

CLINICAL MONITORING FORM

ID No.		-			
Form Type	C	M			

Part I: Visit Identification

1. Patient's initials: -----
2. Date of examination: ----- **F 13 DAYS**
Month Day Year

Part II: History

3. Has the patient ever smoked cigarettes? ----- **EVER SMK** () ()
Yes No

A. Does the patient currently smoke cigarettes? ----- **CURR SMK** () ()
Yes No

1) If Yes, specify number of cigarettes smoked per day: ----- **NUM SMK**

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

Less than six months ago ----- **TIME SMK** ()
Six months to one year ago ----- ()
One to two years ago ----- ()
More than two years ago ----- ()

4. Does the patient ever use alcoholic beverages? ----- **ALC USE** () ()
Yes No

A. Patient's average daily alcohol intake in:

1. Bottles of beer: ----- **BEER**

2. Glasses of wine: ----- **WINE**

3. Ounces of liquor: ----- **LIQUOR**

5. Is the patient pregnant? ----- **PREG** () ()
Yes No

STOP study medication.

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ILLV

6. Has the patient had any illnesses since the last visit? ----- () ()
 Yes No
 ↓

A. Briefly describe: ILL-RMK

B. Describe the relationship between the illness(es) and study treatment (Check all that apply): ILL-ST1

(1) None of the illness(es) is related to study treatment ----- ()

(2) At least one illness is possible related to study treatment ILL-ST2 ----- ()

(3) At least one illness is probably related to study treatment ILL-ST3 ----- ()

(4) At least one illness is definitely related to study treatment ILL-ST4 ----- ()

C. Action taken: ILL-ACT1

Study treatment stopped ----- ()

Dosage of study medication reduced (medication group only)
 (Daily dose reduced from 2 pills to 1) ----- ()

No action taken ----- ()

D. Resolution at time of this examination: ILL-RBS

Problem resolved ----- () ✓

Problem unresolved, mild ----- ()

Problem unresolved, moderate ----- ()

↓

Schedule Interim Follow-up Visit

↓

Problem unresolved, severe ----- ()

↓

↓

Stop patient treatment. If the illness is possibly, probably, or definitely related to study medication, submit the FDA MedWatch Report.

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SIDE EFF

7. Has the patient experience any conditions that might be side effects of study treatment? ----- (1) (2)
 Yes No
 ↓

A. Briefly describe: SIDE-RMK

B. Describe the relationship between the illness(es) and study treatment (Check all that apply):

(1) None of the illness(es) is related to study treatment ----- STILL 1 (1)

(2) At least one illness is possible related to study treatment ----- STILL 2 (1)

(3) At least one illness is probably related to study treatment ----- STILL 3 (1)

(4) At least one illness is definitely related to study treatment ----- STILL 4 (1)

C. Action taken: SID-ACT 1

Study treatment stopped ----- (1)

Dosage of study medication reduced (medication group only)
 (Daily dose reduced from 2 pills to 1) ----- (2)

No action taken ----- (3)

D. Resolution at time of this examination: SID-RES 1

Problem resolved ----- (1)

Problem unresolved, mild ----- (2)

Problem unresolved, moderate ----- (3)

↓

Schedule Interim Follow-up Visit

←

Problem unresolved, severe ----- (4)

↓

←

Stop patient treatment. If the illness is possibly, probably, or definitely related to study medication, submit the FDA MedWatch Report.

8. Is the patient taking any medication for Raynaud's phenomenon other than assigned study medication? ----- (1) (2)
 Yes No
 ↓

ANY MEDS

Patients should not take any non-study medication for Raynaud's phenomenon during the course of the study.

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9. Has the patient started to take any medications for conditions other than Raynaud's phenomenon since the last visit? (1) (2)
 Yes No
 ↓

OTHER MEDS

Generic Name	Dose per day
A. <i>MEDLARMK</i>	
B. <i>MEDLBENK</i>	
C. <i>MEDSCRMK</i>	
D. Are any of the above medications vasodilators? (1) (2) Yes No	

VASO

10. Is the patient assigned to study biofeedback? (1) (2)
 Yes No
 ↓

BIOASS

A. How often did the patient practice biofeedback during the past month? (Check one answer)

BIO MONTH

Never (1)
 Rarely (2)
 Sometimes (3)
 Daily (4)
 ↓

If daily, skip to Item 11.

B. Why didn't the patient practice biofeedback daily? (Check one answer.)

BIO DAILY

Forgetfulness (1)
 Too busy (2)
 Didn't need it (3)
 Too much trouble (4)
 Feeling pain, sick, or worsening condition (5)
 Doesn't think biofeedback works (6)
 Other (7)
 If Other, describe: *Bio_RMK*

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MEDS

11. Is the patient assigned to study medication? (1) (2)
 Yes No
 ↓

A. What is the patient's estimate of the percent of prescribed medication he/she has taken: ESTHED %

1. If < 90%, indicate the reason (check one answer):

Forgetfulness ESTREAS (01)

Too busy (02)

Didn't need it (03)

Side effects (04)

Feeling pain, sick, or worsening condition (05)

Doesn't think medication works (06)

Clinical Unit staff told patient to reduce dose (07)

Other (08)

If Other, describe: EST_RMK

B. How often does the patient take more than the prescribed dose of study medication?

Never MOREMEDS (1)

Rarely (2)

Sometimes (3)

Often (4)

C. When the patient forgets to take his/her study medication, does he/she (check one answer):

Take an extra dose FORGMED (1)

Skip the missed dose (2)

Take the dose at another time (3)

Never forgets medication (4)

Study medication discontinued (5)

Other (6)

If Other, describe: FORG-RMK

D. How many pills per day of study medication are being prescribed for the patient at this visit? MED_DSE

Part III: Patient Assessment of Raynaud's Symptoms and Treatment

12. Number of Raynaud's attacks in an average week: NBR_WK

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13. The patient considers his/her Raynaud's phenomenon:

PTCLASS

- Mild ()
- Moderate ()
- Severe ()
- Very severe ()

14. The patient considers Raynaud's phenomenon to affect his/her life:

PTLIFE

- None ()
- Sometimes ()
- Often ()
- Always ()

15. The patient believes the study treatment has had the following effect on his/her Raynaud's phenomenon:

STUDYTR

- Improved a lot ()
- Improved some ()
- No change ()
- Worsened some ()
- Worsened a lot ()

16. The patient feels:

PTFEELS

- Very well ()
- Well ()
- Ill ()
- Very ill ()

Part IV: Physician's Assessment of Raynaud's Symptoms and Treatment

17. The patient's Raynaud's phenomenon is:

PHYSCLASS

- Mild ()
- Moderate ()
- Severe ()
- Very severe ()

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18. Raynaud's phenomenon affects the patient's life:

LIFE

- None ()
- Sometimes ()
- Often ()
- Always ()

19. Study treatment has had the following effect on the patient's Raynaud's phenomenon:

TRE EFF

- Improved a lot ()
- Improved some ()
- No change ()
- Worsened some ()
- Worsened a lot ()

20. The patient is:

PTIS

- Very well ()
- Well ()
- Ill ()
- Very ill ()

Part V: Physical Examination

21. Weight: pounds

22. Temperature: °F

TEMP

A. Check method:

- Oral ()
- Other ()

METHOD

23. Blood pressure (sitting):

A. Systolic mm Hg

SYS

B. Diastolic mm Hg

DIAS

24. Pulse (sitting): beats/minute

PULSE

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EXTVALUE

25. Do blood pressure and/or pulse measurements represent extreme values? ----- (1) (2)
 Yes No
 ↓

A. Extreme value is:		EXTVAL
Not related to study treatment -----	(1)	
Possibly related to study treatment -----	(2)	
Probably related to study treatment -----	(3)	
Definitely related to study treatment -----	(4)	
B. Action taken:		EXTBL
Study treatment stopped -----	(1)	
Dosage of study medication reduced (medication group only) (Daily dose reduced from 2 pills to 1) -----	(2)	
No action taken -----	(3)	

HEENTABN

26. HEENT abnormal? ----- (1) (2)
 Yes No
 ↓

A. Briefly describe: _____		HEENTDNC
B. Extreme value is:		HEENT-B1
Not related to study treatment -----	(1)	
Possibly related to study treatment -----	(2)	
Probably related to study treatment -----	(3)	
Definitely related to study treatment -----	(4)	
C. Action taken:		HEENT-C1
Study treatment stopped -----	(1)	
Dosage of study medication reduced (medication group only) (Daily dose reduced from 2 pills to 1) -----	(2)	
No action taken -----	(3)	

CPABN

27. Cardio-pulmonary examination abnormal? ----- (1) (2)
 Yes No
 ↓

A. Briefly describe: _____		CPA-RMK
B. Extreme value is:		CPB1
Not related to study treatment -----	(1)	
Possibly related to study treatment -----	(2)	
Probably related to study treatment -----	(3)	
Definitely related to study treatment -----	(4)	
C. Action taken:		CPC1
Study treatment stopped -----	(1)	
Dosage of study medication reduced (medication group only) (Daily dose reduced from 2 pills to 1) -----	(2)	
No action taken -----	(3)	

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SKIN ABN

28. Skin abnormal? ----- (1) (2)
 Yes No
 ↓

A. Briefly describe: SKIN ABN

B. Extreme value is: SKIN 2

Not related to study treatment ----- (1)
 Possibly related to study treatment ----- (2)
 Probably related to study treatment ----- (3)
 Definitely related to study treatment ----- (4)

C. Action taken: SKIN 2

Study treatment stopped ----- (1)
 Dosage of study medication reduced (medication group only) (Daily dose reduced from 2 pills to 1) ----- (2)
 No action taken ----- (3)

EXTRE ABN

29. Extremities abnormal? ----- (1) (2)
 Yes No
 ↓

A. Briefly describe: EXTRE ABN

B. Extreme value is: EXTRE 2

Not related to study treatment ----- (1)
 Possibly related to study treatment ----- (2)
 Probably related to study treatment ----- (3)
 Definitely related to study treatment ----- (4)

C. Action taken: EXTRE 2

Study treatment stopped ----- (1)
 Dosage of study medication reduced (medication group only) (Daily dose reduced from 2 pills to 1) ----- (2)
 No action taken ----- (3)

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30. Is this Monitoring Visit 1 (M01) or Follow-up Visit 4 (FV04)? ----- () ()

Yes No
 ↓

A. Has blood specimen for safety evaluation been drawn? ----- DRAWN () ()
 Yes No

B. Is this Follow-up Visit 4? ----- VISIT 4 () ()
 Yes No

↓

1. Has blood specimen been sent to the Core Laboratory for ANA determination? ----- ANA CORE () ()
 Yes No

a. If YES, record titer. ----- 1: ANA 1

2. Assessment of nailfold capillaries Yes No

a. Uniform distribution of capillaries? ----- NAILA () ()

b. Capillary loop with < 100μ in the distal row? ----- NAILB () ()

c. Capillary loop is without marked tortuosity or other deformation? ----- NAILC () ()

d. Edematous appearance? ----- NAILD () ()

e. Few, if any, capillary hemorrhages with normal outgrowth in the cuticle? ----- NAIL E () ()

f. Localized avascular areas? ----- NAIL F () ()

g. Any other definitely abnormal capillary microscopy findings? ----- NAIL G () ()

h. Does the patient have normal nailfold capillaries? ----- NAIL H () ()

(Items 30B2a, b, c, and e answered "Yes," and Items 30B2d, f, and g answered "No.")

