

MEDICAL EVALUATION

ID No.		-		
Form Type	M	E	O	1

Part I: Visit Identification

1. Patient's initials: -----
2. Evaluation date: ----- F.04-DAYS
 Month Day Year

Part II: Patient Characteristics

3. Sex: ----- () () SEX
 Male Female
4. Race:
 A. White, not of Hispanic origin ----- ()
 B. Black, not of Hispanic origin ----- ()
 C. Hispanic ----- ()
 D. Asian/Pacific Islander ----- ()
 E. American Indian or Alaska native ----- ()
 F. Other ----- ()
 If other, specify: -----

5. Does the patient have a negative ANA (less than 1:320)? ----- () () NEG-ANA
 Yes No
 ↓

A. ANA titer 1: ANA

6. Does the patient have a serum creatinine greater than 2.0 mg/dl? ----- () () CREAT
 Yes No
7. Is the patient a woman of childbearing capacity? ----- () () CHILD
 Yes No
 ↓

A. Was the patient's pregnancy test positive? ----- PREG-POS () ()
 Yes No

B. Is the patient planning to become pregnant during the course of the study? ----- PLANPREG () ()
 Yes No
 ↓

1) Method of contraception: CONTR

C. Is the patient lactating? ----- () () LACT
 Yes No

ID No.		-		
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EVERSMK

8. Has the patient ever smoked cigarettes? ----- (1) (2)
 Yes No
 ↓

A. Does the patient currently smoke cigarettes? CURRSMK ----- (1) (2)
 Yes No
 ↓

(1) If Yes, specify number of cigarettes smoked per day: - - NUMSMK ↓

B. How long ago did the patient stop smoking? (Check one.) TIMESMK

Less than six months ago ----- (1)
 Six months to one year ago ----- (2)
 One to two years ago ----- (3)
 More than two years ago ----- (4)

ALCH-USE

9. Does the patient ever use alcoholic beverages? ----- (1) (2)
 Yes No
 ↓

A. Patient's daily average alcohol intake is:

(1) Bottles of beer: ----- BEER

(2) Glasses of wine: ----- WINE

(3) Ounces of liquor: ----- LIQUOR

B. Does the patient feel that alcohol relieves his/her Raynaud's symptoms? ----- RELIEF
 (1) (2)
 Yes No

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12. Does anyone else in the patient's family have Raynaud's phenomenon?--- () () *FAM*
 Yes No
 ↓

If Yes, specify relationship: FAM - RMK

13. Is the patient currently taking any medications for Raynaud's phenomenon? ----- () () *RAYNMED*
 Yes No
 ↓

Patient must stop taking disallowed medication two months prior to randomization.

14. Is the patient currently taking any medications for other conditions? ----- () () *OTHERMED*
 Yes No
 ↓

	Generic Name	Dose per day
A.	<i>MEDA - RMK</i>	
B.	<i>MEDB - RMK</i>	
C.	<i>MEDC - RMK</i>	
D.	<i>MEDD - RMK</i>	
E.	<i>MED E - RMK</i>	

Part VII: Patient Assessment of Raynaud's Symptoms

15. Does the patient ever have Raynaud's symptoms in his/her toes? ----- () () *TOES*
 Yes No

16. Are Raynaud's symptoms triggered by stress or emotion? ----- () () *STRESS*

17. Which of the following temperature-related conditions trigger Raynaud's symptoms? (Check all that apply.)

- A. Cold weather ----- () *COLD*
- B. Air conditioning ----- () *AC*
- C. Cold water ----- () *WATER*
- D. Drafts ----- () *DRAFTS*
- E. Cold drinks ----- () *DRINKS*
- F. Handling frozen foods ----- () *FOOD*
- G. Driving in winter ----- () *DRIVE*

LD No.				
Form Type	M	E	O	I

18. Number of Raynaud's attacks on an average day in cold weather: ----- COLD-ATT
19. Number of Raynaud's attacks on an average day in warm weather: ----- WARM-ATT
20. Patient considers his/her Raynaud's phenomenon:
- Mild ----- (1)
 - Moderate ----- (2)
 - Severe ----- (3)
 - Very severe ----- (4)
21. Raynaud's phenomenon affects patient's life:
- None ----- (1)
 - Sometimes ----- (2)
 - Often ----- (3)
 - Always ----- (4)

Part V: Physician Assessment of Severity of Raynaud's Phenomenon

22. Patient's Raynaud's phenomenon is:
- Mild ----- (1)
 - Moderate ----- (2)
 - Severe ----- (3)
 - Very severe ----- (4)

Part VI: Physical Examination

23. Height: ----- inches
24. Weight: ----- pounds
25. Temperature: ----- TEMP °F
- A. Check method:
- Oral ----- (1)
 - Rectal ----- (2)
 - Axillary ----- (3)
 - Other ----- (4)
26. Blood Pressure (sitting):
- A. Systolic: ----- SYS mm Hg
 - B. Diastolic: ----- DIAS mm Hg
27. Pulse (sitting): ----- Pulse beats/minute

