ADMISSION AND TREATMENT ASSIGNMENT FORM - T3 FORM 04

PURPOSE: To capture current clinical information to characterize the patient's health status at the time of randomization, and provide a pertinent profile of the patient's past medical history. In addition, this form documents the treatment assignment for the T3 protocol, the details surrounding the study infusion, and major events during the first 24 hours following the study treatment.

PERSONS RESPONSIBLE: Certified Research Coordinator.

SOURCES OF INFORMATION: Patient (family members), medical record, physician, and primary care nurses caring for the patient.

TIME OF DATA COLLECTION: As patient is evaluated for entry into T-3, upon receiving informed consent from the patient, and during the initial 24 hours after study treatment.

GENERAL INSTRUCTIONS: Data collected on this form will be used to record information on the treatment notification form, T-3 Form 5D.

PART I: IDENTIFICATION

1. **NAME CODE:** Record patient's 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 date the patient experienced the qualifying episode of ischemic pain and qualified for T-3. Information collected relevant to the current status of the patient should be ascertained based on the screening date. 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.

PART II: BACKGROUND DATA

3. **EDUCATION:** Self-explanatory.

4. **EMPLOYMENT:** Indicate the patient's employment status at 3 weeks prior to qualifying for T-3. Any temporary changes due to worsening symptoms should not be included. For example, if the patient worked full-time and went on sick leave only after a recent MI and plans to return to work as soon as possible after the procedure, "full-time" should be checked. A patient who retired several years ago and now works in a part-time position should be listed as "part-time" and not "retired."

PART III: MEDICAL HISTORY

5. **HISTORY OF MI:** Record the patient's history of a previous (before the qualifying episode) myocardial infarction. If the patient has ever been told by his/her physician that he/she has had a heart attack and this information has been verified by a written physician's statement in the medical record, then check "yes" to this question. In general, patients with myocardial infarction have been hospitalized for more than 5 days, been told of abnormal blood tests, and/or ECG evidence indicative of heart damage, and have experienced some clinical manifestation of ischemia, such as chest discomfort, nausea, sweating, or shortness of breath lasting 45 minutes in duration. A history of myocardial infarction not fulfilling these criteria (a physician statement, general definition) should not be considered a documented myocardial infarction.

    A. **Date of most recent MI:** If the patient has suffered more than one myocardial infarction, record the date

of the most recent MI prior to the current admission. Record '98' for "month" and "day" if these data are not available.

B. **Thrombolytic therapy:** Check "yes" if the patient was administered a thrombolytic agent for treatment of the most recent myocardial infarction.

C. **Number of previous MIs:** Record the total number of myocardial infarctions that patient has suffered that are documented.

6. **RISK FACTORS:**

A. **History of cigarette smoking:** Check "yes" if the patient ever smoked cigarettes (more than 100 cigarettes ever). The following data items relating to smoking are required in order to calculate the number of pack years a patient smoked.

1. **Daily consumption:** Average number of cigarettes (not packs) smoked per day before patient decided to quit.

2. **Number of years smoked:** Total number of years smoked, excluding any years when the patient quit.

3. **Number of months before study entry that patient quit smoking:** Enter the number of months since the patient quit smoking, if the patient is currently not smoking. Enter all 0's if patient currently smokes.

B. **Family history of CAD:** Check "yes" if the patient's direct blood relatives have a positive history of angina pectoris, myocardial infarction, or sudden abrupt death without obvious cause before the age of 55. Blood relatives include the patient's parents, siblings, or children related by blood. Unknown should only be used if the patient has no knowledge of any cardiac history of blood relatives.

C. **Hypertension:** The patient has been told by a physician that he/she has hypertension and has been treated for hypertension by medication and/or diet.

D. **Elevated serum cholesterol requiring medical treatment:** The patient has been told by a physician that his/her blood cholesterol is > 240 mg/dl. The patient must also have been prescribed medication to lower his/her blood cholesterol. If the patient does not remember or does not know, check "unknown."

E. **Diabetes mellitus requiring medical treatment:** The patient has been told by a physician that he/she has diabetes mellitus and has received medical treatment. Medical treatment includes insulin, all hypoglycemic medications and rigid dietary guidelines.

7. **OTHER ILLNESS:** Check "yes" if the patient has ever been diagnosed by a physician to have experienced a significant illness in one of the major areas listed.

8. **MEDICATIONS:** Record if the patient has been prescribed any of the following medications within the 7 days prior to randomization. If a particular medication, such as heparin, is currently prescribed, check that medication. If a medication has more than one action, check the category of the action for which the medication was prescribed.

A. **Heparin:** Heparin is an anticoagulant which thins the blood to prevent formation of blood clots. The use of heparin requires regular monitoring with blood tests to insure the appropriate dose and level of effectiveness.

B. **Nitrates:** Various forms of long-acting and short-acting nitroglycerin taken regularly to decrease the frequency, duration, and severity of chest discomfort. The medication is given orally or sublingually. Types include: Isordil, Cardiolate, Nitrobid, Nitrospan, Peritrate, Sorbitrate, Nitroglycerin Paste.

C. **Beta blockers:** Beta blockers block the stimulating effect of the nervous system on the heart. This decreases the work of the heart and results in a decrease in angina frequency. They could also be used as antiarrhythmic agents and antihypertensive agents. Common forms of beta blockers include: Atenolol, Metoprolol, Nadolol, Pindolol, Propranolol, Timolol, Propranolol-HCL, Propranolol-LA, Acebutolol, Labetolol.

D. **Calcium channel blockers:** These block the entry of calcium into the cardiac and vascular smooth muscle cells. They are effective in the treatment of chronic stable angina, either alone or in combination with beta adrenoceptor blockers and nitrates. Common forms include: Verapamil, Nifedipine, Diltiazem.

E. **Persantine (dipyridamole)/Sulfinpyrazone:** These drugs are used to reduce blood platelet adhesiveness. Theoretically, the latter has the potential for decreasing the progression of arterial obstruction and thickening.

F. **Anti-platelet agents other than aspirin or persantine:** These drugs are used to reduce blood platelet adhesiveness. Theoretically, the latter has the potential for decreasing the progression of arterial obstruction and thickening.

G. **Aspirin < 24 hours before qualifying event:** Check "yes" if the patient has taken an aspirin tablet within 24 hours of experiencing the ischemic pain episode that qualified for T-3. Aspirin reduces blood platelet adhesiveness.

H. **Anticoagulants other than heparin >48 hours before event:** This refers almost exclusively to coumadin which thins the blood to prevent formation of blood clots. This requires regular monitoring with blood tests to insure the appropriate dose and level of effectiveness.

