SCREENING FORM - T3B

PURPOSE: To guide the Research Coordinator and Study Investigator through the screening process. To verify the inclusion and exclusion criteria. To provide final documentation that the patient is eligible and agrees or declines to participate in the trial.

PERSONS RESPONSIBLE: Certified Research Coordinator, Study Investigator.

SOURCES OF INFORMATION: The Research Coordinator completes the form at the time of randomization whenever possible. All information must be verifiable in the medical record. Whenever a "STOP" or "INEL" is checked, discontinue completing the form and discard it, as the patient is no longer eligible at this time for possible entry.

PART I: VISIT IDENTIFICATION

1. **NAME CODE:** Record patient name code (i.e., the first three letters of the patient's last name and the first two letters of the patient's first name).

2. **SCREENING DATE:** Record the date the patient experienced the qualifying episode of ischemic pain. If the qualifying episode of pain was late in the evening and the patient was screened the following day, the date of screening should be listed.

3. **PATIENT AGREE TO COMPLETION OF THIS FORM:** Check "yes" if the patient agreed to the screening procedure. Check "no" if the patient did not agree to be considered for T-3 or family members objected. If "no" was checked, discontinue filling out this form.

4 **SEX:** Record the gender of the patient.

5. **RACE:** Record the race/ethnic background of the patient.

PART II: INCLUSION CRITERIA

6. **DATE OF BIRTH:** Record the month, day, and year the patient was born.

   6A. **AGE:** Calculating from the date of birth to the present month, day and year, calculate the patient's age and record if the patient's age falls between 21-79 years of age.

   6B. Indicate if the patient's age is between 21 and 79 years.

7. **ISCHEMIC PAIN $\geq$ 5 MINUTES DURATION AT REST:** Indicate whether or not the patient experienced an episode of ischemic pain at rest within the prior 24 hours of the screening date.

8. **WILL TIME BE $\leq$ 25 HOURS FROM PRESENCE OF PAIN TO TREATMENT:** Check "yes" if $\leq$ 25 hours will elapse between the last known presence of pain for the qualifying episode of ischemic pain to the initiation of treatment. If treatment cannot begin within 25 hours of the qualifying episode of ischemic pain, the patient is not eligible for the study.

   8A. Record the date and military time of the initial onset of the qualifying episode of ischemic pain.

   8B. If the ischemic pain terminated prior to study drug initiation, check "yes" and record the date and military time the pain terminated. If ischemic pain is still present at the time of study drug initiation, check "no".

9. **EVIDENCE OF CAD:**

9A. **ECG Evidence Within 24 Hours Before Enrollment:** Record the new or presumably new ECG evidence of myocardial ischemia obtained during the qualifying episode of pain within 24 hours before enrollment. Answer each item "yes" or "no." **NOTE:** ST elevation or ST depression must be $\geq$ 1 mm in two contiguous leads. T-wave changes consist of inversion in at least two contiguous leads as compared to a known baseline. The ECG with evidence of myocardial ischemia can be obtained at the T3 hospital or the referring hospital or physician's office.

9B. **ECG Evidence More Than 24 Hours Before Enrollment:** Check "yes" if there is new or presumably new ECG evidence of myocardial ischemia obtained during the presenting illness, but more than 24 hours before the time of enrollment. This category is intended for patients who present with myocardial ischemia at a referring hospital or physician's office for whom the following scenario is true. ECGs documenting study defined ECG evidence of myocardial ischemia during an episode of myocardial ischemia are available from the referring physician. The patient later experiences another episode of myocardial ischemia within the 24 hours before enrollment, however the ECG obtained for this later episode does not manifest the T3 ECG study defined inclusion criteria. The patient is eligible for T3 based on the ECG evidence obtained at the referring hospital or physician's office.

The ECG documenting study inclusion criteria should be obtained during the presenting illness at the referring hospital, physician's office, or at the T3 hospital, but should be obtained no earlier than seven days prior to the time of enrollment at the T3 hospital.

