

DRUG DISTRIBUTION FORM

ID No.		-			
Form Type	D	D			

Part I: Visit Identification

- Patient's initials:
- Date form was started and medication was dispensed: F20-DAYS
Month Day Year
- Visit at which form was started and medication was dispensed: F20-NUM
- Date form completed: C20-CDYS
Month Day Year

If a new supply of medication was dispensed at the Monitoring Visit or Follow-up Visit at which this form was completed, attach the label page(s) from previously-dispensed medication to this form.

Part II: Medication Information

- If there are no pages with medication labels attached, check here and skip to Item 10. NO ATTACH (1)
- Number of pages with medication labels attached: NUM PAGE
- Number of medication labels: NUM LAB
- Was the medication unblinded? UNBLIND
 - Yes (1)
 - No (2)

If Yes, answer Item 9.
If NO, skip to Item 10.

ID No.		-			
Form Type	D	D			

9. Explain why the medication was unblinded. If the unblinding envelope was opened, attach it to this form.

UNBL - ENK

8/15/05

10. Is this Follow-up Visit 5 (FV05)? (1) (2)
Yes No

Attach medication unblinding envelope to this form.

Part III: Administrative Matters

11. Research Coordinator:

Signature: _____ RTS Staff No.: _____

12. Date this form is being sent to the RTS Coordinating Center:
Month Day Year

COORDINATING CENTER USE ONLY:

13. Medication Information:

A. Number of pages _____

B. Number of labels _____

C. Medication unblinded (1) (2)
Yes No

14. Unblinding envelope attached? (1) (2)
Yes No

ENKCC

ID No.		-			
Form Type	D	D			

RAYNAUD'S TREATMENT STUDY
MEDICATION LABELS

RTS MEDICATION LABELS
RTS Form 20
Rev. 0 11/17/93

Page _____ of _____

Attach medication labels to the boxes below. Use a new page whenever a new supply of medication is dispensed. Clinical Unit staff should retain the label pages from the most recently-dispensed medication until the medication is consumed or returned. Pages with labels from previously-dispensed medication should be submitted with the Drug Distribution Form (Form 20).

1. Date medication dispensed: - -
Month Day Year
2. Visit medication dispensed: - -

MEDICATION LABEL

MEDICATION LABEL

MEDICATION LABEL

MEDICATION LABEL

ID No.		-			
Form Type	D	D			

DRUG DISTRIBUTION FORM

ID No.		-			
Form Type	D	D			

Part I: Visit Identification

1. Patient's initials: -----
2. Date form was started and medication was dispensed: -----
 Month Day Year
F20-DAYS
3. Visit at which form was started and medication was dispensed: -----
F20-NUM
4. Date form completed: -----
 Month Day Year
F20-EDY

If a new supply of medication was dispensed at the Monitoring Visit or Follow-up Visit at which this form was completed, attach the label page(s) from previously-dispensed medication to this form.

Part II: Medication Information

5. If there are no pages with medication labels attached, check here and skip to Item 10. ----- ()
NO LABEL
6. Number of pages with medication labels attached: -----
NUM PAGE
7. Number of medication labels: -----
NUM LAB
8. Was the medication unblinded?
 Yes ----- ()
 No ----- ()
UNBLIND

If Yes, answer Item 9.
 If NO, skip to Item 10.

ID No.		-			
Form Type	D	D			

9. Explain why the medication was unblinded. If the unblinding envelope was opened, attach it to this form.

UNBL-RHK

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.....
.....

Part III: Administrative Matters

10. Research Coordinator:

Signature: RTS Staff No.:

11. Date this form is being sent to the RTS Coordinating Center:

Month Day Year

COORDINATING CENTER USE ONLY:

12. Medication Information:

- A. Number of pages
- B. Number of labels
- C. Medication unblinded () ()
Yes No

ID No.		-			
Form Type	D	D			

RAYNAUD'S TREATMENT STUDY

RTS MEDICATION LABELS

MEDICATION LABELS

RTS Form 20

Rev. 0 11/17/93

Page _____ of _____

Attach medication labels to the boxes below. Use a new page whenever a new supply of medication is dispensed. Clinical Unit staff should retain the label pages from the most recently-dispensed medication until the medication is consumed or returned. Pages with labels from previously-dispensed medication should be submitted with the Drug Distribution Form (Form 20).

