



CORAL

PS: Screening
PT: Screening
Panel: Screening

Site # Site (f, 3)

Patient Screening & Enrollment Log

Date log faxed to DCC: faxdt() (mm/dd/yyyy)

List all patients who are evaluated for consideration of enrollment in CORAL. Fax to the DCC every Monday: 800-589-7692 or 617-632-1580

| Screening Number Example: (0 0 0 1) | Screening date (mm/dd/yyyy) | Gender | Is patient minority? <yesno> | I/E criteria met? | Did patient sign consent prior to diagnostic <yesno> | Patient enrolled? If Yes, answer Pt. Seq. # If No, give reason for exclusion | Pt. Number Record Seq. # only if the Pt. was enrolled | Reason for Exclusion Record the corresponding criteria # from the list below. If code = other, specify | | | |
|---|--------------------------------|--|---|---|---|--|--|---|--------------------------------|--------------------------------|--------------------------------|
| | | | | | | | | reas1 <exclcrit1> | reas2 <exclcrit1> | reas3 <exclcrit1> | reas4 <exclcrit1> |
| <u>ScreenNo (vc, 4)</u> | <u>scrdt()</u> | <input type="checkbox"/> (1) M <input type="checkbox"/> (2) F | <input type="checkbox"/> (1) Yes <input type="checkbox"/> (2) No | <input type="checkbox"/> (1) Yes <input type="checkbox"/> (2) No | <input type="checkbox"/> (1) Yes <input type="checkbox"/> (2) No | <input type="checkbox"/> (1) Yes <input type="checkbox"/> (2) No | <u>pt (vc, 3)</u> | <u>reas1 <exclcrit1></u> | <u>reas2 <exclcrit1></u> | <u>reas3 <exclcrit1></u> | <u>reas4 <exclcrit1></u> |
| | | <u>sex <hcri_gender></u> | <input type="checkbox"/> (1) Yes <input type="checkbox"/> (2) No | <u>ie <yesno></u> | <input type="checkbox"/> (1) Yes <input type="checkbox"/> (2) No | <u>enrolled <yesno></u> | | Specify Other: <u>specify (vc, 200)</u> | | | |
| | | <input type="checkbox"/> (1) M <input type="checkbox"/> (2) F | <input type="checkbox"/> (1) Yes <input type="checkbox"/> (2) No | <input type="checkbox"/> (1) Yes <input type="checkbox"/> (2) No | <input type="checkbox"/> (1) Yes <input type="checkbox"/> (2) No | <input type="checkbox"/> (1) Yes <input type="checkbox"/> (2) No | | Specify Other: _____ | | | |
| | | <input type="checkbox"/> (1) M <input type="checkbox"/> (2) F | <input type="checkbox"/> (1) Yes <input type="checkbox"/> (2) No | <input type="checkbox"/> (1) Yes <input type="checkbox"/> (2) No | <input type="checkbox"/> (1) Yes <input type="checkbox"/> (2) No | <input type="checkbox"/> (1) Yes <input type="checkbox"/> (2) No | | Specify Other: _____ | | | |
| | | <input type="checkbox"/> (1) M <input type="checkbox"/> (2) F | <input type="checkbox"/> (1) Yes <input type="checkbox"/> (2) No | <input type="checkbox"/> (1) Yes <input type="checkbox"/> (2) No | <input type="checkbox"/> (1) Yes <input type="checkbox"/> (2) No | <input type="checkbox"/> (1) Yes <input type="checkbox"/> (2) No | | Specify Other: _____ | | | |
| | | <input type="checkbox"/> (1) M <input type="checkbox"/> (2) F | <input type="checkbox"/> (1) Yes <input type="checkbox"/> (2) No | <input type="checkbox"/> (1) Yes <input type="checkbox"/> (2) No | <input type="checkbox"/> (1) Yes <input type="checkbox"/> (2) No | <input type="checkbox"/> (1) Yes <input type="checkbox"/> (2) No | | Specify Other: _____ | | | |

| | |
|---|---|
| 801. Patient refused | 810. Renal function too poor (Cr > 3.0 mg/dl) |
| 802. Physician preference | 811. Diabetic (retinopathy/proteinuria) |
| 803. Restenosis >50% of prior renal artery stent or bypass OR renal stent in past 9 mo. | 812. Kidney too small (< 7 cm) |
| 804. No history of hypertension req. 2/+ meds OR stage 3 or > CKD | 813. Accessory renal artery supplying < 1/2 of the ipsilateral renal parenchyma |
| 805. Renal artery stenosis < 60% | 814. Major surgery, revasc or MI within 30 days prior |
| 806. Fibromuscular dysplasia | 815. Hospitalization for CHF within 30 days |
| 807. Blood pressure too high (> 200 SBP or > 120 DBP) | 816. Comorbid condition |
| 808. Reference Vessel Diameter < 3.5 mm or > 8.0 mm | 817. Aneurysm of the abdominal aorta >5.0 cm |
| 809. Previous kidney transplant | 818. Other, specify (enter code 916 and specify in the space provided) |

pageno (fl 6, 2)

visno (vc, 20)

subid (vc, 7)

pagerepeat (vc, 5)

visrepeat (vc, 5)

PANEL: Context
PS: Context

CORAL

Site ID: **Site** Pt. No.: **Patient** Randomization #: **PtRando**

enrolldt()

pin (vc, 10)

randdt()

INCLUSION / EXCLUSION CRITERIA FORM

Pag PS: Enroll
PT: Enroll
Panel: Enroll

Inclusion Criteria: All items must be answered YES for subject to be eligible.

| | | | |
|---|----------------------------|----------------------------------|---------------------------------|
| 1. Documented history of systolic hypertension, ≥ 155 mm Hg on 2 or more anti-hypertensive medications | incl01<yesno> | <input type="checkbox"/> (1) YES | <input type="checkbox"/> (2) NO |
| or more renal artery stenosis | | <input type="checkbox"/> (1) YES | <input type="checkbox"/> (2) NO |
| : 60% and < 80% by angiography with a ≥ 20 mmHg systolic pressure gradient | incl02<yesno> | | |
| lumen diameter device, <u>or</u> | | | |
| : 80% and < 100% by angiography | | | |

PS: InclExcl
PT: InclExcl
Panel: InclExcl

Exclusion Criteria: All items must be answered NO for subject to be eligible.

| | | | |
|---|----------------------------|----------------------------------|---------------------------------|
| 1. Unable to provide informed consent | excl01<yesno> | <input type="checkbox"/> (1) YES | <input type="checkbox"/> (2) NO |
| 2. Unable or unwilling to comply with study protocol or procedure | excl02<yesno> | <input type="checkbox"/> (1) YES | <input type="checkbox"/> (2) NO |
| 3. Age < 18 | excl03<yesno> | <input type="checkbox"/> (1) YES | <input type="checkbox"/> (2) NO |
| 4. Documented diastolic hypertension ≥ 120 mmHg and or systolic hypertension ≥ 160 mmHg on day of randomization | excl04<yesno> | <input type="checkbox"/> (1) YES | <input type="checkbox"/> (2) NO |
| 5. Fibromuscular dysplasia or other non-atherosclerotic renal artery stenosis | excl05<yesno> | <input type="checkbox"/> (1) YES | <input type="checkbox"/> (2) NO |
| 6. Pregnancy or unknown pregnancy status in female of childbearing age | excl06<yesno> | <input type="checkbox"/> (1) YES | <input type="checkbox"/> (2) NO |
| 7. Participation in any drug or device trial during the study period, unless approved by Institutional Review Committee | excl07<yesno> | <input type="checkbox"/> (1) YES | <input type="checkbox"/> (2) NO |
| 8. Prior enrollment in the CORAL study | excl08<yesno> | <input type="checkbox"/> (1) YES | <input type="checkbox"/> (2) NO |
| 9. History of stroke within 6 months, if associated with a significant stenosis or occlusion of the carotid artery | excl09<yesno> | <input type="checkbox"/> (1) YES | <input type="checkbox"/> (2) NO |
| 10. Any stroke or TIA within 3 months of study entry or known carotid artery stenosis or occlusion | excl10<yesno> | <input type="checkbox"/> (1) YES | <input type="checkbox"/> (2) NO |
| 11. Any major surgery, major trauma, revascularization procedure, unstable angina, or myocardial infarction 30 days prior to study entry | excl11<yesno> | <input type="checkbox"/> (1) YES | <input type="checkbox"/> (2) NO |
| 12. Any planned major surgery or revascularization procedure, outside of the study protocol, or stenting dictated by this protocol, after randomization | excl12<yesno> | <input type="checkbox"/> (1) YES | <input type="checkbox"/> (2) NO |
| 13. Hospitalization for heart failure within 3 months | excl13<yesno> | <input type="checkbox"/> (1) YES | <input type="checkbox"/> (2) NO |
| 14. Known ejection fraction < 30% | excl14<yesno> | <input type="checkbox"/> (1) YES | <input type="checkbox"/> (2) NO |
| 15. Comorbid condition causing life expectancy ≤ 3 years | excl15<yesno> | <input type="checkbox"/> (1) YES | <input type="checkbox"/> (2) NO |
| 16. Allergic reaction to intravascular contrast, not amenable to premedication | excl16<yesno> | <input type="checkbox"/> (1) YES | <input type="checkbox"/> (2) NO |
| 17. Allergy to stainless steel | excl17<yesno> | <input type="checkbox"/> (1) YES | <input type="checkbox"/> (2) NO |
| 18. Allergy to all of the following: aspirin, clopidogrel, ticlopidine | excl18<yesno> | <input type="checkbox"/> (1) YES | <input type="checkbox"/> (2) NO |
| 19. Known untreated aneurysm of the abdominal aorta > 4.0 cm | excl19<yesno> | <input type="checkbox"/> (1) YES | <input type="checkbox"/> (2) NO |
| 20. Previous kidney transplant | excl20<yesno> | <input type="checkbox"/> (1) YES | <input type="checkbox"/> (2) NO |
| 21. Previous renal artery bypass surgery or angioplasty or stent intervention | excl21<yesno> | <input type="checkbox"/> (1) YES | <input type="checkbox"/> (2) NO |
| 22. Diabetes with either: a. Known diabetic proliferative retinopathy and $\geq 1+$ protein on urine dipstick, or b. $\geq 1+$ protein on urine dipstick and urine protein/cr ratio > 0.5 | excl22<yesno> | <input type="checkbox"/> (1) YES | <input type="checkbox"/> (2) NO |
| 23. Kidney size less than 8 cm supplied by target vessel, measured angiographically | excl23<yesno> | <input type="checkbox"/> (1) YES | <input type="checkbox"/> (2) NO |
| 24. Hydronephrosis, nephritis or other known causes of renal insufficiency not due to large artery stenosis | excl24<yesno> | <input type="checkbox"/> (1) YES | <input type="checkbox"/> (2) NO |
| 25. Only a stenosis of an accessory renal artery supplying < 1/2 of total renal parenchyma | excl25<yesno> | <input type="checkbox"/> (1) YES | <input type="checkbox"/> (2) NO |
| 26. Local lab serum Cr > 3.0 mg/dl on the day of randomization | excl26<yesno> | <input type="checkbox"/> (1) YES | <input type="checkbox"/> (2) NO |
| 27. Vascular disease of the upper and lower extremity precluding access to the femoral artery | excl27<yesno> | <input type="checkbox"/> (1) YES | <input type="checkbox"/> (2) NO |
| 28. Presence of a renal artery stenosis not amenable for treatment with study stent | excl28<yesno> | <input type="checkbox"/> (1) YES | <input type="checkbox"/> (2) NO |
| 29. Abrupt vessel closure or dissection after diagnostic angiography [NOTE: Subjects with abrupt vessel closure or dissection as a result of diagnostic angiography will not be randomized but will receive stent revascularization, receive optimal medical therapy and will be followed for the remainder of the study] | excl29<yesno> | <input type="checkbox"/> (1) YES | <input type="checkbox"/> (2) NO |
| 30. Reference vessel size < 3.5 mm or > 8.0 mm. | excl30<yesno> | <input type="checkbox"/> (1) YES | <input type="checkbox"/> (2) NO |

HCRI USE ONLY
Received: ___/___/___
By: _____

pageno (fl 6, 2)

visno (vc, 20)

subid (vc, 7)

pagerepeat (vc, 5)

visrepeat (vc, 5)

PANEL: Context
PS: Context

CORAL

Site ID: Pt. No.: Randomization #:

Randomization Form

PS: IE
PT: IE
Panel: InclExcl

Randomization

1. Did subject meet all inclusion/exclusion criteria?
(All criteria must be met for subject to be eligible) (1) YES (2) NO → **COMPLETE PROTOCOL DEVIATION FORM**

1.1. Criterion not met:
(enter as letter-number: e.g. I-2, E-5)

2. How was subject randomized?

(1) Renal angiography (≥ 60% stenosis)
 (2) Duplex (systolic velocity of >300 cm/s)
 (3) MRA → **COMPLETE ITEM 2.1**

PS: RandPath
PT: IE
Panel: RandPath

2.1. MRA criteria met:

(1) Stenosis >90%

(2) Stenosis >75% with spin dephasing on 3D phase contrast MRA

(3) Stenosis > 75% and **two** of the following:

- Ischemic kidney > 1 cm smaller than contralateral kidney
- Ischemic kidney enhances less on arterial phase
- Ischemic kidney has delayed Gd excretion
- Ischemic kidney hyper-concentrates the urine
- 2-D phase contrast flow waveform shows delayed systolic peak

Physical Exam

3. Was the baseline H&P performed? (1) YES (2) NO

↓
COMPLETE PROTOCOL DEVIATION FORM

4. Height: _____ (1) Inches (2) Centimeters

5. Weight: _____ (1) Pounds (2) Kilograms

PS: PE
PT: IE
Panel: PhysExam

HCRI USE ONLY

Received: ____/____/____
By: _____

pageno (fl 6, 2)

visno (vc, 20)

subid (vc, 7)

pagerepeat (vc, 5)

visrepeat (vc, 5)

PANEL: Context
PS: Context

CORAL

Site ID: Site Pt. No.: Patient Randomization #: PtRando

Randomization Form

PS: IE
PT: IEV4
Panel: InclExcl

Randomization

allIEmet <yesno>

1. Did subject meet all inclusion/exclusion criteria?
(All criteria must be met for subject to be eligible)

(1) YES (2) NO → **COMPLETE PROTOCOL DEVIATION FORM**

1.1. Criterion not met:
(enter as letter-number: e.g. I-2, E-5)

IE1 (vc 5) IE2 (vc 5) IE3 (vc 5) IE4 (vc 5) IE5 (vc 5)

2. How was subject randomized? random <howrando1>

- (1) Renal angiography (≥ 60% stenosis)
- (2) Duplex (systolic velocity of >300 cm/s)
- (3) MRA → **COMPLETE ITEM 2.1**
- (4) CTA → **COMPLETE ITEM 2.2**

PS: RandPathV4
PT: IEV4
Panel: RandPath

2.1. MRA criteria met:

- (1) Stenosis > 80%
- (2) Stenosis >70% with spin dephasing on 3D phase contrast MRA
- (3) Stenosis > 70% and **two** of the following:
 - Ischemic kidney > 1 cm smaller than contralateral kidney smkid <checked1>
 - Ischemic kidney enhances less on arterial phase gdexcret <checked1>
 - Ischemic kidney has delayed Gd excretion hypcon <checked1>
 - Ischemic kidney hyper-concentrates the urine waveform <checked1>
 - 2-D phase contrast flow waveform shows delay postdilat <checked1>
 - Post-stenotic dilatation

2.2. CTA criteria met:

- (1) Stenosis is > 80% by visual assessment on high quality CTA
- (2) Stenosis is > 70% by visual assessment and **two** of the following:
 - Length of the ischemic kidney > 1 cm smaller than contralateral kidney lengthkid <checked1>
 - Reduced cortical thickness of ischemic kidney redthick <checked1>
 - Less cortical enhancement of ischemic kidney on arterial phase lesscort <checked1>
 - Post-stenotic dilatation poststendil <checked1>

