICROCY	Microcytes	integer	8			LB.LBSTNRLO
A1LO	MONO	Monocytes (GI/L)	float	8	4.2		LB.LBSTNRLO
A1LO	PLAT	Platelet (GI/L)	integer	8			LB.LBSTNRLO
A1LO	POIKILO	Poikilocytes	integer	8			LB.LBSTNRLO
A1LO	POLYCHR	Polychromasia	integer	8			LB.LBSTNRLO
A1LO	_ANISO	Anisocytes change from previous visit, relative to normal range	integer	8			Set to missing

Source Variable	Where PARAMCD=	Where PARAM=	Type	Length	Display Format	Code List / Controlled Term	Source/Derivation/Comments
A1LO	_BASO	Basophils (GI/L) change from previous visit, relative to normal range	integer	8			Set to missing
A1LO	_EOS	Eosinophils (GI/L) change from previous visit, relative to normal range	integer	8			Set to missing
A1LO	_MCHC	Ery. Mean Corpuscular HGB Concentration (mmol/L) change from previous visit, relative to normal rang	integer	8			Set to missing
A1LO	_MCH	Ery. Mean Corpuscular Hemoglobin (fmol(Fe)) change from previous visit, relative to normal range	integer	8			Set to missing
A1LO	_MCV	Ery. Mean Corpuscular Volume (fL) change from previous visit, relative to normal range	integer	8			Set to missing
A1LO	_RBC	Erythrocytes (TI/L) change from previous visit, relative to normal range	integer	8			Set to missing
A1LO	_HCT	Hematocrit change from previous visit, relative to normal range	integer	8			Set to missing

Source Variable	Where PARAMCD=	Where PARAM=	Type	Length	Display Format	Code List / Controlled Term	Source/Derivation/Comments
A1LO	_HGB	Hemoglobin (mmol/L) change from previous visit, relative to normal range	integer	8			Set to missing
A1LO	_WBC	Leukocytes (GI/L) change from previous visit, relative to normal range	integer	8			Set to missing
A1LO	_LYM	Lymphocytes (GI/L) change from previous visit, relative to normal range	integer	8			Set to missing
A1LO	_MACROCY	Macrocytes change from previous visit, relative to normal range	integer	8			Set to missing
A1LO	_MICROCY	Microcytes change from previous visit, relative to normal range	integer	8			Set to missing
A1LO	_MONO	Monocytes (GI/L) change from previous visit, relative to normal range	integer	8			Set to missing
A1LO	_PLAT	Platelet (GI/L) change from previous visit, relative to normal range	integer	8			Set to missing

Source Variable	Where PARAMCD=	Where PARAM=	Type	Length	Display Format	Code List / Controlled Term	Source/Derivation/Comments
A1LO	_POIKILO	Poikilocytes change from previous visit, relative to normal range	integer	8			Set to missing
A1LO	_POLYCHR	Polychromasia change from previous visit, relative to normal range	integer	8			Set to missing

Parameter Value List - ADLBH [ABLFL]

Source Variable	Where PARAMCD=	Where PARAM=	Type	Length	Display Format	Code List / Controlled Term	Source/Derivation/Comments
ABLFL	ANISO	Anisocytes	text	1		Y_BLANK	Y if VISITNUM=1, null otherwise
ABLFL	BASO	Basophils (GI/L)	text	1		Y_BLANK	Y if VISITNUM=1, null otherwise
ABLFL	EOS	Eosinophils (GI/L)	text	1		Y_BLANK	Y if VISITNUM=1, null otherwise
ABLFL	MCHC	Ery. Mean Corpuscular HGB Concentration (mmol/L)	text	1		Y_BLANK	Y if VISITNUM=1, null otherwise
ABLFL	MCH	Ery. Mean Corpuscular Hemoglobin (fmol(Fe))	text	1		Y_BLANK	Y if VISITNUM=1, null otherwise
ABLFL	MCV	Ery. Mean Corpuscular Volume (fL)	text	1		Y_BLANK	Y if VISITNUM=1, null otherwise

Source Variable	Where PARAMCD=	Where PARAM=	Type	Length	Display Format	Code List / Controlled Term	Source/Derivation/Comments
ABLFL	RBC	Erythrocytes (TI/L)	text	1		Y_BLANK	Y if VISITNUM=1, null otherwise
ABLFL	HCT	Hematocrit	text	1		Y_BLANK	Y if VISITNUM=1, null otherwise
ABLFL	HGB	Hemoglobin (mmol/L)	text	1		Y_BLANK	Y if VISITNUM=1, null otherwise
ABLFL	WBC	Leukocytes (GI/L)	text	1		Y_BLANK	Y if VISITNUM=1, null otherwise
ABLFL	LYM	Lymphocytes (GI/L)	text	1		Y_BLANK	Y if VISITNUM=1, null otherwise
ABLFL	MACROCY	Macrocytes	text	1		Y_BLANK	Y if VISITNUM=1, null otherwise
ABLFL	MICROCY	Microcytes	text	1		Y_BLANK	Y if VISITNUM=1, null otherwise
ABLFL	MONO	Monocytes (GI/L)	text	1		Y_BLANK	Y if VISITNUM=1, null otherwise
ABLFL	PLAT	Platelet (GI/L)	text	1		Y_BLANK	Y if VISITNUM=1, null otherwise
ABLFL	POIKILO	Poikilocytes	text	1		Y_BLANK	Y if VISITNUM=1, null otherwise
ABLFL	POLYCHR	Polychromasia	text	1		Y_BLANK	Y if VISITNUM=1, null otherwise
ABLFL	_ANISO	Anisocytes change from previous visit, relative to normal range	text	1			Set to missing

Source Variable	Where PARAMCD=	Where PARAM=	Type	Length	Display Format	Code List / Controlled Term	Source/Derivation/Comments
ABLFL	_BASO	Basophils (GI/L) change from previous visit, relative to normal range	text	1			Set to missing
ABLFL	_EOS	Eosinophils (GI/L) change from previous visit, relative to normal range	text	1			Set to missing
ABLFL	_MCHC	Ery. Mean Corpuscular HGB Concentration (mmol/L) change from previous visit, relative to normal rang	text	1			Set to missing
ABLFL	_MCH	Ery. Mean Corpuscular Hemoglobin (fmol(Fe)) change from previous visit, relative to normal range	text	1			Set to missing
ABLFL	_MCV	Ery. Mean Corpuscular Volume (fL) change from previous visit, relative to normal range	text	1			Set to missing
ABLFL	_RBC	Erythrocytes (TI/L) change from previous visit, relative to normal range	text	1			Set to missing
ABLFL	_HCT	Hematocrit change from previous visit, relative to normal range	text	1			Set to missing

Source Variable	Where PARAMCD=	Where PARAM=	Type	Length	Display Format	Code List / Controlled Term	Source/Derivation/Comments
ABLFL	_HGB	Hemoglobin (mmol/L) change from previous visit, relative to normal range	text	1			Set to missing
ABLFL	_WBC	Leukocytes (GI/L) change from previous visit, relative to normal range	text	1			Set to missing
ABLFL	_LYM	Lymphocytes (GI/L) change from previous visit, relative to normal range	text	1			Set to missing
ABLFL	_MACROCY	Macrocytes change from previous visit, relative to normal range	text	1			Set to missing
ABLFL	_MICROCY	Microcytes change from previous visit, relative to normal range	text	1			Set to missing
ABLFL	_MONO	Monocytes (GI/L) change from previous visit, relative to normal range	text	1			Set to missing
ABLFL	_PLAT	Platelet (GI/L) change from previous visit, relative to normal range	text	1			Set to missing

Source Variable	Where PARAMCD=	Where PARAM=	Type	Length	Display Format	Code List / Controlled Term	Source/Derivation/Comments
ABLFL	_POIKILO	Poikilocytes change from previous visit, relative to normal range	text	1			Set to missing
ABLFL	_POLYCHR	Polychromasia change from previous visit, relative to normal range	text	1			Set to missing

Parameter Value List - ADLBH [ANL01FL]

Source Variable	Where PARAMCD=	Where PARAM=	Type	Length	Display Format	Code List / Controlled Term	Source/Derivation/Comments
ANL01FL	ANISO	Anisocytes	text	1		Y_BLANK	Y if this ALBTRVAL is the largest for the subject in Visits 4-12 inclusive, null otherwise (if this value of ALBTRVAL occurs more than once, the first one is flagged)
ANL01FL	BASO	Basophils (GI/L)	text	1		Y_BLANK	Y if this ALBTRVAL is the largest for the subject in Visits 4-12 inclusive, null otherwise (if this value of ALBTRVAL occurs more than once, the first one is flagged)
ANL01FL	EOS	Eosinophils (GI/L)	text	1		Y_BLANK	Y if this ALBTRVAL is the largest for the subject in Visits 4-12 inclusive, null otherwise (if this value of ALBTRVAL occurs more than once, the first one is flagged)

Source Variable	Where PARAMCD=	Where PARAM=	Type	Length	Display Format	Code List / Controlled Term	Source/Derivation/Comments
ANL01FL	MCHC	Ery. Mean Corpuscular HGB Concentration (mmol/L)	text	1		Y_BLANK	Y if this ALBTRVAL is the largest for the subject in Visits 4-12 inclusive, null otherwise (if this value of ALBTRVAL occurs more than once, the first one is flagged)
ANL01FL	MCH	Ery. Mean Corpuscular Hemoglobin (fmol(Fe))	text	1		Y_BLANK	Y if this ALBTRVAL is the largest for the subject in Visits 4-12 inclusive, null otherwise (if this value of ALBTRVAL occurs more than once, the first one is flagged)
ANL01FL	MCV	Ery. Mean Corpuscular Volume (fL)	text	1		Y_BLANK	Y if this ALBTRVAL is the largest for the subject in Visits 4-12 inclusive, null otherwise (if this value of ALBTRVAL occurs more than once, the first one is flagged)
ANL01FL	RBC	Erythrocytes (TI/L)	text	1		Y_BLANK	Y if this ALBTRVAL is the largest for the subject in Visits 4-12 inclusive, null otherwise (if this value of ALBTRVAL occurs more than once, the first one is flagged)
ANL01FL	HCT	Hematocrit	text	1		Y_BLANK	Y if this ALBTRVAL is the largest for the subject in Visits 4-12 inclusive, null otherwise (if this value of ALBTRVAL occurs more than once, the first one is flagged)
ANL01FL	HGB	Hemoglobin (mmol/L)	text	1		Y_BLANK	Y if this ALBTRVAL is the largest for the subject in Visits 4-12 inclusive, null otherwise (if this value of ALBTRVAL occurs more than once, the first one is flagged)

Source Variable	Where PARAMCD=	Where PARAM=	Type	Length	Display Format	Code List / Controlled Term	Source/Derivation/Comments
ANL01FL	WBC	Leukocytes (GI/L)	text	1		Y_BLANK	Y if this ALBTRVAL is the largest for the subject in Visits 4-12 inclusive, null otherwise (if this value of ALBTRVAL occurs more than once, the first one is flagged)
ANL01FL	LYM	Lymphocytes (GI/L)	text	1		Y_BLANK	Y if this ALBTRVAL is the largest for the subject in Visits 4-12 inclusive, null otherwise (if this value of ALBTRVAL occurs more than once, the first one is flagged)
ANL01FL	MACROCY	Macrocytes	text	1		Y_BLANK	Y if this ALBTRVAL is the largest for the subject in Visits 4-12 inclusive, null otherwise (if this value of ALBTRVAL occurs more than once, the first one is flagged)
ANL01FL	MICROCY	Microcytes	text	1		Y_BLANK	Y if this ALBTRVAL is the largest for the subject in Visits 4-12 inclusive, null otherwise (if this value of ALBTRVAL occurs more than once, the first one is flagged)
ANL01FL	MONO	Monocytes (GI/L)	text	1		Y_BLANK	Y if this ALBTRVAL is the largest for the subject in Visits 4-12 inclusive, null otherwise (if this value of ALBTRVAL occurs more than once, the first one is flagged)
ANL01FL	PLAT	Platelet (GI/L)	text	1		Y_BLANK	Y if this ALBTRVAL is the largest for the subject in Visits 4-12 inclusive, null otherwise (if this value of ALBTRVAL occurs more than once, the first one is flagged)

Source Variable	Where PARAMCD=	Where PARAM=	Type	Length	Display Format	Code List / Controlled Term	Source/Derivation/Comments
ANL01FL	POIKILO	Poikilocytes	text	1		Y_BLANK	Y if this ALBTRVAL is the largest for the subject in Visits 4-12 inclusive, null otherwise (if this value of ALBTRVAL occurs more than once, the first one is flagged)
ANL01FL	POLYCHR	Polychromasia	text	1		Y_BLANK	Y if this ALBTRVAL is the largest for the subject in Visits 4-12 inclusive, null otherwise (if this value of ALBTRVAL occurs more than once, the first one is flagged)
ANL01FL	_ANISO	Anisocytes change from previous visit, relative to normal range	text	1		Y_BLANK	Y if the absolute value of this AVAL is the largest for the subject for VISITS 4-12 inclusive, null otherwise; only the first on-treatment AVAL that has absolute val equal to the max is flagged
ANL01FL	_BASO	Basophils (GI/L) change from previous visit, relative to normal range	text	1		Y_BLANK	Y if the absolute value of this AVAL is the largest for the subject for VISITS 4-12 inclusive, null otherwise; only the first on-treatment AVAL that has absolute val equal to the max is flagged
ANL01FL	_EOS	Eosinophils (GI/L) change from previous visit, relative to normal range	text	1		Y_BLANK	Y if the absolute value of this AVAL is the largest for the subject for VISITS 4-12 inclusive, null otherwise; only the first on-treatment AVAL that has absolute val equal to the max is flagged

Source Variable	Where PARAMCD=	Where PARAM=	Type	Length	Display Format	Code List / Controlled Term	Source/Derivation/Comments
ANL01FL	_MCHC	Ery. Mean Corpuscular HGB Concentration (mmol/L) change from previous visit, relative to normal rang	text	1		Y_BLANK	Y if the absolute value of this AVAL is the largest for the subject for VISITS 4-12 inclusive, null otherwise; only the first on-treatment AVAL that has absolute val equal to the max is flagged
ANL01FL	_MCH	Ery. Mean Corpuscular Hemoglobin (fmol(Fe)) change from previous visit, relative to normal range	text	1		Y_BLANK	Y if the absolute value of this AVAL is the largest for the subject for VISITS 4-12 inclusive, null otherwise; only the first on-treatment AVAL that has absolute val equal to the max is flagged
ANL01FL	_MCV	Ery. Mean Corpuscular Volume (fL) change from previous visit, relative to normal range	text	1		Y_BLANK	Y if the absolute value of this AVAL is the largest for the subject for VISITS 4-12 inclusive, null otherwise; only the first on-treatment AVAL that has absolute val equal to the max is flagged
ANL01FL	_RBC	Erythrocytes (TI/L) change from previous visit, relative to normal range	text	1		Y_BLANK	Y if the absolute value of this AVAL is the largest for the subject for VISITS 4-12 inclusive, null otherwise; only the first on-treatment AVAL that has absolute val equal to the max is flagged

Source Variable	Where PARAMCD=	Where PARAM=	Type	Length	Display Format	Code List / Controlled Term	Source/Derivation/Comments
ANL01FL	_HCT	Hematocrit change from previous visit, relative to normal range	text	1		Y_BLANK	Y if the absolute value of this AVAL is the largest for the subject for VISITS 4-12 inclusive, null otherwise; only the first on-treatment AVAL that has absolute val equal to the max is flagged
ANL01FL	_HGB	Hemoglobin (mmol/L) change from previous visit, relative to normal range	text	1		Y_BLANK	Y if the absolute value of this AVAL is the largest for the subject for VISITS 4-12 inclusive, null otherwise; only the first on-treatment AVAL that has absolute val equal to the max is flagged
ANL01FL	_WBC	Leukocytes (GI/L) change from previous visit, relative to normal range	text	1		Y_BLANK	Y if the absolute value of this AVAL is the largest for the subject for VISITS 4-12 inclusive, null otherwise; only the first on-treatment AVAL that has absolute val equal to the max is flagged
ANL01FL	_LYM	Lymphocytes (GI/L) change from previous visit, relative to normal range	text	1		Y_BLANK	Y if the absolute value of this AVAL is the largest for the subject for VISITS 4-12 inclusive, null otherwise; only the first on-treatment AVAL that has absolute val equal to the max is flagged
ANL01FL	_MACROCY	Macrocytes change from previous visit, relative to normal range	text	1		Y_BLANK	Y if the absolute value of this AVAL is the largest for the subject for VISITS 4-12 inclusive, null otherwise; only the first on-treatment AVAL that has absolute val equal to the max is flagged