1. Date medication dispensed: _____
Month Day Year
2. Visit medication dispensed: _____

MEDICATION LABEL

MEDICATION LABEL

MEDICATION LABEL

MEDICATION LABEL

ID No.					
Form Type	D	D			

FORM 20 (Rev. 0, 1)
DRUG DISTRIBUTION FORM

<u>ITEM</u>	<u>NAME</u>	<u>TYPE AND LENGTH</u>	<u>CODES OR UNITS</u>
HEADER	NEWID	I(4)	Patient ID
2	F20_DAYS	I(4)	Date medication dispensed Days from randomization to medication dispensed
3	F20_NUM	CHAR(4)	RV01, FV01, FV02, FV03, FV04, FV05 XM01, XM02, XT05
4	F20_CDYS	I(4)	Date Form 20 completed Days from randomization
5	NOATTACH	I(1)	1 = No labels
6	NUMPAGE	I(2)	Number of pages
7	NUMLAB	I(2)	Number of labels
8	UNBLIND	I(1)	1 = Yes, 2 = No
9	UNBL_RMK	CHAR(1)	1 = Remark written on form
10	VIS05	I(1)	1 = Yes, 2 = No
14	ENVCC	I(1)	1 = Yes, 2 = No

CONTENTS PROCEDURE

Data Set Name:	RTS.FORM20	Observations:	763
Member Type:	DATA	Variables:	11
Engine:	V612	Indexes:	0
Created:	11:06 Thursday, April 27, 2000	Observation Length:	54
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:	6
File Format:	607
First Data Page:	1
Max Obs per Page:	151
Obs in First Data Page:	120

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

#	Variable	Type	Len	Pos	Format	Informat	Label
7	ENVCC	Num	4	25	1.	BEST22.	f20q14 Unblinding envelope attached
11	F20_CDYS	Num	8	46	4.		f20q4 Date Form 20 completed
9	F20_DAYS	Num	5	33	4.		f20q2 Days from rand. to disp.
8	F20_NUM	Char	4	29			f20q3 Visit medication was dispensed
10	NEWID	Num	8	38	4.		Patient ID
1	NOATTACH	Num	4	0	1.	BEST22.	f20q5 No medication labels
3	NUMLAB	Num	4	8	2.	BEST22.	f20q7 Number of medication labels
2	NUMPAGE	Num	4	4	2.	BEST22.	f20q6 Number of pages with labels
4	UNBLIND	Num	4	12	1.	BEST22.	f20q8 Medication was unblinded
5	UNBL_RMK	Char	1	16			f20q9 Explanation for unblinding
6	VIS05	Num	8	17	1.	BEST22.	f20q10 This is FV05

Variable	Label	N	Mean	Std Dev	Minimum	Maximum
NOATTACH	f20q5 No medication labels	134	1.0	0.0	1.0	1.0
NUMPAGE	f20q6 Number of pages with labels	629	1.0	0.2	0.0	3.0
NUMLAB	f20q7 Number of medication labels	628	1.6	0.7	0.0	4.0
UNBLIND	f20q8 Medication was unblinded	629	2.0	0.0	1.0	2.0
VIS05	f20q10 This is FV05	597	1.8	0.4	1.0	2.0
ENVCC	f20q14 Unblinding envelope attached	597	1.8	0.4	1.0	2.0
F20_DAYS	f20q2 Days from rand. to disp.	763	211.8	164.1	0.0	576.0
NEWID	Patient ID	763	153.4	85.1	3.0	312.0
F20_CDYS	f20q4 Date Form 20 completed	763	317.1	175.5	0.0	933.0

f20q9 Explanation for unblinding

UNBL_RMK	Frequency	Percent	Cumulative Frequency	Cumulative Percent
1	1	100.0	1	100.0

Frequency Missing = 762

f20q3 Visit medication was dispensed

F20_NUM	Frequency	Percent	Cumulative Frequency	Cumulative Percent
FV01	124	16.3	124	16.3
FV02	47	6.2	171	22.4
FV03	102	13.4	273	35.8
FV04	110	14.4	383	50.2
FV05	1	0.1	384	50.3
RV01	149	19.5	533	69.9
XMD1	115	15.1	648	84.9
XMD2	111	14.5	759	99.5
XT05	4	0.5	763	100.0