I. **Lipid-lowering agents:** Drugs given to lower the cholesterol and triglycerides of patients with elevated levels of these lipids. Most frequently prescribed are Nicotinic Acid or Bile Acid Sequestrants, Bile Acid Resins (Cholestyramine or Colestipol), Probucol, Gemfibrozil, and Lovostatin.

J. **Diuretics:** These drugs are used to remove excess fluid from the body. Common forms include Furosemide (Lasix), Ethacrynic Acid, Thiazide (HCTZ), Aldactone (Aldactazide).

K. **ACE inhibitors:** These drugs act by blocking the angiotensin-converting enzyme and are used to treat patients with hypertension and heart failure. Common forms of these drugs are Capoten and Vasotec.

L. **Vasodilators other than ACE inhibitors/nitrates/and calcium channel blockers:** These drugs are used to relax the arterial vessels. They are commonly used in the treatment of patients with hypertension and include: Hydralazine (Apresoline, Minoxidil, Nitroprusside).

M. **Digitalis or derivatives:** This drug is given to patients with congestive heart failure to improve the heart's ability to contract. Common forms include Digoxin, Digitoxin, and Lanoxin.

N. **Inotropic agents:** Drugs used to increase the force of cardiac muscular contractions, for example, Metaraminol (Aramine), Dopamine, Dobutamine (Dobutrex).

O. **Antiarrhythmic agents:** Drugs used to decrease the number of ectopic heart beats, either atrial or ventricular. The most frequently used include: Pronestyl, Quinidine, Dilantin, Norpace, Mexiletine, Amiodarone, Procainamide, Bretylium.

9. **HAS PATIENT EVER EXPERIENCED ANGINA:** Angina pectoris is a discomfort in the chest or adjacent areas which is caused by myocardial ischemia and is associated with a disturbance in myocardial function, but **without necrosis.** This is an important distinction and pain of infarction should not be classified as angina. Angina pectoris is a constellation of sensations where chest discomfort is often described as "constricting, crushing, heavy, squeezing." It can also be a vague numbness or pressure sensation. In some patients, angina equivalents are present, such as shortness of breath, fatigue, and belching. In most cases, angina is precipitated by some form of exertion and is generally relieved upon resting. In differentiating angina from non-angina, features of non-anginal pain are: pain lasting < 5 seconds or > 20 to 30 minutes in the absence of MI, discomfort aggravated by breathing or movement of arms, pain relieved by swallowing water or food, pain localized to a very small area. When evaluating a patient's symptoms and limitations due to ischemia, all features described by the patient should be taken into consideration. Both the quality and factors precipitating the discomfort must be viewed together in order to gauge the presence or severity of the ischemia.

A. **Anginal pain pattern during two months prior to qualifying episode:** Record all patterns of angina

the patient describes as having occurred during the two months prior to the qualifying episode.

B. **Canadian Cardiovascular Society Classification at one month prior to qualifying episode:** Using the definition provided on the forms, indicate which class of angina the patient fulfills at one month prior to the qualifying episode of ischemic pain. If the patient's symptoms have improved or worsened during the one month prior to the qualifying episode, **ONLY** record the Canadian Classification at one month rather than during the one month prior to the qualifying episode.

C. **Onset of New Anginal Symptoms:**

1. **New onset angina** - Check "yes" if the patient experienced their <u>first</u> episode of angina within the prior two months.

2. **Distinct onset of an increase in angina** - Check "yes" if the patient can clearly discern and describe a definite increase in severity or frequency of angina within the prior two months.

3. **First episode of rest angina** - Check "yes" if the patient experienced the <u>first</u> episode of <u>rest</u> pain within the prior two months. The patient may or may not also have experienced exertional angina during this same period.

10. **NUMBER OF ISCHEMIC PAIN EPISODES DURING 48 HOURS PRIOR TO CURRENT EPISODE:** Record the number of episodes of ischemic pain lasting more than 2 minutes and documented by the patient and/or medical record.

11. **PTCA PERFORMED > 6 MONTHS:** Self-explanatory.

A. **Date of most recent PTCA:** If patient has undergone more than 1 PTCA procedure, record the date of the most recent procedure. Record '98' for "month" and "day" if these data are not available.

PART IV: PHYSICAL EXAM

The following items pertain to the physical exam of the patient at the time of confirming T-3 eligibility.

12. **HEIGHT:** Record in centimeters the patient's height (2.54 centimeters/inch).

13. **WEIGHT:** Record in kilograms the patient's weight (2.2 pounds/kilogram).

14. **BLOOD PRESSURE:** Record the patient's supine systolic and diastolic blood pressure.

15. **S_3:** Record the presence or absence of S_3 as verified by a physician and the medical record.

16. **RALES > 1/3 LUNG FIELD:** Record the presence of significant pulmonary rales which do not clear on coughing.

17. **PATIENT STILL ELIGIBLE:** Indicate whether or not the patient remains eligible for randomization at the time of confirming eligibility immediately prior to randomization. If this question is answered "no", then Form 04 and the Screening Form should not be submitted to the Data Coordinating Center since the patient is not eligible for the study and the randomization mailer has not been opened.

    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.

PART V: TREATMENT ASSIGNMENT

18. **T-3 TREATMENT ASSIGNMENT:** Self-explanatory.

19. **CORRECT SEQUENCE NUMBER:** Self-explanatory.

PART VI: T-3 TREATMENT

20. **WAS STUDY TREATMENT INITIATED:** Check "yes" if any study treatment was infused in the patient and answer A through E. If, for some reason, the patient was not treated with any of the study drug, check "no" and answer Section F.

    A1. **DOSE:** Record total dose of study drug administered to patient.

A2. **IF LESS THAN PROTOCOL - SPECIFIED DOSE, GIVE REASON:** Record the primary reason why a smaller dose of study drug was administered to patient. In the case of MI which required that the patient assignment be unblinded and he/she received "placebo", record the amount of placebo administered under "dose" and complete the MI Event Form 23. Form 23 will indicate the amount and type of thrombolytic therapy administered, if applicable.

A3. **IF MORE THAN PROTOCOL - SPECIFIED DOSE, GIVE REASON:** Record the primary reason why a larger study drug dose was administered to the patient. For a patient with a Q-wave MI (ST $\uparrow \geq 1$ mm for at least 30 minutes) and the patient treatment was unblinded and t-PA was administered, record the total amount of t-PA administered including the amount of study drug and additional drug, and complete the MI Event Form 23.

B-E. Record the date and military time for each category.

