PROTOCOL = TACT

TACT SCREENING

FORM = RANDOM

(To be used in conjunction with Screening Worksheet. This is the information the site will be asked to enter in connection with the randomization process.)

RANDOM

Patient's Initials INITIA <V:3> (First Middle Last)

Date of Birth ___/___/____ DOBDT <DATE>
mo day year

Has this patient signed an informed consent form?

0= ☐ No → The patient must sign an informed consent form in order to proceed.

ICF <ZYESNO> <I:3>

1= ☐ Yes → Continue to next question.

Do any of the exclusion criteria (see Screening Worksheet) apply to this patient?

0= ☐ No → Please enter the patient's blood pressure and pulse and complete the Lab Results Page.

Blood pressure: BPSYS<I:3> /BPDIA<I:3> mm Hg

EXCL <ZYESNO> <I:3> Pulse: PULSE<I:3> bpm

1= ☐ Yes → This patient is not eligible to participate in TACT.

Has this patient had a qualifying MI?

0= ☐ No → This patient is not eligible to participate in TACT.

1= ☐ Yes → Brings up Qualifying MI screens (below)

QUALMI <ZYESNO> <I:3>

* Note: All dates on these forms should be entered in MM/DD/YYYY format. Month fields should be 01 (Jan)- 12 (Dec), and day fields should be between 01-31. All times should be entered in military time (00:00 – 23:59).

Qualifying MI

1. Date of most recent qualifying MI ___/___/___ (mo day year) [Year is required.] QMIDT <DATE> **MI**

2. MI location MILOC <TCLOC> <I:3>
   1 = ☐ Anterior 2 = ☐ Non-anterior

Supporting Clinical Evidence of Qualifying MI

Cardiac Marker Evidence

3. Troponin level measured? **MIEVID**
   0 = ☐ No →
   Was CK-MB level measured?
   0 = ☐ No CKMBMS<ZYESNO>
   1 = ☐ Yes → Peak CK-MB level CKMBPA<F:9:3>
   Upper limit of normal CKMBUA <F:9:3>

TROPLV<ZYESNO><I:3>

   1 = ☐ Yes → Peak Troponin level TPEAK <F:9:3> ng/mL
   Upper limit of normal TULN <F:9:3> ng/mL
   Or
   If bedside assay was used, check result below.

BEDASY <ZPOSNEG>

   1 = ☐ Positive 2 = ☐ Negative

ISCHEM.<ZYESNO>

4. Ischemic symptoms 0 = ☐ No 1 = ☐ Yes

PATHQ <ZYESNO>

5. Pathologic Q waves 0 = ☐ No 1 = ☐ Yes

STELEV <ZYESNO>

6. ST elevation 0 = ☐ No 1 = ☐ Yes

STDEP <ZYESNO>

7. ST depression 0 = ☐ No 1 = ☐ Yes

Imaging/Angiographic Evidence

8. Imaging evidence of myocardial scar
   2= ☐ Imaging not done
   0= ☐ No
   1= ☐ Yes → Check all that apply:

MISCAR <TCYSNO><I:3>

NONREV <ZYES>

   ☐ Non-reversible perfusion defect on myocardial radionuclide perfusion imaging

   Severe wall motion abnormality on:

CANGIO<ZYES> ☐ Contrast angiography
RANGIO<ZYES> ☐ Radionuclide angiography
ECHOCA<ZYES> ☐ Echocardiography

9. Angiographic evidence of epicardial coronary disease (luminal diameter narrowing >50% of a major epicardial coronary artery)

ANGEVI<TCANGO><I:3>

   2= ☐ Angiography not done
   0= ☐ No
   1= ☐ Yes → Is the myocardial scar consistent with the coronary lesion(s) on the cath report?

CLESIO<ZYESNO>

   0= ☐ No
   1= ☐ Yes

Imaging and angiographic evidence should be taken from the official cath report and must be reviewed by the Primary Investigator.

Acute MI Since Qualifying MI

10. Since the qualifying MI, has the patient had an **acute MI** within the last 6 weeks?
    0= ☐ No ACUTEM<ZYESNO>
    1= ☐ Yes → Date: ___/___/___ (mo day year) AMIDT<DATE>

Logic checks for MI eligibility:

Qualifying MI must be > 6 weeks prior to randomization.

Patient needs to have either:
- Troponin level measured ("yes") with peak troponin above UL or bedside assay "positive", AND 1 or more of questions 4-7 answered "yes"

OR - if troponin level not measured ("no"), then the patient needs to have CK-MB measured ("yes") with peak level above the upper limit of normal and 1 or more of questions 4-7 answered "yes"

OR - questions 8 and 9 answered "yes" (both parts of question 9)

in order to show clinical evidence of an MI.

Most recent MI must also be > 6 weeks prior to randomization.

After completing all above information…

If patient is not eligible, display in Pop-up Window:
Patient is not eligible to participate in TACT due to [reason].
- If due to #1 or #10: "Randomization cannot occur until at least 6 weeks has passed since qualifying MI or most recent MI. Patient will be eligible for rescreening on ___/___/____."
- If due to #3-#9: "The patient needs to have a peak troponin or peak CK-MB level above the upper limit of normal with appropriate symptoms/ECG changes, or imaging and coronary angiographic evidence in order to be randomized."

If patient is eligible, display in Pop-up Window:
Congratulations, this patient is eligible to enroll in TACT. Please schedule the first infusion for this patient and enter the infusion date and patient's demographic information below. As close to the infusion as possible, but no later than three business days prior to the visit, you may randomize this patient after verifying that he/she will be coming for the first visit.

Pre-randomization baseline information:

1. Scheduled date of first infusion: ___/___/___ (mo day year) **DEMOG**

GENDER<ZSEX>

2. Gender: 1=☐ Male 2=☐ Female

WGT<F:9:3>

3. Weight: _____ lb Weight and height should be converted to kg and cm for the Pharmacy.
   Height: _____ in HGT<F:9:3>
   Creatinine: _____ mg/dL Display from lab results page.

4. Ethnicity (check only one): ETHNIC<TCETH><I:3>
   1=☐ Hispanic or Latino
   2=☐ Not Hispanic or Latino

5. Race (check all that apply):
   ☐ American Indian/Alaska Native AMERIN<ZYES>
   ☐ Asian ASIAN<ZYES>
   ☐ Black or African American BLACK<ZYES>
   ☐ Caucasian CAUCAS<ZYES>
   ☐ Native Hawaiian or Other Pacific Islander HAWAII <ZYES>

Once this information is complete, display a "Randomize" button.

TACT

FORM=PATINFO

CONFIDENTIAL PATIENT INFORMATION

Patient Study # __ __ __-__ __ __ Patient's Initials __ __ __

PATINFO

Patient Contact Information SSN: SOCNUM<V:9> __ __ __ - __ __ - __ __ __ __

Patient name: PTLAST<V:100> PTFRST<V:100> PTMID<V:100>

last first middle

SPNSPK<ZYES>

❑ **Spanish Speaking Only**

Primary home address: **Street:** PSTREE<V:200>

Apt/ P.O. Box PPOBOX<V:20>

City: PCITY<V:100> **State:** PSTATE<V:100>

Zip code: PZIPCO<V:10>

BESTHO<TCBEST>

Primary home telephone number: ( ) HOMENU<V:20> **Best time to call:** 1= ☐ AM 2= ☐ PM 3= ☐ Any Time

Business telephone number: ( ) WORKNU<V:20> **Best time to call:** 1= ☐ AM 2= ☐ PM 3= ☐ Any Time

Secondary telephone number (cell phone, etc.): ( ) SECDNU<V:20> BESTWO<TCBEST>

Spouse or significant other: SPLAST<V:100> SPFIRS<V:100> SPMID<V:100>

last first middle

CONLAS<V:100> CONFIR<V:100> CONMID<V:100>

Contact name *(relative or friend **not living** with patient)*:

last first middle

Relationship to patient: RELATI<V:20> **Contact's telephone number:** ( ) CONNUM<V:20>

Contact's Address: **Street:** CSTREE<V:200>

City: CCITY<V:100> **State:** CSTATE<V:100>

Zip code: CZIPCO<V:10>

1= 2= 3=

Best time to call: ☐ AM ☐ PM ☐ Any Time

BESTCO<TCBEST>

Local/referring doctor: DRLAST<V:100> DRFIRS<V:100> DRMID<V:100>

last first middle

Address: **Street:** DRSTRE<V:200>

City: DRCITY<V:100> **State:** DRSTAT<V:100>

Zip code: DZIPCO<V:10>

Doctor's office telephone number: ( ) DRNUM<V:20>

This should be accessible only by the sites and EQOL.

PROTOCOL=

TACT FORM=BASELINE **BASELINE**

[Study # and Initials to appear automatically on each form from here on.]

Patient Study # __ __ __-__ __ __ Patient's Initials __ __ __

HEPAL <ZYESNO>

Medical History

Record patient history by checking "No" or "Yes" for each condition listed. MEDHX

1. Angina pectoris ANGINA<ZYESNO>	0= ☐ No	1= ☐ Yes	10. Hypercholesterolemia HYPCHO<ZYESNO>	☐ No	☐ Yes
2. Congestive heart failure CHF<ZYESNO>	☐ No	☐ Yes	11. Atrial fibrillation/flutter AFIB<ZYESNO>	☐ No	☐ Yes
3. Valvular heart disease VALVHD<ZYESNO>	☐ No	☐ Yes	12. Cardiac arrest or sustained ventricular tachycardia CASVT<ZYESNO>	☐ No	☐ Yes
4. Stroke STROKE<ZYESNO>	☐ No	☐ Yes	13. Osteoporosis OSTEOP<ZYESNO>	☐ No	☐ Yes
5. TIA TIA<ZYESNO>	☐ No	☐ Yes	14. Cigarette smoking		
6. Diabetes DIABET<ZYESNO>	☐ No	☐ Yes	1= ☐ Former → Quit since SMOKDT <PARTIALDATE> __ __ __/__ __ __ __ (mon. / year) SMOKE<TCSMOK>		
7. Peripheral vascular disease PVD<ZYESNO>	☐ No	☐ Yes	Year is required. Month is required if year=current year. In this case, verify that mon/year is at least 3 months prior to current month/year.		
8. Intermittent claudication INCLAU<ZYESNO>	☐ No	☐ Yes	2= ☐ Never		
If yes, is the claudication severe enough to limit normal activities? CLAUDA<ZYESNO>	☐ No	☐ Yes	15. Thyroid disease THYROI<ZYESNO>	☐ No	☐ Yes
9. Hypertension HYPTEN<ZYESNO>	☐ No	☐ Yes	16. Fracture(s) since age 50 FRACTU<ZYESNO>	☐ No	☐ Yes

Procedure History

PROCHX

1. PCI PCI<ZYESNO>	☐ No	☐ Yes	4. AICD AICD<ZYESNO>	☐ No	☐ Yes
2. CABG CABG<ZYESNO>	☐ No	☐ Yes	5. Revascularization of lower extremeties REVASL<ZYESNO>	☐ No	☐ Yes
3. Pacemaker PACE<ZYESNO>	☐ No	☐ Yes	6. Revascularization of carotid arteries REVASC<ZYESNO>	☐ No	☐ Yes

Presenting Characteristics

CHAR

1. Current Canadian Cardiovascular Society (CCS) angina class (check only one):
NOANG <ZYES> ☐ No angina 1= ☐ I 2= ☐ II 3= ☐ III 4= ☐ IV CCS<TCCCS><I:3>

2. Current NYHA heart failure class (check only one):
NOHF <ZYES> ☐ No heart failure 1= ☐ I 2= ☐ II 3= ☐ III 4= ☐ IV NYHA<TCNYHA><I:3>

VERSION 2.0, 03 FEB 2004

Please refer to document section of TACT web page for list of applicable medications.

