

**Data Set Name: adae.sas7bdat**

<b>Num</b>	<b>Variable</b>	<b>Type</b>	<b>Len</b>	<b>Label</b>
1	SubjRandID	Num	8	Subject Identifier (randomly assigned)
2	STUDYID	Char	10	Study Identifier
3	AGE	Num	8	Age
4	AGE1	Num	8	Age at Baseline
5	AGEM	Num	8	Age at Baseline (Months)
6	AGEU	Char	5	Age Units
7	AGEGR1	Char	14	Pooled Age Group 1
8	AGEGR1N	Num	8	Pooled Age Group 1 (N)
9	RACE	Char	25	Race
10	RACE1	Char	25	Race 1
11	RACE2	Char	5	Race 2
12	RACEN	Num	8	Race (N)
13	SEX	Char	1	Sex
14	SEXN	Num	8	Sex (N)
15	ETHNIC	Char	22	Ethnicity
16	ETHNICN	Num	8	Ethnicity (N)
17	COUNTRY	Char	3	Country
18	SCRNFL	Char	1	Screened Population Flag
19	SCRNFN	Num	8	Screened Population Flag (N)
20	ENRFL	Char	1	Enrolled Population Flag
21	ENRFLN	Num	8	Enrolled Population Flag (N)
22	SAFFL	Char	1	Safety Population Flag
23	SAFFN	Num	8	Safety Population Flag (N)
24	SAFOPFL	Char	1	Safety Population Flag Core Trt
25	SAFOPFN	Num	8	Safety Population Flag Core Trt (N)
26	SAFPA4FL	Char	1	Safety Population Flag PA4
27	SAFPA4FN	Num	8	Safety Population Flag PA4 (N)
28	SAFPA5FL	Char	1	Safety Population Flag PA5
29	SAFPA5FN	Num	8	Safety Population Flag PA5 (N)
30	SAFPA6FL	Char	1	Safety Population Flag PA6
31	SAFPA6FN	Num	8	Safety Population Flag PA6 (N)
32	COMPLFL	Char	1	Completers Population Flag
33	COMPLFN	Num	8	Completers Population Flag (N)
34	COMPL2FL	Char	1	Completers Population Flag 02
35	COMPL2FN	Num	8	Completers Population Flag 02 (N)
36	COMPL3FL	Char	1	Completers Population Flag 03
37	COMPL3FN	Num	8	Completers Population Flag 03 (N)

Num	Variable	Type	Len	Label
38	COMPL4FL	Char	1	Completers Population Flag 04
39	COMPL4FN	Num	8	Completers Population Flag 04 (N)
40	DOSINTFL	Char	1	Drug Interrupted for >28 Days Flag
41	DOSINTFN	Num	8	Drug Interrupted for >28 Days Flag (N)
42	ARM	Char	11	Description of Planned Arm
43	ACTARM	Char	11	Description of Actual Arm
44	TRT01P	Char	3	Planned Treatment for Period 01
45	TRT01PN	Num	8	Planned Treatment for Period 01 (N)
46	TRT01A	Char	3	Actual Treatment for Period 01
47	TRT01AN	Num	8	Actual Treatment for Period 01 (N)
48	TRTSEQP	Char	7	Planned Sequence of Treatments
49	TRTSEQPN	Num	8	Planned Sequence of Treatments (N)
50	TRTSEQA	Char	7	Actual Sequence of Treatments
51	TRTSEQAN	Num	8	Actual Sequence of Treatments (N)
52	TRTP	Char	7	Planned Treatment
53	TRTPN	Num	8	Planned Treatment (N)
54	TRTA	Char	7	Actual Treatment
55	TRTAN	Num	8	Actual Treatment (N)
56	AESEQ	Num	8	Sequence Number
57	AESPID	Char	3	Sponsor-Defined Identifier
58	AEGRPID	Char	9	Group ID
59	AETERM	Char	108	Reported Term for the Adverse Event
60	AELLT	Char	39	Lowest Level Term
61	AELLTCD	Num	8	Lowest Level Term Code
62	AEDECOD	Char	47	Dictionary-Derived Term
63	AEPTCD	Num	8	Preferred Term Code
64	AEHLT	Char	63	High Level Term
65	AEHLTCD	Num	8	High Level Term Code
66	AEHLGT	Char	59	High Level Group Term
67	AEHLGTC	Num	8	High Level Group Term Code
68	AEBODSYS	Char	67	Body System or Organ Class
69	AEBDSYCD	Num	8	Body System or Organ Class Code
70	AESOC	Char	67	Primary System Organ Class
71	AESOC	Num	8	Primary System Organ Class Code
72	AESIDI	Char	16	AEs of Special Interest Diarrhoea
73	AESIDIFL	Char	1	AEs of Special Interest Diarrhoea Flag
74	AESIFS	Char	37	AEs of Special Interest Fat Sl. Vit
75	AESIFSFL	Char	1	AEs of Special Interest Fat Sl. Vit Flag
76	AESIET	Char	29	AEs of Special Interest Elv transaminase

Num	Variable	Type	Len	Label
77	AESIETFL	Char	1	AEs of Special Interest Elv transam Flag
78	AESIEB	Char	25	AEs of Special Interest Elevat Bilirubin
79	AESIEBFL	Char	1	AEs of Special Interest Elevat Bili Flag
80	AESER	Char	1	Serious Event
81	AESERN	Num	8	Serious Event (N)
82	AETOXGR	Char	1	Standard Toxicity Grade
83	AETOXGRN	Num	8	Standard Toxicity Grade (N)
84	ATOXGR	Char	18	Analysis Toxicity Grade
85	ATOXGRN	Num	8	Analysis Toxicity Grade (N)
86	AEACN	Char	16	Action Taken with Study Treatment
87	AEACNN	Num	8	Action Taken with Study Treatment (N)
88	AEACNOTH	Char	99	Other Action Taken
89	AEREL	Char	25	Causality
90	AERELN	Num	8	Causality (N)
91	AREL	Char	25	Analysis Causality
92	ARELN	Num	8	Analysis Causality (N)
93	RELGR1	Char	19	Pooled Causality Group 1
94	RELGR1N	Num	8	Pooled Causality Group 1 (N)
95	AEOUT	Char	32	Outcome of Adverse Event
96	AEOUTN	Num	8	Outcome of Adverse Event (N)
97	AESDTH	Char	1	Results in Death
98	AESHOSP	Char	1	Requires or Prolongs Hospitalization
99	AESLIFE	Char	1	Is Life Threatening
100	AECONTRT	Char	1	Concomitant or Additional Trtmnt Given
101	AETRT	Char	106	Treatment Required
102	AEDIS	Char	1	AE Caused Discontinuation from Study
103	ASTDTF	Char	1	Analysis Start Date Imputation Flag
104	AENDTF	Char	1	Analysis End Date Imputation Flag
105	ASTDY	Num	8	Analysis Start Relative Day (from first treatment date)
106	AESTDY	Num	8	Study Day of Start of Adverse Event (from first treatment date)
107	AENDY	Num	8	Analysis End Relative Day (from first treatment date)
108	AEENDY	Num	8	Study Day of End of Adverse Event (from first treatment date)
109	ADURN	Num	8	AE Duration (N)
110	ADURU	Char	4	AE Duration Units
111	AEENRF	Char	7	End Relative to Reference Period
112	DOSEAEON	Char	8	Study Drug Dose at AE Onset
113	DOSAEONU	Char	9	Study Drug Dose at AE Onset Units
114	TRTEMFL	Char	1	Treatment Emergent Analysis Flag
115	AOCCFL	Char	1	1st Occurrence of Any AE Flag

Num	Variable	Type	Len	Label
116	AOCCSFL	Char	1	1st Occurrence of SOC Flag
117	AOCCPFL	Char	1	1st Occurrence of Preferred Term Flag
118	AOCCIFL	Char	1	1st Max Sev./Int. Occurrence Flag
119	AOCCSIFL	Char	1	1st Max Sev./Int. Occur Within SOC Flag
120	AOCCPIFL	Char	1	1st Max Sev./Int. Occur Within PT Flag
121	AOCSFL	Char	1	Ser. 1st Occurrence of Any AE Flag
122	AOCSSFL	Char	1	Ser. 1st Occurrence of SOC Flag
123	AOCSPFL	Char	1	Ser. 1st Occurrence of PT Flag
124	AOSTRFL	Char	1	Ser. 1st Occ. of Any TRT Rel AE Flag
125	AOSTRSFL	Char	1	Ser. 1st Occ. of TRT Rel SOC Flag
126	AOSTRPFL	Char	1	Ser. 1st Occ. of TRT Rel PT Flag
127	AOCD CFL	Char	1	1st AE Leading to Discontinuation Flag
128	AOCD CSFL	Char	1	1st AE Leading to Discon. SOC Flag
129	AOCD CPFL	Char	1	1st AE Leading to Discon. PT Flag
130	AOCCTFL	Char	1	1st Occurrence of Any Trt Rel AE Flag
131	AOCCTSFL	Char	1	1st Occurrence of Trt Rel SOC Flag
132	AOCCTPFL	Char	1	1st Occurrence of Trt Rel PT Flag
133	AOCTIFL	Char	1	1st Max Sev Trt Rel Occur Flag
134	AOCTSIFL	Char	1	1st Max Sev Trt Rel Occur W/ SOC Flag
135	AOCTPIFL	Char	1	1st Max Sev Trt Rel Occur W/ PT Flag
136	AOTEDIFL	Char	1	1st TEAE for Diarrhoea Events Flag
137	AOTEDSFL	Char	1	1st TEAE for Diarrhoea Event in SOC Flag
138	AOTEDPFL	Char	1	1st TEAE for Diarrhoea Events in PT Flag
139	AOTEVTF L	Char	1	1st TEAE for Vitamin Def Events Flag
140	AOTEVSFL	Char	1	1st TEAE for Vitamin Events in SOC Flag
141	AOTEVPFL	Char	1	1st TEAE for Vitamin Events in PT Flag
142	AOTEETFL	Char	1	1st TEAE for Elevated Transaminases Flag
143	AOTETSFL	Char	1	1st TEAE for Elevated Transa in SOC Flag
144	AOTETPFL	Char	1	1st TEAE for Elevated Transam in PT Flag
145	AOTE EBFL	Char	1	1st TEAE for Elevated Bilirubin Flag
146	AOTEBSFL	Char	1	1st TEAE for Elevated Bili in SOC Flag
147	AOTE BPFL	Char	1	1st TEAE for Elevated Bili in PT Flag