F. **REASON STUDY DRUG TREATMENT NOT INITIATED:** Record the primary reason why the study drug was not administered.

21. **WAS PATIENT ON CONTINUOUS HEPARIN INFUSION FOR AT LEAST 24 HOURS PRIOR TO TREATMENT INITIATION:** Check "yes" if the patient was being treated with a continuous infusion of heparin for at least 24 hours before study drug initiation. Record the current dose of heparin the patient was being treated with, the month, day, and year treatment was initiated, and the time of treatment initiation. If it is not possible to estimate to the nearest hour the time of heparin treatment initiation, record '9898' for military time.

22. **HEPARIN BOLUS WITHIN 24 HOURS PRIOR TO TREATMENT INITIATION:** Check "yes" if the patient received any heparin bolus within the 24 hour period prior to study drug initiation. If the patient is in T3A, this would include the time of catheterization.

23. **COMPLICATIONS OR ENDPOINTS WITHIN THE FIRST 24 HOURS OF STUDY TREATMENT INITIATION:** Check "yes" to any complication or end point listed below, that the patient experienced during the first 24 hours of commencing study treatment.

A. **Death:** Self-explanatory.

B. **MI AFTER STUDY DRUG:** Check "yes" if it is suspected that the patient suffered a myocardial infarction after the <u>conclusion</u> of the study treatment initiation. In

general, myocardial infarction is defined using criteria based on ischemic pain, cardiac enzymes, and ECGs. For specific details concerning the definition of MI, refer to Form 23 instructions.

C. **Ischemic pain <u>at</u> <u>rest</u> with ECG changes:** Check "yes" if the patient experienced a) an episode of ischemic pain $\geq$ 5 minutes in duration associated with $\geq$ 2 mm of ST depression or elevation in at least 2 contiguous leads; b) an episode of ischemic pain lasting $\geq$ 20 minutes in duration associated with $\geq$ 1 mm of ST depression or elevation or T-wave inversion in at least 2 contiguous leads; or c) 2 or more episodes of ischemic pain $\geq$ 5 minutes in duration associated with $\geq$ 1 mm ST depression or elevation or T-wave inversion in at least 2 contiguous leads.

D. **Hemorrhagic event:** Check "yes" if the patient experienced any hemorrhagic event.

E. **Neurologic event:** Check "yes" if the patient experienced any neurologic event including but not limited to coma, stroke, and transient ischemic attack.

24. **TIME INTERVAL FROM LAST EPISODE OF ISCHEMIC PAIN TO TREATMENT INITIATION:** Estimate the number of hours between the end of the last episode of ischemic pain to the start of treatment. If ischemic pain has not ended, check '< 1 hour'. The last episode of ischemic pain is not necessarily the qualifying episode, but that episode of ischemic pain which occurred closest to the treatment initiation.

PART VII: ADMINISTRATIVE MATTERS

Self-explanatory.

To be completed by Research Coordinator at baseline and after treatment is completed.

Clinic No.			-						
ID No.			-						
Form Type	A	T	0	1					

PART I: IDENTIFICATION

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

fm04dys

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

PART II: BACKGROUND DATA

3. Education:

school

Grade 11 or less ---------- (1)
High school graduate or equivalency ---------- (2)
Unknown ---------- (3)

4. Time commitment to employment at 3 weeks prior to episode: (*Check all that apply.*)

deleted

A. Full-time (≥ 32 hr/wk) ---------- (1)
B. Part-time ---------- (1)
C. Homemaker ---------- (1)
D. Retired ---------- (1)
E. Unemployed ---------- (1)
F. Disabled/sick leave ---------- (1)
G. Unknown ---------- (1)

PART III: MEDICAL HISTORY (PRIOR TO CURRENT EPISODE)

5. Does the patient have a history of myocardial infarction prior to the current episode? ---------- mihx (1) Yes (2) No (3) Unknown

↓

A. Date of most recent MI: ---------- midys __ __ - __ __ - __ __ (Month - Day - Year)

miunkdy (1) Unknown

B. For most recent MI was thrombolytic therapy used? ---------- mithrm (1) Yes (2) No (3) Unknown

C. Number of previous MIs: ---------- minum __

miunknum (1) Unknown

6. Record whether patient has any of the following coronary risk factors. (*Answer each item.*)

A. History of cigarette smoking? ---------- smoke (1) Yes (2) No

↓

1) Average number of cigarettes per day ---------- cigday __ __

2) Number of years smoked ---------- yrsmoke __ __

3) Number of months before study entry that patient quit smoking (enter 000 if current smoker) ---------- quitnum __ __ __

	Yes	No	Unknown
B. Family history (parent, sibling, child) of coronary artery disease before age 55? ---------- famcad	(1)	(2)	(3)
C. Hypertension requiring medical treatment? ---------- hbptx	(1)	(2)	(3)
D. Elevated serum cholesterol requiring medical treatment? ---------- choltx	(1)	(2)	(3)
E. Diabetes mellitus requiring medical treatment? ---------- diabtx	(1)	(2)	(3)

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7. Was patient ever diagnosed with any of the following? (*Answer each item.*)

		Yes	No	Unknown
			othcd	
A.	Cardiac disease other than IHD	(1)	(2)	(3)
	Specify: _____			
	pvd			
B.	Peripheral vascular disease	(1)	(2)	(3)
C.	Gastrointestinal disease — gi	(1)	(2)	(3)
D.	Hematological disease — hema	(1)	(2)	(3)
E.	Renal disease — renal	(1)	(2)	(3)
F.	Neurological disease — neuro	(1)	(2)	(3)
G.	Other significant disease — othdis	(1)	(2)	(3)
	Specify: _____			

8. Have any of the following been taken by patient during the week prior to enrollment? (*Answer each item.*)

		Yes	No	Unknown
A.	Heparin — prehep	(1)	(2)	(3)
B.	Nitrates — prenitra	(1)	(2)	(3)
C.	Beta-blocker therapy — prebeta	(1)	(2)	(3)
D.	Calcium channel blockers — preccb	(1)	(2)	(3)
E.	Persantine/sulfinpyrazone — prepers	(1)	(2)	(3)
F.	Antiplatelet agents other than ASA or persantine — preplate	(1)	(2)	(3)
G.	Aspirin < 24 hours before qualifying event — preasa	(1)	(2)	(3)
H.	Anticoagulant other than heparin > 48 hours before event — precoag	(1)	(2)	(3)
I.	Lipid-lowering agent — prelipid	(1)	(2)	(3)
J.	Diuretics — prediur	(1)	(2)	(3)
K.	ACE inhibitors — preacein	(1)	(2)	(3)
L.	Vasodilator other than ACE inhibitor/nitrates/ calcium channel blockers — predilat	(1)	(2)	(3)
M.	Digitalis or derivative — predigit	(1)	(2)	(3)
N.	Inotropic agent — preinot	(1)	(2)	(3)
O.	Antiarrhythmic agent — prerhyth	(1)	(2)	(3)

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9. Has the patient ever experienced angina prior to current episode? - preang

(1) Yes	(2) No	(3) Unknown
↓	↓	↓
	Skip to 10.	