ID No.				
Form Type	M	E	0	1

28. Head and neck abnormal? (1) (2) HEAD-ABN
Yes No

Briefly describe: HEAD-ENK

29. EENT/mouth abnormal? (1) (2) ENT-ABN
Yes No

Briefly describe: ENT-ENK

30. Pulmonary examination abnormal? (1) (2) PULM-ABN
Yes No

Briefly describe: PULM-ENK

31. Cardiac examination abnormal? (1) (2) CARD-ABN
Yes No

Briefly describe: CARD-ENK

32. Breasts abnormal? (1) (2) BR-ABN
Yes No

Briefly describe: BR-ENK

33. Musculoskeletal abnormal? (1) (2) MUSC-ABN
Yes No

Briefly describe: MUSC-ENK

ID No.				
Form Type	M	E	0	1

34. Abdomen abnormal? (1) (2)
Yes No

Briefly describe: ABD-RNK

ABD-RNK
EDEM-RNK

35. Peripheral edema present? (1) (2)
Yes No

Briefly describe: EDEM-RNK

OTHR-ABN

36. Other abnormal extremities findings present? (1) (2)
Yes No

Briefly describe: OTHR-ENK

SKIN-ABN

37. Skin abnormal? (1) (2)
Yes No

Briefly describe: SKIN-RNK

NERV-ABN

38. Nervous system abnormal? (1) (2)
Yes No

Briefly describe: NERV-ENK

39. Is the patient right-handed? (1) (2)
Yes No

HAND

ID No.					
Form Type	M	E	O	1	

Part VII: Administrative Matters

40. Evaluating Physician:

Name: _____

RTS Staff No.: _____

41. Research Coordinator:

Signature: _____

RTS Staff No.: _____

42. Date form completed: _____

_____/_____/_____
Month Day Year

ID No.				
Form Type	M	E	O	I

FORM 04 (Rev. 1)
MEDICAL EVALUATION FORM

<u>ITEM</u>	<u>NAME</u>	<u>TYPE AND LENGTH</u>	<u>CODES OR UNITS</u>
HEADER	NEWID	I(4)	Patient ID
2	F04_DAYS	I(4)	Date of medical evaluation Days from Randomization
3	SEX	I(1)	1 = Male, 2 = Female
5 5A	USE ANA VALUE FROM CORE LABORATORY FILE.		
6	CREAT	I(1)	1 = Yes, 2 = No
7	CHILD	I(1)	1 = Yes, 2 = No
7A	PREG_POS	I(1)	1 = Yes, 2 = No
7B	PLANPREG	I(1)	1 = Yes, 2 = No
7B1	CONTR	CHAR(1)	1 = Remark written on form
7C	LACT	I(1)	1 = Yes, 2 = No
8	EVERSMK	I(1)	1 = Yes, 2 = No
8A	CURRSMK	I(1)	1 = Yes, 2 = No
8A	NUMSMK	I(3)	Cigarettes per day
8B	TIMESMK	I(1)	1 = < 6 months 2 = 6 months-1 year 3 = 1-2 years 4 = > 2 years
9	ALCH_USE	I(1)	1 = Yes, 2 = No
CALC*	TOT_ALCH	F(4.1)	Daily Alcohol Intake (ounces) (BEER+ WINE+ LIQUOR)
9A1	BEER	F(4.1)	Bottles of beer/day
9A2	WINE	F(4.1)	Glasses of wine/day
9A3	LIQUOR	F(4.1)	Ounces of liquor/day
9B	RELIEF	I(1)	1 = Yes, 2 = No
10	ABN	I(1)	1 = Yes, 2 = No
10A	MH_A	I(1)	1 = Yes, 2 = No
	STATA	I(1)	1 = Stable 2 = Unstable 3 = Resolved
10B	RMKA	CHAR (1)	1 = Remark Written on Form
	MH_B	I(1)	1 = Yes, 2 = No
	STATB	I(1)	1 = Stable 2 = Unstable 3 = Resolved
	RMKB	CHAR (1)	1 = Remark Written on Form

* CALC denotes a variable that is computed in the SAS program.

FORM 04 (Rev. 1)
 MEDICAL EVALUATION FORM
 (Continued)

<u>ITEM</u>	<u>NAME</u>	<u>TYPE AND LENGTH</u>	<u>CODES OR UNITS</u>
10C	MH_C STATC	I(1) I(1)	1 = Yes, 2 = No 1 = Stable 2 = Unstable 3 = Resolved
10D	RMKC MH_D STATD	CHAR (1) I(1) I(1)	1 = Remark Written on Form 1 = Yes, 2 = No 1 = Stable 2 = Unstable 3 = Resolved
10E	RMKD MH_E STATE	CHAR (1) I(1) I(1)	1 = Remark Written on Form 1 = Yes, 2 = No 1 = Stable 2 = Unstable 3 = Resolved
10F	RMKE MH_F STATF	CHAR (1) I(1) I(1)	1 = Remark Written on Form 1 = Yes, 2 = No 1 = Stable 2 = Unstable 3 = Resolved
10G	RMKF MH_G STATG	CHAR (1) I(1) I(1)	1 = Remark Written on Form 1 = Yes, 2 = No 1 = Stable 2 = Unstable 3 = Resolved
10H	RMKG MH_H STATH	CHAR (1) I(1) I(1)	1 = Remark Written on Form 1 = Yes, 2 = No 1 = Stable 2 = Unstable 3 = Resolved
10I	RMKH MH_I STATI	CHAR (1) I(1) I(1)	1 = Remark Written on Form 1 = Yes, 2 = No 1 = Stable 2 = Unstable 3 = Resolved
10J	RMKI MH_J STATJ	CHAR (1) I(1) I(1)	1 = Remark Written on Form 1 = Yes, 2 = No 1 = Stable 2 = Unstable 3 = Resolved
10K	RMKJ MH_K STATK	CHAR (1) I(1) I(1)	1 = Remark Written on Form 1 = Yes, 2 = No 1 = Stable 2 = Unstable 3 = Resolved
10L	RMKK MH_L STATL	CHAR (1) I(1) I(1)	1 = Remark Written on Form 1 = Yes, 2 = No 1 = Stable 2 = Unstable 3 = Resolved
10M	RMKL MH_M STATM	CHAR (1) I(1) I(1)	1 = Remark Written on Form 1 = Yes, 2 = No 1 = Stable 2 = Unstable 3 = Resolved
10N	RMKM MH_N STATN	CHAR (1) I(1) I(1)	1 = Remark Written on Form 1 = Yes, 2 = No 1 = Stable 2 = Unstable 3 = Resolved
	RMKN	CHAR (1)	1 = Remark Written on Form

FORM 04 (Rev. 1)
 MEDICAL EVALUATION FORM
 (Continued)