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Part VI: Administrative Matters

.. Evaluating physician:

Name: _____

RTS Staff No.: _____

32. Research Coordinator:

Signature: _____

RTS Staff No.: _____

33. Date form completed: _____

Month Day Year

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Part I: Visit Identification

1. Patient's initials:
2. Date of examination: F13-DAYS
 Month Day Year

Part II: History

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

EVERSMK

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

1) If yes, specify number of cigarettes smoked per day: - - NINSMK

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

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)

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

A. Patient's average daily alcohol intake is:

1. Bottles of beer: BEER

2. Glasses of wine: WINE

3. Ounces of liquor: LIQUOR

5. Is the patient pregnant? (1) (2) PREG
 Yes No
 ↓

STOP study medication.

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6. Has the patient had any illnesses since the last visit? (1) (2) *ILL*
 Yes No

A. Briefly describe: *ILL - RMK*

B. Describe the relationship between the illness(es) and study medication (Check all that apply.):

(1) None of the illness(es) is *ILL SM1* related to study medication (1)

(2) At least one illness is possibly *ILL SM2* related to study medication (1)

(3) At least one illness is probably *ILL SM3* related to study medication (1)

(4) At least one illness is definitely *ILL SM4* related to study medication (1)

C. Action taken: *ILL ACT*

Study medication stopped (1)

Dosage of study medication reduced (2)
 (Daily dose reduced from 2 pills to 1)

No action taken (3)

D. Resolution at time of this examination: *ILL RES*

Problem resolved (1)

Problem unresolved, mild (2)

Problem unresolved, moderate (3)

Schedule Interim Follow-up Visit.

Problem unresolved, severe (4)

Stop patient medication. If the illness is possibly, probably, or definitely related to study medication, submit the FDA MedWatch Report.

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SIDE EFF

7. Has the patient experienced any conditions that might be side effects of study medication? ----- (1) (2)
 Yes No

A. Briefly describe: SIDE-RMK

B. This condition is: SIDE-SM
 Not related to study medication ----- (1)
 Possibly related to study medication ----- (2)
 Probably related to study medication ----- (3)
 Definitely related to study medication --- (4)

C. Action taken: SID-ACT
 Study medication stopped ----- (1)
 Dosage of study medication reduced ----- (2)
 (Daily dose reduced from 2 pills to 1)
 No action taken ----- (3)

D. Resolution at time of this examination: SID-REL
 Problem resolved ----- (1)
 Problem unresolved, mild ----- (2)
 Problem unresolved, moderate ----- (3)

Schedule Interim Follow-up Visit.

Problem unresolved, severe ----- (4)

Stop patient medication. If the illness is possibly, probably, or definitely related to study medication, submit the FDA MedWatch Report.

8. Is the patient taking any medication for Raynaud's phenomenon other than assigned study medication? ----- (1) (2)
 Yes No

ANY MEDS

Patients should not take any non-study medication for Raynaud's phenomenon during course of study.

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OTHER MED 1

9. Has the patient started to take any medications for conditions other than Raynaud's phenomenon since the last visit? (1) (2)
 Yes No

Generic Name	Dose per day
A. MED 3 ARMK	
B. MED 3 BEMK	
C. MED 1 CEMK	
D. Are any of the above medications vasodilators? (1) (2) Yes No	

VAS

BIOAS

10. Is the patient assigned to study biofeedback? (1) (2)
 Yes No

A. How often did the patient practice biofeedback during the past month? (Check one answer.)

BIO MONTH

- Never (1)
- Rarely (2)
- Sometimes (3)
- Daily (4)

If daily, skip to Item 11.

B. Why didn't the patient practice biofeedback daily? (Check one answer.)

BIO DAILY

- Forgetfulness (1)
 - Too busy (2)
 - Didn't need it (3)
 - Too much trouble (4)
 - Feeling pain, sick, or worsening condition (5)
 - Doesn't think biofeedback works (6)
 - Other (7)
- If other, describe: BIO EMK

~~11. Is the patient assigned to study medication? (1) (2)
 Yes No~~

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MEGASS

11. Is the patient assigned to study medication? ----- (1) (2)
 Yes No
 ↓

A. What is the patient's estimate of the percent of prescribed medication he/she has taken: ----- ESTMED %

1. If < 90%, indicate the reason (check one answer):

Forgetfulness ----- ESTREFAS (01)
 Too busy ----- (02)
 Don't need it ----- (03)
 Side effects ----- (04)
 Feeling pain, sick, or worsening condition ----- (05)
 Doesn't think medication works ----- (06)
 Clinical Unit staff told patient to reduce dose ----- (07)
 Other ----- (08)
 If Other, describe: EST-RMK

B. How often does the patient take more than the prescribed dose of study medication? MOREMEDS

Never ----- (1)
 Rarely ----- (2)
 Sometimes ----- (3)
 Often ----- (4)

C. When the patient forgets to take his/her study medication, does he/she (check one answer):

Take an extra dose ----- FOLG MED (1)
 Skip the missed dose ----- (2)
 Take the dose at another time ----- (3)
 Never forgets medication ----- (4)
 Study medication discontinued ----- (5)
 Other ----- (6)
 If Other, describe: FOLG-RMK

D. How many pills per day of study medication are being prescribed for the patient at this visit? ----- MED-NBR

Part III: Patient Assessment of Raynaud's Symptoms and Treatment

NBR - WJK

12. Number of Raynaud's attacks in an average week: -----

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13. The patient considers his/her Raynaud's phenomenon:

PTCLASS

- Mild (1)
- Moderate (2)
- Severe (3)
- Very severe (4)

14. The patient considers Raynaud's phenomenon to affect his/her life:

PTLIFE

- None (1)
- Sometimes (2)
- Often (3)
- Always (4)

15. The patient believes the study treatment has had the following effect on his/her Raynaud's phenomenon:

STUDYTRT

- Improved a lot (1)
- Improved some (2)
- No change (3)
- Worsened some (4)
- Worsened a lot (5)

16. The patient feels:

PTFEELS

- Very well (1)
- Well (2)
- Ill (3)
- Very ill (4)

Part IV: Physician's Assessment of Raynaud's Symptoms and Treatment

17. The patient's Raynaud's phenomenon is:

PHYSAS

- Mild (1)
- Moderate (2)
- Severe (3)
- Very severe (4)

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18. Raynaud's phenomenon affects the patient's life: LIFE

None (1)
 Sometimes (2)
 Often (3)
 Always (4)

19. Study treatment has had the following effect on the patient's Raynaud's phenomenon: TRLEFF

Improved a lot (1)
 Improved some (2)
 No change (3)
 Worsened some (4)
 Worsened a lot (5)

20. The patient is: PTIS

Very well (1)
 Well (2)
 Ill (3)
 Very ill (4)

Part V: Physical Examination

21. Weight: pounds

22. Temperature: TEMP °F

A. Check method: METHOD

Oral (1)
 Other (2)

23. Blood pressure (sitting):

A. Systolic SYS mm Hg
 B. Diastolic DIAS mm Hg

24. Pulse (sitting): PULSE beats/minute

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EXTVALUE

25. Do blood pressure and/or pulse measurements represent extreme values? (1) (2)
 Yes No
 ↓

A. Extreme value is: <u>EXTA</u>	
Not related to study medication	(1)
Possibly related to study medication	(2)
Probably related to study medication	(3)
Definitely related to study medication	(4)
B. Action taken: <u>EXTS</u>	
Study medication stopped	(1)
Dosage of study medication reduced	(2)
(Daily dose reduced from 2 pills to 1)	
No action taken:	(3)

HEENTAB

26. HEENT abnormal? (1) (2)
 Yes No
 ↓

A. Briefly describe: <u>HEENTRMK</u>	
.....	
B. This abnormality is: <u>HEENTLB</u>	
Not related to study medication	(1)
Possibly related to study medication	(2)
Probably related to study medication	(3)
Definitely related to study medication	(4)
C. Action taken: <u>HEENTC</u>	
Study medication stopped	(1)
Dosage of study medication reduced	(2)
(Daily dose reduced from 2 pills to 1)	
No action taken	(3)

CPABN

27. Cardio-pulmonary examination abnormal? (1) (2)
 Yes No
 ↓

A. Briefly describe: <u>CPARMK</u>	
.....	
B. This abnormality is: <u>CPB</u>	
Not related to study medication	(1)
Possibly related to study medication	(2)
Probably related to study medication	(3)
Definitely related to study medication	(4)
C. Action taken: <u>CPC</u>	
Study medication stopped	(1)
Dosage of study medication reduced	(2)
(Daily dose reduced from 2 pills to 1)	
No action taken	(3)

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SKIN ABN

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

A. Briefly describe: SKIN ARMK

B. This abnormality is:

Not related to study medication SKINB (1)
 Possibly related to study medication (2)
 Probably related to study medication (3)
 Definitely related to study medication --- (4)

C. Action taken:

Study medication stopped SKINC (1)
 Dosage of study medication reduced (2)
 (Daily dose reduced from 2 pills to 1)
 No action taken (3)

EXTRABN

29. Extremities abnormal? (1) (2)
 Yes No

A. Briefly describe: EXTRABNK

B. This abnormality is:

Not related to study medication .. EXTRB (1)
 Possibly related to study medication (2)
 Probably related to study medication (3)
 Definitely related to study medication --- (4)

C. Action taken:

Study medication stopped EXTRC (1)
 Dosage of study medication reduced (2)
 (Daily dose reduced from 2 pills to 1)
 No action taken (3)

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30. Is this Monitoring Visit 1 (M01) or Follow-up Visit 4 (FV04)? (1) (2) *MVORFV*
 Yes No

A. Has blood specimen for safety evaluation been drawn? .. *DRAWN* (1) (2)
 Yes No

B. Is this Follow-up Visit 4? *VISIT 4* (1) (2)
 Yes No

1. Has blood specimen been sent to the Core Laboratory for ANA determination? *ANA-COLE* (1) (2)
 Yes No

a. If yes, record titer. 1: *ANA 1*

2. Assessment of nailfold capillaries

- | | Yes | No |
|-----------------------------------------------------------------------------------|-------|---------------------|
| a. Uniform distribution of capillaries? | (1) | (2) <i>NAIL A</i> |
| b. Capillary loop width <100µ in the distal row? | (1) | (2) <i>NAIL B</i> |
| c. Capillary loop is without marked tortuosity or other deformation? | (1) | (2) <i>NAIL C</i> |
| d. Edematous appearance? | (1) | (2) <i>NAIL D</i> |
| e. Few, if any, capillary hemorrhages with normal outgrowth in the cuticle? | (1) | (2) <i>NAIL E</i> |
| f. Localised avascular areas? | (1) | (2) <i>NAIL F</i> |
| g. Any other definitely abnormal capillary microscopy findings? | (1) | (2) <i>NAIL G</i> |
| h. Does the patient have normal nailfold capillaries? | (1) | (2) <i>NAIL H</i> |
- (Items 30B2a, b, c, and e answered "Yes," and Items 30B2d, f, and g answered "No.")