Baseline Medications

BASEMED

1. Aspirin 0=No 1=Yes
BASPIR<ZYESNO>
If no, check primary reason.
BASPRS<TCASPR> <I:3>
1= GI Intolerance
2= Allergy
3= Taking a different anticoagulant
4=
5= Patient refuses
6= Physician preference other than reasons above
98= Other

2. Beta-blocker 0=No 1=Yes
BBBLOC<ZYESNO>
If no, check primary reason.
BBBRSN<TCBBR> <I:3>
1= Bronchospasm
2= Depression
3= Fatigue
4= Cold extremities
5= Active heart failure
6= Allergy
7= Cost
8= Patient refuses
9= Physician preference other than reasons above
98= Other

3. Statin BSTAT<ZYESNO> 0=No 1=Yes
If no, check primary reason.
BSTAR<TCSTR> <I:3>
1= Liver enzyme elevation
2= Myositis
3= Myalgias
4= Allergy
5= Cost
6= Patient refuses
7= Physician preference other than reasons above
98= Other

4. Angiotensin converting enzyme inhibitor
BACEI<ZYESNO> 0=No 1=Yes
If no, check primary reason.
BACERS<TCACER> <I:3>
1= Cough
2= Angioedema, anaphylaxis, neutropenia
3= Hyperkalemia
4= Symptomatic hypotension
5= Renal artery stenosis
6= Renal dysfunction
7= Other adverse events such as taste disturbance, rash, or gastrointestinal upset
8= Patient refuses
9= No CHF or normal LVEF
10= Physician preference other than reasons above
98= Other

BARB<ZYESNO>
5. Angiotensin receptor blocker 0= No 1= Yes
BABLOC<ZYESNO>
6. Alpha-blocker No Yes
BCCB<ZYESNO>
7. Calcium channel blocker No Yes
8. Diuretic BDIU<ZYESNO> No Yes
9. Warfarin BWARFA<ZYESNO> No Yes
BAMIO<ZYESNO>
10. Amiodarone No Yes
BOANTI<ZYESNO>
11. Other antiarrhythmic drug No Yes
12. Digoxin BDIGOX<ZYESNO> No Yes
13. Clopidogrel BCLOP<ZYESNO> No Yes
14. Diabetes medication:
Insulin BDIAIN<ZYESNO> No Yes
BDIABO<ZYESNO>
Oral hypoglycemic No Yes
15. Thyroid replacement therapy BTHYRT<ZYESNO> No Yes
16. Medication for PVD:
Pletal BPVDPL<ZYESNO> No Yes
Pentoxyfilline BPVDPE<ZYESNO> No Yes
17. Medication for osteoporosis BMOSTE<ZYESNO> No Yes
18. Multivitamin BMULTV<ZYESNO> No Yes
19. Other vitamins/minerals BOVTMN<ZYESNO> No Yes
20. Herbal products BHERBA<ZYESNO> No Yes
If "yes", then continue below.

Herbal Supplement Usage

21. Please indicate which of the following supplements the patient is currently taking:

HERBAL

				Reason(s): CV disease	Other health condition
Echinacea ECH<ZYESNO><I:1>	☐ No	☐ Yes	→	ECHCV<ZYES><I:1> ☐	ECHOH<ZYES><I:1> ☐
Fish oils/omega fatty acids FIS<ZYESNO ><I:1>	☐ No	☐ Yes	→	FISCV<ZYES ><I:1> ☐	FISOH<ZYES><I:1> ☐
Garlic supplements GAR<ZYESNO><I:1>	☐ No	☐ Yes	→	GARCV<ZYES><I:1> ☐	GAROH<ZYES><I:1> ☐
Ginkgo biloba GIN<ZYESNO><I:1>	☐ No	☐ Yes	→	GINCV<ZYES><I:1> ☐	GINOH<ZYES><I:1> ☐
Glucosamine with or without chondroitin GLU<ZYESNO><I:1>	☐ No	☐ Yes	→	GLUCV<ZYES><I:1> ☐	GLUOH<ZYES><I:1> ☐
Hawthorn HAW<ZYESNO><I:1>	☐ No	☐ Yes	→	HAWCV<ZYES><I:1> ☐	HAWOH<ZYES><I:1> ☐
Ma huang (ephedra) MHU<ZYESNO><I:1>	☐ No	☐ Yes	→	MHUCV<ZYES><I:1> ☐	MHUOH<ZYES><I:1> ☐
SAM-e SAM<ZYESNO><I:1>	☐ No	☐ Yes	→	SAMCV<ZYES><I:1> ☐	SAMOH<ZYES><I:1> ☐
Saw palmetto SAW <ZYESNO><I:1>	☐ No	☐ Yes	→	SAWCV<ZYES><I:1> ☐	SAWOH<ZYES><I:1> ☐
Soy supplements SOY<ZYESNO><I:1>	☐ No	☐ Yes	→	SOYCV<ZYES><I:1> ☐	SOYOH<ZYES><I:1> ☐
St. John's wort STJ<ZYESNO><I:1>	☐ No	☐ Yes	→	STJCV<ZYES><I:1> ☐	STJOH<ZYES><I:1> ☐
Valerian VAL<ZYESNO><I:1>	☐ No	☐ Yes	→	VALCV<ZYES><I:1> ☐	VALOH<ZYES><I:1> ☐
Other HOT<ZYESNO><I:1>	☐ No	☐ Yes	→	HOTCV<ZYES><I:1> ☐	HOTOH<ZYES><I:1> ☐

TACT FORM=LABS **LAB RESULTS**

CRND, CAND, PCND, ALKND, AND ASTND GREYED OUT WHEN VISIT = SCREENING

Patient Study # ___ ___ ___-___ ___ ___ Patient's Initials ___ ___ ___

Baseline data should be collected when patient is being screened. VISIT

Visit #: _____ Display appropriate visit #.

Date of Visit: ___/___/___ VISTDT<DATE>
mo day year

Urinalysis – Baseline & Infusions 5, 15 & 25 URINAL

Tests			Results				
Glycosuria	GLYND<ZYES>	GLYDT<DATE> Not done	negative	1+	2+	GLYPOS<TCLBR2>	
		PRODT<DATE>	GLYNEG<ZYES>	3+	4+		
Proteinuria	PROND<ZYES>	Not done	negative	1+	2+	PROPOS<TCLBR2>	
		HEMDT<DATE>	PRONEG<ZYES>	3+	4+		
Hematuria	HEMND<ZYES>	Not done	negative	1+	2+	HEMPOS<TCLBR2>	
			HEMNEG<ZYES>	3+	4+		

Metabolic Panel – Baseline & Infusions 2, 5, 10, 15, 20, 25, 30, 36 & 40 METAB

Tests			Results		
Glucose	GLND<ZYES>	GLDT<DATE> Not done	GLVLU<F:9:3>	mg/dL	LABUNT
Creatinine	CRND<ZYES>	CRDT<DATE> Not done	CRVLU<F:9:3>	mg/dL	
Potassium	KND<ZYES>	KDT<DATE> Not done	KVLU<F:9:3>	mmol/L	
Magnesium	MGND<ZYES>	MGDT<DATE> Not done	MGVLU<F:9:3>	mg/dL	
Calcium	CAND<ZYES>	CADT<DATE> Not done	CAVLU<F:9:3>	mg/dL	

Hematology – Baseline & Infusions 2, 5, 10, 15, 20, 25, 30, 36 & 40 HEMAT

Tests			Results		
White blood cell count	WBCND<ZYES>	WBCDT<DATE> Not done	WBCVLU<F:9:3>	$x10^3$cells/µL	LABUNT
Hematocrit	HECND<ZYES>	HECDT<DATE> Not done	HECVLU<F:9:3>	%	
Platelet count	PCND<ZYES>	PCDT<DATE> Not done	PCVLU<F:9:3>	$x10^3$cells/µL	
Neutrophils	NEUND<ZYES>	NEUDT<DATE> Not done	NEUVLU<F:9:3>	$x10^3$cells/µL	

Liver Function – Baseline & Infusions 2, 5, 10, 15, 20, 25, 30, 36 & 40 LIVER

Tests			Results		
Bilirubin, Total	BILND<ZYES>	BILDT<DATE> Not done	BILVLU<F:9:3>	mg/dL	LABUNT
Alkaline phosphatase	ALKND<ZYES>	ALKDT<DATE> Not done	ALKVLU<F:9:3>	U/L	
AST	ASTND<ZYES>	ASTDT<DATE> Not done	ASTVLU<F:9:3>	U/L	
ALT	ALTND<ZYES>	ALTDT<DATE> Not done	ALTVLU<F:9:3>	U/L	

Lipid Profile –Infusions 1 & 30 LIPID

Tests			Results		
Total cholesterol	TCHND<ZYES>	TCHDT<DATE> Not done	TCHVLU<F:9:3>	mg/dL	LABUNT
HDL	HDLND<ZYES>	HDLDT<DATE> Not done	HDLVLU<F:9:3>	mg/dL	
LDL	LDLND<ZYES>	LDLDT<DATE> Not done	LDLVLU<F:9:3>	mg/dL	
Triglycerides	TRIND<ZYES>	TRIDT<DATE> Not done	TRIVLU<F:9:3>	mg/dL	

Additional Labs – Infusions 1 & 30 (& 40 for CRP only) ADDLAB

Tests			Results		
Iron	IROND<ZYES>	IRODT<DATE> Not done	IROVLU<F:9:3>	mg/dL	LABUNT
Total iron binding capacity	TIBND<ZYES>	TIBDT<DATE> Not done	TIBVLU<F:9:3>	µg/dL	
% TIBC			TICVLU<F:9:3>	%	
C-reactive protein	CRPND<ZYES>	CRPDT<DATE> Not done	CRPVLU<F:9:3>	mg/L	

Pharmacy should have read-only access to this page.

Randomization Checks:
If any of the following conditions occur, the patient is not eligible to participate in this study.
Calcium < 8 mg/dL
ALT = 120 IU/L
AST = 100 IU/L
Platelet Count < 100,000/mm^3
Creatinine > 2.0 mg/dL

The alert ranges below should be used as edit checks for laboratory data at baseline and during infusion visits.

Test Name	Alert Parameters
Glucose[#]	< 50 mg/dL (if diabetic) or > 250 mg/dL
Creatinine[†]	= (2 x baseline creatinine) or = 2.5 mg/dL, whichever is lower
Potassium	< 3.2 mmol/L or > 6.0 mmol/L
Magnesium	< 1.0 mg/dL or > 4.0 mg/dL
Calcium[#]	< 8 mg/dL or > 12 mg/dL
Bilirubin[†]	= 3 mg/dL
Alkaline Phosphatase[†]	= 250 U/L
AST[†]	= 100 U/L
ALT[†]	= 120 U/L
White Blood Cell Count[†]	< 3.8 x10^3cells/µL
Hematocrit[†]	< 30.0 % or > 48.0 %
Platelet Count[*]	< 50% of baseline platelet count or < 100,000 cells/µL
Neutrophils[†]	< 1.5 x10^3cells/µL
Glycosuria	> 2 (values of 3+ or 4+)
Proteinuria	> 0
Hematuria	> 0
Total Cholesterol	> 239 mg/dL
HDL	< 35 mg/dL
LDL	> 159 mg/dL
Triglycerides	> 600 mg/dL
Total Iron Binding Capacity	<250 µg/dL or > 460 µg/dL
% Total Iron Binding Capacity	< 10 % Calculation of %TIBC = $\frac{\text{IROVLU} \times 10^5}{\text{TIBVLU}}$
C-reactive Protein	> 10 mg/L

[#,†,*] If these alerts occur, the study coordinator should enter the new results in an identical page called the Additional Required Lab Results page. (This should be available on the fly.)

TACT FORM=INFUS — INFUSION VISIT

Patient Study # __ __ __-__ __ __ Patient's Initials __ __ __

Date of scheduled infusion visit: ___/___/____ display from previous visit or randomization page
mo day year

INFVIST

Did the patient come to the scheduled infusion visit? Set up flag somehow to automatically notify Study Coordinator/Clinician if data are not entered within 4 days of scheduled visit .

0= ☐ No → Prompt: "Has the next visit been scheduled yet?"

PTINFV <ZYESNO> <I:3>

1= ☐ Yes → Please complete the Missed Visit screen.

0= ☐ No → "Please indicate below why the visit was missed and, unless the patient has died, schedule a visit as soon as possible." Background alert if visit not scheduled and "death" not selected as reason for missed visit. Continue to Missed Visit screen.

NEXTVI <ZYESNO><I:3>

1= ☐ Yes → Continues to Cardiovascular Events screen

Missed Visit

MISS

1. Why was the scheduled infusion visit missed? (Check all that apply.)

	☐ Death MVDEAT<ZYES>	→ Please complete Death Page
MVCVEV<ZYES>	☐ Cardiovascular Event	→ Please complete CV Event information
MVSAE<ZYES>	☐ Other Serious Adverse Event	→ Please complete Adverse Event Page
	☐ Non-medical reason MVNONM<ZYES>	
MVCARD<ZYES>	☐ Intercurrent Non-cardiac Illness/Injury	→ Please complete Adverse Event Page
MVPTRE<ZYES>	☐ Patient refuses any further infusions	→ Please complete Therapy Discontinuation Page

Please complete Change of Appointment page so that the pharmacy will know when to prepare the next infusion.