9C. **Evidence of CAD:** Record 1) whether the patient has suffered a documented MI > 21 days prior to the qualifying event and 2) if the patient has undergone a previous catheterization and significant coronary disease, defined as > 70 % luminal diameter narrowing of a major coronary segment, was observed.

PART III: EXCLUSION CRITERIA:

10. **EXCLUSION CONDITIONS:** If any exclusion condition is checked "yes," the patient is rendered ineligible for study entry. All items must be checked "no" for the patient to be eligible.

11. **CONTRAINDICATIONS TO THROMBOLYTIC THERAPY:** Each item must be checked "no" for the patient to be eligible for the study. If an item is checked "yes", the patient is rendered ineligible for study entry.

12. **"INEL" CONDITIONS CHECKED ON FORM:** Check "no" if no is checked for all exclusion criteria. If an ineligible condition is identified, check "yes" and discontinue completing the form.

PART IV: ADMINISTRATIVE MATTERS

13. **WAS PATIENT RANDOMIZED:** Check "yes" if patient provided written informed consent to be randomized and was then actually randomized in the study. Check "no" if either the Primary Physician or Study Investigator refused to enter the patient, or if the patient or family members declined participation in the trial.

    If the patient was eligible for randomization but was not randomized and the randomization mailer was <u>not</u> opened, only Form 3B need be completed and submitted.

    If the patient's medical condition suddenly worsens after enrollment to preclude safely administering the study drug, the patient may be excluded. It should be noted, that if the randomization mailer is <u>not</u> opened, the patient would be considered "ineligible" and no Form 3B should be submitted. If the randomization mailer is opened, the patient is a "randomized" patient. Although the condition of the patient may exclude him/her from study drug treatment, all tests and procedures should be completed according to the protocol unless the procedure or test is medically contraindicated. All requisite study forms on these patients should be completed and submitted to the Data Coordinating Center.

14. **QUALIFYING ECG's:** For each patient entered into the study, a qualifying ECG obtained at the time of qualifying ischemic pain is required to be sent to the ECG Core lab. The original ECG tracing documenting the ECG criteria is sent to the ECG Core Lab and a copy to the Data Coordinating Center. If no ECG can be obtained or retrieved, check "no" and provide an explanation. SHOULD THIS OCCUR, HOWEVER, THIS WILL BE CONSIDERED A PROTOCOL VIOLATION.

THROMBOLYSIS IN MYOCARDIAL ISCHEMIA

SCREENING FORM

To be completed at the time of randomization by the person(s) assessing eligibility.

Clinic No.			-						
ID No.			-						
Form Type	S	B	0	1					

PART I: VISIT IDENTIFICATION

1. Patient's NAME CODE: ---------- ___ ___ ___ ___ ___

2. Screening date: ---------- ___ ___ - ___ ___ - ___ ___
   Month Day Year

consent

3. Does patient agree to completion of this form? ---------- (1) (**STOP**)
   Yes No

sex

4. Sex: ---------- (1) (2)
   Male Female

newrace

5. Race: ---------- (1) (2) (3) (4)
   White Black Hispanic Other

3=Hispanic/Other

PART II: INCLUSION CRITERIA

6. Date of birth: ---------- ___ ___ - ___ ___ - ___ ___
   Month Day Year

   A. Age? ---------- ___ ___

age

deleted

   B. Is patient 21 to 75 years of age? ---------- (1) (**STOP**)
   Yes No

7. Has patient reported episode of ≥ 5 minutes of ischemic pain at rest within the prior 24 hours? ---------- (1) (**STOP**)
   Yes No