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Num	Variable	Type	Len	Label
1	SubjRandID	Num	8	Subject Identifier (randomly assigned)
2	STUDYID	Char	10	Study Identifier
3	AGE	Num	8	Age
4	AGE1	Num	8	Age at Baseline
5	AGEM	Num	8	Age at Baseline (Months)
6	AGEU	Char	5	Age Units
7	AGEGR1	Char	14	Pooled Age Group 1
8	AGEGR1N	Num	8	Pooled Age Group 1 (N)
9	RACE	Char	25	Race
10	RACE1	Char	25	Race 1
11	RACE2	Char	5	Race 2
12	RACEN	Num	8	Race (N)
13	SEX	Char	1	Sex
14	SEXN	Num	8	Sex (N)
15	ETHNIC	Char	22	Ethnicity
16	ETHNICN	Num	8	Ethnicity (N)
17	COUNTRY	Char	3	Country
18	SCRNFL	Char	1	Screened Population Flag
19	SCRNFN	Num	8	Screened Population Flag (N)
20	ENRFL	Char	1	Enrolled Population Flag
21	ENRFLN	Num	8	Enrolled Population Flag (N)
22	SAFFL	Char	1	Safety Population Flag
23	SAFFN	Num	8	Safety Population Flag (N)
24	SAFOPFL	Char	1	Safety Population Flag Core Trt
25	SAFOPFN	Num	8	Safety Population Flag Core Trt (N)
26	SAFPA4FL	Char	1	Safety Population Flag PA4
27	SAFPA4FN	Num	8	Safety Population Flag PA4 (N)
28	SAFPA5FL	Char	1	Safety Population Flag PA5
29	SAFPA5FN	Num	8	Safety Population Flag PA5 (N)
30	SAFPA6FL	Char	1	Safety Population Flag PA6
31	SAFPA6FN	Num	8	Safety Population Flag PA6 (N)
32	COMPLFL	Char	1	Completers Population Flag
33	COMPLFN	Num	8	Completers Population Flag (N)
34	COMPL2FL	Char	1	Completers Population Flag 02
35	COMPL2FN	Num	8	Completers Population Flag 02 (N)
36	COMPL3FL	Char	1	Completers Population Flag 03
37	COMPL3FN	Num	8	Completers Population Flag 03 (N)

Num	Variable	Type	Len	Label
38	COMPL4FL	Char	1	Completers Population Flag 04
39	COMPL4FN	Num	8	Completers Population Flag 04 (N)
40	DOSINTFL	Char	1	Drug Interrupted for >28 Days Flag
41	DOSINTFN	Num	8	Drug Interrupted for >28 Days Flag (N)
42	ARM	Char	11	Description of Planned Arm
43	ACTARM	Char	11	Description of Actual Arm
44	TRT01P	Char	3	Planned Treatment for Period 01
45	TRT01PN	Num	8	Planned Treatment for Period 01 (N)
46	TRT01A	Char	3	Actual Treatment for Period 01
47	TRT01AN	Num	8	Actual Treatment for Period 01 (N)
48	TRTSEQP	Char	7	Planned Sequence of Treatments
49	TRTSEQPN	Num	8	Planned Sequence of Treatments (N)
50	TRTSEQA	Char	7	Actual Sequence of Treatments
51	TRTSEQAN	Num	8	Actual Sequence of Treatments (N)
52	TRTP	Char	7	Planned Treatment
53	TRTPN	Num	8	Planned Treatment (N)
54	TRTA	Char	7	Actual Treatment
55	TRTAN	Num	8	Actual Treatment (N)
56	ASTDTF	Char	1	Analysis Start Date Imputation Flag
57	AENDTF	Char	1	Analysis End Date Imputation Flag
58	ASTDY	Num	8	Analysis Start Relative Day (from first treatment date)
59	CMSTDY	Num	8	Study Day of Start of Medication (from first treatment date)
60	AENDY	Num	8	Analysis End Relative Day (from first treatment date)
61	CMENDY	Num	8	Study Day of End of Medication (from first treatment date)
62	CMENRTPT	Char	7	End Relative to Reference Time Point
63	CMSEQ	Num	8	Sequence Number
64	CMSPID	Char	3	Sponsor-Defined Identifier
65	CMTRT	Char	174	Reported Name of Drug, Med, or Therapy
66	CMDECOD	Char	199	Standardized Medication Name
67	CMDECOD2	Char	36	Standardized Medication Name 2
68	CMCAT	Char	5	Category for Medication
69	CMINDC	Char	104	Indication
70	CMCLAS	Char	64	Medication Class
71	CMDOSE	Num	8	Dose per Administration
72	CMDOSTXT	Char	7	Dose Description
73	CMDOSU	Char	12	Dose Units
74	CMDOSFRQ	Char	45	Dosing Frequency per Interval
75	CMROUTE	Char	24	Route of Administration
76	CMEDFL	Char	1	Concomitant Medication Flag

<b>Num</b>	<b>Variable</b>	<b>Type</b>	<b>Len</b>	<b>Label</b>
77	CMEDFN	Num	8	Concomitant Medication Flag (N)
78	PRURMDFL	Char	1	Pruritus Therapy Medications Flag
79	PRURMDFN	Num	8	Pruritus Therapy Medications Flag (N)
80	PRURMD	Num	8	No. Prior Pruritus Therapy Meds
81	PRURMCAT	Char	22	Prior Pruritus only Category
82	PRURMCAN	Num	8	Prior Pruritus only Category (N)
83	NPRURMD	Num	8	No. Prior Non-Pruritus Therapy Meds
84	NPRURMCT	Char	22	Prior Non-Pruritus only Category
85	NPRURMCN	Num	8	Prior Non-Pruritus only Category (N)

**Data Set Name: adef.sas7bdat**

<b>Num</b>	<b>Variable</b>	<b>Type</b>	<b>Len</b>	<b>Label</b>
1	SubjRandID	Num	8	Subject Identifier (randomly assigned)
2	STUDYID	Char	10	Study Identifier
3	AGE	Num	8	Age
4	AGE1	Num	8	Age at Baseline
5	AGEM	Num	8	Age at Baseline (Months)
6	AGEU	Char	5	Age Units
7	AGEGR1	Char	14	Pooled Age Group 1
8	AGEGR1N	Num	8	Pooled Age Group 1 (N)
9	RACE	Char	25	Race
10	RACE1	Char	25	Race 1
11	RACE2	Char	5	Race 2
12	RACEN	Num	8	Race (N)
13	SEX	Char	1	Sex
14	SEXN	Num	8	Sex (N)
15	ETHNIC	Char	22	Ethnicity
16	ETHNICN	Num	8	Ethnicity (N)
17	COUNTRY	Char	3	Country
18	SCRNFL	Char	1	Screened Population Flag
19	SCRNFN	Num	8	Screened Population Flag (N)
20	ENRFL	Char	1	Enrolled Population Flag
21	ENRFLN	Num	8	Enrolled Population Flag (N)
22	SAFFL	Char	1	Safety Population Flag
23	SAFFN	Num	8	Safety Population Flag (N)
24	SAFOPFL	Char	1	Safety Population Flag Core Trt
25	SAFOPFN	Num	8	Safety Population Flag Core Trt (N)
26	SAFPA4FL	Char	1	Safety Population Flag PA4
27	SAFPA4FN	Num	8	Safety Population Flag PA4 (N)
28	SAFPA5FL	Char	1	Safety Population Flag PA5
29	SAFPA5FN	Num	8	Safety Population Flag PA5 (N)
30	SAFPA6FL	Char	1	Safety Population Flag PA6
31	SAFPA6FN	Num	8	Safety Population Flag PA6 (N)
32	COMPLFL	Char	1	Completers Population Flag
33	COMPLFN	Num	8	Completers Population Flag (N)
34	COMPL2FL	Char	1	Completers Population Flag 02
35	COMPL2FN	Num	8	Completers Population Flag 02 (N)
36	COMPL3FL	Char	1	Completers Population Flag 03
37	COMPL3FN	Num	8	Completers Population Flag 03 (N)



Num	Variable	Type	Len	Label
38	COMPL4FL	Char	1	Completers Population Flag 04
39	COMPL4FN	Num	8	Completers Population Flag 04 (N)
40	DOSINTFL	Char	1	Drug Interrupted for >28 Days Flag
41	DOSINTFN	Num	8	Drug Interrupted for >28 Days Flag (N)
42	ARM	Char	11	Description of Planned Arm
43	ARMCD	Char	2	Description Code of Planned Arm
44	ACTARM	Char	11	Description of Actual Arm
45	ACTARMCD	Char	2	Description Code of Actual Arm
46	TRT01P	Char	3	Planned Treatment for Period 01
47	TRT01PN	Num	8	Planned Treatment for Period 01 (N)
48	TRT01A	Char	3	Actual Treatment for Period 01
49	TRT01AN	Num	8	Actual Treatment for Period 01 (N)
50	TRTSEQP	Char	7	Planned Sequence of Treatments
51	TRTSEQPN	Num	8	Planned Sequence of Treatments (N)
52	TRTSEQA	Char	7	Actual Sequence of Treatments
53	TRTSEQAN	Num	8	Actual Sequence of Treatments (N)
54	TRTP	Char	7	Planned Treatment
55	TRTPN	Num	8	Planned Treatment (N)
56	TRTA	Char	7	Actual Treatment
57	TRTAN	Num	8	Actual Treatment (N)
58	APERIOD	Num	8	Period
59	APERIODC	Char	46	Period (C)
60	LBSEQ	Num	8	Sequence Number
61	VISIT	Char	28	Visit Name
62	VISITNUM	Num	8	Visit Number
63	LBDY	Num	8	Study Day of Specimen Collection
64	AVISITN	Num	8	Analysis Visit (N)
65	AVISIT	Char	13	Analysis Visit
66	DTYPE	Char	23	Derivation Type
67	ADY	Num	8	Analysis Relative Day (from first treatment date)
68	PARAM	Char	46	Parameter
69	PARAMCD	Char	6	Parameter Code
70	PARAMN	Num	8	Parameter (N)
71	PARCAT1	Char	9	Parameter Category 1
72	PARCAT2	Char	22	Parameter Category 2
73	AVAL	Num	8	Analysis Value
74	AVALC	Char	8	Analysis Value (C)
75	BASE	Num	8	Baseline Value
76	BASEC	Char	8	Baseline Value (C)

<b>Num</b>	<b>Variable</b>	<b>Type</b>	<b>Len</b>	<b>Label</b>
77	CHG	Num	8	Change from Baseline
78	PCHG	Num	8	Percent Change from Baseline
79	ABLFL	Char	1	Baseline Record Flag
80	ABLFN	Num	8	Baseline Record Flag (N)
81	ANRLO	Char	3	Analysis Normal Range Lower Limit
82	ANRHI	Char	3	Analysis Normal Range Upper Limit
83	ANRIND	Char	6	Analysis Reference Range Indicator
84	BNRIND	Char	6	Baseline Reference Range Indicator
85	SHIFT1	Char	16	Shift 1
86	CRIT1	Char	36	Analysis Criterion 1
87	CRIT1FL	Char	1	Criterion 1 Evaluation Result Flag
88	CRIT2	Char	9	Analysis Criterion 2
89	CRIT2FL	Char	1	Criterion 2 Evaluation Result Flag
90	CRIT3	Char	10	Analysis Criterion 3
91	CRIT3FL	Char	1	Criterion 3 Evaluation Result Flag
92	CRIT4	Char	10	Analysis Criterion 4
93	CRIT4FL	Char	1	Criterion 4 Evaluation Result Flag