Study coordinator/clinician should fill out CV events, procedures and adverse event information, if applicable, as soon as it is available. We need to have a way to enter this information at a later date if it is not available.

If patient misses a visit and shows up to the next infusion, display information filled in for Interval CV Event panel and/or Adverse Event panel and ask if anything needs to be added.

Missed visits should not count as a visit number.

If the visit is missed due to death, the study coordinator still needs to fill out the CV Events and Procedures section, as well as Adverse Events section.

Missed visit information (reason and date of next infusion [on Change of Appointment page]) should be sent to Pharmacy in an e-mail.

Interval Cardiovascular Events and Procedures Since Last Visit

2. Has the patient been hospitalized **for any reason** since the previous visit? CARDHOSP

0= ☐ No HOSPA<ZYESNO>

1= ☐ Yes → Please complete the following for each hospitalization.

- ❖ If the hospitalization was due to angina, please also complete the Hospitalization for Angina page for this hospitalization.
- ❖ Otherwise, complete the Adverse Event page.

HOSPANG

HOSADA<DATE> Date of hospitalization:	Was the hospitalization due to angina? 0= No 1= Yes HOSAA<ZYESNO>
___/___/___	☐ No ☐ Yes
___/___/___	☐ No ☐ Yes
___/___/___	☐ No ☐ Yes
___/___/___	☐ No ☐ Yes
___/___/___	☐ No ☐ Yes
___/___/___	☐ No ☐ Yes
___/___/___	☐ No ☐ Yes
___/___/___	☐ No ☐ Yes

3. Check No or Yes for each of the following to indicate if the patient has had any cardiovascular events/procedures since last infusion or since randomization, if first infusion: CARDIO

MI 0=☐ No 1=☐ Yes → Date ___/___/___ (mo day year) CVMIA<ZYESNO> → Please complete the MI Page

Stroke 0= ☐ No 1= ☐ Yes → Date ___/___/___ (mo day year) CVSTKA<ZYESNO> → Please complete the Stroke Page

Check to see that events occur within hospitalization intervals for MI, Stroke and CABG.

PCI 0= ☐ No 1= ☐ Yes → Date ___/___/___ (mo day year) CVPCIA<ZYESNO> CVPI1D<DATE>

CABG 0= ☐ No 1= ☐ Yes → Date ___/___/___ (mo day year) CABGA<ZYESNO> CVCG1D<DATE>

ICD 0= ☐ No 1= ☐ Yes → Date ___/___/___ (mo day year) CVICDA<ZYESNO> CVID1D<DATE>

Pacemaker 0= ☐ No 1= ☐ Yes → Date ___/___/___ (mo day year) CVPACE<ZYESNO> CVPM1D<DATE>

Infusion Information

4. Rx number: RXNUM<V:10> # of refills remaining: ~~NUMRFI<V:10>~~ INFINFO

INFUST<ZYESNO>

5. Was the infusion started? INFSTR<TCINRS>

0= ☐ No → Reason: (Check one.)

1= ☐ Adverse Event on previous infusion → Please complete Adverse Event Page now if it was not completed at last visit

2= ☐ Clinically overt CHF → Please complete Adverse Event Page

3= ☐ Venous access not possible

4= ☐ Infusion materials did not arrive

5= ☐ Patient refuses infusion for this visit

6= ☐ Patient refuses any further infusions → Please complete Therapy Discontinuation Page

→ Skip to question #9 after checking reason If no, don't count as a visit – reclassify as an unscheduled visit. Patients still need to fill out the compliance info, however.

1= ☐ Yes → Continue to question #7.

INFSTD<DATE>

6. Start of infusion: Date ___/___/___ (mo day year) Time _____:_____ (00:00 – 23:59) INFSTT

7. End of infusion: INFEND<DATE> Date ___/___/___ (mo day year) Time _____:_____ (00:00 – 23:59) INFENT

8. As estimated by the staff, did the patient receive greater than 50% of the infusion?

0= ☐ No → Does not count as an infusion visit => need to reschedule this visit. Display "Because only 50% or less of the solution was infused, this visit must be rescheduled and the infusion repeated, preferably within one week." INPCNT<ZYESNO>

1= ☐ Yes → Counts as an infusion visit SOLDIS <ZYES>

9. Date of next scheduled infusion: ___/___/___ (mo day year) or check ☐ if final infusion FINALI<ZYES>

Completion of question #9 should trigger an e-mail of the next scheduled infusion date to the pharmacy

Vitamins

10. Were vitamins dispensed at this visit?

VITAMIN

0= ☐ No

1= ☐ Yes → Please complete Vitamin Accountability Page

VITDPN<ZYESNO>

Adverse Events Not Requiring Hospitalization

Please complete the Adverse Event Page if any adverse events, side effects or symptoms occurred during this infusion or prior to this infusion (since the last visit) which did not require hospitalization.

Clinical Data

11. Vital Signs

CLINDATA

	<I:3> Pre-infusion	Mid-infusion	Post-infusion
Blood Pressure (mm Hg):	PREBPS / PREBPD	MIDBPS / MIDBPD	PSTBPS / PSTBPD
Pulse:	PREPUL<I:3>	MIDPUL<I:3>	PSTPUL<I:3>
Pulmonary Rales:	☐ No ☐ Yes		☐ No ☐ Yes
	0= 1= RALESA<ZYESNO>		0= 1= RALESB<ZYESNO>

Pre-infusion measurements should be taken within 1 hour prior to the infusion. Post-infusion measurements should be taken within 1 hour following the infusion.

12. Weight INFSWG<F:9:3> lb [Only collected if lab data are collected at this visit.]

Cigarette Smoking Status

13. Does the patient currently smoke cigarettes? 0= ☐ No 1= ☐ Yes

SMOKE

This question should be asked at visit #40 only. SMOKEA<ZYESNO>

Disposition of patient following infusion (check only one)

DISPOS

1= ☐ Home

DISPOS<TCDISP><I:3>

2= ☐ Emergency Room → Please complete Adverse Event Page.

3= ☐ Admitted to hospital → Please complete Adverse Event Page.

Patient Study # __ __ __-__ __ __ Patient's Initials __ __ __

Vitamin Distribution & Compliance

Bottles

BOTTLE

1. To add distribution or compliance information to bottle record, please complete table below: BTTBLO<I:4> BTTABR<ZYES>

Date distributed BOTTLE<DATE>	Rx # BOTLAB<V:10>	No. of refills Remaining BORFLR<V:10>	No. of tablets distributed BOTPIL<V:10>	Date returned BOTRTN<DATE>	No. of tablets remaining in bottle BOTTAB<V:10>	Bottle permanently lost	Patient refused further vitamin tablets	Percent compliance
/ /				/ /				
/ /				/ /				
/ /				/ /				
/ /				/ /				
/ /				/ /				

If the bottle is permanently lost, assist the patient to recall the number of pills remaining when lost.

TrialMaster should calculate percent compliance for a particular (Rx# and # refills remaining) as:

$$BTPRCN = \frac{(BOTPIL - BOTTAB)}{BOTPIL} * 100$$

BLISTERPACK

Blister-packs

2. To add distribution or compliance information to blister-pack record, please complete table below: BPCKLO<I:4> BPACKR<ZYES>

Date distributed BPCKDT<DATE>	Rx # BPACKL<V:10>	No. of refills Remaining BPRFLR<V:10>	No. of gel-caps distributed BPACKP<V:10>	Date returned PACRTN<DATE>	No. of gel-caps remaining in bottle BPACKT<V:10>	Blister-pack permanently lost	Patient refused further vitamin gel-caps	Percent compliance
/ /				/ /				
/ /				/ /				
/ /				/ /				
/ /				/ /				
/ /				/ /				

If the blister-pack is permanently lost, assist the patient to recall the number of gel-caps remaining when lost.

TrialMaster should calculate percent compliance for a particular (Rx# and # refills remaining) as:

$$BPPRCN = \frac{(BPACKP - BPACKT)}{BPACKP} * 100$$

Repeating page.

TACT **CHANGE OF APPOINTMENT**

Patient Study # __ __ __-__ __ __ Patient's Initials __ __ __

Date of scheduled infusion appointment:	___/___/___ (mo / day / year)
New date of infusion appointment:	___/___/___ (mo / day / year) or ☐ Unknown

Check to make sure that the new appointment does not occur on a Sunday or Monday. If the infusion was scheduled for either of these days, display "Infusions can only occur between Tuesday and Friday. Special permission must be obtained if solution is infused on any other day."

An e-mail should be triggered to the Pharmacy to notify them of the change if either "Unknown" is selected or a new date of infusion is entered. If unknown is selected, the site should be able to return to this page at a later date and enter a new appointment date, which will trigger another e-mail to the Pharmacy.

TACT PREMATURE DISCONTINUATION OF THERAPY

FORM=DISCONT

Patient Study # __ __ __-__ __ __ Patient's Initials __ __ __

Discontinuation

Were the study infusions permanently discontinued? 0= ☐ No 1= ☐ Yes DISCONT

INFDIS<ZYESNO><I:3>

If yes, why? (Check all that apply)

DISTHR<ZYES> ☐ Thrombocytopenia → Please complete the Adverse Event Page

DISAE<ZYES> ☐ Adverse Event → Please complete the Adverse Event Page

DISPTR<ZYES> ☐ Patient refusal

DISOPN<ZYES> ☐ Patient wants to receive open-label EDTA

DISPHY<ZYES> ☐ Physician preference

DISOTH<ZYES> ☐ Other DISOTS<V:20>

Date of last infusion: ___/___/___ (mo day year) LSTINF<DATE>

Were the vitamin tablets permanently discontinued? 0= ☐ No 1= ☐ Yes

VITDIS<ZYESNO>

If yes, why? (Check all that apply)

VITAE<ZYES> ☐ Adverse Event → Please complete Adverse Event Page if event occurred during the infusion phase or within 30 days of the final infusion.

VITPTR<ZYES> ☐ Patient refusal

VITPHY<ZYES> ☐ Physician preference

VITOTH<ZYES> ☐ Other VITOTS<V:20>

Date last tablet was taken: ___/___/___ (mo day year) TABDT<DATE>

Were the vitamin gel-caps permanently discontinued? 0= ☐ No 1= ☐ Yes

GELDIS<ZYESNO>

If yes, why? (Check all that apply)

GELAE<ZYES> ☐ Adverse Event → Please complete Adverse Event Page if event occurred during the infusion phase or within 30 days of the final infusion.

GELPTR<ZYES> ☐ Patient refusal

GELPHY<ZYES> ☐ Physician preference

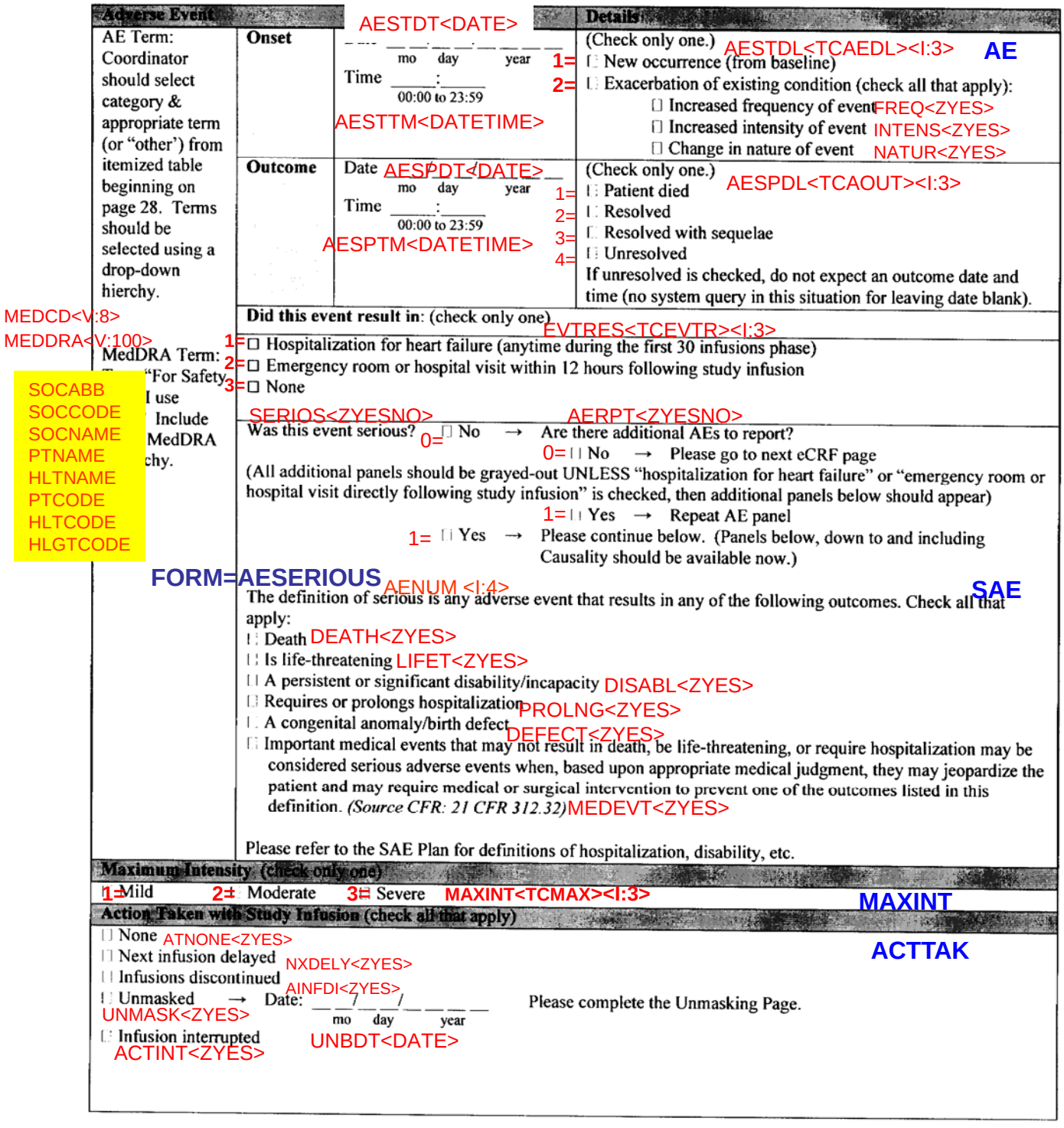
GELOTH<ZYES> ☐ Other GELOTS<V:20>

Date last gel-cap was taken: ___/___/___ (mo day year) GELDT<DATE>

Completion of this form should trigger an e-mail to the Pharmacy.