A. Describe anginal pain pattern during two months prior to qualifying episode: (*Check all that apply.*)

1)	None	prenoang (1)
2)	At rest	prerest (1)
3)	Exertional	preexert (1)
4)	Accelerating	preaccel (1)
5)	Nocturnal	prenight (1)
6)	Angina lasting > 20 minutes	prelong (1)

B. Indicate Canadian Cardiovascular Society Classification at one month prior to qualifying episode: (*Choose one.*)

preccsc

No angina	(1)
I	(2)
II	(3)
III	(4)
IV	(5)

Continue with Item 9C on page 5.

Canadian Cardiovascular Society Classification:

Class I: *"Ordinary physical activity (such as walking and climbing stairs) does not cause...angina". Angina with strenuous or rapid or prolonged exertion at work or recreation.*

Class II: *"Slight limitation of ordinary activity," such as walking or climbing stairs rapidly; walking uphill; walking or stair climbing after meals; or in cold, in wind, or under emotional stress; or only during the few hours after awakening; or walking more than two blocks on the level; or climbing more than one flight of ordinary stairs at a normal pace and in normal conditions.*

Class III: *"Marked limitation of ordinary physical activity," such as walking one or two blocks on the level or climbing one flight of stairs in normal conditions and at a normal pace. "Comfortable at rest."*

Class IV: *"Inability to carry on any physical activity without discomfort... anginal syndrome MAY be present at rest."*

9. Continued....

C. Indicate the onset of new anginal symptoms during prior two months:
(Answer each item and record date of first of each event.)

Event	Yes	No	Unknown	DATE OF EVENT Month	Day	Year
1) New onset angina	(1)	(2) newang	(3)	__ __	nangdys __ __	__ __
2) A distinct onset of an increase in anginal symptoms	(1)	(2) incang	(3)	__ __	iangdys __ __	__ __
3) First episode of rest angina	(1)	(2) frstang	(3)	__ __	fangdys __ __	__ __

10. Number of episodes of ischemic pain during 48 hours prior to current episode? ---------- painnum ___ ___

11. Was PTCA performed > six months prior to enrollment? ---------- preptca (1) Yes (2) No (3) Unknown

↓

A. Date of most recent PTCA: ---------- ptcadys __ __ - __ __ - __ __ (Month - Day - Year)

ptcaunk (1) Unknown

PART IV: PHYSICAL EXAM (AT TIME OF RANDOMIZATION)

THE FOLLOWING ITEMS PERTAIN TO THE PHYSICAL EXAM AT THE TIME OF CONFIRMING T3 ELIGIBILITY. ALL EXCLUSION CRITERIA SHOULD BE REVIEWED WITH THE PATIENT AND THE MEDICAL RECORD IMMEDIATELY PRIOR TO RANDOMIZATION TO AVOID RANDOMIZING A PATIENT WHOSE CONDITION SIGNIFICANTLY CHANGED FULFILLING AN EXCLUSION CRITERION AFTER ENROLLMENT BUT BEFORE RANDOMIZATION.

bmi=(weight/height**2)x

12. Height: ---------- ___ ___ ___ cm

13. Weight: ---------- ___ ___ ___ kg

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14. Blood pressure: (First recording taken at the time of screening for eligibility.)

sysbp

A. Systolic: ---------- ___ ___ ___ mm Hg

diasbp

B. Diastolic: ---------- ___ ___ ___ mm Hg

	Present	Absent	Unknown
15. Heart sounds:			
sounds			
S_3 ----------	(1)	(2)	(3)
rales			
16. Rales in > 1/3 lung field which do not clear on coughing? -----	(1)	(2)	(3)

eligible

17. Is patient still eligible for treatment (immediately prior to opening randomization mailer)? ---------- (1) Yes (STOP) No

↓

PATIENT IS NOT ELIGIBLE FOR STUDY. DO NOT OPEN RANDOMIZATION MAILER. DO NOT SUBMIT ANY STUDY FORMS.

PART V. TREATMENT ASSIGNMENT

18. T3 treatment assignment used.

A. Patient therapy kit number: ---------- ___ ___ - ___ - ___ ___ ___ ___

deleted - see Form5D,Item 7

B. Check one randomization assignment:

1) T3A ---------- (1)

2) Invasive strategy (T3B) ---------- (2)

3) Conservative strategy (T3B) ---------- (3)

C. Mailer Sequence Number: ---------- ___ ___ ___

deleted

19. Was the correct sequence number mailer assigned to this patient? ---------- (1) Yes (2) No

↓

Submit Incorrect Treatment Assignment Form 5C.

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PART VI: T3 TREATMENT

initiate

20. Was study treatment initiated? ---------- (1) Yes ↓ ; (2) No ↓ *Answer F*

A. Study treatment:

t3rxdose

1) Dose: ---------- ___ ___ ___ mg

2) If less than protocol-specified dose given, check primary reason:

lesdos2

MI ---------- (1)*
Intracranial hemorrhage ---------- (2)**
Bleeding ---------- (3)
Death ---------- (4)***
Other ---------- (5)
Specify: _____

3) If more than protocol-specified dose given, check primary reason:

moredose

MI ---------- (1)*
Other ---------- (2)
Specify: _____

B. Date study treatment began: ---------- ___ ___ - ___ ___ - ___ ___ (tx2dy)
Month Day Year

C. Military time study treatment began: ---------- txhr ___ ___ : txmn ___ ___
Military Time

D. Date study treatment completed: ---------- ___ ___ - ___ ___ - ___ ___ (txenddys)
Month Day Year

E. Military time study treatment completed: ---------- txendhr ___ ___ : txendmn ___ ___
Military Time

F. Reason study treatment not initiated:

notx

Patient died ---------- (1)***
Patient refused ---------- (2)
Patient's condition changed ---------- (3)
Other ---------- (4)
Specify: _____

Submit Myocardial Infarction Form 23.