Data Set Name: adex.sas7bdat

Num	Variable	Type	Len	Label
1	SubjRandID	Num	8	Subject Identifier (randomly assigned)
2	STUDYID	Char	10	Study Identifier
3	AGE	Num	8	Age
4	AGE1	Num	8	Age at Baseline
5	AGEM	Num	8	Age at Baseline (Months)
6	AGEU	Char	5	Age Units
7	AGEGR1	Char	14	Pooled Age Group 1
8	AGEGR1N	Num	8	Pooled Age Group 1 (N)
9	RACE	Char	25	Race
10	RACE1	Char	25	Race 1
11	RACE2	Char	5	Race 2
12	RACEN	Num	8	Race (N)
13	SEX	Char	1	Sex
14	SEXN	Num	8	Sex (N)
15	ETHNIC	Char	22	Ethnicity
16	ETHNICN	Num	8	Ethnicity (N)
17	COUNTRY	Char	3	Country
18	SCRNFL	Char	1	Screened Population Flag
19	SCRNFN	Num	8	Screened Population Flag (N)
20	ENRFL	Char	1	Enrolled Population Flag
21	ENRFLN	Num	8	Enrolled Population Flag (N)
22	SAFFL	Char	1	Safety Population Flag
23	SAFFN	Num	8	Safety Population Flag (N)
24	SAFOPFL	Char	1	Safety Population Flag Core Trt
25	SAFOPFN	Num	8	Safety Population Flag Core Trt (N)
26	SAFPA4FL	Char	1	Safety Population Flag PA4
27	SAFPA4FN	Num	8	Safety Population Flag PA4 (N)
28	SAFPA5FL	Char	1	Safety Population Flag PA5
29	SAFPA5FN	Num	8	Safety Population Flag PA5 (N)
30	SAFPA6FL	Char	1	Safety Population Flag PA6
31	SAFPA6FN	Num	8	Safety Population Flag PA6 (N)
32	COMPLFL	Char	1	Completers Population Flag
33	COMPLFN	Num	8	Completers Population Flag (N)
34	COMPL2FL	Char	1	Completers Population Flag 02
35	COMPL2FN	Num	8	Completers Population Flag 02 (N)
36	COMPL3FL	Char	1	Completers Population Flag 03
37	COMPL3FN	Num	8	Completers Population Flag 03 (N)

Num	Variable	Type	Len	Label
38	COMPL4FL	Char	1	Completers Population Flag 04
39	COMPL4FN	Num	8	Completers Population Flag 04 (N)
40	DOSINTFL	Char	1	Drug Interrupted for >28 Days Flag
41	DOSINTFN	Num	8	Drug Interrupted for >28 Days Flag (N)
42	ARM	Char	11	Description of Planned Arm
43	ARMCD	Char	2	Description Code of Planned Arm
44	ACTARM	Char	11	Description of Actual Arm
45	ACTARMCD	Char	2	Description Code of Actual Arm
46	TRT01P	Char	3	Planned Treatment for Period 01
47	TRT01PN	Num	8	Planned Treatment for Period 01 (N)
48	TRT01A	Char	3	Actual Treatment for Period 01
49	TRT01AN	Num	8	Actual Treatment for Period 01 (N)
50	TRTSEQP	Char	7	Planned Sequence of Treatments
51	TRTSEQPN	Num	8	Planned Sequence of Treatments (N)
52	TRTSEQA	Char	7	Actual Sequence of Treatments
53	TRTSEQAN	Num	8	Actual Sequence of Treatments (N)
54	TRTP	Char	7	Planned Treatment
55	TRTPN	Num	8	Planned Treatment (N)
56	TRTA	Char	7	Actual Treatment
57	TRTAN	Num	8	Actual Treatment (N)
58	AVISIT	Char	46	Analysis Visit
59	AVISITN	Num	8	Analysis Visit (N)
60	PARAM	Char	30	Parameter
61	PARAMCD	Char	8	Parameter Code
62	PARAMN	Num	8	Parameter (N)
63	PARAMTYP	Char	7	Parameter Type
64	AVAL	Num	8	Analysis Value
65	CRIT1	Char	30	Analysis Criterion 1
66	CRIT1FL	Char	1	Criterion 1 Evaluation Result Flag
67	CRIT2	Char	35	Analysis Criterion 2
68	CRIT2FL	Char	1	Criterion 2 Evaluation Result Flag
69	CRIT3	Char	35	Analysis Criterion 3
70	CRIT3FL	Char	1	Criterion 3 Evaluation Result Flag
71	CRIT4	Char	36	Analysis Criterion 4
72	CRIT4FL	Char	1	Criterion 4 Evaluation Result Flag
73	CRIT5	Char	37	Analysis Criterion 5
74	CRIT5FL	Char	1	Criterion 5 Evaluation Result Flag
75	CRIT6	Char	37	Analysis Criterion 6
76	CRIT6FL	Char	1	Criterion 6 Evaluation Result Flag

<b>Num</b>	<b>Variable</b>	<b>Type</b>	<b>Len</b>	<b>Label</b>
77	CRIT7	Char	30	Analysis Criterion 7
78	CRIT7FL	Char	1	Criterion 7 Evaluation Result Flag
79	SDFIRRX	Num	8	Study Day of First Exposure to Treatment (from first treatment date)
80	SDLASRX	Num	8	Study Day of Last Exposure to Treatment (from first treatment date)
81	SDSTP1	Num	8	Study Day of Period 01 Start (from first treatment date)
82	SDENP1	Num	8	Study Day of Period 01 End (from first treatment date)
83	SDSTP2	Num	8	Study Day of Period 02 Start (from first treatment date)
84	SDENP2	Num	8	Study Day of Period 02 End (from first treatment date)
85	SDSTP3	Num	8	Study Day of Period 03 Start (from first treatment date)
86	SDENP3	Num	8	Study Day of Period 03 End (from first treatment date)
87	SDSTP4	Num	8	Study Day of Period 04 Start (from first treatment date)
88	SDENP4	Num	8	Study Day of Period 04 End (from first treatment date)
89	SDILASRX1	Num	8	Study Day of Initial Last Exposure 01 (from first treatment date)
90	SDRXAFLEX1	Num	8	Study Day of Drug After Last Exposure 01 (from first treatment date)
91	SDILASRX2	Num	8	Study Day of Initial Last Exposure 02 (from first treatment date)
92	SDRXAFLEX2	Num	8	Study Day of Drug After Last Exposure 02 (from first treatment date)

**Data Set Name: adlb.sas7bdat**

<b>Num</b>	<b>Variable</b>	<b>Type</b>	<b>Len</b>	<b>Label</b>
1	SubjRandID	Num	8	Subject Identifier (randomly assigned)
2	STUDYID	Char	10	Study Identifier
3	AGE	Num	8	Age
4	AGE1	Num	8	Age at Baseline
5	AGEM	Num	8	Age at Baseline (Months)
6	AGEU	Char	5	Age Units
7	AGEGR1	Char	14	Pooled Age Group 1
8	AGEGR1N	Num	8	Pooled Age Group 1 (N)
9	RACE	Char	25	Race
10	RACE1	Char	25	Race 1
11	RACE2	Char	5	Race 2
12	RACEN	Num	8	Race (N)
13	SEX	Char	1	Sex
14	SEXN	Num	8	Sex (N)
15	ETHNIC	Char	22	Ethnicity
16	ETHNICN	Num	8	Ethnicity (N)
17	COUNTRY	Char	3	Country
18	SCRNFL	Char	1	Screened Population Flag
19	SCRNFN	Num	8	Screened Population Flag (N)
20	ENRFL	Char	1	Enrolled Population Flag
21	ENRFLN	Num	8	Enrolled Population Flag (N)
22	SAFFL	Char	1	Safety Population Flag
23	SAFFN	Num	8	Safety Population Flag (N)
24	SAFOPFL	Char	1	Safety Population Flag Core Trt
25	SAFOPFN	Num	8	Safety Population Flag Core Trt (N)
26	SAFPA4FL	Char	1	Safety Population Flag PA4
27	SAFPA4FN	Num	8	Safety Population Flag PA4 (N)
28	SAFPA5FL	Char	1	Safety Population Flag PA5
29	SAFPA5FN	Num	8	Safety Population Flag PA5 (N)
30	SAFPA6FL	Char	1	Safety Population Flag PA6
31	SAFPA6FN	Num	8	Safety Population Flag PA6 (N)
32	COMPLFL	Char	1	Completers Population Flag
33	COMPLFN	Num	8	Completers Population Flag (N)
34	COMPL2FL	Char	1	Completers Population Flag 02
35	COMPL2FN	Num	8	Completers Population Flag 02 (N)
36	COMPL3FL	Char	1	Completers Population Flag 03
37	COMPL3FN	Num	8	Completers Population Flag 03 (N)

Num	Variable	Type	Len	Label
38	COMPL4FL	Char	1	Completers Population Flag 04
39	COMPL4FN	Num	8	Completers Population Flag 04 (N)
40	DOSINTFL	Char	1	Drug Interrupted for >28 Days Flag
41	DOSINTFN	Num	8	Drug Interrupted for >28 Days Flag (N)
42	ARM	Char	11	Description of Planned Arm
43	ARMCD	Char	2	Description Code of Planned Arm
44	ACTARM	Char	11	Description of Actual Arm
45	ACTARMCD	Char	2	Description Code of Actual Arm
46	TRT01P	Char	3	Planned Treatment for Period 01
47	TRT01PN	Num	8	Planned Treatment for Period 01 (N)
48	TRT01A	Char	3	Actual Treatment for Period 01
49	TRT01AN	Num	8	Actual Treatment for Period 01 (N)
50	TRTSEQP	Char	7	Planned Sequence of Treatments
51	TRTSEQPN	Num	8	Planned Sequence of Treatments (N)
52	TRTSEQA	Char	7	Actual Sequence of Treatments
53	TRTSEQAN	Num	8	Actual Sequence of Treatments (N)
54	TRTP	Char	7	Planned Treatment
55	TRTPN	Num	8	Planned Treatment (N)
56	TRTA	Char	7	Actual Treatment
57	TRTAN	Num	8	Actual Treatment (N)
58	APERIOD	Num	8	Period
59	APERIODC	Char	46	Period (C)
60	LBSEQ	Num	8	Sequence Number
61	VISIT	Char	28	Visit Name
62	VISITNUM	Num	8	Visit Number
63	LBDY	Num	8	Study Day of Specimen Collection (from first treatment date)
64	AVISITN	Num	8	Analysis Visit (N)
65	AVISIT	Char	13	Analysis Visit
66	DTYPE	Char	23	Derivation Type
67	ADY	Num	8	Analysis Relative Day (from first treatment date)
68	PARAM	Char	46	Parameter
69	PARAMCD	Char	8	Parameter Code
70	PARAMN	Num	8	Parameter (N)
71	PARAMTYP	Char	7	Parameter Type
72	PARCAT1	Char	11	Parameter Category 1
73	PARCAT2	Char	20	Parameter Category 2
74	AVAL	Num	8	Analysis Value
75	AVALC	Char	13	Analysis Value (C)
76	BASETYPE	Char	11	Baseline Type

