

INACTIVE PATIENT FORM

ID No.				
Form Type	I	A		

PART I: VISIT IDENTIFICATION

1. Patient's initials: _____

2. Date form started: _____
Month Day Year

FARMYNS

5. Is the patient currently experiencing side effects or other problems associated with study treatment? _____ (1) (2)
Yes No

INACTEFF

If YES, describe: _____
EFF, PML

PART II: PATIENT STATUS

3. Why is the patient unwilling or unable to continue scheduled visits to the RTS Clinical Unit? (Check all that apply.)

A. Unwilling to undergo assigned treatment ---- (1)

INACTA

B. Unwilling or unable to take time from work to visit Clinical Unit ---- (1)

INACTE

C. Scheduling conflicts unrelated to work ---- (1)

INACTE

D. Medical illness unrelated to Raynaud's ---- (1)

INACTD

E. Moving out of the area ---- (1)

INACTE

F. Transportation problems ---- (1)

INACTE

G. Family problems ---- (1)

INACTG

H. Other ---- (1)

INACTH

Specify: _____
INACT-PNK

INACTI

I. Unknown ---- (1)

6. Has the patient agreed to complete the Follow-up Attack Cards and Daily Diaries at 12 to 15 months after enrollment? _____ (1) (2)
Yes No

INACTEV

7. Has the patient agreed to complete the Interim Attack Cards and Daily Diaries at 8 weeks after enrollment? -- (1) (2)
Yes No

INACTINT

PART III: ADMINISTRATIVE MATTERS

8. Clinical Unit Physician who reviewed clinical status of patient:

Signature: _____

RTS Staff No.: _____

9. Principal Investigator:

Signature: _____

RTS Staff No.: _____

10. Research Coordinator:

Signature: _____

RTS Staff No.: _____

4. Has the Clinical Unit physician reviewed the patient's clinical status with the patient with regard to whether the patient is experiencing side effects or other problems associated with study treatment? _____ (1) (2)
Yes No

INACTET

11. Date form completed: _____
Month Day Year

FORM 27 (Rev. 0)
INACTIVE PATIENT 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)	IA01, IA02
2	F27_DAYS	I(4)	Date Form 27 started Days from randomization
3A	INACA	I(1)	1 = Yes, 2 = No
3B	INACB		
3C	INACC		
3D	INACD		
3E	INACE		
3F	INACF		
3G	INACG		
3H	INACH		
3I	INACI		
3H	INAC_RMK		
4	INACTRT	I(1)	1 = Yes, 2 = No
5	INACEFF	I(1)	1 = Yes, 2 = No
5	EFF_RMK	CHAR(1)	1 = Remark written on form
6	INAC_FV	I(1)	1 = Yes, 2 = No
7	INACINT	I(1)	1 = Yes, 2 = No

CONTENTS PROCEDURE

Data Set Name:	RTS.FORM27	Observations:	84
Member Type:	DATA	Variables:	18
Engine:	V612	Indexes:	0
Created:	11:06 Thursday, April 27, 2000	Observation Length:	70
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:	8192
Number of Data Set Pages:	2
File Format:	607
First Data Page:	1
Max Obs per Page:	116
Obs in First Data Page:	80

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

#	Variable	Type	Len	Pos	Format	Informat	Label
14	EFF_RMK	Char	1	49			f27q5 Describe side effects
17	F27_DAYS	Num	4	58	4.		f27q2 Days from randomization
1	FMYTP	Char	4	0			FMYTP
2	INACA	Num	4	4	1.	BEST22.	f27q3a Unwilling to undergo assigned trt
3	INACB	Num	4	8	1.	BEST22.	f27q3b Unwilling to take time off work
4	INACC	Num	4	12	1.	BEST22.	f27q3c Schedule conflict other than work
5	INACD	Num	4	16	1.	BEST22.	f27q3d Unrelated medical illness
6	INACE	Num	4	20	1.	BEST22.	f27q3e Moving out of area
13	INACEFF	Num	4	45	1.	BEST22.	f27q5 Patient currently has side effects
7	INACF	Num	4	24	1.	BEST22.	f27q3f Transportation problems
8	INACG	Num	4	28	1.	BEST22.	f27q3g Family problems
9	INACH	Num	4	32	1.	BEST22.	f27q3h Other
11	INACI	Num	4	37	1.	BEST22.	f27q3i Unknown
16	INACINT	Num	4	54	1.	BEST22.	f27q7 Attack cards/diaries at 8 weeks
12	INACTRT	Num	4	41	1.	BEST22.	f27q4 Physician has reviewed status
15	INAC_FV	Num	4	50	1.	BEST22.	f27q6 Attack cards/diaries at 12-15 mos
10	INAC_RMK	Char	1	36			f27q3h Specify other problem
18	NEWID	Num	8	62	4.		Patient ID

Variable	Label	N	Mean	Std Dev	Minimum	Maximum
INACA	f27q3a Unwilling to undergo assigned trt	84	1.6	0.5	1.0	2.0
INACB	f27q3b Unwilling to take time off work	84	1.4	0.5	1.0	2.0
INACC	f27q3c Schedule conflict other than work	84	1.8	0.4	1.0	2.0
INACD	f27q3d Unrelated medical illness	84	1.9	0.3	1.0	2.0
INACE	f27q3e Moving out of area	84	1.9	0.2	1.0	2.0
INACF	f27q3f Transportation problems	84	2.0	0.2	1.0	2.0
INACG	f27q3g Family problems	84	1.9	0.4	1.0	2.0
INACH	f27q3h Other	84	1.7	0.5	1.0	2.0
INACI	f27q3i Unknown	84	2.0	0.2	1.0	2.0
INACTRT	f27q4 Physician has reviewed status	84	1.3	0.5	1.0	2.0
INACEFF	f27q5 Patient currently has side effects	84	2.0	0.7	1.0	8.0
INAC_FV	f27q6 Attack cards/diaries at 12-15 mos	84	1.7	0.5	1.0	2.0
INACINT	f27q7 Attack cards/diaries at 8 weeks	84	1.7	0.5	1.0	2.0
F27_DAYS	f27q2 Days from randomization	84	211.1	141.0	1.0	519.0
NEWID	Patient ID	84	163.7	89.4	1.0	313.0

FMTYP

FMTYP	Frequency	Percent	Cumulative Frequency	Cumulative Percent
IA01	83	98.8	83	98.8
IA02	1	1.2	84	100.0

f27q3h Specify other problem

INAC_RMK	Frequency	Percent	Cumulative Frequency	Cumulative Percent
1	27	100.0	27	100.0

Frequency Missing = 57

f27q5 Describe side effects

EFF_RMK	Frequency	Percent	Cumulative Frequency	Cumulative Percent
1	8	100.0	8	100.0

Frequency Missing = 76