

**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	AGEU	Char	5	Age Units
6	AGEGR1	Char	14	Pooled Age Group 1
7	AGEGR1N	Num	8	Pooled Age Group 1 (N)
8	SEX	Char	1	Sex
9	SEXN	Num	8	Sex (N)
10	WEIGHTBL	Num	8	Weight at Baseline (kg)
11	HEIGHTBL	Num	8	Height at Baseline (cm)
12	BMIBL	Num	8	BMI at Baseline (kg/m2)
13	RACE	Char	25	Race
14	RACEN	Num	8	Race (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	RANDFL	Char	1	Randomized Population Flag
23	RANDFN	Num	8	Randomized Population Flag (N)
24	SAFFL	Char	1	Safety Population Flag
25	SAFFN	Num	8	Safety Population Flag (N)
26	ITTFLL	Char	1	Intent-To-Treat Population Flag
27	ITTFN	Num	8	Intent-To-Treat Population Flag (N)
28	MITTFL	Char	1	Modified ITT Population Flag
29	MITTFN	Num	8	Modified ITT Population Flag (N)
30	PPROTFL	Char	1	Per-Protocol Population Flag
31	PPROTFN	Num	8	Per-Protocol Population Flag (N)
32	STABLEFL	Char	1	Dosed at Stable Dosing Period Flag
33	STABLEFN	Num	8	Dosed at Stable Dosing Period Flag (N)
34	COMPLFL	Char	1	Completers Population Flag
35	COMPLFN	Num	8	Completers Population Flag (N)
36	EXTENFL	Char	1	Entered into LUM001-305 Extension Study
37	EXTENFN	Num	8	Entered into LUM001-305 Extension (N)

Num	Variable	Type	Len	Label
38	LOWDOSFL	Char	1	Recd. Lower Dose Due to Tolerability
39	LOWDOSFN	Num	8	Recd. Lower Dose Due to Tolerability (N)
40	HIDOSEFL	Char	1	Two Highest Tolerated Doses Flag
41	HIDOSEFN	Num	8	Two Highest Tolerated Doses Flag (N)
42	DOSINTFL	Char	1	Drug Interrupted for >14 Days Flag
43	DOSINTFN	Num	8	Drug Interrupted for >14 Days Flag (N)
44	ARM	Char	20	Description of Planned Arm
45	ARMCD	Char	1	Description Code of Planned Arm
46	ACTARM	Char	20	Description of Actual Arm
47	ACTARMCD	Char	1	Description Code of Actual Arm
48	TRT01P	Char	20	Planned Treatment for Period 01
49	TRT01PN	Num	8	Planned Treatment for Period 01 (N)
50	TRT01A	Char	20	Actual Treatment for Period 01
51	TRT01AN	Num	8	Actual Treatment for Period 01 (N)
52	TR01PG1	Char	13	Planned Pooled Treatment 1 for Period 01
53	TR01PG1N	Num	8	Planned Pooled Trt 1 for Period 01 (N)
54	TR01PG2	Char	32	Planned Pooled Treatment 1 for Period 02
55	TR01PG2N	Num	8	Planned Pooled Trt 1 for Period 02 (N)
56	TR01AG1	Char	13	Actual Pooled Treatment 1 for Period 01
57	TR01AG1N	Num	8	Actual Pooled Trt 1 for Period 01 (N)
58	TRT02P	Char	20	Planned Treatment for Period 02
59	TRT02PN	Num	8	Planned Treatment for Period 02 (N)
60	TRT02A	Char	20	Actual Treatment for Period 02
61	TRT02AN	Num	8	Actual Treatment for Period 02 (N)
62	TR02PG1	Char	13	Planned Pooled Treatment 1 for Period 02
63	TR02PG1N	Num	8	Planned Pooled Trt 1 for Period 02 (N)
64	TR02AG1	Char	13	Actual Pooled Treatment 1 for Period 02
65	TR02AG1N	Num	8	Actual Pooled Trt 1 for Period 02 (N)
66	TRTP	Char	20	Planned Treatment
67	TRTPN	Num	8	Planned Treatment (N)
68	TRTA	Char	20	Actual Treatment
69	TRTAN	Num	8	Actual Treatment (N)
70	TRTPG1	Char	13	Planned Pooled Treatment 1
71	TRTPG1N	Num	8	Planned Pooled Treatment 1 (N)
72	TRTPG2	Char	32	Planned Pooled Treatment 2
73	TRTPG2N	Num	8	Planned Pooled Treatment 2 (N)
74	TRTAG1	Char	13	Actual Pooled Treatment 1
75	TRTAG1N	Num	8	Actual Pooled Treatment 1 (N)
76	AESEQ	Num	8	Sequence Number

Num	Variable	Type	Len	Label
77	AESPID	Char	3	Sponsor-Defined Identifier
78	AEGRPID	Char	9	Group ID
79	AETERM	Char	69	Reported Term for the Adverse Event
80	AELLT	Char	36	Lowest Level Term
81	AELLTCD	Num	8	Lowest Level Term Code
82	AEDECOD	Char	40	Dictionary-Derived Term
83	AEPTCD	Num	8	Preferred Term Code
84	AEHLT	Char	59	High Level Term
85	AEHLTCD	Num	8	High Level Term Code
86	AEHLGT	Char	59	High Level Group Term
87	AEHLGTC	Num	8	High Level Group Term Code
88	AEBODSYS	Char	52	Body System or Organ Class
89	AEBDSYCD	Num	8	Body System or Organ Class Code
90	AESOC	Char	52	Primary System Organ Class
91	AESOCCD	Num	8	Primary System Organ Class Code
92	AESIGI	Char	26	AEs of Special Interest GI Disorders
93	AESIGIFL	Char	1	AEs of Special Interest GI Dis. Flag
94	AESILD	Char	19	AEs of Special Interest Liver Det.
95	AESILDFL	Char	1	AEs of Special Interest Liver Det. Flag
96	AESITF	Char	1	AEs of Special Interest Thyroid Fn.
97	AESITFFL	Char	1	AEs of Special Interest Thyroid Fn. Flag
98	AESIFS	Char	30	AEs of Special Interest Fat Sl. Vit
99	AESIFSFL	Char	1	AEs of Special Interest Fat Sl. Vit Flag
100	AESIGR	Char	1	AEs of Special Interest Growth Ret.
101	AESIGRFL	Char	1	AEs of Special Interest Growth Ret. Flag
102	AESER	Char	1	Serious Event
103	AESERN	Num	8	Serious Event (N)
104	AETOXGR	Char	1	Standard Toxicity Grade
105	AETOXGRN	Num	8	Standard Toxicity Grade (N)
106	ATOXGR	Char	18	Analysis Toxicity Grade
107	ATOXGRN	Num	8	Analysis Toxicity Grade (N)
108	AEACN	Char	16	Action Taken with Study Treatment
109	AEACNN	Num	8	Action Taken with Study Treatment (N)
110	AEACNOTH	Char	31	Other Action Taken
111	AEREL	Char	25	Causality
112	AERELN	Num	8	Causality (N)
113	AREL	Char	25	Analysis Causality
114	ARELN	Num	8	Analysis Causality (N)
115	RELGR1	Char	19	Pooled Causality Group 1

Num	Variable	Type	Len	Label
116	RELGR1N	Num	8	Pooled Causality Group 1 (N)
117	AEOUT	Char	26	Outcome of Adverse Event
118	AEOUTN	Num	8	Outcome of Adverse Event (N)
119	AESDTH	Char	1	Results in Death
120	AESHOSP	Char	1	Requires or Prolongs Hospitalization
121	AESLIFE	Char	1	Is Life Threatening
122	AECONTRT	Char	1	Concomitant or Additional Trtmnt Given
123	AETRT	Char	41	Treatment Required
124	AEDIS	Char	1	AE Caused Discontinuation from Study
125	ASTDTF	Char	1	Analysis Start Date Imputation Flag
126	AENDTF	Char	1	Analysis End Date Imputation Flag
127	ASTDY	Num	8	Analysis Start Relative Day (from first treatment date)
128	AESTDY	Num	8	Study Day of Start of Adverse Event (from first treatment date)
129	AENDY	Num	8	Analysis End Relative Day (from first treatment date)
130	AEENDY	Num	8	Study Day of End of Adverse Event (from first treatment date)
131	ADURN	Num	8	AE Duration (N)
132	ADURU	Char	4	AE Duration Units
133	AEENRF	Char	7	End Relative to Reference Period
134	APERIOD	Num	8	Period
135	APERIODC	Char	15	Period (C)
136	DOSEAEON	Char	8	Study Drug Dose at AE Onset
137	DOSAEONU	Char	9	Study Drug Dose at AE Onset Units
138	TRTEMFL	Char	1	Treatment Emergent Analysis Flag
139	AOCCFL	Char	1	1st Occurrence of Any AE Flag
140	AOCCSFL	Char	1	1st Occurrence of SOC Flag
141	AOCCPFL	Char	1	1st Occurrence of Preferred Term Flag
142	AOC01FL	Char	1	1st Occurrence of Any AE Flag 01
143	AOCS01FL	Char	1	1st Occurrence of SOC Flag 01
144	AOCP01FL	Char	1	1st Occurrence of Preferred Term Flag 01
145	AOC02FL	Char	1	1st Occurrence of Any AE Flag 02
146	AOCS02FL	Char	1	1st Occurrence of SOC Flag 02
147	AOCP02FL	Char	1	1st Occurrence of Preferred Term Flag 02
148	AOCCIFL	Char	1	1st Max Sev./Int. Occurrence Flag
149	AOCCSIFL	Char	1	1st Max Sev./Int. Occur Within SOC Flag
150	AOCCPIFL	Char	1	1st Max Sev./Int. Occur Within PT Flag
151	AOI01FL	Char	1	1st Max Sev./Int. Occur Flag 01
152	AOSI01FL	Char	1	1st Max Sev/Int Occur Within SOC Flag 01
153	AOPI01FL	Char	1	1st Max Sev/Int Occur Within PT Flag 01
154	AOI02FL	Char	1	1st Max Sev./Int. Occur Flag 02