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Part VI: Administrative Matters

11. Evaluating physician:

Name: _____

RTS Staff No.: ____ - ____

32. Research Coordinator:

Signature: _____

RTS Staff No.: ____ - ____

33. Date form completed: -----
Month Day Year

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CLINICAL MONITORING FORM

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Part I: Visit Identification

1. Patient's initials:
2. Date of examination: F13 DAYS
 Month Day Year

Part II: History

3. Has the patient ever smoked cigarettes? () ()
 Yes No
 ↓

EVERSMK

A. Does the patient currently smoke cigarettes? CUERSMK () ()
 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 ()
 Six months to one year ago ()
 One to two years ago ()
 More than two years ago ()

4. Does the patient ever use alcoholic beverages? ALCH-USE () ()
 Yes No
 ↓

A. Patient's average daily alcohol intake is:

1. Bottles of beer: BEER

2. Glasses of wine: WINE

3. Ounces of liquor: LIQUOR

5. Is the patient pregnant? PREG () ()
 Yes No
 ↓

STOP study medication.

ID No.		-			
Form Type	C	M			

6. Has the patient had any illnesses since the last visit? () () *ILL*
 Yes No
 ↓

A. Briefly describe: *ILL - RMK*

B. Describe the relationship between the illness(es) and study medication (Check all that apply.):

(1) None of the illness(es) is related to study medication ()

(2) At least one illness is possibly related to study medication ()

(3) At least one illness is probably related to study medication ()

(4) At least one illness is definitely related to study medication ()

C. Action taken: *ILL ACT*

Study medication stopped ()

Dosage of study medication reduced ()
 (Daily dose reduced from 2 pills to 1)

No action taken ()

D. Resolution at time of this examination: *ILL RES*

Problem resolved ()

Problem unresolved, mild ()

Problem unresolved, moderate ()

Schedule Interim Follow-up Visit.

Problem unresolved, severe ()

Stop patient medication. If the illness is possibly, probably, or definitely related to study medication, submit the FDA MedWatch Report.

ILL SM3
ILL SM2
ILL SM3
ILL SM4

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SIDE EFF

7. Has the patient experienced any conditions that might be side effects of study medication? ----- (1) (2)
 Yes No
 ↓

A. Briefly describe: SIDE-EAK

B. This condition is: SIDE SM
 Not related to study medication ----- (1)
 Possibly related to study medication ----- (2)
 Probably related to study medication ----- (3)
 Definitely related to study medication --- (4)

C. Action taken: SID-ACT
 Study medication stopped ----- (1)
 Dosage of study medication reduced ----- (2)
 (Daily dose reduced from 2 pills to 1)
 No action taken ----- (3)

D. Resolution at time of this examination: SID-REL
 Problem resolved ----- (1)
 Problem unresolved, mild ----- (2)
 Problem unresolved, moderate ----- (3)

Schedule Interim Follow-up Visit.

Problem unresolved, severe ----- (4)

Stop patient medication. If the illness is possibly, probably, or definitely related to study medication, submit the FDA MedWatch Report.

8. Is the patient taking any medication for Raynaud's phenomenon other than assigned study medication? ----- (1) (2)
 Yes No
 ↓

ANY MEDS

Patients should not take any non-study medication for Raynaud's phenomenon during course of study.

ID No.		-			
Form Type	C	M			

OTHER MED

9. Has the patient started to take any medications for conditions other than Raynaud's phenomenon since the last visit? ----- (1) (2)
 Yes No
 ↓

Generic Name	Dose per day
A. MEDJACHK	
B. MED3BCHK	
C. MED2CENK	
D. Are any of the above medications vasodilators? ----- (1) (2) Yes No	VASO

BIOASS

10. Is the patient assigned to study biofeedback? ----- (1) (2)
 Yes No
 ↓

A. How often did the patient practice biofeedback during the past month? (Check one answer.)

BIO MONTH

- Never ----- (1)
- Rarely ----- (2)
- Sometimes ----- (3)
- Daily ----- (4)

If daily, skip to Item 11.

B. Why didn't the patient practice biofeedback daily? (Check one answer.)

BIO DAILY

- Forgetfulness ----- (1)
- Too busy ----- (2)
- Didn't need it ----- (3)
- Too much trouble ----- (4)
- Feeling pain, sick, or worsening condition ----- (5)
- Doesn't think biofeedback works ----- (6)
- Other ----- (7)
- If other, describe: BIO RMX

ID No.				
Form Type	C	M		

NEOASS

11. Is the patient assigned to study medication? ----- (1) (2)
 Yes No
 ↓

A. What is the patient's estimate of the percent of prescribed medication he/she has taken: ----- ESTMED %

1. If < 90%, indicate the reason (check one answer):

Forgetfulness ----- ESTREAS (01)
 Too busy ----- (02)
 Don't need it ----- (03)
 Side effects ----- (04)
 Feeling pain, sick, or worsening condition ----- (05)
 Doesn't think medication works ----- (06)
 Clinical Unit staff told patient to reduce dose ----- (07)
 Other ----- (08)
 If Other, describe: EST-LMK

B. How often does the patient take more than the prescribed dose of study medication? MORENEAS

Never ----- (1)
 Rarely ----- (2)
 Sometimes ----- (3)
 Often ----- (4)

C. When the patient forgets to take his/her study medication, does he/she (check one answer): FORG-NEA

Take an extra dose ----- (1)
 Skip the missed dose ----- (2)
 Take the dose at another time ----- (3)
 Never forgets medication ----- (4)
 Study medication discontinued ----- (5)
 Other ----- (6)
 If Other, describe: FORG-RML

D. How many pills per day of study medication are being prescribed for the patient at this visit? ----- MED-NBR

Part III: Patient Assessment of Raynaud's Symptoms and Treatment

12. Number of Raynaud's attacks in an average week: ----- NBR-WK

ID No.				
Form Type	C	M		

13. The patient considers his/her Raynaud's phenomenon: PT ASS

Mild (1)
 Moderate (2)
 Severe (3)
 Very severe (4)

14. The patient considers Raynaud's phenomenon to affect his/her life: PT LIFE

None (1)
 Sometimes (2)
 Often (3)
 Always (4)

15. The patient believes the study treatment has had the following effect on his/her Raynaud's phenomenon: STUDY TRT

Improved a lot (1)
 Improved some (2)
 No change (3)
 Worsened some (4)
 Worsened a lot (5)

16. The patient feels: PT FEELS

Very well (1)
 Well (2)
 Ill (3)
 Very ill (4)

Part IV: Physician's Assessment of Raynaud's Symptoms and Treatment

17. The patient's Raynaud's phenomenon is: PHYS ASS

Mild (1)
 Moderate (2)
 Severe (3)
 Very severe (4)

ID No.				
Form Type	C	M		

18. Raynaud's phenomenon affects the patient's life:

LIFE

- None (1)
- Sometimes (2)
- Often (3)
- Always (4)

19. Study treatment has had the following effect on the patient's Raynaud's phenomenon:

TRT. EFF

- Improved a lot (1)
- Improved some (2)
- No change (3)
- Worsened some (4)
- Worsened a lot (5)

20. The patient is:

PTIS

- Very well (1)
- Well (2)
- Ill (3)
- Very ill (4)

Part V: Physical Examination

21. Weight: pounds

22. Temperature: °F

TEMP

A. Check method:

METHOD

- Oral (1)
- Other (2)

23. Blood pressure (sitting):

- A. Systolic *SYS* mm Hg
- B. Diastolic *DIAS* mm Hg

24. Pulse (sitting): *PULSE* beats/minute

ID No.		-			
Form Type	G	M			

25. Do blood pressure and/or pulse measurements represent extreme values? ----- (1) (2)
 Yes No
 ↓

EXT VALUE

A. Extreme value is: *EXTA*

Not related to study medication ----- (1)
 Possibly related to study medication ----- (2)
 Probably related to study medication ----- (3)
 Definitely related to study medication --- (4)

B. Action taken: *EXTB*

Study medication stopped ----- (1)
 Dosage of study medication reduced ----- (2)
 (Daily dose reduced from 2 pills to 1)
 No action taken: ----- (3)

26. HEENT abnormal? ----- (1) (2)
 Yes No
 ↓

HEENTABN

A. Briefly describe: *HEENTRMK*

B. This abnormality is: *HEENTLB*

Not related to study medication ----- (1)
 Possibly related to study medication ----- (2)
 Probably related to study medication ----- (3)
 Definitely related to study medication --- (4)

C. Action taken: *HEENTC*

Study medication stopped ----- (1)
 Dosage of study medication reduced ----- (2)
 (Daily dose reduced from 2 pills to 1)
 No action taken ----- (3)

27. Cardio-pulmonary examination abnormal? ----- (1) (2)
 Yes No
 ↓

CPABN

A. Briefly describe: *CPA-RMK*

B. This abnormality is: *CPB*

Not related to study medication ----- (1)
 Possibly related to study medication ----- (2)
 Probably related to study medication ----- (3)
 Definitely related to study medication --- (4)