Physical Exam

3. Was the Baseline H&P performed? (1) YES (2) NO baseHP <yesno>

COMPLETE PROTOCOL DEVIATION FORM

4. Height: height2 (fl 6, 2) (1) Inches (2) Centimeters htunit <height1>

5. Weight: weight2 (fl 6, 2) (1) Pounds (2) Kilograms wtunit <crf_wt>

PS: PE
PT: IEV4
Panel: PhysExam

Received: _____/_____/_____
By: _____

CORAL

PANEL: Context
PS: Context

Site ID: _____ Pt. No.: _____ Randomization #: _____

Baseline Form

Page 1 of 3

PS: Baseln
PT: Baseln
Panel: Baseln

Demographics

1. Age at time of enrollment: age (f 5)
2. Sex: sex <hcri_gender> (1) Male (2) Female

Baseline Evaluation Tests and Procedures

| TEST/EVALUATION | Performed? | IF YES | IF NO |
|-------------------------------|--|---|---|
| 3. Baseline Blood Pressure | <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO blinbp <yesno> | 3.1. Date of Assessment: bpdt() bpmm/bpdd/bpyy bpdt() <small>(mm/dd/yyyy)</small> 3.2. Time Sys/Dias Heart Rate bp1hr:bp1mn sys1 (f 5) dias1(f 5) hrtrt1(f 5) bp2hr:bp2mn sys2 (f 5) dias2 (f 5) hrtrt2(f 5) bp3hr:bp2mn sys3 (f 5) dias3 (f 5) hrtrt3(f 5) | DM: BP in range: dmbprng <yesno> COMPLETE PROTOCOL DEVIATION FORM |
| 4. Biochem Core Lab Bloodwork | <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO labblood<yesno> | 4.1. Date and time of collection: blooddt() bloodmm/blooddd/bloodyy bloodhr:bloodmn <small>(mm/dd/yyyy) (24 hour)</small> 4.2. Did subject fast prior to lipid collection? <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO fast<yesno> 4.3. Was DNA sample collected? <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO dna<yesno> | COMPLETE PROTOCOL DEVIATION FORM labelnum (f, 8) PLACE BIOCHEM LABEL HERE |
| 5. Biochem Core Lab Urine | <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO laburine<yesno> | urinedt() Date and time of collection: urinemm/urinedd/urineyy urinehr:urinemn <small>(mm/dd/yyyy) (24 hour)</small> | COMPLETE PROTOCOL DEVIATION FORM |
| 6. Local Lab Creatinine | <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO creat <yesno> | 6.1. Date and time of collection: creatdt() creatmm/creatdd/creaty creathr:creatmn <small>(mm/dd/yyyy) (24 hour)</small> 6.2. Value: creatval (fl 6, 2) Unit: creatunt (vc 5) | COMPLETE PROTOCOL DEVIATION FORM |
| 7. Local Lab Urine Dipstick | <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO urinedip <yesno> | 7.1. Date and time of collection: dipdt() dipmm/dipdd/dipy diphr:dipmn <small>(mm/dd/yyyy) (24 hour)</small> 7.2. Protein (mg/dl) <input type="checkbox"/> (1) Neg <input type="checkbox"/> (2) Trace <input type="checkbox"/> (3) 30 <input type="checkbox"/> (4) 100 <input type="checkbox"/> (5) 300 <input type="checkbox"/> (6) protein <urineprotein> | COMPLETE PROTOCOL DEVIATION FORM |

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|---------------------------------|
| HCRI USE ONLY |
| Received: _____ / _____ / _____ |
| By: _____ |

CORAL

Site ID: _____ Pt. No.: _____ Randomization #: _____

Baseline Form

PS: Base
PT: Base
Panel: Baseln

Demographics

1. Age at time of enrollment: age (f 5)
2. Sex: sex <hcri_gender> (1) Male (2) Female

Baseline Evaluation Tests and Procedures

| TEST/EVALUATION | Performed | IF YES | IF NO |
|---------------------------------------|--|---|--|
| 3. Baseline blood pressure assessment | <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO <u>blinbp <yesno></u> | 3.1. Date of Assessment: <u>bpmm/bpdd/bpyy</u> / <u>bpdt()</u> (mm/dd/yyyy) 3.2. Time Sys/Dias <u>bp1hr:bp1mn</u> <u>sys1(f 5)</u> <u>dias1(f 5)</u> <u>bp2hr:bp2mn</u> <u>sys2(f 5)</u> <u>dias2(f 5)</u> <u>bp3hr:bp2mn</u> <u>sys3(f 5)</u> <u>dias3(f 5)</u> | DM: BP in range: <u>dmbprng <yesno></u> COMPLETE PROTOCOL DEVIATION FORM |
| 4. Biochem Core Lab bloodwork | <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO <u>labblood <yesno></u> | 4.1. Did subject fast prior to lipid collection? <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO <u>fast <yesno></u> 4.2. Was DNA sample collected? <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO <u>dna <yesno></u> | COMPLETE PROTOCOL DEVIATION FORM P <u>labelnum (f, 8)</u> EM LABEL HERE (on all 3 parts) |
| 5. Biochem Core Lab urine | <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO <u>laburine <yesno></u> | | COMPLETE PROTOCOL DEVIATION FORM |
| 6. Local Lab creatinine | <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO <u>creat <yesno></u> | <u>creatval (fl 6, 2)</u> 6.1. Value: _____ Unit: <u>creatunt (vc 10)</u> | COMPLETE PROTOCOL DEVIATION FORM |
| 7. Local lab urine dipstick | <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO <u>urinedip <yesno></u> | 7.1. Protein (mg/dl) <u>protein <urineprotein></u> <input type="checkbox"/> (1) Neg <input type="checkbox"/> (2) Trace <input type="checkbox"/> (3) 30 <input type="checkbox"/> (4) 100 <input type="checkbox"/> (5) 300 <input type="checkbox"/> (6) ≥2000 | COMPLETE PROTOCOL DEVIATION FORM |
| 8. Estimated GFR | <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO <u>gfr <yesno></u> | 8.1. Value: _____ mL/min/1.73 m2 <u>gfrsign (vc 3)</u> <u>gfrval (fl 6, 2)</u> | |

HCRI USE ONLY

Received: _____ / _____ / _____
By: _____

CORAL

PANEL: Context
PS: Context

Site ID: _____ Pt. No.: _____ Randomization #: _____

Baseline Form

P
PS: Baseln2
PT: Baseln2
Panel: Baseln2

| TEST/EVALUATION | Performed? | IF YES | IF NO |
|----------------------|--|---|---|
| 8. 12-Lead ECG | <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO ecg <yesno> | 8.1. Date: ecgmm/ecgdd/ecgyy (mm/dd/yyyy) ecgdt() 8.2. Time: ecghr:ecgmn (4 hour) | COMPLETE PROTOCOL DEVIATION FORM |
| 9. Renal Angiography | <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO angio <yesno> | COMPLETE BASELINE DIAGNOSTIC ANGIOGRAPHY FORM | COMPLETE PROTOCOL DEVIATION FORM |

10. Was the Baseline Quality of Life Survey completed? (1) YES (2) NO qol <yesno>

| | |
|--|-------------------------------|
| <p>10.1. Did subject refuse to answer questions? <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO refuse <yesno></p> <p>10.2. Was there a language barrier? lang <yesno> <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO</p> <p>10.3. Other: <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO other <yesno></p> <p>10.3.1. Specify: othspec (vc, 100)</p> | <p>↓ CRL 200-210 ↓</p> |
|--|-------------------------------|

11. Did the subject sign the Patient Address Form? (1) YES (2) NO addr <yesno>

↓
FAX TO EQOL CORE LAB

History of Cardiovascular Disease and Associated Risk Factors

| History / Current Condition | IF YES |
|--|--|
| 12. History of premature atherosclerotic disease in family: (CAD, Cerebrovascular disease, PVD in male relatives < 55 and/or female relatives < 65 years old.) <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO <input type="checkbox"/> UNK atherohx <yesnounc7> | |
| 13. History of prior MI: <input type="checkbox"/> (1) YES mihx <yesnounc7> | Date of most recent midtd() mimm/midd/miyy (mm/dd/yyyy) |
| 14. History of coronary artery bypass surgery: <input type="checkbox"/> (1) YES bypassx <yesnounc7> | Date of most recent bypdt() bypmm/bypdd/bypyy (mm/dd/yyyy) |
| 15. History of percutaneous coronary intervention: <input type="checkbox"/> (1) YES perchx <yesnounc7> | Date of most recent percdt() percmm/percdd/percyy (mm/dd/yyyy) |
| 16. History of peripheral vascular disease: <input type="checkbox"/> (1) YES vaschx <yesnounc7> | |
| 17. History of peripheral claudication: <input type="checkbox"/> (1) YES claudhx <yesnounc7> | |
| 18. History of peripheral artery bypass: <input type="checkbox"/> (1) YES artbyphx <yesnounc7> | Date of most recent artdt() artmm/artdd/artyy (mm/dd/yyyy) |

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| HCRI USE ONLY |
| Received: _____ / _____ / _____ |
| By: _____ |

CORAL

Site ID: _____ Pt. No.: _____ Randomization #: _____

Baseline Form

PS: Base2
PT: Base2
Panel: Baseln2

| TEST/EVALUATION | Performed? | IF YES | IF NO |
|--|---|---|---|
| 9. 12-lead ECG ecg <yesno> | <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO | LABEL TRACING AND SUBMIT WITH CRFs | COMPLETE PROTOCOL DEVIATION FORM |

10. Was the Baseline Quality of Life Survey completed? (1) YES (2) NO qol <yesno>

↓
COMPLETE AND SUBMIT CRL 200-210

11. Did the subject sign the Patient Address Form? (1) YES (2) NO addr <yesno>

↓
FAX TO EQOL CORE LAB

History of Cardiovascular Disease and Associated Risk Factors

12. History of premature atherosclerotic disease in family:
(CAD, Cerebrovascular disease, PVD in male relatives < 55 and/or female relatives < 65 years old.) (1) YES (2) NO UNK atherohx <yesnounc7>

13. History of prior MI: (1) YES (2) NO UNK mihx <yesnounc7>

14. History of peripheral vascular disease: (1) YES (2) NO UNK vaschx <yesnounc7>

| |
|---------------------------------|
| HCRI USE ONLY |
| Received: _____ / _____ / _____ |
| By: _____ |

CORAL

PANEL: Context
PS: Context

Site ID: _____ Pt. No.: _____ Randomization #: _____

Baseline Form

PS: Baseln3
PT: Baseln3
Panel: Baseln3

| History / Current Condition | IF YES |
|--|--|
| 19. History of peripheral artery intervention: <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO <input type="checkbox"/> UNK periarthx <yesnunk7> | Date of most recent: peridd() perimm/peridd/periyy (mm/dd/yyyy) |
| 20. History of stroke or TIA: <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO <input type="checkbox"/> UNK tiahx <yesnunk7> | Date of most recent: tiadt() tiamm/tiadd/tiayy (mm/dd/yyyy) |
| 21. Current carotid bruit: <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO <input type="checkbox"/> UNK bruit <yesnunk7> | |
| 22. History of carotid stenosis: <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO <input type="checkbox"/> UNK carsten <yesnunk7> | |
| 23. History of carotid stent implantation: <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO <input type="checkbox"/> UNK implant <yesnunk7> | Date of most recent: impdt() impmm/impdd/impyy (mm/dd/yyyy) |
| 24. History of carotid endarterectomy: <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO <input type="checkbox"/> UNK endart <yesnunk7> | Date of most recent: surgdt() surgmm/surgdd/surgyy (mm/dd/yyyy) |
| 25. History of diabetes mellitus: <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO <input type="checkbox"/> UNK diabhx <yesnunk7> | 25.1. Diabetes controlled/treated: (CHECK ONLY ONE, MAXIMAL) <input type="checkbox"/> (1) Diet controlled <input type="checkbox"/> (2) Treated by oral medication <input type="checkbox"/> (3) diabetes <diabetes1> injection <input type="checkbox"/> (4) Treated by both oral medications and insulin |
| 26. History of hyperlipidemia: (total Cholesterol > 200 or requiring medication) <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO <input type="checkbox"/> UNK nylipid <yesnunk7> | |
| 27. Cigarette smoking in the past year: <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO <input type="checkbox"/> UNK smoke <yesnunk7> | |
| 28. History of CHF: (hospitalized within last 3 months) <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO <input type="checkbox"/> UNK chfmx <yesnunk7> | Date of most recent hospitalization: hosppmm/hosppdd/hosppydd/yy hosppdt |
| 29. Current symptoms of CHF: <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO <input type="checkbox"/> UNK chfsx <yesnunk7> | 29.1. NHYA: <input type="checkbox"/> I <input type="checkbox"/> nyha <nyha7> <input type="checkbox"/> III <input type="checkbox"/> IV |
| 30. History of aortic aneurysm > 4.0 cm: <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO <input type="checkbox"/> UNK aoraneur <yesnunk7> | |
| 31. History of angina pectoris: <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO <input type="checkbox"/> UNK anghx <yesnunk7> | |
| 32. Current Canadian Cardiovascular Classification: <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO <input type="checkbox"/> UNK CCCC <yesnunk7> | 32.1. <input type="checkbox"/> No Angina <input type="checkbox"/> I <input type="checkbox"/> II <input type="checkbox"/> III <input type="checkbox"/> IV classif <ccsc11> |
| 33. History of any cancer: <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO <input type="checkbox"/> UNK canchx <yesnunk7> | |

| |
|---------------------------------|
| HCRI USE ONLY |
| Received: _____ / _____ / _____ |
| By: _____ |

CORAL

Site ID: _____ Pt. No.: _____ Randomization #: _____

Baseline Form

PS: Base3
PT: Base3
Panel: Baseln3

15. History of stroke or TIA: (1) YES (2) NO UNK tiahx <yesnounc7>

16. History of diabetes mellitus: (1) YES (2) NO UNK diabhx <yesnounc7>

16.1 Is the subject currently taking insulin? (1) YES (2) NO curinsul <yesno>

17. History of hyperlipidemia: (total Cholesterol > 200 or requiring medication) (1) YES (2) NO UNK hyplipid <yesnounc7>

18. Cigarette smoking in the past year: (1) YES (2) NO UNK smoke <yesnounc7>

19. History of CHF: (1) YES (2) NO UNK chfhx <yesnounc7>

20. Current symptoms of CHF, NYHA Classification: chfsx1 <nyha9> I II III IV (5) No symptoms

21. Current Canadian Cardiovascular Classification: (0) No Angina I II III IV UNK CardClas <ccsc14>

22. CKD (defined as eGFR <60 ml/min/1.73m2 or urinary albumin/creatinine ratio >30 mg/g on baseline lab work): (1) YES (2) NO UNK CKD <yesnounc7>

HCRI USE ONLY

Received: _____ / _____ / _____
By: _____

CORAL

PANEL: Context
PS: Context

Site ID: _____ Pt. No.: _____ Randomization #: _____

Baseline Medical History Form

PS: MedHx
PT: MedHx
Panel: MedHx

1. Were there any conditions / diagnoses / surgical procedures that were not specified on Baseline Form? **procs <yesno>** (2) NO → **FORM COMPLETE. SKIP TO NEXT PAGE**
2. Date information collected: ()

| | Site/System (Enter code from below) | Description | Onset Date (MM, YYYY) | Currently Symptomatic |
|----------------|--|------------------|--------------------------|--|
| lineno (vc, 5) | sitesyst <bodysystem1> | specify (vc, 50) | mo (vc, 5) / yr (vc, 5) | <input type="checkbox"/> sympt <yesno> NO |
| | | | ___ / ____ | <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO |
| 2.3. | | | ___ / ____ | <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO |
| 2.4. | | | ___ / ____ | <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO |
| 2.5. | | | ___ / ____ | <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO |
| 2.6. | | | ___ / ____ | <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO |
| 2.7. | | | ___ / ____ | <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO |
| 2.8. | | | ___ / ____ | <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO |
| 2.9. | | | ___ / ____ | <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO |
| 2.10. | | | ___ / ____ | <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO |

PS: MedHx1
PT: MedHx
Panel: MedHx

| KEY | |
|----------------------------|-------------------------|
| 1. Eye, Ear, Nose, Throat | 7. Gastrointestinal |
| 2. Pulmonary | 8. Metabolic, Endocrine |
| 3. Cardiovascular | 9. Genitourinary |
| 4. Blood | 10. Dermatologic |
| 5. Neurologic, Psychiatric | 11. Whole Body |
| 6. Musculoskeletal | 12. Other, specify |

| HCRI USE ONLY |
|---------------------------|
| Received: ___ / ___ / ___ |
| By: _____ |

CORAL

Site ID: _____ Pt. No.: _____ Randomization #: _____

Baseline Lesion Diagnostic Form

PS: Blang1
PT: Blang1
Panel: Blangio1

1. Did patient under go baseline renal angiography? (1) YES (2) NO → **SKIP TO NEXT PAGE**
↓

1.1. This angiogram was performed at: (1) Investigative site (2) Outside hospital
 1.1.1. Name of physician performing angiogram: (1) Investigative site (2) Outside hospital
 1.1.1.1. Name of physician performing angiogram: (1) Investigative site (2) Outside hospital
 1.2. Date of procedure: _____ (mm/dd/yyyy) (1) Investigative site (2) Outside hospital
 1.3. Time subject arrived in procedure room: _____ (24 hour format)
 1.4. Was a renal intervention performed during this procedure? (1) YES (2) NO **interven <yesno>**
 (SKIP TO CRL 006) ↓
 1.4.1. Time angiography procedure began: _____ (24 hour format)
 (first xylocaine injection)
 1.4.2. Time of insertion of first renal angiography catheter: _____ (24 hour format)
 1.4.3. Time procedure ended: _____ (24 hour format)
 (last catheter removed)
 1.4.4. Total amount of contrast used: (1) Investigative site (2) Outside hospital _____ cc

1.4.5. Were any non-renal angiographies or revascularizations performed during this procedure? (1) YES (2) NO **nonrenal <yesno>**

- 1.4.5.1. **corangio <checked1>** Coronary angiography
 carotang <checked1> Carotid angiography
 othangio <checked1> Other peripheral angiography, specify: **othang (vc, 50)**
 corerevasc <checked1> Coronary revascularization
 carotrev <checked1> Carotid revascularization
 othrevas <checked1> Other revascularization, specify: **othrev (vc, 50)**

PS: Blang2
PT: Blang1
Panel: Blangio2

HCRI USE ONLY
 Received: _____ / _____ / _____
 By: _____

CORAL

Site ID: _____ Pt. No.: _____ Randomization #: _____

Baseline Lesion Diagnostic Form

2. Was right kidney present? rkidney <yesno> (1) YES (2) NO

PS: Blang3
PT: Blang2
Panel: Blangio3

3. Was left kidney present? lkidney <yesno> (1) YES (2) NO

4. Report all lesions $\geq 60\%$ stenosed using the Renal Artery Site Map provided:

PS: Blang5
PT: Blang2
Panel: Kidney

| colnum (f, 5) | Renal Artery Site* | Percent Stenosis | Pressure Gradient |
|---|--|---|--|
| 1 | rensite2 (vc, 5) | stensign (vc, 3) % stenosis (fl 6, 2) | press (fl 6, 2) Hg <input type="checkbox"/> ND pressND<checked1> |
| 2 | | _____ % | _____ mmHg <input type="checkbox"/> ND |
| 3 | | _____ % | _____ mmHg <input type="checkbox"/> ND |
| 4 | | _____ % | _____ mmHg <input type="checkbox"/> ND |

*Please note: ALL Renal Artery Site codes contain a LETTER **and** a NUMBER.

| |
|---------------------------------|
| HCRI USE ONLY |
| Received: _____ / _____ / _____ |
| By: _____ |

CORAL

PANEL: Context
PS: Context

Site ID: _____ Pt. No.: _____ Randomization #: _____

Baseline Physical Exam Form

Date information collected:

collmm/colldd/collyy (mm/dd/yyyy) colldt()

PS: PhysExam
PT: PhysExam
Panel: PhysExam

1. Height: height (f, 5) height2 (fl 6, 2) (1) Inches (2) Centimeters htunit <height1>
2. Weight: weight (f, 5) weight2 (fl 6, 2) (1) Pounds (2) Kilograms wtunit <crf_wt>

| Site/System | If Abnormal, provide details |
|---|--|
| 3. Appearance <input type="checkbox"/> (1) Normal <input type="checkbox"/> (2) Abnormal appear <result3> | specify3 (vc, 100) |
| 4. Skin <input type="checkbox"/> (1) Normal skin <result3> <input type="checkbox"/> ND | specify4 (vc, 100) |
| 5. Ears/ Eyes/ Nose/ Throat <input type="checkbox"/> (1) Normal <input type="checkbox"/> EENT <result3> <input type="checkbox"/> ND | specify5 (vc, 100) |
| 6. Head/ Neck <input type="checkbox"/> (1) Normal <input type="checkbox"/> head <result3> <input type="checkbox"/> ND | specify6 (vc, 100) |
| 7. Lymphatic <input type="checkbox"/> (1) Normal <input type="checkbox"/> lymph <result3> <input type="checkbox"/> ND | specify7 (vc, 100) |
| 8. Cardiovascular <input type="checkbox"/> (1) Normal <input type="checkbox"/> cardio <result3> <input type="checkbox"/> ND | specify8 (vc, 100) |
| 9. Lungs/ Chest <input type="checkbox"/> (1) Normal lungs <result3> <input type="checkbox"/> ND | specify9 (vc, 100) |
| 10. Gastrointestinal <input type="checkbox"/> (1) Normal gi <result3> <input type="checkbox"/> ND | specify10 (vc, 100) |
| 11. Genitourinary <input type="checkbox"/> (1) Normal gu <result3> <input type="checkbox"/> ND | specify11 (vc, 100) |
| 12. Extremities <input type="checkbox"/> (1) Normal extrem <result3> <input type="checkbox"/> ND | specify12 (vc, 100) |
| 13. Musculoskeletal <input type="checkbox"/> (1) Normal <input type="checkbox"/> musculo <result3> <input type="checkbox"/> ND | specify13 (vc, 100) |
| 14. Neurologic <input type="checkbox"/> (1) Normal <input type="checkbox"/> neuro <result3> <input type="checkbox"/> ND | specify14 (vc, 100) |
| 15. Other Specify: othspec (vc, 100) <input type="checkbox"/> (1) Normal <input type="checkbox"/> (2) other <result3> | specify15 (vc, 100) |

| |
|---------------------------------|
| HCRI USE ONLY |
| Received: _____ / _____ / _____ |
| By: _____ |

CORAL

PANEL: Context
PS: Context

Site ID: _____ Pt. No.: _____ Randomization #: _____

Baseline Diagnostic Angiography Form

PS: Blangio1
PT: Blangio1
Panel: Blangio1

1. This angiogram was performed at: **angsite <angsite>** Investigative site (2) Outside hospital
- 1.1. Name of physician performing angiogram:
FIRST Last
2. Date of procedure: (mm/dd/yyyy)
3. Time subject arrived in procedure room: (24 hour format)
4. Vascular access (sheath): (1) Femoral (2) Brachial (3) Radial
5. Was a renal intervention performed during this procedure? (1) YES (2) NO

↓
SKIP TO ITEM 14 AND COMPLETE INTERVENTION PROCEDURE FORM AND LESION TREATMENT FORM

6. Time procedure began: (first xylocaine injection) (24 hour format)
7. Time of insertion of first renal angiography catheter: (24 hour format)
8. Time procedure ended: (last catheter removed) (24 hour format)
9. Type and dose of contrast: **ionic <checked1>** Ionic cc
(Check all that apply) **nonionic <checked1>** Non-Ionic cc
 lowosmo <checked1> Low Osmolar cc
 isosmol <checked1> Isosmolar cc

10. Did the subject receive Fenoldopam? (1) YES (2) NO
11. Did the subject receive N-acetylcysteine? (1) YES (2) NO
12. Did the subject receive sodium bicarbonate? (1) YES (2) NO

12.1 Was subject considered high risk? (subjects with diabetes mellitus and/or serum creatinine \geq 1.4 mg/dL) (1) YES (2) NO

12.1.1. Explain why no sodium bicarbonate was given:

HCRI USE ONLY
Received: _____ / _____ / _____
By: _____

CORAL

PANEL: Context
PS: Context

Site ID: _____ Pt. No.: _____ Randomization #: _____

Baseline Diagnostic Angiography Form

Page 2 of 2

13. Were any non-renal angiographies or revascularizations performed during this procedure? (1) YES (2) NO nonrenal <yesno>

PS: Blangio2
PT: Blangio2
Panel: Blangio2

13.1. Check all that apply:

corangio <checked1> coronary angiography

carotang <checked1> carotid angiography

othangio <checked1> other peripheral angiography, specify: othang (vc, 50)

corevasc <checked1> carotid revascularization

carotrev <checked1> carotid revascularization

othrev <checked1> other revascularization, specify: othrev (vc, 50)

othrevas <checked1> other revascularization, specify: _____

14. Right Kidney is present: (1) YES (2) NO rkidney <yesno>



| colnum (f, 5) | Renal Artery Site | rensite2 (vc, 5) | kidna <checked1> | rensite (f, 5) | |
|---------------|---------------------------|--|---|------------------------------|------------------------------|
| 14.1 | Stenosis | stensign (vc, 3) stenosis (fl 6, 2) % | _____ % | _____ % | _____ % |
| 14.2 | Pressure Gradient | pressign (vc, 3) press (fl 6, 2) mmHg | _____ mmHg | _____ mmHg | _____ mmHg |
| | | pressND<checked1> <input type="checkbox"/> ND* | <input type="checkbox"/> ND* | <input type="checkbox"/> ND* | <input type="checkbox"/> ND* |
| 14.3 | Reference Vessel Diameter | refdiam (fl 6, 2) (mm) | refnd <checked1> (mm) | _____ (mm) | _____ (mm) |
| 14.4 | Lesion Length | lesleng (fl 6, 2) (mm) | lennd <checked1> (mm) | _____ (mm) | _____ (mm) |

PS: RKidney
PT: Blangio2
Panel: RKidney

***COMPLETE PROTOCOL DEVIATION FORM IF < 80% STENOSIS AND PRESSURE GRADIENT NOT DONE**

15. Left Kidney is present: lkidney <yesno> (1) YES (2) NO

PS: Blangio3
PT: Blangio2
Panel: Blangio2



| colnum (f, 5) | Renal Artery Site | rensite2 (vc, 5) | kidna <checked1> | rensite (f, 5) | |
|---------------|---------------------------|--|---|------------------------------|------------------------------|
| 15.1 | Stenosis | stensign (vc, 3) stenosis (fl 6, 2) % | _____ % | _____ % | _____ % |
| 15.2 | Pressure Gradient | pressign (vc, 3) press (fl 6, 2) mmHg | _____ mmHg | _____ mmHg | _____ mmHg |
| | | pressND<checked1> <input type="checkbox"/> ND* | <input type="checkbox"/> ND* | <input type="checkbox"/> ND* | <input type="checkbox"/> ND* |
| 15.3 | Reference Vessel Diameter | refdiam (fl 6, 2) (mm) | refnd <checked1> (mm) | _____ (mm) | _____ (mm) |
| 15.4 | Lesion Length | lesleng (fl 6, 2) (mm) | lennd <checked1> (mm) | _____ (mm) | _____ (mm) |

PS: LKidney
PT: Blangio2
Panel: LKidney

***COMPLETE PROTOCOL DEVIATION FORM IF < 80% STENOSIS AND PRESSURE GRADIENT NOT DONE**

HCRI USE ONLY

Received: _____ / _____ / _____

By: _____

CORAL

PANEL: Context
PS: Context

Site ID: _____ Pt. No.: _____ Randomization #: _____

Intervention Procedure Form

PS: Proc
PT: Proc
Panel: Proc

COMPLETE ONLY IF RANDOMIZED TO STENT PLUS MEDICAL THERAPY

1. Date of procedure: (m)

2. Time subject arrived in procedure room: (24 hour)

3. Time procedure began (first xylocaine injection): (24 hour)

4. Time of insertion of first renal angiography catheter: (24 hour)

5. Time procedure ended (last catheter removed): (24 hour)

6. Type and dose of contrast used: Ionic Non-Ionic
(Check all that apply) Non-Ionic Low Osmolar Isosmolar

Ioval (f, 5) cc Nonval (f, 5) cc Lowval (f, 5) cc
 Isosval (f, 5) cc

7. Did the subject receive Fenoldopam? (1) YES (2) NO

8. Did the subject receive N-acetylcysteine? (1) YES (2) NO

9. Highest recorded ACT (if Angioguard used, ACT ≥ 300): Seconds

10. Was subject given Bivalirudin? (1) YES (2) NO

10.1 Bolus? (1) YES (2) NO

10.2 Infusion duration (hr:min): NA

COMPLETE PROTOCOL DEVIATION FORM

11. Did the subject receive sodium bicarbonate? (1) YES (2) NO

11.1 Was subject considered high risk? (subjects with diabetes mellitus and/or serum creatinine ≥ 1.4 mg/dL) (1) YES (2) NO

11.1.1. Explain why no sodium bicarbonate was given:

Device Utilization (if none, enter "0")

| | Number Used | | Number Used |
|-----------------------------------|--|--|---|
| 12. RADI pressure wire | <input type="text" value="radi (f, 5)"/> | 19. Non-study bare metal stents | <input type="text" value="nsbare (f, 5)"/> |
| 13. Pressure catheters | <input type="text" value="press (f, 5)"/> | 20. Atherectomy devices | <input type="text" value="ather (f, 5)"/> |
| 14. Guidewires | <input type="text" value="gdwire (f, 5)"/> | 21. Study embolic protection devices | <input type="text" value="studepd (f, 5)"/> |
| 15. Guiding catheters | <input type="text" value="gdcath (f, 5)"/> | 22. Non-study embolic protection devices | <input type="text" value="nsepd (f, 5)"/> |
| 16. Angioplasty balloons | <input type="text" value="angball (f, 5)"/> | 23. Other, specify | <input type="text" value="othsp1 (vc, 100)"/> |
| 17. Study stents | <input type="text" value="studstnt (f, 5)"/> | | <input type="text" value="oth1 (f, 5)"/> |
| 18. Non-study drug-eluting stents | <input type="text" value="nsdrugel (f, 5)"/> | 24. Other, specify | <input type="text" value="othsp2 (vc, 100)"/> |
| | | | <input type="text" value="oth2 (f, 5)"/> |

25. Were any non-renal angiographies or revascularizations performed during this procedure? (1) YES (2) NO

25.1. Check all that apply: Coronary angiography

Carotid angiography Other peripheral angiography, specify:

Coronary revascularization Carotid revascularization

Other revascularization, specify:

HCRI USE ONLY
Received: _____ / _____ / _____
By: _____

CORAL

Site ID: _____ Pt. No.: _____ Randomization #: _____

Intervention Procedure Form

Panel: Proc
PT: Proc
PS: Proc

COMPLETE ONLY IF RANDOMIZED TO STENT PLUS MEDICAL THERAPY

- Date of procedure: (mm/dd/yyyy)
- Time subject arrived in procedure room: (24 hour)
- Time procedure began (first xylocaine injection): (24 hour)
- Time of insertion of first renal angiography catheter: (24 hour)
- Time procedure ended (last catheter removed): (24 hour)
- Total amount of contrast used: cc
- Highest recorded ACT: seconds
(IF ANGIOGUARD USED AND ACT < 300, COMPLETE PROTOCOL DEVIATION FORM)
- Was subject given Bivalirudin? (1) YES (2) NO

Device Utilization (if none, enter "0")