Num	Variable	Type	Len	Label
155	AOSI02FL	Char	1	1st Max Sev/Int Occur Within SOC Flag 02
156	AOPI02FL	Char	1	1st Max Sev/Int Occur Within PT Flag 02
157	AOCCTFL	Char	1	1st Occurrence of Any Trt Rel AE Flag
158	AOCCTSFL	Char	1	1st Occurrence of Trt Rel SOC Flag
159	AOCCTPFL	Char	1	1st Occurrence of Trt Rel PT Flag
160	AOT01FL	Char	1	1st Occurrence of Any Trt Rel AE Flag 01
161	AOTS01FL	Char	1	1st Occurrence of Trt Rel SOC Flag 01
162	AOTP01FL	Char	1	1st Occurrence of Trt Rel PT Flag 01
163	AOT02FL	Char	1	1st Occurrence of Any Trt Rel AE Flag 02
164	AOTS02FL	Char	1	1st Occurrence of Trt Rel SOC Flag 02
165	AOTP02FL	Char	1	1st Occurrence of Trt Rel PT Flag 02
166	AOCTIFL	Char	1	1st Max Sev Trt Rel Occur Flag
167	AOCTSIFL	Char	1	1st Max Sev Trt Rel Occur W/ SOC Flag
168	AOCTPIFL	Char	1	1st Max Sev Trt Rel Occur W/ PT Flag
169	ATI01FL	Char	1	1st Max Sev Trt Rel Occur Flag 01
170	ATSI01FL	Char	1	1st Max Sev Trt Rel Occ. W/ SOC Flag 01
171	ATPI01FL	Char	1	1st Max Sev Trt Rel Occur W/ PT Flag 01
172	ATI02FL	Char	1	1st Max Sev Trt Rel Occur Flag 02
173	ATSI02FL	Char	1	1st Max Sev Trt Rel Occ. W/ SOC Flag 02
174	ATPI02FL	Char	1	1st Max Sev Trt Rel Occur W/ PT Flag 02
175	AOCSSFL	Char	1	Ser. 1st Occurrence of Any AE Flag
176	AOCSSSFL	Char	1	Ser. 1st Occurrence of SOC Flag
177	AOCSPFL	Char	1	Ser. 1st Occurrence of PT Flag
178	AOS01FL	Char	1	Ser. 1st Occurrence of Any AE Flag 01
179	AOSS01FL	Char	1	Ser. 1st Occurrence of SOC Flag 01
180	AOSP01FL	Char	1	Ser. 1st Occurrence of PT Flag 01
181	AOS02FL	Char	1	Ser. 1st Occurrence of Any AE Flag 02
182	AOSS02FL	Char	1	Ser. 1st Occurrence of SOC Flag 02
183	AOSP02FL	Char	1	Ser. 1st Occurrence of PT Flag 02
184	AOSTRFL	Char	1	Ser. 1st Occ. of Any TRT Rel AE Flag
185	AOSTRSFL	Char	1	Ser. 1st Occurrence of TRT Rel SOC Flag
186	AOSTRPFL	Char	1	Ser. 1st Occurrence of TRT Rel PT Flag
187	ASR01FL	Char	1	Ser. 1st Occ. of Any TRT Rel AE Flag 01
188	ASRS01FL	Char	1	Ser. 1st Occ. of TRT Rel SOC Flag 01
189	ASRP01FL	Char	1	Ser. 1st Occ. of TRT Rel PT Flag 01
190	ASR02FL	Char	1	Ser. 1st Occ. of Any TRT Rel AE Flag 02
191	ASRS02FL	Char	1	Ser. 1st Occ. of TRT Rel SOC Flag 02
192	ASRP02FL	Char	1	Ser. 1st Occ. of TRT Rel PT Flag 02
193	AOCDCFL	Char	1	1st AE Leading to Discontinuation Flag

Num	Variable	Type	Len	Label
194	AOCDCSFL	Char	1	1st AE Leading to Discon. in SOC Flag
195	AOCDPFL	Char	1	1st AE Leading to Discon. in PT Flag
196	ADC01FL	Char	1	1st AE Leading to Discon. Flag 01
197	ADCS01FL	Char	1	1st AE Leading to Discon. in SOC Flag 01
198	ADCP01FL	Char	1	1st AE Leading to Discon. in PT Flag 01
199	ADC02FL	Char	1	1st AE Leading to Discon. Flag 02
200	ADCS02FL	Char	1	1st AE Leading to Discon. in SOC Flag 02
201	ADCP02FL	Char	1	1st AE Leading to Discon. in PT Flag 02
202	AOTEGIFL	Char	1	1st TEAE for GI Events Flag
203	AOTEGSFL	Char	1	1st TEAE for GI Events in SOC Flag
204	AOTEGPFL	Char	1	1st TEAE for GI Events in PT Flag
205	ATGI01FL	Char	1	1st TEAE for GI Events Flag 01
206	ATGS01FL	Char	1	1st TEAE for GI Events in SOC Flag 01
207	ATGP01FL	Char	1	1st TEAE for GI Events in PT Flag 01
208	ATGI02FL	Char	1	1st TEAE for GI Events Flag 02
209	ATGS02FL	Char	1	1st TEAE for GI Events in SOC Flag 02
210	ATGP02FL	Char	1	1st TEAE for GI Events in PT Flag 02
211	AOTELDFL	Char	1	1st TEAE for Liver Det. Events Flag
212	AOTELSFL	Char	1	1st TEAE for Liver Events in SOC Flag
213	AOTELPFL	Char	1	1st TEAE for Liver Events in PT Flag
214	ATLD01FL	Char	1	1st TEAE for Liver Det. Events Flag 01
215	ATLS01FL	Char	1	1st TEAE for Liver Events in SOC Flag 01
216	ATLP01FL	Char	1	1st TEAE for Liver Events in PT Flag 01
217	ATLD02FL	Char	1	1st TEAE for Liver Det. Events Flag 02
218	ATLS02FL	Char	1	1st TEAE for Liver Events in SOC Flag 02
219	ATLP02FL	Char	1	1st TEAE for Liver Events in PT Flag 02
220	AOTETHFL	Char	1	1st TEAE for Thyroid Events Flag
221	AOTETSFL	Char	1	1st TEAE for Thyroid Events in SOC Flag
222	AOTETPFL	Char	1	1st TEAE for Thyroid Events in PT Flag
223	ATTH01FL	Char	1	1st TEAE for Thyroid Events Flag 01
224	ATTS01FL	Char	1	1st TEAE for Thy. Events in SOC Flag 01
225	ATTP01FL	Char	1	1st TEAE for Thy. Events in PT Flag 01
226	ATTH02FL	Char	1	1st TEAE for Thyroid Events Flag 02
227	ATTS02FL	Char	1	1st TEAE for Thy. Events in SOC Flag 02
228	ATTP02FL	Char	1	1st TEAE for Thy. Events in PT Flag 02
229	AOTEVTFL	Char	1	1st TEAE for Vit. Def Events Flag
230	AOTEVSFL	Char	1	1st TEAE for Vitamin Events in SOC Flag
231	AOTEVPFL	Char	1	1st TEAE for Vitamin Events in PT Flag
232	ATVT01FL	Char	1	1st TEAE for Vitamin Events Flag 01

<b>Num</b>	<b>Variable</b>	<b>Type</b>	<b>Len</b>	<b>Label</b>
233	ATVS01FL	Char	1	1st TEAE for Vit. Events in SOC Flag 01
234	ATVP01FL	Char	1	1st TEAE for Vit. Events in PT Flag 01
235	ATVT02FL	Char	1	1st TEAE for Vitamin Events Flag 02
236	ATVS02FL	Char	1	1st TEAE for Vit. Events in SOC Flag 02
237	ATVP02FL	Char	1	1st TEAE for Vit. Events in PT Flag 02
238	AOTEGRFL	Char	1	1st TEAE for Growth Ret. Events Flag
239	AOTERSFL	Char	1	1st TEAE for Growth Events in SOC Flag
240	AOTERPFL	Char	1	1st TEAE for Growth Events in PT Flag
241	ATGR01FL	Char	1	1st TEAE for Growth Events Flag 01
242	ATRS01FL	Char	1	1st TEAE for Grth. Events in SOC Flag 01
243	ATRP01FL	Char	1	1st TEAE for Grth. Events in PT Flag 01
244	ATGR02FL	Char	1	1st TEAE for Growth Events Flag 02
245	ATRS02FL	Char	1	1st TEAE for Grth. Events in SOC Flag 02
246	ATRP02FL	Char	1	1st TEAE for Grth. Events in PT Flag 02
247	AOCCDFL	Char	1	1st Occurrence of Any AE Death Flag
248	CRIT1	Char	45	Analysis Criterion 1
249	CRIT1FL	Char	1	Criterion 1 Evaluation Result Flag

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<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	AGEU	Char	5	Age Units
6	AGEGR1	Char	14	Pooled Age Group 1
7	AGEGR1N	Num	8	Pooled Age Group 1 (N)
8	SEX	Char	1	Sex
9	SEXN	Num	8	Sex (N)
10	WEIGHTBL	Num	8	Weight at Baseline (kg)
11	HEIGHTBL	Num	8	Height at Baseline (cm)
12	BMIBL	Num	8	BMI at Baseline (kg/m2)
13	RACE	Char	25	Race
14	RACEN	Num	8	Race (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	RANDFL	Char	1	Randomized Population Flag
23	RANDFN	Num	8	Randomized Population Flag (N)
24	SAFFL	Char	1	Safety Population Flag
25	SAFFN	Num	8	Safety Population Flag (N)
26	ITTFLL	Char	1	Intent-To-Treat Population Flag
27	ITTFN	Num	8	Intent-To-Treat Population Flag (N)
28	MITTFLL	Char	1	Modified ITT Population Flag
29	MITTFN	Num	8	Modified ITT Population Flag (N)
30	PPROTFL	Char	1	Per-Protocol Population Flag
31	PPROTFN	Num	8	Per-Protocol Population Flag (N)
32	STABLEFL	Char	1	Dosed at Stable Dosing Period Flag
33	STABLEFN	Num	8	Dosed at Stable Dosing Period Flag (N)
34	COMPLFL	Char	1	Completers Population Flag
35	COMPLFN	Num	8	Completers Population Flag (N)
36	EXTENFL	Char	1	Entered into LUM001-305 Extension Study
37	EXTENFN	Num	8	Entered into LUM001-305 Extension (N)

Num	Variable	Type	Len	Label
38	LOWDOSFL	Char	1	Recd. Lower Dose Due to Tolerability
39	LOWDOSFN	Num	8	Recd. Lower Dose Due to Tolerability (N)
40	HIDOSEFL	Char	1	Two Highest Tolerated Doses Flag
41	HIDOSEFN	Num	8	Two Highest Tolerated Doses Flag (N)
42	DOSINTFL	Char	1	Drug Interrupted for >14 Days Flag
43	DOSINTFN	Num	8	Drug Interrupted for >14 Days Flag (N)
44	ARM	Char	20	Description of Planned Arm
45	ARMCD	Char	1	Description Code of Planned Arm
46	ACTARM	Char	20	Description of Actual Arm
47	ACTARMCD	Char	1	Description Code of Actual Arm
48	TRT01P	Char	20	Planned Treatment for Period 01
49	TRT01PN	Num	8	Planned Treatment for Period 01 (N)
50	TRT01A	Char	20	Actual Treatment for Period 01
51	TRT01AN	Num	8	Actual Treatment for Period 01 (N)
52	TR01PG1	Char	13	Planned Pooled Treatment 1 for Period 01
53	TR01PG1N	Num	8	Planned Pooled Trt 1 for Period 01 (N)
54	TR01PG2	Char	32	Planned Pooled Treatment 1 for Period 02
55	TR01PG2N	Num	8	Planned Pooled Trt 1 for Period 02 (N)
56	TR01AG1	Char	13	Actual Pooled Treatment 1 for Period 01
57	TR01AG1N	Num	8	Actual Pooled Trt 1 for Period 01 (N)
58	TRT02P	Char	20	Planned Treatment for Period 02
59	TRT02PN	Num	8	Planned Treatment for Period 02 (N)
60	TRT02A	Char	20	Actual Treatment for Period 02
61	TRT02AN	Num	8	Actual Treatment for Period 02 (N)
62	TR02PG1	Char	13	Planned Pooled Treatment 1 for Period 02
63	TR02PG1N	Num	8	Planned Pooled Trt 1 for Period 02 (N)
64	TR02AG1	Char	13	Actual Pooled Treatment 1 for Period 02
65	TR02AG1N	Num	8	Actual Pooled Trt 1 for Period 02 (N)
66	TRTP	Char	20	Planned Treatment
67	TRTPN	Num	8	Planned Treatment (N)
68	TRTA	Char	20	Actual Treatment
69	TRTAN	Num	8	Actual Treatment (N)
70	TRTPG1	Char	13	Planned Pooled Treatment 1
71	TRTPG1N	Num	8	Planned Pooled Treatment 1 (N)
72	TRTPG2	Char	32	Planned Pooled Treatment 2
73	TRTPG2N	Num	8	Planned Pooled Treatment 2 (N)
74	TRTAG1	Char	13	Actual Pooled Treatment 1
75	TRTAG1N	Num	8	Actual Pooled Treatment 1 (N)
76	ASTDTF	Char	1	Analysis Start Date Imputation Flag