Patient Study # __ __ __ - __ __ __ Patient's Initials __ __ __

CRFINSNo display appropriate visit number



Adverse Event

AE Term: Coordinator should select category & appropriate term (or "other") from itemized table beginning on page 28. Terms should be selected using a drop-down hierchy.

MEDCD<V:8>
MEDDRA<V:100>
MedDRA Term: "For Safety
I use
Include
MedDRA
chy.

SOCABB
SOCCODE
SOCNAME
PTNAME
HLTNAME
PTCODE
HLTCODE
HLGTCODE

Onset

AESTDT<DATE>

mo day year

Time ____:____ 00:00 to 23:59

AESTTM<DATETIME>

Outcome

Date AESPDT<DATE>

mo day year

Time ____:____ 00:00 to 23:59

AESPTM<DATETIME>

Details

(Check only one) AESTDL<TCAEDL><I:3> AE

1= ☐ New occurrence (from baseline)

2= ☐ Exacerbation of existing condition (check all that apply):

- ☐ Increased frequency of event FREQ<ZYES>
- ☐ Increased intensity of event INTENS<ZYES>
- ☐ Change in nature of event NATUR<ZYES>

(Check only one) AESPDL<TCAOUT><I:3>

1= ☐ Patient died
2= ☐ Resolved
3= ☐ Resolved with sequelae
4= ☐ Unresolved

If unresolved is checked, do not expect an outcome date and time (no system query in this situation for leaving date blank).

Did this event result in: (check only one) EVTRES<TCEVTR><I:3>

1= ☐ Hospitalization for heart failure (anytime during the first 30 infusions phase)
2= ☐ Emergency room or hospital visit within 12 hours following study infusion
3= ☐ None

SERIOS<ZYESNO> AERPT<ZYESNO>

Was this event serious? 0= ☐ No → Are there additional AEs to report?

0= ☐ No → Please go to next eCRF page

(All additional panels should be grayed-out UNLESS "hospitalization for heart failure" or "emergency room or hospital visit directly following study infusion" is checked, then additional panels below should appear)

1= ☐ Yes → Repeat AE panel

1= ☐ Yes → Please continue below. (Panels below, down to and including Causality should be available now.)

FORM=AESERIOUS AENUM <I:4> SAE

The definition of serious is any adverse event that results in any of the following outcomes. Check all that apply:

- ☐ Death DEATH<ZYES>
- ☐ Is life-threatening LIFET<ZYES>
- ☐ A persistent or significant disability/incapacity DISABL<ZYES>
- ☐ Requires or prolongs hospitalization PROLNG<ZYES>
- ☐ A congenital anomaly/birth defect DEFECT<ZYES>
- ☐ Important medical events that may not result in death, be life-threatening, or require hospitalization may be considered serious adverse events when, based upon appropriate medical judgment, they may jeopardize the patient and may require medical or surgical intervention to prevent one of the outcomes listed in this definition. *(Source CFR: 21 CFR 312.32)* MEDEVT<ZYES>

Please refer to the SAE Plan for definitions of hospitalization, disability, etc.

Maximum Intensity (check only one)

1= ☐ Mild 2= ☐ Moderate 3= ☐ Severe MAXINT<TCMAX><I:3> MAXINT

Action Taken with Study Infusion (check all that apply) ACTTAK

- ☐ None ATNONE<ZYES>
- ☐ Next infusion delayed NXDELY<ZYES>
- ☐ Infusions discontinued AINFDI<ZYES>
- ☐ Unmasked → Date: __ __/__ __/__ __ __ __ UNMASK<ZYES> Please complete the Unmasking Page.

mo day year

- ☐ Infusion interrupted ACTINT<ZYES> UNBDT<DATE>

Causality (check only one)

Relationship to study infusion: CAUSAL<TCCSI><I:3> **CAUSAL**

1= ☐ Associated

2= ☐ Not associated → Due to other cause (check all that apply):

- ☐ Vitamin therapy AEVIT<ZYES>
- ☐ Concomitant disease AEDIS<ZYES>
- ☐ Concomitant medication AEMED<ZYES>
- ☐ Surgery/medical procedure AEPROC<ZYES>
- ☐ Progression of disease under study AEPROG<ZYES>

If causality is not associated → Are there additional AEs to report? PROGYN<ZYESNO>

0= ☐ No → Please go to next eCRF page
(All additional panels should be grayed-out)

1= ☐ Yes → Repeat AE panel

If causality is associated → Please continue below. (The remaining panels should now be available, except for Additional Lab Results.)

Patient Demographic Information

Date of birth: RANDOM:DOBDT DISPLAY ONLY (mo day year) Gender: ☐ Male ☐ Female (Display gender from Rand page 3)

PTAGE<I:3> (Display birth date from Rand page 1) RANDOM:GENDER DISPLAY ONLY **PATDEM**

Age: _ _ Years (system calculation: AE onset Date – date of birth from Random page 1) AESTDT-RANDOM:DOBDT DISPLAY ONLY

Weight _ _ _ lbs (display Weight from Rand page 3) RANDOM:WGT DISPLAY ONLY

Randomization date: _ _/_ _/_ _ _ _ (mo day year) (Display randomization date from Subject Screen) RANDOM:RANDDT DISPLAY ONLY

Study Drug Information

Date of most recent infusion: SINDT<DATE> _ _/_ _/_ _ _ _ (mo day year) Time _ _:_ _ (00:00 to 23:59) SINTM<DATETIME> **DRUGINFO**

Perform edit check here to check that this start date and time= Start of infusion date and time on the Infusion information screen and is < or = the onset date of this adverse event.

End of most recent infusion: Date EINDT<DATE> _ _/_ _/_ _ _ _ (mo day year) Time EINTM<DATETIME> _ _:_ _ (00:00 to 23:59)

Perform edit check here to check that this stop date and time = End of infusion date and time on the infusion information screen < or = the onset date of this adverse event.

Infusion visit number: INFNUM<I:3> (number of completed infusions to date)

FIFTY<ZYESNO>

Did the patient receive greater than 50% of the infusion? 0= ☐ No 1= ☐ Yes

Perform edit check here to check that this Start date and 50% of infusion selection of Yes or No = the Start date and corresponding 50% infusion selection of Yes or No on the Infusion information screen.

Relevant Concomitant Medications **CONMED**

REPEAT

Name CNAME	*Dose*	*Units*	*Freq.*	*Start Date*	*Continued*	*Stop D...* CSPDT<DATE>
Free text <V:100>	CDOSE <F:9:3>	CUNIT <V:20>	Free text CFREQ <V:10>	_ _/_ _/_ _ _ _ (mo day year) CSTDT<DATE>	0= ☐ No 1= ☐ Yes CONT <ZYESNO>	_ _/_ _/_ _ _ _ (mo day year) If continued is checked "no", then stop date should have a value. Otherwise, it should be blank.
Repeat for 20 rows total.						

Relevant Laboratory Results **LAB**

REPEAT

Name of Test	*Result*	*Unit*	*Date* LABDT<DATE>	*Nor...ge*
Repeat for 12 rows total. LNAME<V:100>	LRSLT<F:9:3>	LUNIT<V:20>	_ _/_ _/_ _ _ _ (mo day year)	Min LLN <F:9:3> Max ULN <F:9:3>

Medical History

Display Medical History terms checked "Yes" on Baseline Page 5, and display Procedure History terms checked "Yes" on Baseline Case Report Page.

Is there additional relevant medical history? 0= ☐ No LABVAL<ZYESNO> **RELMED**

1= ☐ Yes → Please enter this information below.

The Additional Relevant Medical History section should be grayed-out unless the answer to this question is "yes".

REPEAT

Additional Relevant Medical History

Condition ADDCON<V:100>	*Date* ADDMED
Repeat for 6 rows total.	__ __/__ __/__ __ __ __ ADCODT<DATE> (mo day year)

If AE term is an endpoint, see appropriate endpoint page.

Narrative

This should be auto-generated based on selected fields above. Ability to write to this field should be limited to the site. This field should be readable by CEC and DCRI Safety Surveillance.
Black (non-bold) is template info that should automatically appear in each narrative section, but can be edited by site. The Black Bolded text is place holder that shows what information is needed. It is patient sensitive information that will be entered by the site, and the Black Bolded text should be written over/deleted. The Blue text gives the displayed information, which should be shown when the narrative is opened.

AESTDT-RANDOM:DOBDT DISPLAY ONLY

RANDOM:INITIAL DISPLAY ONLY SUBJNO DISPLAY ONLY

Patient [(Display Patient initials from Rand page 1)], ID number [(Display Patient Study # from Subject Screen)], is a [display Age from this AE form page 17]-year-old [(Display Race from Rand page 3)] [(Display Gender from Rand page 3)] who enrolled in the Trial to Assess Chelation Therapy (TACT). The patient has a history of [(Display all Medical History terms checked "Yes" on Baseline Page 5 and display all Procedure History terms checked "Yes" on Baseline Page 5. Display Additional Relevant Medical History entered on AE page 18)].

SEE NEXT PAGE

RANDOM:AMERIN; RANDOM:ASIAN; RANDOM:BLACK; RANDOM:GENDER DISPLAY ONLY
RANDOM:CAUCAS; RANDOM:HAWAII DISPLAY ONLY

RANDDT DISPLAY ONLY

The patient was randomized on [(Display Date of Rand from Subject Screen)] and received the first IV infusion of chelation solution or placebo on [**Date of First Infusion**]. The patient has received a total of [**Infusion Visit Number**] infusions to date, with the most recent infusion on [**Date of most recent infusion**]. Patient is currently receiving infusions [**infusion schedule – e.g. once weekly**].

AEINFD<DATE> AEMRIF<DATE> AEIFVS<I:3> AEIFSC<V:20>

AESTDT DISPLAY ONLY AESTTM DISPLAY ONLY AETRM DISPLAY ONLY

AESDRG <V:20>

On [Display this AE onset date page 16] at [Display this AE Onset Time from page 16)] hours, the patient experienced [Display this AE term selected on page 16]. [**Enter specific details relating to this adverse event**]. The investigator assessed the intensity of the event as [Display this AE Maximum intensity from page 16)]. The study drug was [**continued, interrupted, decreased, increased, or discontinued on {Date Discontinued}**]. [**Enter if applicable: The study infusion was unmasked on {Unmask date}**]. The patient was also receiving [(Display this AE Relevant Concomitant Medications from page 17)].

AEDISC <V:20>

UNMASK:DRGDT DISPLAY ONLY

MAXINT DISPLAY ONLY CNAME DISPLAY ONLY

The investigator has assessed the causal relationship between the study drug and the serious adverse event as [Display this AE Causality from page 17)], stating [**List reasons provided by PI**].