<u>ITEM</u>	<u>NAME</u>	<u>TYPE AND LENGTH</u>	<u>CODES OR UNITS</u>
11	COND	I(1)	1 = Yes, 2 = No
11A	SCLER	}	1 = Yes, 2 = No
11B	ARTH		
11C	TOS		
11D	CARP		
11E	VIBDIS		
11F	HRTDIS		
12	FAM	I(1)	1 = Yes, 2 = No
12	FAM_RMK	CHAR(1)	1 = Remark written on form
13	RAYNMED	I(1)	1 = Yes, 2 = No
14	OTHRMED	I(1)	1 = Yes, 2 = No
14A	MEDA_RMK	}	1 = Remark written on form
14B	MEDB_RMK		
14C	MEDC_RMK		
14D	MEDD_RMK		
14E	MEDE_RMK		
15	TOES	I(1)	1 = Yes, 2 = No
16	STRESS	I(1)	1 = Yes, 2 = No
17A	COLD	}	1 = Yes, 2 = No
17B	AC		
17C	WATER		
17D	DRAFTS		
17E	DRINKS		
17F	FOOD		
17G	DRIVE		
18	COLD_ATT	I(2)	Attacks/day
19	WARM_ATT	I(2)	Attacks/day
20	PT_ASS	I(1)	1 = Mild 2 = Moderate 3 = Severe 4 = Very Severe
21	LIFE	I(1)	1 = None 2 = Sometimes 3 = Often 4 = Always
22	PHY_ASS	I(1)	1 = Mild 2 = Moderate 3 = Severe 4 = Very Severe
23/24	BODYMASS	F(6.3)	Body Mass Index (weight/2.2)/(((height*2.54)/100)**2)
25	TEMP	F(5.1)	°F
25A	METHOD	I(1)	1 = Oral 2 = Rectal 3 = Axillary 4 = Other

FORM 04 (Rev. 1)
 MEDICAL EVALUATION FORM
 (Continued)

<u>ITEM</u>	<u>NAME</u>	<u>TYPE AND LENGTH</u>	<u>CODES OR UNITS</u>
26A	SYS	I(3)	mm Hg
26B	DIAS	((3)	mm Hg
27	PULSE	I(3)	Beats/minute
28	HEAD_ABN	I(1)	1 = Yes, 2 = No
28	HEAD_RMK	CHAR(1)	1 = Remark written on form
29	EENT_ABN	I(1)	1 = Yes, 2 = No
29	EENT_RMK	CHAR(1)	1 = Remark written on form
30	PULM_ABN	I(1)	1 = Yes, 2 = No
30	PULM_RMK	CHAR(1)	1 = Remark written on form
31	CARD_ABN	I(1)	1 = Yes, 2 = No
31	CARD_RMK	CHAR(1)	1 = Remark written on form
32	BR_ABN	I(1)	1 = Yes, 2 = No
32	BR_RMK	CHAR(1)	1 = Remark written on form
33	MUSC_ABN	I(1)	1 = Yes, 2 = No
33	MUSC_RMK	CHAR(1)	1 = Remark written on form
34	ABD_ABN	I(1)	1 = Yes, 2 = No
34	ABD_RMK	CHAR(1)	1 = Remark written on form
35	EDEM_ABN	I(1)	1 = Yes, 2 = No
35	EDEM_RMK	CHAR(1)	1 = Remark written on form
36	OTHR_ABN	I(1)	1 = Yes, 2 = No
36	OTHR_RMK	CHAR(1)	1 = Remark written on form
37	SKIN_ABN	I(1)	1 = Yes, 2 = No
37	SKIN_RMK	CHAR(1)	1 = Remark written on form
38	NERV_ABN	I(1)	1 = Yes, 2 = No
38	NERV_RMK	CHAR(1)	1 = Remark written on form
39	HAND	I(1)	1 = Right handed 2 = Left handed

CONTENTS PROCEDURE

Data Set Name:	RTS.FORM04	Observations:	385
Member Type:	DATA	Variables:	158
Engine:	V612	Indexes:	0
Created:	9:04 Monday, May 15, 2000	Observation Length:	593
Last Modified:	9:04 Monday, May 15, 2000	Deleted Observations:	0
Protection:		Compressed:	NO
Data Set Type:		Sorted:	NO
Label:			

-----Engine/Host Dependent Information-----

Data Set Page Size:	16384
Number of Data Set Pages:	16
File Format:	607
First Data Page:	2
Max Obs per Page:	27
Obs in First Data Page:	21

-----Alphabetic List of Variables and Attributes-----

#	Variable	Type	Len	Pos	Format	Informat	Label
ff							
120	AALLERGY	Num	4	429	1.		MED-ALERT -- Antiallergy
121	AASTHMA	Num	4	433	1.		MED-ALERT -- Antiasthma
107	ABD_ABN	Num	4	387	1.	BEST22.	f04q34 Abdomen abnormal
108	ABD_RMK	Char	1	391			f04q34 Describe abdomen
122	ABIOTIC	Num	4	437	1.		MED-ALERT -- Antibiotic
17	ABN	Num	4	77	1.	BEST22.	f04q10 Any systems/conditions abnormal
79	AC	Num	4	265	1.	BEST22.	f04q17b Air conditioning
123	ACEINHIB	Num	4	441	1.		MED-ALERT -- ACE Inhibitor
124	ACHOLIN	Num	4	445	1.		MED-ALERT -- Anticholinergic
125	ADEPRESS	Num	4	449	1.		MED-ALERT -- Antidepressant
126	ADOPANEU	Num	4	453	1.		MED-ALERT -- Antidopaneuragic
127	AFUNGAL	Num	4	457	1.		MED-ALERT -- Antifungal
128	AGLACOMA	Num	4	461	1.		MED-ALERT -- Antiglaucoma
129	AHISTAM	Num	4	465	1.		MED-ALERT -- Antihistamine
12	ALCH_USE	Num	4	45	1.	BEST22.	f04q9 Patient uses alcoholic beverages
130	ANXIOLYT	Num	4	469	1.		MED-ALERT -- Anxiolytic
131	APARKIN	Num	4	473	1.		MED-ALERT -- Antiparkinson
132	APYRETIC	Num	4	477	1.		MED-ALERT -- Antipyretic
62	ARTH	Num	4	215	1.	BEST22.	f04q11b Rheumatoid arthritis
133	AVIRAL	Num	4	481	1.		MED-ALERT -- Antiviral
135	BBLOCKER	Num	4	489	1.		MED-ALERT -- Beta Blocker
13	BEER	Num	8	49	4.1	BEST22.	f04q9a1 Daily beer intake (bottles)
134	BENZODIA	Num	4	485	1.		MED-ALERT -- Benzodiazepine
158	BODYMASS	Num	8	585	6.3		weight(kg) divided by height(m) squared
136	BRONCHOD	Num	4	493	1.		MED-ALERT -- Bronchodilator
103	BR_ABN	Num	4	377	1.	BEST22.	f04q32 Breasts abnormal
104	BR_RMK	Char	1	381			f04q32 Describe breasts
101	CARD_ABN	Num	4	372	1.	BEST22.	f04q31 Cardiac abnormal
102	CARD_RMK	Char	1	376			f04q31 Describe cardiac
64	CARP	Num	4	223	1.	BEST22.	f04q11d Carpal tunnel syndrome
137	CHEMO	Num	4	497	1.		MED-ALERT -- Chemotherapeutic agent