***Submit Severe Neurologic Event Form 27.*

****Submit Death Notification Form 15 to DCC within 72 hours of death. Submit Cause of Death Form 16 within 14 days of death.*

21. Was patient on continuous heparin infusion for at least 24 hours prior to treatment initiation? ---------- conthep (1) Yes (2) No

↓

A. Dose: ---------- hepdose ___ ___ ___ ___ (USP)/HR

B. Date infusion began: ---------- hepdys ___ ___ - ___ ___ - ___ ___ (Month - Day - Year)

C. Military time infusion began: ---------- hephr ___ ___ : hepmn ___ ___ (Hours : Minutes)

22. Did patient receive a heparin bolus within 24 hours prior to treatment initiation (T3A or T3B) or at time of catheterization (T3A only)? --------- hepbolus (1) Yes (2) No

↓

A. Dose: ---------- bolusdse ___ ___ ___ ___ (USP)

B. Date bolus administered: ---------- boldys ___ ___ - ___ ___ - ___ ___ (Month - Day - Year)

C. Military time bolus administered: ---------- bolushr ___ ___ : bolusmn ___ ___ (Hours : Minutes)

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23. Were there any of the following end points or complications within the first 24 hours after study treatment initiation? ---------- comp24 (1) Yes (2) No

Check all that apply.

A. Death ---------- death24 (1)*

B. MI after study drug treatment ---------- mi24 (1)*

C. Ischemic pain at rest with ECG changes meeting study criteria ---------- ischem24 (1)*

(*Check all that apply.*)

1) Single episode of pain lasting at least 5 minutes with ST elevation/depression ≥ 2 mm in ≥ 2 contiguous leads ---------- ischt1 (1)

2) Single episode of pain lasting at least 20 minutes with:
a) ST elevation/depression ≥ 1 mm in ≥ 2 contiguous leads; or b) T-wave inversion in ≥ 2 contiguous leads ---------- ischt2 (1)

3) Two or more episodes of pain lasting at least 5 minutes with: a) ≥ 1 mm ST elevation/depression in ≥ 2 contiguous leads; or b) T-wave inversion in ≥ 2 contiguous leads ---------- ischt3 (1)

D. Hemorrhagic event ---------- bleed24 (1)*

E. Neurologic event ---------- stroke24 (1)*

**Submit appropriate event, ECGs and test forms to Core Laboratories and the DCC.*

24. Record time interval between the presence of the last episode of ischemic pain and treatment initiation: intervl2

< 1 hour ---------- (1)
1 to 3.5 hours ---------- (2)
>3.5 to 6.0 hours ---------- (3)
>6.0 to 12.0 hours ---------- (4)
> 12.0 hours ---------- (5)

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PART VII: ADMINISTRATIVE MATTERS

25. The following items are being submitted to the Data Coordinating Center with this form. *(Check all that apply.)*

A.	Unblinding envelope: ---------- deleted	(1)
B.	MI Event Form 23 ---------- deleted	(1)
C.	Hemorrhagic Event Form 24 ---------- deleted	(1)
D.	Cause of Death Form 16 ---------- deleted	(1)
E.	Severe Neurologic Event Form 27 ---------- deleted	(1)

26. Is the used patient therapy kit being sent to Drug Distribution Center? --- amtkit (1) Yes (2) No

27. Research Coordinator:

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

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

FOR DATA COORDINATING CENTER USE ONLY
29. Documents received: Unblinding envelope ----- (1)

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T3 Form 04: Variable from earlier revision

LESSDOSE Revision 0, Item 20A2
If less than protocol-specified dose given, check primary reason
1=Intracranial hemorrhage
2=Bleeding
3=Death
4=Other

T3 Form 04: Data Set Revisions

The following item was deleted, use Form 5D, Item 7

Item 18B: Randomization Assignment

The following items were deleted due to privacy concerns:

Item 4A: Employment Status Full-time
Item 4B: Employment Status Part-time
Item 4C: Employment Status Homemaker
Item 4D: Employment Status Retired
Item 4E: Employment Status Unemployed
Item 4F: Employment Status Disabled or Sick Leave
Item 4G: Employment Status Unknown

The following items were deleted – no relevant information provided

Item 19: Correct mailer assigned
Item 25A: Unblinding Envelope with form
Item 25B: Form 23 with this form
Item 25C: Form 24 with this form
Item 25D: Death Form with this form
Item 25E: Form 27 with this form
Item 26: Used Kit sent to Drug Dist Ctr

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The CONTENTS Procedure

Data Set Name:	WORK.FORM04	**Observations:**	1473
Member Type:	DATA	**Variables:**	97
Engine:	V8	**Indexes:**	0
Created:	12:03 Friday, January 30, 2004	**Observation Length:**	448
Last Modified:	12:03 Friday, January 30, 2004	**Deleted Observations:**	0
Protection:		**Compressed:**	NO
Data Set Type:		**Sorted:**	NO
Label:			

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

#	Variable	Type	Len	Pos	Label
82	BLEED24	Num	4	416	f04q23D: Hemorrhagic event within 24 hrs
87	BMI	Num	8	16	f04: Body Mass Index
94	BOLDYS	Num	8	72	f04q22B: Bolus Days
72	BOLUSDSE	Num	5	437	f04q22A: Bolus Dose
73	BOLUSHR	Num	4	380	f04q22CHR: Bolus Hr
74	BOLUSMN	Num	4	384	f04q22CMN: Bolus Min
14	CHOLTX	Num	4	152	f04q6D: Treatment for Elev. Cholestrol
9	CIGDAY	Num	4	132	f04q6A1: Avg. Cigarettes per Day
75	COMP24	Num	4	388	f04q23: Complications
67	CONTHEP	Num	4	364	f04q21: Contiuous Heparin
76	DEATH24	Num	4	392	f04q23A: Death within 24 hrs
15	DIABTX	Num	4	156	f04q6E: Treatment for Diabetes
53	DIASBP	Num	4	308	f04q14B: Diastolic Blood Pressure
56	ELIGIBLE	Num	4	320	f04q17: Patient Eligible
12	FAMCAD	Num	4	144	f04q6B: Family History CAD
89	FANGDYS	Num	8	32	f04q9C3: First Episode Rest Angina Days
95	FM04DYS	Num	8	80	f04q2: Screening Days
48	FRSTANG	Num	4	288	f04q9C3: First Episode Rest Angina
18	GI	Num	4	168	f04q7C: Gastrointestinal Disease
13	HBPTX	Num	4	148	f04q6C: Treatment for Hypertension
19	HEMA	Num	4	172	f04q7D: Hematological Disease
71	HEPBOLUS	Num	4	376	f04q22: Heparin Bolus