Source Variable	Where PARAMCD=	Where PARAM=	Type	Length	Display Format	Code List / Controlled Term	Source/Derivation/Comments
ANL01FL	_MICROCY	Microcytes change from previous visit, relative to normal range	text	1		Y_BLANK	Y if the absolute value of this AVAL is the largest for the subject for VISITS 4-12 inclusive, null otherwise; only the first on-treatment AVAL that has absolute val equal to the max is flagged
ANL01FL	_MONO	Monocytes (GI/L) change from previous visit, relative to normal range	text	1		Y_BLANK	Y if the absolute value of this AVAL is the largest for the subject for VISITS 4-12 inclusive, null otherwise; only the first on-treatment AVAL that has absolute val equal to the max is flagged
ANL01FL	_PLAT	Platelet (GI/L) change from previous visit, relative to normal range	text	1		Y_BLANK	Y if the absolute value of this AVAL is the largest for the subject for VISITS 4-12 inclusive, null otherwise; only the first on-treatment AVAL that has absolute val equal to the max is flagged
ANL01FL	_POIKILO	Poikilocytes change from previous visit, relative to normal range	text	1		Y_BLANK	Y if the absolute value of this AVAL is the largest for the subject for VISITS 4-12 inclusive, null otherwise; only the first on-treatment AVAL that has absolute val equal to the max is flagged
ANL01FL	_POLYCHR	Polychromasia change from previous visit, relative to normal range	text	1		Y_BLANK	Y if the absolute value of this AVAL is the largest for the subject for VISITS 4-12 inclusive, null otherwise; only the first on-treatment AVAL that has absolute val equal to the max is flagged

Parameter Value List - ADLBH [ANRIND]

Source Variable	Where PARAMCD=	Where PARAM=	Type	Length	Display Format	Code List / Controlled Term	Source/Derivation/Comments
ANRIND	ANISO	Anisocytes	text	1		LNH	if AVAL < (0.5*LBSTNRLO) then ANRIND='L'; if LAVAL > 1.5* LBSTNRHI then ANRIND='H'; ANRIND='N' otherwise. Used for shift tables
ANRIND	BASO	Basophils (GI/L)	text	1		LNH	if AVAL < (0.5*LBSTNRLO) then ANRIND='L'; if LAVAL > 1.5* LBSTNRHI then ANRIND='H'; ANRIND='N' otherwise. Used for shift tables
ANRIND	EOS	Eosinophils (GI/L)	text	1		LNH	if AVAL < (0.5*LBSTNRLO) then ANRIND='L'; if LAVAL > 1.5* LBSTNRHI then ANRIND='H'; ANRIND='N' otherwise. Used for shift tables
ANRIND	MCHC	Ery. Mean Corpuscular HGB Concentration (mmol/L)	text	1		LNH	if AVAL < (0.5*LBSTNRLO) then ANRIND='L'; if LAVAL > 1.5* LBSTNRHI then ANRIND='H'; ANRIND='N' otherwise. Used for shift tables
ANRIND	MCH	Ery. Mean Corpuscular Hemoglobin (fmol(Fe))	text	1		LNH	if AVAL < (0.5*LBSTNRLO) then ANRIND='L'; if LAVAL > 1.5* LBSTNRHI then ANRIND='H'; ANRIND='N' otherwise. Used for shift tables
ANRIND	MCV	Ery. Mean Corpuscular Volume (fL)	text	1		LNH	if AVAL < (0.5*LBSTNRLO) then ANRIND='L'; if LAVAL > 1.5* LBSTNRHI then ANRIND='H'; ANRIND='N' otherwise. Used for shift tables

Source Variable	Where PARAMCD=	Where PARAM=	Type	Length	Display Format	Code List / Controlled Term	Source/Derivation/Comments
ANRIND	RBC	Erythrocytes (TI/L)	text	1		LNH	if AVAL < (0.5*LBSTNRLO) then ANRIND='L'; if LAVAL > 1.5* LBSTNRHI then ANRIND='H'; ANRIND='N' otherwise. Used for shift tables
ANRIND	HCT	Hematocrit	text	1		LNH	if AVAL < (0.5*LBSTNRLO) then ANRIND='L'; if LAVAL > 1.5* LBSTNRHI then ANRIND='H'; ANRIND='N' otherwise. Used for shift tables
ANRIND	HGB	Hemoglobin (mmol/L)	text	1		LNH	if AVAL < (0.5*LBSTNRLO) then ANRIND='L'; if LAVAL > 1.5* LBSTNRHI then ANRIND='H'; ANRIND='N' otherwise. Used for shift tables
ANRIND	WBC	Leukocytes (GI/L)	text	1		LNH	if AVAL < (0.5*LBSTNRLO) then ANRIND='L'; if LAVAL > 1.5* LBSTNRHI then ANRIND='H'; ANRIND='N' otherwise. Used for shift tables
ANRIND	LYM	Lymphocytes (GI/L)	text	1		LNH	if AVAL < (0.5*LBSTNRLO) then ANRIND='L'; if LAVAL > 1.5* LBSTNRHI then ANRIND='H'; ANRIND='N' otherwise. Used for shift tables
ANRIND	MACROCY	Macrocytes	text	1		LNH	if AVAL < (0.5*LBSTNRLO) then ANRIND='L'; if LAVAL > 1.5* LBSTNRHI then ANRIND='H'; ANRIND='N' otherwise. Used for shift tables

Source Variable	Where PARAMCD=	Where PARAM=	Type	Length	Display Format	Code List / Controlled Term	Source/Derivation/Comments
ANRIND	MICROCY	Microcytes	text	1		LNH	if AVAL < (0.5*LBSTNRLO) then ANRIND='L'; if LAVAL > 1.5* LBSTNRHI then ANRIND='H'; ANRIND='N' otherwise. Used for shift tables
ANRIND	MONO	Monocytes (GI/L)	text	1		LNH	if AVAL < (0.5*LBSTNRLO) then ANRIND='L'; if LAVAL > 1.5* LBSTNRHI then ANRIND='H'; ANRIND='N' otherwise. Used for shift tables
ANRIND	PLAT	Platelet (GI/L)	text	1		LNH	if AVAL < (0.5*LBSTNRLO) then ANRIND='L'; if LAVAL > 1.5* LBSTNRHI then ANRIND='H'; ANRIND='N' otherwise. Used for shift tables
ANRIND	POIKILO	Poikilocytes	text	1		LNH	if AVAL < (0.5*LBSTNRLO) then ANRIND='L'; if LAVAL > 1.5* LBSTNRHI then ANRIND='H'; ANRIND='N' otherwise. Used for shift tables
ANRIND	POLYCHR	Polychromasia	text	1		LNH	if AVAL < (0.5*LBSTNRLO) then ANRIND='L'; if LAVAL > 1.5* LBSTNRHI then ANRIND='H'; ANRIND='N' otherwise. Used for shift tables
ANRIND	_ANISO	Anisocytes change from previous visit, relative to normal range	text	1			if AVAL < -1 then ANRIND='L'; if AVAL > 1 then ANRIND='H'; ANRIND='N' otherwise; null if LBBLFL=Y or AVAL=null

Source Variable	Where PARAMCD=	Where PARAM=	Type	Length	Display Format	Code List / Controlled Term	Source/Derivation/Comments
ANRIND	_BASO	Basophils (GI/L) change from previous visit, relative to normal range	text	1			if AVAL < -1 then ANRIND='L'; if AVAL > 1 then ANRIND='H'; ANRIND='N' otherwise; null if LBBLFL=Y or AVAL=null
ANRIND	_EOS	Eosinophils (GI/L) change from previous visit, relative to normal range	text	1			if AVAL < -1 then ANRIND='L'; if AVAL > 1 then ANRIND='H'; ANRIND='N' otherwise; null if LBBLFL=Y or AVAL=null
ANRIND	_MCHC	Ery. Mean Corpuscular HGB Concentration (mmol/L) change from previous visit, relative to normal rang	text	1			if AVAL < -1 then ANRIND='L'; if AVAL > 1 then ANRIND='H'; ANRIND='N' otherwise; null if LBBLFL=Y or AVAL=null
ANRIND	_MCH	Ery. Mean Corpuscular Hemoglobin (fmol(Fe)) change from previous visit, relative to normal range	text	1			if AVAL < -1 then ANRIND='L'; if AVAL > 1 then ANRIND='H'; ANRIND='N' otherwise; null if LBBLFL=Y or AVAL=null
ANRIND	_MCV	Ery. Mean Corpuscular Volume (fL) change from previous visit, relative to normal range	text	1			if AVAL < -1 then ANRIND='L'; if AVAL > 1 then ANRIND='H'; ANRIND='N' otherwise; null if LBBLFL=Y or AVAL=null

Source Variable	Where PARAMCD=	Where PARAM=	Type	Length	Display Format	Code List / Controlled Term	Source/Derivation/Comments
ANRIND	_RBC	Erythrocytes (TI/L) change from previous visit, relative to normal range	text	1			if AVAL < -1 then ANRIND='L'; if AVAL > 1 then ANRIND='H'; ANRIND='N' otherwise; null if LBBLFL=Y or AVAL=null
ANRIND	_HCT	Hematocrit change from previous visit, relative to normal range	text	1			if AVAL < -1 then ANRIND='L'; if AVAL > 1 then ANRIND='H'; ANRIND='N' otherwise; null if LBBLFL=Y or AVAL=null
ANRIND	_HGB	Hemoglobin (mmol/L) change from previous visit, relative to normal range	text	1			if AVAL < -1 then ANRIND='L'; if AVAL > 1 then ANRIND='H'; ANRIND='N' otherwise; null if LBBLFL=Y or AVAL=null
ANRIND	_WBC	Leukocytes (GI/L) change from previous visit, relative to normal range	text	1			if AVAL < -1 then ANRIND='L'; if AVAL > 1 then ANRIND='H'; ANRIND='N' otherwise; null if LBBLFL=Y or AVAL=null
ANRIND	_LYM	Lymphocytes (GI/L) change from previous visit, relative to normal range	text	1			if AVAL < -1 then ANRIND='L'; if AVAL > 1 then ANRIND='H'; ANRIND='N' otherwise; null if LBBLFL=Y or AVAL=null
ANRIND	_MACROCY	Macrocytes change from previous visit, relative to normal range	text	1			if AVAL < -1 then ANRIND='L'; if AVAL > 1 then ANRIND='H'; ANRIND='N' otherwise; null if LBBLFL=Y or AVAL=null

Source Variable	Where PARAMCD=	Where PARAM=	Type	Length	Display Format	Code List / Controlled Term	Source/Derivation/Comments
ANRIND	_MICROCY	Microcytes change from previous visit, relative to normal range	text	1			if AVAL < -1 then ANRIND='L'; if AVAL > 1 then ANRIND='H'; ANRIND='N' otherwise; null if LBBLFL=Y or AVAL=null
ANRIND	_MONO	Monocytes (GI/L) change from previous visit, relative to normal range	text	1			if AVAL < -1 then ANRIND='L'; if AVAL > 1 then ANRIND='H'; ANRIND='N' otherwise; null if LBBLFL=Y or AVAL=null
ANRIND	_PLAT	Platelet (GI/L) change from previous visit, relative to normal range	text	1			if AVAL < -1 then ANRIND='L'; if AVAL > 1 then ANRIND='H'; ANRIND='N' otherwise; null if LBBLFL=Y or AVAL=null
ANRIND	_POIKILO	Poikilocytes change from previous visit, relative to normal range	text	1			if AVAL < -1 then ANRIND='L'; if AVAL > 1 then ANRIND='H'; ANRIND='N' otherwise; null if LBBLFL=Y or AVAL=null
ANRIND	_POLYCHR	Polychromasia change from previous visit, relative to normal range	text	1			if AVAL < -1 then ANRIND='L'; if AVAL > 1 then ANRIND='H'; ANRIND='N' otherwise; null if LBBLFL=Y or AVAL=null

Parameter Value List - ADLBH [AVAL]

Source Variable	Where PARAMCD=	Where PARAM=	Type	Length	Display Format	Code List / Controlled Term	Source/Derivation/Comments
AVAL	ANISO	Anisocytes	integer	8			LB.LBSTRESN
AVAL	BASO	Basophils (GI/L)	float	8	4.2		LB.LBSTRESN
AVAL	EOS	Eosinophils (GI/L)	float	8	4.2		LB.LBSTRESN
AVAL	MCHC	Ery. Mean Corpuscular HGB Concentration (mmol/L)	float	8	7.4		LB.LBSTRESN
AVAL	MCH	Ery. Mean Corpuscular Hemoglobin (fmol(Fe))	float	8	7.5		LB.LBSTRESN
AVAL	MCV	Ery. Mean Corpuscular Volume (fL)	integer	8			LB.LBSTRESN
AVAL	RBC	Erythrocytes (TI/L)	float	8	3.1		LB.LBSTRESN
AVAL	HCT	Hematocrit	float	8	4.2		LB.LBSTRESN
AVAL	HGB	Hemoglobin (mmol/L)	float	8	8.5		LB.LBSTRESN
AVAL	WBC	Leukocytes (GI/L)	float	8	5.2		LB.LBSTRESN
AVAL	LYM	Lymphocytes (GI/L)	float	8	4.2		LB.LBSTRESN
AVAL	MACROCY	Macrocytes	integer	8			LB.LBSTRESN

Source Variable	Where PARAMCD=	Where PARAM=	Type	Length	Display Format	Code List / Controlled Term	Source/Derivation/Comments
AVAL	MICROCY	Microcytes	integer	8			LB.LBSTRESN
AVAL	MONO	Monocytes (GI/L)	float	8	4.2		LB.LBSTRESN
AVAL	PLAT	Platelet (GI/L)	integer	8			LB.LBSTRESN
AVAL	POIKILO	Poikilocytes	integer	8			LB.LBSTRESN
AVAL	POLYCHR	Polychromasia	integer	8			LB.LBSTRESN
AVAL	_ANISO	Anisocytes change from previous visit, relative to normal range	float	8	4.1		(LBSTRESN - previous LBSTRESN)/(.5*(LBSTNRHI-LBSTNRLO)); null if LBBLFL=Y
AVAL	_BASO	Basophils (GI/L) change from previous visit, relative to normal range	float	8	4.1		(LBSTRESN - previous LBSTRESN)/(.5*(LBSTNRHI-LBSTNRLO)); null if LBBLFL=Y
AVAL	_EOS	Eosinophils (GI/L) change from previous visit, relative to normal range	float	8	4.1		(LBSTRESN - previous LBSTRESN)/(.5*(LBSTNRHI-LBSTNRLO)); null if LBBLFL=Y
AVAL	_MCHC	Ery. Mean Corpuscular HGB Concentration (mmol/L) change from previous visit, relative to normal rang	float	8	4.1		(LBSTRESN - previous LBSTRESN)/(.5*(LBSTNRHI-LBSTNRLO)); null if LBBLFL=Y

Source Variable	Where PARAMCD=	Where PARAM=	Type	Length	Display Format	Code List / Controlled Term	Source/Derivation/Comments
AVAL	_MCH	Ery. Mean Corpuscular Hemoglobin (fmol(Fe)) change from previous visit, relative to normal range	float	8	4.1		(LBSTRESN - previous LBSTRESN)/(.5*(LBSTNRHI-LBSTNRLO)); null if LBBLFL=Y
AVAL	_MCV	Ery. Mean Corpuscular Volume (fL) change from previous visit, relative to normal range	float	8	4.1		(LBSTRESN - previous LBSTRESN)/(.5*(LBSTNRHI-LBSTNRLO)); null if LBBLFL=Y
AVAL	_RBC	Erythrocytes (TI/L) change from previous visit, relative to normal range	float	8	4.1		(LBSTRESN - previous LBSTRESN)/(.5*(LBSTNRHI-LBSTNRLO)); null if LBBLFL=Y
AVAL	_HCT	Hematocrit change from previous visit, relative to normal range	float	8	4.1		(LBSTRESN - previous LBSTRESN)/(.5*(LBSTNRHI-LBSTNRLO)); null if LBBLFL=Y
AVAL	_HGB	Hemoglobin (mmol/L) change from previous visit, relative to normal range	float	8	4.1		(LBSTRESN - previous LBSTRESN)/(.5*(LBSTNRHI-LBSTNRLO)); null if LBBLFL=Y
AVAL	_WBC	Leukocytes (GI/L) change from previous visit, relative to normal range	float	8	4.1		(LBSTRESN - previous LBSTRESN)/(.5*(LBSTNRHI-LBSTNRLO)); null if LBBLFL=Y