CONTENTS PROCEDURE

#	Variable	Type	Len	Pos	Format	Informat	Label
ff							
3	CHILD	Num	4	8	1.	BEST22.	f04q7 Woman of childbearing capacity
138	CHOLESTR	Num	4	501	1.		MED-ALERT -- Cholesterol Lowering Agent
139	CNSDEPR	Num	4	505	1.		MED-ALERT -- CNS Depressant
78	COLD	Num	4	261	1.	BEST22.	f04q17a Cold weather
85	COLD_ATT	Num	8	289	2.	BEST22.	f04q18 Cold weather attacks/day
60	COND	Num	4	207	1.	BEST22.	f04q11 Any of the following conditions
6	CONTR	Char	1	20	1.		f04q7b Method of contraception
2	CREAT	Num	4	4	1.	BEST22.	f04q6 Serum creatinine > 2.0 mg/dl
9	CURRSMK	Num	4	29	1.	BEST22.	f04q8a Patient is currently smoking
140	CYTOKINE	Num	4	509	1.		MED-ALERT -- Cytokine
141	DECONGES	Num	4	513	1.		MED-ALERT -- Decongestant
93	DIAS	Num	8	341	3.	BEST22.	f04q26b Diastolic blood pressure (mm Hg)
142	DIURETIC	Num	4	517	1.		MED-ALERT -- Diuretic
81	DRAFTS	Num	4	273	1.	BEST22.	f04q17d Drafts
82	DRINKS	Num	4	277	1.	BEST22.	f04q17e Cold drinks
84	DRIVE	Num	4	285	1.	BEST22.	f04q17g Driving in winter
109	EDEM_ABN	Num	4	392	1.	BEST22.	f04q35 Peripheral edema abnormal
110	EDEM_RMK	Char	1	396			f04q35 Describe peripheral edema
97	EENT_ABN	Num	4	362	1.	BEST22.	f04q29 EENT/mouth abnormal
98	EENT_RMK	Char	1	366			f04q29 Describe EENT/mouth
8	EVERSMK	Num	4	25	1.	BEST22.	f04q8 Has patient ever smoked
119	F04_DAYS	Num	5	424	4.		f04q2 Days from randomization
67	FAM	Num	4	235	1.	BEST22.	f04q12 Family member has Raynauds
68	FAM_RMK	Char	1	239			f04q12 Specify relationship
83	FOOD	Num	4	281	1.	BEST22.	f04q17f Handling frozen foods
143	GIRELIEF	Num	4	521	1.		MED-ALERT -- GI Relief
117	HAND	Num	4	412	1.	BEST22.	f04q39 Patient is right-handed
95	HEAD_ABN	Num	4	357	1.	BEST22.	f04q28 Head and neck abnormal
96	HEAD_RMK	Char	1	361			f04q28 Describe head and neck
144	HIPI	Num	4	525	1.		MED-ALERT -- Hydrogen Ion Pump Inhibitor
145	HORMONE	Num	4	529	1.		MED-ALERT -- Hormone
66	HRTDIS	Num	4	231	1.	BEST22.	f04q11f Any heart disease
146	HYPOLIP	Num	4	533	1.		MED-ALERT -- Hypolipidemic Agent
7	LACT	Num	4	21	1.	BEST22.	f04q7c Patient is lactating
88	LIFE	Num	8	309	1.	BEST22.	f04q21 Affects patients life
147	LIPIDREG	Num	4	537	1.		MED-ALERT -- Lipid Regulating Agent
15	LIQUOR	Num	8	65	4.1	BEST22.	f04q9a3 Daily liquor intake (ounces)
71	MEDA_RMK	Char	1	248			f04q14a Generic name
72	MEDB_RMK	Char	1	249			f04q14b Generic name
73	MEDC_RMK	Char	1	250			f04q14c Generic name
74	MEDD_RMK	Char	1	251			f04q14d Generic name
75	MEDE_RMK	Char	1	252			f04q14e Generic name
91	METHOD	Num	4	329	1.	BEST22.	f04q25a Temperature method used
18	MH_A	Num	4	81	1.	BEST22.	f04q10a1 HEENT abnormal history
21	MH_B	Num	4	90	1.	BEST22.	f04q10b1 Allergic abnormal history
24	MH_C	Num	4	99	1.	BEST22.	f04q10c1 Pulmonary abnormal history
27	MH_D	Num	4	108	1.	BEST22.	f04q10d1 Cardiovascular abnormal history