<b>Num</b>	<b>Variable</b>	<b>Type</b>	<b>Len</b>	<b>Label</b>
77	BASE	Num	8	Baseline Value
78	BASEC	Char	13	Baseline Value (C)
79	CHG	Num	8	Change from Baseline
80	PCHG	Num	8	Percent Change from Baseline
81	ABLFL	Char	1	Baseline Record Flag
82	ABLFN	Num	8	Baseline Record Flag (N)
83	ANRLO	Char	5	Analysis Normal Range Lower Limit
84	ANRHI	Char	4	Analysis Normal Range Upper Limit
85	ANRIND	Char	6	Analysis Reference Range Indicator
86	BNRIND	Char	6	Baseline Reference Range Indicator
87	SHIFT1	Char	16	Shift 1
88	CRIT1	Char	32	Analysis Criterion 1
89	CRIT1FL	Char	1	Criterion 1 Evaluation Result Flag
90	CRIT2	Char	29	Analysis Criterion 2
91	CRIT2FL	Char	1	Criterion 2 Evaluation Result Flag
92	CRIT3	Char	29	Analysis Criterion 3
93	CRIT3FL	Char	1	Criterion 3 Evaluation Result Flag



Data Set Name: adpc.sas7bdat

Num	Variable	Type	Len	Label
1	SubjRandID	Num	8	Subject Identifier (randomly assigned)
2	STUDYID	Char	10	Study Identifier
3	AGE	Num	8	Age
4	AGE1	Num	8	Age at Baseline
5	AGEM	Num	8	Age at Baseline (Months)
6	AGEU	Char	5	Age Units
7	AGEGR1	Char	14	Pooled Age Group 1
8	AGEGR1N	Num	8	Pooled Age Group 1 (N)
9	RACE	Char	25	Race
10	RACE1	Char	25	Race 1
11	RACE2	Char	5	Race 2
12	RACEN	Num	8	Race (N)
13	SEX	Char	1	Sex
14	SEXN	Num	8	Sex (N)
15	ETHNIC	Char	22	Ethnicity
16	ETHNICN	Num	8	Ethnicity (N)
17	COUNTRY	Char	3	Country
18	SCRNFL	Char	1	Screened Population Flag
19	SCRNFN	Num	8	Screened Population Flag (N)
20	ENRFL	Char	1	Enrolled Population Flag
21	ENRFLN	Num	8	Enrolled Population Flag (N)
22	SAFFL	Char	1	Safety Population Flag
23	SAFFN	Num	8	Safety Population Flag (N)
24	SAFOPFL	Char	1	Safety Population Flag Core Trt
25	SAFOPFN	Num	8	Safety Population Flag Core Trt (N)
26	SAFPA4FL	Char	1	Safety Population Flag PA4
27	SAFPA4FN	Num	8	Safety Population Flag PA4 (N)
28	SAFPA5FL	Char	1	Safety Population Flag PA5
29	SAFPA5FN	Num	8	Safety Population Flag PA5 (N)
30	SAFPA6FL	Char	1	Safety Population Flag PA6
31	SAFPA6FN	Num	8	Safety Population Flag PA6 (N)
32	COMPLFL	Char	1	Completers Population Flag
33	COMPLFN	Num	8	Completers Population Flag (N)
34	COMPL2FL	Char	1	Completers Population Flag 02
35	COMPL2FN	Num	8	Completers Population Flag 02 (N)
36	COMPL3FL	Char	1	Completers Population Flag 03
37	COMPL3FN	Num	8	Completers Population Flag 03 (N)

Num	Variable	Type	Len	Label
38	COMPL4FL	Char	1	Completers Population Flag 04
39	COMPL4FN	Num	8	Completers Population Flag 04 (N)
40	DOSINTFL	Char	1	Drug Interrupted for >28 Days Flag
41	DOSINTFN	Num	8	Drug Interrupted for >28 Days Flag (N)
42	ARM	Char	11	Description of Planned Arm
43	ARMCD	Char	2	Description Code of Planned Arm
44	ACTARM	Char	11	Description of Actual Arm
45	ACTARMCD	Char	2	Description Code of Actual Arm
46	TRT01P	Char	3	Planned Treatment for Period 01
47	TRT01PN	Num	8	Planned Treatment for Period 01 (N)
48	TRT01A	Char	3	Actual Treatment for Period 01
49	TRT01AN	Num	8	Actual Treatment for Period 01 (N)
50	TRTSEQP	Char	7	Planned Sequence of Treatments
51	TRTSEQPN	Num	8	Planned Sequence of Treatments (N)
52	TRTSEQA	Char	7	Actual Sequence of Treatments
53	TRTSEQAN	Num	8	Actual Sequence of Treatments (N)
54	TRTP	Char	7	Planned Treatment
55	TRTPN	Num	8	Planned Treatment (N)
56	TRTA	Char	7	Actual Treatment
57	TRTAN	Num	8	Actual Treatment (N)
58	APERIOD	Num	8	Period
59	APERIODC	Char	46	Period (C)
60	PCSEQ	Num	8	Sequence Number
61	VISIT	Char	28	Visit Name
62	VISITNUM	Num	8	Visit Number
63	PCDY	Num	8	Actual Study Day of Specimen Collection (from first treatment date)
64	AVISITN	Num	8	Analysis Visit (N)
65	AVISIT	Char	12	Analysis Visit
66	DTYPE	Char	3	Derivation Type
67	ADY	Num	8	Analysis Relative Day (from first treatment date)
68	PARCAT1	Char	7	Parameter Category 1
69	PARAM	Char	11	Parameter
70	PARAMCD	Char	3	Parameter Code
71	PARAMN	Num	8	Parameter (N)
72	AVAL	Num	8	Analysis Value
73	AVALC	Char	5	Analysis Value (C)
74	ABLFL	Char	1	Baseline Record Flag
75	ABLFN	Num	8	Baseline Record Flag (N)
76	BASE	Num	8	Baseline Value

<b>Num</b>	<b>Variable</b>	<b>Type</b>	<b>Len</b>	<b>Label</b>
77	CHG	Num	8	Change from Baseline
78	DOSEON	Char	8	Study Drug Dose at Onset
79	DOSEONU	Char	9	Study Drug Dose at Onset Units

**Data Set Name: adqs.sas7bdat**

Num	Variable	Type	Len	Label
1	SubjRandID	Num	8	Subject Identifier (randomly assigned)
2	STUDYID	Char	10	Study Identifier
3	AGE	Num	8	Age
4	AGE1	Num	8	Age at Baseline
5	AGEM	Num	8	Age at Baseline (Months)
6	AGEU	Char	5	Age Units
7	AGEGR1	Char	14	Pooled Age Group 1
8	AGEGR1N	Num	8	Pooled Age Group 1 (N)
9	RACE	Char	25	Race
10	RACE1	Char	25	Race 1
11	RACE2	Char	5	Race 2
12	RACEN	Num	8	Race (N)
13	SEX	Char	1	Sex
14	SEXN	Num	8	Sex (N)
15	ETHNIC	Char	22	Ethnicity
16	ETHNICN	Num	8	Ethnicity (N)
17	COUNTRY	Char	3	Country
18	SCRNFL	Char	1	Screened Population Flag
19	SCRNFN	Num	8	Screened Population Flag (N)
20	ENRFL	Char	1	Enrolled Population Flag
21	ENRFLN	Num	8	Enrolled Population Flag (N)
22	SAFFL	Char	1	Safety Population Flag
23	SAFFN	Num	8	Safety Population Flag (N)
24	SAFOPFL	Char	1	Safety Population Flag Core Trt
25	SAFOPFN	Num	8	Safety Population Flag Core Trt (N)
26	SAFPA4FL	Char	1	Safety Population Flag PA4
27	SAFPA4FN	Num	8	Safety Population Flag PA4 (N)
28	SAFPA5FL	Char	1	Safety Population Flag PA5
29	SAFPA5FN	Num	8	Safety Population Flag PA5 (N)
30	SAFPA6FL	Char	1	Safety Population Flag PA6
31	SAFPA6FN	Num	8	Safety Population Flag PA6 (N)
32	COMPLFL	Char	1	Completers Population Flag
33	COMPLFN	Num	8	Completers Population Flag (N)
34	COMPL2FL	Char	1	Completers Population Flag 02
35	COMPL2FN	Num	8	Completers Population Flag 02 (N)
36	COMPL3FL	Char	1	Completers Population Flag 03
37	COMPL3FN	Num	8	Completers Population Flag 03 (N)

Num	Variable	Type	Len	Label
38	COMPL4FL	Char	1	Completers Population Flag 04
39	COMPL4FN	Num	8	Completers Population Flag 04 (N)
40	DOSINTFL	Char	1	Drug Interrupted for >28 Days Flag
41	DOSINTFN	Num	8	Drug Interrupted for >28 Days Flag (N)
42	ARM	Char	11	Description of Planned Arm
43	ARMCD	Char	2	Description Code of Planned Arm
44	ACTARM	Char	11	Description of Actual Arm
45	ACTARMCD	Char	2	Description Code of Actual Arm
46	TRTSEQP	Char	7	Planned Sequence of Treatments
47	TRTSEQPN	Num	8	Planned Sequence of Treatments (N)
48	TRTSEQA	Char	7	Actual Sequence of Treatments
49	TRTSEQAN	Num	8	Actual Sequence of Treatments (N)
50	TRTP	Char	7	Planned Treatment
51	TRTPN	Num	8	Planned Treatment (N)
52	TRTA	Char	7	Actual Treatment
53	TRTAN	Num	8	Actual Treatment (N)
54	APERIOD	Num	8	Period
55	APERIODC	Char	46	Period (C)
56	ADY	Num	8	Analysis Relative Day (from first treatment date)
57	MRXADY	Num	8	MRX Analysis Relative Day
58	AVISITN	Num	8	Analysis Visit (N)
59	AVISIT	Char	13	Analysis Visit
60	VISIT	Char	28	Visit Name
61	VISITNUM	Num	8	Visit Number
62	QSSEQ	Num	8	Sequence Number
63	PARAM	Char	47	Parameter
64	PARAMCD	Char	8	Parameter Code
65	PARAMN	Num	8	Parameter (N)
66	PARAMTYP	Char	7	Parameter Type
67	PARCAT1	Char	30	Parameter Category 1
68	PARCAT2	Char	26	Parameter Category 2
69	AVAL	Num	8	Analysis Value
70	ABLFL	Char	1	Baseline Record Flag
71	ABLFN	Num	8	Baseline Record Flag (N)
72	BASE	Num	8	Baseline Value
73	CHG	Num	8	Change from Baseline
74	PCHG	Num	8	Percent Change from Baseline
75	CRIT1	Char	33	Analysis Criterion 1
76	CRIT1FL	Char	1	Criterion 1 Evaluation Result Flag