- | | Number Used | | Number Used |
|-----------------------------------|--|--|---|
| 9. RADI pressure wire | <input type="text" value="radi (f, 5)"/> | 16. Non-study bare metal stents | <input type="text" value="nsbare (f, 5)"/> |
| 10. Pressure catheters | <input type="text" value="press (f, 5)"/> | 17. Atherectomy devices | <input type="text" value="ather (f, 5)"/> |
| 11. Guidewires | <input type="text" value="gdwire (f, 5)"/> | 18. Study embolic protection devices | <input type="text" value="studepd (f, 5)"/> |
| 12. Guiding catheters | <input type="text" value="gdcath (f, 5)"/> | 19. Non-study embolic protection devices | <input type="text" value="nsepd (f, 5)"/> |
| 13. Angioplasty balloons | <input type="text" value="angball (f, 5)"/> | 20. Other, specify | <input type="text" value="othsp1 (vc, 100)"/> <input type="text" value="oth1 (f, 5)"/> |
| 14. Study stents | <input type="text" value="studstnt (f, 5)"/> | 21. Other, specify | <input type="text" value="othsp2 (vc, 100)"/> <input type="text" value="oth2 (f, 5)"/> |
| 15. Non-study drug-eluting stents | <input type="text" value="nsdrugel (f, 5)"/> | | |

22. Were any non-renal angiographies or revascularizations performed during this procedure? (1) YES (2) NO

22.1. Check all that apply:

Coronary angiography

Carotid angiography

Other peripheral angiography, specify:

Coronary revascularization

Carotid revascularization

Other revascularization, specify:

HCRI USE ONLY

Received: _____ / _____ / _____

By: _____

CORAL

Site ID: _____ Pt. No.: _____ Randomization #: _____

Intervention Procedure Form

Panel: ProcV3
PT: ProcV3
Panel: Proc

COMPLETE ONLY IF RANDOMIZED TO STENT PLUS MEDICAL THERAPY

- Date of procedure: (mm/dd/yyyy)
- Time subject arrived in procedure room: (24 hour)
- Time procedure began (first xylocaine injection): (24 hour)
- Time of insertion of first renal angiography catheter: (24 hour)
- Time procedure ended (last catheter removed): (24 hour)
- Total amount of contrast used: cc
- Highest recorded ACT: seconds
- Was subject given Bivalirudin? (1) YES (2) NO

Device Utilization (if none, enter "0")

- | | Number Used | | Number Used |
|--------------------------|--|--|--|
| 9. RADI pressure wire | <input type="text" value="radi (f, 5)"/> | 15. Non-study drug-eluting stents | <input type="text" value="nsdrugel (f, 5)"/> |
| 10. Pressure catheters | <input type="text" value="press (f, 5)"/> | 16. Non-study bare metal stents | <input type="text" value="nsbare (f, 5)"/> |
| 11. Guidewires | <input type="text" value="gdwire (f, 5)"/> | 17. Atherectomy devices | <input type="text" value="ather (f, 5)"/> |
| 12. Guiding catheters | <input type="text" value="gdcath (f, 5)"/> | 18. Embolic protection devices | <input type="text" value="epdv3 (f, 5)"/> |
| 13. Angioplasty balloons | <input type="text" value="angball (f, 5)"/> | 19. Other, specify <input type="text" value="othsp1 (vc, 100)"/> | <input type="text" value="oth1 (f, 5)"/> |
| 14. Study stents | <input type="text" value="studstnt (f, 5)"/> | 20. Other, specify <input type="text" value="othsp2 (vc, 100)"/> | <input type="text" value="oth2 (f, 5)"/> |

21. Were any non-renal angiographies or revascularizations performed during this procedure? (1) YES (2) NO

21.1. Check all that apply:

| | | |
|-------------------------------------|--|--|
| <input type="checkbox"/> | Coronary angiography | |
| <input checked="" type="checkbox"/> | Carotid angiography | <input type="text" value="othang (vc, 50)"/> |
| <input type="checkbox"/> | Other peripheral angiography, specify: _____ | |
| <input checked="" type="checkbox"/> | Coronary revascularization | |
| <input checked="" type="checkbox"/> | Carotid revascularization | |
| <input type="checkbox"/> | Other revascularization, specify: _____ | <input type="text" value="othrev (vc, 50)"/> |

COMPLETE PROTOCOL

HCRI USE ONLY
Received: _____ / _____ / _____
By: _____

CORAL

Site ID: _____ Pt. No.: _____ Randomization #: _____

Lesion Treatment Form

COMPLETE FOR FIRST LESION TREATED. ADDITIONAL LESION TREATMENTS SHOULD BE CAPTURED ON ADDITIONAL LESION TREATMENT FORM

PS: LesTx1
PT: LesTx1
Panel: LesTx1

- Date of procedure:
 - 1.1. Time subject arrived in procedure room:
- Name of physician performing intervention:
- Renal artery site treated

procmm/procdd/procyy

procdt() y

prochr:procmn

(24 hour)

physfirs (vc, 50)

First

physlast (vc, 50)

Last

rensite2 (vc, 5)

rensite (f, 5)

Angioguard

- Was Angioguard attempted?
 - attempt <yesno>
 - (1) YES
 - (2) NO →
 - (1) Unfavorable anatomy anatomy <checked1>
 - (2) Unfavorable anatomy anatomy <checked1>
 - (99) Other: other<checked1>
 - othspec (vc, 50)

| (4.1) No. | (4.2) Angioguard | (4.3) Angioguard Basket Size (mm) | (4.4) Package opened and used? (If NO, row is complete) | (4.5) Able to cross lesion? | (4.6) Successfully deployed? | (4.7) Protection achieved? | (4.8) Problems and/or complication with device | (4.9) Subsequent |
|-----------|------------------|--|---|---|---|----------------------------|--|---|
| Lot # | Cat # | basket <basketsize> | pkgopen <yesno> | crosslen <yesno> | deployed <yesno> | protect <protection> | complic <yesno> | othlesn <yesno> |
| 1 | catnum (vc, 15) | <input type="checkbox"/> 6 <input type="checkbox"/> 8 | <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO | <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO | <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO | | probcode1 <complicationcode> probcode2 <complicationcode> probcode3 <complicationcode> | <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO |
| 2 | lotnum (vc, 15) | <input type="checkbox"/> 5 <input type="checkbox"/> 7 <input type="checkbox"/> 6 <input type="checkbox"/> 8 | <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO | <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO | <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO | | probcode4 <complicationcode> | <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO |
| 3 | | <input type="checkbox"/> 5 <input type="checkbox"/> 7 <input type="checkbox"/> 6 <input type="checkbox"/> 8 | <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO | <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO | <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO | | othspec (vc, 50) | <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO |

*Codes
 1 = Slow / No flow 3 = Thrombus formation 5 = Side branch occlusion 7 = Angioguard entanglement with renal stent at time of device removal 9 = Other, specify
 2 = Abrupt Closure 4 = Distal embolization 6 = Spasm 8 = Landing zone problems during placement

† Provide additional comments as needed on the Narrative Form.

HCRI USE ONLY
 Received: ____/____/____
 By: _____

CORAL

PANEL: Context
PS: Context

Site ID: _____ Pt. No.: _____ Randomization #: _____

Lesion Treatment Form

COMPLETE FOR FIRST LESION TREATED. ADDITIONAL LESION TREATMENTS SHOULD BE CAPTURED ON ADDITIONAL LESION TREATMENT FORM

PS: LesTrt1
PT: LesTrt1
Panel: LesTx1

1. Date of procedure: procmm/procdd/procyy (mm/dd/yyyy) procdt()
2. Name of physician performing intervention: physfirs (vc, 50) physlast (vc, 50)
3. Renal artery site treated renlsite2 (vc, 5) Percent stenosis: pctnsten (vc, 5)

Protection Device

4. Was Angioguard attempted? attempt <yesno>

(1) YES (2) NO → (1) Unfavorable anatomy
 (2) Unfavorable anatomy
 (99) Other: othspec (vc, 50)

anatomy <checked1>

other<checked1>

landing <checked1>

| (4.1) No. | (4.2) Angioguard | | (4.3) Angioguard Basket Size (mm) | (4.4) Package opened and used? (If NO, row is complete) | (4.5) Able to cross lesion? | (4.6) Successfully deployed? | (4.7) Protection achieved? | (4.8) Problems and/or complication with device treatment? | (4.8.1) (separate each sub-lesion?) | (4.9) Device treated of lesion? |
|--------------|---|---|--|---|---|---|---|---|---|---|
| | Lot # | Cat # | basket <basketsize> | pkgopen <yesno> | croslen <yesno> | deployed <yesno> | protect <protection> | complic <yesno> | probcde1 <complicationcode> | othlesn <yesno> |
| 1 | lotnum (vc, 15) | | <input type="checkbox"/> 5 <input type="checkbox"/> 7 <input type="checkbox"/> 6 <input type="checkbox"/> 8 | <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO | <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO | <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO | <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO | <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO | probcde2 <complicationcode> | <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO |
| 2 | | catnum (vc, 15) | <input type="checkbox"/> 5 <input type="checkbox"/> 7 <input type="checkbox"/> 6 <input type="checkbox"/> 8 | <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO | <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO | <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO | <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO | <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO | probcde3 <complicationcode> | <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO |
| 3 | | | <input type="checkbox"/> 5 <input type="checkbox"/> 7 <input type="checkbox"/> 6 <input type="checkbox"/> 8 | <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO | <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO | <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO | <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO | <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO | probcde4 <complicationcode> | <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO |

PS: EPD
PT: LesTrt1
Panel: AngGuard

| | | | | | |
|---------------|--------------------|-------------------------|---------------------------|--|---|
| *Codes | 1 = Slow / No flow | 3 = Thrombus formation | 5 = Side branch occlusion | 7 = Angioguard entanglement with renal stent at time of device removal | 9 = Other, specify: COMPLETE NARRATIVE FORM |
| | 2 = Abrupt Closure | 4 = Distal embolization | 6 = Spasm | 8 = Landing zone problems during placement | |

† Submit Narrative Form to provide details if only partial protection is achieved or to specify if code 9 (Other) is entered.

5. Was a protection device other than the Angioguard used? (1) YES (2) NO othEPD <yesno>
 - 5.1. Device Manufacturer: manuf (vc, 50)
 - 5.2. Device Name: devname (vc, 50)
 - 5.3. Device size: devsize (vc, 15)
 - 5.4. Why was this device used? reasused (vc, 100)
(complete Narrative Form if more space is needed)

HCRI USE ONLY

Received: _____ / _____ / _____

By: _____

PS: LesTrt2
PT: LesTrt1
Panel: LesTx1

CORAL

PANEL: Context
PS: Context

Site ID: _____ Pt. No.: _____ Randomization #: _____

Lesion Treatment Form

Page 1 of 1
PS: LesTrtV3
PT: LesTrtV3
Panel: LesTx1

COMPLETE FOR FIRST LESION TREATED. ADDITIONAL LESION TREATMENTS SHOULD BE CAPTURED ON ADDITIONAL LESION TREATMENT FORM

1. Date of procedure: procmm/procdd/procy (mm/dd/yyyy) procdt()
2. Name of physician performing intervention: physfirs (vc, 50) physlast (vc, 50)

First
Last
3. Renal artery site treated rensite2 (vc, 5) Percent stenosis: pcntsten (vc, 5)

Embolic Protection Device (EPD)

4. Was embolic protection attempted? attempt <yesno> (1) YES (2) NO → Skip to page 009

| No. | EPD used: | | | Size (mm) | Protection achieved? <small>1 = None 2 = Complete 3 = Partial</small> | Problems and/or complications with device / treatment? | If YES, indicate with code(s) *† <small>(separate each code with <code>)</small> |
|---------------|------------------|-----------------|-----------------|-----------------|--|---|---|
| | Name | Lot # | Cat # | | | | |
| lineno (f, 5) | | | | | | | |
| 1 | epdname (vc, 50) | lotnum (vc, 15) | catnum (vc, 15) | epdsz (fl 4, 2) | protect <protection> | <input type="checkbox"/> complic <yesno> <input type="checkbox"/> (1) YES → <input type="checkbox"/> (2) NO | probcde2a <complicationcode1> probcde1a <complicationcode1> |
| 2 | | | | | | <input type="checkbox"/> (1) YES → <input type="checkbox"/> (2) NO | probcde4a <complicationcode1> |
| 3 | | | | | | <input type="checkbox"/> (1) YES → <input type="checkbox"/> (2) NO | probcde3a <complicationcode1> |

PS: EPDV3
PT: LesTrtV3
Panel: AngGuard

| | | | | | |
|---------------|--------------------|-------------------------|---------------------------|---|--|
| *Codes | 1 = Slow / No flow | 3 = Thrombus formation | 5 = Side branch occlusion | 7 = Entanglement with renal stent at time of device removal | othspec (vc, 50) COMPLETE NARRATIVE FORM |
| | 2 = Abrupt Closure | 4 = Distal embolization | 6 = Spasm | 8 = Landing zone problems during placement | |

† Submit Narrative Form to to specify if code 9 (Other) is entered.

HCRI USE ONLY

Received: _____ / _____ / _____

By: _____

CORAL

PANEL: Context
PS: Context

Site ID: _____ Pt. No.: _____ Randomization #: _____

Lesion Treatment Form

PS: LesTx2
PT: LesTx2
Panel: LesTx2

Page 2 of 2

Target Lesion Study Stent Delivery Information

5. Was stent attempted? stnattem <yesno> (1) YES (2) NO

| (5.1) | (5.2) | (5.3) | (5.4) | (5.5) | (5.6) | | (5.7) |
|-------|--|---|--|--|---|--|---|
| | Type of stent | Was lesion pre-dilated? | Max stent deployment pressure (ATM) | Was post-dilation performed? | If YES, | | Problem with delivery / deployment of stent? [If Yes, complete Narrative Form] |
| | | | | | Largest balloon diameter (mm) | Maximum pressure (ATM) | |
| | lieno (f, 5) Name: stent (vc, 50) diam (f, 5) diam2 (fl 6, 2) Diameter: _____ mm Length: len (f, 5) _____ mm | predil <yesno> <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO | dpress2 (fl 6, 2) _____ mmHg dpress (f, 5) | postdil <yesno> <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO | maxdiam (fl 6, 2) _____ mm | maxpress2 (fl 6, 2) _____ mmHg maxpress (f, 5) | delvprob <yesno> <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO |
| | Name: _____ Diameter: _____ mm Length: _____ mm | <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO | | <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO | | | <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO |

Details of Target Lesion (Post All Treatments)

6. Total length of stent(s) placed: totleng (fl, 6.2) _____ mm

7. Final percent stenosis: finsten (fl 6, 2) _____ %

8. Pressure gradient: pressign (vc, 3) _____ mmHg ND pressND <checked1>

Additional Treatments

9. Was an additional percutaneous treatment performed to another target lesion? (1) YES (2) NO perctarg <yesno>

COMPLETE ADDITIONAL LESION TREATMENT FORM

10. Were additional percutaneous treatment(s) performed to a non-target lesion? (1) YES (2) NO nontarg <yesno>

COMPLETE PROTOCOL DEVIATION FORM AND NARRATIVE FORM

11. Were there complications that required additional treatment? (1) YES (2) NO addltx <yesno>

| | | | |
|--|----------------------------------|---------------------------------|--|
| 11.1. Complication during pre-treatment: | <input type="checkbox"/> (1) YES | <input type="checkbox"/> (2) NO | pretx <yesno> |
| 11.2. Never able to cross lesion with stent: nocross <yesno> | <input type="checkbox"/> (1) YES | <input type="checkbox"/> (2) NO | dissect <yesno> |
| 11.3. Dissection beyond stented area: | <input type="checkbox"/> (1) YES | <input type="checkbox"/> (2) NO | diffseg <yesno> |
| 11.4. Complication in different segment: diffseg <yesno> | <input type="checkbox"/> (1) YES | <input type="checkbox"/> (2) NO | diffvess <yesno> |
| 11.5. Complication in different vessel: | <input type="checkbox"/> (1) YES | <input type="checkbox"/> (2) NO | unplan <yesno> |
| 11.6. Unplanned treatment of other lesion: unplan <yesno> | <input type="checkbox"/> (1) YES | <input type="checkbox"/> (2) NO | |
| 11.6.1 Specify: lesnspec (vc, 50) _____ | | | |
| 11.7. Other: othspec1 (vc, 50) _____ | <input type="checkbox"/> (1) YES | <input type="checkbox"/> (2) NO | other <yesno> |

PROVIDE ADDITIONAL COMMENTS AS NEEDED ON NARRATIVE FORM

| HCRI USE ONLY | |
|---------------------------------|--|
| Received: _____ / _____ / _____ | |
| By: _____ | |

CORAL

Site ID: _____ Pt. No.: _____ Randomization #: _____

Lesion Treatment Form

PS: LesTrt3
PT: LesTrt2
Panel: LesTx2

Lesion Stent Delivery Information

stnattem <yesno>

lesssten <yesno>

as stent attempted?