CONTENTS PROCEDURE

#	Variable	Type	Len	Pos	Format	Informat	Label
30	MH_E	Num	4	117	1.	BEST22.	f04q10e1 Gastrointest. abnormal history
33	MH_F	Num	4	126	1.	BEST22.	f04q10f1 Hepatobiliary abnormal history
36	MH_G	Num	4	135	1.	BEST22.	f04q10g1 Genitourinary abnormal history
39	MH_H	Num	4	144	1.	BEST22.	f04q10h1 Musculoskel. abnormal history
42	MH_I	Num	4	153	1.	BEST22.	f04q10i1 Endocrine abnormal history
45	MH_J	Num	4	162	1.	BEST22.	f04q10j1 Neurologic abnormal history
48	MH_K	Num	4	171	1.	BEST22.	f04q10k1 Depression abnormal history
51	MH_L	Num	4	180	1.	BEST22.	f04q10l1 Anxiety abnormal history
54	MH_M	Num	4	189	1.	BEST22.	f04q10m1 Other psych. abnormal history
57	MH_N	Num	4	198	1.	BEST22.	f04q10n1 Dermatologic abnormal history
148	MUCOLYTC	Num	4	541	1.		MED-ALERT -- Mucolytic
149	MUSCLERE	Num	4	545	1.		MED-ALERT -- Muscle Relaxant
105	MUSC_ABN	Num	4	382	1.	BEST22.	f04q33 Musculoskeletal abnormal
106	MUSC_RMK	Char	1	386			f04q33 Describe musculoskeletal
115	NERV_ABN	Num	4	407	1.	BEST22.	f04q38 Nervous system abnormal
116	NERV_RMK	Char	1	411			f04q38 Describe nervous system
157	NEWID	Num	8	577	4.		Patient ID
151	NSAESTRO	Num	4	553	1.		MED-ALERT -- Nonsteroidal Antiestrogen
150	NSAID	Num	4	549	1.		MED-ALERT -- NSAID
10	NUMSMK	Num	8	33	3.	BEST22.	f04q8a Cigarettes per day
70	OTHRMED	Num	4	244	1.	BEST22.	f04q14 Other medications
111	OTHR_ABN	Num	4	397	1.	BEST22.	f04q36 Other extremities abnormal
112	OTHR_RMK	Char	1	401			f04q36 Describe other extremities
152	PAINREL	Num	4	557	1.		MED-ALERT -- Pain relief
89	PHY_ASS	Num	4	317	1.	BEST22.	f04q22 Physician assessment
5	PLANPREG	Num	4	16	1.	BEST22.	f04q7b Planning to become pregnant
4	PREG_POS	Num	4	12	1.	BEST22.	f04q7a Positive pregnancy test
87	PT_ASS	Num	4	305	1.	BEST22.	f04q20 Patient assessment
99	PULM_ABN	Num	4	367	1.	BEST22.	f04q30 Pulmonary abnormal
100	PULM_RMK	Char	1	371			f04q30 Describe pulmonary
94	PULSE	Num	8	349	3.	BEST22.	f04q27 Pulse (beats/minute)
69	RAYNMED	Num	4	240	1.	BEST22.	f04q13 Taking medication for Raynauds
16	RELIEF	Num	4	73	1.	BEST22.	f04q9b Alcohol relieves symptoms
20	RMKA	Char	1	89			f04q10a3 HEENT problem statement
23	RMKB	Char	1	98			f04q10b3 Allergic problem statement
26	RMKC	Char	1	107			f04q10c3 Pulmonary problem statement
29	RMKD	Char	1	116			f04q10d3 Cardiovas. problem statement
32	RMKE	Char	1	125			f04q10e3 Gastrointest. problem statement
35	RMKF	Char	1	134			f04q10f3 Hepatobil. problem statement
38	RMKG	Char	1	143			f04q10g3 Genitourinary problem statement
41	RMKH	Char	1	152			f04q10h3 Musculoskel. problem statement
44	RMKI	Char	1	161			f04q10i3 Endocrine problem statement
47	RMKJ	Char	1	170			f04q10j3 Neurologic problem statement
50	RMKK	Char	1	179			f04q10k3 Depression problem statement
53	RMKL	Char	1	188			f04q10l3 Anxiety problem statement
56	RMKM	Char	1	197			f04q10m3 Other psych problem statement

CONTENTS PROCEDURE

#	Variable	Type	Len	Pos	Format	Informat	Label
59	RMKN	Char	1	206			f04q10n3 Dermatologic problem statement
61	SCLER	Num	4	211	1.	BEST22.	f04q11a Scleroderma
153	SERATON	Num	4	561	1.		MED-ALERT -- Serotonin Antagonist
1	SEX	Num	4	0	1.	BEST22.	f04q3 Sex
113	SKIN_ABN	Num	4	402	1.	BEST22.	f04q37 Skin abnormal
114	SKIN_RMK	Char	1	406			f04q37 Describe skin
19	STATA	Num	4	85	1.	BEST22.	f04q10a2 HEENT status
22	STATB	Num	4	94	1.	BEST22.	f04q10b2 Allergic status
25	STATC	Num	4	103	1.	BEST22.	f04q10c2 Pulmonary status
28	STATD	Num	4	112	1.	BEST22.	f04q10d2 Cardiovascular status
31	STATE	Num	4	121	1.	BEST22.	f04q10e2 Gastrointestinal status
34	STATF	Num	4	130	1.	BEST22.	f04q10f2 Hepatobiliary status
37	STATG	Num	4	139	1.	BEST22.	f04q10g2 Genitourinary status
40	STATH	Num	4	148	1.	BEST22.	f04q10h2 Musculoskeletal status
43	STATI	Num	4	157	1.	BEST22.	f04q10i2 Endocrine status
46	STATJ	Num	4	166	1.	BEST22.	f04q10j2 Neurologic status
49	STATK	Num	4	175	1.	BEST22.	f04q10k2 Depression status
52	STATL	Num	4	184	1.	BEST22.	f04q10l2 Anxiety status
55	STATM	Num	4	193	1.	BEST22.	f04q10m2 Other psych. status
58	STATN	Num	4	202	1.	BEST22.	f04q10n2 Dermatologic status
154	STEROID	Num	4	565	1.		MED-ALERT -- Steroid
77	STRESS	Num	4	257	1.	BEST22.	f04q16 Raynauds triggered by stress
92	SYS	Num	8	333	3.	BEST22.	f04q26a Systolic blood pressure (mm Hg)
90	TEMP	Num	8	321	5.1	BEST22.	f04q25 Temperature (F)
11	TIMESMK	Num	4	41	1.	BEST22.	f04q8b When patient stopped smoking
76	TOES	Num	4	253	1.	BEST22.	f04q15 Raynauds symptoms in toes
63	TOS	Num	4	219	1.	BEST22.	f04q11c Thoracic outlet syndrome
118	TOT_ALCH	Num	8	416	4.1		f04q9 Total daily alcohol (ounces)
155	UNK	Num	4	569	1.		MED-ALERT -- Unknown/Other
65	VIBDIS	Num	4	227	1.	BEST22.	f04q11e Vibration disease
156	VITAMIN	Num	4	573	1.		MED-ALERT -- Vitamin
86	WARM_ATT	Num	8	297	2.	BEST22.	f04q19 Warm weather attacks/day
80	WATER	Num	4	269	1.	BEST22.	f04q17c Cold water
14	WINE	Num	8	57	4.1	BEST22.	f04q9a2 Daily wine intake (glasses)