<b>Num</b>	<b>Variable</b>	<b>Type</b>	<b>Len</b>	<b>Label</b>
77	CRIT2	Char	33	Analysis Criterion 2
78	CRIT2FL	Char	1	Criterion 2 Evaluation Result Flag
79	CRIT3	Char	22	Analysis Criterion 3
80	CRIT3FL	Char	1	Criterion 3 Evaluation Result Flag
81	DTYPE	Char	14	Derivation Type
82	ANL01FL	Char	1	Analysis Record Flag 01

**Data Set Name: adsl.sas7bdat**

Num	Variable	Type	Len	Label
1	SubjRandID	Num	8	Subject Identifier (randomly assigned)
2	STUDYID	Char	10	Study Identifier
3	AGE	Num	8	Age
4	AGE1	Num	8	Age at Baseline
5	AGEM	Num	8	Age at Baseline (Months)
6	AGESCRN	Num	8	Age at 301 Screening
7	AGEMRX	Num	8	Age at First MRX Dose
8	AGEU	Char	5	Age Units
9	AGEGR1	Char	14	Pooled Age Group 1
10	AGEGR1N	Num	8	Pooled Age Group 1 (N)
11	RACE	Char	25	Race
12	RACE1	Char	25	Race 1
13	RACE2	Char	5	Race 2
14	RACEN	Num	8	Race (N)
15	SEX	Char	1	Sex
16	SEXN	Num	8	Sex (N)
17	ETHNIC	Char	22	Ethnicity
18	ETHNICN	Num	8	Ethnicity (N)
19	COUNTRY	Char	3	Country
20	SCRNFL	Char	1	Screened Population Flag
21	SCRNFN	Num	8	Screened Population Flag (N)
22	ENRFL	Char	1	Enrolled Population Flag
23	ENRFLN	Num	8	Enrolled Population Flag (N)
24	SAFFL	Char	1	Safety Population Flag
25	SAFFN	Num	8	Safety Population Flag (N)
26	SAFOPFL	Char	1	Safety Population Flag Core Trt
27	SAFOPFN	Num	8	Safety Population Flag Core Trt (N)
28	SAFPA4FL	Char	1	Safety Population Flag PA4
29	SAFPA4FN	Num	8	Safety Population Flag PA4 (N)
30	SAFPA5FL	Char	1	Safety Population Flag PA5
31	SAFPA5FN	Num	8	Safety Population Flag PA5 (N)
32	SAFPA6FL	Char	1	Safety Population Flag PA6
33	SAFPA6FN	Num	8	Safety Population Flag PA6 (N)
34	LWDOPFL	Char	1	Recd. Lower Dose Flag Core Trt
35	LWDOPFN	Num	8	Recd. Lower Dose Flag Core Trt (N)
36	LWDPA4FL	Char	1	Recd. Lower Dose Flag PA4
37	LWDPA4FN	Num	8	Recd. Lower Dose Flag PA4 (N)

Num	Variable	Type	Len	Label
38	LWDPA5FL	Char	1	Recd. Lower Dose Flag PA5
39	LWDPA5FN	Num	8	Recd. Lower Dose Flag PA5 (N)
40	LWDPA6FL	Char	1	Recd. Lower Dose Flag PA6
41	LWDPA6FN	Num	8	Recd. Lower Dose Flag PA6 (N)
42	COMPLFL	Char	1	Completers Population Flag
43	COMPLFN	Num	8	Completers Population Flag (N)
44	COMPL2FL	Char	1	Completers Population Flag 02
45	COMPL2FN	Num	8	Completers Population Flag 02 (N)
46	COMPL3FL	Char	1	Completers Population Flag 03
47	COMPL3FN	Num	8	Completers Population Flag 03 (N)
48	COMPL4FL	Char	1	Completers Population Flag 04
49	COMPL4FN	Num	8	Completers Population Flag 04 (N)
50	DOSINTFL	Char	1	Drug Interrupted for >28 Days Flag
51	DOSINTFN	Num	8	Drug Interrupted for >28 Days Flag (N)
52	ARM	Char	11	Description of Planned Arm
53	ARMCD	Char	2	Description Code of Planned Arm
54	ACTARM	Char	11	Description of Actual Arm
55	ACTARMCD	Char	2	Description Code of Actual Arm
56	TRT01P	Char	3	Planned Treatment for Period 01
57	TRT01PN	Num	8	Planned Treatment for Period 01 (N)
58	TRT01A	Char	3	Actual Treatment for Period 01
59	TRT01AN	Num	8	Actual Treatment for Period 01 (N)
60	TRTSEQP	Char	7	Planned Sequence of Treatments
61	TRTSEQPN	Num	8	Planned Sequence of Treatments (N)
62	TRTSEQA	Char	7	Actual Sequence of Treatments
63	TRTSEQAN	Num	8	Actual Sequence of Treatments (N)
64	DSTERM	Char	23	Reported Term for the Disposition Event
65	DSTERMN	Num	8	Rep. Term for the Disposition Event (N)
66	DSTERMSP	Char	200	Disposition Event Other, Specify
67	DSTERM2	Char	30	Reported Term for the Disp. Event 02
68	DSTERMN2	Num	8	Rep. Term for the Disp. Event 02 (N)
69	DSTERMS2	Char	1	Disposition Event Other, Specify 02
70	DSTERM3	Char	19	Reported Term for the Disp. Event 03
71	DSTERMN3	Num	8	Rep. Term for the Disp. Event 03 (N)
72	DSTERMS3	Char	45	Disposition Event Other, Specify 03
73	DSTERM4	Char	21	Reported Term for the Disp. Event 04
74	DSTERMN4	Num	8	Rep. Term for the Disp. Event 04 (N)
75	DSTERMS4	Char	55	Disposition Event Other, Specify 04
76	PAICSTAT	Char	22	PA4/PA5/PA6 Informed Consent Status



Num	Variable	Type	Len	Label
77	ALGSDN	Num	8	Time Since Diagnosis of ALGS (Months)
78	ALGSHX	Char	1	Family History of ALGS
79	PAUCITY	Char	1	Presence of Paucity
80	MUTATION	Char	7	Mutation Present
81	CHOLEST	Char	1	Chronic Cholestasis
82	CARDIAC	Char	1	Cardiac Disease
83	RENAL	Char	1	Renal Abnormalities
84	VASCULAR	Char	1	Vascular Abnormalities
85	SKELETAL	Char	1	Skeletal Abnormalities
86	OCULAR	Char	1	Ocular Abnormalities
87	FACIAL	Char	1	Characteristic Facial Features
88	ALGSCRT	Num	8	No. Clinical Criteria/Features of ALGS
89	ALGSCAT	Char	6	Critical Criteria of ALGS Category
90	ALGSCATN	Num	8	Critical Criteria of ALGS Category (N)
91	ITCHTRT	Char	1	Used Anything to Treat Itch in the Past
92	TCORTICO	Char	1	Topical Corticosteroids
93	TCALCIN	Char	1	Topical Calcineurin Inhibitors
94	TANTIHIS	Char	1	Topical Antihistamines
95	TMENTHOL	Char	1	Topical Menthol
96	TCAPSAIS	Char	1	Topical Capsaicin
97	TSALICYL	Char	1	Topical Salicylic Acid
98	TLOCAL	Char	1	Topical Local Anesthetics
99	OANDROG	Char	1	Oral Androgens
100	OANTICHO	Char	1	Oral Anticholestatic Agents
101	OANTICON	Char	1	Oral Anticonvulsants
102	OANTIDEP	Char	1	Oral Antidepressants
103	OANTIHIS	Char	1	Oral Antihistamines
104	OANTIOX	Char	1	Oral Anti-Oxidants
105	OBINDING	Char	1	Oral Binding Resins
106	OCOLCHIC	Char	1	Oral Colchicine
107	OCANNABI	Char	1	Oral Cannabinoid Agonist
108	OENZYMEI	Char	1	Oral Enzyme Inducers
109	OIMMUNO	Char	1	Oral Immunosuppressants
110	OOPATE	Char	1	Oral Opiate Antagonists
111	OSEROTON	Char	1	Oral Serotonin Antagonists
112	LOUDCA	Char	1	Oral Ursodiol (UDCA)
113	PHOTO	Char	1	Other Phototherapy
114	HEMOFILT	Char	1	Other Hemofiltration (MARS)
115	PLASMAPH	Char	1	Other Plasmapheresis

<b>Num</b>	<b>Variable</b>	<b>Type</b>	<b>Len</b>	<b>Label</b>
116	NASALBIL	Char	1	Other Nasal Biliary Drainage
117	SPECIFY	Char	51	Other Specify
118	PRURTHER	Num	8	No. Prior Pruritus Therapies Per Patient
119	PRURCAT	Char	20	Prior Pruritus Therapy Category
120	PRURCATN	Num	8	Prior Pruritus Therapy Category (N)
121	HEIGHTBL	Num	8	Height at Baseline (cm)
122	WEIGHTBL	Num	8	Weight at Baseline (kg)
123	BMIBL	Num	8	BMI at Baseline (kg/m2)
124	ZHGTL	Num	8	Height Z-Score at Baseline
125	ZWGTBL	Num	8	Weight Z-Score at Baseline
126	ZBMIBL	Num	8	BMI Z-Score at Baseline
127	SDSTDISP	Num	8	Study Day of Disposition Event from Infomed Consent Date
128	SEALGDIAG	Num	8	Study Day of Diagnosis of ALGS from Infomed Consent Date
129	SDRXST	Num	8	Study Day of RX First Exposure from Infomed Consent Date
130	SDRXEN	Num	8	Study Day of RX Last Exposure from Infomed Consent Date
131	SDWK48DT	Num	8	Study Day of Week 48 Date from Infomed Consent Date
132	SDWK96DT	Num	8	Study Day of Week 96/ET Date from Infomed Consent Date
133	SDWK144DT	Num	8	Study Day of Week 144/ET Date from Infomed Consent Date
134	SDWK216DT	Num	8	Study Day of Week 216/ET Date from Infomed Consent Date