(1) YES

(2) NO

Was stenosis less than 60%? (1) YES (2) NO

| (6.1) | (6.2) | (6.3) | (6.4) |
|---------------|--|---|--|
| lineno (f, 5) | stnttyp <stenttype3> | Stent Information | Problem with delivery / deployment? |
| 1 | <input type="checkbox"/> (1) Study <input type="checkbox"/> (2) Non-study ↓ 6.2.1 Why was non-study stent used? _____ whyNSS (vc, 150) (complete Narrative Form if more space is needed) | Manufacturer: _____ Name _____ Lot # _____ diam2 (fl 6, 2) mm Length _____ mm Delivery _____ mm | <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO COMPLETE NARRATIVE FORM delvprob <yesno> |
| 2 | <input type="checkbox"/> (1) Study <input type="checkbox"/> (2) Non-study ↓ 6.2.1 Why was non-study stent used? _____ (complete Narrative Form if more space is needed) | Manufacturer: _____ Name _____ Lot # _____ Diameter _____ mm Length _____ mm Delivery system length _____ mm | <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO COMPLETE NARRATIVE FORM |

PS: StentV2
PT: LesTrt2
Panel: Stent

Details of Target Lesion (Post All Treatments)

7. Total length of stent(s) placed: _____ mm

8. Final percent stenosis: _____

9. Pressure gradient: _____ mmHg

ND

pressign (vc, 3)

pressgrd (fl 6, 2)

pressND <checked1>

PS: LesTrt4
PT: LesTrt2
Panel: LesTx2

Additional Treatments

10. Was an additional percutaneous treatment performed to another target lesion?

(1) YES

(2) NO

perctarg <yesno>

COMPLETE ADDITIONAL LESION TREATMENT FORM

11. Were additional percutaneous treatment(s) performed to non-target lesion(s)?

(1) YES

(2) NO

nontarg <yesno>

COMPLETE PROTOCOL DEVIATION FORM AND NARRATIVE FORM

12. Were there complications that required additional treatment?

(1) YES

(2) NO

additx <yesno>

12.1. Complication during pre-treatment:

(1) YES

(2) NO

pretx <yesno>

12.2. Never able to cross lesion with stent:

nocross <yesno>

(1) YES

(2) NO

12.3. Dissection beyond stented area:

diffseg <yesno>

(1) YES

(2) NO

12.4. Complication in different segment:

diffvess <yesno>

(1) YES

(2) NO

12.5. Complication in different vessel:

unplan <yesno>

(1) YES

(2) NO

12.6. Unplanned treatment of other lesion:

lesnspec (vc, 50)

(1) YES

(2) NO

12.6.1 Specify:

12.7. Other: _____

othspec1 (vc, 50)

(1) YES

(2) NO

other <yesno>

PROVIDE ADDITIONAL COMMENTS AS NEEDED ON NARRATIVE FORM

CORAL

PANEL: Context
PS: Context

Site ID: _____ Pt. No.: _____ Randomization #: _____

Index Visit Completion Form

Page 1 of 3

1. Was subject admitted to hospital? admitted<yesno> (1) YES (2) NO

| | | |
|----------------------|---|---|
| 1.1. Admit date: | admmm/admdd/admyy (admdt()) | PS: IndxVis1 PT: IndxVis1 Panel: IndxVis1 |
| 1.2. Discharge date: | dischmm/dischdd/dischyy (dischdt()) | |
| 1.3. Hospital stay: | | |



| Check Type of Unit | | | | | | |
|---|---|---|--|--|--|---|
| Sequence of | Med/Surg | ICU/CCU | Step-Down | admmm/admdd/admyy | Disc Trans | |
| stayseq (f, 5) | medsurg <checked1> | | | admdt() | dischmm/dischdd/dischyy | PS: HospUnit PT: IndxVis1 Panel: HospUnit |
| 1. | <input type="checkbox"/> (1) | icuccu<checked1> | <input type="checkbox"/> (3) | | | |
| 2. | <input type="checkbox"/> (1) | <input type="checkbox"/> (2) | stepdown <checked1> | | dischdt() | |
| 3. | <input type="checkbox"/> (1) | <input type="checkbox"/> (2) | <input type="checkbox"/> (3) | | | |
| 4. | <input type="checkbox"/> (1) | <input type="checkbox"/> (2) | <input type="checkbox"/> (3) | | | |

| TEST/EVALUATION | Performed at index visit completion? | IF YES | IF NO | | | | | | | | | | | | |
|------------------------------|---|--|---|-----------|------------|-------------|-------------|-----------|------------|-------------|-------------|-----------|------------|-------------|----------------------------------|
| 2. Physical Exam | <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO phys <yesno> | RECORD ANY SIGNIFICANT CHANGES ON AE LOG | PS: IndxVis2 PT: IndxVis1 Panel: IndxVis1 | | | | | | | | | | | | |
| 3. Blood Pressure Assessment | <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO bp <yesno> | 3.1. Date of Assessment: bpmm/bpdd/bpyy (bpdt()) <small>(mm/dd/yyyy)</small> 3.2. Time Sys/Dias Heart Rate <table style="width: 100%; border-collapse: collapse;"> <tr> <td style="border: 1px solid blue; padding: 2px;">bp1hr:bp1mn</td> <td style="border: 1px solid blue; padding: 2px;">sys1(f 5)</td> <td style="border: 1px solid blue; padding: 2px;">dias1(f 5)</td> <td style="border: 1px solid blue; padding: 2px;">hrtrt1(f 5)</td> </tr> <tr> <td style="border: 1px solid blue; padding: 2px;">bp2hr:bp2mn</td> <td style="border: 1px solid blue; padding: 2px;">sys2(f 5)</td> <td style="border: 1px solid blue; padding: 2px;">dias2(f 5)</td> <td style="border: 1px solid blue; padding: 2px;">hrtrt2(f 5)</td> </tr> <tr> <td style="border: 1px solid blue; padding: 2px;">bp3hr:bp2mn</td> <td style="border: 1px solid blue; padding: 2px;">sys3(f 5)</td> <td style="border: 1px solid blue; padding: 2px;">dias3(f 5)</td> <td style="border: 1px solid blue; padding: 2px;">hrtrt3(f 5)</td> </tr> </table> | bp1hr:bp1mn | sys1(f 5) | dias1(f 5) | hrtrt1(f 5) | bp2hr:bp2mn | sys2(f 5) | dias2(f 5) | hrtrt2(f 5) | bp3hr:bp2mn | sys3(f 5) | dias3(f 5) | hrtrt3(f 5) | COMPLETE PROTOCOL DEVIATION FORM |
| bp1hr:bp1mn | sys1(f 5) | dias1(f 5) | hrtrt1(f 5) | | | | | | | | | | | | |
| bp2hr:bp2mn | sys2(f 5) | dias2(f 5) | hrtrt2(f 5) | | | | | | | | | | | | |
| bp3hr:bp2mn | sys3(f 5) | dias3(f 5) | hrtrt3(f 5) | | | | | | | | | | | | |
| 4. Local Lab Urine Dipstick | <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO urinedip <yesno> | 4.1. Date and time dipdt() dipmm/dipdd/dipy (diphr:dipmn) <small>(mm/dd/yyyy) (24-hour)</small> 4.2. Protein (mg/dl) <input type="checkbox"/> (1) Neg <input type="checkbox"/> (2) Trace <input type="checkbox"/> (3) 30 <input type="checkbox"/> (4) 300 <input type="checkbox"/> (5) 300 protein <urineprotein> | COMPLETE PROTOCOL DEVIATION FORM | | | | | | | | | | | | |

5. Did subject experience any AEs from randomization through index visit completion? (1) YES (2) NO anyaes <yesno>

COMPLETE ADVERSE EVENT LOG

| |
|---------------------------------|
| HCRI USE ONLY |
| Received: _____ / _____ / _____ |
| By: _____ |

CORAL

Site ID: _____ Pt. No.: _____ Randomization #: _____

Index Visit Completion Form

1. Was subject admitted to hospital? (1) YES (2) NO

admitted <yesno>

1.1. Admit date: ()
 1.2. Discharge date: ()
 1.3. Hospital stay:

PS: IndxVis1
PT: IndxVis1V2
Panel: IndxVis1

| Check Type of Unit (check only one per line) | | | | | |
|---|---|--|---|---|---|
| Sequence of | Med/Surg | ICU/CCU | Step-Down | Admission Date | Disc Trans |
| 1. <input type="text" value="stayseq (f, 5)"/> | <input checked="" type="checkbox"/> (1) <input type="checkbox"/> (2) <input type="checkbox"/> (3) <input type="checkbox"/> (4) <input type="checkbox"/> (5) <input type="checkbox"/> (6) <input type="checkbox"/> (7) <input type="checkbox"/> (8) <input type="checkbox"/> (9) <input type="checkbox"/> (10) | <input type="checkbox"/> (1) <input type="checkbox"/> (2) <input type="checkbox"/> (3) <input type="checkbox"/> (4) <input type="checkbox"/> (5) <input type="checkbox"/> (6) <input type="checkbox"/> (7) <input type="checkbox"/> (8) <input type="checkbox"/> (9) <input type="checkbox"/> (10) | <input type="checkbox"/> (1) <input type="checkbox"/> (2) <input type="checkbox"/> (3) <input type="checkbox"/> (4) <input type="checkbox"/> (5) <input type="checkbox"/> (6) <input type="checkbox"/> (7) <input type="checkbox"/> (8) <input type="checkbox"/> (9) <input type="checkbox"/> (10) | <input type="text" value="admmm/admdd/admyy"/> (<input type="text" value="admdt()"/>) | <input type="text" value="dischmm/dischdd/dischyy"/> (<input type="text" value="dischdt()"/>) |
| 2. | <input type="checkbox"/> (1) <input type="checkbox"/> (2) <input type="checkbox"/> (3) <input type="checkbox"/> (4) <input type="checkbox"/> (5) <input type="checkbox"/> (6) <input type="checkbox"/> (7) <input type="checkbox"/> (8) <input type="checkbox"/> (9) <input type="checkbox"/> (10) | <input type="checkbox"/> (1) <input type="checkbox"/> (2) <input type="checkbox"/> (3) <input type="checkbox"/> (4) <input type="checkbox"/> (5) <input type="checkbox"/> (6) <input type="checkbox"/> (7) <input type="checkbox"/> (8) <input type="checkbox"/> (9) <input type="checkbox"/> (10) | <input checked="" type="checkbox"/> (1) <input type="checkbox"/> (2) <input type="checkbox"/> (3) <input type="checkbox"/> (4) <input type="checkbox"/> (5) <input type="checkbox"/> (6) <input type="checkbox"/> (7) <input type="checkbox"/> (8) <input type="checkbox"/> (9) <input type="checkbox"/> (10) | | |
| 3. | <input type="checkbox"/> (1) <input type="checkbox"/> (2) <input type="checkbox"/> (3) <input type="checkbox"/> (4) <input type="checkbox"/> (5) <input type="checkbox"/> (6) <input type="checkbox"/> (7) <input type="checkbox"/> (8) <input type="checkbox"/> (9) <input type="checkbox"/> (10) | <input type="checkbox"/> (1) <input type="checkbox"/> (2) <input type="checkbox"/> (3) <input type="checkbox"/> (4) <input type="checkbox"/> (5) <input type="checkbox"/> (6) <input type="checkbox"/> (7) <input type="checkbox"/> (8) <input type="checkbox"/> (9) <input type="checkbox"/> (10) | <input type="checkbox"/> (1) <input type="checkbox"/> (2) <input type="checkbox"/> (3) <input type="checkbox"/> (4) <input type="checkbox"/> (5) <input type="checkbox"/> (6) <input type="checkbox"/> (7) <input type="checkbox"/> (8) <input type="checkbox"/> (9) <input type="checkbox"/> (10) | | |
| 4. | <input type="checkbox"/> (1) <input type="checkbox"/> (2) <input type="checkbox"/> (3) <input type="checkbox"/> (4) <input type="checkbox"/> (5) <input type="checkbox"/> (6) <input type="checkbox"/> (7) <input type="checkbox"/> (8) <input type="checkbox"/> (9) <input type="checkbox"/> (10) | <input type="checkbox"/> (1) <input type="checkbox"/> (2) <input type="checkbox"/> (3) <input type="checkbox"/> (4) <input type="checkbox"/> (5) <input type="checkbox"/> (6) <input type="checkbox"/> (7) <input type="checkbox"/> (8) <input type="checkbox"/> (9) <input type="checkbox"/> (10) | <input type="checkbox"/> (1) <input type="checkbox"/> (2) <input type="checkbox"/> (3) <input type="checkbox"/> (4) <input type="checkbox"/> (5) <input type="checkbox"/> (6) <input type="checkbox"/> (7) <input type="checkbox"/> (8) <input type="checkbox"/> (9) <input type="checkbox"/> (10) | | |

PS: HospUnit
PT: IndxVis1V2
Panel: HospUnit

| TEST/EVALUATION | Performed at index visit completion? | IF YES | IF NO |
|------------------------------|---|---|---|
| 2. Physical Exam | <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO | RECORD ANY SIGNIFICANT CHANGES ON AE LOG | COMPLETE DEVIATION |
| 3. Blood Pressure Assessment | <input checked="" type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO | 3.1. Date of Assessment: <input type="text" value="bpd()"/> (mm/dd/yyyy) 3.2. Time Sys/Dias <input type="text" value="bp1hr:bp1mn"/> <input type="text" value="sys1(f 5)"/> <input type="text" value="dias1(f 5)"/> <input type="text" value="bp2hr:bp2mn"/> <input type="text" value="sys2 (f 5)"/> <input type="text" value="dias2 (f 5)"/> <input type="text" value="bp3hr:bp3mn"/> <input type="text" value="sys3 (f 5)"/> <input type="text" value="dias3 (f 5)"/> | COMPLETE PROTOCOL DEVIATION FORM |
| 4. Local Lab Urine Dipstick | <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO | 4.1. Protein (mg/dl) <input type="checkbox"/> (1) Neg <input type="checkbox"/> (2) Trace <input type="checkbox"/> (3) 30 <input type="checkbox"/> (4) 100 <input type="checkbox"/> (5) 300 <input type="checkbox"/> (6) ≥2000 | COMPLETE PROTOCOL DEVIATION FORM |

PS: IndxVis2V2
PT: IndxVis1V2
Panel: IndxVis1

5. Did any endpoint events occur since randomization? (1) YES (2) NO (3) YES

COMPLETE AE LOG AND APPROPRIATE ENDPOINT FORMS

6. Did any other AEs occur since randomization? (1) YES (2) NO (3) YES

COMPLETE AE LOG AND FAX SAE FORM IF SERIOUS

| |
|---------------------------------|
| HCRI USE ONLY |
| Received: _____ / _____ / _____ |
| By: _____ |

CORAL

Site ID: _____ Pt. No.: _____ Randomization #: _____

Index Visit Completion Form

1. Was subject admitted to hospital? (1) YES (2) NO

admitted <yesno>

1.1. Admit date: admymm/admdd/admyy (admdt()) y

1.2. Discharge date: dischymm/dischdd/dischy (dischdt())

1.3. Hospital stay:

PS: IndxVis1
PT: IndxVis1V2
Panel: IndxVis1

| Check Type of Unit | | | | | |
|--------------------|------------------------------|------------------------------|------------------------------|--------------------|-------------------------|
| Sequence of | Med/Surg | ICU/CCU | Step-Down | Admission | Discharge |
| stayseq (f, 5) | medsurg <checked1> | | | admymm/admdd/admyy | Discharge Transf |
| 1. | <input type="checkbox"/> (1) | icuccu <checked1> | <input type="checkbox"/> (3) | admdt() | dischymm/dischdd/dischy |
| 2. | <input type="checkbox"/> (1) | <input type="checkbox"/> (2) | stepdown <checked1> | | dischdt() |
| 3. | <input type="checkbox"/> (1) | <input type="checkbox"/> (2) | <input type="checkbox"/> (3) | | |
| 4. | <input type="checkbox"/> (1) | <input type="checkbox"/> (2) | <input type="checkbox"/> (3) | | |