elpain2

* Age 40=40 or younger, 73=73 or older

ID No.			-						

eltime2

8. Will time be ≤ 25 hours from presence of pain to treatment? ---------- (1) (**STOP**)
Yes No
↓

A. Time of onset of pain:

paindys

1) Date: ---------- ___ ___ - ___ ___ - ___ ___
Month Day Year

painhr painmn

2) Military time: ---------- ___ ___ : ___ ___
Hours Minutes

nopnbfrx

B. Did pain terminate before study treatment initiation? ------- (1) (2)
Yes No
↓

1) Time of termination of pain:

nopaindy

a. Date: ---------- ___ ___ - ___ ___ - ___ ___
Month Day Year

nopainhr nopainmn

b. Military time: ---------- ___ ___ : ___ ___
Hours Minutes

ID No.				-					

	Yes	No	
9. Is there evidence of coronary artery disease?	(1)	(2) (STOP)	cad

A. New or presumably new ECG evidence of myocardial ischemia obtained during the qualifying episode of pain within 24 hours before enrollment or new enzyme evidence of non-Q-wave MI

1) ST elevation criterion (≥ 1 mm in ≥ 2 contiguous leads) --	(1)	(2)	stelcrit
2) ST depression criterion (≥ 1 mm in ≥ 2 contiguous leads) -	(1)	(2)	stdecrit
3) T wave criterion (T wave inversion in ≥ 2 contiguous leads)	(1)	(2)	twcrit
4) Known non-Q-wave MI (elevated enzymes within 24 hours before enrollment)	(1)	(2)	noqcrit

B. New or presumably new ECG evidence of myocardial ischemia obtained during the presenting illness, but more than 24 hours* before enrollment (1) (2) newecgmi

**This ECG evidence should be obtained no more than 7 days prior to enrollment.*

C. Evidence of coronary artery disease:

1) Documented MI > 21 days prior to enrollment	(1)	(2)	micrit
2) ≥ 70% luminal diameter narrowing of major coronary artery on a previous angiogram	(1)	(2)	stencrit
3) Positive exercise thallium test	(1)	(2)	xerttst

Both items below must be checked for a positive exercise thallium test.

a) ≥ 1 mm ST segment depression during exercise or recovery compared to baseline and	(1)	stsegdep
b) ≥ 1 definite reversible defect	(1)	strevdef

If all items marked NO, STOP.

ID No.				-					

PART III: EXCLUSION CRITERIA

10. Are any exclusion conditions satisfied? (*Answer each item.*)

		Yes	No	
A.	Pain suggestive of aortic dissection	(INEL)	(2)	adex
B.	Constant ischemic pain of > 6 hours duration	(INEL)	(2)	durex
C.	New or presumably new ST segment elevation of ≥ 0.10 mV in ≥ 2 contiguous leads not reverting to < 0.10 mV within 30 minutes of administration of therapy (e.g., nitroglycerin)	(INEL)	(2)	acmiex
D.	Left bundle branch block	(INEL)	(2)	lbbex
E.	Treatable cause of angina pectoris	(INEL)	(2)	trange
F.	Acute pulmonary edema	(INEL)	(2)	edemaex
G.	Documented myocardial infarction within prior 21 days	(INEL)	(2)	miex
H.	Systolic arterial blood pressure < 90 mm Hg noted on two recordings 15 minutes apart	(INEL)	(2)	lbpex
I.	Inability to cooperate with the protocol	(INEL)	(2)	locoex
J.	Female of childbearing potential	(INEL)	(2)	femex
K.	PTCA or atherectomy within prior six months	(INEL)	(2)	ptcaex
L.	Prior coronary artery bypass graft surgery	(INEL)	(2)	cabgex
M.	Oral anticoagulant Rx at time of initial enrollment	(INEL)	(2)	coagex
N.	Heparin allergy or intolerance	(INEL)	(2)	hepex
O.	Other major illness (e.g. major infection, active cancer within 5 years, severe hepatic disease, heart disease, renal failure)	(INEL)	(2)	illex
P.	Cardiac catheterization within prior 30 days	(INEL)	(2)	cathex
Q.	Thrombolytic therapy within 72 hours	(INEL)	(2)	thrombex