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The CONTENTS Procedure

-----Alphabetic List of Variables and Attributes-----					
#	**Variable**	**Type**	**Len**	**Pos**	**Label**
68	HEPDOSE	Num	5	432	f04q21A: Heparin Dose
93	HEPDYS	Num	8	64	f04q21B: Heparin Began Days
69	HEPHR	Num	4	368	f04q21CHR: Heparin Began Hr
70	HEPMN	Num	4	372	f04q21CMN: Heparin Began Min
88	IANGDYS	Num	8	24	f04q9C2: Increased Angina Days
47	INCANG	Num	4	284	f04q9C2: Increased Angina Symptoms
57	INITIATE	Num	4	324	f04q20: Treatment Initiated
84	INTERVAL	Num	4	424	f04q24: Interval ischemic pain to treatm
85	INTERVL2	Num	4	428	f04q24: Interval ischemic pain to treatm
78	ISCHEM24	Num	4	400	f04q23C: Ischemic Pain within 24 hrs
79	ISCHT1	Num	4	404	f04q23C1: Ischemic Pain Single Episode 5
80	ISCHT2	Num	4	408	f04q23C2: Ischemic Pain Single Episode 2
81	ISCHT3	Num	4	412	f04q23C3: Ischemic Pain Multiple Episode
60	LESDOS2	Num	4	336	f04q20A2: Reason Less Dose Given Specify
59	LESSDOSE	Num	4	332	f04q20A2: Reason Less Dose Given
77	MI24	Num	4	396	f04q23B: MI within 24 hrs
96	MIDYS	Num	8	88	f04q5A: Most Recent MI Days
3	MIHX	Num	4	108	f04q5: History of Previous MI
6	MINUM	Num	4	120	f04q5C: Number of Previous MI
5	MITHRM	Num	4	116	f04q5B: Thombolytic Therapy Most Recent
4	MIUNKDY	Num	4	112	f04q5A1: Date of Most Recent MI Unknown
7	MIUNKNUM	Num	4	124	f04q5C1: Number of Previous MI Unknown
61	MOREDOSE	Num	4	340	f04q20A3: Reason More Dose Given
97	NANGDYS	Num	8	96	f04q9C1: New Angina Days
21	NEURO	Num	4	180	f04q7F: Neurological Disease
46	NEWANG	Num	4	280	f04q9C1: New Angina
86	NEWID	Num	8	8	
66	NOTX	Num	4	360	f04q20F: Reason Treatment Not Initiated
16	OTHCD	Num	4	160	f04q7A: Other Cardiac Disease
22	OTHDIS	Num	4	184	f04q7G: Other Significant Disease
49	PAINNUM	Num	4	292	f04q10: Ischemic Pain Number Episodes

T3B form04

The CONTENTS Procedure

-----Alphabetic List of Variables and Attributes-----					
#	**Variable**	**Type**	**Len**	**Pos**	**Label**
43	PREACCEL	Num	4	268	f04q9A4: Angina within 2 mos - Accelerat
33	PREACEIN	Num	4	228	f04q8K: ACE Inhibitors
38	PREANG	Num	4	248	f04q9: Previous Angina
29	PREASA	Num	4	212	f04q8G: Aspirin with 24 hrs
25	PREBETA	Num	4	196	f04q8C: Beta-blocker
26	PRECCB	Num	4	200	f04q8D: Calcium Channel Blocker
39	PRECCSC	Num	4	252	f04q9B: CCSC one month prior
30	PRECOAG	Num	4	216	f04q8H: Anticoagulant
35	PREDIGIT	Num	4	236	f04q8M: Digitalis
34	PREDILAT	Num	4	232	f04q8L: Other Vasodilator
32	PREDIUR	Num	4	224	f04q8J: Diuretics
42	PREEXERT	Num	4	264	f04q9A3: Angina within 2 mos - Exertiona
23	PREHEP	Num	4	188	f04q8A: Heparin
36	PREINOT	Num	4	240	f04q8N: Inotropic Agent
31	PRELIPLO	Num	4	220	f04q8I: Lipid-lowering Agent
45	PRELONG	Num	4	276	f04q9A6: Angina within 2 mos - 20 mi or
44	PRENIGHT	Num	4	272	f04q9A5: Angina within 2 mos - Nocturnal
24	PRENITRA	Num	4	192	f04q8B: Nitrates
40	PRENOANG	Num	4	256	f04q9A1: Angina within 2 mos - None
27	PREPERS	Num	4	204	f04q8E: Persantine
28	PREPLATE	Num	4	208	f04q8F: Antiplatelet agents
50	PREPTCA	Num	4	296	f04q11: PTCA within 6 mos
41	PREREST	Num	4	260	f04q9A2: Angina within 2 mos - At rest
37	PRERHYTH	Num	4	244	f04q8O: Antiarrhythmic Agent
90	PTCADYS	Num	8	40	f04q11A: Most Recent PTCA Days
51	PTCAUNK	Num	4	300	f04q11A1: Most Recent PTCA Date Unknown
17	PVD	Num	4	164	f04q7B: Peripheral Vascular Disease
11	QUITNUM	Num	4	140	f04q6A3: Quit Smoking Months Prior to En
55	RALES	Num	4	316	f04q16: Rales
20	RENAL	Num	4	176	f04q7E: Renal Disease
1	REV	Num	8	0	Revision

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The CONTENTS Procedure

-----Alphabetic List of Variables and Attributes-----					
#	**Variable**	**Type**	**Len**	**Pos**	**Label**
2	SCHOOL	Num	4	104	f04q3: Education
8	SMOKE	Num	4	128	f04q6A: History Cigarette Smoking
54	SOUNDS	Num	4	312	f04q15: S3 Heart Sounds
83	STROKE24	Num	4	420	f04q23E: Neurologic event within 24 hrs
52	SYSBP	Num	4	304	f04q14A: Systolic Blood Pressure
58	T3RXDOSE	Num	4	328	f04q20A: Dose
91	TX2DY	Num	8	48	f04q20B: Treatment Began Days
92	TXENDDYS	Num	8	56	f04q20D: Treatment Ended Days
64	TXENDHR	Num	4	352	f04q20EHR: Treatment Ended Hr
65	TXENDMN	Num	4	356	f04q20EMN: Treatment Ended Min
62	TXHR	Num	4	344	f04q20CHR: Treatment Began Hr
63	TXMN	Num	4	348	f04q20CMN: Treatment Began Min
10	YRSMOKE	Num	4	136	f04q6A2: Years Smoked