Source Variable	Where PARAMCD=	Where PARAM=	Type	Length	Display Format	Code List / Controlled Term	Source/Derivation/Comments
AVAL	_LYM	Lymphocytes (GI/L) change from previous visit, relative to normal range	float	8	4.1		(LBSTRESN - previous LBSTRESN)/(.5*(LBSTNRHI-LBSTNRLO)); null if LBBLFL=Y
AVAL	_MACROCY	Macrocytes change from previous visit, relative to normal range	float	8	4.1		(LBSTRESN - previous LBSTRESN)/(.5*(LBSTNRHI-LBSTNRLO)); null if LBBLFL=Y
AVAL	_MICROCY	Microcytes change from previous visit, relative to normal range	float	8	4.1		(LBSTRESN - previous LBSTRESN)/(.5*(LBSTNRHI-LBSTNRLO)); null if LBBLFL=Y
AVAL	_MONO	Monocytes (GI/L) change from previous visit, relative to normal range	float	8	4.1		(LBSTRESN - previous LBSTRESN)/(.5*(LBSTNRHI-LBSTNRLO)); null if LBBLFL=Y
AVAL	_PLAT	Platelet (GI/L) change from previous visit, relative to normal range	float	8	4.1		(LBSTRESN - previous LBSTRESN)/(.5*(LBSTNRHI-LBSTNRLO)); null if LBBLFL=Y
AVAL	_POIKILO	Poikilocytes change from previous visit, relative to normal range	float	8	4.1		(LBSTRESN - previous LBSTRESN)/(.5*(LBSTNRHI-LBSTNRLO)); null if LBBLFL=Y
AVAL	_POLYCHR	Polychromasia change from previous visit, relative to normal range	float	8	4.1		(LBSTRESN - previous LBSTRESN)/(.5*(LBSTNRHI-LBSTNRLO)); null if LBBLFL=Y

Parameter Value List - ADLBH [BASE]

Source Variable	Where PARAMCD=	Where PARAM=	Type	Length	Display Format	Code List / Controlled Term	Source/Derivation/Comments
BASE	ANISO	Anisocytes	integer	8			LBSTRESN when ADLBC.ABLFL=Y
BASE	BASO	Basophils (GI/L)	float	8	4.2		LBSTRESN when ADLBC.ABLFL=Y
BASE	EOS	Eosinophils (GI/L)	float	8	4.2		LBSTRESN when ADLBC.ABLFL=Y
BASE	MCHC	Ery. Mean Corpuscular HGB Concentration (mmol/L)	float	8	7.4		LBSTRESN when ADLBC.ABLFL=Y
BASE	MCH	Ery. Mean Corpuscular Hemoglobin (fmol(Fe))	float	8	7.5		LBSTRESN when ADLBC.ABLFL=Y
BASE	MCV	Ery. Mean Corpuscular Volume (fL)	integer	8			LBSTRESN when ADLBC.ABLFL=Y
BASE	RBC	Erythrocytes (TI/L)	float	8	3.1		LBSTRESN when ADLBC.ABLFL=Y
BASE	HCT	Hematocrit	float	8	4.2		LBSTRESN when ADLBC.ABLFL=Y
BASE	HGB	Hemoglobin (mmol/L)	float	8	8.5		LBSTRESN when ADLBC.ABLFL=Y
BASE	WBC	Leukocytes (GI/L)	float	8	5.2		LBSTRESN when ADLBC.ABLFL=Y
BASE	LYM	Lymphocytes (GI/L)	float	8	4.2		LBSTRESN when ADLBC.ABLFL=Y
BASE	MACROCY	Macrocytes	integer	8			LBSTRESN when ADLBC.ABLFL=Y

Source Variable	Where PARAMCD=	Where PARAM=	Type	Length	Display Format	Code List / Controlled Term	Source/Derivation/Comments
BASE	MICROCY	Microcytes	integer	8			LBSTRESN when ADLBC.ABLFL=Y
BASE	MONO	Monocytes (GI/L)	float	8	4.2		LBSTRESN when ADLBC.ABLFL=Y
BASE	PLAT	Platelet (GI/L)	integer	8			LBSTRESN when ADLBC.ABLFL=Y
BASE	POIKILO	Poikilocytes	integer	8			LBSTRESN when ADLBC.ABLFL=Y
BASE	POLYCHR	Polychromasia	integer	8			LBSTRESN when ADLBC.ABLFL=Y
BASE	_ANISO	Anisocytes change from previous visit, relative to normal range	integer	8			Set to missing
BASE	_BASO	Basophils (GI/L) change from previous visit, relative to normal range	integer	8			Set to missing
BASE	_EOS	Eosinophils (GI/L) change from previous visit, relative to normal range	integer	8			Set to missing
BASE	_MCHC	Ery. Mean Corpuscular HGB Concentration (mmol/L) change from previous visit, relative to normal rang	integer	8			Set to missing

Source Variable	Where PARAMCD=	Where PARAM=	Type	Length	Display Format	Code List / Controlled Term	Source/Derivation/Comments
BASE	_MCH	Ery. Mean Corpuscular Hemoglobin (fmol(Fe)) change from previous visit, relative to normal range	integer	8			Set to missing
BASE	_MCV	Ery. Mean Corpuscular Volume (fL) change from previous visit, relative to normal range	integer	8			Set to missing
BASE	_RBC	Erythrocytes (TI/L) change from previous visit, relative to normal range	integer	8			Set to missing
BASE	_HCT	Hematocrit change from previous visit, relative to normal range	integer	8			Set to missing
BASE	_HGB	Hemoglobin (mmol/L) change from previous visit, relative to normal range	integer	8			Set to missing
BASE	_WBC	Leukocytes (GI/L) change from previous visit, relative to normal range	integer	8			Set to missing
BASE	_LYM	Lymphocytes (GI/L) change from previous visit, relative to normal range	integer	8			Set to missing

Source Variable	Where PARAMCD=	Where PARAM=	Type	Length	Display Format	Code List / Controlled Term	Source/Derivation/Comments
BASE	_MACROCY	Macrocytes change from previous visit, relative to normal range	integer	8			Set to missing
BASE	_MICROCY	Microcytes change from previous visit, relative to normal range	integer	8			Set to missing
BASE	_MONO	Monocytes (GI/L) change from previous visit, relative to normal range	integer	8			Set to missing
BASE	_PLAT	Platelet (GI/L) change from previous visit, relative to normal range	integer	8			Set to missing
BASE	_POIKILO	Poikilocytes change from previous visit, relative to normal range	integer	8			Set to missing
BASE	_POLYCHR	Polychromasia change from previous visit, relative to normal range	integer	8			Set to missing

Parameter Value List - ADLBH [BNRIND]

Source Variable	Where PARAMCD=	Where PARAM=	Type	Length	Display Format	Code List / Controlled Term	Source/Derivation/Comments
BNRIND	ANISO	Anisocytes	text	1		LNH	ADLBH.ANRIND when ADLBH.ABLFL=Y
BNRIND	BASO	Basophils (GI/L)	text	1		LNH	ADLBH.ANRIND when ADLBH.ABLFL=Y
BNRIND	EOS	Eosinophils (GI/L)	text	1		LNH	ADLBH.ANRIND when ADLBH.ABLFL=Y
BNRIND	MCHC	Ery. Mean Corpuscular HGB Concentration (mmol/L)	text	1		LNH	ADLBH.ANRIND when ADLBH.ABLFL=Y
BNRIND	MCH	Ery. Mean Corpuscular Hemoglobin (fmol(Fe))	text	1		LNH	ADLBH.ANRIND when ADLBH.ABLFL=Y
BNRIND	MCV	Ery. Mean Corpuscular Volume (fL)	text	1		LNH	ADLBH.ANRIND when ADLBH.ABLFL=Y
BNRIND	RBC	Erythrocytes (TI/L)	text	1		LNH	ADLBH.ANRIND when ADLBH.ABLFL=Y
BNRIND	HCT	Hematocrit	text	1		LNH	ADLBH.ANRIND when ADLBH.ABLFL=Y
BNRIND	HGB	Hemoglobin (mmol/L)	text	1		LNH	ADLBH.ANRIND when ADLBH.ABLFL=Y

Source Variable	Where PARAMCD=	Where PARAM=	Type	Length	Display Format	Code List / Controlled Term	Source/Derivation/Comments
BNRIND	WBC	Leukocytes (GI/L)	text	1		LNH	ADLBH.ANRIND when ADLBH.ABLFL=Y
BNRIND	LYM	Lymphocytes (GI/L)	text	1		LNH	ADLBH.ANRIND when ADLBH.ABLFL=Y
BNRIND	MACROCY	Macrocytes	text	1		LNH	ADLBH.ANRIND when ADLBH.ABLFL=Y
BNRIND	MICROCY	Microcytes	text	1		LNH	ADLBH.ANRIND when ADLBH.ABLFL=Y
BNRIND	MONO	Monocytes (GI/L)	text	1		LNH	ADLBH.ANRIND when ADLBH.ABLFL=Y
BNRIND	PLAT	Platelet (GI/L)	text	1		LNH	ADLBH.ANRIND when ADLBH.ABLFL=Y
BNRIND	POIKILO	Poikilocytes	text	1		LNH	ADLBH.ANRIND when ADLBH.ABLFL=Y
BNRIND	POLYCHR	Polychromasia	text	1		LNH	ADLBH.ANRIND when ADLBH.ABLFL=Y
BNRIND	_ANISO	Anisocytes change from previous visit, relative to normal range	text	1			Set to missing

Source Variable	Where PARAMCD=	Where PARAM=	Type	Length	Display Format	Code List / Controlled Term	Source/Derivation/Comments
BNRIND	_BASO	Basophils (GI/L) change from previous visit, relative to normal range	text	1			Set to missing
BNRIND	_EOS	Eosinophils (GI/L) change from previous visit, relative to normal range	text	1			Set to missing
BNRIND	_MCHC	Ery. Mean Corpuscular HGB Concentration (mmol/L) change from previous visit, relative to normal rang	text	1			Set to missing
BNRIND	_MCH	Ery. Mean Corpuscular Hemoglobin (fmol(Fe)) change from previous visit, relative to normal range	text	1			Set to missing
BNRIND	_MCV	Ery. Mean Corpuscular Volume (fL) change from previous visit, relative to normal range	text	1			Set to missing
BNRIND	_RBC	Erythrocytes (TI/L) change from previous visit, relative to normal range	text	1			Set to missing
BNRIND	_HCT	Hematocrit change from previous visit, relative to normal range	text	1			Set to missing

Source Variable	Where PARAMCD=	Where PARAM=	Type	Length	Display Format	Code List / Controlled Term	Source/Derivation/Comments
BNRIND	_HGB	Hemoglobin (mmol/L) change from previous visit, relative to normal range	text	1			Set to missing
BNRIND	_WBC	Leukocytes (GI/L) change from previous visit, relative to normal range	text	1			Set to missing
BNRIND	_LYM	Lymphocytes (GI/L) change from previous visit, relative to normal range	text	1			Set to missing
BNRIND	_MACROCY	Macrocytes change from previous visit, relative to normal range	text	1			Set to missing
BNRIND	_MICROCY	Microcytes change from previous visit, relative to normal range	text	1			Set to missing
BNRIND	_MONO	Monocytes (GI/L) change from previous visit, relative to normal range	text	1			Set to missing
BNRIND	_PLAT	Platelet (GI/L) change from previous visit, relative to normal range	text	1			Set to missing

Source Variable	Where PARAMCD=	Where PARAM=	Type	Length	Display Format	Code List / Controlled Term	Source/Derivation/Comments
BNRIND	_POIKILO	Poikilocytes change from previous visit, relative to normal range	text	1			Set to missing
BNRIND	_POLYCHR	Polychromasia change from previous visit, relative to normal range	text	1			Set to missing

Parameter Value List - ADLBH [CHG]

Source Variable	Where PARAMCD=	Where PARAM=	Type	Length	Display Format	Code List / Controlled Term	Source/Derivation/Comments
CHG	ANISO	Anisocytes	integer	8			AVAL - BASE
CHG	BASO	Basophils (GI/L)	float	8	4.2		AVAL - BASE
CHG	EOS	Eosinophils (GI/L)	float	8	4.2		AVAL - BASE
CHG	MCHC	Ery. Mean Corpuscular HGB Concentration (mmol/L)	float	8	7.4		AVAL - BASE
CHG	MCH	Ery. Mean Corpuscular Hemoglobin (fmol(Fe))	float	8	7.5		AVAL - BASE
CHG	MCV	Ery. Mean Corpuscular Volume (fL)	integer	8			AVAL - BASE

Source Variable	Where PARAMCD=	Where PARAM=	Type	Length	Display Format	Code List / Controlled Term	Source/Derivation/Comments
CHG	RBC	Erythrocytes (TI/L)	float	8	3.1		AVAL - BASE
CHG	HCT	Hematocrit	float	8	4.2		AVAL - BASE
CHG	HGB	Hemoglobin (mmol/L)	float	8	8.5		AVAL - BASE
CHG	WBC	Leukocytes (GI/L)	float	8	5.2		AVAL - BASE
CHG	LYM	Lymphocytes (GI/L)	float	8	4.2		AVAL - BASE
CHG	MACROCY	Macrocytes	integer	8			AVAL - BASE
CHG	MICROCY	Microcytes	integer	8			AVAL - BASE
CHG	MONO	Monocytes (GI/L)	float	8	4.2		AVAL - BASE
CHG	PLAT	Platelet (GI/L)	integer	8			AVAL - BASE
CHG	POIKILO	Poikilocytes	integer	8			AVAL - BASE
CHG	POLYCHR	Polychromasia	integer	8			AVAL - BASE
CHG	_ANISO	Anisocytes change from previous visit, relative to normal range	integer	8			Set to missing

Source Variable	Where PARAMCD=	Where PARAM=	Type	Length	Display Format	Code List / Controlled Term	Source/Derivation/Comments
CHG	_BASO	Basophils (GI/L) change from previous visit, relative to normal range	integer	8			Set to missing
CHG	_EOS	Eosinophils (GI/L) change from previous visit, relative to normal range	integer	8			Set to missing
CHG	_MCHC	Ery. Mean Corpuscular HGB Concentration (mmol/L) change from previous visit, relative to normal rang	integer	8			Set to missing
CHG	_MCH	Ery. Mean Corpuscular Hemoglobin (fmol(Fe)) change from previous visit, relative to normal range	integer	8			Set to missing
CHG	_MCV	Ery. Mean Corpuscular Volume (fL) change from previous visit, relative to normal range	integer	8			Set to missing
CHG	_RBC	Erythrocytes (TI/L) change from previous visit, relative to normal range	integer	8			Set to missing
CHG	_HCT	Hematocrit change from previous visit, relative to normal range	integer	8			Set to missing

Source Variable	Where PARAMCD=	Where PARAM=	Type	Length	Display Format	Code List / Controlled Term	Source/Derivation/Comments
CHG	_HGB	Hemoglobin (mmol/L) change from previous visit, relative to normal range	integer	8			Set to missing
CHG	_WBC	Leukocytes (GI/L) change from previous visit, relative to normal range	integer	8			Set to missing
CHG	_LYM	Lymphocytes (GI/L) change from previous visit, relative to normal range	integer	8			Set to missing
CHG	_MACROCY	Macrocytes change from previous visit, relative to normal range	integer	8			Set to missing
CHG	_MICROCY	Microcytes change from previous visit, relative to normal range	integer	8			Set to missing
CHG	_MONO	Monocytes (GI/L) change from previous visit, relative to normal range	integer	8			Set to missing
CHG	_PLAT	Platelet (GI/L) change from previous visit, relative to normal range	integer	8			Set to missing