PS: HospUnit
PT: IndxVis1V2
Panel: HospUnit

| TEST/EVALUATION | Performed at index visit completion? | IF YES | IF NO |
|--|---|--|--|
| 2. Physical Exam phys <yesnona8> | <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO <input type="checkbox"/> NA | RECORD ANY SIGNIFICANT CHANGES ON AE LOG | COMPLETE PROTOCOL DEVIATION FORM IF APPLICABLE |
| 3. Blood Pressure Assessment bp <yesnona8> | <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO <input type="checkbox"/> NA | 3.1. Date of Assessment: bpdmt() (mm/dd/yyyy) 3.2. Time Sys/Dias bp1hr:bp1mn sys1(f 5) dias1(f 5) bp2hr:bp2mn sys2(f 5) dias2(f 5) bp3hr:bp3mn sys3(f 5) dias3(f 5) | COMPLETE PROTOCOL DEVIATION FORM IF APPLICABLE |
| 4. Local Lab Urine Dipstick urinedip <yesnona8> | <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO <input type="checkbox"/> NA | 4.1. Protein (mg/dl) <input type="checkbox"/> (1) Neg <input type="checkbox"/> (2) Trace <input type="checkbox"/> (3) 30 <input type="checkbox"/> (4) 100 <input type="checkbox"/> (5) 300 <input type="checkbox"/> (6) ≥2000 | COMPLETE PROTOCOL DEVIATION FORM IF APPLICABLE |

PS: IndxVis2
PT: IndxVis1
Panel: IndxVis1

5. Did any endpoint events occur since randomization? (1) YES (2) NO anyendpt <yesno>

COMPLETE AE LOG AND APPROPRIATE Endpoint Forms

6. Did any other AEs occur since randomization? (1) YES (2) NO anyaes <yesno>

COMPLETE AE LOG AND FAX SAE FORM IF SERIOUS

| |
|---------------------------------|
| HCRI USE ONLY |
| Received: _____ / _____ / _____ |
| By: _____ |

| | | |
|----------------|----------------|------------------------|
| Site ID: _____ | Pt. No.: _____ | Randomization #: _____ |
|----------------|----------------|------------------------|

Index Visit Completion Form

6. Record the number of procedures performed during the index visit

| Procedure | Quantity (If none, enter 0) | |
|--|-----------------------------|---------------------|
| | Before Randomization | After Randomization |
| 6.1. Renal diagnostic angiography (EXCLUDE BASELINE DIAGNOSTIC ANGIOGRAPHY) | preangio (f, 5) | postangi (f, 5) |
| 6.2. Surgical renal revascularization | prerevas (f, 5) | postrev (f, 5) |
| 6.3. Percutaneous renal revascularization (EXCLUDE INDEX AND STAGED PROCEDURES) | preperc (f, 5) | postperc (f, 5) |
| 6.4. Renal MRA | preMRA (f, 5) | postMRA (f, 5) |
| 6.5. Renal duplex scan (EXCLUDE PROTOCOL REQUIRED SCAN) | preUS (f, 5) | postUS (f, 5) |
| 6.6. CT angiography | preCT (f, 5) | postCT (f, 5) |
| 6.7. Coronary diagnostic angiography | predxang (f, 5) | postdxag (f, 5) |
| 6.8. Coronary PCI | prePCI (f, 5) | postPCI (f, 5) |
| 6.9. CABG operation | preCABG (f, 5) | postCABG (f, 5) |
| 6.10. Whole blood or PRBC transfusion (# of units) | preblood (f, 5) | postbld (f, 5) |
| 6.11. Surgical repair of vascular access site | prerep (f, 5) | postrep (f, 5) |
| 6.12. Other vascular surgery | preosurg (f, 5) | postsurg (f, 5) |
| 6.13. Hemodialysis | prehemo (f, 5) | posthemo (f, 5) |
| 6.14. Peritoneal dialysis | preperi (f, 5) | postperi (f, 5) |
| 6.15. Renal transplant | pretrans (f, 5) | posttran (f, 5) |
| 6.16. Other, specify _____ | preoth (f, 5) | postoth (f, 5) |

PS: IndxVis3
 PT: IndxVis2
 Panel: IndxVis2

7. Subject left research facility for:

- (CHECK ONE) destin <dcdestin>
- (1) Home
 (2) Rehabilitation/skilled nursing facility
 (3) Another hospital (IF YES, FILL OUT _____ HOSPITALIZATION FORM)
 (4) If Other, specify: _____ othspec2 (vc, 100)

8. Record subject DRG _____ DRG (vc, 50)
 (Obtain from Medical Records or Billing Office)

9. Principal Diagnosis (describe) _____ diag (vc, 200)

HCRI USE ONLY

Received: _____ / _____ / _____

By: _____

CORAL

Site ID: _____ Pt. No.: _____ Randomization #: _____

Index Visit Completion Form

PS: IndxVis3V2
PT: IndxVis2V2
Panel: IndxVis2

7. Record the number of procedures performed during the index visit

Quantity (If none, enter 0)

| Procedure | Before Randomization | After Randomization |
|--|----------------------|---------------------|
| 7.1. Renal diagnostic angiography (EXCLUDE BASELINE DIAGNOSTIC ANGIOGRAPHY) | preangio (f, 5) | postangi (f, 5) |
| 7.2. Surgical renal revascularization | prerevas (f, 5) | postrev (f, 5) |
| 7.3. Percutaneous renal revascularization (EXCLUDE INDEX AND STAGED PROCEDURES) | preperc (f, 5) | postperc (f, 5) |
| 7.4. Renal MRA | preMRA (f, 5) | postMRA (f, 5) |
| 7.5. Renal duplex scan (EXCLUDE DUPLEX SUB-STUDY SCAN) | preUS (f, 5) | postUS (f, 5) |
| 7.6. CT angiography | preCT (f, 5) | postCT (f, 5) |
| 7.7. Coronary diagnostic angiography | predxang (f, 5) | postdxag (f, 5) |
| 7.8. Coronary PCI | prePCI (f, 5) | postPCI (f, 5) |
| 7.9. CABG operation | preCABG (f, 5) | postCABG (f, 5) |
| 7.10. Whole blood or PRBC transfusion (# of units) | preblood (f, 5) | postbld (f, 5) |
| 7.11. Surgical repair of vascular access site | prerep (f, 5) | postrep (f, 5) |
| 7.12. Other vascular surgery | preosurg (f, 5) | postsurg (f, 5) |
| 7.13. Hemodialysis | prehemo (f, 5) | posthemo (f, 5) |
| 7.14. Peritoneal dialysis | preperi (f, 5) | postperi (f, 5) |
| 7.15. Renal transplant | pretrans (f, 5) | posttran (f, 5) |
| 7.16. Other, specify _____ | othspec1 (vc, 100) | postoth (f, 5) |

8. Subject left research facility for:

(CHECK ONE)

destin <dcdestin>

- (1) Home
 (2) Rehabilitation/skilled nursing facility
 (3) Another hospital (IF CHECKED, FILL OUT SUBSEQUENT HOSPITALIZATION FORM)
 (4) If Other, specify: _____

othspec2 (vc, 100)

9. Record subject DRG _____

DRG (vc, 50)

NA

NA <checked1>

(Obtain from Medical Records or Billing Office)

10. Principal Diagnosis (describe) _____

diag (vc, 200)

| HCRI USE ONLY | |
|---------------|--------------------|
| Received: | ____ / ____ / ____ |
| By: | _____ |

| | | |
|----------------|----------------|------------------------|
| Site ID: _____ | Pt. No.: _____ | Randomization #: _____ |
|----------------|----------------|------------------------|

Index Visit Completion Form

10. Did the subject sign the Medical Billing Release form? (1) YES (2) releasfrm <yesno>

PS: IndxVis4
 PT: IndxVis3
 Panel: IndxVis3

| | | |
|-------|--|---|
| 10.1. | Record Principal Diagnosis (ICD-9) Code (Obtain from Medical Records or Billing Office) | icd91 (vc 50) |
| 10.2. | Record secondary Diagnosis (ICD-9) Codes | <div style="display: flex; flex-wrap: wrap;"> <div style="width: 30%;">icd92 (vc 50)</div> <div style="width: 30%;">icd921 (vc 50)</div> <div style="width: 30%;">icd922 (vc 50)</div> <div style="width: 30%;">icd923 (vc 50)</div> </div> |
| 10.3. | Record Principal Procedure (ICD-9) Code | icd93 (vc 50) |
| 10.4. | Record secondary Procedure (ICD-9) Codes | <div style="display: flex; flex-wrap: wrap;"> <div style="width: 30%;">icd94 (vc 50)</div> <div style="width: 30%;">icd941 (vc 50)</div> <div style="width: 30%;">icd942 (vc 50)</div> <div style="width: 30%;">icd943 (vc 50)</div> </div> |

11. Was study medication started? medstart <yesno> (1) YES (2) NO

11.1. Date study medication started: medmm/meddd/medyy (n meddt())

MEDICATION INFORMATION MUST ALSO BE DOCUMENTED ON CONCOMITANT MEDICATION LOG.

12. Has subject been prescribed to take study medication after index visit completion? meds <yesno> (1) YES (2) NO

12.1. Indicate study drug option subject will use at home:

| Option | Type | Dose | Frequency |
|---|---------|--|--|
| <input type="checkbox"/> Study drug drugvouch <checked1> | Atacand | dose1 (fl 8, 2) units1 (vc, 6) | medfreq1 <coralmedfreq> |
| | | dose2 (fl 8, 2) hctdose2 (fl 8, 2) units2 (vc, 6) | medfreq2 <coralmedfreq> |
| <input type="checkbox"/> Personal Atacand script <checked1> | Atacand | dose3 (fl 8, 2) units3 (vc, 6) | medfreq3 <coralmedfreq> |
| | | dose4 (fl 8, 2) hctdose4 (fl 8, 2) units4 (vc, 6) | medfreq4 <coralmedfreq> |

I HAVE REVIEWED THE INFORMATION IN THIS CASE REPORT FORM AND ALL ATTACHED DOCUMENTS AND CERTIFY THAT THE INFORMATION CONTAINED HEREIN IS ACCURATE.

Plsig <yesno>

Signature of Investigator

Plsigdt()

Date (mm/dd/yyyy)

HCRI USE ONLY

Received: ____/____/____

By: _____

CORAL

Site ID: _____ Pt. No.: _____ Randomization #: _____

Index Visit Completion Form

releasfrm <yesno>

PS: IndxVis4V2
PT: IndxVis3V2
Panel: IndxVis3

11. Did the subject sign the Medical Billing Release form? (1) YES (2) NO

| | | | | |
|--|---------------|---------------|----------------|----------------|
| 11.1. Record Principal Diagnosis (ICD-9) Code (Obtain from Medical Records or Billing Office) | _____ | icd91 (vc 50) | _____ | icd912 (vc 50) |
| 11.2. Record secondary Diagnosis (ICD-9) Codes | icd92 (vc 50) | _____ | icd921 (vc 50) | _____ |
| 11.3. Record Principal Procedure (ICD-9) Code | _____ | icd93 (vc 50) | _____ | icd932 (vc 50) |
| 11.4. Record secondary Procedure (ICD-9) Codes | icd94 (vc 50) | _____ | icd941 (vc 50) | _____ |

12. Has subject been prescribed to take study medication after index visit completion? (1) YES (2) NO medstart <yesno>

12.1. Indicate study drug:

| Drug | Dose | Frequency | Date Started (mm/dd/yyyy) |
|---|---|----------------------------|-----------------------------------|
| Atacand <input type="checkbox"/> Not prescribed | dose1 (fl 8, 2) units1 (vc, 6) | medfreq1 <coralmedfreq> | atacmm/atacdd/atacyy atacdd () |
| Atacand/HCT <input type="checkbox"/> Not prescribed | dose2 (fl 8, 2) hctdose2 (fl 8, 2) units2 (vc, 6) | medfreq2 <coralmedfreq> | hctmm/hctdd/hctyy hctdd () |
| Caduet <input type="checkbox"/> Not prescribed | dose5 (fl 8,2) caddose (fl 8,2) units5 (vc, 6) | medfreq5 <coralmedfreq> | cadmm/caddd/cady caddd () |

13. Has subject been prescribed other anti-hypertensive medications post-randomization? (1) YES (2) NO antihyp <yesno>

RECORD ON CONCOMITANT MEDICATION LOG

I HAVE REVIEWED THE INFORMATION IN THIS CASE REPORT FORM AND ALL ATTACHED DOCUMENTS AND CERTIFY THAT THE INFORMATION CONTAINED HEREIN IS ACCURATE.

Plsig <yesno>

Plsigdt()

Signature of Investigator

Date (mm/dd/yyyy)

| HCRI USE ONLY | |
|---------------------------------|--|
| Received: _____ / _____ / _____ | |
| By: _____ | |

CORAL

PANEL: Context
PS: Context

Site ID: _____ Pt. No.: _____ Randomization #: _____

Contact Form

Page 1 of 4

Time Interval:

| | | | | |
|--|--|---|---|--|
| <input type="checkbox"/> (1) 2 Week | <input type="checkbox"/> (7) 9 Mos | <input type="checkbox"/> (13) 2 Yrs 3 Mos | <input type="checkbox"/> (19) 3 Yrs 9 Mos | <input type="checkbox"/> (25) Study Completion |
| <input type="checkbox"/> (2) 4 Week | <input type="checkbox"/> (8) 1 Year | <input type="checkbox"/> (14) 2 Yrs 6 Mos | <input type="checkbox"/> (20) 4 Years | |
| <input type="checkbox"/> (3) 6 Week | <input type="checkbox"/> (9) 1 Yr 3 Mos | <input type="checkbox"/> (15) 2 Yrs 9 Mos | <input type="checkbox"/> (21) 4 Yrs 3 Mos | |
| <input type="checkbox"/> (4) 8 Week | <input type="checkbox"/> (10) 1 Yr 6 Mos | <input type="checkbox"/> (16) 3 Years | <input type="checkbox"/> (22) 4 Yrs 6 Mos | |
| <input type="checkbox"/> (5) 3 Mos | <input type="checkbox"/> (11) 1 Yr 9 Mos | <input type="checkbox"/> (17) 3 Yrs 3 Mos | <input type="checkbox"/> (23) 4 Yrs 9 Mos | |
| <input type="checkbox"/> (6) 6 Mos | <input type="checkbox"/> (12) 2 Years | <input type="checkbox"/> (18) 3 Yrs 6 Mos | <input type="checkbox"/> (24) 5 Years | |
| <input type="checkbox"/> (99) Other, specify _____ | | | | |

timept <interval46>

PS: Fup1
PT: Fup1
Panel: Fup1

intoth (vc, 50)

Questions should be asked as changes since last contact.