Num	Variable	Type	Len	Label
77	AENDTF	Char	1	Analysis End Date Imputation Flag
78	ASTDY	Num	8	Analysis Start Relative Day (from first treatment date)
79	CMSTDY	Num	8	Study Day of Start of Medication (from first treatment date)
80	AENDY	Num	8	Analysis End Relative Day (from first treatment date)
81	CMENDY	Num	8	Study Day of End of Medication (from first treatment date)
82	CMENRF	Char	7	End Relative to Reference Period
83	CMSEQ	Num	8	Sequence Number
84	CMSPID	Char	3	Sponsor-Defined Identifier
85	CMTRT	Char	104	Reported Name of Drug, Med, or Therapy
86	CMDECOD	Char	193	Standardized Medication Name
87	CMCAT	Char	5	Category for Medication
88	CMINDC	Char	89	Indication
89	CMCLAS	Char	64	Medication Class
90	CMDOSE	Num	8	Dose per Administration
91	CMDOSTXT	Char	7	Dose Description
92	CMDOSU	Char	11	Dose Units
93	CMDOSFRQ	Char	16	Dosing Frequency per Interval
94	CMROUTE	Char	24	Route of Administration
95	CMEDFL	Char	11	Prior/Concomitant Medication Flag
96	CMEDFN	Num	8	Prior/Concomitant Medication Flag (N)
97	PRDISFL	Char	1	Prior Disease Medications Flag
98	PRDISFN	Num	8	Prior Disease Medications Flag (N)
99	PRURMDFL	Char	1	Prior Pruritus Therapy Medications Flag
100	PRURMDFN	Num	8	Prior Pruritus Therapy Meds Flag (N)
101	PDPRUR	Num	8	No. Prior Disease and/or Pruritus Meds
102	PDPRCAT	Char	22	Prior Disease and Pruritus Category
103	PDPRCATN	Num	8	Prior Disease and Pruritus Category (N)
104	PRURMD	Num	8	No. Prior Pruritus Therapy Meds
105	PRURMCAT	Char	22	Prior Pruritus only Category
106	PRURMCAN	Num	8	Prior Pruritus only Category (N)

**Data Set Name: adef.sas7bdat**

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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	AGEU	Char	5	Age Units
6	AGEGR1	Char	14	Pooled Age Group 1
7	AGEGR1N	Num	8	Pooled Age Group 1 (N)
8	SEX	Char	1	Sex
9	SEXN	Num	8	Sex (N)
10	WEIGHTBL	Num	8	Weight at Baseline (kg)
11	HEIGHTBL	Num	8	Height at Baseline (cm)
12	BMIBL	Num	8	BMI at Baseline (kg/m2)
13	RACE	Char	25	Race
14	RACEN	Num	8	Race (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	RANDFL	Char	1	Randomized Population Flag
23	RANDFN	Num	8	Randomized Population Flag (N)
24	SAFFL	Char	1	Safety Population Flag
25	SAFFN	Num	8	Safety Population Flag (N)
26	ITTFL	Char	1	Intent-To-Treat Population Flag
27	ITTFN	Num	8	Intent-To-Treat Population Flag (N)
28	MITTFL	Char	1	Modified ITT Population Flag
29	MITTFN	Num	8	Modified ITT Population Flag (N)
30	PPROTFL	Char	1	Per-Protocol Population Flag
31	PPROTFN	Num	8	Per-Protocol Population Flag (N)
32	STABLEFL	Char	1	Dosed at Stable Dosing Period Flag
33	STABLEFN	Num	8	Dosed at Stable Dosing Period Flag (N)
34	COMPLFL	Char	1	Completers Population Flag
35	COMPLFN	Num	8	Completers Population Flag (N)
36	EXTENFL	Char	1	Entered into LUM001-305 Extension Study
37	EXTENFN	Num	8	Entered into LUM001-305 Extension (N)

Num	Variable	Type	Len	Label
38	LOWDOSFL	Char	1	Recd. Lower Dose Due to Tolerability
39	LOWDOSFN	Num	8	Recd. Lower Dose Due to Tolerability (N)
40	HIDOSEFL	Char	1	Two Highest Tolerated Doses Flag
41	HIDOSEFN	Num	8	Two Highest Tolerated Doses Flag (N)
42	DOSINTFL	Char	1	Drug Interrupted for >14 Days Flag
43	DOSINTFN	Num	8	Drug Interrupted for >14 Days Flag (N)
44	ARM	Char	20	Description of Planned Arm
45	ARMCD	Char	1	Description Code of Planned Arm
46	ACTARM	Char	20	Description of Actual Arm
47	ACTARMCD	Char	1	Description Code of Actual Arm
48	TRT01P	Char	20	Planned Treatment for Period 01
49	TRT01PN	Num	8	Planned Treatment for Period 01 (N)
50	TRT01A	Char	20	Actual Treatment for Period 01
51	TRT01AN	Num	8	Actual Treatment for Period 01 (N)
52	TR01PG1	Char	13	Planned Pooled Treatment 1 for Period 01
53	TR01PG1N	Num	8	Planned Pooled Trt 1 for Period 01 (N)
54	TR01PG2	Char	32	Planned Pooled Treatment 1 for Period 02
55	TR01PG2N	Num	8	Planned Pooled Trt 1 for Period 02 (N)
56	TR01AG1	Char	13	Actual Pooled Treatment 1 for Period 01
57	TR01AG1N	Num	8	Actual Pooled Trt 1 for Period 01 (N)
58	TRT02P	Char	20	Planned Treatment for Period 02
59	TRT02PN	Num	8	Planned Treatment for Period 02 (N)
60	TRT02A	Char	20	Actual Treatment for Period 02
61	TRT02AN	Num	8	Actual Treatment for Period 02 (N)
62	TR02PG1	Char	13	Planned Pooled Treatment 1 for Period 02
63	TR02PG1N	Num	8	Planned Pooled Trt 1 for Period 02 (N)
64	TR02AG1	Char	13	Actual Pooled Treatment 1 for Period 02
65	TR02AG1N	Num	8	Actual Pooled Trt 1 for Period 02 (N)
66	TRTP	Char	20	Planned Treatment
67	TRTPN	Num	8	Planned Treatment (N)
68	TRTA	Char	20	Actual Treatment
69	TRTAN	Num	8	Actual Treatment (N)
70	TRTPG1	Char	13	Planned Pooled Treatment 1
71	TRTPG1N	Num	8	Planned Pooled Treatment 1 (N)
72	TRTPG2	Char	32	Planned Pooled Treatment 2
73	TRTPG2N	Num	8	Planned Pooled Treatment 2 (N)
74	TRTAG1	Char	13	Actual Pooled Treatment 1
75	TRTAG1N	Num	8	Actual Pooled Treatment 1 (N)
76	ADY	Num	8	Analysis Relative Day (from first treatment date)

Num	Variable	Type	Len	Label
77	AVISITN	Num	8	Analysis Visit (N)
78	AVISIT	Char	21	Analysis Visit
79	VISIT	Char	10	Visit Name
80	VISITNUM	Num	8	Visit Number
81	LBSEQ	Num	8	Sequence Number
82	PARAM	Char	46	Parameter
83	PARAMCD	Char	6	Parameter Code
84	PARAMN	Num	8	Parameter (N)
85	PARCAT1	Char	9	Parameter Category 1
86	PARCAT2	Char	22	Parameter Category 2
87	AVAL	Num	8	Analysis Value
88	BASE	Num	8	Baseline Value
89	CHG	Num	8	Change from Baseline
90	PCHG	Num	8	Percent Change from Baseline
91	CRIT1	Char	41	Analysis Criterion 1
92	CRIT1FL	Char	1	Criterion 1 Evaluation Result Flag
93	CRIT1FN	Num	8	Criterion 1 Evaluation Result Flag (N)
94	CRIT2	Char	16	Analysis Criterion 2 sBA <= -50
95	CRIT2FL	Char	1	Criterion 2 Evaluation Result Flag
96	CRIT3	Char	16	Analysis Criterion 3 sBA <= -70
97	CRIT3FL	Char	1	Criterion 3 Evaluation Result Flag
98	CRIT4	Char	16	Analysis Criterion 4 sBA <= -80
99	CRIT4FL	Char	1	Criterion 4 Evaluation Result Flag
100	CRIT5	Char	17	Analysis Criterion 5 sBA <= 8.5 umol/L
101	CRIT5FL	Char	1	Criterion 5 Evaluation Result Flag
102	CRIT6	Char	15	Analysis Criterion 6 C4 >= 100
103	CRIT6FL	Char	1	Criterion 6 Evaluation Result Flag
104	CRIT7	Char	38	Analysis Criterion 7 Shift in AST
105	CRIT7FL	Char	1	Criterion 7 Evaluation Result Flag
106	CRIT8	Char	38	Analysis Criterion 8 Shift in ALT
107	CRIT8FL	Char	1	Criterion 8 Evaluation Result Flag
108	CRIT9	Char	50	Analysis Criterion 9 Shift in Total Bili
109	CRIT9FL	Char	1	Criterion 9 Evaluation Result Flag
110	CRIT10	Char	22	Analysis Criterion 10 -70 < sBA <= -50
111	CRIT10FL	Char	1	Criterion 10 Evaluation Result Flag
112	CRIT11	Char	22	Analysis Criterion 11 -80 < sBA <= -70
113	CRIT11FL	Char	1	Criterion 11 Evaluation Result Flag
114	DTYPE	Char	18	Derivation Type
115	ANRIND	Char	6	Analysis Reference Range Indicator