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Variable	Label	Value	N	%	<= 20
SCHOOL	f04q3: Education	1	525	35.6	
		2	854	58.0	
		3	94	6.4	
MIHX	f04q5: History of Previous MI	1	595	40.4	
		2	858	58.2	
		3	20	1.4	*
MIUNKDY	f04q5A1: Date of Most Recent MI Unknown	.	1441	97.8	
		1	32	2.2	
MITHRM	f04q5B: Thombolytic Therapy Most Recent	.	878	59.6	
		1	112	7.6	
		2	387	26.3	
		3	96	6.5	
MIUNKNUM	f04q5C1: Number of Previous MI Unknown	.	1458	99.0	
		1	15	1.0	*
SMOKE	f04q6A: History Cigarette Smoking	1	1020	69.2	
		2	453	30.8	
FAMCAD	f04q6B: Family History CAD	1	572	38.8	
		2	840	57.0	
		3	61	4.1	
HBPTX	f04q6C: Treatment for Hypertension	1	615	41.8	
		2	842	57.2	
		3	16	1.1	*

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Variable	Label	Value	N	%	<= 20
CHOLTX	f04q6D: Treatment for Elev. Cholestrol	1	288	19.6	
		2	1082	73.5	
		3	103	7.0	
DIABTX	f04q6E: Treatment for Diabetes	.	688	46.7	
		1	114	7.7	
		2	668	45.3	
		3	3	0.2	*
OTHCD	f04q7A: Other Cardiac Disease	1	65	4.4	
		2	1403	95.2	
		3	5	0.3	*
PVD	f04q7B: Peripheral Vascular Disease	1	91	6.2	
		2	1376	93.4	
		3	6	0.4	*
GI	f04q7C: Gastrointestinal Disease	1	191	13.0	
		2	1279	86.8	
		3	3	0.2	*
HEMA	f04q7D: Hematological Disease	1	14	1.0	*
		2	1459	99.0	
RENAL	f04q7E: Renal Disease	1	40	2.7	
		2	1433	97.3	
NEURO	f04q7F: Neurological Disease	1	26	1.8	
		2	1444	98.0	
		3	3	0.2	*

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Variable	Label	Value	N	%	<= 20
OTHDIS	f04q7G: Other Significant Disease	1	276	18.7	
		2	1193	81.0	
		3	4	0.3	*
PREHEP	f04q8A: Heparin	1	222	15.1	
		2	1251	84.9	
PRENITRA	f04q8B: Nitrates	1	699	47.5	
		2	773	52.5	
		3	1	0.1	*
PREBETA	f04q8C: Beta-blocker	1	501	34.0	
		2	968	65.7	
		3	4	0.3	*
PRECCB	f04q8D: Calcium Channel Blocker	1	628	42.6	
		2	842	57.2	
		3	3	0.2	*
PREPERS	f04q8E: Persantine	1	37	2.5	
		2	1434	97.4	
		3	2	0.1	*
PREPLATE	f04q8F: Antiplatelet agents	1	8	0.5	*
		2	1464	99.4	
		3	1	0.1	*
PREASA	f04q8G: Aspirin with 24 hrs	1	705	47.9	
		2	759	51.5	
		3	9	0.6	*

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Variable	Label	Value	N	%	<= 20
PRECOAG	f04q8H: Anticoagulant	2	1472	99.9	
		3	1	0.1	*
PRELIPLO	f04q8I: Lipid-lowering Agent	1	162	11.0	
		2	1309	88.9	
		3	2	0.1	*
PREDIUR	f04q8J: Diuretics	1	242	16.4	
		2	1228	83.4	
		3	3	0.2	*
PREACEIN	f04q8K: ACE Inhibitors	1	148	10.0	
		2	1321	89.7	
		3	4	0.3	*
PREDILAT	f04q8L: Other Vasodilator	1	25	1.7	
		2	1444	98.0	
		3	4	0.3	*
PREDIGIT	f04q8M: Digitalis	1	77	5.2	
		2	1395	94.7	
		3	1	0.1	*
PREINOT	f04q8N: Inotropic Agent	1	5	0.3	*
		2	1468	99.7	
PRERHYTH	f04q8O: Antiarrhythmic Agent	1	50	3.4	
		2	1423	96.6	
PREANG	f04q9: Previous Angina	1	1260	85.5	
		2	211	14.3	
		3	2	0.1	*

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Variable	Label	Value	N	%	<= 20
PRENOANG	f04q9A1: Angina within 2 mos - None	.	1327	90.1	
		1	146	9.9	
PREREST	f04q9A2: Angina within 2 mos - At rest	.	781	53.0	
		1	692	47.0	
PREEXERT	f04q9A3: Angina within 2 mos - Exertiona	.	567	38.5	
		1	906	61.5	
PREACCEL	f04q9A4: Angina within 2 mos - Accelerat	.	974	66.1	
		1	499	33.9	
PRENIGHT	f04q9A5: Angina within 2 mos - Nocturnal	.	1165	79.1	
		1	308	20.9	
PRELONG	f04q9A6: Angina within 2 mos - 20 mi or	.	1208	82.0	
		1	265	18.0	
PRECCSC	f04q9B: CCSC one month prior	.	213	14.5	
		1	384	26.1	
		2	283	19.2	
		3	372	25.3	
		4	144	9.8	
		5	77	5.2	
NEWANG	f04q9C1: New Angina	.	397	27.0	
		1	426	28.9	
		2	628	42.6	
		3	22	1.5	

T3B form04

Variable	Label	Value	N	%	<= 20
INCANG	f04q9C2: Increased Angina Symptoms	.	398	27.0	
		1	729	49.5	
		2	321	21.8	
		3	25	1.7	
FRSTANG	f04q9C3: First Episode Rest Angina	.	398	27.0	
		1	619	42.0	
		2	411	27.9	
		3	45	3.1	
PREPTCA	f04q11: PTCA within 6 mos	1	198	13.4	
		2	1275	86.6	
PTCAUNK	f04q11A1: Most Recent PTCA Date Unknown	.	1469	99.7	
		1	4	0.3	*
SOUNDS	f04q15: S3 Heart Sounds	1	15	1.0	*
		2	1439	97.7	
		3	19	1.3	*
RALES	f04q16: Rales	1	11	0.7	*
		2	1455	98.8	
		3	7	0.5	*
ELIGIBLE	f04q17: Patient Eligible	1	1471	99.9	
		2	2	0.1	*
INITIATE	f04q20: Treatment Initiated	1	1456	98.8	
		2	17	1.2	*
LESSDOSE	f04q20A2: Reason Less Dose Given	.	1471	99.9	
		4	2	0.1	*