CAUSALITY:CAUSAL DISPLAY ONLY

AESPDT OR AESTDT IF AESPDL = 4 DISPLAY ONLY

As of [Display this AE Outcome Date or Date of Entry (if AE Outcome is Unresolved)] the outcome of the [Display this AE term selected on page 16)] is [Display this AE Outcome Details from page 16].

AETRM DISPLAY ONLY

AESPDL DISPLAY ONLY

Person performing entry: _____ Date of entry: __ __/__ __/__ __ __ __ (mo day year)

PI Electronic Signature: _____

BASELINE:ANGINA = 1; BASELINE:CHF = 1; BASELINE:VALVHD = 1;
BASELINE:STROKE = 1; BASELINE:TIA = 1; BASELINE:DIABET = 1;
BASELINE:PVD = 1; BASELINE:INCLAU = 1; BASELINE:HYPTEN = 1;
BASELINE:HYPCHO = 1; BASELINE:AFIB = 1; BASELINE:CASVT = 1;
BASELINE:OSTEOP; BASELINE:SMOKE; BASELINE:THYROI = 1;
BASELINE:FRACTU = 1; BASELINE:PCI = 1; BASELINE:CABG = 1; BASELINE:PACE= 1;
BASELINE:AICD = 1; BASELINE:REVASL = 1; BASELINE:REVASC = 1 DISPLAY ONLY

AE:ADDCON DISPLAY ONLY

TACT AE CRF: Itemized AE table

The site will select the appropriate AE term from list provided under relevant category on the AE CRF page. This list is not meant to be all inclusive, but will include common terms seen with this disease and/or drug. If the term is not available, the site will type the AE term into a free text field under the "Other" category. This approach will provide guidance to sites for reporting common AE terms, encourage consistent AE terminology for endpoints on AE page and Ancillary forms, increase coding consistency across reported terms, collect data in a fashion consistent with electronic data capture. A free text field will be provided for the collection of non-common terms.

AE terms will be saved as verbatim terms. Verbatim terms will be coded using the MedDRA coding dictionary. AE verbatim terms and coded terms will be saved in the database. Categories will not be saved, but used only as a reference to find the appropriate AE term.

AE

CATTRM <TCCAT><I:1>

Site will choose from these AE Terms:

	Category	General Term		AE Term	
1=	Endpoint	Stroke	1=	Stroke	ENPTRM<TCDNP><I:1>
			2=	Stroke intracranial hemorrhage	
			3=	Stroke non-hemorrhagic	
			4=	Stroke hemorrhagic conversion of an infarct	
			5=	Stroke uncertain type	
		Myocardial Infarction	6=	Myocardial infarction	
			7=	Anterior myocardial infarction	
			8=	Non-anterior myocardial infarction	
		Angina	9=	Angina	
			10=	Unstable angina	
			11=	Nocturnal angina	
			12=	Intermittent angina	
			13=	Death (Note :Please provide the cause of death as AE term)	
2=	**Cardiovascular**		1=	Palpitations	CARTRM<TCCAR><I:1>
			2=	Shortness of breath related to heart failure	
			3=	Hypotension	
			4=	Hypertension	
		Congestive Heart Failure	5=	Congestive heart failure	
			6=	New onset of congestive heart failure	
			7=	Worsening of congestive heart failure	
		Arrythmia	8=	Arrythmia	
			9=	Atrial tachycardia	
			10=	Atrial fibrillation/flutter	
			11=	Ventricular Tachycardia	
			12=	Sustained	
			13=	Nonsustained	
			14=	Ventricular fibrillation	
			15=	Asystole	
			16=	Sinus bradycardia	
			17=	Sinus tachycardia	
3=	**General Body System Disorder**	Allergic reaction	1=	Allergic reaction	GENTRM<TCGEN><I:1>
			2=	Rash	
			3=	Itching	
			4=	Flushing	
			5=	Dermatitis	

			6= Anaphylactic Reaction	
			7= Fever	
			8= Malaise	
			9= Chills	
	General Body System Disorder		10= Fatigue	
			11= Myalgia	
			12= Arthritis	
			13= Excessive thrist	
			14= Ascites	
			15= Edema	
			16= Gout	
			17= Gossitis/sore tongue	
			18= Anemia	
			19= Neutropenia	
4=	**Venous access associated problems**		1= Pain at the infusion site	
			2= Infection at the infusion site	VENTRM <TCVEN><I:1>
			3= Phlebitis at the infusion site	
			4= Swelling at the infusion site	
			5= Abscess at the infusion site	
			6= Hematoma at the infusion site	
5=	**Renal Disorder**		1= Hematuria	
			2= Decrease frequency of urination	RENTRM <TCREN><I:1>
			3= Unable to urinate ≥ 24 hours	
			4= Renal insufficiency	
			5= Proteinuria	
			6= Glycosuria	
			7= Renal toxicity	
			8= Renal failure	
6=	**Gastrointestinal Disorder**		1= Nausea	
			2= Vomiting	GASTRM <TCGAS><I:1>
			3= Diarrhea	
			4= Anorexia	
			5= Constipation	
			6= Abdominal cramps	
			7= Diverticulitis	
7=	**Laboratory abnormalities**		1= Hypoglycemia	
			2= Hypocalcemia	LABTRM <TCLAB><I:1>
			3= Thrombocytopenia	
			4= ALT/AST increased	
			5= Serum creatinine increased	
			6= Bilirubin increased	
			7= Alkaline phosphatase increased	
8=	**Nervous System Disorder**		1= Numbness of extremities	NERTRM <TCNER><I:1>
			2= Tingling of extremities	
			3= Headache	
			4= Tremors	
			5= Fainting	
			6= Dizziness	
			7= Confusion	
			8= Tetany	
			9= Depression	
			10= Aggression	
98=	**Other**	(free text field):	OTHTRM<V:20>	

Patient Study # __ __ __-__ __ __ Patient's Initials __ __ __

If the treatments were unmasked for any reason, please submit this page.

Unmasking

UNMASK

1. Was the study infusion unmasked? DRGUNB<ZYESNO>
   0= ☐ No
   1= ☐ Yes → Date of unmasking ___/___/___ DRGDT<DATE>
   (mo day year)

   Reason(s): Check all that apply.

   DDTOX<ZYES> ☐ Suspected drug toxicity → Please complete Adverse Event Page
   DSAE<ZYES> ☐ Serious adverse event → Please complete Adverse Event Page
   DOTHER<ZYES> ☐ Other: Specify UOTSP<V:20>_____

2. Was the vitamin dosage unmasked? VITUNB<ZYESNO>
   0= ☐ No
   1= ☐ Yes → Date of unmasking ___/___/___ VITDT<DATE>
   (mo day year)

   Reason(s): Check all that apply.

   VDTOX<ZYES> ☐ Suspected vitamin toxicity → Please complete Adverse Event Page if event occurred during the infusion phase or within 30 days of the final infusion.

   VSAE<ZYES> ☐ Serious adverse event → Please complete Adverse Event Page if event occurred during the infusion phase or within 30 days of the final infusion.

   VOTHER<ZYES> ☐ Other: Specify VOTSP<V:20>_____

TACT FORM=CONMED CONCOMITANT MEDICATIONS

Patient Study # __ __ __-__ __ __ Patient's Initials __ __ __

[This should be collected at Infusion Visits 15, 30, 36 and 40.]

MEDSSIN

Medications Since Last Time Completed

1. Aspirin 0= No 1= Yes FASPIR<ZYESNO>
   If no, check primary reason. FASPRS<TCASPR> <I:3>
   1= GI Intolerance
   2= Allergy
   3= Taking a different anticoagulant
   4= Patient refuses
   5= Physician preference other than reasons above
   6= Other
   98=

2. Beta-blocker 0= No 1= Yes FBBLOC<ZYESNO>
   If no, check primary reason. FBBRSN<TCBBR> <I:3>
   1= Bronchospasm
   2= Depression
   3= Fatigue
   4= Cold extremities
   5= Active heart failure
   6= Allergy
   7= Cost
   8= Patient refuses
   9= Physician preference other than reasons above
   98= Other

3. Statin 0= No 1= Yes FSTATI<ZYESNO>
   If no, check primary reason. FSTAR<TCSTR> <I:3>
   1= Liver enzyme elevation
   2= Myositis
   3= Myalgias
   4= Allergy
   5= Cost
   6= Patient refuses
   7= Physician preference other than reasons above
   98= Other

4. Angiotensin converting enzyme inhibitor FACE<ZYESNO> 0= No 1= Yes
   If no, check primary reason. FACERS<TCACER> <I:3>
   1= Cough
   2= Angioedema, anaphylaxis, neutropenia
   3= Hyperkalemia
   4= Symptomatic hypotension
   5= Renal artery stenosis
   6= Renal dysfunction
   7= Other adverse events such as taste disturbance, rash, or gastrointestinal upset
   8= Patient refuses
   9= No CHF or normal LVEF
   10= Physician preference other than reasons above
   98= Other

FARB<ZYESNO>
5. Angiotensin receptor blocker 0= No 1= Yes
FABLOC<ZYESNO>
6. Alpha-blocker No Yes
FCCB<ZYESNO>
7. Calcium channel blocker No Yes
FDIUR<ZYESNO>
8. Diuretic No Yes
FWARFA<ZYESNO>
9. Warfarin No Yes
FAMIO<ZYESNO>
10. Amiodarone No Yes
FOANTI<ZYESNO>
11. Other antiarrhythmic drug No Yes
FDIGOX<ZYESNO>
12. Digoxin No Yes
FCLOP<ZYESNO>
13. Clopidogrel No Yes
14. Diabetes medication:
FDIAIN<ZYESNO>
Insulin No Yes
FDIABO<ZYESNO>
Oral hypoglycemic No Yes
FTHYRT<ZYESNO>
15. Thyroid replacement therapy No Yes
16. Medication for PVD:
FPVDPL<ZYESNO>
Pletal No Yes
FPVDPE<ZYESNO>
Pentoxyfilline No Yes
FMOSTE<ZYESNO>
17. Medication for osteoporosis No Yes
FMULTV<ZYESNO>
18. Multivitamin No Yes
FOVTMN<ZYESNO>
19. Other vitamins/minerals No Yes
FHERBA<ZYESNO>
20. Herbal products No Yes

If "yes" and Visit number = 40, then continue below.

Herbal Supplement Usage (Visit 40 Only)

21. Please indicate which of the following supplements the patient is currently taking:

HERBSUP

			Reason(s): CV disease	Other health condition
Echinacea ECHA<ZYESNO><I:1>	No	Yes →	ECHCVA<ZYES><I:1>	ECHOHA<ZYES><I:1>
Fish oils/omega fatty acids FISA<ZYESNO><I:1>	No	Yes →	FISCVA<ZYES><I:1>	FISOHA<ZYES><I:1>
Garlic supplements GARA<ZYESNO><I:1>	No	Yes →	GARCVA<ZYES><I:1>	GAROHA<ZYES><I:1>
Ginkgo biloba GINA<ZYESNO><I:1>	No	Yes →	GINCVA<ZYES><I:1>	GINOHA<ZYES><I:1>
Glucosamine with or without chondroitin GLUA<ZYESNO><I:1>	No	Yes →	GLUCVA<ZYES><I:1>	GLUOHA<ZYES><I:1>
Hawthorn HAWA<ZYESNO><I:1>	No	Yes →	HAWCVA<ZYES><I:1>	HAWOHA<ZYES><I:1>
Ma huang (ephedra) MHUA<ZYESNO><I:1>	No	Yes →	MHUCVA<ZYES><I:1>	MHUOHA<ZYES><I:1>
SAM-e SAMA<ZYESNO><I:1>	No	Yes →	SAMCVA<ZYES><I:1>	SAMOHA<ZYES><I:1>
Saw palmetto SAWA<ZYESNO><I:1>	No	Yes →	SAWCVA<ZYES><I:1>	SAWOHA<ZYES><I:1>
Soy supplements SOYA<ZYESNO><I:1>	No	Yes →	SOYCVA<ZYES><I:1>	SOYOHA<ZYES><I:1>
St. John's wort STJA<ZYESNO><I:1>	No	Yes →	STJCVA<ZYES><I:1>	STJOHA<ZYES><I:1>
Valerian VALA<ZYESNO><I:1>	No	Yes →	VALCVA<ZYES><I:1>	VALOHA<ZYES><I:1>
Other HOTA<ZYESNO><I:1>	No	Yes →	HOTCVA<ZYES><I:1>	HOTOHA<ZYES><I:1>

FORM=TELEFU

Patient Study # ___ ___ ___-___ ___ ___   Patient's Initials ___ ___ ___

Status of Telephone Follow-Up

TELEFU

1. Was the telephone follow-up conducted?
   - 0= ☐ No → Complete question #2 only.
   - TELEFU<ZYESNO><I:3>1= ☐ Yes → Continue with question #3.