ID No.				-					

11. Are any of the following contraindications of thrombolytic therapy satisfied? (*Answer each item.*)

		Yes	No	
A.	Past or present bleeding disorder or active bleeding	(**INEL**)	(2)	bleedex
B.	Any confirmed recording of systolic pressure > 180 mm Hg, diastolic pressure > 110 mm Hg on two measurements during presenting illness prior to randomization or uncontrolled hypertension at any time prior to entry	(**INEL**)	(2)	hbpex
C.	Any history of cerebrovascular disease	(**INEL**)	(2)	cvdex
D.	Prolonged cardiopulmonary resuscitation with ≥ 1 minute of external cardiac massage within prior two weeks	(**INEL**)	(2)	resusex
E.	Severe trauma within prior six months	(**INEL**)	(2)	traumaex
F.	History of parenteral or other drug abuse	(**INEL**)	(2)	deleted
G.	Significant surgical procedures within prior two months	(**INEL**)	(2)	surgex
H.	Active peptic ulcer disease within prior six months	(**INEL**)	(2)	ulcerex
I.	Invasive procedure within prior 14 days creating significantly increased risk of hemorrhage	(**INEL**)	(2)	procex
J.	Probable pericarditis	(**INEL**)	(2)	periex

12. Are any "**INEL**" conditions checked on this form? (**INEL**) Yes (2) No — inel

ID No.			-					

PART IV: ADMINISTRATIVE MATTERS

13. Was this patient randomized? ---------- (1) Yes (2) No random

Qualifying ECGs are required for all randomized patients.

A. Reason not randomized: (*Check all that apply.*)

1) M.D. refused ---------- (1) mdref

2) Patient refused ---------- (1) ptref

3) Other ---------- (1) othnrand

Explain: _____

14. Were qualifying ECG's labelled and sent to the Core Lab and copies of ECG Form 09 sent to the DCC? ---------- deleted (1) Yes (2) No

Explain: _____

_____

15. Research Coordinator:

Signature: _____ T3 Staff No.: ---- ___ ___ - ___ ___ ___

16. Date form completed: ---------- ___ ___ - ___ ___ - ___ ___
Month Day Year

ID No.			-					

T3 Form 3B: Variables from earlier revisions

ELPAIN Revision 1 Item 7
Has patient reported episode of $\geq$ 5 minutes of ischemic pain <u>at</u> <u>rest</u> within the prior 12 hours?
1=Yes 2=No (STOP)

ELTIME Revision 1 Item 8
Will time be $\leq$ 13 hours from presence of pain to treatment?
1=Yes 2=No (STOP)

T3 Form 3B: Data Set Revisions

The following items were deleted due to privacy concerns

Item 6B: Patient between 21 and 75 years of age

Item 11F: Parenteral drug abuse

The following item was deleted – no relevant information provided

Item 14: Qualifying ECG sent to Core Lab

The following items were modified

NEWRACE	Item 5: Race 1=White 2=Black 3=Hispanic or Other
AGE	Item 6A: Age Actual age truncated 40=40 or younger 73=73 or older
NOPAINDY	Item8B1: Number of days to termination of pain 1 record corrected for keying error in year

T3B form3b

The CONTENTS Procedure

Data Set Name:	WORK.FORM3B	**Observations:**	1473
Member Type:	DATA	**Variables:**	60
Engine:	V8	**Indexes:**	0
Created:	11:18 Friday, January 23, 2004	**Observation Length:**	264
Last Modified:	11:18 Friday, January 23, 2004	**Deleted Observations:**	0
Protection:		**Compressed:**	NO
Data Set Type:		**Sorted:**	NO
Label:			