Variable	Label	N	Mean	Std Dev	Minimum	Maximum
SEX	f04q3 Sex	385	1.7	0.4	1.0	2.0
CREAT	f04q6 Serum creatinine > 2.0 mg/dl	380	2.0	0.0	2.0	2.0
CHILD	f04q7 Woman of childbearing capacity	385	1.5	0.5	1.0	2.0
PREG_POS	f04q7a Positive pregnancy test	182	2.0	0.1	1.0	2.0
PLANPREG	f04q7b Planning to become pregnant	184	2.0	0.0	2.0	2.0
LACT	f04q7c Patient is lactating	184	2.0	0.0	2.0	2.0
EVERSMK	f04q8 Has patient ever smoked	385	1.5	0.5	1.0	2.0
CURRSMK	f04q8a Patient is currently smoking	385	1.9	0.3	1.0	2.0
NUMSMK	f04q8a Cigarettes per day	54	20.6	10.4	1.0	40.0
TIMESMK	f04q8b When patient stopped smoking	126	3.8	0.7	1.0	4.0
ALCH_USE	f04q9 Patient uses alcoholic beverages	385	1.4	0.5	1.0	2.0
BEER	f04q9a1 Daily beer intake (bottles)	385	0.3	0.9	0.0	8.3
WINE	f04q9a2 Daily wine intake (glasses)	385	0.2	0.7	0.0	8.0
LIQUOR	f04q9a3 Daily liquor intake (ounces)	385	0.1	0.7	0.0	10.0
RELIEF	f04q9b Alcohol relieves symptoms	216	1.9	0.3	1.0	2.0
ABN	f04q10 Any systems/conditions abnormal	385	1.2	0.4	1.0	2.0
MH_A	f04q10a1 HEENT abnormal history	385	1.8	0.4	1.0	2.0
STATA	f04q10a2 HEENT status	89	1.4	0.8	1.0	3.0
MH_B	f04q10b1 Allergic abnormal history	385	1.7	0.5	1.0	2.0
STATB	f04q10b2 Allergic status	129	1.1	0.5	1.0	3.0
MH_C	f04q10c1 Pulmonary abnormal history	385	1.9	0.2	1.0	2.0
STATC	f04q10c2 Pulmonary status	22	1.3	0.7	1.0	3.0
MH_D	f04q10d1 Cardiovascular abnormal history	385	1.9	0.3	1.0	2.0
STATD	f04q10d2 Cardiovascular status	41	1.2	0.5	1.0	3.0
MH_E	f04q10e1 Gastrointest. abnormal history	385	1.9	0.3	1.0	2.0
STATE	f04q10e2 Gastrointestinal status	54	1.4	0.8	1.0	3.0
MH_F	f04q10f1 Hepatobiliary abnormal history	385	2.0	0.2	1.0	2.0
STATF	f04q10f2 Hepatobiliary status	13	1.3	0.8	1.0	3.0
MH_G	f04q10g1 Genitourinary abnormal history	385	1.8	0.4	1.0	2.0
STATG	f04q10g2 Genitourinary status	58	1.7	0.9	1.0	3.0
MH_H	f04q10h1 Musculoskel. abnormal history	385	1.7	0.5	1.0	2.0
STATH	f04q10h2 Musculoskeletal status	118	1.2	0.6	1.0	3.0
MH_I	f04q10i1 Endocrine abnormal history	385	1.9	0.3	1.0	2.0
STATI	f04q10i2 Endocrine status	38	1.1	0.5	1.0	3.0
MH_J	f04q10j1 Neurologic abnormal history	385	1.9	0.3	1.0	2.0
STATJ	f04q10j2 Neurologic status	28	1.4	0.8	1.0	3.0
MH_K	f04q10k1 Depression abnormal history	385	1.9	0.3	1.0	2.0
STATK	f04q10k2 Depression status	42	1.2	0.7	1.0	3.0

Variable	Label	N	Mean	Std Dev	Minimum	Maximum
MH_L	f04q10l1 Anxiety abnormal history	385	2.0	0.2	1.0	2.0
STATL	f04q10l2 Anxiety status	15	1.3	0.7	1.0	3.0
MH_M	f04q10m1 Other psych. abnormal history	385	2.0	0.1	1.0	2.0
STATM	f04q10m2 Other psych. status	8	1.3	0.7	1.0	3.0
MH_N	f04q10n1 Dermatologic abnormal history	385	1.8	0.4	1.0	2.0
STATN	f04q10n2 Dermatologic status	72	1.3	0.7	1.0	3.0
COND	f04q11 Any of the following conditions	385	1.9	0.3	1.0	2.0
SCLER	f04q11a Scleroderma	382	2.0	0.1	1.0	2.0
ARTH	f04q11b Rheumatoid arthritis	382	2.0	0.1	1.0	2.0
TOS	f04q11c Thoracic outlet syndrome	381	2.0	0.1	1.0	2.0
CARP	f04q11d Carpal tunnel syndrome	381	1.9	0.2	1.0	2.0
VIBDIS	f04q11e Vibration disease	382	2.0	0.0	2.0	2.0
HRTDIS	f04q11f Any heart disease	385	2.0	0.2	1.0	2.0
FAM	f04q12 Family member has Raynauds	385	1.7	0.5	1.0	2.0
RAYNMED	f04q13 Taking medication for Raynauds	385	2.0	0.0	2.0	2.0
OTHRMED	f04q14 Other medications	385	1.4	0.5	1.0	2.0
TOES	f04q15 Raynauds symptoms in toes	383	1.4	0.5	1.0	2.0
STRESS	f04q16 Raynauds triggered by stress	384	1.8	0.4	1.0	2.0
COLD	f04q17a Cold weather	385	1.0	0.0	1.0	1.0
AC	f04q17b Air conditioning	385	1.3	0.5	1.0	2.0
WATER	f04q17c Cold water	385	1.2	0.4	1.0	2.0
DRAFTS	f04q17d Drafts	385	1.4	0.5	1.0	2.0
DRINKS	f04q17e Cold drinks	385	1.4	0.5	1.0	2.0
FOOD	f04q17f Handling frozen foods	385	1.1	0.3	1.0	2.0
DRIVE	f04q17g Driving in winter	385	1.1	0.2	1.0	2.0
COLD_ATT	f04q18 Cold weather attacks/day	385	3.7	2.7	2.0	20.0
WARM_ATT	f04q19 Warm weather attacks/day	385	0.8	1.5	0.0	15.0
PT_ASS	f04q20 Patient assessment	385	2.1	0.7	1.0	4.0
LIFE	f04q21 Affects patients life	385	2.2	0.8	1.0	4.0
PHY_ASS	f04q22 Physician assessment	383	1.9	0.6	1.0	4.0
TEMP	f04q25 Temperature (F)	378	98.0	0.8	94.8	100.5
METHOD	f04q25a Temperature method used	379	1.1	0.6	1.0	4.0
SYS	f04q26a Systolic blood pressure (mm Hg)	384	118.9	14.9	90.0	198.0
DIAS	f04q26b Diastolic blood pressure (mm Hg)	384	75.6	8.7	50.0	110.0
PULSE	f04q27 Pulse (beats/minute)	385	71.0	10.0	42.0	100.0
HEAD_ABN	f04q28 Head and neck abnormal	385	2.0	0.2	1.0	2.0
EENT_ABN	f04q29 EENT/mouth abnormal	385	2.0	0.2	1.0	2.0
PULM_ABN	f04q30 Pulmonary abnormal	385	2.0	0.1	1.0	2.0