Source Variable	Where PARAMCD=	Where PARAM=	Type	Length	Display Format	Code List / Controlled Term	Source/Derivation/Comments
CHG	_POIKILO	Poikilocytes change from previous visit, relative to normal range	integer	8			Set to missing
CHG	_POLYCHR	Polychromasia change from previous visit, relative to normal range	integer	8			Set to missing

Parameter Value List - ADLBHY [A1HI]

Source Variable	Where PARAMCD=	Where PARAM=	Type	Length	Display Format	Code List / Controlled Term	Source/Derivation/Comments
A1HI	ALT	Alanine Aminotransferase (U/L)	integer	8			ADLBC.A1HI
A1HI	AST	Aspartate Aminotransferase (U/L)	integer	8			ADLBC.A1HI
A1HI	BILI	Bilirubin (umol/L)	float	8	4.1		ADLBC.A1HI
A1HI	BILIHY	Bilirubin 1.5 x ULN	integer	8			Set to missing
A1HI	TRANSHY	Transaminase 1.5 x ULN	integer	8			Set to missing
A1HI	HYLAW	Total Bili 1.5 x ULN and Transaminase 1.5 x ULN	integer	8			Set to missing

Parameter Value List - ADLBHY [A1LO]

Source Variable	Where PARAMCD=	Where PARAM=	Type	Length	Display Format	Code List / Controlled Term	Source/Derivation/Comments
A1LO	ALT	Alanine Aminotransferase (U/L)	integer	8			ADLBC.A1LO
A1LO	AST	Aspartate Aminotransferase (U/L)	integer	8			ADLBC.A1LO
A1LO	BILI	Bilirubin (umol/L)	float	8	4.1		ADLBC.A1LO
A1LO	BILIHY	Bilirubin 1.5 x ULN	integer	8			Set to missing
A1LO	TRANSHY	Transaminase 1.5 x ULN	integer	8			Set to missing
A1LO	HYLAW	Total Bili 1.5 x ULN and Transaminase 1.5 x ULN	integer	8			Set to missing

Parameter Value List - ADLBHY [AVAL]

Source Variable	Where PARAMCD=	Where PARAM=	Type	Length	Display Format	Code List / Controlled Term	Source/Derivation/Comments
AVAL	ALT	Alanine Aminotransferase (U/L)	integer	8			ADLBC.AVAL

Source Variable	Where PARAMCD=	Where PARAM=	Type	Length	Display Format	Code List / Controlled Term	Source/Derivation/Comments
AVAL	AST	Aspartate Aminotransferase (U/L)	integer	8			ADLBC.AVAL
AVAL	BILI	Bilirubin (umol/L)	float	8	6.2		ADLBC.AVAL
AVAL	BILIHY	Bilirubin 1.5 x ULN	integer	8		YNN	for a given visit, if param='BILI' and r2a1hi > 1.5 then aval=1. otherwise if param='BILI' then aval=0
AVAL	TRANSHY	Transaminase 1.5 x ULN	integer	8		YNN	for a given visit, if param='ALT' or 'AST' and if either r2a1hi > 1.5 then aval=1. otherwise if param='ALT' or 'AST' then aval=0
AVAL	HYLAW	Total Bili 1.5 x ULN and Transaminase 1.5 x ULN	integer	8		YNN	for a given visit, if param='BILHY' or 'TRANSHY' and if both has aval=1 then for this param then aval=1. otherwise if for a given visit, if param='BILHY' or 'TRANSHY' then aval=0.

Parameter Value List - ADLBHY [BASE]

Source Variable	Where PARAMCD=	Where PARAM=	Type	Length	Display Format	Code List / Controlled Term	Source/Derivation/Comments
BASE	ALT	Alanine Aminotransferase (U/L)	integer	8			ADLBC.AVAL when ADLBC.ABLFL=Y

Source Variable	Where PARAMCD=	Where PARAM=	Type	Length	Display Format	Code List / Controlled Term	Source/Derivation/Comments
BASE	AST	Aspartate Aminotransferase (U/L)	integer	8			ADLBC.AVAL when ADLBC.ABLFL=Y
BASE	BILI	Bilirubin (umol/L)	float	8	6.2		ADLBC.AVAL when ADLBC.ABLFL=Y
BASE	BILIHY	Bilirubin 1.5 x ULN	integer	8		YNN	ADLBC.AVAL when ADLBC.ABLFL=Y
BASE	TRANSHY	Transaminase 1.5 x ULN	integer	8		YNN	ADLBC.AVAL when ADLBC.ABLFL=Y
BASE	HYLAW	Total Bili 1.5 x ULN and Transaminase 1.5 x ULN	integer	8		YNN	ADLBC.AVAL when ADLBC.ABLFL=Y

Parameter Value List - ADLBHY [BR2A1HI]

Source Variable	Where PARAMCD=	Where PARAM=	Type	Length	Display Format	Code List / Controlled Term	Source/Derivation/Comments
BR2A1HI	ALT	Alanine Aminotransferase (U/L)	float	8	3.1		ADLBC.BR2A1HI
BR2A1HI	AST	Aspartate Aminotransferase (U/L)	float	8	3.1		ADLBC.BR2A1HI
BR2A1HI	BILI	Bilirubin (umol/L)	float	8	3.1		ADLBC.BR2A1HI

Source Variable	Where PARAMCD=	Where PARAM=	Type	Length	Display Format	Code List / Controlled Term	Source/Derivation/Comments
BR2A1HI	BILIHY	Bilirubin 1.5 x ULN	float	8	3.1		Set to missing
BR2A1HI	TRANSHY	Transaminase 1.5 x ULN	float	8	3.1		Set to missing
BR2A1HI	HYLAW	Total Bili 1.5 x ULN and Transaminase 1.5 x ULN	float	8	3.1		Set to missing

Parameter Value List - ADLBHY [BR2A1LO]

Source Variable	Where PARAMCD=	Where PARAM=	Type	Length	Display Format	Code List / Controlled Term	Source/Derivation/Comments
BR2A1LO	ALT	Alanine Aminotransferase (U/L)	float	8	3.1		ADLBC.BR2A1LO
BR2A1LO	AST	Aspartate Aminotransferase (U/L)	float	8	3.1		ADLBC.BR2A1LO
BR2A1LO	BILI	Bilirubin (umol/L)	float	8	3.1		ADLBC.BR2A1LO
BR2A1LO	BILIHY	Bilirubin 1.5 x ULN	float	8	3.1		Set to missing
BR2A1LO	TRANSHY	Transaminase 1.5 x ULN	float	8	3.1		Set to missing
BR2A1LO	HYLAW	Total Bili 1.5 x ULN and Transaminase 1.5 x ULN	float	8	3.1		Set to missing

Parameter Value List - ADLBHY [CRIT1]

Source Variable	Where PARAMCD=	Where PARAM=	Type	Length	Display Format	Code List / Controlled Term	Source/Derivation/Comments
CRIT1	ALT	Alanine Aminotransferase (U/L)	text	40			Set to missing
CRIT1	AST	Aspartate Aminotransferase (U/L)	text	40			Set to missing
CRIT1	BILI	Bilirubin (umol/L)	text	40			Set to missing
CRIT1	BILIHY	Bilirubin 1.5 x ULN	text	40			Set to 'R2A1HI > 1.5'
CRIT1	TRANSHY	Transaminase 1.5 x ULN	text	40			Set to 'R2A1HI > 1.5'
CRIT1	HYLAW	Total Bili 1.5 x ULN and Transaminase 1.5 x ULN	text	40			Set to 'R2A1HI > 1.5'

Parameter Value List - ADLBHY [CRIT1FL]

Source Variable	Where PARAMCD=	Where PARAM=	Type	Length	Display Format	Code List / Controlled Term	Source/Derivation/Comments
CRIT1FL	ALT	Alanine Aminotransferase (U/L)	text	1		YN	if R21AHI > 1.5 then set to 'Y'. If R2A1HI is not missing then set to 'N'. Else set to missing.

Source Variable	Where PARAMCD=	Where PARAM=	Type	Length	Display Format	Code List / Controlled Term	Source/Derivation/Comments
CRIT1FL	AST	Aspartate Aminotransferase (U/L)	text	1		YN	if R21AHI > 1.5 then set to 'Y'. If R2A1HI is not missing then set to 'N'. Else set to missing.
CRIT1FL	BILI	Bilirubin (umol/L)	text	1		YN	if R21AHI > 1.5 then set to 'Y'. If R2A1HI is not missing then set to 'N'. Else set to missing.
CRIT1FL	BILIHY	Bilirubin 1.5 x ULN	text	1			Set to missing
CRIT1FL	TRANSHY	Transaminase 1.5 x ULN	text	1			Set to missing
CRIT1FL	HYLAW	Total Bili 1.5 x ULN and Transaminase 1.5 x ULN	text	1			Set to missing

Parameter Value List - ADLBHY [PARAMTYP]

Source Variable	Where PARAMCD=	Where PARAM=	Type	Length	Display Format	Code List / Controlled Term	Source/Derivation/Comments
PARAMTYP	ALT	Alanine Aminotransferase (U/L)	text	7		PARAMTYP	Set to missing
PARAMTYP	AST	Aspartate Aminotransferase (U/L)	text	7		PARAMTYP	Set to missing

Source Variable	Where PARAMCD=	Where PARAM=	Type	Length	Display Format	Code List / Controlled Term	Source/Derivation/Comments
PARAMTYP	BILI	Bilirubin (umol/L)	text	7		PARAMTYP	Set to missing
PARAMTYP	BILIHY	Bilirubin 1.5 x ULN	text	7		PARAMTYP	Set to "DERIVED"
PARAMTYP	TRANSHY	Transaminase 1.5 x ULN	text	7		PARAMTYP	Set to "DERIVED"
PARAMTYP	HYLAW	Total Bili 1.5 x ULN and Transaminase 1.5 x ULN	text	7		PARAMTYP	Set to "DERIVED"

Parameter Value List - ADLBHY [PARCAT1]

Source Variable	Where PARAMCD=	Where PARAM=	Type	Length	Display Format	Code List / Controlled Term	Source/Derivation/Comments
PARCAT1	ALT	Alanine Aminotransferase (U/L)	text	8		ADLBCAT	ADLBC.PARCAT1
PARCAT1	AST	Aspartate Aminotransferase (U/L)	text	8		ADLBCAT	ADLBC.PARCAT1
PARCAT1	BILI	Bilirubin (umol/L)	text	8		ADLBCAT	ADLBC.PARCAT1
PARCAT1	BILIHY	Bilirubin 1.5 x ULN	text	8		ADLBCAT	Set to "HYLAW"
PARCAT1	TRANSHY	Transaminase 1.5 x ULN	text	8		ADLBCAT	Set to "HYLAW"

Source Variable	Where PARAMCD=	Where PARAM=	Type	Length	Display Format	Code List / Controlled Term	Source/Derivation/Comments
PARCAT1	HYLAW	Total Bili 1.5 x ULN and Transaminase 1.5 x ULN	text	8		ADLBCAT	Set to "HYLAW"

Parameter Value List - ADLBHY [R2A1HI]

Source Variable	Where PARAMCD=	Where PARAM=	Type	Length	Display Format	Code List / Controlled Term	Source/Derivation/Comments
R2A1HI	ALT	Alanine Aminotransferase (U/L)	float	8	3.1		ADLBC.R2A1HI
R2A1HI	AST	Aspartate Aminotransferase (U/L)	float	8	3.1		ADLBC.R2A1HI
R2A1HI	BILI	Bilirubin (umol/L)	float	8	3.1		ADLBC.R2A1HI
R2A1HI	BILIHY	Bilirubin 1.5 x ULN	float	8	3.1		Set to missing
R2A1HI	TRANSHY	Transaminase 1.5 x ULN	float	8	3.1		Set to missing
R2A1HI	HYLAW	Total Bili 1.5 x ULN and Transaminase 1.5 x ULN	float	8	3.1		Set to missing

Parameter Value List - ADLBHY [R2A1LO]

Source Variable	Where PARAMCD=	Where PARAM=	Type	Length	Display Format	Code List / Controlled Term	Source/Derivation/Comments
R2A1LO	ALT	Alanine Aminotransferase (U/L)	float	8	3.1		ADLBC.R2A1LO
R2A1LO	AST	Aspartate Aminotransferase (U/L)	float	8	3.1		ADLBC.R2A1LO
R2A1LO	BILI	Bilirubin (umol/L)	float	8	3.1		ADLBC.R2A1LO
R2A1LO	BILIHY	Bilirubin 1.5 x ULN	float	8	3.1		Set to missing
R2A1LO	TRANSHY	Transaminase 1.5 x ULN	float	8	3.1		Set to missing
R2A1LO	HYLAW	Total Bili 1.5 x ULN and Transaminase 1.5 x ULN	float	8	3.1		Set to missing

Parameter Value List - ADLBHY [SHIFT1]

Source Variable	Where PARAMCD=	Where PARAM=	Type	Length	Display Format	Code List / Controlled Term	Source/Derivation/Comments
SHIFT1	ALT	Alanine Aminotransferase (U/L)	text	40			Set to missing

Source Variable	Where PARAMCD=	Where PARAM=	Type	Length	Display Format	Code List / Controlled Term	Source/Derivation/Comments
SHIFT1	AST	Aspartate Aminotransferase (U/L)	text	40			Set to missing
SHIFT1	BILI	Bilirubin (umol/L)	text	40			Set to missing
SHIFT1	BILIHY	Bilirubin 1.5 x ULN	text	40		SHIFT	Set to "High to Normal" if base=1 and aval=0, set to "Normal to Normal" if base=0 and aval=0, and set to "Normal to High" if base=0 and aval=1
SHIFT1	TRANSHY	Transaminase 1.5 x ULN	text	40		SHIFT	Set to "High to Normal" if base=1 and aval=0, set to "Normal to Normal" if base=0 and aval=0, and set to "Normal to High" if base=0 and aval=1
SHIFT1	HYLAW	Total Bili 1.5 x ULN and Transaminase 1.5 x ULN	text	40		SHIFT	Set to "High to Normal" if base=1 and aval=0, set to "Normal to Normal" if base=0 and aval=0, and set to "Normal to High" if base=0 and aval=1

Parameter Value List - ADLBHY [SHIFT1N]

Source Variable	Where PARAMCD=	Where PARAM=	Type	Length	Display Format	Code List / Controlled Term	Source/Derivation/Comments
SHIFT1N	ALT	Alanine Aminotransferase (U/L)	integer	1			Set to missing

Source Variable	Where PARAMCD=	Where PARAM=	Type	Length	Display Format	Code List / Controlled Term	Source/Derivation/Comments
SHIFT1N	AST	Aspartate Aminotransferase (U/L)	integer	1			Set to missing
SHIFT1N	BILI	Bilirubin (umol/L)	integer	1			Set to missing
SHIFT1N	BILIHY	Bilirubin 1.5 x ULN	integer	1		SHIFTN	Numeric code for SHIFT1
SHIFT1N	TRANSHY	Transaminase 1.5 x ULN	integer	1		SHIFTN	Numeric code for SHIFT1
SHIFT1N	HYLAW	Total Bili 1.5 x ULN and Transaminase 1.5 x ULN	integer	1		SHIFTN	Numeric code for SHIFT1

Parameter Value List - ADQSADAS [AVAL]

Source Variable	Where PARAMCD=	Where PARAM=	Type	Length	Display Format	Code List / Controlled Term	Source/Derivation/Comments
AVAL	ACITM01	Word Recall Task	integer	8			QS.QSSTRESN where QSTESTCD=PARAMCD
AVAL	ACITM02	Naming Objects And Fingers (Refer To 5 C	integer	8			QS.QSSTRESN where QSTESTCD=PARAMCD
AVAL	ACITM03	Delayed Word Recall	integer	8			QS.QSSTRESN where QSTESTCD=PARAMCD
AVAL	ACITM04	Commands	integer	8			QS.QSSTRESN where QSTESTCD=PARAMCD

Source Variable	Where PARAMCD=	Where PARAM=	Type	Length	Display Format	Code List / Controlled Term	Source/Derivation/Comments
AVAL	ACITM05	Constructional Praxis	integer	8			QS.QSSTRESN where QSTESTCD=PARAMCD
AVAL	ACITM06	Ideational Praxis	integer	8			QS.QSSTRESN where QSTESTCD=PARAMCD
AVAL	ACITM07	Orientation	integer	8			QS.QSSTRESN where QSTESTCD=PARAMCD
AVAL	ACITM08	Word Recognition	integer	8			QS.QSSTRESN where QSTESTCD=PARAMCD
AVAL	ACITM09	Attention/Visual Search Task	integer	8			QS.QSSTRESN where QSTESTCD=PARAMCD
AVAL	ACITM10	Maze Solution	integer	8			QS.QSSTRESN where QSTESTCD=PARAMCD
AVAL	ACITM11	Spoken Language Ability	integer	8			QS.QSSTRESN where QSTESTCD=PARAMCD
AVAL	ACITM12	Comprehension Of Spoken Language	integer	8			QS.QSSTRESN where QSTESTCD=PARAMCD
AVAL	ACITM13	Word Finding Difficulty In Spontaneous S	integer	8			QS.QSSTRESN where QSTESTCD=PARAMCD
AVAL	ACITM14	Recall Of Test Instructions	integer	8			QS.QSSTRESN where QSTESTCD=PARAMCD

Source Variable	Where PARAMCD=	Where PARAM=	Type	Length	Display Format	Code List / Controlled Term	Source/Derivation/Comments
AVAL	ACTOT	Adas-Cog(11) Subscore	integer	8			Sum of ADAS scores for items 1, 2, 4, 5, 6, 7, 8, 11, 12, 13, and 14, see SAP section 14.2 for details on adjusting for missing values.