**Data Set Name: advs.sas7bdat**

Num	Variable	Type	Len	Label
1	SubjRandID	Num	8	Subject Identifier (randomly assigned)
2	STUDYID	Char	10	Study Identifier
3	AGE	Num	8	Age
4	AGE1	Num	8	Age at Baseline
5	AGEM	Num	8	Age at Baseline (Months)
6	AGEU	Char	5	Age Units
7	AGEGR1	Char	14	Pooled Age Group 1
8	AGEGR1N	Num	8	Pooled Age Group 1 (N)
9	RACE	Char	25	Race
10	RACE1	Char	25	Race 1
11	RACE2	Char	5	Race 2
12	RACEN	Num	8	Race (N)
13	SEX	Char	1	Sex
14	SEXN	Num	8	Sex (N)
15	ETHNIC	Char	22	Ethnicity
16	ETHNICN	Num	8	Ethnicity (N)
17	COUNTRY	Char	3	Country
18	SCRNFL	Char	1	Screened Population Flag
19	SCRNFN	Num	8	Screened Population Flag (N)
20	ENRFL	Char	1	Enrolled Population Flag
21	ENRFLN	Num	8	Enrolled Population Flag (N)
22	SAFFL	Char	1	Safety Population Flag
23	SAFFN	Num	8	Safety Population Flag (N)
24	SAFOPFL	Char	1	Safety Population Flag Core Trt
25	SAFOPFN	Num	8	Safety Population Flag Core Trt (N)
26	SAFPA4FL	Char	1	Safety Population Flag PA4
27	SAFPA4FN	Num	8	Safety Population Flag PA4 (N)
28	SAFPA5FL	Char	1	Safety Population Flag PA5
29	SAFPA5FN	Num	8	Safety Population Flag PA5 (N)
30	SAFPA6FL	Char	1	Safety Population Flag PA6
31	SAFPA6FN	Num	8	Safety Population Flag PA6 (N)
32	COMPLFL	Char	1	Completers Population Flag
33	COMPLFN	Num	8	Completers Population Flag (N)
34	COMPL2FL	Char	1	Completers Population Flag 02
35	COMPL2FN	Num	8	Completers Population Flag 02 (N)
36	COMPL3FL	Char	1	Completers Population Flag 03
37	COMPL3FN	Num	8	Completers Population Flag 03 (N)

Num	Variable	Type	Len	Label
38	COMPL4FL	Char	1	Completers Population Flag 04
39	COMPL4FN	Num	8	Completers Population Flag 04 (N)
40	DOSINTFL	Char	1	Drug Interrupted for >28 Days Flag
41	DOSINTFN	Num	8	Drug Interrupted for >28 Days Flag (N)
42	ARM	Char	11	Description of Planned Arm
43	ARMCD	Char	2	Description Code of Planned Arm
44	ACTARM	Char	11	Description of Actual Arm
45	ACTARMCD	Char	2	Description Code of Actual Arm
46	TRT01P	Char	3	Planned Treatment for Period 01
47	TRT01PN	Num	8	Planned Treatment for Period 01 (N)
48	TRT01A	Char	3	Actual Treatment for Period 01
49	TRT01AN	Num	8	Actual Treatment for Period 01 (N)
50	TRTSEQP	Char	7	Planned Sequence of Treatments
51	TRTSEQPN	Num	8	Planned Sequence of Treatments (N)
52	TRTSEQA	Char	7	Actual Sequence of Treatments
53	TRTSEQAN	Num	8	Actual Sequence of Treatments (N)
54	TRTPN	Num	8	Planned Treatment (N)
55	TRTP	Char	7	Planned Treatment
56	TRTAN	Num	8	Actual Treatment (N)
57	TRTA	Char	7	Actual Treatment
58	APERIOD	Num	8	Period
59	APERIODC	Char	46	Period (C)
60	VSSEQ	Num	8	Sequence Number
61	VISIT	Char	28	Visit Name
62	VISITNUM	Num	8	Visit Number
63	VSDY	Num	8	Study Day of Vital Signs (from first treatment date)
64	AVISITN	Num	8	Analysis Visit (N)
65	AVISIT	Char	13	Analysis Visit
66	DTYPE	Char	13	Derivation Type
67	ADY	Num	8	Analysis Relative Day (from first treatment date)
68	PARAM	Char	31	Parameter
69	PARAMCD	Char	7	Parameter Code
70	PARAMN	Num	8	Parameter (N)
71	PARAMTYP	Char	7	Parameter Type
72	AVAL	Num	8	Analysis Value
73	ABLFL	Char	1	Baseline Record Flag
74	ABLFN	Num	8	Baseline Record Flag (N)
75	BASE	Num	8	Baseline Value
76	BASETYPE	Char	11	Baseline Type

<b>Num</b>	<b>Variable</b>	<b>Type</b>	<b>Len</b>	<b>Label</b>
77	CHG	Num	8	Change from Baseline
78	PCHG	Num	8	Percent Change from Baseline
79	ANRLO	Num	8	Analysis Normal Range Lower Limit
80	ANRHI	Num	8	Analysis Normal Range Upper Limit
81	ANRIND	Char	6	Analysis Reference Range Indicator
82	BNRIND	Char	6	Baseline Reference Range Indicator

**Data Set Name: ae.sas7bdat**

Num	Variable	Type	Len	Label
1	SubjRandID	Num	8	Subject Identifier (randomly assigned)
2	STUDYID	Char	10	Study Identifier
3	DOMAIN	Char	2	Domain Abbreviation
4	AESEQ	Num	8	Sequence Number
5	AEGRPID	Char	9	Group ID
6	AESPID	Char	3	Sponsor-Defined Identifier
7	AETERM	Char	108	Reported Term for the Adverse Event
8	AELLT	Char	39	Lowest Level Term
9	AELLTCD	Num	8	Lowest Level Term Code
10	AEDECOD	Char	47	Dictionary-Derived Term
11	AEPTCD	Num	8	Preferred Term Code
12	AEHLT	Char	63	High Level Term
13	AEHLTCD	Num	8	High Level Term Code
14	AEHLGT	Char	59	High Level Group Term
15	AEHLGTC	Num	8	High Level Group Term Code
16	AEBODSYS	Char	67	Body System or Organ Class
17	AEBDSYCD	Num	8	Body System or Organ Class Code
18	AESOC	Char	67	Primary System Organ Class
19	AESOC	Num	8	Primary System Organ Class Code
20	AESER	Char	1	Serious Event
21	AEACN	Char	16	Action Taken with Study Treatment
22	AEACNOTH	Char	99	Other Action Taken
23	AEREL	Char	25	Causality
24	AEOUT	Char	32	Outcome of Adverse Event
25	AESDTH	Char	1	Results in Death
26	AESHOSP	Char	1	Requires or Prolongs Hospitalization
27	AESLIFE	Char	1	Is Life Threatening
28	AECONTRT	Char	1	Concomitant or Additional Trtmnt Given
29	AETOXGR	Char	1	Standard Toxicity Grade
30	EPOCH	Char	45	Epoch
31	AESTDY	Num	8	Study Day of Start of Adverse Event (from first treatment date)
32	AEENDY	Num	8	Study Day of End of Adverse Event (from first treatment date)
33	AEENRF	Char	7	End Relative to Reference Period

**Data Set Name: cm.sas7bdat**

<b>Num</b>	<b>Variable</b>	<b>Type</b>	<b>Len</b>	<b>Label</b>
1	SubjRandID	Num	8	Subject Identifier (randomly assigned)
2	STUDYID	Char	10	Study Identifier
3	DOMAIN	Char	2	Domain Abbreviation
4	CMSEQ	Num	8	Sequence Number
5	CMSPID	Char	3	Sponsor-Defined Identifier
6	CMTRT	Char	174	Reported Name of Drug, Med, or Therapy
7	CMDECOD	Char	199	Standardized Medication Name
8	CMCAT	Char	5	Category for Medication
9	CMINDC	Char	104	Indication
10	CMCLAS	Char	64	Medication Class
11	CMCLASCD	Char	3	Medication Class Code
12	CMDOSE	Num	8	Dose per Administration
13	CMDOSTXT	Char	7	Dose Description
14	CMDOSU	Char	12	Dose Units
15	CMDOSFRQ	Char	45	Dosing Frequency per Interval
16	CMROUTE	Char	24	Route of Administration
17	EPOCH	Char	45	Epoch
18	CMSTDY	Num	8	Study Day of Start of Medication (from first treatment date)
19	CMENDY	Num	8	Study Day of End of Medication (from first treatment date)
20	CMENRTPT	Char	7	End Relative to Reference Time Point

**Data Set Name: co.sas7bdat**

<b>Num</b>	<b>Variable</b>	<b>Type</b>	<b>Len</b>	<b>Label</b>
1	SubjRandID	Num	8	Subject Identifier (randomly assigned)
2	STUDYID	Char	10	Study Identifier
3	DOMAIN	Char	2	Domain Abbreviation
4	RDOMAIN	Char	2	Related Domain Abbreviation
5	COSEQ	Num	8	Sequence Number
6	IDVAR	Char	5	Identifying Variable
7	IDVARVAL	Char	4	Identifying Variable Value
8	COREF	Char	20	Comment Reference
9	COVAL	Char	200	Comment
10	COVAL1	Char	198	Comment 1
11	COVAL2	Char	200	Comment 2
12	COVAL3	Char	166	Comment 3



**Data Set Name: da.sas7bdat**

<b>Num</b>	<b>Variable</b>	<b>Type</b>	<b>Len</b>	<b>Label</b>
1	SubjRandID	Num	8	Subject Identifier (randomly assigned)
2	STUDYID	Char	10	Study Identifier
3	DOMAIN	Char	2	Domain Abbreviation
4	DASEQ	Num	8	Sequence Number
5	DAGRPID	Char	7	Group ID
6	DAREFID	Char	3	Reference ID
7	DATESTCD	Char	7	Short Name of Accountability Assessment
8	DATEST	Char	16	Name of Accountability Assessment
9	DAORRES	Char	1	Assessment Result in Original Units
10	DAORRESU	Char	4	Original Units
11	DASTRESC	Char	1	Assessment Result in Std Format
12	DASTRESN	Num	8	Numeric Result/Finding in Standard Units
13	DASTRESU	Char	4	Assessment Standard Units
14	EPOCH	Char	45	Epoch
15	DADY	Num	8	Study Day of Accountability Assessment
16	SDaccass	Num	8	Study Day from Informed Consent of Accountability Assessment

**Data Set Name: dm.sas7bdat**

<b>Num</b>	<b>Variable</b>	<b>Type</b>	<b>Len</b>	<b>Label</b>
1	SubjRandID	Num	8	Subject Identifier (randomly assigned)
2	STUDYID	Char	10	Study Identifier
3	DOMAIN	Char	2	Domain Abbreviation
4	DTHFL	Char	1	Subject Death Flag
5	AGE	Num	8	Age
6	AGEU	Char	5	Age Units
7	SEX	Char	1	Sex
8	RACE	Char	25	Race
9	ETHNIC	Char	22	Ethnicity
10	ARMCD	Char	2	Planned Arm Code
11	ARM	Char	11	Description of Planned Arm
12	ACTARMCD	Char	2	Actual Arm Code
13	ACTARM	Char	11	Description of Actual Arm
14	COUNTRY	Char	3	Country
15	SDmedst	Num	8	Med Start Study Day from Infomed Consent
16	SDmedsp	Num	8	Med Stop Study Day from Infomed Consent
17	SDlastp	Num	8	Study Day of last participation from Infomed Consent

