

CLOSE-OUT FORM

ID No.				
Form Type	G	L	0	1

PART I: VISIT IDENTIFICATION

- Patient's initials: .....
- Date of visit or interview: ..... *F 10 - DAYS*  

Month	Day	Year
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PART II: CLOSE-OUT INFORMATION

- Type of contact: .....
 

( 1 )	( 2 )
Clinic	Telephone
Visit	↓

A. Physician note written .....	( 1 )	( 2 )
	Yes	No

- Has the patient's health status worsened between Randomization and FV04? .....
 

( 1 )	( 2 )	( 3 )
Yes	No	Insufficient
		Medical
		Monitoring Data
		↓

A. Did patient report problem(s) between Randomization and scheduled time of FV04 during FV05 telephone contact or visit? .....	( 1 )	( 2 )
	Yes	No

- Did the patient report any new symptoms between FV04 and FV05? .....
 

( 1 )	( 2 )
Yes	No
	↓

A. Action taken:	
Patient seen, treated and released .....	( 1 )
Problem unresolved and patient referred to physician .....	( 2 )
Problem insignificant .....	( 3 )

- If Questions 4 or 5 are checked yes, what is the relationship to study treatment?
 

Not related .....	( 1 )
Possibly related .....	( 2 )
Probably related .....	( 3 )
Definitely related .....	( 4 )

- Did the physician or principal investigator discuss continuing care with the patient? .....
 

( 1 )	( 2 )
Yes	No
	↓

	Yes	No
A. Referral to patient's current physician .....	( 1 )	( 2 )
B. Referral to new physician .....	( 1 )	( 2 )
C. Referral to biofeedback therapist .....	( 1 )	( 2 )

- Did the physician or principal investigator advise the patient that he/she would be told of the results of the study at the completion of the study? .....
 

( 1 )	( 2 )
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9 Was the patient assigned to study medications? ( ) ( )  
 Yes No

Skip to Question 14.

10 Did the physician advise the patient to stop taking study medication at this time? ( ) ( )

11 Did the coordinator collect all medication and medication bottles and have the pills counted? ( ) ( )

12 Have the Medication Compliance Form (Form 18) and the Drug Distribution Form (Form 20) been completed? ( ) ( )

13 Has the medication unblinding envelope been attached to the Form 20? ( ) ( )

Skip to Question 15.

14 Has the second Voluntary Control Assessment been performed? ( ) ( )

15 Did the coordinator collect all one-year Attack Card Booklets? ( ) ( )  
 Yes No

	Yes	No
A. Did the Principal Investigator call the patient to stress the importance of collecting one-year information? . . .	( )	( )
B. Has the reason for non-collection been documented? . . .	( )	( )

16 Did the coordinator collect all one-year Daily Diaries? ( ) ( )

17 Did the coordinator collect all Diaries between FV04 and FV05? ( ) ( )

PART III: ADMINISTRATIVE MATTERS

18. Physician or Principal Investigator:

Signature: \_\_\_\_\_ RTS Staff No.: \_\_\_\_\_

19. Research Coordinator:

Signature: \_\_\_\_\_ RTS Staff No.: \_\_\_\_\_

20. Date of visit or interview: \_\_\_\_\_  
 Month Day Year

FORM COMPLETED

ID No.		-			
Form Type	C	L	0	1	

MED ASS 1

STEPHES

PILLOUT

MEDCOMP

UNBL - F30

VC ASS

COLATT

PI CALL

NONCOLL

COLL 1YR

COLL DIAR

## FORM 70 (Rev. 0)

## CLOSE-OUT FORM

<u>ITEM</u>	<u>NAME</u>	<u>TYPE AND LENGTH</u>	<u>CODES OR UNITS</u>
HEADER	NEWID	I(4)	Patient ID
2	F70_DAYS	I(4)	Date of close out visit or interview Days from randomization
3	CONTACT	I(1)	1 = Clinical Visit 2 = Telephone
3A	NOTE	I(1)	1 = Yes, 2 = No
4	HLTH	I(1)	1 = Yes 2 = No 3 = Insufficient medical monitoring data
4A	PROBLEM	I(1)	1 = Yes, 2 = No
5	NEWSYMP	I(1)	1 = Yes, 2 = No
5A	ACTIONA	I(1)	1 = Patient seen, treated and released 2 = Problem unresolved and patient referred to physician 3 = Problem insignificant
6	RELATION	I(1)	1 = Not related 2 = Possibly related 3 = Probably related 4 = Definitely related
7	CARE	I(1)	1 = Yes, 2 = No
7A 7B 7C	CURRPHYS NEWPHYS BIOREF	I(1)	1 = Yes, 2 = No
8	RESULT	I(1)	1 = Yes, 2 = No
9	MEDASS1		
10	STOPMED		
11	PILLCNT		
12	MEDCOMP		
13	UNBL_F20		
14	VC_ASS		
15 15A 15B	COLLATT PI_CALL NONCOLL		
16	COLL1YR		
17	COLLDIAR		