C. Action taken: *CPC*

Study medication stopped ----- (1)
 Dosage of study medication reduced ----- (2)
 (Daily dose reduced from 2 pills to 1)
 No action taken ----- (3)

ID No.		-			
Form Type	C	M			

SKINABN

28. Skin abnormal? (1) (2)
 Yes No
 ↓

A. Briefly describe: SKINABN

B. This abnormality is: SKINB

Not related to study medication (1)
 Possibly related to study medication (2)
 Probably related to study medication (3)
 Definitely related to study medication --- (4)

C. Action taken: SKINC

Study medication stopped (1)
 Dosage of study medication reduced (2)
 (Daily dose reduced from 2 pills to 1)
 No action taken (3)

EXTRABN

29. Extremities abnormal? (1) (2)
 Yes No
 ↓

A. Briefly describe: EXTRABN

B. This abnormality is: EXTRB

Not related to study medication (1)
 Possibly related to study medication (2)
 Probably related to study medication (3)
 Definitely related to study medication --- (4)

C. Action taken: EXTRC

Study medication stopped (1)
 Dosage of study medication reduced (2)
 (Daily dose reduced from 2 pills to 1)
 No action taken (3)

ID No.				
Form Type	G	M		

30. Is this Monitoring Visit 1 (M01) or Follow-up Visit 4 (FV04)? ----- (1) (2)
 Yes No
 ↓

A. Has blood specimen for safety evaluation been drawn? -- DRAWN (1) (2)
 Yes No
 ↓

B. Is this Follow-up Visit 4? ----- VISIT 4 (1) (2)
 Yes No
 ↓

1. Has blood specimen been sent to the Core Laboratory for ANA determination? ----- ANA CORE (1) (2)
 Yes No
 ↓

a. If yes, record titer. ----- 1: ANA 1

2. Assessment of nailfold capillaries

		Yes	No
a. Uniform distribution of capillaries? -----	(1)	(2)	<u>NAIL A</u>
b. Capillary loop width <100µ in the distal row? -----	(1)	(2)	<u>NAIL B</u>
c. Capillary loop is without marked tortuosity or other deformation? -----	(1)	(2)	<u>NAIL C</u>
d. Edematous appearance? -----	(1)	(2)	<u>NAIL D</u>
e. Few, if any, capillary hemorrhages with normal outgrowth in the cuticle? -----	(1)	(2)	<u>NAIL E</u>
f. Localized avascular areas? -----	(1)	(2)	<u>NAIL F</u>
g. Any other definitely abnormal capillary microscopy findings? -----	(1)	(2)	<u>NAIL G</u>
h. Does the patient have normal nailfold capillaries? ----- (Items 30B2a, b, c, and e answered "Yes," and Items 30B2d, f, and g answered "No.")	(1)	(2)	<u>NAIL H</u>

3. Has the medication unblinding envelope been attached to this form? ----- (1) (2)
 Yes No

UNBL ATT

ID No.		-			
Form Type	C	M			

Part VI: Administrative Matters

31. Evaluating physician:

Name: _____

RTS Staff No.: ____-____-____

32. Research Coordinator:

Signature: _____

RTS Staff No.: ____-____-____

33. Date form completed: _____

____/____/____
 Month Day Year

FOR COORDINATING CENTER USE ONLY

34. Unblinding envelope attached? ----- (1) (2)
 Yes No

ID No.		-			
Form Type	C	M			

CLINICAL MONITORING FORM

ID No.				
Form Type	C	M		

Part I: Visit Identification

1. Patient's initials:

2. Date of examination: F13 DAYS
Month Day Year

Part II: History

EVERSMK

3. 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)

4. Does the patient ever use alcoholic beverages? ALCH USE (1) (2)
Yes No
↓

A. Patient's average daily alcohol intake is:

1. Bottles of beer: BEER

2. Glasses of wine: WINE

3. Ounces of liquor: LIQUOR

PREG

5. Is the patient pregnant? (1) (2)
Yes No
↓

STOP study medication.

ID No.				
Form Type	C	M		

6. Has the patient had any illnesses since the last visit? ----- (1) (2) ILLN
 Yes No
 ↓

A. Briefly describe: ILL-RMK

B. This illness is: ILL-SH
 Not related to study medication ----- (1)
 Possibly related to study medication ----- (2)
 Probably related to study medication ----- (3)
 Definitely related to study medication --- (4)

C. Action taken: ILL-AC T
 Study medication stopped ----- (1)
 Dosage of study medication reduced ----- (2)
 (Daily dose reduced from 2 pills to 1)
 No action taken ----- (3)

D. Resolution at time of this examination: ILL-RES
 Problem resolved ----- (1)
 Problem unresolved, mild ----- (2)
 Problem unresolved, moderate ----- (3)

Schedule Interim Follow-up Visit.

Problem unresolved, severe ----- (4)

Stop patient medication. If the illness is possibly, probably, or definitely related to study medication, submit the FDA MedWatch Report.

ID No.		-			
Form Type	C	M			

SIDE EFF

7. Has the patient experienced any conditions that might be side effects of study medication? (1) (2)
 Yes No
 ↓

A. Briefly describe: SIDE-RMK

B. This illness is: SIDE EFF
 Not related to study medication (1)
 Possibly related to study medication (2)
 Probably related to study medication (3)
 Definitely related to study medication --- (4)

C. Action taken: SIDE ACT
 Study medication stopped (1)
 Dosage of study medication reduced (2)
 (Daily dose reduced from 2 pills to 1)
 No action taken (3)

D. Resolution at time of this examination: SIDE REL
 Problem resolved (1)
 Problem unresolved, mild (2)
 Problem unresolved, moderate (3)
 Problem unresolved, severe (4)

Schedule Interim Follow-up Visit.

Stop patient medication. If the illness is possibly, probably, or definitely related to study medication, submit the FDA MedWatch Report.

8. Is the patient taking any medication for Raynaud's phenomenon other than assigned study medication? (1) (2)
 Yes No
 ↓

ANY MEDS

Patients should not take any non-study medication for Raynaud's phenomenon during course of study.

ID No.		-			
Form Type	C	M			

OTHER MEDS

9. Has the patient started to take any medications for conditions other than Raynaud's phenomenon since the last visit? ----- (1) (2)
 Yes No
 ↓

Generic Name	Dose per day
A. <i>MEOSAMK</i>	
B. <i>MEOBAMK</i>	
C. <i>MEOCAMK</i>	
D. Are any of the above medications vasodilators? ----- (1) (2) Yes No	<i>VASO</i>

BIOASS

10. Is the patient assigned to study biofeedback? ----- (1) (2)
 Yes No
 ↓

A. How often did the patient practice biofeedback during the past month? (Check one answer.) *BIO MONTH*

Never ----- (1)
 Rarely ----- (2)
 Sometimes ----- (3)
 Daily ----- (4)
 ↓

If daily, skip to Item 11.

B. Why didn't the patient practice biofeedback daily? (Check one answer.) *BIO DAILY*

Forgetfulness ----- (1)
 Too busy ----- (2)
 Didn't need it ----- (3)
 Too much trouble ----- (4)
 Feeling pain, sick, or worsening condition ----- (5)
 Doesn't think biofeedback works ----- (6)
 Other ----- (7)
 If other, describe: *BIO LMK*

ID No.					
Form Type	C	M			

MEGASS

11. Is the patient assigned to study medication? (1) (2)
 Yes No
 ↓

A. What is the patient's estimate of the percent of prescribed medication he/she has taken: ESTMED %
 If < 90%, indicate the reason (check one answer):

Forgetfulness ESTREAS (1)
 Too busy (2)
 Don't need it (3)
 Side effects (4)
 Feeling pain, sick, or worsening condition (5)
 Doesn't think medication works (6)
 Clinical Unit staff told patient to reduce dose (7)
 Other (8)
 If Other, describe: ESTRMK

B. How often does the patient take more than the prescribed dose of study medication? MORENEOS

Never (1)
 Rarely (2)
 Sometimes (3)
 Often (4)

C. When the patient forgets to take his/her study medication, does he/she (check one answer):

Take an extra dose FORGMED (1)
 Skip the missed dose (2)
 Take the dose at another time (3)
 Never forgets medication (4)
 Study medication discontinued (5)
 Other (6)
 If Other, describe: FORGRMK

D. How many pills per day of study medication are being prescribed for the patient at this visit? MEDNR

Part III: Patient Assessment of Raynaud's Symptoms and Treatment

NCR DAY

12. Number of Raynaud's attacks on an average day:

ID No.		-			
Form Type	C	M			

13. The patient considers his/her Raynaud's phenomenon:

- Mild (1)
- Moderate (2)
- Severe (3)
- Very severe (4)

PLEASE

14. The patient considers Raynaud's phenomenon to affect his/her life:

- None (1)
- Sometimes (2)
- Often (3)
- Always (4)

PT LIFE

15. The patient believes the study treatment has had the following effect on his/her Raynaud's phenomenon:

- Improved a lot (1)
- Improved some (2)
- No change (3)
- Worsened some (4)
- Worsened a lot (5)

STUDY TRT

16. The patient feels:

- Very well (1)
- Well (2)
- Ill (3)
- Very ill (4)

PT FEELS

Part IV: Physician's Assessment of Raynaud's Symptoms and Treatment

17. The patient's Raynaud's phenomenon is:

- Mild (1)
- Moderate (2)
- Severe (3)
- Very severe (4)

PHYS-AS

ID No.		-			
Form Type	G	M			

18. Raynaud's phenomenon affects the patient's life:

- None (1) *LIFE*
- Sometimes (2)
- Often (3)
- Always (4)

19. Study treatment has had the following effect on the patient's Raynaud's phenomenon:

- Improved a lot (1) *TET EFF*
- Improved some (2)
- No change (3)
- Worsened some (4)
- Worsened a lot (5)

20. The patient is:

- Very well (1) *PTD*
- Well (2)
- Ill (3)
- Very ill (4)

Part V: Physical Examination

21. Weight: pounds

22. Temperature: °F *TEMP*

A. Check method:

- Oral (1) *METHOD*
- Other (2)

23. Blood pressure (sitting):

- A. Systolic *SYS* mm Hg
- B. Diastolic *DIAS* mm Hg

24. Pulse (sitting): *Pulse* beats/minute

ID No.		-		
Form Type	C	M		

25. Do blood pressure and/or pulse measurements represent extreme values? ----- (1) (2)
 Yes No
 ↓

EXT VALUE

A. Extreme value is:	
Not related to study medication -----	(1)
Possibly related to study medication -----	(2)
Probably related to study medication -----	(3)
Definitely related to study medication ---	(4)
B. Action taken:	
Study medication stopped -----	(1)
Dosage of study medication reduced ----- (Daily dose reduced from 2 pills to 1)	(2)
No action taken: -----	(3)