<b>Num</b>	<b>Variable</b>	<b>Type</b>	<b>Len</b>	<b>Label</b>
116	BNRIND	Char	6	Baseline Reference Range Indicator
117	ANRLO	Char	3	Analysis Normal Range Lower Limit
118	ANRHI	Char	3	Analysis Normal Range Upper Limit
119	ABLFL	Char	1	Baseline Record Flag
120	ABLFN	Num	8	Baseline Record Flag (N)

**Data Set Name: adeg.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	AGEU	Char	5	Age Units
6	AGEGR1	Char	14	Pooled Age Group 1
7	AGEGR1N	Num	8	Pooled Age Group 1 (N)
8	SEX	Char	1	Sex
9	SEXN	Num	8	Sex (N)
10	WEIGHTBL	Num	8	Weight at Baseline (kg)
11	HEIGHTBL	Num	8	Height at Baseline (cm)
12	BMIBL	Num	8	BMI at Baseline (kg/m2)
13	RACE	Char	25	Race
14	RACEN	Num	8	Race (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	RANDFL	Char	1	Randomized Population Flag
23	RANDFN	Num	8	Randomized Population Flag (N)
24	SAFFL	Char	1	Safety Population Flag
25	SAFFN	Num	8	Safety Population Flag (N)
26	ITTFL	Char	1	Intent-To-Treat Population Flag
27	ITTFN	Num	8	Intent-To-Treat Population Flag (N)
28	MITTFL	Char	1	Modified ITT Population Flag
29	MITTFN	Num	8	Modified ITT Population Flag (N)
30	PPROTFL	Char	1	Per-Protocol Population Flag
31	PPROTFN	Num	8	Per-Protocol Population Flag (N)
32	STABLEFL	Char	1	Dosed at Stable Dosing Period Flag
33	STABLEFN	Num	8	Dosed at Stable Dosing Period Flag (N)
34	COMPLFL	Char	1	Completers Population Flag
35	COMPLFN	Num	8	Completers Population Flag (N)
36	EXTENFL	Char	1	Entered into LUM001-305 Extension Study
37	EXTENFN	Num	8	Entered into LUM001-305 Extension (N)

Num	Variable	Type	Len	Label
38	LOWDOSFL	Char	1	Recd. Lower Dose Due to Tolerability
39	LOWDOSFN	Num	8	Recd. Lower Dose Due to Tolerability (N)
40	HIDOSEFL	Char	1	Two Highest Tolerated Doses Flag
41	HIDOSEFN	Num	8	Two Highest Tolerated Doses Flag (N)
42	DOSINTFL	Char	1	Drug Interrupted for >14 Days Flag
43	DOSINTFN	Num	8	Drug Interrupted for >14 Days Flag (N)
44	ARM	Char	20	Description of Planned Arm
45	ARMCD	Char	1	Description Code of Planned Arm
46	ACTARM	Char	20	Description of Actual Arm
47	ACTARMCD	Char	1	Description Code of Actual Arm
48	TRT01P	Char	20	Planned Treatment for Period 01
49	TRT01PN	Num	8	Planned Treatment for Period 01 (N)
50	TRT01A	Char	20	Actual Treatment for Period 01
51	TRT01AN	Num	8	Actual Treatment for Period 01 (N)
52	TR01PG1	Char	13	Planned Pooled Treatment 1 for Period 01
53	TR01PG1N	Num	8	Planned Pooled Trt 1 for Period 01 (N)
54	TR01PG2	Char	32	Planned Pooled Treatment 1 for Period 02
55	TR01PG2N	Num	8	Planned Pooled Trt 1 for Period 02 (N)
56	TR01AG1	Char	13	Actual Pooled Treatment 1 for Period 01
57	TR01AG1N	Num	8	Actual Pooled Trt 1 for Period 01 (N)
58	TRT02P	Char	20	Planned Treatment for Period 02
59	TRT02PN	Num	8	Planned Treatment for Period 02 (N)
60	TRT02A	Char	20	Actual Treatment for Period 02
61	TRT02AN	Num	8	Actual Treatment for Period 02 (N)
62	TR02PG1	Char	13	Planned Pooled Treatment 1 for Period 02
63	TR02PG1N	Num	8	Planned Pooled Trt 1 for Period 02 (N)
64	TR02AG1	Char	13	Actual Pooled Treatment 1 for Period 02
65	TR02AG1N	Num	8	Actual Pooled Trt 1 for Period 02 (N)
66	TRTP	Char	20	Planned Treatment
67	TRTPN	Num	8	Planned Treatment (N)
68	TRTA	Char	20	Actual Treatment
69	TRTAN	Num	8	Actual Treatment (N)
70	TRTPG1	Char	13	Planned Pooled Treatment 1
71	TRTPG1N	Num	8	Planned Pooled Treatment 1 (N)
72	TRTPG2	Char	32	Planned Pooled Treatment 2
73	TRTPG2N	Num	8	Planned Pooled Treatment 2 (N)
74	TRTAG1	Char	13	Actual Pooled Treatment 1
75	TRTAG1N	Num	8	Actual Pooled Treatment 1 (N)
76	EGSEQ	Num	8	Sequence Number

<b>Num</b>	<b>Variable</b>	<b>Type</b>	<b>Len</b>	<b>Label</b>
77	VISIT	Char	10	Visit Name
78	VISITNUM	Num	8	Visit Number
79	EGDY	Num	8	Study Day of ECG (from first treatment date)
80	AVISITN	Num	8	Analysis Visit (N)
81	AVISIT	Char	21	Analysis Visit
82	DTYPE	Char	8	Derivation Type
83	ADY	Num	8	Analysis Relative Day (from first treatment date)
84	PARAM	Char	14	Parameter
85	PARAMCD	Char	4	Parameter Code
86	PARAMN	Num	8	Parameter (N)
87	AVALC	Char	8	Analysis Value (C)
88	ABLFL	Char	1	Baseline Record Flag
89	ABLFN	Num	8	Baseline Record Flag (N)
90	BASEC	Char	8	Baseline Value (C)
91	EGSTAT	Char	1	Completion Status

**Data Set Name: adex.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	AGEU	Char	5	Age Units
6	AGEGR1	Char	14	Pooled Age Group 1
7	AGEGR1N	Num	8	Pooled Age Group 1 (N)
8	SEX	Char	1	Sex
9	SEXN	Num	8	Sex (N)
10	WEIGHTBL	Num	8	Weight at Baseline (kg)
11	HEIGHTBL	Num	8	Height at Baseline (cm)
12	BMIBL	Num	8	BMI at Baseline (kg/m2)
13	RACE	Char	25	Race
14	RACEN	Num	8	Race (N)
15	ETHNIC	Char	22	Ethnicity
16	ETHNICN	Num	8	Ethnicity (N)
17	COUNTRY	Char	3	Country
18	ACOUNTRY	Char	13	Analysis Country
19	SCRNFL	Char	1	Screened Population Flag
20	SCRNFN	Num	8	Screened Population Flag (N)
21	ENRFL	Char	1	Enrolled Population Flag
22	ENRFLN	Num	8	Enrolled Population Flag (N)
23	RANDFL	Char	1	Randomized Population Flag
24	RANDFN	Num	8	Randomized Population Flag (N)
25	SAFFL	Char	1	Safety Population Flag
26	SAFFN	Num	8	Safety Population Flag (N)
27	ITTFLL	Char	1	Intent-To-Treat Population Flag
28	ITTFN	Num	8	Intent-To-Treat Population Flag (N)
29	MITTFL	Char	1	Modified ITT Population Flag
30	MITTFN	Num	8	Modified ITT Population Flag (N)
31	STABLEFL	Char	1	Dosed at Stable Dosing Period Flag
32	STABLEFN	Num	8	Dosed at Stable Dosing Period Flag (N)
33	COMPLFL	Char	1	Completers Population Flag
34	COMPLFN	Num	8	Completers Population Flag (N)
35	EXTENFL	Char	1	Entered into LUM001-305 Extension Study
36	EXTENFN	Num	8	Entered into LUM001-305 Extension (N)
37	LOWDOSFL	Char	1	Recd. Lower Dose Due to Tolerability

Num	Variable	Type	Len	Label
38	LOWDOSFN	Num	8	Recd. Lower Dose Due to Tolerability (N)
39	HIDOSEFL	Char	1	Two Highest Tolerated Doses Flag
40	HIDOSEFN	Num	8	Two Highest Tolerated Doses Flag (N)
41	DOSINTFL	Char	1	Drug Interrupted for >14 Days Flag
42	DOSINTFN	Num	8	Drug Interrupted for >14 Days Flag (N)
43	ARM	Char	20	Description of Planned Arm
44	ARMCD	Char	1	Description Code of Planned Arm
45	ACTARM	Char	20	Description of Actual Arm
46	ACTARMCD	Char	1	Description Code of Actual Arm
47	TRTP	Char	20	Planned Treatment
48	TRTPN	Num	8	Planned Treatment (N)
49	TRTA	Char	20	Actual Treatment
50	TRTAN	Num	8	Actual Treatment (N)
51	TRT01P	Char	20	Planned Treatment for Period 01
52	TRT01PN	Num	8	Planned Treatment for Period 01 (N)
53	TRT01A	Char	20	Actual Treatment for Period 01
54	TRT01AN	Num	8	Actual Treatment for Period 01 (N)
55	TR01PG1	Char	13	Planned Pooled Treatment 1 for Period 01
56	TR01PG1N	Num	8	Planned Pooled Trt 1 for Period 01 (N)
57	TR01PG2	Char	32	Planned Pooled Treatment 1 for Period 02
58	TR01PG2N	Num	8	Planned Pooled Trt 1 for Period 02 (N)
59	TR01AG1	Char	13	Actual Pooled Treatment 1 for Period 01
60	TR01AG1N	Num	8	Actual Pooled Trt 1 for Period 01 (N)
61	TRT02P	Char	20	Planned Treatment for Period 02
62	TRT02PN	Num	8	Planned Treatment for Period 02 (N)
63	TRT02A	Char	20	Actual Treatment for Period 02
64	TRT02AN	Num	8	Actual Treatment for Period 02 (N)
65	TR02PG1	Char	13	Planned Pooled Treatment 1 for Period 02
66	TR02PG1N	Num	8	Planned Pooled Trt 1 for Period 02 (N)
67	TR02AG1	Char	13	Actual Pooled Treatment 1 for Period 02
68	TR02AG1N	Num	8	Actual Pooled Trt 1 for Period 02 (N)
69	AVISIT	Char	22	Analysis Visit
70	AVISITN	Num	8	Analysis Visit (N)
71	PARAM	Char	30	Parameter
72	PARAMCD	Char	8	Parameter Code
73	PARAMN	Num	8	Parameter (N)
74	PARAMTYP	Char	7	Parameter Type
75	AVAL	Num	8	Analysis Value
76	WGTSRN	Num	8	Weight at Screening (kg)