2. If no, why was it missed? (Check all that apply.)
   - ☐ Death TELDTH<ZYES> → Please complete Death Page
   - ☐ Hospitalization TELHOS<ZYES> → Continue with question #3.
   - ☐ Non-medical reason TELNON<ZYES>
   - ☐ Intercurrent Non-cardiac Illness/Injury TELNCA<ZYES>
   - TELWDR<ZYES> ☐ Withdrew consent for the study → Please complete End of Study Page
   - ☐ Patient refusal TELPTR<ZYES>
   - ☐ Unable to reach patient TELPT<ZYES>

Study coordinator/clinician should fill out CV event/procedures/symptoms information and other adverse event information, if applicable, as soon as it is available.

Interval Cardiovascular Events, Procedures and Symptoms

INTCARD

3. Date of telephone follow-up ___/___/___ (mo day year) TLFUDT<DATE>

4. Has the patient been hospitalized **for any reason** since the previous contact?
   - 0= ☐ No HOSPB<ZYESNO><I:3>
   - 1= ☐ Yes → Please complete the following for each hospitalization.
     - ❖ If the hospitalization was due to angina, please also complete the Hospitalization for Angina page for this hospitalization.

HOSPITAL

HOSADB<DATE> Date of hospitalization:	HOSDSB<DATE> Date of discharge:	HOSREB<V:20> Reason for hospitalization:	HOSAB<ZYESNO> Was the hospitalization due to angina?
___/___/___	___/___/___	________	☐ No ☐ Yes
___/___/___	___/___/___	________	☐ No ☐ Yes
___/___/___	___/___/___	________	☐ No ☐ Yes
___/___/___	___/___/___	________	☐ No ☐ Yes
___/___/___	___/___/___	________	☐ No ☐ Yes
___/___/___	___/___/___	________	☐ No ☐ Yes
___/___/___	___/___/___	________	☐ No ☐ Yes
___/___/___	___/___/___	________	☐ No ☐ Yes

5. Cardiovascular events/procedures since last contact:

MI CVMIB <ZYESNO>
- 0= ☐ No
- 1= ☐ Yes → Date ___/___/___ (mo day year)
  - → Please complete the MI Page

Stroke CVSTKB <ZYESNO>
- 0= ☐ No
- 1= ☐ Yes → Date ___/___/___ (mo day year)
  - → Please complete the Stroke Page

PCI CVPCIB <ZYESNO>
- 0= ☐ No
- 1= ☐ Yes → Date ___/___/___ (mo day year) CVPI2D<DATE>

CABG CABGB <ZYESNO>
- 0= ☐ No
- 1= ☐ Yes → Date ___/___/___ (mo day year) CVCG2D<DATE>

ICD CVICDB <ZYESNO>
- 0= ☐ No
- 1= ☐ Yes → Date ___/___/___ (mo day year) CVID2D<DATE>

Pacemaker CVPACB <ZYESNO>
- 0= ☐ No
- 1= ☐ Yes → Date ___/___/___ (mo day year) CVPM2D<DATE>

If "yes" to any of these, display: "Obtain required source documents and send to DCRI."

Non-TACT Dietary Supplements

NONTACT

6. Has the patient taken any supplements not supplied by TACT? SUPPLM<ZYESNO><I:3>
   - 0= ☐ No
   - 1= ☐ Yes → Please indicate which type (check one): SUPTYP<TCTYP><I:3>
     - 1= ☐ Multivitamin
     - 2= ☐ Other vitamins/minerals
     - 3= ☐ Herbal supplements

Patient Study # __ __ __-__ __ __ Patient's Initials __ __ __

CLNVS <TCCLVS> <I:3> CLINVIS

Visit: 1= ☐ **Clinic Follow-Up Visit** 2= ☐ **Closeout Clinic Visit**

Status of Clinic Visit

1. Was the clinic visit missed? 0= ☐ No → Go to question #3.
   CLNMIS<ZYESNO> 1= ☐ Yes → Go to question #2. CLINSTAT

2. If yes, why was it missed? (Check all that apply.)
   - ☐ Death CLDTH<ZYES> → Please complete Death Page
   - ☐ Cardiovascular Event CLCVET<ZYES> → Continue to CV Event panel (below)
   - ☐ Other Serious Adverse Event CLSAE<ZYES>
   - ☐ Non-medical reason CLNMED<ZYES>
   - ☐ Intercurrent Non-cardiac Illness/Injury CLILL<ZYES>
   - ☐ Withdrew consent for the study → Please complete End of Study Page
     CLWTDR<ZYES>

   If not due to death or withdrawn consent, please reschedule this visit.

Study coordinator/clinician should fill out CV event/procedures/symptoms information and other adverse event information, if applicable, as soon as it is available.

Cardiovascular Events, Procedures and Symptoms

3. Date of clinic visit ___/___/___ (mo day year) CLVIST<DATE> CLINCARD

4. Has the patient been hospitalized **for any reason** since the previous contact?
   0= ☐ No HOSPC<ZYESNO><I:3>
   1= ☐ Yes → Please complete the following for each hospitalization.
   - ❖ If the hospitalization was due to angina, please also complete the Hospitalization for Angina page for this hospitalization.

HOSPITAL

Date of hospitalization HSPLDT<DATE>	Date of discharge DISGDT<DATE>	Reason for hospitalization: REASNH<V:20>	Angina? HSPANG<ZYESNO><I:3>
___/___/___	___/___/___	_____	☐ No ☐ Yes
___/___/___	___/___/___	_____	☐ No ☐ Yes
___/___/___	___/___/___	_____	☐ No ☐ Yes
___/___/___	___/___/___	_____	☐ No ☐ Yes
___/___/___	___/___/___	_____	☐ No ☐ Yes
___/___/___	___/___/___	_____	☐ No ☐ Yes
___/___/___	___/___/___	_____	☐ No ☐ Yes
___/___/___	___/___/___	_____	☐ No ☐ Yes

5. Cardiovascular events/procedures since last contact:

MI 0= ☐ No
1= ☐ Yes → Date ___/___/___ (mo day year)
CVMIC <ZYESNO> → Please complete the MI Page

Stroke 0= ☐ No
1= ☐ Yes → Date ___/___/___ (mo day year)
CVSTKC <ZYESNO> → Please complete the Stroke Page

PCI 0= ☐ No
1= ☐ Yes → Date ___/___/___ (mo day year) CVPI3D<DATE>
CVPCIC <ZYESNO>

CABG 0= ☐ No
1= ☐ Yes → Date ___/___/___ (mo day year) CVCG3D<DATE>
CABGC <ZYESNO>

ICD 0= ☐ No
1= ☐ Yes → Date ___/___/___ (mo day year) CVID3D<DATE>
CVICDC <ZYESNO>

Pacemaker 0= ☐ No
1= ☐ Yes → Date ___/___/___ (mo day year) CVPM3D<DATE>
CVPACC <ZYESNO>

Check to see that events occur within hospitalization intervals.
If "yes" to any of these, display: "Obtain required source documents and send to DCRI."

Clinical Data

6. Vital Signs

CLBPSY CLBPDI

Blood Pressure (mm Hg): <I:3> / <I:3> Pulse: CLPULS<I:3> **CLINDAT2**

Pulmonary Rales: 0=☐ No 1=☐ Yes

CLRALE<ZYSNO>

An alert should be triggered if BP is above 160/100.

Cigarette Smoking Status

7. Does the patient currently smoke cigarettes? 0= ☐ No 1= ☐ Yes CLSMOK<ZYESNO><I:3> **CLINSMOK**

Current Characteristics

8. Current Canadian Cardiovascular Society (CCS) angina class (check only one): **CURCHAR**

CLNOAN<ZYES> ☐ No angina 1= ☐ I 2= ☐ II 3= ☐ III 4= ☐ IV CLCCS<TCCCS><I:3>

9. Current NYHA heart failure class (check only one):

CLNOHF<ZYES> ☐ No heart failure 1= ☐ I 2= ☐ II 3= ☐ III 4= ☐ IV CLNYHA<TCNYHA><I:3>

10. Current intermittent claudication?

0= ☐ No CLCLAU<ZYESNO><I:3> CLAUDS<ZYESNO><I:3>

1= ☐ Yes → Is the claudication severe enough to limit normal activities? 0= ☐ No 1= ☐ Yes

Patient Study # __ __ __-__ __ __ Patient's Initials __ __ __

End of Study

1. End of study date: ___/___/___ (mo day year) ENDSTY<DATE>

EOS

TERM<TCTERM><I:3>

2. Reason for patient terminating the study (check only one):
   - 1☐ Completed the study
   - 2☐ Withdrew consent
   - 3☐ Died

Form completed by: _____ Date: ___/___/___ (mo day year)

"I believe that this is a true and accurate record of the data pertaining to this patient. I have checked these data for accuracy and completeness."

Investigators signature: _____ Date: ___/___/___ (mo day year)

This form will be added on the fly, but should be completed for all patients when they have finished or terminated the study.

Completion of this form should trigger an e-mail to the Pharmacy.

FORM=PHARMINF

PHARMACY INFORMATION

Patient Study # __ __ __-__ __ __ Patient's Initials __ __ __

Treatment Information

TREAT

Infusion

1. Infusion bag Rx number — INFUSB<V:10> _____
   # refills remaining — INRFLR<V:10> _____

2. Treatment sent to site — ITRTSI<TCSITE> 1= ☐ EDTA 2= ☐ Placebo

3. Date shipped to site — ITRTDT<DATE> ___/___/___ (mo day year)

4. Was there a change in dosage from the previous infusion? — IDOSEC<ZYESNO>
   0= ☐ No
   1= ☐ Yes →
   Dosage changed:
   ☐ EDTA — EDTA<ZYES> → New dosage: _____ grams — EDTADS<F:9:3>
   ☐ Heparin — HEPARN<ZYES> → New dosage: _____ units — HEPRDS<F:9:3>
   ☐ Other — OTHDOS<ZYES>

Vitamins – High dose (bottle)

5. Rx number on bottle — ~~HIGHLA<V:10>~~ _____ or ☐ N/A
   # refills remaining — ~~HIRFLR<V:10>~~ _____ HGHNA<ZYES>

6. Treatment sent to site — HTRTSI<TCHSTE> 1= ☐ High-dose vitamins 2= ☐ Placebo 3= ☐ None

7. Date shipped to site — VTRTDT<DATE> ___/___/___ (mo day year)

VDOSEC<ZYESNO>

8. Was there a change in dosage?
   0= ☐ No
   1= ☐ Yes → New dosage: VNEWDO<F:9:3> tablets bid

Vitamins – Low dose (blister-pack)

9. Rx number on blister-pack — LOWLAB<V:10> _____ or ☐ N/A
   # refills remaining — LORFLR<V:10> _____ LOWNA<ZYES>

10. Treatment dispensed — LTRTSI<TCLSTE>
    1= ☐ Low-dose vitamins 2= ☐ None

Patient Study # __ __ __-__ __ __ Patient's Initials __ __ __

AENUM<V:5>

Circumstances of Death

DEATH

1. Date of death: ___/___/___ (mo day year) DETHDT<DATE>

CAUSE<TCDTHC><I:3>

2. Cause of death (check one category, and check one subcategory under the checked category (if applicable)):

1= Atherosclerotic coronary heart disease
- 1= Fatal MI
- 2= Sudden Death
- 3= Heart Failure
- 4= Presumed Cardiovascular
- 5= Procedural: Specify: PSPECA<V:20>

DTHTYP <TCCUST>

2= Atherosclerotic vascular disease, excluding coronary disease
- 6= Cerebrovascular disease, including stroke and hemorrhage
- 7= Aortic, mesenteric, renal vascular or PVD
- 5= Procedural: Specify: _____
- 98= Other: Specify: OSPECA<V:20>

3= Other cardiovascular (non-atherosclerotic)
- 8= Pulmonary Embolism
- 9= Endocarditis
- 10= Valvular Disease
- 5= Procedural: Specify: _____
- 98= Other: Specify: _____

4= Non-cardiovascular
- 11= Infectious
- 12= Malignancy
- 13= Pulmonary
- 14= Gastrointestinal
- 15= Accidental
- 16= Suicide
- 17= Diabetes
- 18= (Non-CV) Unwitnessed (not seen > 24 hrs)
- 98= Other: Specify: _____

99= Unknown

DEATH

3. Location of death (check one): 1= ☐ At home → Submit all pertinent source documents to DCRI. Provide in the Narrative Summary section of the iCRF a clear and accurate narrative description of events leading up to the patient's death and provide reasons to support the cause of death as above. NOTE: It is not necessary to obtain a death certificate.