26. HEENT abnormal? ----- (1) (2)
 Yes No
 ↓

HEENT

A. Briefly describe: <u>HEENT-RNK</u>	
B. This abnormality is:	
Not related to study medication -----	(1)
Possibly related to study medication -----	(2)
Probably related to study medication -----	(3)
Definitely related to study medication ---	(4)
C. Action taken:	
Study medication stopped -----	(1)
Dosage of study medication reduced ----- (Daily dose reduced from 2 pills to 1)	(2)
No action taken -----	(3)

CPABN

27. Cardio-pulmonary examination abnormal? ----- (1) (2)
 Yes No
 ↓

A. Briefly describe: <u>CPA-RNK</u>	
B. This abnormality is:	
Not related to study medication -----	(1)
Possibly related to study medication -----	(2)
Probably related to study medication -----	(3)
Definitely related to study medication ---	(4)
C. Action taken:	
Study medication stopped -----	(1)
Dosage of study medication reduced ----- (Daily dose reduced from 2 pills to 1)	(2)
No action taken -----	(3)

ID No.				
Form Type	C	M		

SKINABN

28. Skin abnormal? () ()
 Yes No
 ↓

A. Briefly describe: SKINARMK

B. This abnormality is: SKINB
 Not related to study medication ()
 Possibly related to study medication ()
 Probably related to study medication ()
 Definitely related to study medication --- ()

C. Action taken: SKINC
 Study medication stopped ()
 Dosage of study medication reduced ()
 (Daily dose reduced from 2 pills to 1)
 No action taken ()

EXTRABN

29. Extremities abnormal? () ()
 Yes No
 ↓

A. Briefly describe: EXTRARMK

B. This abnormality is: EXTRB
 Not related to study medication ()
 Possibly related to study medication ()
 Probably related to study medication ()
 Definitely related to study medication --- ()

C. Action taken: EXTRC
 Study medication stopped ()
 Dosage of study medication reduced ()
 (Daily dose reduced from 2 pills to 1)
 No action taken ()

ID No.				
Form Type	C	M		

30. Is this Monitoring Visit 1 (M01) or Follow-up Visit 4 (FV04)? ----- (1) (2)
 Yes No
 ↓

A. Has blood specimen for safety evaluation been drawn? *-DRAWN* (1) (2)
 Yes No

B. Is this Follow-up Visit 4? *V0174* ----- (1) (2)
 Yes No
 ↓

1. Has blood specimen been sent to the Core Laboratory for ANA determination? ----- (1) (2)
 Yes No
 ↓
ANA-CORE
ANA
 a. If yes, record titer. ----- 1: _____

2. Assessment of nailfold capillaries

- | | Yes | No |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------|-----|--------------|
| a. Uniform distribution of capillaries? ----- (1) (2) | | <i>NAILA</i> |
| b. Capillary loop width <100µ in the distal row? ----- (1) (2) | | <i>NAILB</i> |
| c. Capillary loop is without marked tortuosity or other deformation? ----- (1) (2) | | <i>NAILC</i> |
| d. Edematous appearance? ----- (1) (2) | | <i>NAILD</i> |
| e. Few, if any, capillary hemorrhages with normal outgrowth in the cuticle? ----- (1) (2) | | <i>NAILE</i> |
| f. Localized avascular areas? ----- (1) (2) | | <i>NAILF</i> |
| g. Any other definitely abnormal capillary microscopy findings? ----- (1) (2) | | <i>NAILG</i> |
| h. Does the patient have normal nailfold capillaries? ----- (1) (2)
(Items 30B2a, b, c, and e answered "Yes," and Items 30B2d, f, and g answered "No.") | | <i>NAILH</i> |

3. Has the medication unblinding envelope been attached to this form? ----- (1) (2)
 Yes No

ID No.				
Form Type	C	M		

Part VI: Administrative Matters

31. Evaluating physician:

Name: _____ RTS Staff No.: _____

32. Research Coordinator:

Signature: _____ RTS Staff No.: _____

33. Date form completed: _____
Month Day Year

FOR COORDINATING CENTER USE ONLY	
34. Unblinding envelope attached? _____	(1) (2) Yes No

ID No.		-			
Form Type	G	M			

FORM 13 (Rev. 0, 1, 2, 3)

CLINICAL MONITORING FORM

<u>ITEM</u>	<u>NAME</u>	<u>TYPE AND LENGTH</u>	<u>CODES OR UNITS</u>
HEADER	NEWID	I(4)	Patient ID
HEADER	FMTYP	CHAR(4)	CM01 - CM04
2	F13_DAYS	I(4)	Date of examination Days from randomization
3	EVERSMK	I(1)	1 = Yes, 2 = No
3A	CURRSMK	I(1)	1 = Yes, 2 = No
3A1	NUMSMK	I(3)	Cigarettes per day
3B	TIMESMK	I(1)	1 = < 6 months ago 2 = 6 months - 1 year ago 3 = 1-2 years ago 4 = > 2 years ago
4	ALCH_USE	I(1)	1 = Yes, 2 = No
4A1	BEER	F(4.1)	Bottles of beer/day
4A2	WINE	F(4.1)	Glasses of wine/day
4A3	LIQUOR	F(4.1)	Ounces of liquor/day
5	PREG	I(1)	1 = Yes, 2 = No
6	ILLLV	I(1)	1 = Yes, 2 = No
6A	ILL_RMK	CHAR(1)	1 = Remark written on form
	ILL1	I(1)	1 = Cold/Flu/Sinusitis
	ILL2	I(1)	1 = Diarrhea
	ILL3	I(1)	1 = Minor Infections
	ILL4	I(1)	1 = Joint Diseases
	ILL5	I(1)	1 = Muscle
	ILL6	I(1)	1 = Tumor
	ILL7	I(1)	1 = Gastric Complaints
	ILL8	I(1)	1 = Chest Pain
	ILL9	I(1)	1 = Rash/Urticaria
	ILL10	I(1)	1 = Headache/Lighthead/ Visual Changes
	ILL11	I(1)	1 = Gynecological Complaints
	ILL12	I(1)	1 = Insect Bites
	ILL13	I(1)	1 = Fatigue
	ILL14	I(1)	1 = Hernia
	ILL15	I(1)	1 = Hemorrhoids
	ILL16	I(1)	1 = Cholecystitis
	ILL17	I(1)	1 = Dermatological
	ILL18	I(1)	1 = Glaucoma
	ILL19	I(1)	1 = Eye Problems
	ILL20	I(1)	1 = Mood Change/Anxiety/Depression
	ILL21	I(1)	1 = Hypoglycemia
	ILL22	I(1)	1 = Cardiovascular
	ILL23	I(1)	1 = Plantar Warts
	ILL24	I(1)	1 = Allergies
	ILL25	I(1)	1 = Asthma
	ILL26	I(1)	1 = Dental Problems
	ILL27	I(1)	1 = Ischemia
	ILL28	I(1)	1 = Cold-induced Numbness

FORM 13 (Rev. 0, 1, 2, 3)
 CLINICAL MONITORING FORM
 (Continued)

<u>ITEM</u>	<u>NAME</u>	<u>TYPE</u>	<u>CODES OR UNITS</u>
6B*	ILL_SM	I(1)	1 = Not related 2 = Possibly related 3 = Probably related 4 = Definitely related
6C	ILL_ACT	I(1)	1 = Study medication stopped 2 = Dosage of study medication reduced 3 = No action taken
6D	ILL_RES	I(1)	1 = Problem resolved 2 = Problem unresolved, mild 3 = Problem unresolved, moderate 4 = Problem unresolved, severe
7	SIDEEFF	I(1)	1 = Yes, 2 = No
7A	SIDE_RMK	CHAR(1)	1 = Remark written on form
	SFX1	I(1)	1 = Swelling/Headaches/Light Headed
	SFX2	I(1)	1 = Flushing
	SFX3	I(1)	1 = Color Change in Extremities
	SFX4	I(1)	1 = Myalgia
	SFX5	I(1)	1 = Gastric Pain/Symptoms
	SFX6	I(1)	1 = Fatigue
	SFX7	I(1)	1 = Mood change/anxiety/jitters
	SFX8	I(1)	1 = Constipation
	SFX9	I(1)	1 = Cardiac (tachycardia/chest pain)
	SFX10	I(1)	1 = Heavy Menses
	SFX11	I(1)	1 = Extremity Pain
	SFX12	I(1)	1 = Dyspnea
	SFX13	I(1)	1 = Rash/Urticaria
	SFX14	I(1)	1 = Diarrhea
	SFX15	I(1)	1 = Bruising
	SFX16	I(1)	1 = Weight Gain/Loss
	SFX17	I(1)	1 = Tinnitus
	SFX18	I(1)	1 = Parasthesias
	SFX19	I(1)	1 = Impotence
	SFX20	I(1)	1 = Worsening Raynauds Attacks
7B*	SIDE_SM	I(1)	1 = Not related 2 = Possibly related 3 = Probably related 4 = Definitely related
7C	SID_ACT	I(1)	1 = Study medication stopped 2 = Dosage of study medication reduced 3 = No action taken

* Depending on the revision, there may be **four** questions for this item instead of one. In this event, the most serious code (highest number) is kept in the database.