Parameter Value List - ADQSADAS [DTYPE]

Source Variable	Where PARAMCD=	Where PARAM=	Type	Length	Display Format	Code List / Controlled Term	Source/Derivation/Comments
DTYPE	ACITM01	Word Recall Task	text	10		DTYPE	Value: null
DTYPE	ACITM02	Naming Objects And Fingers (Refer To 5 C	text	10		DTYPE	Value: null
DTYPE	ACITM03	Delayed Word Recall	text	10		DTYPE	Value: null
DTYPE	ACITM04	Commands	text	10		DTYPE	Value: null
DTYPE	ACITM05	Constructional Praxis	text	10		DTYPE	Value: null
DTYPE	ACITM06	Ideational Praxis	text	10		DTYPE	Value: null
DTYPE	ACITM07	Orientation	text	10		DTYPE	Value: null

Source Variable	Where PARAMCD=	Where PARAM=	Type	Length	Display Format	Code List / Controlled Term	Source/Derivation/Comments
DTYPE	ACITM08	Word Recognition	text	10		DTYPE	Value: null
DTYPE	ACITM09	Attention/Visual Search Task	text	10		DTYPE	Value: null
DTYPE	ACITM10	Maze Solution	text	10		DTYPE	Value: null
DTYPE	ACITM11	Spoken Language Ability	text	10		DTYPE	Value: null
DTYPE	ACITM12	Comprehension Of Spoken Language	text	10		DTYPE	Value: null
DTYPE	ACITM13	Word Finding Difficulty In Spontaneous S	text	10		DTYPE	Value: null
DTYPE	ACITM14	Recall Of Test Instructions	text	10		DTYPE	Value: null
DTYPE	ACTOT	Adas-Cog(11) Subscore	text	10		DTYPE	Value: LOCF denotes that the LOCF imputation method was used to impute the value for the given parameter and analysis visit.

Parameter Value List - ADQSADAS [QSSEQ]

Source Variable	Where PARAMCD=	Where PARAM=	Type	Length	Display Format	Code List / Controlled Term	Source/Derivation/Comments
QSSEQ	ACITM01	Word Recall Task	integer	8			QS.QSSEQ
QSSEQ	ACITM02	Naming Objects And Fingers (Refer To 5 C	integer	8			QS.QSSEQ
QSSEQ	ACITM03	Delayed Word Recall	integer	8			QS.QSSEQ
QSSEQ	ACITM04	Commands	integer	8			QS.QSSEQ
QSSEQ	ACITM05	Constructional Praxis	integer	8			QS.QSSEQ
QSSEQ	ACITM06	Ideational Praxis	integer	8			QS.QSSEQ
QSSEQ	ACITM07	Orientation	integer	8			QS.QSSEQ
QSSEQ	ACITM08	Word Recognition	integer	8			QS.QSSEQ
QSSEQ	ACITM09	Attention/Visual Search Task	integer	8			QS.QSSEQ
QSSEQ	ACITM10	Maze Solution	integer	8			QS.QSSEQ
QSSEQ	ACITM11	Spoken Language Ability	integer	8			QS.QSSEQ

Source Variable	Where PARAMCD=	Where PARAM=	Type	Length	Display Format	Code List / Controlled Term	Source/Derivation/Comments
QSSEQ	ACITM12	Comprehension Of Spoken Language	integer	8			QS.QSSEQ
QSSEQ	ACITM13	Word Finding Difficulty In Spontaneous S	integer	8			QS.QSSEQ
QSSEQ	ACITM14	Recall Of Test Instructions	integer	8			QS.QSSEQ
QSSEQ	ACTOT	Adas-Cog(11) Subscore	integer	8			Set QSSEQ to missing for post baseline records. Set to QS.QSSEQ where QS.VISIT=BASELINE and QS.QSTESTCD=ACTOT.

Parameter Value List - ADQSNPIX [ABLFL]

Source Variable	Where PARAMCD=	Where PARAM=	Type	Length	Display Format	Code List / Controlled Term	Source/Derivation/Comments
ABLFL	NPITM01S	NPI-X Item A (Delusion) Score	text	1		Y_BLANK	QS.QSBLFL
ABLFL	NPITM02S	NPI-X Item B (Hallucination) Score	text	1		Y_BLANK	QS.QSBLFL
ABLFL	NPITM03S	NPI-X Item C (Agitation/Agression) Score	text	1		Y_BLANK	QS.QSBLFL

Source Variable	Where PARAMCD=	Where PARAM=	Type	Length	Display Format	Code List / Controlled Term	Source/Derivation/Comments
ABLFL	NPITM04S	NPI-X Item D (Depression/Dysphoria) Score	text	1		Y_BLANK	QS.QSBLFL
ABLFL	NPITM05S	NPI-X Item E (Anxiety) Score	text	1		Y_BLANK	QS.QSBLFL
ABLFL	NPITM06S	NPI-X Item F (Eupohoria/Elation) Score	text	1		Y_BLANK	QS.QSBLFL
ABLFL	NPITM07S	NPI-X Item G (Apathy/Indifference) Score	text	1		Y_BLANK	QS.QSBLFL
ABLFL	NPITM08S	NPI-X Item H (Disinhibition) Score	text	1		Y_BLANK	QS.QSBLFL
ABLFL	NPITM09S	NPI-X Item I (Irritability/Lability) Score	text	1		Y_BLANK	QS.QSBLFL
ABLFL	NPITM10S	NPI-X Item J (Aberrant Motor Behavior) Score	text	1		Y_BLANK	QS.QSBLFL
ABLFL	NPITM11S	NPI-X Item K (Night-time Behavior) Score	text	1		Y_BLANK	QS.QSBLFL
ABLFL	NPITM12S	NPI-X Item L (Appetite/Eating Change) Score	text	1		Y_BLANK	QS.QSBLFL

Source Variable	Where PARAMCD=	Where PARAM=	Type	Length	Display Format	Code List / Controlled Term	Source/Derivation/Comments
ABLFL	NPTOT	NPI-X (9) Total Score	text	1		Y_BLANK	QS.QSBLFL
ABLFL	NPTOTMN	Mean NPI-X (9) Total (Week 4 to 24)	text	1		Y_BLANK	Set ABLFL to missing.

Parameter Value List - ADQSNPIX [ANL01FL]

Source Variable	Where PARAMCD=	Where PARAM=	Type	Length	Display Format	Code List / Controlled Term	Source/Derivation/Comments
ANL01FL	NPITM01S	NPI-X Item A (Delusion) Score	text	1		Y_BLANK	Set ANL01FL=Y based on SAP Page 10 analysis windows.
ANL01FL	NPITM02S	NPI-X Item B (Hallucination) Score	text	1		Y_BLANK	Set ANL01FL=Y based on SAP Page 10 analysis windows.
ANL01FL	NPITM03S	NPI-X Item C (Agitation/Agression) Score	text	1		Y_BLANK	Set ANL01FL=Y based on SAP Page 10 analysis windows.
ANL01FL	NPITM04S	NPI-X Item D (Depression/Dysphoria) Score	text	1		Y_BLANK	Set ANL01FL=Y based on SAP Page 10 analysis windows.
ANL01FL	NPITM05S	NPI-X Item E (Anxiety) Score	text	1		Y_BLANK	Set ANL01FL=Y based on SAP Page 10 analysis windows.
ANL01FL	NPITM06S	NPI-X Item F (Eupohoria/Elation) Score	text	1		Y_BLANK	Set ANL01FL=Y based on SAP Page 10 analysis windows.

Source Variable	Where PARAMCD=	Where PARAM=	Type	Length	Display Format	Code List / Controlled Term	Source/Derivation/Comments
ANL01FL	NPITM07S	NPI-X Item G (Apathy/Indifference) Score	text	1		Y_BLANK	Set ANL01FL=Y based on SAP Page 10 analysis windows.
ANL01FL	NPITM08S	NPI-X Item H (Disinhibition) Score	text	1		Y_BLANK	Set ANL01FL=Y based on SAP Page 10 analysis windows.
ANL01FL	NPITM09S	NPI-X Item I (Irritability/Lability) Score	text	1		Y_BLANK	Set ANL01FL=Y based on SAP Page 10 analysis windows.
ANL01FL	NPITM10S	NPI-X Item J (Aberrant Motor Behavior) Score	text	1		Y_BLANK	Set ANL01FL=Y based on SAP Page 10 analysis windows.
ANL01FL	NPITM11S	NPI-X Item K (Night-time Behavior) Score	text	1		Y_BLANK	Set ANL01FL=Y based on SAP Page 10 analysis windows.
ANL01FL	NPITM12S	NPI-X Item L (Appetite/Eating Change) Score	text	1		Y_BLANK	Set ANL01FL=Y based on SAP Page 10 analysis windows.
ANL01FL	NPTOT	NPI-X (9) Total Score	text	1		Y_BLANK	Set ANL01FL=Y based on SAP Page 10 analysis windows.
ANL01FL	NPTOTMN	Mean NPI-X (9) Total (Week 4 to 24)	text	1		Y_BLANK	Set ANL01FL to Y

Parameter Value List - ADQSNPIX [AVAL]

Source Variable	Where PARAMCD=	Where PARAM=	Type	Length	Display Format	Code List / Controlled Term	Source/Derivation/Comments
AVAL	NPITM01S	NPI-X Item A (Delusion) Score	integer	8			QS.QSSTRESN where QSTESTCD = given PARAMCD
AVAL	NPITM02S	NPI-X Item B (Hallucination) Score	integer	8			QS.QSSTRESN where QSTESTCD = given PARAMCD
AVAL	NPITM03S	NPI-X Item C (Agitation/Agression) Score	integer	8			QS.QSSTRESN where QSTESTCD = given PARAMCD
AVAL	NPITM04S	NPI-X Item D (Depression/Dysphoria) Score	integer	8			QS.QSSTRESN where QSTESTCD = given PARAMCD
AVAL	NPITM05S	NPI-X Item E (Anxiety) Score	integer	8			QS.QSSTRESN where QSTESTCD = given PARAMCD
AVAL	NPITM06S	NPI-X Item F (Eupohoria/Elation) Score	integer	8			QS.QSSTRESN where QSTESTCD = given PARAMCD
AVAL	NPITM07S	NPI-X Item G (Apathy/Indifference) Score	integer	8			QS.QSSTRESN where QSTESTCD = given PARAMCD
AVAL	NPITM08S	NPI-X Item H (Disinhibition) Score	integer	8			QS.QSSTRESN where QSTESTCD = given PARAMCD

Source Variable	Where PARAMCD=	Where PARAM=	Type	Length	Display Format	Code List / Controlled Term	Source/Derivation/Comments
AVAL	NPITM09S	NPI-X Item I (Irritability/Lability) Score	integer	8			QS.QSSTRESN where QSTESTCD = given PARAMCD
AVAL	NPITM10S	NPI-X Item J (Aberrant Motor Behavior) Score	integer	8			QS.QSSTRESN where QSTESTCD = given PARAMCD
AVAL	NPITM11S	NPI-X Item K (Night-time Behavior) Score	integer	8			QS.QSSTRESN where QSTESTCD = given PARAMCD
AVAL	NPITM12S	NPI-X Item L (Appetite/Eating Change) Score	integer	8			QS.QSSTRESN where QSTESTCD = given PARAMCD
AVAL	NPTOT	NPI-X (9) Total Score	integer	8			QS.QSSTRESN where QSTESTCD = given PARAMCD
AVAL	NPTOTMN	Mean NPI-X (9) Total (Week 4 to 24)	integer	8			take the mean of AVAL when PARAMCD=NPTOT from week 4 to 24.

Parameter Value List - ADQSNPIX [BASE]

Source Variable	Where PARAMCD=	Where PARAM=	Type	Length	Display Format	Code List / Controlled Term	Source/Derivation/Comments
BASE	NPITM01S	NPI-X Item A (Delusion) Score	integer	8			QS.QSSTRESN when QS.QSBLFL=Y.

Source Variable	Where PARAMCD=	Where PARAM=	Type	Length	Display Format	Code List / Controlled Term	Source/Derivation/Comments
BASE	NPITM02S	NPI-X Item B (Hallucination) Score	integer	8			QS.QSSTRESN when QS.QSBLFL=Y.
BASE	NPITM03S	NPI-X Item C (Agitation/Agression) Score	integer	8			QS.QSSTRESN when QS.QSBLFL=Y.
BASE	NPITM04S	NPI-X Item D (Depression/Dysphoria) Score	integer	8			QS.QSSTRESN when QS.QSBLFL=Y.
BASE	NPITM05S	NPI-X Item E (Anxiety) Score	integer	8			QS.QSSTRESN when QS.QSBLFL=Y.
BASE	NPITM06S	NPI-X Item F (Eupohoria/Elation) Score	integer	8			QS.QSSTRESN when QS.QSBLFL=Y.
BASE	NPITM07S	NPI-X Item G (Apathy/Indifference) Score	integer	8			QS.QSSTRESN when QS.QSBLFL=Y.
BASE	NPITM08S	NPI-X Item H (Disinhibition) Score	integer	8			QS.QSSTRESN when QS.QSBLFL=Y.
BASE	NPITM09S	NPI-X Item I (Irritability/Lability) Score	integer	8			QS.QSSTRESN when QS.QSBLFL=Y.
BASE	NPITM10S	NPI-X Item J (Aberrant Motor Behavior) Score	integer	8			QS.QSSTRESN when QS.QSBLFL=Y.

Source Variable	Where PARAMCD=	Where PARAM=	Type	Length	Display Format	Code List / Controlled Term	Source/Derivation/Comments
BASE	NPITM11S	NPI-X Item K (Night-time Behavior) Score	integer	8			QS.QSSTRESN when QS.QSBLFL=Y.
BASE	NPITM12S	NPI-X Item L (Appetite/Eating Change) Score	integer	8			QS.QSSTRESN when QS.QSBLFL=Y.
BASE	NPTOT	NPI-X (9) Total Score	integer	8			QS.QSSTRESN when QS.QSBLFL=Y.
BASE	NPTOTMN	Mean NPI-X (9) Total (Week 4 to 24)	integer	8			Set BASE to QS.QSSTRESN when QS.QSTESTCD=NPTOT and QS.QSBLFL=Y.

Parameter Value List - ADQSNPIX [CHG]

Source Variable	Where PARAMCD=	Where PARAM=	Type	Length	Display Format	Code List / Controlled Term	Source/Derivation/Comments
CHG	NPITM01S	NPI-X Item A (Delusion) Score	integer	8			AVAL - BASE, for post baseline records.
CHG	NPITM02S	NPI-X Item B (Hallucination) Score	integer	8			AVAL - BASE, for post baseline records.
CHG	NPITM03S	NPI-X Item C (Agitation/Agression) Score	integer	8			AVAL - BASE, for post baseline records.