**Data Set Name: ds.sas7bdat**

<b>Num</b>	<b>Variable</b>	<b>Type</b>	<b>Len</b>	<b>Label</b>
1	SubjRandID	Num	8	Subject Identifier (randomly assigned)
2	STUDYID	Char	10	Study Identifier
3	DOMAIN	Char	2	Domain Abbreviation
4	DSSEQ	Num	8	Sequence Number
5	DSTERM	Char	200	Reported Term for the Disposition Event
6	DSDECOD	Char	36	Standardized Disposition Term
7	DSCAT	Char	18	Category for Disposition Event
8	EPOCH	Char	45	Epoch
9	DSSTDY	Num	8	Study Day of Start of Disposition Event (from first treatment date)

**Data Set Name: dv.sas7bdat**

<b>Num</b>	<b>Variable</b>	<b>Type</b>	<b>Len</b>	<b>Label</b>
1	SubjRandID	Num	8	Subject Identifier (randomly assigned)
2	STUDYID	Char	10	Study Identifier
3	DOMAIN	Char	2	Domain Abbreviation
4	DVSEQ	Num	8	Sequence Number
5	DVTERM	Char	200	Protocol Deviation Term
6	DVDECOD	Char	38	Protocol Deviation Coded Term
7	DVCAT	Char	5	Category for Protocol Deviation
8	EPOCH	Char	45	Epoch
9	DVDY	Num	8	Study Day of Collection (from first treatment date)
10	DVSTDY	Num	8	Study Day of Start of Deviation (from first treatment date)

**Data Set Name: ec.sas7bdat**

<b>Num</b>	<b>Variable</b>	<b>Type</b>	<b>Len</b>	<b>Label</b>
1	SubjRandID	Num	8	Subject Identifier (randomly assigned)
2	STUDYID	Char	10	Study Identifier
3	DOMAIN	Char	2	Domain Abbreviation
4	ECSEQ	Num	8	Sequence Number
5	ECGRPID	Char	12	Group ID
6	ECREFID	Char	8	Reference ID
7	ECTRT	Char	3	Name of Treatment
8	ECDOSE	Num	8	Dose
9	ECDOSU	Char	2	Dose Units
10	ECDOSFRM	Char	20	Dose Form
11	ECDOSFRQ	Char	2	Dosing Frequency per Interval
12	ECROUTE	Char	4	Route of Administration
13	ECPSTRG	Num	8	Pharmaceutical Strength
14	ECPSTRGU	Char	9	Pharmaceutical Strength Units
15	EPOCH	Char	45	Epoch
16	ECSTDY	Num	8	Study Day of Start of Treatment
17	ECENDY	Num	8	Study Day of End of Treatment (from first treatment date)

**Data Set Name: ex.sas7bdat**

<b>Num</b>	<b>Variable</b>	<b>Type</b>	<b>Len</b>	<b>Label</b>
1	SubjRandID	Num	8	Subject Identifier (randomly assigned)
2	STUDYID	Char	10	Study Identifier
3	DOMAIN	Char	2	Domain Abbreviation
4	EXSEQ	Num	8	Sequence Number
5	EXTRT	Char	3	Name of Treatment
6	EXDOSE	Num	8	Dose
7	EXDOSU	Char	9	Dose Units
8	EXDOSFRM	Char	20	Dose Form
9	EXDOSFRQ	Char	2	Dosing Frequency per Interval
10	EXROUTE	Char	4	Route of Administration
11	EPOCH	Char	43	Epoch
12	EXSTDY	Num	8	Study Day of Start of Treatment (from first treatment date)
13	EXENDY	Num	8	Study Day of End of Treatment (from first treatment date)

**Data Set Name: fa.sas7bdat**

<b>Num</b>	<b>Variable</b>	<b>Type</b>	<b>Len</b>	<b>Label</b>
1	SubjRandID	Num	8	Subject Identifier (randomly assigned)
2	STUDYID	Char	10	Study Identifier
3	DOMAIN	Char	2	Domain Abbreviation
4	FASEQ	Num	8	Sequence Number
5	FAGRPID	Char	5	Group ID
6	FASPID	Char	2	Sponsor-Defined Identifier
7	FATESTCD	Char	8	Findings About Test Short Name
8	FATEST	Char	20	Findings About Test Name
9	FAOBJ	Char	23	Object of the Observation
10	FACAT	Char	21	Category for Findings About
11	FAORRES	Char	9	Result or Finding in Original Units
12	FASTRESC	Char	9	Character Result/Finding in Std Format
13	VISITNUM	Num	8	Visit Number
14	VISIT	Char	28	Visit Name
15	EPOCH	Char	45	Epoch
16	FADY	Num	8	Study Day of Collection (from first treatment date)

**Data Set Name: ie.sas7bdat**

<b>Num</b>	<b>Variable</b>	<b>Type</b>	<b>Len</b>	<b>Label</b>
1	SubjRandID	Num	8	Subject Identifier (randomly assigned)
2	STUDYID	Char	10	Study Identifier
3	DOMAIN	Char	2	Domain Abbreviation
4	IESEQ	Num	8	Sequence Number
5	IETESTCD	Char	8	Inclusion/Exclusion Criterion Short Name
6	IETEST	Char	50	Inclusion/Exclusion Criterion
7	IECAT	Char	9	Inclusion/Exclusion Category
8	IEORRES	Char	1	I/E Criterion Original Result
9	IESTRESC	Char	1	I/E Criterion Result in Std Format



**Data Set Name: lb.sas7bdat**

<b>Num</b>	<b>Variable</b>	<b>Type</b>	<b>Len</b>	<b>Label</b>
1	SubjRandID	Num	8	Subject Identifier (randomly assigned)
2	STUDYID	Char	10	Study Identifier
3	DOMAIN	Char	2	Domain Abbreviation
4	LBSEQ	Num	8	Sequence Number
5	LBGRPID	Char	11	Group ID
6	LBREFID	Char	8	Specimen ID
7	LBTESTCD	Char	8	Lab Test or Examination Short Name
8	LBTEST	Char	39	Lab Test or Examination Name
9	LBCAT	Char	11	Category for Lab Test
10	LBSCAT	Char	22	Subcategory for Lab Test
11	LBORRES	Char	9	Result or Finding in Original Units
12	LBORRESU	Char	8	Original Units
13	LBORNRL0	Char	5	Reference Range Lower Limit in Orig Unit
14	LBORNRLHI	Char	5	Reference Range Upper Limit in Orig Unit
15	LBSTRESC	Char	13	Character Result/Finding in Std Format
16	LBSTRESN	Num	8	Numeric Result/Finding in Standard Units
17	LBSTRESU	Char	8	Standard Units
18	LBSTNRLO	Num	8	Reference Range Lower Limit-Std Units
19	LBSTNRHI	Num	8	Reference Range Upper Limit-Std Units
20	LBNRIND	Char	6	Reference Range Indicator
21	LBSTAT	Char	8	Completion Status
22	LBREASND	Char	154	Reason Test Not Done
23	LBNAM	Char	30	Vendor Name
24	LBSPEC	Char	6	Specimen Type
25	LBBLFL	Char	1	Baseline Flag
26	LBFAST	Char	1	Fasting Status
27	VISITNUM	Num	8	Visit Number
28	VISIT	Char	28	Visit Name
29	EPOCH	Char	45	Epoch
30	LBDY	Num	8	Study Day of Specimen Collection (from first treatment date)

**Data Set Name: mh.sas7bdat**

<b>Num</b>	<b>Variable</b>	<b>Type</b>	<b>Len</b>	<b>Label</b>
1	SubjRandID	Num	8	Subject Identifier (randomly assigned)
2	STUDYID	Char	10	Study Identifier
3	DOMAIN	Char	2	Domain Abbreviation
4	MHSEQ	Num	8	Sequence Number
5	MHSPID	Char	3	Sponsor-Defined Identifier
6	MHTERM	Char	32	Reported Term for the Medical History
7	MHLLT	Char	20	Lowest Level Term
8	MHLLTCD	Num	8	Lowest Level Term Code
9	MHDECOD	Char	29	Dictionary-Derived Term
10	MHPTCD	Num	8	Preferred Term Code
11	MHHLT	Char	54	High Level Term
12	MHHLTCD	Num	8	High Level Term Code
13	MHHLGT	Char	52	High Level Group Term
14	MHHLGTCD	Num	8	High Level Group Term Code
15	MHCAT	Char	43	Category for Medical History
16	MHBODSYS	Char	47	Body System or Organ Class
17	MHBDSYCD	Num	8	Body System or Organ Class Code
18	MHSOC	Char	47	Primary System Organ Class
19	MHSOCCD	Num	8	Primary System Organ Class Code
20	MHSTDY	Num	8	Study Day of Start of Observation (from first treatment date)
21	MHENDY	Num	8	Study Day of End of Observation (from first treatment date)
22	MHENRTPT	Char	7	End Relative to Reference Time Point

**Data Set Name: pc.sas7bdat**

<b>Num</b>	<b>Variable</b>	<b>Type</b>	<b>Len</b>	<b>Label</b>
1	SubjRandID	Num	8	Subject Identifier (randomly assigned)
2	STUDYID	Char	10	Study Identifier
3	DOMAIN	Char	2	Domain Abbreviation
4	PCSEQ	Num	8	Sequence Number
5	PCREFID	Char	12	Reference ID
6	PCTESTCD	Char	3	Pharmacokinetic Test Short Name
7	PCTEST	Char	3	Pharmacokinetic Test Name
8	PCCAT	Char	7	Test Category
9	PCORRES	Char	11	Result or Finding in Original Units
10	PCORRESU	Char	5	Original Units
11	PCSTRESC	Char	11	Character Result/Finding Standard Format
12	PCSTRESN	Num	8	Numeric Result/Finding in Standard Units
13	PCSTRESU	Char	5	Standard Units
14	PCSTAT	Char	8	Completion Status
15	PCREASND	Char	59	Reason Test Not Done
16	PCNAM	Char	7	Vendor Name
17	PCSPEC	Char	6	Specimen Material Type
18	PCMETHOD	Char	21	Method of Test or Examination
19	PCBLFL	Char	1	Baseline Flag
20	PCFAST	Char	1	Fasting Status
21	PCLLOQ	Num	8	Lower Limit of Quantitation
22	VISITNUM	Num	8	Visit Number
23	VISIT	Char	28	Visit Name
24	EPOCH	Char	45	Epoch
25	PCDY	Num	8	Actual Study Day of Specimen Collection (from first treatment date)