<b>Num</b>	<b>Variable</b>	<b>Type</b>	<b>Len</b>	<b>Label</b>
77	SDFIRRX	Num	8	Study Day of First Exposure to Treatment (from first treatment date)
78	SDFIRRX1	Num	8	Study Day of First Exposure in Period 01 (from first treatment date)
79	SDLASRX1	Num	8	Study Day of Last Exposure in Period 01 (from first treatment date)
80	SDFIRRX2	Num	8	Study Day of First Exposure in Period 02 (from first treatment date)
81	SDLASRX2	Num	8	Study Day of Last Exposure in Period 02 (from first treatment date)
82	SDLASRX	Num	8	Study Day of Last Exposure to Treatment (from first treatment date)
83	SDSTP1	Num	8	Study Day of Period 01 Start (from first treatment date)
84	SDENP1	Num	8	Study Day of Period 01 End (from first treatment date)
85	SDSTP2	Num	8	Study Day of Period 02 Start (from first treatment date)
86	SDENP2	Num	8	Study Day of Period 02 End (from first treatment date)
87	SDILASRX	Num	8	Study Day of Initial Last Exposure 01 (from first treatment date)
88	SDRXAFLEX	Num	8	Study Day of Drug After Last Exposure 01 (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	AGEU	Char	5	Age Units
6	AGEGR1	Char	14	Pooled Age Group 1
7	AGEGR1N	Num	8	Pooled Age Group 1 (N)
8	SEX	Char	1	Sex
9	SEXN	Num	8	Sex (N)
10	WEIGHTBL	Num	8	Weight at Baseline (kg)
11	HEIGHTBL	Num	8	Height at Baseline (cm)
12	BMIBL	Num	8	BMI at Baseline (kg/m2)
13	RACE	Char	25	Race
14	RACEN	Num	8	Race (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	RANDFL	Char	1	Randomized Population Flag
23	RANDFN	Num	8	Randomized Population Flag (N)
24	SAFFL	Char	1	Safety Population Flag
25	SAFFN	Num	8	Safety Population Flag (N)
26	ITTFLL	Char	1	Intent-To-Treat Population Flag
27	ITTFN	Num	8	Intent-To-Treat Population Flag (N)
28	MITTFLL	Char	1	Modified ITT Population Flag
29	MITTFN	Num	8	Modified ITT Population Flag (N)
30	PPROTFL	Char	1	Per-Protocol Population Flag
31	PPROTFN	Num	8	Per-Protocol Population Flag (N)
32	STABLEFL	Char	1	Dosed at Stable Dosing Period Flag
33	STABLEFN	Num	8	Dosed at Stable Dosing Period Flag (N)
34	COMPLFL	Char	1	Completers Population Flag
35	COMPLFN	Num	8	Completers Population Flag (N)
36	EXTENFL	Char	1	Entered into LUM001-305 Extension Study
37	EXTENFN	Num	8	Entered into LUM001-305 Extension (N)

Num	Variable	Type	Len	Label
38	LOWDOSFL	Char	1	Recd. Lower Dose Due to Tolerability
39	LOWDOSFN	Num	8	Recd. Lower Dose Due to Tolerability (N)
40	HIDOSEFL	Char	1	Two Highest Tolerated Doses Flag
41	HIDOSEFN	Num	8	Two Highest Tolerated Doses Flag (N)
42	DOSINTFL	Char	1	Drug Interrupted for >14 Days Flag
43	DOSINTFN	Num	8	Drug Interrupted for >14 Days Flag (N)
44	ARM	Char	20	Description of Planned Arm
45	ARMCD	Char	1	Description Code of Planned Arm
46	ACTARM	Char	20	Description of Actual Arm
47	ACTARMCD	Char	1	Description Code of Actual Arm
48	TRT01P	Char	20	Planned Treatment for Period 01
49	TRT01PN	Num	8	Planned Treatment for Period 01 (N)
50	TRT01A	Char	20	Actual Treatment for Period 01
51	TRT01AN	Num	8	Actual Treatment for Period 01 (N)
52	TR01PG1	Char	13	Planned Pooled Treatment 1 for Period 01
53	TR01PG1N	Num	8	Planned Pooled Trt 1 for Period 01 (N)
54	TR01PG2	Char	32	Planned Pooled Treatment 1 for Period 02
55	TR01PG2N	Num	8	Planned Pooled Trt 1 for Period 02 (N)
56	TR01AG1	Char	13	Actual Pooled Treatment 1 for Period 01
57	TR01AG1N	Num	8	Actual Pooled Trt 1 for Period 01 (N)
58	TRT02P	Char	20	Planned Treatment for Period 02
59	TRT02PN	Num	8	Planned Treatment for Period 02 (N)
60	TRT02A	Char	20	Actual Treatment for Period 02
61	TRT02AN	Num	8	Actual Treatment for Period 02 (N)
62	TR02PG1	Char	13	Planned Pooled Treatment 1 for Period 02
63	TR02PG1N	Num	8	Planned Pooled Trt 1 for Period 02 (N)
64	TR02AG1	Char	13	Actual Pooled Treatment 1 for Period 02
65	TR02AG1N	Num	8	Actual Pooled Trt 1 for Period 02 (N)
66	TRTP	Char	20	Planned Treatment
67	TRTPN	Num	8	Planned Treatment (N)
68	TRTA	Char	20	Actual Treatment
69	TRTAN	Num	8	Actual Treatment (N)
70	TRTPG1	Char	13	Planned Pooled Treatment 1
71	TRTPG1N	Num	8	Planned Pooled Treatment 1 (N)
72	TRTPG2	Char	32	Planned Pooled Treatment 2
73	TRTPG2N	Num	8	Planned Pooled Treatment 2 (N)
74	TRTAG1	Char	13	Actual Pooled Treatment 1
75	TRTAG1N	Num	8	Actual Pooled Treatment 1 (N)
76	VISIT	Char	11	Visit Name

<b>Num</b>	<b>Variable</b>	<b>Type</b>	<b>Len</b>	<b>Label</b>
77	VISITNUM	Num	8	Visit Number
78	LBDY	Num	8	Study Day of Specimen Collection (from first treatment date)
79	AVISITN	Num	8	Analysis Visit (N)
80	AVISIT	Char	21	Analysis Visit
81	LBSEQ	Num	8	Sequence Number
82	DTYPE	Char	18	Derivation Type
83	ADY	Num	8	Analysis Relative Day (from first treatment date)
84	PARAM	Char	46	Parameter
85	PARAMCD	Char	8	Parameter Code
86	PARAMN	Num	8	Parameter (N)
87	PARAMTYP	Char	7	Parameter Type
88	PARCAT1	Char	11	Parameter Category 1
89	PARCAT2	Char	22	Parameter Category 2
90	LBSPEC	Char	6	Specimen Type
91	LBFAST	Char	1	Fasting Status
92	AVAL	Num	8	Analysis Value
93	AVALC	Char	13	Analysis Value (C)
94	BASE	Num	8	Baseline Value
95	BASEC	Char	13	Baseline Value (C)
96	CHG	Num	8	Change from Baseline
97	PCHG	Num	8	Percent Change from Baseline
98	ABLFL	Char	1	Baseline Record Flag
99	ABLFN	Num	8	Baseline Record Flag (N)
100	ANRLO	Char	5	Analysis Normal Range Lower Limit
101	ANRHI	Char	4	Analysis Normal Range Upper Limit
102	ANRIND	Char	6	Analysis Reference Range Indicator
103	BNRIND	Char	6	Baseline Reference Range Indicator
104	SHIFT1	Char	16	Shift 1
105	CRIT1	Char	98	Analysis Criterion 1
106	CRIT1FL	Char	1	Criterion 1 Evaluation Result Flag

**Data Set Name: adpc.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	AGEU	Char	5	Age Units
6	AGEGR1	Char	14	Pooled Age Group 1
7	AGEGR1N	Num	8	Pooled Age Group 1 (N)
8	SEX	Char	1	Sex
9	SEXN	Num	8	Sex (N)
10	WEIGHTBL	Num	8	Weight at Baseline (kg)
11	HEIGHTBL	Num	8	Height at Baseline (cm)
12	BMIBL	Num	8	BMI at Baseline (kg/m2)
13	RACE	Char	25	Race
14	RACEN	Num	8	Race (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	RANDFL	Char	1	Randomized Population Flag
23	RANDFN	Num	8	Randomized Population Flag (N)
24	SAFFL	Char	1	Safety Population Flag
25	SAFFN	Num	8	Safety Population Flag (N)
26	ITTFLL	Char	1	Intent-To-Treat Population Flag
27	ITTFN	Num	8	Intent-To-Treat Population Flag (N)
28	MITTFLL	Char	1	Modified ITT Population Flag
29	MITTFN	Num	8	Modified ITT Population Flag (N)
30	PPROTFL	Char	1	Per-Protocol Population Flag
31	PPROTFN	Num	8	Per-Protocol Population Flag (N)
32	STABLEFL	Char	1	Dosed at Stable Dosing Period Flag
33	STABLEFN	Num	8	Dosed at Stable Dosing Period Flag (N)
34	COMPLFL	Char	1	Completers Population Flag
35	COMPLFN	Num	8	Completers Population Flag (N)
36	EXTENFL	Char	1	Entered into LUM001-305 Extension Study
37	EXTENFN	Num	8	Entered into LUM001-305 Extension (N)

Num	Variable	Type	Len	Label
38	LOWDOSFL	Char	1	Recd. Lower Dose Due to Tolerability
39	LOWDOSFN	Num	8	Recd. Lower Dose Due to Tolerability (N)
40	HIDOSEFL	Char	1	Two Highest Tolerated Doses Flag
41	HIDOSEFN	Num	8	Two Highest Tolerated Doses Flag (N)
42	DOSINTFL	Char	1	Drug Interrupted for >14 Days Flag
43	DOSINTFN	Num	8	Drug Interrupted for >14 Days Flag (N)
44	ARM	Char	20	Description of Planned Arm
45	ARMCD	Char	1	Description Code of Planned Arm
46	ACTARM	Char	20	Description of Actual Arm
47	ACTARMCD	Char	1	Description Code of Actual Arm
48	TRT01P	Char	20	Planned Treatment for Period 01
49	TRT01PN	Num	8	Planned Treatment for Period 01 (N)
50	TRT01A	Char	20	Actual Treatment for Period 01
51	TRT01AN	Num	8	Actual Treatment for Period 01 (N)
52	TR01PG1	Char	13	Planned Pooled Treatment 1 for Period 01
53	TR01PG1N	Num	8	Planned Pooled Trt 1 for Period 01 (N)
54	TR01PG2	Char	32	Planned Pooled Treatment 1 for Period 02
55	TR01PG2N	Num	8	Planned Pooled Trt 1 for Period 02 (N)
56	TR01AG1	Char	13	Actual Pooled Treatment 1 for Period 01
57	TR01AG1N	Num	8	Actual Pooled Trt 1 for Period 01 (N)
58	TRT02P	Char	20	Planned Treatment for Period 02
59	TRT02PN	Num	8	Planned Treatment for Period 02 (N)
60	TRT02A	Char	20	Actual Treatment for Period 02
61	TRT02AN	Num	8	Actual Treatment for Period 02 (N)
62	TR02PG1	Char	13	Planned Pooled Treatment 1 for Period 02
63	TR02PG1N	Num	8	Planned Pooled Trt 1 for Period 02 (N)
64	TR02AG1	Char	13	Actual Pooled Treatment 1 for Period 02
65	TR02AG1N	Num	8	Actual Pooled Trt 1 for Period 02 (N)
66	TRTP	Char	20	Planned Treatment
67	TRTPN	Num	8	Planned Treatment (N)
68	TRTA	Char	20	Actual Treatment
69	TRTAN	Num	8	Actual Treatment (N)
70	TRTPG1	Char	13	Planned Pooled Treatment 1
71	TRTPG1N	Num	8	Planned Pooled Treatment 1 (N)
72	TRTPG2	Char	32	Planned Pooled Treatment 2
73	TRTPG2N	Num	8	Planned Pooled Treatment 2 (N)
74	TRTAG1	Char	13	Actual Pooled Treatment 1
75	TRTAG1N	Num	8	Actual Pooled Treatment 1 (N)
76	PCSEQ	Num	8	Sequence Number