Source Variable	Where PARAMCD=	Where PARAM=	Type	Length	Display Format	Code List / Controlled Term	Source/Derivation/Comments
CHG	NPITM04S	NPI-X Item D (Depression/Dysphoria) Score	integer	8			AVAL - BASE, for post baseline records.
CHG	NPITM05S	NPI-X Item E (Anxiety) Score	integer	8			AVAL - BASE, for post baseline records.
CHG	NPITM06S	NPI-X Item F (Eupohoria/Elation) Score	integer	8			AVAL - BASE, for post baseline records.
CHG	NPITM07S	NPI-X Item G (Apathy/Indifference) Score	integer	8			AVAL - BASE, for post baseline records.
CHG	NPITM08S	NPI-X Item H (Disinhibition) Score	integer	8			AVAL - BASE, for post baseline records.
CHG	NPITM09S	NPI-X Item I (Irritability/Lability) Score	integer	8			AVAL - BASE, for post baseline records.
CHG	NPITM10S	NPI-X Item J (Aberrant Motor Behavior) Score	integer	8			AVAL - BASE, for post baseline records.
CHG	NPITM11S	NPI-X Item K (Night-time Behavior) Score	integer	8			AVAL - BASE, for post baseline records.
CHG	NPITM12S	NPI-X Item L (Appetite/Eating Change) Score	integer	8			AVAL - BASE, for post baseline records.

Source Variable	Where PARAMCD=	Where PARAM=	Type	Length	Display Format	Code List / Controlled Term	Source/Derivation/Comments
CHG	NPTOT	NPI-X (9) Total Score	integer	8			AVAL - BASE, for post baseline records.
CHG	NPTOTMN	Mean NPI-X (9) Total (Week 4 to 24)	integer	8			Set CHG to missing.

Parameter Value List - ADQSNPIX [DTYPE]

Source Variable	Where PARAMCD=	Where PARAM=	Type	Length	Display Format	Code List / Controlled Term	Source/Derivation/Comments
DTYPE	NPITM01S	NPI-X Item A (Delusion) Score	text	10		DTYPE	Set to missing
DTYPE	NPITM02S	NPI-X Item B (Hallucination) Score	text	10		DTYPE	Set to missing
DTYPE	NPITM03S	NPI-X Item C (Agitation/Agression) Score	text	10		DTYPE	Set to missing
DTYPE	NPITM04S	NPI-X Item D (Depression/Dysphoria) Score	text	10		DTYPE	Set to missing
DTYPE	NPITM05S	NPI-X Item E (Anxiety) Score	text	10		DTYPE	Set to missing

Source Variable	Where PARAMCD=	Where PARAM=	Type	Length	Display Format	Code List / Controlled Term	Source/Derivation/Comments
DTYPE	NPITM06S	NPI-X Item F (Eupohoria/Elation) Score	text	10		DTYPE	Set to missing
DTYPE	NPITM07S	NPI-X Item G (Apathy/Indifference) Score	text	10		DTYPE	Set to missing
DTYPE	NPITM08S	NPI-X Item H (Disinhibition) Score	text	10		DTYPE	Set to missing
DTYPE	NPITM09S	NPI-X Item I (Irritability/Lability) Score	text	10		DTYPE	Set to missing
DTYPE	NPITM10S	NPI-X Item J (Aberrant Motor Behavior) Score	text	10		DTYPE	Set to missing
DTYPE	NPITM11S	NPI-X Item K (Night-time Behavior) Score	text	10		DTYPE	Set to missing
DTYPE	NPITM12S	NPI-X Item L (Appetite/Eating Change) Score	text	10		DTYPE	Set to missing
DTYPE	NPTOT	NPI-X (9) Total Score	text	10		DTYPE	Set to missing
DTYPE	NPTOTMN	Mean NPI-X (9) Total (Week 4 to 24)	text	10		DTYPE	Value: AVERAGE

Parameter Value List - ADQSNPIX [PARAMTYP]

Source Variable	Where PARAMCD=	Where PARAM=	Type	Length	Display Format	Code List / Controlled Term	Source/Derivation/Comments
PARAMTYP	NPITM01S	NPI-X Item A (Delusion) Score	text	15		PARAMTYP	Set PARAMTYP to missing.
PARAMTYP	NPITM02S	NPI-X Item B (Hallucination) Score	text	15		PARAMTYP	Set PARAMTYP to missing.
PARAMTYP	NPITM03S	NPI-X Item C (Agitation/Agression) Score	text	15		PARAMTYP	Set PARAMTYP to missing.
PARAMTYP	NPITM04S	NPI-X Item D (Depression/Dysphoria) Score	text	15		PARAMTYP	Set PARAMTYP to missing.
PARAMTYP	NPITM05S	NPI-X Item E (Anxiety) Score	text	15		PARAMTYP	Set PARAMTYP to missing.
PARAMTYP	NPITM06S	NPI-X Item F (Eupohoria/Elation) Score	text	15		PARAMTYP	Set PARAMTYP to missing.
PARAMTYP	NPITM07S	NPI-X Item G (Apathy/Indifference) Score	text	15		PARAMTYP	Set PARAMTYP to missing.
PARAMTYP	NPITM08S	NPI-X Item H (Disinhibition) Score	text	15		PARAMTYP	Set PARAMTYP to missing.
PARAMTYP	NPITM09S	NPI-X Item I (Irritability/Lability) Score	text	15		PARAMTYP	Set PARAMTYP to missing.

Source Variable	Where PARAMCD=	Where PARAM=	Type	Length	Display Format	Code List / Controlled Term	Source/Derivation/Comments
PARAMTYP	NPITM10S	NPI-X Item J (Aberrant Motor Behavior) Score	text	15		PARAMTYP	Set PARAMTYP to missing.
PARAMTYP	NPITM11S	NPI-X Item K (Night-time Behavior) Score	text	15		PARAMTYP	Set PARAMTYP to missing.
PARAMTYP	NPITM12S	NPI-X Item L (Appetite/Eating Change) Score	text	15		PARAMTYP	Set PARAMTYP to missing.
PARAMTYP	NPTOT	NPI-X (9) Total Score	text	15		PARAMTYP	Set PARAMTYP to missing.
PARAMTYP	NPTOTMN	Mean NPI-X (9) Total (Week 4 to 24)	text	15		PARAMTYP	Set PARAMTYP to DERIVED.

Parameter Value List - ADQSNPIX [PCHG]

Source Variable	Where PARAMCD=	Where PARAM=	Type	Length	Display Format	Code List / Controlled Term	Source/Derivation/Comments
PCHG	NPITM01S	NPI-X Item A (Delusion) Score	integer	8			100* (CHG/BASE), for post baseline records.
PCHG	NPITM02S	NPI-X Item B (Hallucination) Score	integer	8			100* (CHG/BASE), for post baseline records.
PCHG	NPITM03S	NPI-X Item C (Agitation/Agression) Score	integer	8			100* (CHG/BASE), for post baseline records.

Source Variable	Where PARAMCD=	Where PARAM=	Type	Length	Display Format	Code List / Controlled Term	Source/Derivation/Comments
PCHG	NPITM04S	NPI-X Item D (Depression/Dysphoria) Score	integer	8			100* (CHG/BASE), for post baseline records.
PCHG	NPITM05S	NPI-X Item E (Anxiety) Score	integer	8			100* (CHG/BASE), for post baseline records.
PCHG	NPITM06S	NPI-X Item F (Eupohoria/Elation) Score	integer	8			100* (CHG/BASE), for post baseline records.
PCHG	NPITM07S	NPI-X Item G (Apathy/Indifference) Score	integer	8			100* (CHG/BASE), for post baseline records.
PCHG	NPITM08S	NPI-X Item H (Disinhibition) Score	integer	8			100* (CHG/BASE), for post baseline records.
PCHG	NPITM09S	NPI-X Item I (Irritability/Lability) Score	integer	8			100* (CHG/BASE), for post baseline records.
PCHG	NPITM10S	NPI-X Item J (Aberrant Motor Behavior) Score	integer	8			100* (CHG/BASE), for post baseline records.
PCHG	NPITM11S	NPI-X Item K (Night-time Behavior) Score	integer	8			100* (CHG/BASE), for post baseline records.
PCHG	NPITM12S	NPI-X Item L (Appetite/Eating Change) Score	integer	8			100* (CHG/BASE), for post baseline records.

Source Variable	Where PARAMCD=	Where PARAM=	Type	Length	Display Format	Code List / Controlled Term	Source/Derivation/Comments
PCHG	NPTOT	NPI-X (9) Total Score	integer	8			100* (CHG/BASE), for post baseline records.
PCHG	NPTOTMN	Mean NPI-X (9) Total (Week 4 to 24)	integer	8			Set PCHG to missing.

Parameter Value List - ADQSNPIX [QSSEQ]

Source Variable	Where PARAMCD=	Where PARAM=	Type	Length	Display Format	Code List / Controlled Term	Source/Derivation/Comments
QSSEQ	NPITM01S	NPI-X Item A (Delusion) Score	integer	8			QS.QSSEQ
QSSEQ	NPITM02S	NPI-X Item B (Hallucination) Score	integer	8			QS.QSSEQ
QSSEQ	NPITM03S	NPI-X Item C (Agitation/Agression) Score	integer	8			QS.QSSEQ
QSSEQ	NPITM04S	NPI-X Item D (Depression/Dysphoria) Score	integer	8			QS.QSSEQ
QSSEQ	NPITM05S	NPI-X Item E (Anxiety) Score	integer	8			QS.QSSEQ

Source Variable	Where PARAMCD=	Where PARAM=	Type	Length	Display Format	Code List / Controlled Term	Source/Derivation/Comments
QSSEQ	NPITM06S	NPI-X Item F (Eupohoria/Elation) Score	integer	8			QS.QSSEQ
QSSEQ	NPITM07S	NPI-X Item G (Apathy/Indifference) Score	integer	8			QS.QSSEQ
QSSEQ	NPITM08S	NPI-X Item H (Disinhibition) Score	integer	8			QS.QSSEQ
QSSEQ	NPITM09S	NPI-X Item I (Irritability/Lability) Score	integer	8			QS.QSSEQ
QSSEQ	NPITM10S	NPI-X Item J (Aberrant Motor Behavior) Score	integer	8			QS.QSSEQ
QSSEQ	NPITM11S	NPI-X Item K (Night-time Behavior) Score	integer	8			QS.QSSEQ
QSSEQ	NPITM12S	NPI-X Item L (Appetite/Eating Change) Score	integer	8			QS.QSSEQ
QSSEQ	NPTOT	NPI-X (9) Total Score	integer	8			QS.QSSEQ
QSSEQ	NPTOTMN	Mean NPI-X (9) Total (Week 4 to 24)	integer	8			Set QSSEQ to missing for post baseline records. Set to QS.QSSEQ where QS.VISIT=BASELINE and QS.QSTESTCD=NPTOT.

Parameter Value List - ADVS [AVAL]

Source Variable	Where PARAMCD=	Where PARAM=	Type	Length	Display Format	Code List / Controlled Term	Source/Derivation/Comments
AVAL	DIABP	Diastolic Blood Pressure (mmHg)	integer	8			VS.VSSTRESN
AVAL	HEIGHT	Height (cm)	integer	8			VS.VSSTRESN
AVAL	PULSE	Pulse Rate (BEATS/MIN)	integer	8			VS.VSSTRESN
AVAL	SYSBP	Systolic Blood Pressure (mmHg)	integer	8			VS.VSSTRESN
AVAL	TEMP	Temperature (C)	float	8	4.1		VS.VSSTRESN
AVAL	WEIGHT	Weight (kg)	float	8	4.1		VS.VSSTRESN

Parameter Value List - ADVS [BASE]

Source Variable	Where PARAMCD=	Where PARAM=	Type	Length	Display Format	Code List / Controlled Term	Source/Derivation/Comments
BASE	DIABP	Diastolic Blood Pressure (mmHg)	integer	8			VS.VSSTRESN where VSBLFL="Y"
BASE	HEIGHT	Height (cm)	integer	8			VS.VSSTRESN where VSBLFL="Y"
BASE	PULSE	Pulse Rate (BEATS/MIN)	integer	8			VS.VSSTRESN where VSBLFL="Y"

Source Variable	Where PARAMCD=	Where PARAM=	Type	Length	Display Format	Code List / Controlled Term	Source/Derivation/Comments
BASE	SYSBP	Systolic Blood Pressure (mmHg)	integer	8			VS.VSSTRESN where VSBLFL="Y"
BASE	TEMP	Temperature (C)	float	8	4.1		VS.VSSTRESN where VSBLFL="Y"
BASE	WEIGHT	Weight (kg)	float	8	4.1		VS.VSSTRESN where VSBLFL="Y"

Parameter Value List - ADVS [CHG]

Source Variable	Where PARAMCD=	Where PARAM=	Type	Length	Display Format	Code List / Controlled Term	Source/Derivation/Comments
CHG	DIABP	Diastolic Blood Pressure (mmHg)	integer	8			AVAL-BASE
CHG	HEIGHT	Height (cm)	integer	8			AVAL-BASE
CHG	PULSE	Pulse Rate (BEATS/MIN)	integer	8			AVAL-BASE
CHG	SYSBP	Systolic Blood Pressure (mmHg)	integer	8			AVAL-BASE
CHG	TEMP	Temperature (C)	float	8	4.1		AVAL-BASE
CHG	WEIGHT	Weight (kg)	float	8	4.1		AVAL-BASE

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Code List - ADLBCAT, Reference Name (ADLBCAT)

Coded Value	Decode
CHEM	Chemistry
HEM	Hematology
HYLAW	Hy's Law

Code List - AECAUS, Reference Name (AECAUS)

Coded Value	Decode
NONE	NONE
POSSIBLE	POSSIBLE
PROBABLE	PROBABLE
REMOTE	REMOTE

Code List - AGEGR1, Reference Name (AGEGR1)

Coded Value	Decode
<65	<65
65-80	65-80
>80	>80

Code List - AGEGR1N, Reference Name (AGEGR1N)

Coded Value	Decode
1	<65
2	65-80
3	>80

Code List - AGEU, Reference Name (AGEU)

Coded Value	Decode
YEARS	YEARS

Code List - ARM, Reference Name (ARM)

Coded Value	Decode
Placebo	Placebo
Xanomeline Low Dose	Xanomeline Low Dose
Xanomeline High Dose	Xanomeline High Dose

Code List - ARMN, Reference Name (ARMN)

Coded Value	Decode
0	Placebo
54	Xanomeline Low Dose
81	Xanomeline High Dose

Code List - ATPT, Reference Name (ATPT)

Coded Value	Decode
AFTER LYING DOWN FOR 5 MINUTES	AFTER LYING DOWN FOR 5 MINUTES
AFTER STANDING FOR 1 MINUTE	AFTER STANDING FOR 1 MINUTE
AFTER STANDING FOR 3 MINUTES	AFTER STANDING FOR 3 MINUTES

Code List - AVISIT, Reference Name (AVISIT)

Coded Value	Decode
Baseline	Baseline
Week 2	Week 2
Week 4	Week 4
Week 6	Week 6
Week 8	Week 8
Week 10	Week 10
Week 12	Week 12
Week 14	Week 14
Week 16	Week 16
Week 18	Week 18
Week 20	Week 20
Week 22	Week 22
Week 24	Week 24
Week 26	Week 26

Coded Value	Decode
Weeks 4-24	Weeks 4-24
End of Treatment	End of Treatment

Code List - AVISITN, Reference Name (AVISITN)

Coded Value	Decode
0	Baseline
2	Week 2
4	Week 4
6	Week 6
8	Week 8
10	Week 10
12	Week 12
14	Week 14
16	Week 16
18	Week 18
20	Week 20

Coded Value	Decode
22	Week 22
24	Week 24
26	Week 26
98	Weeks 4-24
99	End of Treatment

Code List - AWU, Reference Name (AWU)

Coded Value	Decode
DAYS	DAYS

Code List - BMICAT, Reference Name (BMICAT)

Coded Value	Decode
<25	Normal
25-<30	Overweight
>30	Obese

Code List - CENSOR, Reference Name (CENSOR)

Coded Value	Decode
0	Event
1	Censored

Code List - DISCCD, Reference Name (DISCCD)