FORM 13 (Rev. 0, 1, 2, 3)
 CLINICAL MONITORING FORM
 (Continued)

<u>ITEM</u>	<u>NAME</u>	<u>TYPE</u>	<u>CODES OR UNITS</u>
7D	SID_REL	I(1)	1 = Problem resolved 2 = Problem unresolved, mild 3 = Problem unresolved, moderate 4 = Problem unresolved, severe
8	ANYMEDS	I(1)	1 = Yes, 2 = No
9	OTHRMED1	I(1)	1 = Yes, 2 = No
9A	MED1ARMK	} CHAR(1)	1 = Remark written on form
9B	MED1BRMK		
9C	MED1CRMK		
9D	VASO		
10	BIOASS	I(1)	1 = Yes, 2 = No
10A	BIOMONTH	I(1)	1 = Never 2 = Rarely 3 = Sometimes 4 = Daily
10B	BIODAILY	I(1)	1 = Forgetfulness 2 = Too busy 3 = Didn't need it 4 = Too much trouble 5 = Feeling pain, sick or worsening condition 6 = Don't think biofeedback works 7 = Other
10B1	BIORMK	CHAR(1)	1 = Remark written on form
11	MEDASS	I(1)	1 = Yes, 2 = No
11A	ESTMED	I(3)	Percent
11A1	ESTREAS	I(1)	1 = Forgetfulness 2 = Too busy 3 = Don't need it 4 = Side effects 5 = Feeling pain, sick, worsening condition 6 = Doesn't think medication works 7 = Clinical unit staff told patient to reduce dose 8 = Other
11A1	EST_RMK	CHAR(1)	1 = Remark written on form
11B	MOREMEDS	I(1)	1 = Never 2 = Rarely 3 = Sometimes 4 = Often
11C	FORGMED	I(1)	1 = Take an extra dose 2 = Skip the missed dose 3 = Take the dose at another time 4 = Never forgets medication 5 = Study medication discontinued 6 = Other
11C	FORG_RMK	CHAR(1)	1 = Remark written on form

FORM 13 (Rev. 0, 1, 2, 3)
 CLINICAL MONITORING FORM
 (Continued)

<u>ITEM</u>	<u>NAME</u>	<u>TYPE</u>	<u>CODES OR UNITS</u>
11D	MED_NBR	I(1)	Pills per day
12 (REV 0)	NBR_DAY	I(2)	Attacks per day
12 (REV 1)	NBR_WK	F(4.1)	Attacks per week
13	PT_ASS	I(1)	1 = Mild 2 = Moderate 3 = Severe 4 = Very severe
14	PTLIFE	I(1)	1 = None 2 = Sometimes 3 = Often 4 = Always
15	STUDYTRT	I(1)	1 = Improved a lot 2 = Improved some 3 = No change 4 = Worsened some 5 = Worsened a lot
16	PTFEELS	I(1)	1 = Very well 2 = Well 3 = Ill 4 = Very ill
17	PHYS_ASS	I(1)	1 = Mild 2 = Moderate 3 = Severe 4 = Very severe
18	LIFE	I(1)	1 = None 2 = Sometimes 3 = Often 4 = Always
19	TRT_EFF	I(1)	1 = Improved a lot 2 = Improved some 3 = No change 4 = Worsened some 5 = Worsened a lot
20	PTIS	I(1)	1 = Very well 2 = Well 3 = Ill 4 = Very ill
22	TEMP	F(5.1)	Degrees F
22A	METHOD1	I(1)	1 = Oral, 2 = Other
23A	SYS	I(3)	mm Hg
23B	DIAS	I(3)	mm Hg
24	PULSE	I(3)	Beats per minute
25	EXTVALUE	I(1)	1 = Yes, 2 = No
25A	EXTA	I(1)	1 = Not related 2 = Possibly related 3 = Probably related

FORM 13 (Rev. 0, 1, 2, 3)
 CLINICAL MONITORING FORM
 (Continued)

<u>ITEM</u>	<u>NAME</u>	<u>TYPE</u>	<u>CODES OR UNITS</u>
			4 = Definitely related
25B	EXTB	I(1)	1 = Study medication stopped 2 = Dosage of study medication reduced 3 = No action taken
26	HEENTABN	I(1)	1 = Yes, 2 = No
26A	HEENTRMK	CHAR(1)	1 = Remark written on form
26B	HEENT_B	I(1)	1 = No related 2 = Possibly related 3 = Probably related 4 = Definitely related
26C	HEENT_C	I(1)	1 = Study medication stopped 2 = Dosage of study medication reduced 3 = No action taken
27	CPABN	I(1)	1 = Yes, 2 = No
27A	CPA_RMK	CHAR(1)	1 = Remark written on form
27B	CPB	I(1)	1 = Not related 2 = Possibly related 3 = Probably related 4 = Definitely related
27C	CPC	I(1)	1 = Study medication stopped 2 = Dosage of study medication reduced 3 = No action taken
28	SKINABN	I(1)	1 = Yes, 2 = No
28A	SKINARMK	CHAR(1)	1 = Remark written on form
28B	SKINB	I(1)	1 = Not related 2 = Possibly related 3 = Probably related 4 = Definitely related
28C	SKINC	I(1)	1 = Study medication stopped 2 = Dosage of study medication reduced 3 = No action taken
29	EXTRABN	I(1)	1 = Yes, 2 = No
29A	EXTRARMK	CHAR(1)	1 = Remark written on form
29B	EXTRB	I(1)	1 = Not related 2 = Possibly related 3 = Probably related 4 = Definitely related

FORM 13 (Rev. 0, 1, 2, 3)
 CLINICAL MONITORING FORM
 (Continued)

<u>ITEM</u>	<u>NAME</u>	<u>TYPE</u>	<u>CODES OR UNITS</u>		
29C	EXTRC	I(1)	1 = Study medication stopped 2 = Dosage of study medication reduced 3 = No action taken		
30	MVORFV	I(1)	1 = Yes, 2 = No		
30A	DRAWN	I(1)	1 = Yes, 2 = No		
30B	VISIT4	I(1)	1 = Yes, 2 = No		
30B1	ANA_CORE	I(1)	1 = Yes, 2 = No		
30B1A	ANA1	I(4)	Titer 1: _ _ _ _		
30B2A	NAILA	}			
30B2B	NAILB				
30B2C	NAILC				
30B2D	NAILD				
30B2E	NAILE			I(1)	1 = Yes, 2 = No
30B2F	NAILF				
30B2G	NAILG				
30B2H	NAILH				

CONTENTS PROCEDURE

Data Set Name:	RTS.FORM13	Observations:	917
Member Type:	DATA	Variables:	135
Engine:	V612	Indexes:	0
Created:	11:06 Thursday, April 27, 2000	Observation Length:	552
Last Modified:	11:06 Thursday, April 27, 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:	33
File Format:	607
First Data Page:	2
Max Obs per Page:	29
Obs in First Data Page:	28

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

#	Variable	Type	Len	Pos	Format	Informat	Label
6	ALCH_USE	Num	4	24	2.	BEST22.	f13q4 Patient uses alcoholic beverages
76	ANA1	Num	8	300	4.	BEST22.	f13q30b1a ANA titer 1:
75	ANA_CORE	Num	4	296	2.	BEST22.	f13q30b1 Blood sent to Core Lab
21	ANYMEDS	Num	4	90	2.	BEST22.	f13q8 Any other medication for Raynauds
7	BEER	Num	8	28	4.1	BEST22.	f13q4a1 Daily beer intake (bottles)
27	BIOASS	Num	4	105	2.	BEST22.	f13q10 Patient assigned to biofeedback
29	BIODAILY	Num	4	113	2.	BEST22.	f13q10b Why not daily practice
28	BIOMONTH	Num	4	109	2.	BEST22.	f13q10a How often did patient practice
30	BIORMK	Char	1	117			f13q10b Other reason, describe
60	CPABN	Num	4	245	2.	BEST22.	f13q27 Cardio-pulmonary abnormal
61	CPA_RMK	Char	1	249			f13q27a Describe CP abnormality
62	CPB	Num	4	250	2.	BEST22.	f13q27b CP ab. related to medication
63	CPC	Num	4	254	2.	BEST22.	f13q27c Action taken
3	CURRSMK	Num	4	8	2.	BEST22.	f13q3a Patient is currently smoking
51	DIAS	Num	8	204	3.	BEST22.	f13q23b Diastolic blood pressure (mm Hg)
73	DRAWN	Num	4	288	2.	BEST22.	f13q30a Blood drawn
32	ESTMED	Num	8	122	3.	BEST22.	f13q11a Patient estimate of med. taken
33	ESTREAS	Num	4	130	2.	BEST22.	f13q11a1 Reason less than 90%
34	EST_RMK	Char	1	134			f13q11a1 Other, describe
2	EVERSMK	Num	4	4	2.	BEST22.	f12q3 Has patient ever smoked
54	EXTA	Num	4	224	2.	BEST22.	f13q25a Extreme is related to medication
55	EXTB	Num	4	228	2.	BEST22.	f13q25b Action taken
68	EXTRABN	Num	4	271	2.	BEST22.	f13q29 Extremities abnormal
69	EXTRARMK	Char	1	275			f13q29 Describe extremities abnormality
70	EXTRB	Num	4	276	2.	BEST22.	f13q29b Extremities ab. related to med.
71	EXTRC	Num	4	280	2.	BEST22.	f13q29c Action taken
53	EXTVALUE	Num	4	220	2.	BEST22.	f13q25 BP or pulse are extreme