Variable	Label	N	Mean	Std Dev	Minimum	Maximum
CARD_ABN	f04q31 Cardiac abnormal	385	2.0	0.2	1.0	2.0
BR_ABN	f04q32 Breasts abnormal	383	2.0	0.1	1.0	2.0
MUSC_ABN	f04q33 Musculoskeletal abnormal	385	1.9	0.3	1.0	2.0
ABD_ABN	f04q34 Abdomen abnormal	385	2.0	0.2	1.0	2.0
EDEM_ABN	f04q35 Peripheral edema abnormal	385	2.0	0.1	1.0	2.0
OTHR_ABN	f04q36 Other extremities abnormal	384	2.0	0.2	1.0	2.0
SKIN_ABN	f04q37 Skin abnormal	385	1.9	0.3	1.0	2.0
NERV_ABN	f04q38 Nervous system abnormal	385	2.0	0.1	1.0	2.0
HAND	f04q39 Patient is right-handed	385	1.1	0.3	1.0	2.0
TOT_ALCH	f04q9 Total daily alcohol (ounces)	385	0.6	1.3	0.0	10.0
FO4_DAYS	f04q2 Days from randomization	313	-41.2	13.0	-121.0	0.0
AALLERGY	MED-ALERT -- Anti allergy	313	2.0	0.1	1.0	2.0
AASTHMA	MED-ALERT -- Anti asthma	313	2.0	0.1	1.0	2.0
ABIOTIC	MED-ALERT -- Antibiotic	313	1.9	0.3	1.0	2.0
ACEINHIB	MED-ALERT -- ACE Inhibitor	313	2.0	0.1	1.0	2.0
ACHOLIN	MED-ALERT -- Anticholinergic	313	2.0	0.1	1.0	2.0
ADEPRESS	MED-ALERT -- Antidepressant	313	1.9	0.2	1.0	2.0
ADOPANEU	MED-ALERT -- Antidopaneuragic	313	2.0	0.1	1.0	2.0
AFUNGAL	MED-ALERT -- Antifungal	313	2.0	0.1	1.0	2.0
AGLACOMA	MED-ALERT -- Antiglaucoma	313	2.0	0.1	1.0	2.0
AHISTAM	MED-ALERT -- Antihistamine	313	1.9	0.3	1.0	2.0
ANXIOLYT	MED-ALERT -- Anxiolytic	313	2.0	0.1	1.0	2.0
APARKIN	MED-ALERT -- Antiparkinson	313	2.0	0.1	1.0	2.0
APYRETIC	MED-ALERT -- Antipyretic	313	1.9	0.3	1.0	2.0
AVIRAL	MED-ALERT -- Antiviral	314	2.0	0.1	1.0	2.0
BENZODIA	MED-ALERT -- Benzodiazepine	313	2.0	0.1	1.0	2.0
BBLOCKER	MED-ALERT -- Beta Blocker	313	2.0	0.1	1.0	2.0
BRONCHOD	MED-ALERT -- Bronchodilator	313	2.0	0.1	1.0	2.0
CHEMO	MED-ALERT -- Chemotherapeutic agent	313	2.0	0.1	1.0	2.0
CHOLESTR	MED-ALERT -- Cholesterol Lowering Agent	313	2.0	0.1	1.0	2.0
CNSDEPR	MED-ALERT -- CNS Depressant	313	2.0	0.1	1.0	2.0
CYTOKINE	MED-ALERT -- Cytokine	313	2.0	0.1	1.0	2.0
DECONGES	MED-ALERT -- Decongestant	313	2.0	0.2	1.0	2.0
DIURETIC	MED-ALERT -- Diuretic	313	2.0	0.2	1.0	2.0
GIRELIEF	MED-ALERT -- GI Relief	313	2.0	0.1	1.0	2.0
HIPPI	MED-ALERT -- Hydrogen Ion Pump Inhibitor	313	2.0	0.1	1.0	2.0
HORMONE	MED-ALERT -- Hormone	313	1.8	0.4	1.0	2.0
HYPOLIP	MED-ALERT -- Hypolipemic Agent	313	2.0	0.1	1.0	2.0

Variable	Label	N	Mean	Std Dev	Minimum	Maximum
LIPIDREG	MED-ALERT -- Lipid Regulating Agent	313	2.0	0.1	1.0	2.0
MUCOLYTC	MED-ALERT -- Mucolytic	313	2.0	0.1	1.0	2.0
MUSCLERE	MED-ALERT -- Muscle Relaxant	313	2.0	0.1	1.0	2.0
NSAID	MED-ALERT -- NSAID	313	1.9	0.3	1.0	2.0
NSAESTRO	MED-ALERT -- Nonsteroidal Antiestrogen	313	2.0	0.1	1.0	2.0
PAINREL	MED-ALERT -- Pain relief	313	2.0	0.1	1.0	2.0
SERATON	MED-ALERT -- Serotonin Antagonist	313	2.0	0.1	1.0	2.0
STEROID	MED-ALERT -- Steroid	313	1.9	0.2	1.0	2.0
UNK	MED-ALERT -- Unknown/Other	313	2.0	0.2	1.0	2.0
VITAMIN	MED-ALERT -- Vitamin	313	1.9	0.2	1.0	2.0
NEWID	Patient ID	385	209.5	140.5	1.0	556.0
BODYMASS	weight(kg) divided by height(m) squared	383	23.4	4.1	15.8	50.5

f04q7b Method of contraception

CONTR	Frequency	Percent	Cumulative Frequency	Cumulative Percent
1	184	100.0	184	100.0