<b>Num</b>	<b>Variable</b>	<b>Type</b>	<b>Len</b>	<b>Label</b>
77	VISIT	Char	10	Visit Name
78	VISITNUM	Num	8	Visit Number
79	PCDY	Num	8	Actual Study Day of Specimen Collection (from first treatment date)
80	AVISITN	Num	8	Analysis Visit (N)
81	AVISIT	Char	21	Analysis Visit
82	DTYPE	Char	13	Derivation Type
83	ADY	Num	8	Analysis Relative Day (from first treatment date)
84	PARCAT1	Char	7	Parameter Category 1
85	PARAM	Char	14	Parameter
86	PARAMCD	Char	6	Parameter Code
87	PARAMN	Num	8	Parameter (N)
88	AVAL	Num	8	Analysis Value
89	AVALC	Char	5	Analysis Value (C)
90	ABLFL	Char	1	Baseline Record Flag
91	ABLFN	Num	8	Baseline Record Flag (N)
92	BASE	Num	8	Baseline Value
93	CHG	Num	8	Change from Baseline

**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	AGEU	Char	5	Age Units
6	AGEGR1	Char	14	Pooled Age Group 1
7	AGEGR1N	Num	8	Pooled Age Group 1 (N)
8	SEX	Char	1	Sex
9	SEXN	Num	8	Sex (N)
10	WEIGHTBL	Num	8	Weight at Baseline (kg)
11	HEIGHTBL	Num	8	Height at Baseline (cm)
12	BMIBL	Num	8	BMI at Baseline (kg/m2)
13	RACE	Char	25	Race
14	RACEN	Num	8	Race (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	RANDFL	Char	1	Randomized Population Flag
23	RANDFN	Num	8	Randomized Population Flag (N)
24	SAFFL	Char	1	Safety Population Flag
25	SAFFN	Num	8	Safety Population Flag (N)
26	ITTFL	Char	1	Intent-To-Treat Population Flag
27	ITTFN	Num	8	Intent-To-Treat Population Flag (N)
28	MITTFL	Char	1	Modified ITT Population Flag
29	MITTFN	Num	8	Modified ITT Population Flag (N)
30	PPROTFL	Char	1	Per-Protocol Population Flag
31	PPROTFN	Num	8	Per-Protocol Population Flag (N)
32	STABLEFL	Char	1	Dosed at Stable Dosing Period Flag
33	STABLEFN	Num	8	Dosed at Stable Dosing Period Flag (N)
34	COMPLFL	Char	1	Completers Population Flag
35	COMPLFN	Num	8	Completers Population Flag (N)
36	EXTENFL	Char	1	Entered into LUM001-305 Extension Study
37	EXTENFN	Num	8	Entered into LUM001-305 Extension (N)

Num	Variable	Type	Len	Label
38	LOWDOSFL	Char	1	Recd. Lower Dose Due to Tolerability
39	LOWDOSFN	Num	8	Recd. Lower Dose Due to Tolerability (N)
40	HIDOSEFL	Char	1	Two Highest Tolerated Doses Flag
41	HIDOSEFN	Num	8	Two Highest Tolerated Doses Flag (N)
42	DOSINTFL	Char	1	Drug Interrupted for >14 Days Flag
43	DOSINTFN	Num	8	Drug Interrupted for >14 Days Flag (N)
44	ARM	Char	20	Description of Planned Arm
45	ARMCD	Char	1	Description Code of Planned Arm
46	ACTARM	Char	20	Description of Actual Arm
47	ACTARMCD	Char	1	Description Code of Actual Arm
48	TRT01P	Char	20	Planned Treatment for Period 01
49	TRT01PN	Num	8	Planned Treatment for Period 01 (N)
50	TRT01A	Char	20	Actual Treatment for Period 01
51	TRT01AN	Num	8	Actual Treatment for Period 01 (N)
52	TR01PG1	Char	13	Planned Pooled Treatment 1 for Period 01
53	TR01PG1N	Num	8	Planned Pooled Trt 1 for Period 01 (N)
54	TR01PG2	Char	32	Planned Pooled Treatment 1 for Period 02
55	TR01PG2N	Num	8	Planned Pooled Trt 1 for Period 02 (N)
56	TR01AG1	Char	13	Actual Pooled Treatment 1 for Period 01
57	TR01AG1N	Num	8	Actual Pooled Trt 1 for Period 01 (N)
58	TRT02P	Char	20	Planned Treatment for Period 02
59	TRT02PN	Num	8	Planned Treatment for Period 02 (N)
60	TRT02A	Char	20	Actual Treatment for Period 02
61	TRT02AN	Num	8	Actual Treatment for Period 02 (N)
62	TR02PG1	Char	13	Planned Pooled Treatment 1 for Period 02
63	TR02PG1N	Num	8	Planned Pooled Trt 1 for Period 02 (N)
64	TR02AG1	Char	13	Actual Pooled Treatment 1 for Period 02
65	TR02AG1N	Num	8	Actual Pooled Trt 1 for Period 02 (N)
66	TRTP	Char	20	Planned Treatment
67	TRTPN	Num	8	Planned Treatment (N)
68	TRTA	Char	20	Actual Treatment
69	TRTAN	Num	8	Actual Treatment (N)
70	TRTPG1	Char	13	Planned Pooled Treatment 1
71	TRTPG1N	Num	8	Planned Pooled Treatment 1 (N)
72	TRTPG2	Char	32	Planned Pooled Treatment 2
73	TRTPG2N	Num	8	Planned Pooled Treatment 2 (N)
74	TRTAG1	Char	13	Actual Pooled Treatment 1
75	TRTAG1N	Num	8	Actual Pooled Treatment 1 (N)
76	ADY	Num	8	Analysis Relative Day (from first treatment date)

Num	Variable	Type	Len	Label
77	AVISITN	Num	8	Analysis Visit (N)
78	AVISIT	Char	21	Analysis Visit
79	VISIT	Char	10	Visit Name
80	VISITNUM	Num	8	Visit Number
81	QSSEQ	Num	8	Sequence Number
82	PARAM	Char	47	Parameter
83	PARAMCD	Char	8	Parameter Code
84	PARAMN	Num	8	Parameter (N)
85	PARAMTYP	Char	7	Parameter Type
86	PARCAT1	Char	36	Parameter Category 1
87	PARCAT2	Char	26	Parameter Category 2
88	AVAL	Num	8	Analysis Value
89	ABLFL	Char	1	Baseline Record Flag
90	ABLFN	Num	8	Baseline Record Flag (N)
91	BASE	Num	8	Baseline Value
92	CHG	Num	8	Change from Baseline
93	PCHG	Num	8	Percent Change from Baseline
94	CRIT1	Char	21	Analysis Criterion 1
95	CRIT1FL	Char	1	Criterion 1 Evaluation Result Flag
96	CRIT2	Char	21	Analysis Criterion 2
97	CRIT2FL	Char	1	Criterion 2 Evaluation Result Flag
98	CRIT3	Char	11	Analysis Criterion 3
99	CRIT3FL	Char	1	Criterion 3 Evaluation Result Flag
100	CRIT4	Char	11	Analysis Criterion 4
101	CRIT4FL	Char	1	Criterion 4 Evaluation Result Flag
102	CRIT5	Char	11	Analysis Criterion 5
103	CRIT5FL	Char	1	Criterion 5 Evaluation Result Flag
104	CRIT6	Char	18	Analysis Criterion 6
105	CRIT6FL	Char	1	Criterion 6 Evaluation Result Flag
106	CRIT7	Char	19	Analysis Criterion 7
107	CRIT7FL	Char	1	Criterion 7 Evaluation Result Flag
108	CRIT8	Char	12	Analysis Criterion 8
109	CRIT8FL	Char	1	Criterion 8 Evaluation Result Flag
110	DTYPE	Char	8	Derivation Type

**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	AGEU	Char	5	Age Units
6	AGEGR1	Char	14	Pooled Age Group 1
7	AGEGR1N	Num	8	Pooled Age Group 1 (N)
8	SEX	Char	1	Sex
9	SEXN	Num	8	Sex (N)
10	WEIGHTBL	Num	8	Weight at Baseline (kg)
11	HEIGHTBL	Num	8	Height at Baseline (cm)
12	BMIBL	Num	8	BMI at Baseline (kg/m2)
13	RACE	Char	25	Race
14	RACEN	Num	8	Race (N)
15	ARACE	Char	25	Analysis Race
16	ARACEN	Num	8	Analysis Race (N)
17	RACE1	Char	41	Race 1
18	RACE2	Char	5	Race 2
19	RACE3	Char	1	Race 3
20	RACE4	Char	1	Race 4
21	RACE5	Char	1	Race 5
22	ETHNIC	Char	22	Ethnicity
23	ETHNICN	Num	8	Ethnicity (N)
24	COUNTRY	Char	3	Country
25	ACOUNTRY	Char	13	Analysis Country
26	SCRNFL	Char	1	Screened Population Flag
27	SCRNFN	Num	8	Screened Population Flag (N)
28	ENRFL	Char	1	Enrolled Population Flag
29	ENRFLN	Num	8	Enrolled Population Flag (N)
30	RANDFL	Char	1	Randomized Population Flag
31	RANDFN	Num	8	Randomized Population Flag (N)
32	SAFFL	Char	1	Safety Population Flag
33	SAFFN	Num	8	Safety Population Flag (N)
34	ITTFLL	Char	1	Intent-To-Treat Population Flag
35	ITTFN	Num	8	Intent-To-Treat Population Flag (N)
36	MITTFL	Char	1	Modified ITT Population Flag
37	MITTFN	Num	8	Modified ITT Population Flag (N)