CONTENTS PROCEDURE

#	Variable	Type	Len	Pos	Format	Informat	Label
ffffffffffffffffffffffffffffffffffffffffffffffffffffffffffffffffffffffffffffffffffffff							
134	F13_DAYS	Num	4	540	4.		f13q2 Days from randomization
1	FMYTP	Char	4	0	\$4.		FMYTP
36	FORGMED	Num	4	139	2.	BEST22.	f13q11c Action when dose forgotten
37	FORG_RMK	Char	1	143			f13q11c Other, describe
56	HEENTABN	Num	4	232	2.	BEST22.	f13q26 HEENT abnormal
57	HEENTRMK	Char	1	236			f13q26a Describe HEENT abnormality
58	HEENT_B	Num	4	237	2.	BEST22.	f13q26b HEENT ab. related to medication
59	HEENT_C	Num	4	241	2.	BEST22.	f13q26c Action taken
86	ILL1	Num	4	348	1.		Cold/Flu/Sinusitis
87	ILL2	Num	4	352	1.		Diarrhea
88	ILL3	Num	4	356	1.		Minor Infections
89	ILL4	Num	4	360	1.		Joint Diseases
90	ILL5	Num	4	364	1.		Muscle
91	ILL6	Num	4	368	1.		Tumor
92	ILL7	Num	4	372	1.		Gastric Complaints
93	ILL8	Num	4	376	1.		Chest Pain
94	ILL9	Num	4	380	1.		Rash/Urticaria
95	ILL10	Num	4	384	1.		Headache/Lighthead/Visual Changes
96	ILL11	Num	4	388	1.		Gynecological Complaints
97	ILL12	Num	4	392	1.		Insect Bites
98	ILL13	Num	4	396	1.		Fatigue
99	ILL14	Num	4	400	1.		Hernia
100	ILL15	Num	4	404	1.		Hemorrhoids
101	ILL16	Num	4	408	1.		Cholecystitis
102	ILL17	Num	4	412	1.		Dermatological
103	ILL18	Num	4	416	1.		Glaucoma
104	ILL19	Num	4	420	1.		Eye Problems (Detached Retina)
105	ILL20	Num	4	424	1.		Mood change/Anxiety/Depression
106	ILL21	Num	4	428	1.		Hypoglycemia
107	ILL22	Num	4	432	1.		Cardiovascular (Hypertension, MI)
108	ILL23	Num	4	436	1.		Plantar Warts
109	ILL24	Num	4	440	1.		Allergies (not insect bites)
110	ILL25	Num	4	444	1.		Asthma
111	ILL26	Num	4	448	1.		Dental Problems (not abscesses)
112	ILL27	Num	4	452	1.		Ischemia
113	ILL28	Num	4	456	1.		Cold-induced Numbness
11	ILLV	Num	4	56	2.	BEST22.	f13q6 Illnesses since last visit
14	ILL_ACT	Num	4	65	2.	BEST22.	f13q6c Action taken
15	ILL_RES	Num	4	69	2.	BEST22.	f13q6d Resolution at this exam
12	ILL_RMK	Char	1	60	2.		f13q6a Describe illnesses
13	ILL_SM	Num	4	61	2.	BEST22.	f13q6b Illness related to study med.
45	LIFE	Num	4	172	2.	BEST22.	f13q18 Phys. opinion of affect on life
9	LIQUOR	Num	8	44	4.1	BEST22.	f13q4a3 Daily liquor intake (ounces)
23	MED1ARMK	Char	1	98			f13q9a Generic name
24	MED1BRMK	Char	1	99			f13q9b Generic name
25	MED1CRMK	Char	1	100			f13q9c Generic name
31	MEDASS	Num	4	118	2.	BEST22.	f13q11 Patient assigned to study med.
38	MED_NBR	Num	4	144	2.	BEST22.	f11q11d Pills prescribed at this visit
49	METHOD1	Num	4	192	2.	BEST22.	f13q22a Method for temperature
35	MOREMEDS	Num	4	135	2.	BEST22.	f13q11b Takes more than prescribed dose

CONTENTS PROCEDURE

#	Variable	Type	Len	Pos	Format	Informat	Label
72	MWORFV	Num	4	284	2.	BEST22.	f13q30 MD1 or FV04
77	NAILA	Num	4	308	2.	BEST22.	f13q30b2a Uniform dist. of capillaries
78	NAILB	Num	4	312	2.	BEST22.	f13q30b2b Capillary loop width <100u
79	NAILC	Num	4	316	2.	BEST22.	f13q30b2c Capillary loop not deformed
80	NAILD	Num	4	320	2.	BEST22.	f13q30b2d Edematous appearance
81	NAILE	Num	4	324	2.	BEST22.	f13q30b2e Few if any hemorrhages
82	NAILF	Num	4	328	2.	BEST22.	f13q30b2f Localized avascular areas
83	NAILG	Num	4	332	2.	BEST22.	f13q30b2g Abnormal microscopy findings
84	NAILH	Num	4	336	2.	BEST22.	f13q30b2h Normal nailfold capillaries
39	NBR_DAY	Num	4	148	2.	BEST22.	f11q12(r0) No. of attacks on average day
85	NBR_WK	Num	8	340	4.1	BEST22.	f13q12(r1) No. of attacks in average wk
135	NEWID	Num	8	544	4.		Patient ID
4	NUMSMK	Num	8	12	2.	BEST22.	f13q3a1 Cigarettes per day
22	OTHRMED1	Num	4	94	2.	BEST22.	f13q9 Medications for other conditions
44	PHYS_ASS	Num	4	168	2.	BEST22.	f13q17 Physician assessment of Raynauds
10	PREG	Num	4	52	2.	BEST22.	f13q5 Patient is pregnant
43	PTFEELS	Num	4	164	2.	BEST22.	f13q16 How patient feels
47	PTIS	Num	4	180	2.	BEST22.	f13q20 How patient is
41	PTLIFE	Num	4	156	2.	BEST22.	f13q14 Patient opinion of affect on life
40	PT_ASS	Num	4	152	2.	BEST22.	f13q13 Patient assessment of Raynauds
52	PULSE	Num	8	212	3.	BEST22.	f13q24 Pulse (beats/minute)
114	SFX1	Num	4	460	2.		Swelling/Headaches/Lightheaded
115	SFX2	Num	4	464	2.		Flushing
116	SFX3	Num	4	468	2.		Color Change in Extremities
117	SFX4	Num	4	472	2.		Myalgia
118	SFX5	Num	4	476	2.		Gastric Pain/symptoms
119	SFX6	Num	4	480	2.		Fatigue
120	SFX7	Num	4	484	2.		Mood change/anxiety/jitters
121	SFX8	Num	4	488	2.		Constipation
122	SFX9	Num	4	492	2.		Cardiac (tachycardia/chest pain)
123	SFX10	Num	4	496	2.		Heavy Menses
124	SFX11	Num	4	500	2.		Extremity Pain
125	SFX12	Num	4	504	2.		Dyspnea
126	SFX13	Num	4	508	2.		Rash/Urticaria
127	SFX14	Num	4	512	2.		Diarrhea
128	SFX15	Num	4	516	2.		Bruising
129	SFX16	Num	4	520	2.		Weight Gain/Loss Inability
130	SFX17	Num	4	524	2.		Tinnitus
131	SFX18	Num	4	528	2.		Parasthesias
132	SFX19	Num	4	532	2.		Impotence
133	SFX20	Num	4	536	2.		Worsening Raynauds Attacks
16	SIDEFF	Num	4	73	2.	BEST22.	f13q7 Possible side effects
17	SIDE_RMK	Char	1	77			f13q7a Describe side effect
18	SIDE_SM	Num	4	78	2.	BEST22.	f13q7b Relation to study medication
19	SID_ACT	Num	4	82	2.	BEST22.	f13q7c Action taken
20	SID_REL	Num	4	86	2.	BEST22.	f13q7d Resolution at this exam
64	SKINABN	Num	4	258	2.	BEST22.	f13q28 Skin abnormal
65	SKINARMK	Char	1	262			f13q28a Describe skin abnormality

CONTENTS PROCEDURE

#	Variable	Type	Len	Pos	Format	Informat	Label
66	SKINB	Num	4	263	2.	BEST22.	f13q28b Skin ab. related to medication
67	SKINC	Num	4	267	2.	BEST22.	f13q28c Action taken
42	STUDYTRT	Num	4	160	2.	BEST22.	f13q15 Patient opinion of trt effect
50	SYS	Num	8	196	3.	BEST22.	f13q23a Systolic blood pressure (mm Hg)
48	TEMP	Num	8	184	5.1	BEST22.	f13q22 Temperature (F)
5	TIMESMK	Num	4	20	2.	BEST22.	f13q3b When patient stopped smoking
46	TRT_EFF	Num	4	176	2.	BEST22.	f13q19 Physician opinion of trt effect
26	VASO	Num	4	101	2.	BEST22.	f13q9d Patient taking vasodilators
74	VISIT4	Num	4	292	2.	BEST22.	f13q30b FV04
8	WINE	Num	8	36	4.1	BEST22.	f13q4a2 Daily wine intake (glasses)

Variable	Label	N	Mean	Std Dev	Minimum	Maximum
EVERSMK	f12q3 Has patient ever smoked	917	1.6	0.5	1.0	2.0
CURRSMK	f13q3a Patient is currently smoking	917	1.9	0.3	1.0	2.0
NUMSMK	f13q3a1 Cigarettes per day	91	17.1	10.0	1.0	40.0
TIMESMK	f13q3b When patient stopped smoking	307	3.9	0.5	1.0	4.0
ALCH_USE	f13q4 Patient uses alcoholic beverages	916	1.4	0.5	1.0	2.0
BEER	f13q4a1 Daily beer intake (bottles)	917	0.2	0.7	0.0	8.0
WINE	f13q4a2 Daily wine intake (glasses)	917	0.2	0.6	0.0	7.0
LIQUOR	f13q4a3 Daily liquor intake (ounces)	917	0.1	0.5	0.0	8.0
PREG	f13q5 Patient is pregnant	917	2.0	0.0	1.0	2.0
ILLLV	f13q6 Illnesses since last visit	916	1.7	0.5	1.0	2.0
ILL_SM	f13q6b Illness related to study med.	295	1.1	0.3	1.0	3.0
ILL_ACT	f13q6c Action taken	295	2.9	0.5	1.0	3.0
ILL_RES	f13q6d Resolution at this exam	295	1.4	0.5	1.0	3.0
SIDEEFF	f13q7 Possible side effects	916	1.9	0.3	1.0	2.0
SIDE_SM	f13q7b Relation to study medication	118	2.4	0.8	1.0	4.0
SID_ACT	f13q7c Action taken	118	2.4	0.8	1.0	3.0
SID_REL	f13q7d Resolution at this exam	118	1.6	0.5	1.0	3.0
ANYMEDS	f13q8 Any other medication for Raynauds	914	2.0	0.1	1.0	2.0
OTHRMED1	f13q9 Medications for other conditions	916	1.7	0.4	1.0	2.0
VASO	f13q9d Patient taking vasodilators	250	2.0	0.1	1.0	2.0
BIOASS	f13q10 Patient assigned to biofeedback	917	1.5	0.5	1.0	2.0
BIOMDNTH	f13q10a How often did patient practice	432	2.8	1.0	1.0	4.0
BIODAILY	f13q10b Why not daily practice	314	3.0	1.5	1.0	7.0
MEDASS	f13q11 Patient assigned to study med.	917	1.5	0.5	1.0	2.0
ESTMED	f13q11a Patient estimate of med. taken	484	84.0	30.7	0.0	100.0
ESTREAS	f13q11a1 Reason less than 90%	73	3.1	1.8	1.0	7.0
MOREMEDS	f13q11b Takes more than prescribed dose	485	1.0	0.2	1.0	4.0
FORGMED	f13q11c Action when dose forgotten	485	3.2	1.2	1.0	6.0
MED_NBR	f11q11d Pills prescribed at this visit	485	1.6	0.7	0.0	2.0
NBR_DAY	f11q12(r0) No. of attacks on average day	96	1.0	1.0	0.0	6.0
PT_ASS	f13q13 Patient assessment of Raynauds	916	1.5	0.6	1.0	4.0
PTLIFE	f13q14 Patient opinion of affect on life	916	1.6	0.7	1.0	4.0
STUDYTRT	f13q15 Patient opinion of trt effect	910	2.2	0.8	1.0	5.0
PTFEELS	f13q16 How patient feels	916	1.4	0.5	1.0	4.0
PHYS_ASS	f13q17 Physician assessment of Raynauds	913	1.4	0.5	1.0	3.0
LIFE	f13q18 Phys. opinion of affect on life	912	1.6	0.6	1.0	4.0
TRT_EFF	f13q19 Physician opinion of trt effect	908	2.2	0.8	1.0	5.0
PTIS	f13q20 How patient is	912	1.3	0.5	1.0	3.0