LOCDTH<TCLOC1><I:3>

2= ☐ In hospital → Submit all pertinent source documents to DCRI. Provide in the Narrative Summary section of the iCRF a clear and accurate narrative description of events leading up to the patient's death and provide reasons to support the cause of death as above. Refer to the inservice manual for a complete list of source documents.

98= ☐ Other: Specify LOCDSP<V:20> → Provide in the Narrative Summary section of the iCRF a clear and accurate narrative description of events leading up to the patient's death and provide reasons to support the cause of death as above.
If patient died in a medical setting →
Submit all pertinent source documents to DCRI Refer to the inservice manual for a complete list of source documents.
If patient died outside of a medical setting → Submit all pertinent source documents to DCRI. NOTE: It is not necessary to obtain a death certificate.

DEATC<ZYES>

4. Documentation of death (check all that apply):
☐ Death certificate
☐ Hospital record HOSPRC<ZYES>
☐ Verbal report from next-of-kin or significant other VERBAL<ZYES>
DOTHR<ZYES> ☐ Other: Specify _____ DOCDSP<V:20>

DTHWIT<ZYESNO>

5. Was the death witnessed?
0= ☐ No
1= ☐ Yes → Was emergency resuscitation attempted? RESUSC<ZYNUNK>
99= ☐ Unknown
0= ☐ No
1= ☐ Yes

AUTOPS<ZYESNO>

6. Was an autopsy performed?
0= ☐ No
1= ☐ Yes → Warning message: Please provide autopsy report or physician statement of key findings if report unobtainable.

Please complete the Adverse Event Page for this death if the death occurred during the infusion phase or within 30 days of the final infusion.

Interval Cardiovascular Events and Procedures Since Last Contact

CARDSIN

7. Has the patient been hospitalized **for any reason** since the previous contact?
0= ☐ No HOSPD<ZYESNO><I:3>
1= ☐ Yes → Please complete the following for each hospitalization.
- ❖ If the hospitalization was due to angina, please also complete the Hospitalization for Angina page for this hospitalization.
- ❖ Otherwise, complete the Adverse Event page if the event occurred during the infusion phase or within 30 days of the final infusion.

HOSPITAL

HOSADD<DATE> Date of hospitalization:	HOSDSD<DATE> Date of discharge:	HOSRED<V:20> Reason for hospitalization:	HOSAD<ZYESNO> Was the hospitalization due to angina?
___/___/___	___/___/___	_____	☐ No ☐ Yes
___/___/___	___/___/___	_____	☐ No ☐ Yes
___/___/___	___/___/___	_____	☐ No ☐ Yes
___/___/___	___/___/___	_____	☐ No ☐ Yes
___/___/___	___/___/___	_____	☐ No ☐ Yes
___/___/___	___/___/___	_____	☐ No ☐ Yes
___/___/___	___/___/___	_____	☐ No ☐ Yes
___/___/___	___/___/___	_____	☐ No ☐ Yes

8. Cardiovascular events/procedures since last contact: CARDSIN

MI 0= ☐ No
1= ☐ Yes → Date ___/___/___ mo day year
CVMID <ZYESNO>
→ Please complete the MI Page

Stroke 0= ☐ No
1= ☐ Yes → Date ___/___/___ mo day year
CVSTKD <ZYESNO>
→ Please complete the Stroke Page

Check to see that events occur within hospitalization intervals for MI, Stroke and CABG.

PCI 0= ☐ No
CVPCID 1= ☐ Yes → Date ___/___/___ mo day year CVPI4D<DATE>
<ZYESNO>

CABG 0= ☐ No
CABGD 1= ☐ Yes → Date ___/___/___ mo day year CVCG4D<DATE>
<ZYESNO>

ICD 0= ☐ No
CVICDD 1= ☐ Yes → Date ___/___/___ mo day year CVID4D<DATE>
<ZYESNO>

Pacemaker 0= ☐ No
CVPACD 1= ☐ Yes → Date ___/___/___ mo day year CVPM4D<DATE>
<ZYESNO>

Narrative Summary

Narrative Summary of Events Leading to Death:

The narrative summary will be used as a source document for CEC.

Patient Study # __ __ __-__ __ __ Patient's Initials __ __ __

AENUM<V:5>

Circumstances of MI

CIRMI

1. Date of MI: ___/___/___ (mo day year) MIDATE<DATE>

→ Warning message: "Please provide the hospital discharge summary to the DCRI."

2. Did the patient experience ischemic symptoms (pain, dyspnea, pressure) for ≥ 10 minutes, and are the symptoms determined by the investigator to be secondary to ischemia?

0= ☐ No
1= ☐ Yes ISCHEM<ZYESNO><I:3>

3. Were there new ECG changes consistent with myocardial ischemia in 2 or more contiguous leads? (Please consult with Site Investigator prior to answering this question.)

0= ☐ No AECGCH<ZYESNO>
1= ☐ Yes → Check all that apply:

ASTDEP<ZYES> ☐ ≥ 0.5 mm transient ST segment depression in two contiguous limb or precordial leads
ASTELE<ZYES> ☐ ≥ 1 mm transient ST elevation in two contiguous leads
ATWAVE<ZYES> ☐ ≥ 2 mm transient T wave change in two or more contiguous leads
A5MMCH<ZYES> ☐ ≥ 0.5 mm change as compared to most recent ECG or during the previous stable phase
ANEWQ<ZYES> ☐ New significant Q waves (or R waves in V1-V2) in two contiguous leads in the absence of previous LVH or conduction abnormalities
ADEPEL<ZYES> ☐ Evolving ST-segment to T-wave changes in two or more contiguous leads
ALBBB<ZYES> ☐ Development of new left bundle branch block
ASTPCI<ZYES> ☐ ST segment elevation requiring thrombolytics or PCI
AECGOT<ZYES> ☐ Other: ~~AECGSP<V:20>~~

Warning message: Please submit at least 2 ECGs documenting the change as reported above. ECGs should be clearly labeled with date and time. If ECGs are not able to be released, please submit a Physician Narrative describing the changes and dates and times comparative ECGs were performed along with a statement explaining why ECGs were not able to be obtained.

CRDMRA<ZYESNO><I:3>

4. Were there cardiac markers drawn in association with this event?

0= ☐ No
1= ☐ Yes → ECKVAA<ZYESNO> Elevated CK values

		0=	1=	Peak	ULN
ECKMBA<ZYESNO>	Elevated CKMB values	☐ No	☐ Yes →	~~CKMBPA<F:9:3>~~	~~CKMBUA<F:9:3>~~
ETROPA<ZYESNO>	Elevated Troponin values	☐ No	☐ Yes →	~~TROPPA<F:9:3>~~	~~TROPUA<F:9:3>~~

Warning message: "Provide lab reports for peak values of elevated lab values as reported above. Be sure to include ULN and date and time lab was performed. If actual lab reports with ULN are not able to be released, please submit a Physician Narrative of the requested information and state why the lab reports were not able to be obtained. If CK is the only elevated marker, please provide all CK results to show serial change. If Troponin is reported in ranges, please provide all applicable ranges. If the event is suspected to have occurred after a coronary revascularization, please provide all elevated markers drawn within 24 hours of procedure.

CIRMI

5. Did a coronary revascularization occur during this hospitalization?

0= ☐ No
1= ☐ Yes REVAS<ZYESNO>

☐ CABG → Date ___/___/___ (mo day year) RCABDT<DATE> Time ____:____ (00:00 to 23:59) RCABTM<DATETIME>
RCABG<ZYES>

☐ PCI → Date ___/___/___ (mo day year) RPCIDT<DATE> Time ____:____ (00:00 to 23:59) RPCITM<DATETIME>
RPCI<ZYES>

☐ Other → Date ___/___/___ (mo day year) ROTHDT<DATE> Time ____:____ (00:00 to 23:59) ROTHTM<DATETIME>
ROTHER<ZYES>

Display date of CABG and/or PCI, if available.

In the investigator's opinion, did a peri-procedural or post-procedural MI occur?

0= ☐ No
1= ☐ Yes PPMIA<ZYESNO><I:3>

6. Did the MI occur following a surgical intervention other than coronary revascularization?

0= ☐ No
1= ☐ Yes MSURG<ZYESNO>

Please complete the Adverse Event Page if the event occurred during the infusion phase or within 30 days of the final infusion and if you have not already done so for this event.

FORM=ANGINA

Patient Study # __ __ __-__ __ __ Patient's Initials __ __ __

AENUM<V:5>

Circumstances of Hospitalization for Angina

1. Date of Admission: ___/___/___ (mo day year) ADMTDT<DATE> CIRHOSP

→ Warning message: "This form should be completed when a patient is admitted specifically for the management of angina. Please provide the hospital discharge summary to the DCRI."

ANGSYM<ZYNUNK>
2. Were the patient's anginal symptoms determined by the investigator to be attributed to myocardial ischemia?
0= ☐ No → Specify cause of symptoms: SPCAUS<V:20>
1= ☐ Yes
99= ☐ Unknown

3. Was this a planned admission?
0= ☐ No
1= ☐ Yes PLNADM<ZYESNO>

4. Please complete below for all procedures that occurred during this hospitalization:

CARCTH<ZYESNO>
Cardiac catheterization
0= ☐ No
1= ☐ Yes → Date: ___/___/___ (mo day year) CCDATE<DATE>

CABG ANCABG<ZYESNO>
0= ☐ No
1= ☐ Yes → Date: ___/___/___ (mo day year) ANCADT<DATE>

PPMIB<ZYESNO><I:3>
In the investigator's opinion, did a peri-procedural or post-procedural MI occur?
0= ☐ No
1= ☐ Yes → Please complete MI Details page.

PCI ANGPCI<ZYESNO>
0= ☐ No
1= ☐ Yes → Date: ___/___/___ (mo day year) ANGPDT<DATE>

PPMIC<ZYESNO><I:3>
In the investigator's opinion, did a peri-procedural or post-procedural MI occur?
0= ☐ No
1= ☐ Yes → Please complete MI Details page.

ANREVS<ZYESNO>
Other revascularization
0= ☐ No
1= ☐ Yes → Specify: REVASP<V:20> Date: ___/___/___ (mo day year) ANREDT<DATE>

ANTMED<ZYESNO>
5. Was there either an increase in previously prescribed anti-ischemic medication or an addition of new anti-ischemic medication on discharge?
0= ☐ No
1= ☐ Yes → Check all that apply:
ANTPLT<ZYES> ☐ Anti-platelet
BETBLC<ZYES> ☐ Beta blocker
CALCNL<ZYES> ☐ Calcium channel
NITRAT<ZYES> ☐ Nitrates
OTANMD<ZYES> ☐ Other anti-ischemic medication: Specify OTANSP<V:20>

Warning message: "In order to provide the required supporting source documents, please review the discharge summary and make the determination of whether the data in #5 are documented. Discharge Summary should state medications and dosage on admission, and on discharge. If the Discharge Summary is not this specific, please provide documentation of outpatient medical therapy prior to admission and discharge medication."

6. Were there new ECG changes consistent with myocardial ischemia in 2 or more contiguous leads? (Please consult with Site Investigator prior to answering this question.)

0= ☐ No AECGCA<ZYESNO>
1= ☐ Yes → Check all that apply:

ASTDEB<ZYES> ☐ ≥ 0.5 mm transient ST segment depression in two contiguous limb or precordial leads
ASTELB<ZYES> ☐ ≥ 1 mm transient ST elevation in two contiguous leads
ATWAVB<ZYES> ☐ ≥ 2 mm transient T wave change in two or more contiguous leads
A5MMCB<ZYES> ☐ ≥ 0.5 mm change as compared to most recent ECG or during the previous stable phase
ANEWQB<ZYES> ☐ New significant Q waves (or R waves in V1-V2) in two contiguous leads in the absence of previous LVH or conduction abnormalities
ADEPEB<ZYES> ☐ Evolving ST-segment to T-wave changes in two or more contiguous leads
ALBBBB<ZYES> ☐ Development of new left bundle branch block
ASTPCB<ZYES> ☐ ST segment elevation requiring thrombolytics or PCI
AECGOB<ZYES> ☐ Other: AEC2SP<V:20>

Warning message: Please submit at least 2 ECGs documenting the change as reported above. ECGs should be clearly labeled with date and time. If ECGs are not able to be released, please submit a Physician Narrative describing the changes and dates and times comparative ECGs were performed along with a statement explaining why ECGs were not able to be obtained.