Coded Value	Decode
COMPLETED	COMPLETED
ADVERSE EVENT	ADVERSE EVENT
DEATH	DEATH
LACK OF EFFICACY	LACK OF EFFICACY
LOST TO FOLLOW-UP	LOST TO FOLLOW-UP
WITHDRAWAL BY SUBJECT	WITHDRAWAL BY SUBJECT
STUDY TERMINATED BY SPONSOR	STUDY TERMINATED BY SPONSOR
PHYSICIAN DECISION	PHYSICIAN DECISION
PROTOCOL VIOLATION	PROTOCOL VIOLATION

Code List - DISCREAS, Reference Name (DISCREAS)

Coded Value	Decode
Completed	Completed
Adverse Event	Adverse Event
Death	Death
I/E Not Met	I/E Not Met
Lack of Efficacy	Lack of Efficacy
Lost to Follow-up	Lost to Follow-up
Physician Decision	Physician Decision
Protocol Violation	Protocol Violation
Sponsor Decision	Sponsor Decision
Withdrew Consent	Withdrew Consent

Code List - DMY, Reference Name (DMY)

Coded Value	Decode
D	Day imputed
M	Day and Month imputed
Y	Date (Day, Month and Year) imputed

Code List - DTYPE, Reference Name (DTYPE)

Coded Value	Decode
LOCF	Last Observation Carried Forward
AVERAGE	Average

Code List - DURDISC, Reference Name (DURDISC)

Coded Value	Decode
<12	<12
>=12	>=12

Code List - ETHNIC, Reference Name (ETHNIC)

Coded Value	Decode
NOT HISPANIC OR LATINO	NOT HISPANIC OR LATINO
HISPANIC OR LATINO	HISPANIC OR LATINO

Code List - LBNRIND, Reference Name (LBNRIND)

Coded Value	Decode
LOW	LOW
NORMAL	NORMAL
HIGH	HIGH

Code List - LNH, Reference Name (LNH)

Coded Value	Decode
L	Low
N	Normal
H	High

Code List - OUT, Reference Name (OUT)

Coded Value	Decode
RECOVERED/RESOLVED	RECOVERED/RESOLVED
NOT RECOVERED/NOT RESOLVED	NOT RECOVERED/NOT RESOLVED
FATAL	FATAL

Code List - PARAMCD_ADLBC, Reference Name (PARAMCD_ADLBC)

Coded Value	Decode
ALB	Albumin (g/L)
ALP	Alkaline Phosphatase (U/L)
ALT	Alanine Aminotransferase (U/L)
AST	Aspartate Aminotransferase (U/L)
BILI	Bilirubin (umol/L)
BUN	Blood Urea Nitrogen (mmol/L)
CA	Calcium (mmol/L)
CHOL	Cholesterol (mmol/L)
CK	Creatine Kinase (U/L)

Coded Value	Decode
CL	Chloride (mmol/L)
CREAT	Creatinine (umol/L)
GGT	Gamma Glutamyl Transferase (U/L)
GLUC	Glucose (mmol/L)
K	Potassium (mmol/L)
PHOS	Phosphate (mmol/L)
PROT	Protein (g/L)
SODIUM	Sodium (mmol/L)
URATE	Urate (umol/L)
_ALB	Albumin (g/L) change from previous visit, relative to normal range
_ALP	Alkaline Phosphatase (U/L) change from previous visit, relative to normal range
_ALT	Alanine Aminotransferase (U/L) change from previous visit, relative to normal range
_AST	Aspartate Aminotransferase (U/L) change from previous visit, relative to normal range
_BILI	Bilirubin (umol/L) change from previous visit, relative to normal range
_BUN	Blood Urea Nitrogen (mmol/L) change from previous visit, relative to normal range

Coded Value	Decode
_CA	Calcium (mmol/L) change from previous visit, relative to normal range
_CHOL	Cholesterol (mmol/L) change from previous visit, relative to normal range
_CK	Creatine Kinase (U/L) change from previous visit, relative to normal range
_CL	Chloride (mmol/L) change from previous visit, relative to normal range
_CREAT	Creatinine (umol/L) change from previous visit, relative to normal range
_GGT	Gamma Glutamyl Transferase (U/L) change from previous visit, relative to normal range
_GLUC	Glucose (mmol/L) change from previous visit, relative to normal range
_K	Potassium (mmol/L) change from previous visit, relative to normal range
_PHOS	Phosphate (mmol/L) change from previous visit, relative to normal range
_PROT	Protein (g/L) change from previous visit, relative to normal range
_SODIUM	Sodium (mmol/L) change from previous visit, relative to normal range
_URATE	Urate (umol/L) change from previous visit, relative to normal range

Code List - PARAMCD_ADLBH, Reference Name (PARAMCD_ADLBH)

Coded Value	Decode
ANISO	Anisocytes
BASO	Basophils (GI/L)
EOS	Eosinophils (GI/L)
HCT	Hematocrit
HGB	Hemoglobin (mmol/L)
LYM	Lymphocytes (GI/L)
MACROCY	Macrocytes
MCH	Ery. Mean Corpuscular Hemoglobin (fmol(Fe))
MCHC	Ery. Mean Corpuscular HGB Concentration (mmol/L)
MCV	Ery. Mean Corpuscular Volume (fL)
MICROCY	Microcytes
MONO	Monocytes (GI/L)
PLAT	Platelet (GI/L)
POIKILO	Poikilocytes

Coded Value	Decode
POLYCHR	Polychromasia
RBC	Erythrocytes (TI/L)
WBC	Leukocytes (GI/L)
_ANISO	Anisocytes change from previous visit, relative to normal range
_BASO	Basophils (GI/L) change from previous visit, relative to normal range
_EOS	Eosinophils (GI/L) change from previous visit, relative to normal range
_HCT	Hematocrit change from previous visit, relative to normal range
_HGB	Hemoglobin (mmol/L) change from previous visit, relative to normal range
_LYM	Lymphocytes (GI/L) change from previous visit, relative to normal range
_MACROCY	Macrocytes change from previous visit, relative to normal range
_MCH	Ery. Mean Corpuscular Hemoglobin (fmol(Fe)) change from previous visit, relative to normal range
_MCHC	Ery. Mean Corpuscular HGB Concentration (mmol/L) change from previous visit, relative to normal rang
_MCV	Ery. Mean Corpuscular Volume (fL) change from previous visit, relative to normal range
_MICROCY	Microcytes change from previous visit, relative to normal range
_MONO	Monocytes (GI/L) change from previous visit, relative to normal range

Coded Value	Decode
_PLAT	Platelet (GI/L) change from previous visit, relative to normal range
_POIKILO	Poikilocytes change from previous visit, relative to normal range
_POLYCHR	Polychromasia change from previous visit, relative to normal range
_RBC	Erythrocytes (TI/L) change from previous visit, relative to normal range
_WBC	Leukocytes (GI/L) change from previous visit, relative to normal range

Code List - PARAMCD_ADLBHY, Reference Name (PARAMCD_ADLBHY)

Coded Value	Decode
ALT	Alanine Aminotransferase (U/L)
AST	Aspartate Aminotransferase (U/L)
BILI	Bilirubin (umol/L)
BILIHY	Bilirubin 1.5 x ULN
TRANSHY	Transaminase 1.5 x ULN
HYLAW	Total Bili 1.5 x ULN and Transaminase 1.5 x ULN

Code List - PARAMCD_ADQSADAS, Reference Name (PARAMCD_ADQSADAS)

Coded Value	Decode
ACITM01	Word Recall Task
ACITM02	Naming Objects And Fingers (Refer To 5 C
ACITM03	Delayed Word Recall
ACITM04	Commands
ACITM05	Constructional Praxis
ACITM06	Ideational Praxis
ACITM07	Orientation
ACITM08	Word Recognition
ACITM09	Attention/Visual Search Task
ACITM10	Maze Solution
ACITM11	Spoken Language Ability
ACITM12	Comprehension Of Spoken Language
ACITM13	Word Finding Difficulty In Spontaneous S
ACITM14	Recall Of Test Instructions

Coded Value	Decode
ACTOT	Adas-Cog(11) Subscore

Code List - PARAMCD_ADQSCIBC, Reference Name (PARAMCD_ADQSCIBC)

Coded Value	Decode
CIBICVAL	CIBIC Score

Code List - PARAMCD_ADQSNPIX, Reference Name (PARAMCD_ADQSNPIX)

Coded Value	Decode
NPITM01S	NPI-X Item A (Delusion) Score
NPITM02S	NPI-X Item B (Hallucination) Score
NPITM03S	NPI-X Item C (Agitation/Agression) Score
NPITM04S	NPI-X Item D (Depression/Dysphoria) Score
NPITM05S	NPI-X Item E (Anxiety) Score
NPITM06S	NPI-X Item F (Eupohoria/Elation) Score
NPITM07S	NPI-X Item G (Apathy/Indifference) Score
NPITM08S	NPI-X Item H (Disinhibition) Score

Coded Value	Decode
NPITM09S	NPI-X Item I (Irritability/Lability) Score
NPITM10S	NPI-X Item J (Aberrant Motor Behavior) Score
NPITM11S	NPI-X Item K (Night-time Behavior) Score
NPITM12S	NPI-X Item L (Appetite/Eating Change) Score
NPTOT	NPI-X (9) Total Score
NPTOTMN	Mean NPI-X (9) Total (Week 4 to 24)

Code List - PARAMCD_ADTTE, Reference Name (PARAMCD_ADTTE)

Coded Value	Decode
TTDE	Time to Derm. Event or End of Study

Code List - PARAMCD_ADVS, Reference Name (PARAMCD_ADVS)

Coded Value	Decode
SYSBP	Systolic Blood Pressure (mmHg)
DIABP	Diastolic Blood Pressure (mmHg)
PULSE	Pulse Rate (BEATS/MIN)
WEIGHT	Weight (kg)
HEIGHT	Height (cm)
TEMP	Temperature (C)

Code List - PARAMN_ADLBC, Reference Name (PARAMN_ADLBC)

Coded Value	Decode
18	Sodium (mmol/L)
19	Potassium (mmol/L)
20	Chloride (mmol/L)
21	Bilirubin (umol/L)
22	Alkaline Phosphatase (U/L)
23	Gamma Glutamyl Transferase (U/L)

Coded Value	Decode
24	Alanine Aminotransferase (U/L)
25	Aspartate Aminotransferase (U/L)
26	Blood Urea Nitrogen (mmol/L)
27	Creatinine (umol/L)
28	Urate (umol/L)
29	Phosphate (mmol/L)
30	Calcium (mmol/L)
31	Glucose (mmol/L)
32	Protein (g/L)
33	Albumin (g/L)
34	Cholesterol (mmol/L)
35	Creatine Kinase (U/L)
118	Sodium (mmol/L) change from previous visit, relative to normal range
119	Potassium (mmol/L) change from previous visit, relative to normal range
120	Chloride (mmol/L) change from previous visit, relative to normal range

Coded Value	Decode
121	Bilirubin (umol/L) change from previous visit, relative to normal range
122	Alkaline Phosphatase (U/L) change from previous visit, relative to normal range
123	Gamma Glutamyl Transferase (U/L) change from previous visit, relative to normal range
124	Alanine Aminotransferase (U/L) change from previous visit, relative to normal range
125	Aspartate Aminotransferase (U/L) change from previous visit, relative to normal range
126	Blood Urea Nitrogen (mmol/L) change from previous visit, relative to normal range
127	Creatinine (umol/L) change from previous visit, relative to normal range
128	Urate (umol/L) change from previous visit, relative to normal range
129	Phosphate (mmol/L) change from previous visit, relative to normal range
130	Calcium (mmol/L) change from previous visit, relative to normal range
131	Glucose (mmol/L) change from previous visit, relative to normal range
132	Protein (g/L) change from previous visit, relative to normal range
133	Albumin (g/L) change from previous visit, relative to normal range
134	Cholesterol (mmol/L) change from previous visit, relative to normal range
135	Creatine Kinase (U/L) change from previous visit, relative to normal range

Code List - PARAMN_ADLBH, Reference Name (PARAMN_ADLBH)

Coded Value	Decode
1	Hemoglobin (mmol/L)
2	Hematocrit
3	Ery. Mean Corpuscular Volume (fL)
4	Ery. Mean Corpuscular Hemoglobin (fmol(Fe))
5	Ery. Mean Corpuscular HGB Concentration (mmol/L)
6	Leukocytes (GI/L)
7	Lymphocytes (GI/L)
8	Monocytes (GI/L)
9	Eosinophils (GI/L)
10	Basophils (GI/L)
11	Platelet (GI/L)
12	Erythrocytes (TI/L)
13	Anisocytes
14	Macrocytes

Coded Value	Decode
15	Microcytes
16	Poikilocytes
17	Polychromasia
101	Hemoglobin (mmol/L) change from previous visit, relative to normal range
102	Hematocrit change from previous visit, relative to normal range
103	Ery. Mean Corpuscular Volume (fL) change from previous visit, relative to normal range
104	Ery. Mean Corpuscular Hemoglobin (fmol(Fe)) change from previous visit, relative to normal range
105	Ery. Mean Corpuscular HGB Concentration (mmol/L) change from previous visit, relative to normal rang
106	Leukocytes (GI/L) change from previous visit, relative to normal range
107	Lymphocytes (GI/L) change from previous visit, relative to normal range
108	Monocytes (GI/L) change from previous visit, relative to normal range
109	Eosinophils (GI/L) change from previous visit, relative to normal range
110	Basophils (GI/L) change from previous visit, relative to normal range
111	Platelet (GI/L) change from previous visit, relative to normal range
112	Erythrocytes (TI/L) change from previous visit, relative to normal range

Coded Value	Decode
113	Anisocytes change from previous visit, relative to normal range
114	Macrocytes change from previous visit, relative to normal range
115	Microcytes change from previous visit, relative to normal range
116	Poikilocytes change from previous visit, relative to normal range
117	Polychromasia change from previous visit, relative to normal range

Code List - PARAMN_ADLBHY, Reference Name (PARAMN_ADLBHY)

Coded Value	Decode
1	Alanine Aminotransferase (U/L)
2	Aspartate Aminotransferase (U/L)
3	Bilirubin (umol/L)
4	Bilirubin 1.5 x ULN
5	Transaminase 1.5 x ULN
6	Total Bili 1.5 x ULN and Transaminase 1.5 x ULN

Code List - PARAMN_ADQSADAS, Reference Name (PARAMN_ADQSADAS)

Coded Value	Decode
1	Word Recall Task
2	Naming Objects And Fingers (Refer To 5 C
3	Delayed Word Recall
4	Commands
5	Constructional Praxis
6	Ideational Praxis
7	Orientation
8	Word Recognition
9	Attention/Visual Search Task
10	Maze Solution
11	Spoken Language Ability
12	Comprehension Of Spoken Language
13	Word Finding Difficulty In Spontaneous S
14	Recall Of Test Instructions

Coded Value	Decode
15	Adas-Cog(11) Subscore

Code List - PARAMN_ADQSCIBC, Reference Name (PARAMN_ADQSCIBC)

Coded Value	Decode
1	CIBIC Score

Code List - PARAMN_ADQSNPIX, Reference Name (PARAMN_ADQSNPIX)

Coded Value	Decode
1	NPI-X Item A (Delusion) Score
2	NPI-X Item B (Hallucination) Score
3	NPI-X Item C (Agitation/Agression) Score
4	NPI-X Item D (Depression/Dysphoria) Score
5	NPI-X Item E (Anxiety) Score
6	NPI-X Item F (Eupohoria/Elation) Score
7	NPI-X Item G (Apathy/Indifference) Score
8	NPI-X Item H (Disinhibition) Score

Coded Value	Decode
9	NPI-X Item I (Irritability/Lability) Score
10	NPI-X Item J (Aberrant Motor Behavior) Score
11	NPI-X Item K (Night-time Behavior) Score
12	NPI-X Item L (Appetite/Eating Change) Score
13	NPI-X (9) Total Score
14	Mean NPI-X (9) Total (Week 4 to 24)

Code List - PARAMN_ADVS, Reference Name (PARAMN_ADVS)

Coded Value	Decode
1	Systolic Blood Pressure (mmHg)
2	Diastolic Blood Pressure (mmHg)
3	Pulse Rate (BEATS/MIN)
4	Weight (kg)
5	Height (cm)
6	Temperature (C)

Code List - PARAMTYP, Reference Name (PARAMTYP)

Coded Value	Decode
DERIVED	DERIVED

Code List - PARAM_ADLBC, Reference Name (PARAM_ADLBC)

