

NON-RANDOMIZATION REPORT

Complete this form for any patient who was considered eligible at the Screening Visit, but who later was determined to be ineligible.

ID No.				
Form Type	N	R	O	1

Part I: Visit Identification

- 1. Patient's initials: -----
- 2. Date the patient was determined to be ineligible: -----
Month Day Year

Part II: Reason for Ineligibility

- 3. The patient has a positive ANA titer (greater than 1:320): ----- (1) (2)
Yes No *POS ANA*
- 4. The patient withdrew from evaluation for eligibility for the study: ----- (1) (2)
Yes No *WITHDREW*
- 5. The patient was unable or unwilling to complete the Raynaud's Attack Cards and Daily Diaries: ----- (1) (2)
Yes No *UNABLE*
- 6. The patient is pregnant, planning to become pregnant, or lactating: ----- (1) (2)
Yes No *PREG 05*
- 7. Serum creatinine > 2.0 mg/dl: ----- (1) (2)
Yes No *CREAT*
- 8. Other ----- (1) (2)
Yes No *OTH REAS*
Specify: REAS RMK

Part III: Administrative Matters

- 9. Research Coordinator:
Signature: _____ RTS Staff No.: _____
- 10. Date form completed: -----
Month Day Year

NON-RANDOMIZATION REPORT

Complete this form for any patient for whom a Patient Screening Report (Form 02) was submitted but who is not eligible for randomization.

ID No.		-		
Form Type	N	R	0	1

Part I: Visit Identification

- 1. Patient's initials:
- 2. Date the patient was determined to be ineligible: -----
Month Day Year

Part II: Reason for Ineligibility

- 3. The patient has a positive ANA titer (greater than 1:320): ----- () ()
Yes No *POS ANA*
 - 4. The patient withdrew from the study: ----- () ()
Yes No *WITHDREW*
 - 5. The patient was unable or unwilling to complete the Raynaud's Attack Cards and Daily Diaries: ----- () ()
Yes No *UNABLE*
 - 6. Other ----- () ()
Yes No *OTHERS*
- Specify: REAS-RMK

Part III: Administrative Matters

- 7. Research Coordinator:
Signature: RTS Staff No.: -----
- 8. Date form completed: -----
Month Day Year

FORM 05 (Rev. 0, 1)

NON-RANDOMIZATION REPORT

<u>ITEM</u>	<u>NAME</u>	<u>TYPE AND LENGTH</u>	<u>CODES OR UNITS</u>
HEADER	NEWID	I(4)	Patient ID
3	POS_ANA	I(1)	1 = Yes, 2 = No
4 (Rev 0)	WITHDREW	I(1)	1 = Yes, 2 = No
4 (Rev 1)	WITHDRW1	I(1)	1 = Yes, 2 = No
5	UNABLE	I(1)	1 = Yes, 2 = No
6 (Rev 0)	OTHREAS REAS_RMK	I(1) CHAR(1)	1 = Yes, 2 = No 1 = Remark written on form
6 (Rev 1)	PREG05	I(1)	1 = Yes, 2 = No
7 (Rev 1)	CREAT	I(1)	1 = Yes, 2 = No
8 (Rev 1)	OTHREAS REAS_RMK	I(1) CHAR(1)	1 = Yes, 2 = No 1 = Remark written on form

CONTENTS PROCEDURE

Data Set Name:	RTS.FORM05	Observations:	100
Member Type:	DATA	Variables:	9
Engine:	V612	Indexes:	0
Created:	11:06 Thursday, April 27, 2000	Observation Length:	37
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:	1
File Format:	607
First Data Page:	1
Max Obs per Page:	220
Obs in First Data Page:	100

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

#	Variable	Type	Len	Pos	Format	Informat	Label
8	CREAT	Num	4	25	1.	BEST22.	f05q7 Serum creatinine > 2.0
9	NEWID	Num	8	29	4.		Patient ID
4	OTHREAS	Num	4	12	1.	BEST22.	f05q8 Other reason for ineligibility
1	POS_ANA	Num	4	0	1.	BEST22.	f05q3 Positive ANA titer
7	PREG05	Num	4	21	1.	BEST22.	f05q6 Pregnant, planning, or lactating
5	REAS_RMK	Char	1	16			f05q8 Specify other reason
3	UNABLE	Num	4	8	1.	BEST22.	f05q5 Unable to complete attack cards
2	WITHDREW	Num	4	4	1.	BEST22.	f05q4(r0) Withdrew from the study
6	WITHDRWI	Num	4	17	1.	BEST22.	f05q4(r1) Withdrew from evaluation

Variable	Label	N	Mean	Std Dev	Minimum	Maximum
POS_ANA	f05q3 Positive ANA titer	100	1.8	0.4	1.0	2.0
WITHDREW	f05q4(r0) Withdrew from the study	6	1.7	0.5	1.0	2.0
UNABLE	f05q5 Unable to complete attack cards	100	1.7	0.5	1.0	2.0
OTHREAS	f05q8 Other reason for ineligibility	100	1.4	0.5	1.0	2.0
WITHDRW1	f05q4(r1) Withdrew from evaluation	94	1.6	0.5	1.0	2.0
PREG05	f05q6 Pregnant, planning, or lactating	94	1.9	0.2	1.0	2.0
CREAT	f05q7 Serum creatinine > 2.0	94	2.0	0.0	2.0	2.0
NEWID	Patient ID	100	437.3	72.8	314.0	556.0

f05q8 Specify other reason

REAS_RMK	Frequency	Percent	Cumulative Frequency	Cumulative Percent
1	56	100.0	56	100.0

Frequency Missing = 44