CRDMRB<ZYESNO><I:3>

7. Were there cardiac markers drawn in association with this event?

0= ☐ No
1= ☐ Yes →

				Peak	ULN
ECKVAB<ZYESNO>	Elevated CK values	0= ☐ No	1= ☐ Yes →	CKPKB<F:9:3>	CKULNB<F:9:3>
ECKMBB<ZYESNO>	Elevated CKMB values	☐ No	☐ Yes →	CKMBPB<F:9:3>	CKMBUB<F:9:3>
ETROPB<ZYESNO>	Elevated Troponin values	☐ No	☐ Yes →	TROPPB<F:9:3>	TROPUB<F:9:3>

Warning message: "Provide lab reports for peak values of elevated lab values as reported above. Be sure to include ULN and date and time lab was performed. If actual lab reports with ULN are not able to be released, please submit a Physician Narrative of the requested information and state why the lab reports were not able to be obtained. If CK is the only elevated marker, please provide all CK results to show serial change. If Troponin is reported in ranges, please provide all applicable ranges. If the event is suspected to have occurred after a coronary revascularization, please provide all elevated markers drawn within 24 hours of procedure.

Please complete the Adverse Event Page now if the event occurred during the infusion phase or within 30 days of the final infusion and if you have not already done so for this event.

Patient Study # __ __ __-__ __ __ Patient's Initials __ __ __

AENUM<V:5>

Circumstances of Stroke

STROKE

1. Date of event: _____ SYMPDT<DATE>

SNEURO<ZYESNO>
Did the patient experience a focal neurological deficit in association with this event?

0= ☐ No
1= ☐ Yes → Symptoms: Check all that apply.

☐ Aphasia SAPHAS<ZYES>
☐ Focal motor weakness SWEAK<ZYES>
☐ Altered sensation/sensory deficit SSENAT<ZYES>
SOTHRB<ZYES> ☐ Other: Specify SOTHSB<V:20>

SSYMP<ZYNUNK>
Was there a sudden onset of symptoms? 0= ☐ No 1= ☐ Yes 99= ☐ Unknown

SSYMDR<TCSSYM>
Duration of symptoms: 1= ☐ < 24 hours 2= ☐ 24-72 hours 3= ☐ > 72 hours 99= ☐ Unknown

SCAUSE<ZYNUNK><I:3>
2. Was there any readily identifiable cause for the above symptoms (e.g. trauma, brain tumor) other than stroke?

99= ☐ Unknown
0= ☐ No
1= ☐ Yes → Specify: SCAUSP<V:20>

Is there documentation of a hemorrhage associated with this event?

99= ☐ Unknown STKDOC<ZYNUNK>
0= ☐ No
1= ☐ Yes → How was the hemorrhage documented?

☐ CT SCT<ZYES>
☐ MRI SMRI<ZYES>
☐ Angiography SANGIO<ZYES>
SOTHER<ZYES> ☐ Other: Specify SOTHSP<V:20>

3. Did a specialist in neurology or neurosurgery examine the subject?

99= ☐ Unknown SEXAM<ZYNUNK>
0= ☐ No
1= ☐ Yes → In the opinion of the neurologist, were the findings consistent with a stroke? NEUOPN<ZYNUNK>

99= ☐ Unknown
0= ☐ No
1= ☐ Yes

→ Warning message: "Please provide all relevant information including the discharge summary, neurology consult note (if obtained), and imaging reports (if performed) to the DCRI."

Please complete the Adverse Event Page now if the event occurred during the infusion phase or within 30 days of the final infusion and if you have not already done so for this event.

TACT Death Adjudication Form

DTHADJ

Patient Study #: ___ ___ ___ - ___ ___ ___ **Patient Initials:** ___ ___ ___

Event #: DEVNUM<V:10> **Date of Site Reported Event:** DVENDT<DATE> ___ ___ - ___ ___ ___ - 200 ___

Date of Event: DTEVNT<TCEVNT><I:3>

___ 1=SITE REPORTED DATE OF EVENT AS ABOVE

___ 2= ADJUDICATED DATE OF EVENT DADJDT<DATE> ____/____/____ (month / day / year)

DTHCUS<ZYNUNK><I:3>

Is death due to a cardiovascular cause?

99= ___ Unknown

1= YES 0= NO

RDTHCS<TCDTHC>

1= **I. Atherosclerotic Coronary Heart Disease:**

CUSTYP<TCCUST><I:3>

- ___ 1= Fatal MI
- ___ 2= Sudden Death
- ___ 3= Heart Failure
- ___ 4= Presumed Cardiovascular
- ___ 5= Procedural: Specify: PSPEC<V:20>

2= **II. Atherosclerotic Vascular Disease, excluding coronary disease:**

- ___ 6= Cerebrovascular disease, including stroke and hemorrhage
- ___ 7= Aortic, mesenteric, renal vascular or PVD
- ___ 5= Procedural: Specify: OSPEC<V:20>
- ___ 98= Other: Specify: _____

3= **III. Other Cardiovascular (Non-Atherosclerotic)**

- ___ 8= Pulmonary Embolism
- ___ 9= Endocarditis
- ___ 10 Valvular Disease
- ___ 5= Procedural: Specify: _____
- ___ 98= Other: Specify: _____

4= **IV. Non-Cardiovascular:**

- ___ 11= Infectious
- ___ 12= Malignancy
- ___ 13= Pulmonary
- ___ 14= Gastrointestinal
- ___ 15= Accidental
- ___ 16= Suicide
- ___ 17= Diabetes
- ___ 18= (Non-CV) Unwitnessed (not seen > 24 hrs)
- ___ 98= Other:

Specify: _____

CEC Request for Additional Information:

_____

___ Additional Information Recd

Comments: _____

Physician Reviewer Signature: _____ DPSIG <ZYES> **Date:** ____/____/____ (day / month / year) DPDT <DATE>

CEC Administrative Signature: _____ DCSIG <ZYES> **Date:** ____/____/____ (day / month / year) DCDT <DATE>

TACT MI/Hospitalization for Angina Adjudication Form

MIADJ

MAEVNT<TCMEVT>

Patient Study #: ___ ___ ___ - ___ ___ ___ Patient Initials: ___ ___ ___ Event: MI ___ 1= Hosp Angina ___ 2=

MEVNDT<DATE>

Event #: MEVNUM<V:10> Date of Site Reported Event: ___ ___ - ___ ___ ___ - 200 ___

ISCSYM<ZYSNO>

0=__ NO 1=__ YES

1. Did the patient satisfy the ischemic symptom criteria for this event?

MI: (pain, dyspnea, pressure) at rest or accelerated ischemic symptoms, either of which lasts >= 10 minutes and is determined by the investigator to be secondary to ischemia.

Hosp Angina: patient was admitted for the management of angina AND the angina symptoms were confirmed to be attributed to myocardial ischemia.

ECGCHG<ZYSNO>

0=__ NO 1=__ YES

2. ECG changes consistent with ischemia/infarction? If yes, check below for all that apply to this event.

Hospitalization for Angina:

STSEGD<ZYES> ___ >= 0.5 mm transient ST segment depression in two contiguous limb or precordial leads

STELEV<ZYES> ___ >= 1 mm transient ST elevation in two contiguous leads (or ST depression in V1 or V2)

TTWAVE<ZYES> ___ >= 2 mm transient T wave change in two or more contiguous leads

RECECG<ZYES> ___ >= 0.5 mm change as compared to most recent ECG or during the previous stable phase

Myocardial Infarction:

NSQWAV<ZYES> ___ new significant Q waves (or R waves in V1-V2) in two contiguous leads in the absence of previous LVH or conduction abnormalities

ELVSTT<ZYES> ___ evolving ST-segment to T-wave changes in two or more contiguous leads

NLBBB<ZYES> ___ development of new left bundle branch block

STSEGE<ZYES> ___ ST segment elevation requiring thrombolytics or PCI

ECRMRK<ZYSNO>

0=__ NO 1=__ YES

3. Were there elevated cardiac markers that meet TACT criteria? If yes, check below for specific event criteria.

MARKER<TCMARK><I:3>

Hospitalization for Angina
1=__ A. Elevated markers not meeting criteria for TACT MI

Non-Procedural MI
2=
3=__ B. Troponin in necrosis range
__ C. Troponin not in necrosis range, CKMB >= 2 x ULN
4=__ D. No Troponin, CK and MB are both >= ULN
5=__ E. No Troponin, CK < ULN, MB >= 2 x ULN
6=__ F. No Troponin, CKMB < ULN, CK >= 2 x ULN
7=__ G. No Troponin or CK, CKMB >= 2 x ULN
8=__ H. Only CK drawn, serial changes in CK >= 2 x ULN

Peri-PCI MI
9=__ I. Marker >= 3 x ULN and >= 50% above last measurement, if last measure was >= ULN.

Peri-CABG MI
10=
__ J. CKMB >= 5 x ULN and >= 50% above last measurement, if last measure was >= ULN.

CRITER<TCCRIT><I:3>

MIEVDC<TCMIEV>

1=__ A. TACT MI criteria met: 1=__ Non-Procedural 2=__ Peri-PCI 3=__ Peri-CABG

2=__ B. Clinical MI not meeting TACT criteria

3=__ C. Unplanned Hospitalization for Angina:

1=__ 1. with objective evidence (ECGs and/or Marker criteria as above)

2=__ 2. prompting 1=__ a. unplanned 2=__ b. planned coronary revascularization

3=__ 3. prompting intensification of outpatient medical therapy

4=__ 4. not requiring a change in medical therapy

5=__ 5. attributed to non-cardiac etiologies: Specify: NONSP<V:20>

98=__ 6. Other: Specify: OTRSPE<V:20>

HOSPIT<TCHOSP>

4=__ D. Planned Hospitalization for Angina

PROMP<TCPROM>

1=__ 1. with objective evidence (ECGs and/or Marker criteria as above)

2=__ 2. prompting 1=__ a. unplanned 2=__ b. planned coronary revascularization

3=__ 3. prompting intensification of outpatient medical therapy

4=__ 4. not requiring a change in medical therapy

5=__ 5. attributed to non-cardiac etiologies: Specify: NONSP<V:20>

98=__ 6. Other: Specify: OTRSPE<V:20>

5=__ E. No Event

Date of Event: MIEVNT <TCEVNT><I:3>

1=__ SITE REPORTED DATE OF EVENT AS ABOVE

2=__ ADJUDICATED DATE OF EVENT: MADJDT <DATE>

____/____/____

month day year

CEC Request for Additional Information:

___ Additional Information Recd

Comments: _____

Physician Reviewer Signature: APSIG <ZYES> Date: APDT <DATE>

____/____/____

day month year

CEC Administrative Signature: ACSIG <ZYES> Date: ACDT <DATE>

____/____/____

day month year

TACT Stroke Adjudication Form

STRKADJ

Patient Study #: ___ ___ ___ - ___ ___ ___ Patient Initials: ___ ___ ___

Event #: SEVNUM<V:10> Date of Site Reported Event: ___ ___ - ___ ___ ___ - 200 ___ SEVNDT<DATE>

FOCNUR<ZYSNO>

0=__ NO 1=__ YES

1. Focal neurological deficit (resulting from a vascular cause involving the central nervous system) of sudden onset which is not due to a readily identifiable cause (i.e., brain tumor, trauma)?

SYMRVS<ZYSNO>

0=__ NO 1=__ YES

2. Were symptoms reversible within 24 hours?

0=__ NO 1=__ YES 99=__ UNKNOWN

3. Was an imaging study performed?

IMAGST<ZYNUNK>

If Yes, Is there documentation of a hemorrhage?

1=__ Yes DOCHEM<ZYSNO>

0=__ No

STCRTA<TCSTCR><I:3>

STEVDC<TCSTEV>

1=TACT Stroke Criteria Met:

1=__ Hemorrhagic Stroke

2=__ Non-Hemorrhagic Stroke

3=__ Unknown*

* when there is no clinical, radiological, or other substantial evidence to document either a hemorrhagic or non-hemorrhagic stroke but a Stroke is believed to have occurred.

Date of Event: SKEVNT<TCEVNT><I:3>

1=__ SITE REPORTED DATE OF EVENT AS ABOVE

2=__ ADJUDICATED DATE OF EVENT SADJDT<DATE> ___/___/___ month day year

2=__ TACT Stroke Criteria NOT Met

CEC Request for Additional Information:

_____

___ Additional Information Recd

Comments: _____

Physician Reviewer Signature: SPSIG <ZYES> _____ Date: SPDT <DATE> ___/___/___ day month year

CEC Administrative Signature: SCSIG <ZYES> _____ Date: SCDT <DATE> ___/___/___ day month year