Num	Variable	Type	Len	Label
38	PPROTFL	Char	1	Per-Protocol Population Flag
39	PPROTFN	Num	8	Per-Protocol Population Flag (N)
40	STABLEFL	Char	1	Dosed at Stable Dosing Period Flag
41	STABLEFN	Num	8	Dosed at Stable Dosing Period Flag (N)
42	COMPLFL	Char	1	Completers Population Flag
43	COMPLFN	Num	8	Completers Population Flag (N)
44	EOSSTT	Char	12	End of Study Status
45	EXTENFL	Char	1	Entered into LUM001-305 Extension Study
46	EXTENFN	Num	8	Entered into LUM001-305 Extension (N)
47	LOWDOSFL	Char	1	Recd. Lower Dose Due to Tolerability
48	LOWDOSFN	Num	8	Recd. Lower Dose Due to Tolerability (N)
49	HIDOSEFL	Char	1	Two Highest Tolerated Doses Flag
50	HIDOSEFN	Num	8	Two Highest Tolerated Doses Flag (N)
51	DOSINTFL	Char	1	Drug Interrupted for >14 Days Flag
52	DOSINTFN	Num	8	Drug Interrupted for >14 Days Flag (N)
53	ARM	Char	20	Description of Planned Arm
54	ARMCD	Char	8	Description Code of Planned Arm
55	ACTARM	Char	20	Description of Actual Arm
56	ACTARMCD	Char	8	Description Code of Actual Arm
57	TRT01P	Char	20	Planned Treatment for Period 01
58	TRT01PN	Num	8	Planned Treatment for Period 01 (N)
59	TRT01A	Char	20	Actual Treatment for Period 01
60	TRT01AN	Num	8	Actual Treatment for Period 01 (N)
61	TR01PG1	Char	13	Planned Pooled Treatment 1 for Period 01
62	TR01PG1N	Num	8	Planned Pooled Trt 1 for Period 01 (N)
63	TR01PG2	Char	32	Planned Pooled Treatment 1 for Period 02
64	TR01PG2N	Num	8	Planned Pooled Trt 1 for Period 02 (N)
65	TR01AG1	Char	13	Actual Pooled Treatment 1 for Period 01
66	TR01AG1N	Num	8	Actual Pooled Trt 1 for Period 01 (N)
67	TRT02P	Char	20	Planned Treatment for Period 02
68	TRT02PN	Num	8	Planned Treatment for Period 02 (N)
69	TRT02A	Char	20	Actual Treatment for Period 02
70	TRT02AN	Num	8	Actual Treatment for Period 02 (N)
71	TR02PG1	Char	13	Planned Pooled Treatment 1 for Period 02
72	TR02PG1N	Num	8	Planned Pooled Trt 1 for Period 02 (N)
73	TR02AG1	Char	13	Actual Pooled Treatment 1 for Period 02
74	TR02AG1N	Num	8	Actual Pooled Trt 1 for Period 02 (N)
75	SFREAS	Char	35	Reason for Screen Failure
76	SFIECAT	Char	9	Screen Failure Criterion Type

Num	Variable	Type	Len	Label
77	SFIECD	Char	2	Screen Failure Criterion Number
78	DSREAS	Char	17	Reported Term for the Disposition Event
79	DSREASN	Num	8	Reported Term for Disposition Event (N)
80	ALGSDTF	Char	1	Date of Diagnosis of ALGS Imput. Flag
81	ALGSDN	Num	8	Time Since Diagnosis of ALGS (Months)
82	ALGSHX	Char	1	Family History of ALGS
83	PAUCITY	Char	1	Presence of Paucity
84	MUTATION	Char	7	Mutation Present
85	CHOLEST	Char	1	Chronic Cholestasis
86	CARDIAC	Char	1	Cardiac Disease
87	RENAL	Char	1	Renal Abnormalities
88	VASCULAR	Char	1	Vascular Abnormalities
89	SKELETAL	Char	1	Skeletal Abnormalities
90	OCULAR	Char	1	Ocular Abnormalities
91	FACIAL	Char	1	Characteristic Facial Features
92	ALGSCRT	Num	8	No. Clinical Criteria/Features of ALGS
93	ALGSCAT	Char	6	Critical Criteria of ALGS Category
94	ALGSCATN	Num	8	Critical Criteria of ALGS Category (N)
95	ITCHTRT	Char	1	Used Anything to Treat Itch in the Past
96	TCORTICO	Char	1	Topical Corticosteroids
97	TCALCIN	Char	1	Topical Calcineurin Inhibitors
98	TANTIHIS	Char	1	Topical Antihistamines
99	TMENTHOL	Char	1	Topical Menthol
100	TCAPSAIS	Char	1	Topical Capsaicin
101	TSALICYL	Char	1	Topical Salicylic Acid
102	TLOCAL	Char	1	Topical Local Anesthetics
103	OANDROG	Char	1	Oral Androgens
104	OANTICHO	Char	1	Oral Anticholestatic Agents
105	OANTICON	Char	1	Oral Anticonvulsants
106	OANTIDEP	Char	1	Oral Antidepressants
107	OANTIHIHIS	Char	1	Oral Antihistamines
108	OANTIOX	Char	1	Oral Anti-Oxidants
109	OBINDING	Char	1	Oral Binding Resins
110	OCOLCHIC	Char	1	Oral Colchicine
111	OCANNABI	Char	1	Oral Cannabinoid Agonist
112	OENZYMEI	Char	1	Oral Enzyme Inducers
113	OIMMUNO	Char	1	Oral Immunosuppressants
114	OOPATE	Char	1	Oral Opiate Antagonists
115	OSEROTON	Char	1	Oral Serotonin Antagonists

Num	Variable	Type	Len	Label
116	OUDECA	Char	1	Oral Ursodiol (UDCA)
117	PHOTO	Char	1	Other Phototherapy
118	HEMOFILT	Char	1	Other Hemofiltration (MARS)
119	PLASMAPH	Char	1	Other Plasmapheresis
120	NASALBIL	Char	1	Other Nasal Biliary Drainage
121	SPECIFY	Char	51	Other Specify
122	PRURTHER	Num	8	No. Prior Pruritus Therapies Per Patient
123	PRURCAT	Char	20	Prior Pruritus Therapy Category
124	PRURCATN	Num	8	Prior Pruritus Therapy Category (N)
125	SSCORBL	Char	1	Clinician Scratch Scale Score
126	SSCORBLN	Num	8	Clinician Scratch Scale Score (N)
127	CLXANBL	Char	1	Clinician Xanthoma Scale Score
128	CLXANBLN	Num	8	Clinician Xanthoma Scale Score (N)
129	ITCHOBBL	Num	8	ItchRO(Obs) Avg. Daily Score at Baseline
130	ITCHPTBL	Num	8	ItchRO(Pt) Avg. Daily Score at Baseline
131	BILEBL	Num	8	Serum Bile Acid (umol/L) at Baseline
132	ALPBL	Num	8	Alkaline Phosphatase (U/L) at Baseline
133	ASTBL	Num	8	Aspartate Aminotransferase (U/L) at BL
134	ALTBL	Num	8	Alanine Aminotransferase (U/L) at BL
135	GGTBL	Num	8	Gamma Glutamyl Transferase (U/L) at BL
136	BILIBL	Num	8	Total Bilirubin (mg/dL) at Baseline
137	BILDIRBL	Num	8	Direct Bilirubin (mg/dL) at Baseline
138	TCHOLBL	Num	8	Cholesterol (mg/dL) at Baseline
139	LDLCHBL	Num	8	LDL Cholesterol (mg/dL) at Baseline
140	HYDRXBL	Num	8	7 a-hydroxy-4-cholesten-3-one (ng/mL) BL
141	VITDBL	Num	8	25-Hydroxyvitamin D (ng/mL) at Baseline
142	VITABL	Num	8	Vitamin A (ug/dL) at Baseline
143	VITEBL	Num	8	Alpha Tocopherol (mg/dL) at Baseline
144	INRBL	Num	8	Prothrombin Intl. Normalized Ratio at BL
145	SDSTDISP	Num	8	Study Day of Disposition Event from Infomed Consent Date
146	SDENDPT	Num	8	Study Day of End of Participation from Infomed Consent Date
147	SEALGDIAG	Num	8	Study Day of Diagnosis of ALGS from Infomed Consent Date
148	SDRXST	Num	8	Study Day of RX First Exposure from Infomed Consent Date
149	SDRXEN	Num	8	Study Day of RX Last Exposure from Infomed Consent Date

**Data Set Name: advs.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	AGEU	Char	5	Age Units
6	AGEGR1	Char	14	Pooled Age Group 1
7	AGEGR1N	Num	8	Pooled Age Group 1 (N)
8	SEX	Char	1	Sex
9	SEXN	Num	8	Sex (N)
10	WEIGHTBL	Num	8	Weight at Baseline (kg)
11	HEIGHTBL	Num	8	Height at Baseline (cm)
12	BMIBL	Num	8	BMI at Baseline (kg/m2)
13	RACE	Char	25	Race
14	RACEN	Num	8	Race (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	RANDFL	Char	1	Randomized Population Flag
23	RANDFN	Num	8	Randomized Population Flag (N)
24	SAFFL	Char	1	Safety Population Flag
25	SAFFN	Num	8	Safety Population Flag (N)
26	ITTFLL	Char	1	Intent-To-Treat Population Flag
27	ITTFN	Num	8	Intent-To-Treat Population Flag (N)
28	MITTFL	Char	1	Modified ITT Population Flag
29	MITTFN	Num	8	Modified ITT Population Flag (N)
30	PPROTFL	Char	1	Per-Protocol Population Flag
31	PPROTFN	Num	8	Per-Protocol Population Flag (N)
32	STABLEFL	Char	1	Dosed at Stable Dosing Period Flag
33	STABLEFN	Num	8	Dosed at Stable Dosing Period Flag (N)
34	COMPLFL	Char	1	Completers Population Flag
35	COMPLFN	Num	8	Completers Population Flag (N)
36	EXTENFL	Char	1	Entered into LUM001-305 Extension Study
37	EXTENFN	Num	8	Entered into LUM001-305 Extension (N)