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

#	Variable	Type	Len	Pos	Label
27	ACMIEX	Num	4	140	f3Bq10C: New ST elevation
25	ADEX	Num	4	132	f3Bq10A: Aortic dissection
4	AGE	Num	4	48	f3Bq6A: Age
42	BLEEDEX	Num	4	200	f3Bq11A: Bleeding disorder
36	CABGEX	Num	4	176	f3Bq10L: Prior CABG
14	CAD	Num	4	88	f3Bq9: Evidence of Coronary Artery Disea
40	CATHEX	Num	4	192	f3Bq10P: Cardiac cath within 30 days pri
37	COAGRXEX	Num	4	180	f3Bq10M: Oral anticoagulant
2	CONSENT	Num	4	40	f3Bq3: Patient agrees
44	CVDEX	Num	4	208	f3Bq11C: History cerebrovascular disease
26	DUREX	Num	4	136	f3Bq10B: Constant ischemic pain
30	EDEMAEX	Num	4	152	f3Bq10F: Acute pulmonary edema
5	ELPAIN	Num	4	52	f3Bq7: Ischemic pain within 12 hrs
6	ELPAIN2	Num	4	56	f3Bq7: Ischemic pain within 24 hrs
7	ELTIME	Num	4	60	f3Bq8: Treatment within 13 hrs of pain
8	ELTIME2	Num	4	64	f3Bq8: Treatment within 25 hrs of pain
34	FEMEX	Num	4	168	f3Bq10J: Childbearing potential
43	HBPEX	Num	4	204	f3Bq11B: Hypertension
38	HEPEX	Num	4	184	f3Bq10N: Heparin allergy
39	ILLEX	Num	4	188	f3Bq10O: Other major illness
51	INEL	Num	4	236	f3Bq12: Ineligible conditions
28	LBBBEX	Num	4	144	f3Bq10D: Left Bundle Branch Block

T3B form3b

The CONTENTS Procedure

-----Alphabetic List of Variables and Attributes-----					
#	Variable	Type	Len	Pos	Label
32	LBPEX	Num	4	160	f3Bq10H: SBP < 90
33	LOCOEX	Num	4	164	f3Bq10I: Inability to cooperate w/ proto
53	MDREF	Num	4	244	f3Bq13A1: MD refused
20	MICRIT	Num	4	112	f3Bq9C1: MI > 21 days prior
31	MIEX	Num	4	156	f3Bq10G: MI within 21 days prior
19	NEWECGMI	Num	4	108	f3Bq9B: New ECG evidence of MI
56	NEWID	Num	8	8	Patient Identification
58	NEWRACE	Num	8	24	f3Bq5: Race
59	NOPAINDY	Num	5	256	f3Bq8B1: Termination of pain days
12	NOPAINHR	Num	4	80	f3Bq8B1HR: Termination of pain hr
13	NOPAINMN	Num	4	84	f3Bq8B1MN: Termination of pain min
11	NOPNBFRX	Num	4	76	f3Bq8B: Pain terminate before treatment
18	NOQCRIT	Num	4	104	f3Bq9A4: Known non Q-wave MI
55	OTHNRAND	Num	4	252	f3Bq13A3: Other reason not randomized
60	PAINDYS	Num	8	32	f3bq8a1: Onset of pain days
9	PAINHR	Num	4	68	f3Bq8A2HR: Onset of pain hr
10	PAINMN	Num	4	72	f3Bq8A2MN: Onset of pain min
50	PERIEX	Num	4	232	f3Bq11J: Probable pericarditis
49	PROCEX	Num	4	228	f3Bq11I: Invasive procedure within 14 da
35	PTCAEX	Num	4	172	f3Bq10K: PTCA within 6 mos
54	PTREF	Num	4	248	f3Bq13A2: Patient refused
52	RANDOM	Num	4	240	f3Bq13: Randomized
45	RESUSEX	Num	4	212	f3Bq11D: CPR within 2 wks prior
1	REV	Num	8	0	Revision
3	SEX	Num	4	44	f3Bq4: Sex
16	STDECRIT	Num	4	96	f3Bq9A2: ST Depression Criterion
15	STELCRIT	Num	4	92	f3Bq9A1: ST Elevation Criterion
21	STENCRIT	Num	4	116	f3Bq9C2: 70 % Stenosis
24	STREVDEF	Num	4	128	f3Bq9CB: Def reversible defect on ETT
23	STSEGDEP	Num	4	124	f3Bq9CA: ST Depression on ETT
47	SURGEX	Num	4	220	f3Bq11G: Surgery within 2 mos prior