**Data Set Name: pe.sas7bdat**

<b>Num</b>	<b>Variable</b>	<b>Type</b>	<b>Len</b>	<b>Label</b>
1	SubjRandID	Num	8	Subject Identifier (randomly assigned)
2	STUDYID	Char	10	Study Identifier
3	DOMAIN	Char	2	Domain Abbreviation
4	PESEQ	Num	8	Sequence Number
5	PETESTCD	Char	5	Body System Examined Short Name
6	PETEST	Char	20	Body System Examined
7	PECAT	Char	30	Category for Examination
8	PEORRES	Char	8	Verbatim Examination Finding
9	PESTRESC	Char	8	Character Result/Finding Standard Format
10	PESTAT	Char	8	Completion Status
11	PEBLFL	Char	1	Baseline Flag
12	VISITNUM	Num	8	Visit Number
13	VISIT	Char	28	Visit Name
14	EPOCH	Char	45	Epoch
15	PEDY	Num	8	Study Day of Examination (from first treatment date)

**Data Set Name: qs.sas7bdat**

<b>Num</b>	<b>Variable</b>	<b>Type</b>	<b>Len</b>	<b>Label</b>
1	SubjRandID	Num	8	Subject Identifier (randomly assigned)
2	STUDYID	Char	10	Study Identifier
3	DOMAIN	Char	2	Domain Abbreviation
4	QSSEQ	Num	8	Sequence Number
5	QSGRPID	Char	8	Group ID
6	QSSPID	Char	3	Sponsor-Defined Identifier
7	QSTESTCD	Char	8	Question Short Name
8	QSTEST	Char	40	Question Name
9	QSCAT	Char	52	Category of Question
10	QSSCAT	Char	26	Subcategory for Question
11	QSORRES	Char	54	Finding in Original Units
12	QSSTRESC	Char	25	Character Result/Finding Standard Format
13	QSSTRESN	Num	8	Numeric Finding in Standard Units
14	QSSTAT	Char	8	Completion Status
15	QSREASND	Char	14	Reason Not Performed
16	QSBFL	Char	1	Baseline Flag
17	VISITNUM	Num	8	Visit Number
18	VISIT	Char	28	Visit Name
19	EPOCH	Char	45	Epoch
20	QSDY	Num	8	Study Day of Finding (from first treatment date)

**Data Set Name: se.sas7bdat**

<b>Num</b>	<b>Variable</b>	<b>Type</b>	<b>Len</b>	<b>Label</b>
1	SubjRandID	Num	8	Subject Identifier (randomly assigned)
2	STUDYID	Char	10	Study Identifier
3	DOMAIN	Char	2	Domain Abbreviation
4	SESEQ	Num	8	Sequence Number
5	ETCD	Char	8	Element Code
6	ELEMENT	Char	19	Description of Element
7	TAETORD	Num	8	Planned Order of Element within Arm
8	EPOCH	Char	45	Epoch
9	SESTDY	Num	8	Study Day of Start of Element (from first treatment date)
10	SEENDY	Num	8	Study Day of End of Element (from first treatment date)

**Data Set Name: suppaes.sas7bdat**

<b>Num</b>	<b>Variable</b>	<b>Type</b>	<b>Len</b>	<b>Label</b>
1	SubjRandID	Num	8	Subject Identifier (randomly assigned)
2	STUDYID	Char	10	Study Identifier
3	RDOMAIN	Char	2	Related Domain Abbreviation
4	IDVAR	Char	5	Identifying Variable
5	IDVARVAL	Char	3	Identifying Variable Value
6	QNAM	Char	7	Qualifier Variable Name
7	QLABEL	Char	31	Qualifier Variable Label
8	QVAL	Char	1	Data Value
9	QORIG	Char	3	Origin
10	QEVAL	Char	1	Evaluator

**Data Set Name: suppcm.sas7bdat**

<b>Num</b>	<b>Variable</b>	<b>Type</b>	<b>Len</b>	<b>Label</b>
1	SubjRandID	Num	8	Subject Identifier (randomly assigned)
2	STUDYID	Char	10	Study Identifier
3	RDOMAIN	Char	2	Related Domain Abbreviation
4	IDVAR	Char	5	Identifying Variable
5	IDVARVAL	Char	2	Identifying Variable Value
6	QNAM	Char	8	Qualifier Variable Name
7	QLABEL	Char	30	Qualifier Variable Label
8	QVAL	Char	36	Data Value
9	QORIG	Char	3	Origin
10	QEVAL	Char	1	Evaluator



**Data Set Name: supdm.sas7bdat**

<b>Num</b>	<b>Variable</b>	<b>Type</b>	<b>Len</b>	<b>Label</b>
1	SubjRandID	Num	8	Subject Identifier (randomly assigned)
2	STUDYID	Char	10	Study Identifier
3	RDOMAIN	Char	2	Related Domain Abbreviation
4	IDVAR	Char	1	Identifying Variable
5	IDVARVAL	Char	1	Identifying Variable Value
6	QNAM	Char	8	Qualifier Variable Name
7	QLABEL	Char	40	Qualifier Variable Label
8	QVAL	Char	25	Data Value
9	QORIG	Char	3	Origin
10	QEVAL	Char	1	Evaluator

**Data Set Name: suppbs.sas7bdat**

<b>Num</b>	<b>Variable</b>	<b>Type</b>	<b>Len</b>	<b>Label</b>
1	SubjRandID	Num	8	Subject Identifier (randomly assigned)
2	STUDYID	Char	10	Study Identifier
3	RDOMAIN	Char	2	Related Domain Abbreviation
4	IDVAR	Char	5	Identifying Variable
5	IDVARVAL	Char	1	Identifying Variable Value
6	QNAM	Char	8	Qualifier Variable Name
7	QLABEL	Char	34	Qualifier Variable Label
8	QVAL	Char	14	Data Value
9	QORIG	Char	3	Origin
10	QEVAL	Char	1	Evaluator

**Data Set Name: suppdv.sas7bdat**

<b>Num</b>	<b>Variable</b>	<b>Type</b>	<b>Len</b>	<b>Label</b>
1	SubjRandID	Num	8	Subject Identifier (randomly assigned)
2	STUDYID	Char	10	Study Identifier
3	RDOMAIN	Char	2	Related Domain Abbreviation
4	IDVAR	Char	5	Identifying Variable
5	IDVARVAL	Char	2	Identifying Variable Value
6	QNAM	Char	7	Qualifier Variable Name
7	QLABEL	Char	25	Qualifier Variable Label
8	QVAL	Char	200	Data Value
9	QORIG	Char	3	Origin
10	QEVAL	Char	12	Evaluator

**Data Set Name: suppfa.sas7bdat**

<b>Num</b>	<b>Variable</b>	<b>Type</b>	<b>Len</b>	<b>Label</b>
1	SubjRandID	Num	8	Subject Identifier (randomly assigned)
2	STUDYID	Char	10	Study Identifier
3	RDOMAIN	Char	2	Related Domain Abbreviation
4	IDVAR	Char	5	Identifying Variable
5	IDVARVAL	Char	2	Identifying Variable Value
6	QNAM	Char	8	Qualifier Variable Name
7	QLABEL	Char	24	Qualifier Variable Label
8	QVAL	Char	192	Data Value
9	QORIG	Char	3	Origin
10	QEVAL	Char	1	Evaluator

**Data Set Name: supplb.sas7bdat**

<b>Num</b>	<b>Variable</b>	<b>Type</b>	<b>Len</b>	<b>Label</b>
1	SubjRandID	Num	8	Subject Identifier (randomly assigned)
2	STUDYID	Char	10	Study Identifier
3	RDOMAIN	Char	2	Related Domain Abbreviation
4	IDVAR	Char	8	Identifying Variable
5	IDVARVAL	Char	4	Identifying Variable Value
6	QNAM	Char	5	Qualifier Variable Name
7	QLABEL	Char	17	Qualifier Variable Label
8	QVAL	Char	10	Data Value
9	QORIG	Char	3	Origin
10	QEVAL	Char	1	Evaluator
11	SDQval	Num	8	Study Day of QVAL from date of consent

**Data Set Name: suppqs.sas7bdat**

<b>Num</b>	<b>Variable</b>	<b>Type</b>	<b>Len</b>	<b>Label</b>
1	SubjRandID	Num	8	Subject Identifier (randomly assigned)
2	STUDYID	Char	10	Study Identifier
3	RDOMAIN	Char	2	Related Domain Abbreviation
4	IDVAR	Char	5	Identifying Variable
5	IDVARVAL	Char	4	Identifying Variable Value
6	QNAM	Char	8	Qualifier Variable Name
7	QLABEL	Char	34	Qualifier Variable Label
8	QVAL	Char	27	Data Value
9	QORIG	Char	3	Origin
10	QEVAL	Char	1	Evaluator

**Data Set Name: sv.sas7bdat**

<b>Num</b>	<b>Variable</b>	<b>Type</b>	<b>Len</b>	<b>Label</b>
1	SubjRandID	Num	8	Subject Identifier (randomly assigned)
2	STUDYID	Char	10	Study Identifier
3	DOMAIN	Char	2	Domain Abbreviation
4	VISITNUM	Num	8	Visit Number
5	VISIT	Char	28	Visit Name
6	VISITDY	Num	8	Planned Study Day of Visit (from first treatment date)
7	EPOCH	Char	45	Epoch
8	SVSTDY	Num	8	Study Day of Start of Visit (from first treatment date)
9	SVENDY	Num	8	Study Day of End of Visit (from first treatment date)

**Data Set Name: vs.sas7bdat**

<b>Num</b>	<b>Variable</b>	<b>Type</b>	<b>Len</b>	<b>Label</b>
1	SubjRandID	Num	8	Subject Identifier (randomly assigned)
2	STUDYID	Char	10	Study Identifier
3	DOMAIN	Char	2	Domain Abbreviation
4	VSSEQ	Num	8	Sequence Number
5	VSTESTCD	Char	6	Vital Signs Test Short Name
6	VSTEST	Char	24	Vital Signs Test Name
7	VSORRES	Char	4	Result or Finding in Original Units
8	VSORRESU	Char	11	Original Units
9	VSORNRLO	Char	3	Normal Range Lower Limit-Original Units
10	VSORNRHI	Char	3	Normal Range Upper Limit-Original Units
11	VSSTRESC	Char	4	Character Result/Finding in Std Format
12	VSSTRESN	Num	8	Numeric Result/Finding in Standard Units
13	VSSTRESU	Char	11	Standard Units
14	VSSTNRLO	Num	8	Normal Range Lower Limit-Standard Units
15	VSSTNRHI	Num	8	Normal Range Upper Limit-Standard Units
16	VSNRIND	Char	6	Normal/Reference Range Indicator
17	VSSTAT	Char	8	Completion Status
18	VSBLFL	Char	1	Baseline Flag
19	VISITNUM	Num	8	Visit Number
20	VISIT	Char	28	Visit Name
21	EPOCH	Char	45	Epoch
22	VSDY	Num	8	Study Day of Vital Signs (from first treatment date)