CONTENTS PROCEDURE

Data Set Name:	RTS.FORM70	Observations:	274
Member Type:	DATA	Variables:	25
Engine:	V612	Indexes:	0
Created:	11:06 Thursday, April 27, 2000	Observation Length:	104
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:	4
File Format:	607
First Data Page:	1
Max Obs per Page:	78
Obs in First Data Page:	45

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

#	Variable	Type	Len	Pos	Format	Informat	Label
6	ACTIONA	Num	4	20	1.	BEST22.	f70q5a Action taken on new symptoms
11	BIOREF	Num	4	40	1.	BEST22.	f70q7c Referral to BF therapist
8	CARE	Num	4	28	1.	BEST22.	f70q7 Continuing care discussed
22	COLLIYR	Num	4	84	1.	BEST22.	f70q16 All 1 yr diaries
19	COLLATT	Num	4	72	1.	BEST22.	f70q15 All 1 yr attack booklets
23	COLLDIAR	Num	4	88	1.	BEST22.	f70q17 All diaries bt FV04 and FV05
1	CONTACT	Num	4	0	1.	BEST22.	f70q3 Type of Contact
9	CURRPHYS	Num	4	32	1.	BEST22.	f70q7a Referral to current physician
24	F70_DAYS	Num	4	92	4.		f70q2 Days from randomization
3	HLTH	Num	4	8	1.	BEST22.	f70q4 Health status worsened
13	MEDASS1	Num	4	48	1.	BEST22.	f70q9 Patient assigned to medication
16	MEDCOMP	Num	4	60	1.	BEST22.	f70q12 Form 18 and Form 20 completed
25	NEWID	Num	8	96	4.		Patient ID
10	NEWPHYS	Num	4	36	1.	BEST22.	f70q7b Referral to new physician
5	NEWSYMP	Num	4	16	1.	BEST22.	f70q5 Patient reported new symptoms
21	NONCOLL	Num	4	80	1.	BEST22.	f70q15b Non-collection is documented
2	NOTE	Num	4	4	1.	BEST22.	f70q3a Physician note written
15	PILLCNT	Num	4	56	1.	BEST22.	f70q11 Collected and counted medication
20	PI_CALL	Num	4	76	1.	BEST22.	f70q15a PI called patient
4	PROBLEM	Num	4	12	1.	BEST22.	f70q4a Patient reported problems
7	RELATION	Num	4	24	1.	BEST22.	f70q6 Relationship to study treatment
12	RESULT	Num	4	44	1.	BEST22.	f70q8 Results at end of study
14	STOPMED	Num	4	52	1.	BEST22.	f70q10 Advised to stop medication
17	UNBL_F20	Num	4	64	1.	BEST22.	f70q13 Unblinding envelope on Form 20
18	VC_ASS	Num	4	68	1.	BEST22.	f70q14 Second VC assessment

Variable	Label	N	Mean	Std Dev	Minimum	Maximum
CONTACT	f70q3 Type of Contact	269	1.5	0.5	1.0	2.0
NOTE	f70q3a Physician note written	128	1.5	0.5	1.0	2.0
HLTH	f70q4 Health status worsened	274	2.0	0.3	1.0	3.0
PROBLEM	f70q4a Patient reported problems	18	2.0	0.0	2.0	2.0
NEWSYMP	f70q5 Patient reported new symptoms	274	2.0	0.1	1.0	2.0
ACTIONA	f70q5a Action taken on new symptoms	6	1.8	0.4	1.0	2.0
RELATION	f70q6 Relationship to study treatment	13	1.1	0.3	1.0	2.0
CARE	f70q7 Continuing care discussed	274	1.2	0.4	1.0	2.0
CURRPHYS	f70q7a Referral to current physician	222	1.0	0.1	1.0	2.0
NEUPHYS	f70q7b Referral to new physician	39	1.8	0.4	1.0	2.0
BIOREF	f70q7c Referral to BF therapist	38	1.8	0.4	1.0	2.0
RESULT	f70q8 Results at end of study	274	1.1	0.2	1.0	2.0
MEDASS1	f70q9 Patient assigned to medication	274	1.5	0.5	1.0	2.0
STOPMED	f70q10 Advised to stop medication	132	1.0	0.1	1.0	2.0
PILLCNT	f70q11 Collected and counted medication	135	1.1	0.3	1.0	2.0
MEDCOMP	f70q12 Form 18 and Form 20 completed	130	1.1	0.2	1.0	2.0
UNBL_F20	f70q13 Unblinding envelope on Form 20	131	1.0	0.2	1.0	2.0
VC_ASS	f70q14 Second VC assessment	138	1.4	0.5	1.0	2.0
COLLATT	f70q15 All 1 yr attack booklets	274	1.1	0.4	1.0	2.0
PI_CALL	f70q15a PI called patient	40	1.2	0.4	1.0	2.0
NONCOLL	f70q15b Non-collection is documented	41	1.1	0.3	1.0	2.0
COLL1YR	f70q16 All 1 yr diaries	274	1.2	0.4	1.0	2.0
COLLDIAR	f70q17 All diaries bt FV04 and FV05	274	1.2	0.4	1.0	2.0
F70_DAYS	f70q2 Days from randomization	274	513.2	36.4	432.0	633.0
NEWID	Patient ID	274	155.2	91.4	2.0	313.0