(23JAN04--11:18)

T3B form3b

The CONTENTS Procedure

-----Alphabetic List of Variables and Attributes-----					
#	**Variable**	**Type**	**Len**	**Pos**	**Label**
41	THROMBEX	Num	4	196	f3Bq10Q: Thrombolytic therapy within 72
29	TRANGEX	Num	4	148	f3Bq10E: Treatable angina
46	TRAUMAEX	Num	4	216	f3Bq11E: Trauma within 6 mos prior
17	TWCRIT	Num	4	100	f3Bq9A3: T wave Criterion
57	TXDATE	Num	8	16	F5D/1/8A Date TX Init, Else Onset Date
48	ULCEREX	Num	4	224	f3Bq11H: Peptic ulcer within 6 mos prior
22	XERTTST	Num	4	120	f3Bq9C3: Positive ETT

T3B form3b

	f3Bq4: Sex		
	Male	**Female**	**Total**
f3Bq5: Race			
White	808	366	1174
Black	89	82	171
Other	79	49	128
Total	976	497	1473

T3B form3b

Variable	Label	Value	N	%	<= 20
ELPAIN	f3Bq7: Ischemic pain within 12 hrs	.	988	67.1	
		1	485	32.9	
ELPAIN2	f3Bq7: Ischemic pain within 24 hrs	.	485	32.9	
		1	988	67.1	
ELTIME	f3Bq8: Treatment within 13 hrs of pain	.	988	67.1	
		1	484	32.9	
		2	1	0.1	*
ELTIME2	f3Bq8: Treatment within 25 hrs of pain	.	485	32.9	
		1	987	67.0	
		2	1	0.1	*
NOPNBFRX	f3Bq8B: Pain terminate before treatment	.	226	15.3	
		1	1165	79.1	
		2	82	5.6	
CAD	f3Bq9: Evidence of Coronary Artery Disea	1	1472	99.9	
		2	1	0.1	*
STELCRIT	f3Bq9A1: ST Elevation Criterion	.	1	0.1	*
		1	151	10.3	
		2	1321	89.7	
STDECRIT	f3Bq9A2: ST Depression Criterion	.	2	0.1	*
		1	480	32.6	
		2	991	67.3	
TWCRIT	f3Bq9A3: T wave Criterion	.	2	0.1	*
		1	683	46.4	
		2	788	53.5	

T3B form3b

Variable	Label	Value	N	%	<= 20
NOQCRIT	f3Bq9A4: Known non Q-wave MI	.	1214	82.4	
		1	11	0.7	*
		2	248	16.8	
NEWECGMI	f3Bq9B: New ECG evidence of MI	.	487	33.1	
		1	39	2.6	
		2	947	64.3	
MICRIT	f3Bq9C1: MI > 21 days prior	.	1	0.1	*
		1	568	38.6	
		2	904	61.4	
STENCRIT	f3Bq9C2: 70 % Stenosis	.	2	0.1	*
		1	483	32.8	
		2	988	67.1	
XERTTST	f3Bq9C3: Positive ETT	.	1213	82.3	
		1	11	0.7	*
		2	249	16.9	
STSEGDEP	f3Bq9CA: ST Depression on ETT	.	1462	99.3	
		1	11	0.7	*
STREVDEF	f3Bq9CB: Def reversible defect on ETT	.	1462	99.3	
		1	11	0.7	*
ADEX	f3Bq10A: Aortic dissection	2	1473	100.0	
DUREX	f3Bq10B: Constant ischemic pain	2	1473	100.0	
ACMIEX	f3Bq10C: New ST elevation	2	1473	100.0	