1. Was contact performed? (1) YES (2) NO → COMPLETE PROTOCOL DEVIATION FORM EXCEPT AT 4, 6 AND 8 WK

contact <yesno>

1.1. Date of contact _____ fumm/fudd/fuyy fudt()/yyyy)

1.2. Type of contact : (1) Office visit with hypertension MD
 (2) Office visit with interventional MD firstnm (vc, 50) lastnm (vc, 50)
 (3) Office visit with coordinator
 (99) Other, specify _____ cntctoht (vc, 50)

contype <contacttype6>

2. Has the subject taken the study medication since last contact? (1) YES (2) NO → SKIP TO 3

meds <yesno>

2.1. Has subject's study medication dose changed since last contact? (1) YES (2) NO

2.1.1. Indicate current study drug option:

| Option | Type | Dose | Frequency |
|--|---------|------------------------------------|--|
| <input type="checkbox"/> Study drug | Atacand | dose1 (fl 8, 2) | units1 (vc, 6) medfreq1 <coralmedfreq> |
| <input checked="" type="checkbox"/> drugvouch <checked1> | | dose2 (fl 8, 2) hctdose2 (fl 8, 2) | units2 (vc, 6) medfreq2 <coralmedfreq> |
| <input type="checkbox"/> Personal Atacand | Atacand | dose3 (fl 8, 2) | units3 (vc, 6) medfreq3 <coralmedfreq> |
| <input checked="" type="checkbox"/> script <checked1> | | dose4 (fl 8, 2) hctdose4 (fl 8, 2) | units4 (vc, 6) medfreq4 <coralmedfreq> |

2.2. Number of days study medication taken since last contact: _____ days (f, 5)

3. Has subject been prescribed to continue study medication at this contact? (1) YES (2) NO

contmed <yesno>

3.1.1. Indicate study drug option:

| Option | Type | Dose | Frequency |
|---|---------|--------------------------------------|--|
| <input type="checkbox"/> Study drug | Atacand | dose11 (fl 8, 2) | units11 (vc, 6) medfreq11 <coralmedfreq> |
| <input checked="" type="checkbox"/> drugvouch1 <checked1> | | dose21 (fl 8, 2) hctdose21 (fl 8, 2) | units21 (vc, 6) medfreq21 <coralmedfreq> |
| <input type="checkbox"/> Personal | Atacand | dose31 (fl 8, 2) | units31 (vc, 6) medfreq31 <coralmedfreq> |
| <input checked="" type="checkbox"/> script1 <checked1> | | dose41 (fl 8, 2) hctdose41 (fl 8, 2) | units41 (vc, 6) medfreq41 <coralmedfreq> |

IF SUBJECT DISCONTINUED STUDY MEDICATION AT ANY TIME, COMPLETE STUDY DRUG DISCONTINUATION FORM

| |
|---------------------------------|
| HCRI USE ONLY |
| Received: _____ / _____ / _____ |
| By: _____ |

CORAL

Site ID: _____ Pt. No.: _____ Randomization #: _____

Contact Form

Time Interval: (1) 2 Week (2) 4 Week (3) 6 Week (4) 8 Week (5) 3 Mos
 (6) 6 Mos (7) 1 Year (8) 1 Yrs 6 Mos (9) 2 Years (10) 2 Yrs 6 Mos
 (11) 3 Years (12) 3 Yrs 6 Mos (13) 4 Years (14) 4 Yrs 6 Mos (15) 5 Years
 (16) Study Completion (99) Other, specify intoth (vc, 50)

timeptV2 <interval59>

PS: Fup1V2
PT: Fup1V2
Panel: Fup1

Questions should be answered as changes since last contact.

1. Was contact performed? (1) YES (2) NO → COMPLETE PROTOCOL DEVIATION FORM EXCEPT AT 4, 6 AND 8 WK

contact <yesno>

1.1. Date of contact fumm/fudd/fuyy (mm/dd/yyyy) fudt()

fumm/fudd/fuyy

fudt()

1.2. Type of contact : (check one only)
 (1) Office visit
 (2) Telephone contact
 (99) Other, specify _____

contctV2 <contacttype8>

cntctoth (vc, 50)

2. Has there been any change to subject's study medication since the last contact? (1) YES (2) NO chngmeds <yesno>

chngmeds <yesno>

2.1. Indicate study drug:

| Drug | Dose (mg) | Frequency | Date Started (mm/dd/yyyy) |
|---|---|--------------------------------------|--|
| Atacand <input type="checkbox"/> Not prescribed | <u>dose1 (fl 8, 2)</u> <u>units1 (vc, 6)</u> | <u>medfreq1 <coralmedfreq></u> | <u>atacmm/atacdd/atacyy</u> <u>atacdt ()</u> |
| Atacand/HCT <input type="checkbox"/> Not prescribed | <u>dose2 (fl 8, 2)</u> <u>units2 (vc, 6)</u> | <u>medfreq2 <coralmedfreq></u> | <u>hctmm/hctdd/hctyy</u> <u>hctdt ()</u> |
| Caduet <input type="checkbox"/> Not prescribed | <u>dose5 (fl 8, 2)</u> <u>caddose (fl 8, 2)</u> <u>units5 (vc, 6)</u> | <u>medfreq5 <coralmedfreq></u> | <u>cadmm/caddd/cadyy</u> <u>caddt ()</u> |

noscrpt1 <checked1>

noscrpt2 <checked1>

noscrpt3 <checked1>

IF SUBJECT DISCONTINUED STUDY MEDICATION AT ANY TIME, COMPLETE STUDY DRUG DISCONTINUATION FORM

3. Has the subject taken any ~~other~~ anti-hypertensive medications since last contact? (1) YES (2) NO antihyp <yesno>

antihyp <yesno>

RECORD ON CONCOMITANT MEDICATION LOG

HCRI USE ONLY
 Received: _____ / _____ / _____
 By: _____

CORAL

Site ID: _____ Pt. No.: _____ Randomization #: _____

Contact Form

Time Interval: (1) 2 Week (2) 4 Week (3) 6 Week (4) 8 Week (5) 3 Mos
 (6) 6 Mos (7) 1 Year (8) 1 Yrs 6 Mos (9) 2 Years (10) 2 Yrs 6 Mos
 (11) 3 Years (12) 3 Yrs 6 Mos (13) 4 Years (14) 4 Yrs 6 Mos (15) 5 Years
 (16) Study Completion (99) Other, specify intoth (vc, 50)

timeptV2 <interval59>

PS: Fup1V4
PT: Fup1V4
Panel: Fup1

Questions should be answered as changes since last contact.

1. Was contact performed? (1) YES (2) NO → COMPLETE PROTOCOL DEVIATION FORM EXCEPT AT 4, 6 AND 8 WK

contact <yesno>

1.1. Date of contact fumm/fudd/fuyy (mm/dd/yyyy) fudt()

1.2. Type of contact : (check one only)
 (1) Office visit
 (2) Telephone contact
 (99) Other, specify cntctoth (vc, 50)

contctV2 <contacttype8>

2. STUDY MEDICATION – ANSWER ALL

2.1. Indicate study drug:

| Drug | Dose | Frequency | Date Started (mm/dd/yyyy) |
|---|------------------------|---------------------------------------|---|
| Atacand <input type="checkbox"/> Not prescribed | <u>dose1 (fl 8, 2)</u> | <u>medfreq1</u> <u>oralmedfreq</u> | <u>atacmm/atacdd/atacyy</u> <u>atacddt ()</u> |
| Atacand/HCT <input type="checkbox"/> Not prescribed | <u>dose2 (fl 8, 2)</u> | <u>medfreq2</u> <u>oralmedfreq</u> | <u>hctmm/hctdd/hctyy</u> <u>hctddt ()</u> |
| Caduet <input type="checkbox"/> Not prescribed | <u>dose5 (fl 8, 2)</u> | <u>units5 (vc, 6)</u> | <u>cadmm/caddd/cadyy</u> <u>cadddt ()</u> |

noscrpt1 <checked1>
noscrpt2 <checked1>
noscrpt3 <checked1>

IF SUBJECT DISCONTINUED STUDY MEDICATION, COMPLETE THIS DRUG DISCONTINUATION FORM

3. Has the subject taken any non-study anti-hypertensive medications since last contact? (1) YES (2) NO

antihyp <yesno>

RECORD ALL NEW OR CHANGED MEDICATIONS ON THE CONCOMITANT MEDICATION LOG

HCRI USE ONLY
 Received: _____ / _____ / _____
 By: _____

CORAL

Site ID: _____ Pt. No.: _____ Randomization #: _____

Contact Form

Time Interval:

| | | | | |
|--|---------------------------------------|--|--|---|
| <input type="checkbox"/> (1) 2 Week | <input type="checkbox"/> (2) 4 Week | <input type="checkbox"/> (3) 6 Week | <input type="checkbox"/> (4) 8 Week | <input type="checkbox"/> (5) 3 Mos |
| <input type="checkbox"/> (6) 6 Mos | <input type="checkbox"/> (7) 1 Year | <input type="checkbox"/> (8) 1 Yrs 6 Mos | <input type="checkbox"/> (9) 2 Years | <input type="checkbox"/> (10) 2 Yrs 6 Mos |
| <input type="checkbox"/> (11) 3 Years | <input type="checkbox"/> (13) 4 Years | <input type="checkbox"/> (15) 5 Years | <input type="checkbox"/> (16) Study Completion | |
| <input type="checkbox"/> (18) 6 Years | <input type="checkbox"/> (19) 7 Years | <input type="checkbox"/> (20) 8 Years | | |
| <input type="checkbox"/> (99) Other, specify _____ | | | | |

timeptV2 <interval59>

intoth (vc, 50)

PS: Fup1V4
PT: Fup1V4
Panel: Fup1



Questions should be answered as changes since last contact.

1. Was contact performed? (1) YES (2) NO → COMPLETE PROTOCOL DEVIATION FORM EXCEPT AT 4, 6 AND 8 WK

1.1. Date of contact: fumm/fudd/fuyy / / (mm/dd/yyyy) fudt()

1.2. Type of contact: (check one only)
 (1) Office visit
 (2) Telephone contact
 (99) Other, specify _____ cntctoth (vc, 50)

contact <yesno>

contctV2 <contacttype8>

2. STUDY MEDICATION – ANSWER ALL

2.1. Indicate study drug:

| Drug | dose1 (fl 8, 2) | units1 (vc, 6) | medfreq1 <coralmedfreq> | Date Started | atacd () |
|---|-----------------|--------------------|-------------------------|---------------------|-----------|
| Atacand <input type="checkbox"/> Not prescribed | | | | atamm/atacdd/atacyy | |
| Atacand/HCT <input type="checkbox"/> Not prescribed | dose2 (fl 8, 2) | hctdose2 (fl 8, 2) | medfreq2 <coralmedfreq> | hctmm/hctdd/hctyy | hctdt () |
| Caduet <input type="checkbox"/> Not prescribed | dose5 (fl 8,2) | units2 (vc, 6) | medfreq5 <coralmedfreq> | cadmm/caddd/cadyy | caddt () |

noscript1 <checked1>

noscript2 <checked1>

noscript3 <checked1>

IF SUBJECT DISCONTINUED STUDY MEDICATION AT ANY TIME COMPLETE STUDY DRUG DISCONTINUATION FORM

3. Has the subject taken any non-study anti-hypertensive medications since last contact? (1) YES (2) NO antihyp <yesno>

RECORD ALL NEW OR CHANGED MEDICATIONS ON THE CONCOMITANT MEDICATION LOG

HCRI USE ONLY
 Received: ____ / ____ / ____
 By: _____

CORAL

PANEL: Context
PS: Context

Site ID: _____ Pt. No.: _____ Randomization #: _____

Contact Form

Page 2 of 4

| | | | | | |
|-----------------------|--|--|---|---|--|
| Time Interval: | <input type="checkbox"/> (1) 2 Week | <input type="checkbox"/> (7) 9 Mos | <input type="checkbox"/> (13) 2 Yrs 3 Mos | <input type="checkbox"/> (19) 3 Yrs 9 Mos | <input type="checkbox"/> (25) Study Completion |
| timept <interval46> | <input type="checkbox"/> (2) 4 Week | <input type="checkbox"/> (8) 1 Year | <input type="checkbox"/> (14) 2 Yrs 6 Mos | <input type="checkbox"/> (20) 4 Years | |
| | <input type="checkbox"/> (3) 6 Week | <input type="checkbox"/> (9) 1 Yr 3 Mos | <input type="checkbox"/> (15) 2 Yrs 9 Mos | <input type="checkbox"/> (21) 4 Yrs 3 Mos | |
| | <input type="checkbox"/> (4) 8 Week | <input type="checkbox"/> (10) 1 Yr 6 Mos | <input type="checkbox"/> (16) 3 Years | <input type="checkbox"/> (22) 4 Yrs 6 Mos | |
| | <input type="checkbox"/> (5) 3 Mos | <input type="checkbox"/> (11) 1 Yr 9 Mos | <input type="checkbox"/> (17) 3 Yrs 3 Mos | <input type="checkbox"/> (23) 4 Yrs 9 Mos | |
| | <input type="checkbox"/> (6) 6 Mos | <input type="checkbox"/> (12) 2 Yrs | <input type="checkbox"/> (18) 3 Yrs 6 Mos | <input type="checkbox"/> (24) 5 Years | |
| | <input type="checkbox"/> (99) Other, specify _____ | intoth (vc, 50) | | | PS: Fup2 PT: Fup2 Panel: Fup2 |

| TEST/EVALUATION/PROCEDURES | Performed? | IF YES | IF NO |
|--|--|--|---|
| 4. Blood Pressure Assessment? | <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO bp <yesno> | 4.1. Date of Assessment: <input type="checkbox"/> bpdtd() (mm/dd/yyyy) 4.2. Time Sys/Dias Heart Rate bp1hr:bp1mn sys1(f 5) dias1(f 5) hrtrt1(f 5) bp2hr:bp2mn sys2(f 5) dias2(f 5) hrtrt2(f 5) bp3hr:bp2mn sys3(f 5) dias3(f 5) hrtrt3(f 5) | COM DEV DM: BP in range: dmbprng <yesno> labelnum (f, 8) PLACE BIOCHEM LABEL HERE ↓ |
| 5. Biochem Core Lab Bloodwork | <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO labblood <yesno> | 5. <input type="checkbox"/> bloodtd and time of collection: bloodmm/blooddd/bloodyy bloodhr:bloodmn | COMPLETE PROTOCOL DEVIATION FORM IF 2 W; 3, 6, 9 M; 1, 2, 3, 4, 5 YEAR OR STUDY COMPLETION |
| 6. Lipid Profile For to Biochem Core Lab | <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO lipid <yesno> | 6.1. Did subject fast prior to lipid collection? <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO fast <yesno> | COMPLETE PROTOCOL DEVIATION FORM IF 1, 2, 3, 4, 5 YEAR OR STUDY COMPLETION |
| 7. Local Lab Creatinine | <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO creat <yesno> | 7.1. Date of collection: creattd() creatmm/creatdd/creaty (mm/dd/yyyy) creathr:creatmn (24 hour) 7.2. V creatval (fl 6, 2) Unit: creatunt (vc 5) | |
| 8. Local Lab Urine Dipstick | <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO urinedip <yesno> | dipmm/dipdd/dipy dipdt() diphr:dipmn (mm/dd/yyyy) (24 hour) 8.2. Protein (mg/dl) <input type="checkbox"/> (1) Neg <input type="checkbox"/> (2) Trace <input type="checkbox"/> (3) 30 <input type="checkbox"/> (4) 100 <input type="checkbox"/> (5) 300 <input type="checkbox"/> (6) ≥2000 protein <urineprotein> | COMPLETE PROTOCOL DEVIATION FORM IF 1, 2, 3, 4, 5 YEAR OR STUDY COMPLETION |
| 9. Duplex scan | <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO duplex <yesno> | | COMPLETE PROTOCOL DEVIATION FORM IF 1 YEAR OR STUDY COMPLETION IF PART OF SUB-STUDY |
| 10. 12-Lead ECG | <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO ecg <yesno> | 10.1. Date: ecgmm/ecgdd/ecgyy (mm/dd/yyyy) ecgtd() 10.2. Time: ecghr:ecgmn (24 hour) | COMPLETE PROTOCOL DEVIATION FORM IF 6M, 1, 2, 3, 4, 5 YEAR OR STUDY COMPLETION |

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|---------------------------------|
| HCRI USE ONLY |
| Received: _____ / _____ / _____ |
| By: _____ |