Coded Value	Decode
Albumin (g/L)	Albumin (g/L)
Alkaline Phosphatase (U/L)	Alkaline Phosphatase (U/L)
Alanine Aminotransferase (U/L)	Alanine Aminotransferase (U/L)
Aspartate Aminotransferase (U/L)	Aspartate Aminotransferase (U/L)
Bilirubin (umol/L)	Bilirubin (umol/L)
Blood Urea Nitrogen (mmol/L)	Blood Urea Nitrogen (mmol/L)
Calcium (mmol/L)	Calcium (mmol/L)
Cholesterol (mmol/L)	Cholesterol (mmol/L)
Creatine Kinase (U/L)	Creatine Kinase (U/L)

Coded Value	Decode
Chloride (mmol/L)	Chloride (mmol/L)
Creatinine (umol/L)	Creatinine (umol/L)
Gamma Glutamyl Transferase (U/L)	Gamma Glutamyl Transferase (U/L)
Glucose (mmol/L)	Glucose (mmol/L)
Potassium (mmol/L)	Potassium (mmol/L)
Phosphate (mmol/L)	Phosphate (mmol/L)
Protein (g/L)	Protein (g/L)
Sodium (mmol/L)	Sodium (mmol/L)
Urate (umol/L)	Urate (umol/L)
Albumin (g/L) change from previous visit, relative to normal range	Albumin (g/L) change from previous visit, relative to normal range
Alkaline Phosphatase (U/L) change from previous visit, relative to normal range	Alkaline Phosphatase (U/L) change from previous visit, relative to normal range

Coded Value	Decode
Alanine Aminotransferase (U/L) change from previous visit, relative to normal range	Alanine Aminotransferase (U/L) change from previous visit, relative to normal range
Aspartate Aminotransferase (U/L) change from previous visit, relative to normal range	Aspartate Aminotransferase (U/L) change from previous visit, relative to normal range
Bilirubin (umol/L) change from previous visit, relative to normal range	Bilirubin (umol/L) change from previous visit, relative to normal range
Blood Urea Nitrogen (mmol/L) change from previous visit, relative to normal range	Blood Urea Nitrogen (mmol/L) change from previous visit, relative to normal range
Calcium (mmol/L) change from previous visit, relative to normal range	Calcium (mmol/L) change from previous visit, relative to normal range
Cholesterol (mmol/L) change from previous visit, relative to normal range	Cholesterol (mmol/L) change from previous visit, relative to normal range

Coded Value	Decode
Creatine Kinase (U/L) change from previous visit, relative to normal range	Creatine Kinase (U/L) change from previous visit, relative to normal range
Chloride (mmol/L) change from previous visit, relative to normal range	Chloride (mmol/L) change from previous visit, relative to normal range
Creatinine (umol/L) change from previous visit, relative to normal range	Creatinine (umol/L) change from previous visit, relative to normal range
Gamma Glutamyl Transferase (U/L) change from previous visit, relative to normal range	Gamma Glutamyl Transferase (U/L) change from previous visit, relative to normal range
Glucose (mmol/L) change from previous visit, relative to normal range	Glucose (mmol/L) change from previous visit, relative to normal range
Potassium (mmol/L) change from previous visit, relative to normal range	Potassium (mmol/L) change from previous visit, relative to normal range
Phosphate (mmol/L) change from previous visit, relative to normal range	Phosphate (mmol/L) change from previous visit, relative to normal range

Coded Value	Decode
Protein (g/L) change from previous visit, relative to normal range	Protein (g/L) change from previous visit, relative to normal range
Sodium (mmol/L) change from previous visit, relative to normal range	Sodium (mmol/L) change from previous visit, relative to normal range
Urate (umol/L) change from previous visit, relative to normal range	Urate (umol/L) change from previous visit, relative to normal range

Code List - PARAM_ADLBH, Reference Name (PARAM_ADLBH)

Coded Value	Decode
Anisocytes	Anisocytes
Basophils (GI/L)	Basophils (GI/L)
Eosinophils (GI/L)	Eosinophils (GI/L)
Hematocrit	Hematocrit
Hemoglobin (mmol/L)	Hemoglobin (mmol/L)
Lymphocytes (GI/L)	Lymphocytes (GI/L)
Macrocytes	Macrocytes

Coded Value	Decode
Ery. Mean Corpuscular Hemoglobin (fmol(Fe))	Ery. Mean Corpuscular Hemoglobin (fmol(Fe))
Ery. Mean Corpuscular HGB Concentration (mmol/L)	Ery. Mean Corpuscular HGB Concentration (mmol/L)
Ery. Mean Corpuscular Volume (fL)	Ery. Mean Corpuscular Volume (fL)
Microcytes	Microcytes
Monocytes (GI/L)	Monocytes (GI/L)
Platelet (GI/L)	Platelet (GI/L)
Poikilocytes	Poikilocytes
Polychromasia	Polychromasia
Erythrocytes (TI/L)	Erythrocytes (TI/L)
Leukocytes (GI/L)	Leukocytes (GI/L)
Anisocytes change from previous visit, relative to normal range	Anisocytes change from previous visit, relative to normal range

Coded Value	Decode
Basophils (GI/L) change from previous visit, relative to normal range	Basophils (GI/L) change from previous visit, relative to normal range
Eosinophils (GI/L) change from previous visit, relative to normal range	Eosinophils (GI/L) change from previous visit, relative to normal range
Hematocrit change from previous visit, relative to normal range	Hematocrit change from previous visit, relative to normal range
Hemoglobin (mmol/L) change from previous visit, relative to normal range	Hemoglobin (mmol/L) change from previous visit, relative to normal range
Lymphocytes (GI/L) change from previous visit, relative to normal range	Lymphocytes (GI/L) change from previous visit, relative to normal range
Macrocytes change from previous visit, relative to normal range	Macrocytes change from previous visit, relative to normal range
Ery. Mean Corpuscular Hemoglobin (fmol(Fe)) change from previous visit, relative to normal range	Ery. Mean Corpuscular Hemoglobin (fmol(Fe)) change from previous visit, relative to normal range

Coded Value	Decode
Ery. Mean Corpuscular HGB Concentration (mmol/L) change from previous visit, relative to normal rang	Ery. Mean Corpuscular HGB Concentration (mmol/L) change from previous visit, relative to normal rang
Ery. Mean Corpuscular Volume (fL) change from previous visit, relative to normal range	Ery. Mean Corpuscular Volume (fL) change from previous visit, relative to normal range
Microcytes change from previous visit, relative to normal range	Microcytes change from previous visit, relative to normal range
Monocytes (GI/L) change from previous visit, relative to normal range	Monocytes (GI/L) change from previous visit, relative to normal range
Platelet (GI/L) change from previous visit, relative to normal range	Platelet (GI/L) change from previous visit, relative to normal range
Poikilocytes change from previous visit, relative to normal range	Poikilocytes change from previous visit, relative to normal range
Polychromasia change from previous visit, relative to normal range	Polychromasia change from previous visit, relative to normal range

Coded Value	Decode
Erythrocytes (TI/L) change from previous visit, relative to normal range	Erythrocytes (TI/L) change from previous visit, relative to normal range
Leukocytes (GI/L) change from previous visit, relative to normal range	Leukocytes (GI/L) change from previous visit, relative to normal range

Code List - PARAM_ADLBHY, Reference Name (PARAM_ADLBHY)

Coded Value	Decode
Alanine Aminotransferase (U/L)	Alanine Aminotransferase (U/L)
Aspartate Aminotransferase (U/L)	Aspartate Aminotransferase (U/L)
Bilirubin (umol/L)	Bilirubin (umol/L)
Bilirubin 1.5 x ULN	Bilirubin 1.5 x ULN
Transaminase 1.5 x ULN	Transaminase 1.5 x ULN
Total Bili 1.5 x ULN and Transaminase 1.5 x ULN	Total Bili 1.5 x ULN and Transaminase 1.5 x ULN

Code List - PARAM_ADQSADAS, Reference Name (PARAM_ADQSADAS)

Coded Value	Decode
Word Recall Task	Word Recall Task
Naming Objects And Fingers (Refer To 5 C	Naming Objects And Fingers (Refer To 5 C
Delayed Word Recall	Delayed Word Recall
Commands	Commands
Constructional Praxis	Constructional Praxis
Ideational Praxis	Ideational Praxis
Orientation	Orientation
Word Recognition	Word Recognition
Attention/Visual Search Task	Attention/Visual Search Task
Maze Solution	Maze Solution
Spoken Language Ability	Spoken Language Ability
Comprehension Of Spoken Language	Comprehension Of Spoken Language

Coded Value	Decode
Word Finding Difficulty In Spontaneous S	Word Finding Difficulty In Spontaneous S
Recall Of Test Instructions	Recall Of Test Instructions
Adas-Cog(11) Subscore	Adas-Cog(11) Subscore

Code List - PARAM_ADQSCIBC, Reference Name (PARAM_ADQSCIBC)

Coded Value	Decode
CIBIC Score	CIBIC Score

Code List - PARAM_ADQSNPIX, Reference Name (PARAM_ADQSNPIX)

Coded Value	Decode
NPI-X Item A (Delusion) Score	NPI-X Item A (Delusion) Score
NPI-X Item B (Hallucination) Score	NPI-X Item B (Hallucination) Score
NPI-X Item C (Agitation/Agression) Score	NPI-X Item C (Agitation/Agression) Score
NPI-X Item D (Depression/Dysphoria) Score	NPI-X Item D (Depression/Dysphoria) Score

Coded Value	Decode
NPI-X Item E (Anxiety) Score	NPI-X Item E (Anxiety) Score
NPI-X Item F (Eupohoria/Elation) Score	NPI-X Item F (Eupohoria/Elation) Score
NPI-X Item G (Apathy/Indifference) Score	NPI-X Item G (Apathy/Indifference) Score
NPI-X Item H (Disinhibition) Score	NPI-X Item H (Disinhibition) Score
NPI-X Item I (Irritability/Lability) Score	NPI-X Item I (Irritability/Lability) Score
NPI-X Item J (Aberrant Motor Behavior) Score	NPI-X Item J (Aberrant Motor Behavior) Score
NPI-X Item K (Night-time Behavior) Score	NPI-X Item K (Night-time Behavior) Score
NPI-X Item L (Appetite/Eating Change) Score	NPI-X Item L (Appetite/Eating Change) Score
NPI-X (9) Total Score	NPI-X (9) Total Score
Mean NPI-X (9) Total (Week 4 to 24)	Mean NPI-X (9) Total (Week 4 to 24)

Code List - PARAM_ADTTE, Reference Name (PARAM_ADTTE)

Coded Value	Decode
Time to First Dermatologic Event	Time to Derm. Event or End of Study

Code List - PARAM_ADVS, Reference Name (PARAM_ADVS)

Coded Value	Decode
Systolic Blood Pressure (mmHg)	Systolic Blood Pressure (mmHg)
Diastolic Blood Pressure (mmHg)	Diastolic Blood Pressure (mmHg)
Pulse Rate (BEATS/MIN)	Pulse Rate (BEATS/MIN)
Weight (kg)	Weight (kg)
Height (cm)	Height (cm)
Temperature (C)	Temperature (C)

Code List - RACE, Reference Name (RACE)

Coded Value	Decode
WHITE	WHITE
BLACK OR AFRICAN AMERICAN	BLACK OR AFRICAN AMERICAN
AMERICAN INDIAN OR ALASKA NATIVE	AMERICAN INDIAN OR ALASKA NATIVE
ASIAN	ASIAN

Code List - RACEN, Reference Name (RACEN)

Coded Value	Decode
1	WHITE
2	BLACK OR AFRICAN AMERICAN
6	AMERICAN INDIAN OR ALASKA NATIVE
7	ASIAN

Code List - SEV, Reference Name (SEV)

Coded Value	Decode
MILD	MILD
MODERATE	MODERATE
SEVERE	SEVERE

Code List - SEX, Reference Name (SEX)

Coded Value	Decode
F	Female
M	Male
U	Unknown

Code List - SHIFT, Reference Name (SHIFT)

Coded Value	Decode
High to Normal	High to Normal
Normal to Normal	Normal to Normal
Normal to High	Normal to High

Code List - SHIFTN, Reference Name (SHIFTN)

Coded Value	Decode
0	High to Normal
1	Normal to Normal
2	Normal to High

Code List - VISIT, Reference Name (VISIT)

Coded Value	Decode
SCREENING 1	SCREENING 1
UNSCHEDULED 1.1	UNSCHEDULED 1.1
UNSCHEDULED 1.2	UNSCHEDULED 1.2
UNSCHEDULED 1.3	UNSCHEDULED 1.3
SCREENING 2	SCREENING 2
BASELINE	BASELINE
UNSCHEDULED 3.1	UNSCHEDULED 3.1
AMBUL ECG PLACEMENT	AMBUL ECG PLACEMENT
WEEK 2	WEEK 2

Coded Value	Decode
UNSCHEDULED 4.1	UNSCHEDULED 4.1
UNSCHEDULED 4.2	UNSCHEDULED 4.2
WEEK 4	WEEK 4
UNSCHEDULED 5.1	UNSCHEDULED 5.1
AMBUL ECG REMOVAL	AMBUL ECG REMOVAL
UNSCHEDULED 6.1	UNSCHEDULED 6.1
WEEK 6	WEEK 6
UNSCHEDULED 7.1	UNSCHEDULED 7.1
WEEK 8	WEEK 8
WEEK 10 (T)	WEEK 10 (T)
UNSCHEDULED 8.2	UNSCHEDULED 8.2
WEEK 12	WEEK 12
WEEK 14 (T)	WEEK 14 (T)
UNSCHEDULED 9.2	UNSCHEDULED 9.2
UNSCHEDULED 9.3	UNSCHEDULED 9.3

Coded Value	Decode
WEEK 16	WEEK 16
WEEK 18 (T)	WEEK 18 (T)
UNSCHEDULED 10.2	UNSCHEDULED 10.2
WEEK 20	WEEK 20
WEEK 22 (T)	WEEK 22 (T)
UNSCHEDULED 11.2	UNSCHEDULED 11.2
WEEK 24	WEEK 24
UNSCHEDULED 12.1	UNSCHEDULED 12.1
WEEK 26	WEEK 26
UNSCHEDULED 13.1	UNSCHEDULED 13.1
AE FOLLOW-UP	AE FOLLOW-UP
RETRIEVAL	RETRIEVAL
Rash followup	Rash followup

Code List - VISITNUM, Reference Name (VISITNUM)

Coded Value	Decode
1	SCREENING 1
1.1	UNSCHEDULED 1.1
1.2	UNSCHEDULED 1.2
1.3	UNSCHEDULED 1.3
2	SCREENING 2
3	BASELINE
3.1	UNSCHEDULED 3.1
3.5	AMBUL ECG PLACEMENT
4	WEEK 2
4.1	UNSCHEDULED 4.1
4.2	UNSCHEDULED 4.2
5	WEEK 4
5.1	UNSCHEDULED 5.1
6	AMBUL ECG REMOVAL

Coded Value	Decode
6.1	UNSCHEDULED 6.1
7	WEEK 6
7.1	UNSCHEDULED 7.1
8	WEEK 8
8.1	WEEK 10 (T)
8.2	UNSCHEDULED 8.2
9	WEEK 12
9.1	WEEK 14 (T)
9.2	UNSCHEDULED 9.2
9.3	UNSCHEDULED 9.3
10	WEEK 16
10.1	WEEK 18 (T)
10.2	UNSCHEDULED 10.2
11	WEEK 20
11.1	WEEK 22 (T)

Coded Value	Decode
11.2	UNSCHEDULED 11.2
12	WEEK 24
12.1	UNSCHEDULED 12.1
13	WEEK 26
13.1	UNSCHEDULED 13.1
101	AE FOLLOW-UP
201	RETRIEVAL
501	Rash followup

Code List - YN, Reference Name (YN)

Coded Value	Decode
N	No
Y	Yes

Code List - YNN, Reference Name (YNN)

Coded Value	Decode
0	No
1	Yes

Code List - Y_BLANK, Reference Name (Y_BLANK)

Coded Value	Decode
Y	Yes

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External Dictionaries

Reference Name	External Dictionary	Dictionary Version
ADVERSE EVENT DICTIONARY (AEDICT)	MedDRA	8.0

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