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Variable	Label	Value	N	%	<= 20
LESDOS2	f04q20A2: Reason Less Dose Given Specify	.	1461	99.2	
		1	1	0.1	*
		2	1	0.1	*
		4	1	0.1	*
		5	9	0.6	*
MOREDOSE	f04q20A3: Reason More Dose Given	.	1471	99.9	
		2	2	0.1	*
NOTX	f04q20F: Reason Treatment Not Initiated	.	1456	98.8	
		2	3	0.2	*
		3	5	0.3	*
		4	9	0.6	*
CONTHEP	f04q21: Contiuous Heparin	1	179	12.2	
		2	1294	87.8	
HEPBOLUS	f04q22: Heparin Bolus	1	1239	84.1	
		2	233	15.8	
		8	1	0.1	*
COMP24	f04q23: Complications	1	128	8.7	
		2	1345	91.3	
DEATH24	f04q23A: Death within 24 hrs	.	1468	99.7	
		1	5	0.3	*
MI24	f04q23B: MI within 24 hrs	.	1447	98.2	
		1	26	1.8	
ISCHEM24	f04q23C: Ischemic Pain within 24 hrs	.	1371	93.1	
		1	102	6.9	

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Variable	Label	Value	N	%	<= 20
ISCHT1	f04q23C1: Ischemic Pain Single Episode 5	.	1456	98.8	
		1	17	1.2	*
ISCHT2	f04q23C2: Ischemic Pain Single Episode 2	.	1421	96.5	
		1	52	3.5	
ISCHT3	f04q23C3: Ischemic Pain Multiple Episode	.	1441	97.8	
		1	32	2.2	
BLEED24	f04q23D: Hemorrhagic event within 24 hrs	.	1456	98.8	
		1	17	1.2	*
STROKE24	f04q23E: Neurologic event within 24 hrs	.	1468	99.7	
		1	5	0.3	*
INTERVAL	f04q24: Interval ischemic pain to treatm	.	786	53.4	
		1	43	2.9	
		2	139	9.4	
		3	194	13.2	
		4	311	21.1	
INTERVL2	f04q24: Interval ischemic pain to treatm	.	688	46.7	
		1	35	2.4	
		2	139	9.4	
		3	178	12.1	
		4	203	13.8	
		5	230	15.6	

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Variable	Label	N	Percentile	Value	n	<= 20
MINUM	f04q5C: Number of Previous MI	580	5	1	482	
			25	1	0	*
			50	1	0	*
			75	1	0	*
			95	2	80	
			100	4	18	*
CIGDAY	f04q6A1: Avg. Cigarettes per Day	1017	5	4	53	
			25	20	517	
			50	20	0	*
			75	30	225	
			95	60	205	
			100	97	17	*
YRSMOKE	f04q6A2: Years Smoked	1014	5	8	52	
			25	20	245	
			50	30	268	
			75	40	281	
			95	50	137	
			100	60	31	
QUITNUM	f04q6A3: Quit Smoking Months Prior to En	1015	5	0	545	
			25	0	0	*
			50	0	0	*
			75	84	222	
			95	312	198	
			100	700	50	

T3B form04

Variable	Label	N	Percentile	Value	n	<= 20
PAINNUM	f04q10: Ischemic Pain Number Episodes	1472	5	0	311	
			25	1	275	
			50	2	281	
			75	4	298	
			95	10	252	
			100	50	55	
BMI	f04: Body Mass Index	1465	5	21.2	77	
			25	24.8	300	
			50	27.5	362	
			75	30.9	372	
			95	37.9	281	
			100	67.2	73	
SYSBP	f04q14A: Systolic Blood Pressure	1473	5	100	92	
			25	120	411	
			50	130	313	
			75	146	294	
			95	170	322	
			100	210	41	
DIASBP	f04q14B: Diastolic Blood Pressure	1472	5	60	157	
			25	70	357	
			50	80	463	
			75	88	133	
			95	100	330	
			100	128	32	

T3B form04

Variable	Label	N	Percentile	Value	n	<= 20
T3RXDOSE	f04q20A: Dose	1456	5	44	78	
			25	55	317	
			50	62	348	
			75	70	355	
			95	80	357	
			100	100	1	*
HEPDOSE	f04q21A: Heparin Dose	177	5	750	10	*
			25	1000	142	
			50	1000	0	*
			75	1000	0	*
			95	2500	18	*
			100	8000	7	*
BOLUSDSE	f04q22A: Bolus Dose	1238	5	5000	1209	
			25	5000	0	*
			50	5000	0	*
			75	5000	0	*
			95	5000	0	*
			100	9997	29	

T3B form04

Variable	Label	N	Mean	Std Dev	Minimum	Maximum
FM04DYS	f04q2: Screening Days	1473	1.0	0.4	0.0	10.0
MIDYS	f04q5A: Most Recent MI Days	419	-1484.8	1573.0	-12369.0	-25.0
NANGDYS	f04q9C1: New Angina Days	398	-14.4	48.4	-731.0	339.0
IANGDYS	f04q9C2: Increased Angina Days	697	-11.8	36.3	-392.0	304.0
FANGDYS	f04q9C3: First Episode Rest Angina Days	600	-6.6	29.8	-509.0	2.0
PTCADYS	f04q11A: Most Recent PTCA Days	167	-893.5	657.9	-3348.0	-183.0
TX2DY	f04q20B: Treatment Began Days	1456	1.0	0.1	1.0	5.0
TXHR	f04q20CHR: Treatment Began Hr	1456	14.2	5.1	0.0	24.0
TXMN	f04q20CMN: Treatment Began Min	1456	26.1	17.7	0.0	59.0
TXENDDYS	f04q20D: Treatment Ended Days	1456	2.3	39.3	1.0	1462.0
TXENDHR	f04q20EHR: Treatment Ended Hr	1455	14.8	5.6	0.0	24.0
TXENDMN	f04q20EMN: Treatment Ended Min	1455	25.5	17.0	0.0	59.0
HEPDYS	f04q21B: Heparin Began Days	178	-4.2	38.8	-368.0	1.0
HEPHR	f04q21CHR: Heparin Began Hr	177	13.3	5.5	0.0	24.0
HEPMN	f04q21CMN: Heparin Began Min	177	19.1	18.8	0.0	57.0
BOLDYS	f04q22B: Bolus Days	1239	0.0	0.0	0.0	1.0
BOLUSHR	f04q22CHR: Bolus Hr	1236	13.0	6.0	0.0	24.0
BOLUSMN	f04q22CMN: Bolus Min	1236	23.7	17.7	0.0	59.0