Frequency Missing = 201

f04q10a3 HEENT problem statement

RMKA	Frequency	Percent	Cumulative Frequency	Cumulative Percent
1	1	100.0	1	100.0

Frequency Missing = 384

f04q10b3 Allergic problem statement

RMKB	Frequency	Percent	Cumulative Frequency	Cumulative Percent
1	2	100.0	2	100.0

Frequency Missing = 383

f04q10c3 Pulmonary problem statement

RMKC	Frequency	Percent	Cumulative Frequency	Cumulative Percent
ff				

Frequency Missing = 385

f04q10d3 Cardiovas. problem statement

RMKD	Frequency	Percent	Cumulative Frequency	Cumulative Percent
ff				
1	3	100.0	3	100.0

Frequency Missing = 382

f04q10e3 Gastrointest. problem statement

RMKE	Frequency	Percent	Cumulative Frequency	Cumulative Percent
ff				
1	1	100.0	1	100.0

Frequency Missing = 384

f04q10f3 Hepatobil. problem statement

RMKF	Frequency	Percent	Cumulative Frequency	Cumulative Percent
ff				

Frequency Missing = 385

f04q10g3 Genitourinary problem statement

RMKG	Frequency	Percent	Cumulative Frequency	Cumulative Percent
1	3	100.0	3	100.0

Frequency Missing = 382

f04q10h3 Musculoskel. problem statement

RMKH	Frequency	Percent	Cumulative Frequency	Cumulative Percent
1	4	100.0	4	100.0

Frequency Missing = 381

f04q10i3 Endocrine problem statement

RMKI	Frequency	Percent	Cumulative Frequency	Cumulative Percent
1	1	100.0	1	100.0

Frequency Missing = 384

f04q10j3 Neurologic problem statement

RMKJ	Frequency	Percent	Cumulative Frequency	Cumulative Percent
<i>ff</i>				

Frequency Missing = 385

f04q10k3 Depression problem statement

RMKK	Frequency	Percent	Cumulative Frequency	Cumulative Percent
<i>ff</i>				

Frequency Missing = 385

f04q10l3 Anxiety problem statement

RMKL	Frequency	Percent	Cumulative Frequency	Cumulative Percent
<i>ff</i>				
1	1	100.0	1	100.0

Frequency Missing = 384

f04q10m3 Other psych problem statement

RMKM	Frequency	Percent	Cumulative Frequency	Cumulative Percent
<i>ff</i>				

Frequency Missing = 385

f04q10n3 Dermatologic problem statement

RMKN	Frequency	Percent	Cumulative Frequency	Cumulative Percent
1	3	100.0	3	100.0

Frequency Missing = 382

f04q12 Specify relationship

FAM_RMK	Frequency	Percent	Cumulative Frequency	Cumulative Percent
1	123	100.0	123	100.0

Frequency Missing = 262

f04q14a Generic name

MEDA_RMK	Frequency	Percent	Cumulative Frequency	Cumulative Percent
1	213	100.0	213	100.0

Frequency Missing = 172

f04q14b Generic name

MEDB_RMK	Frequency	Percent	Cumulative Frequency	Cumulative Percent
1	105	100.0	105	100.0

Frequency Missing = 280

f04q14c Generic name

MEDC_RMK	Frequency	Percent	Cumulative Frequency	Cumulative Percent
1	56	100.0	56	100.0

Frequency Missing = 329

f04q14d Generic name

MEDD_RMK	Frequency	Percent	Cumulative Frequency	Cumulative Percent
1	27	100.0	27	100.0

Frequency Missing = 358

f04q14e Generic name

MEDE_RMK	Frequency	Percent	Cumulative Frequency	Cumulative Percent
1	12	100.0	12	100.0

Frequency Missing = 373

f04q28 Describe head and neck

HEAD_RMK	Frequency	Percent	Cumulative Frequency	Cumulative Percent
1	19	100.0	19	100.0

Frequency Missing = 366

f04q29 Describe EENT/mouth

EENT_RMK	Frequency	Percent	Cumulative Frequency	Cumulative Percent
1	15	100.0	15	100.0

Frequency Missing = 370

f04q30 Describe pulmonary

PULM_RMK	Frequency	Percent	Cumulative Frequency	Cumulative Percent
1	3	100.0	3	100.0

Frequency Missing = 382

f04q31 Describe cardiac

CARD_RMK	Frequency	Percent	Cumulative Frequency	Cumulative Percent
1	18	100.0	18	100.0

Frequency Missing = 367

f04q32 Describe breasts

BR_RMK	Frequency	Percent	Cumulative Frequency	Cumulative Percent
1	3	100.0	3	100.0

Frequency Missing = 382

f04q33 Describe musculoskeletal

MUSC_RMK	Frequency	Percent	Cumulative Frequency	Cumulative Percent
1	49	100.0	49	100.0

Frequency Missing = 336

f04q34 Describe abdomen

ABD_RMK	Frequency	Percent	Cumulative Frequency	Cumulative Percent
1	9	100.0	9	100.0

Frequency Missing = 376

f04q35 Describe peripheral edema

EDEM_RMK	Frequency	Percent	Cumulative Frequency	Cumulative Percent
1	8	100.0	8	100.0

Frequency Missing = 377

f04q36 Describe other extremities

OTHR_RMK	Frequency	Percent	Cumulative Frequency	Cumulative Percent
1	12	100.0	12	100.0

Frequency Missing = 373

f04q37 Describe skin

SKIN_RMK	Frequency	Percent	Cumulative Frequency	Cumulative Percent
1	54	100.0	54	100.0

Frequency Missing = 331

f04q38 Describe nervous system

NERV_RMK	Frequency	Percent	Cumulative Frequency	Cumulative Percent
1	6	100.0	6	100.0

Frequency Missing = 379