Num	Variable	Type	Len	Label
38	LOWDOSFL	Char	1	Recd. Lower Dose Due to Tolerability
39	LOWDOSFN	Num	8	Recd. Lower Dose Due to Tolerability (N)
40	HIDOSEFL	Char	1	Two Highest Tolerated Doses Flag
41	HIDOSEFN	Num	8	Two Highest Tolerated Doses Flag (N)
42	DOSINTFL	Char	1	Drug Interrupted for >14 Days Flag
43	DOSINTFN	Num	8	Drug Interrupted for >14 Days Flag (N)
44	ARM	Char	20	Description of Planned Arm
45	ARMCD	Char	1	Description Code of Planned Arm
46	ACTARM	Char	20	Description of Actual Arm
47	ACTARMCD	Char	1	Description Code of Actual Arm
48	TRT01P	Char	20	Planned Treatment for Period 01
49	TRT01PN	Num	8	Planned Treatment for Period 01 (N)
50	TRT01A	Char	20	Actual Treatment for Period 01
51	TRT01AN	Num	8	Actual Treatment for Period 01 (N)
52	TR01PG1	Char	13	Planned Pooled Treatment 1 for Period 01
53	TR01PG1N	Num	8	Planned Pooled Trt 1 for Period 01 (N)
54	TR01PG2	Char	32	Planned Pooled Treatment 1 for Period 02
55	TR01PG2N	Num	8	Planned Pooled Trt 1 for Period 02 (N)
56	TR01AG1	Char	13	Actual Pooled Treatment 1 for Period 01
57	TR01AG1N	Num	8	Actual Pooled Trt 1 for Period 01 (N)
58	TRT02P	Char	20	Planned Treatment for Period 02
59	TRT02PN	Num	8	Planned Treatment for Period 02 (N)
60	TRT02A	Char	20	Actual Treatment for Period 02
61	TRT02AN	Num	8	Actual Treatment for Period 02 (N)
62	TR02PG1	Char	13	Planned Pooled Treatment 1 for Period 02
63	TR02PG1N	Num	8	Planned Pooled Trt 1 for Period 02 (N)
64	TR02AG1	Char	13	Actual Pooled Treatment 1 for Period 02
65	TR02AG1N	Num	8	Actual Pooled Trt 1 for Period 02 (N)
66	TRTP	Char	20	Planned Treatment
67	TRTPN	Num	8	Planned Treatment (N)
68	TRTA	Char	20	Actual Treatment
69	TRTAN	Num	8	Actual Treatment (N)
70	TRTPG1	Char	13	Planned Pooled Treatment 1
71	TRTPG1N	Num	8	Planned Pooled Treatment 1 (N)
72	TRTPG2	Char	32	Planned Pooled Treatment 2
73	TRTPG2N	Num	8	Planned Pooled Treatment 2 (N)
74	TRTAG1	Char	13	Actual Pooled Treatment 1
75	TRTAG1N	Num	8	Actual Pooled Treatment 1 (N)
76	VSSEQ	Num	8	Sequence Number

<b>Num</b>	<b>Variable</b>	<b>Type</b>	<b>Len</b>	<b>Label</b>
77	VISIT	Char	10	Visit Name
78	VISITNUM	Num	8	Visit Number
79	VSDY	Num	8	Study Day of Vital Signs (from first treatment date)
80	AVISITN	Num	8	Analysis Visit (N)
81	AVISIT	Char	21	Analysis Visit
82	DTYPE	Char	8	Derivation Type
83	ADY	Num	8	Analysis Relative Day (from first treatment date)
84	PARAM	Char	31	Parameter
85	PARAMCD	Char	7	Parameter Code
86	PARAMN	Num	8	Parameter (N)
87	PARAMTYP	Char	7	Parameter Type
88	AVAL	Num	8	Analysis Value
89	ANRLO	Num	8	Analysis Normal Range Lower Limit
90	ANRHI	Num	8	Analysis Normal Range Upper Limit
91	ANRIND	Char	6	Analysis Reference Range Indicator
92	BASE	Num	8	Baseline Value
93	BNRIND	Char	6	Baseline Reference Range Indicator
94	CHG	Num	8	Change from Baseline
95	ABLFL	Char	1	Baseline Record Flag
96	ABLFN	Num	8	Baseline Record Flag (N)
97	VSSTAT	Char	1	Completion Status

**Data Set Name: ae.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	AESEQ	Num	8	Sequence Number
5	AEGRPID	Char	9	Group ID
6	AESPID	Char	3	Sponsor-Defined Identifier
7	AETERM	Char	69	Reported Term for the Adverse Event
8	AELLT	Char	36	Lowest Level Term
9	AELLTCD	Num	8	Lowest Level Term Code
10	AEDECOD	Char	40	Dictionary-Derived Term
11	AEPTCD	Num	8	Preferred Term Code
12	AEHLT	Char	59	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	52	Body System or Organ Class
17	AEBDSYCD	Num	8	Body System or Organ Class Code
18	AESOC	Char	52	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	31	Other Action Taken
23	AEREL	Char	25	Causality
24	AEOUT	Char	26	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	AESTDY	Num	8	Study Day of Start of Adverse Event (from first treatment date)
31	AEENDY	Num	8	Study Day of End of Adverse Event (from first treatment date)
32	AEENRF	Char	7	End Relative to Reference Period

**Data Set Name: ce.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	CESEQ	Num	8	Sequence Number
5	CETERM	Char	17	Reported Term for the Clinical Event
6	CEDECOD	Char	17	Dictionary-Derived Term
7	CEDY	Num	8	Study Day of Event Collection (from first treatment date)

**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	104	Reported Name of Drug, Med, or Therapy
7	CMDECOD	Char	193	Standardized Medication Name
8	CMCAT	Char	5	Category for Medication
9	CMINDC	Char	89	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	11	Dose Units
15	CMDOSFRQ	Char	16	Dosing Frequency per Interval
16	CMROUTE	Char	24	Route of Administration
17	CMSTDY	Num	8	Study Day of Start of Medication (from first treatment date)
18	CMENDY	Num	8	Study Day of End of Medication (from first treatment date)
19	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	3	Identifying Variable Value
8	COREF	Char	20	Comment Reference
9	COVAL	Char	200	Comment
10	COVAL1	Char	200	Comment 1
11	COVAL2	Char	21	Comment 2
12	CODY	Num	8	Study Day of Comment (from first treatment date)

**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	8	Planned Arm Code
11	ARM	Char	20	Description of Planned Arm
12	ACTARMCD	Char	8	Actual Arm Code
13	ACTARM	Char	20	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	49	Reported Term for the Disposition Event
6	DSDECOD	Char	25	Standardized Disposition Term
7	DSCAT	Char	18	Category for Disposition Event
8	EPOCH	Char	9	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	42	Protocol Deviation Coded Term
7	DVCAT	Char	21	Category for Protocol Deviation
8	DVDY	Num	8	Study Day of Collection (from first treatment date)
9	DVSTDY	Num	8	Study Day of Start of Deviation (from first treatment date)

**Data Set Name: eg.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	EGSEQ	Num	8	Sequence Number
5	EGTESTCD	Char	4	ECG Test or Examination Short Name
6	EGTEST	Char	14	ECG Test or Examination Name
7	EGORRES	Char	8	Result or Finding in Original Units
8	EGSTRESC	Char	8	Character Result/Finding in Std Format
9	EGSTAT	Char	8	Completion Status
10	EGBLFL	Char	1	Baseline Flag
11	EGEVAL	Char	12	Evaluator
12	VISITNUM	Num	8	Visit Number
13	VISIT	Char	10	Visit Name
14	EGDY	Num	8	Study Day of ECG (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	7	Name of Treatment
6	EXDOSE	Num	8	Dose
7	EXDOSU	Char	9	Dose Units
8	EXDOSFRM	Char	20	Dose Form
9	EXROUTE	Char	4	Route of Administration
10	EXSTDY	Num	8	Study Day of Start of Treatment (from first treatment date)
11	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	38	Object of the Observation
10	FACAT	Char	21	Category for Findings About
11	FASCAT	Char	28	Subcategory for Findings About
12	FAORRES	Char	11	Result or Finding in Original Units
13	FASTRESC	Char	11	Character Result/Finding in Std Format
14	VISITNUM	Num	8	Visit Number
15	VISIT	Char	17	Visit Name
16	FADY	Num	8	Study Day of Collection (from first treatment date)

**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	9	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	11	Visit Name
29	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	78	Reported Term for the Medical History
7	MHLLT	Char	41	Lowest Level Term
8	MHLLTCD	Num	8	Lowest Level Term Code
9	MHDECOD	Char	46	Dictionary-Derived Term
10	MHPTCD	Num	8	Preferred Term Code
11	MHHLT	Char	67	High Level Term
12	MHHLTCD	Num	8	High Level Term Code
13	MHHLGT	Char	63	High Level Group Term
14	MHHLGTCD	Num	8	High Level Group Term Code
15	MHBODSYS	Char	67	Body System or Organ Class
16	MHBDSYCD	Num	8	Body System or Organ Class Code
17	MHSOC	Char	67	Primary System Organ Class
18	MHSOCCD	Num	8	Primary System Organ Class Code
19	MHSTDY	Num	8	Study Day of Start of Observation (from first treatment date)
20	MHENDY	Num	8	Study Day of End of Observation (from first treatment date)
21	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	8	Reference ID
6	PCTESTCD	Char	6	Pharmacokinetic Test Short Name
7	PCTEST	Char	6	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	1	Completion Status
15	PCREASND	Char	1	Reason Test Not Done
16	PCNAM	Char	6	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	7	Lower Limit of Quantitation
22	VISITNUM	Num	8	Visit Number
23	VISIT	Char	10	Visit Name
24	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	8	Body System Examined Short Name
6	PETEST	Char	30	Body System Examined
7	PECAT	Char	30	Category for Examination
8	PEORRES	Char	180	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	10	Visit Name
14	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	17	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	10	Visit Name
19	QSDY	Num	8	Study Day of Finding (from first treatment date)

**Data Set Name: qs\_raw\_data\_itthro.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	17	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	QSBLFL	Char	1	Baseline Flag
17	VISITNUM	Num	8	Visit Number
18	VISIT	Char	10	Visit Name
19	QSDY	Num	8	Study Day of Finding

**Data Set Name: relrec.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	12	Identifying Variable Value
6	RELTYPE	Char	1	Relationship Type
7	RELID	Char	3	Relationship Identifier

**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	4	Element Code
6	ELEMENT	Char	36	Description of Element
7	TAETORD	Num	8	Planned Order of Element within Arm
8	EPOCH	Char	9	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: 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	17	Visit Name
6	VISITDY	Num	8	Planned Study Day of Visit (from first treatment date)
7	SVSTDY	Num	8	Study Day of Start of Visit (from first treatment date)
8	SVENDY	Num	8	Study Day of End of Visit (from first treatment date)

**Data Set Name: ta.sas7bdat**

<b>Num</b>	<b>Variable</b>	<b>Type</b>	<b>Len</b>	<b>Label</b>
1	STUDYID	Char	10	Study Identifier
2	DOMAIN	Char	2	Domain Abbreviation
3	ARMCD	Char	1	Planned Arm Code
4	ARM	Char	20	Description of Planned Arm
5	TAETORD	Num	8	Planned Order of Element within Arm
6	ETCD	Char	4	Element Code
7	ELEMENT	Char	36	Description of Element
8	TABRANCH	Char	34	Branch
9	TATRANS	Char	1	Transition Rule
10	EPOCH	Char	9	Epoch

**Data Set Name: tv.sas7bdat**

<b>Num</b>	<b>Variable</b>	<b>Type</b>	<b>Len</b>	<b>Label</b>
1	STUDYID	Char	10	Study Identifier
2	DOMAIN	Char	2	Domain Abbreviation
3	VISITNUM	Num	8	Visit Number
4	VISIT	Char	17	Visit Name
5	VISITDY	Num	8	Planned Study Day of Visit
6	ARMCD	Char	1	Planned Arm Code
7	ARM	Char	1	Description of Planned Arm
8	TVSTRL	Char	39	Visit Start Rule
9	TVENRL	Char	58	Visit End Rule

**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	10	Visit Name
21	VSDY	Num	8	Study Day of Vital Signs (from first treatment date)