T3B form3b

Variable	Label	Value	N	%	<= 20
LBBBEX	f3Bq10D: Left Bundle Branch Block	2	1473	100.0	
TRANGEX	f3Bq10E: Treatable angina	2	1473	100.0	
EDEMAEX	f3Bq10F: Acute pulmonary edema	2	1473	100.0	
MIEX	f3Bq10G: MI within 21 days prior	2	1473	100.0	
LBPEX	f3Bq10H: SBP < 90	2	1473	100.0	
LOCOEX	f3Bq10I: Inability to cooperate w/ proto	2	1473	100.0	
FEMEX	f3Bq10J: Childbearing potential	2	1473	100.0	
PTCAEX	f3Bq10K: PTCA within 6 mos	2	1473	100.0	
CABGEX	f3Bq10L: Prior CABG	2	1473	100.0	
COAGRXEX	f3Bq10M: Oral anticoagulant	2	1473	100.0	
HEPEX	f3Bq10N: Heparin allergy	2	1473	100.0	
ILLEX	f3Bq10O: Other major illness	2	1473	100.0	
CATHEX	f3Bq10P: Cardiac cath within 30 days pri	2	1473	100.0	
THROMBEX	f3Bq10Q: Thrombolytic therapy within 72	.	225	15.3	
		2	1248	84.7	
BLEEDEX	f3Bq11A: Bleeding disorder	2	1473	100.0	

T3B form3b

Variable	Label	Value	N	%	<= 20
HBPEX	f3Bq11B: Hypertension	1	1	0.1	*
		2	1472	99.9	
CVDEX	f3Bq11C: History cerebrovascular disease	2	1473	100.0	
RESUSEX	f3Bq11D: CPR within 2 wks prior	2	1473	100.0	
TRAUMAEX	f3Bq11E: Trauma within 6 mos prior	2	1473	100.0	
SURGEX	f3Bq11G: Surgery within 2 mos prior	2	1473	100.0	
ULCEREX	f3Bq11H: Peptic ulcer within 6 mos prior	2	1473	100.0	
PROCEX	f3Bq11I: Invasive procedure within 14 da	2	1473	100.0	
PERIEX	f3Bq11J: Probable pericarditis	2	1473	100.0	
INEL	f3Bq12: Ineligible conditions	1	2	0.1	*
		2	1471	99.9	
RANDOM	f3Bq13: Randomized	1	1472	99.9	
		2	1	0.1	*
MDREF	f3Bq13A1: MD refused	.	1473	100.0	
PTREF	f3Bq13A2: Patient refused	.	1473	100.0	
OTHNRAND	f3Bq13A3: Other reason not randomized	.	1472	99.9	
		1	1	0.1	*

T3B form3b

Variable	Label	N	Percentile	Value	n	<= 20
AGE	f3Bq6A: Age	1473	5	42	88	
			25	51	285	
			50	59	368	
			75	67	394	
			95	73	338	
			100	73	0	*

T3B form3b

Variable	Label	N	Mean	Std Dev	Minimum	Maximum
PAINDYS	f3bq8a1: Onset of pain days	1472	0.7	0.4	-1.0	1.0
PAINHR	f3Bq8A2HR: Onset of pain hr	1472	11.5	6.3	0.0	24.0
PAINMN	f3Bq8A2MN: Onset of pain min	1472	16.5	17.7	0.0	59.0
NOPAINDY	f3Bq8B1: Termination of pain days	1389	0.9	3.1	-31.0	98.0
NOPAINHR	f3Bq8B1HR: Termination of pain hr	1387	11.7	6.2	0.0	24.0
NOPAINMN	f3Bq8B1MN: Termination of pain min	1387	20.9	17.1	0.0	59.0