Variable	Label	N	Mean	Std Dev	Minimum	Maximum
TEMP	f13q22 Temperature (F)	909	97.8	0.9	93.5	100.8
METHOD1	f13q22a Method for temperature	914	1.0	0.0	1.0	2.0
SYS	f13q23a Systolic blood pressure (mm Hg)	912	115.2	13.2	80.0	164.0
DIAS	f13q23b Diastolic blood pressure (mm Hg)	912	72.6	8.9	40.0	102.0
PULSE	f13q24 Pulse (beats/minute)	913	70.7	9.3	44.0	108.0
EXTVALUE	f13q25 BP or pulse are extreme	911	2.0	0.1	1.0	2.0
EXTA	f13q25a Extreme is related to medication	13	1.0	0.0	1.0	1.0
EXTB	f13q25b Action taken	13	3.0	0.0	3.0	3.0
HEENTABN	f13q26 HEENT abnormal	912	1.9	0.2	1.0	2.0
HEENT_B	f13q26b HEENT ab. related to medication	60	1.1	0.5	1.0	4.0
HEENT_C	f13q26c Action taken	60	3.0	0.3	1.0	3.0
CPABN	f13q27 Cardio-pulmonary abnormal	912	2.0	0.1	1.0	2.0
CPB	f13q27b CP ab. related to medication	20	1.0	0.0	1.0	1.0
CPC	f13q27c Action taken	5	3.0	0.0	3.0	3.0
SKINABN	f13q28 Skin abnormal	912	1.9	0.3	1.0	2.0
SKINB	f13q28b Skin ab. related to medication	98	1.0	0.2	1.0	3.0
SKINC	f13q28c Action taken	98	2.9	0.4	1.0	3.0
EXTRABN	f13q29 Extremities abnormal	912	1.8	0.4	1.0	2.0
EXTRB	f13q29b Extremities ab. related to med.	139	1.2	0.5	1.0	3.0
EXTRC	f13q29c Action taken	139	3.0	0.3	1.0	3.0
MWORFV	f13q30 MD1 or FV04	917	1.5	0.5	1.0	2.0
DRAWN	f13q30a Blood drawn	437	1.0	0.1	1.0	2.0
VISIT4	f13q30b FV04	437	1.5	0.5	1.0	2.0
ANA_CORE	f13q30b1 Blood sent to Core Lab	209	1.0	0.1	1.0	2.0
ANA1	f13q30b1a ANA titer 1:	204	70.2	158.5	0.0	1280.0
NAILA	f13q30b2a Uniform dist. of capillaries	209	1.0	0.1	1.0	2.0
NAILB	f13q30b2b Capillary loop width <100u	209	1.0	0.1	1.0	2.0
NAILC	f13q30b2c Capillary loop not deformed	209	1.0	0.1	1.0	2.0
NAILD	f13q30b2d Edematous appearance	209	2.0	0.0	2.0	2.0
NAILE	f13q30b2e Few if any hemorrhages	209	1.0	0.1	1.0	2.0
NAILF	f13q30b2f Localized avascular areas	209	2.0	0.1	1.0	2.0
NAILG	f13q30b2g Abnormal microscopy findings	209	2.0	0.1	1.0	2.0
NAILH	f13q30b2h Normal nailfold capillaries	209	1.0	0.2	1.0	2.0
NBR_WK	f13q12(r1) No. of attacks in average wk	820	3.6	5.9	0.0	42.0
ILL1	Cold/Flu/Sinusitis	295	0.3	0.5	0.0	1.0
ILL2	Diarrhea	295	0.0	0.1	0.0	1.0
ILL3	Minor Infections	295	0.4	0.5	0.0	1.0
ILL4	Joint Diseases	295	0.1	0.3	0.0	1.0

Variable	Label	N	Mean	Std Dev	Minimum	Maximum
ILL5	Muscle	295	0.1	0.3	0.0	1.0
ILL6	Tumor	295	0.0	0.2	0.0	1.0
ILL7	Gastric Complaints	295	0.1	0.2	0.0	1.0
ILL8	Chest Pain	295	0.0	0.1	0.0	1.0
ILL9	Rash/Urticaria	295	0.0	0.1	0.0	1.0
ILL10	Headache/Lighthead/Visual Changes	295	0.1	0.2	0.0	1.0
ILL11	Gynecological Complaints	295	0.0	0.1	0.0	1.0
ILL12	Insect Bites	295	0.0	0.1	0.0	1.0
ILL13	Fatigue	295	0.0	0.1	0.0	1.0
ILL14	Hernia	295	0.0	0.1	0.0	1.0
ILL15	Hemorrhoids	295	0.0	0.1	0.0	1.0
ILL16	Cholecystitis	295	0.0	0.1	0.0	1.0
ILL17	Dermatological	295	0.0	0.1	0.0	1.0
ILL18	Glaucoma	295	0.0	0.1	0.0	1.0
ILL19	Eye Problems (Detached Retina)	295	0.0	0.1	0.0	1.0
ILL20	Mood change/Anxiety/Depression	295	0.0	0.1	0.0	1.0
ILL21	Hypoglycemia	295	0.0	0.1	0.0	1.0
ILL22	Cardiovascular (Hypertension, MI)	295	0.0	0.1	0.0	1.0
ILL23	Plantar Warts	295	0.0	0.1	0.0	1.0
ILL24	Allergies (not insect bites)	295	0.0	0.1	0.0	1.0
ILL25	Asthma	295	0.0	0.1	0.0	1.0
ILL26	Dental Problems (not abscesses)	295	0.0	0.1	0.0	1.0
ILL27	Ischemia	295	0.0	0.1	0.0	1.0
ILL28	Cold-induced Numbness	295	0.0	0.1	0.0	1.0
SFX1	Swelling/Headaches/Lightheaded	118	0.6	0.5	0.0	1.0
SFX2	Flushing	118	0.1	0.3	0.0	1.0
SFX3	Color Change in Extremities	118	0.0	0.2	0.0	1.0
SFX4	Myalgia	118	0.0	0.2	0.0	1.0
SFX5	Gastric Pain/symptoms	118	0.1	0.3	0.0	1.0
SFX6	Fatigue	118	0.1	0.3	0.0	1.0
SFX7	Mood change/anxiety/jitters	118	0.1	0.2	0.0	1.0
SFX8	Constipation	118	0.0	0.2	0.0	1.0
SFX9	Cardiac (tachycardia/chest pain)	118	0.0	0.2	0.0	1.0
SFX10	Heavy Menses	118	0.0	0.1	0.0	1.0
SFX11	Extremity Pain	118	0.0	0.1	0.0	1.0
SFX12	Dyspnea	118	0.0	0.1	0.0	1.0
SFX13	Rash/Urticaria	118	0.0	0.1	0.0	1.0
SFX14	Diarrhea	118	0.0	0.2	0.0	1.0

Variable	Label	N	Mean	Std Dev	Minimum	Maximum
SFX15	Bruising	118	0.0	0.1	0.0	1.0
SFX16	Weight Gain/Loss Inability	118	0.0	0.2	0.0	1.0
SFX17	Tinnitus	118	0.0	0.1	0.0	1.0
SFX18	Parasthesias	118	0.0	0.1	0.0	1.0
SFX19	Impotence	118	0.0	0.1	0.0	1.0
SFX20	Worsening Raynauds Attacks	118	0.0	0.1	0.0	1.0
F13_DAYS	f13q2 Days from randomization	917	249.5	138.5	43.0	576.0
NEWID	Patient ID	917	155.4	89.8	2.0	312.0

FMTYP

FMTYP	Frequency	Percent	Cumulative Frequency	Cumulative Percent
CMD1	259	28.2	259	28.2
CMD2	227	24.8	486	53.0
CMD3	222	24.2	708	77.2
CMD4	209	22.8	917	100.0

f13q6a Describe illnesses

I LL_RMK	Frequency	Percent	Cumulative Frequency	Cumulative Percent
1	295	100.0	295	100.0

Frequency Missing = 622

f13q7a Describe side effect

SIDE_RMK	Frequency	Percent	Cumulative Frequency	Cumulative Percent
1	118	100.0	118	100.0

Frequency Missing = 799

f13q9a Generic name

MED1ARMK	Frequency	Percent	Cumulative Frequency	Cumulative Percent
1	250	100.0	250	100.0

Frequency Missing = 667

f13q9b Generic name

MED1BRMK	Frequency	Percent	Cumulative Frequency	Cumulative Percent
1	93	100.0	93	100.0

Frequency Missing = 824

f13q9c Generic name

MED1CRMK	Frequency	Percent	Cumulative Frequency	Cumulative Percent
1	27	100.0	27	100.0

Frequency Missing = 890

f13q10b Other reason, describe

BIORMK	Frequency	Percent	Cumulative Frequency	Cumulative Percent
1	15	100.0	15	100.0

Frequency Missing = 902

f13q11a1 Other, describe

EST_RMK	Frequency	Percent	Cumulative Frequency	Cumulative Percent
1	37	100.0	37	100.0

Frequency Missing = 880

f13q11c Other, describe

FORG_RMK	Frequency	Percent	Cumulative Frequency	Cumulative Percent
1	13	100.0	13	100.0

Frequency Missing = 904

f13q26a Describe HEENT abnormality

HEENTRMK	Frequency	Percent	Cumulative Frequency	Cumulative Percent
1	60	100.0	60	100.0

Frequency Missing = 857

f13q27a Describe CP abnormality

CPA_RMK	Frequency	Percent	Cumulative Frequency	Cumulative Percent
1	20	100.0	20	100.0

Frequency Missing = 897

f13q28a Describe skin abnormality

SKINARMK	Frequency	Percent	Cumulative Frequency	Cumulative Percent
1	99	100.0	99	100.0

Frequency Missing = 818

f13q29 Describe extremities abnormality

EXTRARMK	Frequency	Percent	Cumulative Frequency	Cumulative Percent
1	139	100.0	139	100.0

Frequency Missing = 778