CORAL

Site ID: _____ Pt. No.: _____ Randomization #: _____

Contact Form

Time Interval: (1) 2 Week (2) 4 Week (3) 6 Week (4) 8 Week (5) 3 Mos
 (6) 6 Mos (7) 1 Year (8) 1 Yrs 6 Mos (9) 2 Years (10) 2 Yrs 6 Mos
 (11) 3 Years (12) 3 Yrs 6 Mos (13) 4 Years (14) 4 Yrs 6 Mos (15) 5 Years
 (16) Study Completion
 (99) Other, specify intoth (vc, 50)

timeptV2 <interval59>

PS: Fup2V2
PT: Fup2V2
Panel: Fup2

| TEST/EVALUATION/PROCEDURES | Performed? | IF YES | | |
|---|---|--|---|---|
| 4. Blood pressure assessment? | <input type="checkbox"/> (1) <u>bp <yesno></u> <input type="checkbox"/> (2) NO | 4.1. Date of Assessment: <u>bpdtd()</u> <u>bpmm/bpdd/bpyy</u> (mm/dd/yyyy) 4.2. Time Sys/Dias <u>bp1hr:bp1mn</u> <u>sys1(f 5)</u> <u>dias1(f 5)</u> <u>bp2hr:bp2mn</u> <u>sys2(f 5)</u> <u>dias2(f 5)</u> <u>bp3hr:bp3mn</u> <u>sys3(f 5)</u> <u>dias3(f 5)</u> | DM: BP in range: <u>dmbprng <yesno></u> | ROTOCOL FORM <u>labelnum (f, 8)</u> PLACE BIOCHEM LABEL HERE ↓ |
| 5. Biochem Core Lab bloodwork | <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO <u>labblood<yesno></u> | | COMPLETE PROTOCOL DEVIATION FORM | |
| 6. Biochem Core Lab lipid profile and urine | <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO <u>lipid <yesno></u> | 6.1. Did subject fast prior to lipid collection? <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO <u>fast<yesno></u> | COMPLETE PROTOCOL DEVIATION FORM IF 1, 2, 3, 4, 5 YEAR OR STUDY COMPLETION | |
| 7. Local lab creatinine | <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO <u>creat <yesno></u> | 7.1. Value: <u>creatval (fl 6, 2)</u> Unit: <u>creatunt (vc 10)</u> | | |
| 8. Local lab urine dipstick | <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO <u>urinedip <yesno></u> | 8.1. Protein (mg/dl) <input type="checkbox"/> (1) Neg <input type="checkbox"/> (2) Trace <input type="checkbox"/> (3) 30 <input type="checkbox"/> (4) 100 <input type="checkbox"/> (5) 300 <input type="checkbox"/> (6) ≥2000 <u>protein <urineprotein></u> | COMPLETE PROTOCOL DEVIATION FORM IF 1, 2, 3, 4, 5 YEAR OR STUDY COMPLETION | |
| 9. Duplex scan | <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO <u>duplex <yesno></u> | | IF PART OF SUB-STUDY, COMPLETE PROTOCOL DEVIATION FORM IF 1 YEAR OR STUDY COMPLETION | |
| 10. 12-lead ECG | <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO <u>ecg <yesno></u> | | COMPLETE PROTOCOL DEVIATION FORM IF 6M, 1, 2, 3, 4, 5 YEAR OR STUDY COMPLETION | |

HCRI USE ONLY
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By: _____

CORAL

Site ID: _____ Pt. No.: _____ Randomization #: _____

Contact Form

Time Interval: (1) 2 Week (2) 4 Week (3) 6 Week (4) 8 Week (5) 3 Mos
 (6) 6 Mos (7) 1 Year (8) 1 Yrs 6 Mos (9) 2 Years (10) 2 Yrs 6 Mos
 (11) 3 Years (13) 4 Years (15) 5 Years
 (18) 6 Years (19) 7 Years (20) 8 Years (16) Study Completion
 (99) Other, specify intoth (vc, 50)

timeptV2 <interval59>

PS: Fup2V5
PT: Fup2V5
Panel: Fup2

| TEST/EVALUATION/PROCEDURES | Performed? | IF YES | IF NO |
|-------------------------------|--|---|---|
| 4. Blood Pressure Assessment? | <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO bp <yesno> | 4. <u>bpmm/bpdd/bpyy</u> <u>ssn</u> <u>bpd()</u> (mm/dd/yyyy) 4.2. Time <u>sys1(f 5)</u> / <u>dias1(f 5)</u> <u>bp1hr:bp1mn</u> <u>sys2 (f 5)</u> / <u>dias2 (f 5)</u> <u>bp2hr:bp2mn</u> <u>sys3 (f 5)</u> / <u>dias3 (f 5)</u> <u>bp3hr:bp3mn</u> | COMPLETE PROTOCOL DEVIATION FORM DM: BP in range: dmbprng <yesno> PLACE BIOCHEM LABEL HERE ↓ labelnum (f, 8) |
| 5. Biochem Core Lab Bloodwork | <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO labblood <yesno> | | COMPLETE PROTOCOL DEVIATION FORM IF 2 W; 3, 6, 9 M; 1, 2, 3, 4, 5 YEAR OR STUDY COMPLETION |
| 7. Local Lab Creatinine | <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO creat <yesno> | 7.1. Value: <u>creatval (f 6, 2)</u> Ur <u>creatunt (vc 10)</u> | |
| 8. Local Lab Urine Dipstick | <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO urinedip <yesno> | 8.1. Protein (mg/dl) <input type="checkbox"/> (1) Neg <input type="checkbox"/> (2) Trace <input type="checkbox"/> (3) 30 <input type="checkbox"/> (4) 100 <u>protein <urineprotein></u> <input type="checkbox"/> (5) 300 <input type="checkbox"/> (6) ≥200 | |
| 9. Duplex scan | <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO duplex <yesno> | | COMPLETE PROTOCOL DEVIATION FORM IF 1 YEAR OR STUDY COMPLETION IF PART OF SUB-STUDY |
| 10. 12-Lead ECG | <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO ecg <yesno> | | COMPLETE PROTOCOL DEVIATION FORM IF 6M, 1, 2, 3, 4, 5 YEAR OR STUDY COMPLETION |

HCRI USE ONLY
Received: _____ / _____ / _____
By: _____

CORAL

PANEL: Context
PS: Context

Site ID: _____ Pt. No.: _____ Randomization #: _____

Contact Form

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| | | | | |
|---|---|--|--|--|
| Time Interval: <input type="checkbox"/> (1) 2 Week <input type="checkbox"/> (2) 4 Week <input type="checkbox"/> (3) 6 Week <input type="checkbox"/> (4) 8 Week <input type="checkbox"/> (5) 3 Mos <input type="checkbox"/> (6) 6 Mos <input type="checkbox"/> (99) Other, specify | <input type="checkbox"/> (7) 9 Mos <input type="checkbox"/> (8) 1 Year <input type="checkbox"/> (9) 1 Yr 3 Mos <input type="checkbox"/> (10) 1 Yr 6 Mos <input type="checkbox"/> (11) 1 Yr 9 Mos <input type="checkbox"/> (12) 2 Years | <input type="checkbox"/> (13) 2 Yrs 3 Mos <input type="checkbox"/> (14) 2 Yrs 6 Mos <input type="checkbox"/> (15) 2 Yrs 9 Mos <input type="checkbox"/> (16) 3 Years <input type="checkbox"/> (17) 3 Yrs 3 Mos <input type="checkbox"/> (18) 3 Yrs 6 Mos | <input type="checkbox"/> (19) 3 Yrs 9 Mos <input type="checkbox"/> (20) 4 Years <input type="checkbox"/> (21) 4 Yrs 3 Mos <input type="checkbox"/> (22) 4 Yrs 6 Mos <input type="checkbox"/> (23) 4 Yrs 9 Mos <input type="checkbox"/> (24) 5 Years | <input type="checkbox"/> (25) Study Completion |
|---|---|--|--|--|

intoth (vc, 50)

PS: Fup3
PT: Fup3
Panel: Fup3

| TEST/EVALUATION | Performed? | IF YES | IF NO |
|------------------------|--|---|--|
| 11. Physical Exam | <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO phys <yesno> | RECORD ANY SIGNIFICANT CHANGES ON AE LOG | COMPLETE PROTOCOL DEVIATION FORM FOR ALL PHYSICIAN OFFICE VISITS EXCEPT Wk 6 |
| 12. Renal Angiography | <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO angio <yesno> | 12.1. # of procedures: angnum (f, 5) COMPLETE REPEAT ANGIOGRAPHY FORM FOR EACH PROCEDURE | |
| 13. Renal Intervention | <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO interven <yesno> | 13.1. # of procedures: intrvnum (f, 5) COMPLETE REPEAT REVASCULARIZATION FORM FOR EACH PROCEDURE | |

14. Were there any new adverse events or changes to adverse events since the last contact? (1) YES (2) NO anyaes <yesno>

↓
COMPLETE ADVERSE EVENT LOG

15. Were there any changes or additions to the concomitant medications since last visit? (1) YES (2) NO medchx <yesno>

↓
COMPLETE CONCOMITANT MEDICATION LOG

Medical Care Resource Utilization – Complete for ALL Contacts

16. Was subject hospitalized? (1) YES (2) NO rehossp <yesno>

| | | |
|----------------------------------|----------------|--|
| 16.1 Number of hospitalizations: | hospnum (f, 5) | COMPLETE SUBJECT HOSPITALIZATION FORM FOR EACH HOSPITALIZATION |
|----------------------------------|----------------|--|

17. Number of Emergency Room visits, renal, cardiac or vascular related, NOT resulting in hospitalization: ERvisits (f, 5)

18. Number of **outpatient** physician visits: outptvis (f, 5)

| |
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| HCRI USE ONLY |
| Received: _____ / _____ / _____ |
| By: _____ |

CORAL

Site ID: _____ Pt. No.: _____ Randomization #: _____

Contact Form

Time Interval: (1) 2 Week (2) 4 Week (3) 6 Week (4) 8 Week (5) 3 M
 (6) 6 Mos (7) 1 Year (8) 1 Yrs 6 Mos (9) 2 Years (10) 2 Y
 (11) 3 Years (12) 3 Yrs 6 Mos (13) 4 Years (14) 4 Yrs 6 Mos (15) 5 Y
 (16) Study Completion
 (99) Other, specify intoth (vc, 50)

timeptV2 <interval59>

PS: Fup3V2
PT: Fup3V2
Panel: Fup3

| TEST/EVALUATION/PROCEDURES | Performed? | IF YES | IF NO |
|----------------------------|--|---|--|
| 11. Physical exam | <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO phys <yesno> | RECORD ANY CHANGES ON AE LOG | COMPLETE PROTOCOL DEVIATION FORM FOR ALL PROTOCOL-REQUIRED OFFICE VISITS |
| 12. Renal angiography | <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO angio <yesno> | 12.1. # of procedures: angnum (f, 5) COMPLETE REPEAT ANGIOGRAPHY FORM FOR EACH PROCEDURE | |
| 13. Renal intervention | <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO interven <yesno> | 13.1. # of procedures: intrvnum (f, 5) COMPLETE REPEAT REVASCULARIZATION FORM FOR EACH PROCEDURE | |

14. Did any endpoint events occur since last contact? (1) YES (2) NO anyendpt <yesno>

COMPLETE AE LOG AND APPROPRIATE ENDPOINT FORMS

15. Did any other AEs occur since last contact? (1) YES (2) NO anyaes <yesno>

COMPLETE AE LOG AND FAX SAE FORM IF SERIOUS

Medical Care Resource Utilization - Complete for ALL Contacts

16. Was subject hospitalized? (1) YES (2) NO rehospt <yesno>

16.1 Number of hospitalizations: hospnum (f, 5)
COMPLETE SUBSEQUENT HOSPITALIZATION FORM FOR EACH HOSPITALIZATION
COMPLETE AND FAX SAE FORM

17. Number of Emergency Room visits, renal, cardiac or vascular related, NOT resulting in hospitalization: ERvisits (f, 5)

18. Number of **outpatient** physician visits: outptvis (f, 5)

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By: _____

CORAL

Site ID: _____ Pt. No.: _____ Randomization #: _____

Contact Form

Time Interval: (1) 2 Week (2) 4 Week (3) 6 Week (4) 8 Week (5) 3 Mos
 (6) 6 Mos (7) 1 Year (8) 1 Yrs 6 Mos (9) 2 Years (10) 3 Yrs
 (11) 3 Years (12) 3 Yrs 6 Mos (13) 4 Years (14) 4 Yrs 6 Mos (15) 5 Yrs
 (16) Study Completion
 (99) Other, specify intoth (vc, 50)

PS: Fup3V4
PT: Fup3V4
Panel: Fup3

| TEST/EVALUATION/PROCEDURES | Performed? | IF YES | IF NO |
|----------------------------|---|--|--|
| 11. Physical Exam | <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO <u>phys <yesno></u> | RECORD ANY CHANGES ON AE LOG | COMPLETE PROTOCOL DEVIATION FORM FOR ALL PROTOCOL-REQUIRED OFFICE VISITS |
| 12. Renal Angiography | <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO <u>angio <yesno></u> | 12.1. # of procedures: <u>angnum (f, 5)</u> COMPLETE REPEAT ANGIOGRAPHY FORM FOR EACH PROCEDURE | |
| 13. Renal Intervention | <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO <u>interven <yesno></u> | 13.1. # of procedures: <u>intrvnum (f, 5)</u> COMPLETE REPEAT REVASCULARIZATION FORM FOR EACH PROCEDURE | |

14. Did any AEs occur since last contact? (1) YES (2) NO anyaes <yesno>
 ↓
 COMPLETE AE LOG AND FAX SAE FORM IF SERIOUS

Medical Care Resource Utilization - Complete for ALL Contacts

15. Was subject hospitalized? (1) YES (2) NO rehosp <yesno>

15.1 Number of hospitalizations: _____ hospnum (f, 5)
 COMPLETE SUBSEQUENT HOSPITALIZATION FORM FOR EACH HOSPITALIZATION
 COMPLETE AND FAX SAE FORM

16. Number of Emergency Room visits, renal, cardiac or vascular related, NOT resulting in hospitalization: _____ ERvisits (f, 5)

17. Number of **outpatient** physician visits: _____ outptvis (f, 5)

HCRI USE ONLY
 Received: _____ / _____ / _____
 By: _____

CORAL

PANEL: Context
PS: Context

Site ID: _____ Pt. No.: _____ Randomization #: _____

Contact Form

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| | | | | | |
|--|---|--|---|---|--|
| Time Interval: | <input type="checkbox"/> (1) 2 Week | <input type="checkbox"/> (7) 9 Mos | <input type="checkbox"/> (13) 2 Yrs 3 Mos | <input type="checkbox"/> (19) 3 Yrs 9 Mos | <input type="checkbox"/> (25) Study Completion |
| timept <interval46> | <input type="checkbox"/> (2) 4 Week | <input type="checkbox"/> (8) 1 Year | <input type="checkbox"/> (14) 2 Yrs 6 Mos | <input type="checkbox"/> (20) 4 Years | |
| | <input type="checkbox"/> (3) 6 Week | <input type="checkbox"/> (9) 1 Yr 3 Mos | <input type="checkbox"/> (15) 2 Yrs 9 Mos | <input type="checkbox"/> (21) 4 Yrs 3 Mos | |
| | <input type="checkbox"/> (4) 8 Week | <input type="checkbox"/> (10) 1 Yr 6 Mos | <input type="checkbox"/> (16) 3 Years | <input type="checkbox"/> (22) 4 Yrs 6 Mos | |
| | <input type="checkbox"/> (5) 3 Mos | <input type="checkbox"/> (11) 1 Yr 9 Mos | <input type="checkbox"/> (17) 3 Yrs 3 Mos | <input type="checkbox"/> (23) 4 Yrs 9 Mos | |
| | <input type="checkbox"/> (6) 6 Mos | <input type="checkbox"/> (12) 2 Years | <input type="checkbox"/> (18) 3 Yrs 6 Mos | <input type="checkbox"/> (24) 5 Years | |
| | <input type="checkbox"/> (99) Other, specify intoth (vc, 50) | | | | |

PS: Fup4
PT: Fup4
Panel: Fup4

Outpatient Resource Utilization – Complete For All Contacts

| Procedure | Quantity | Procedure | Quantity |
|---|--|---|--|
| 19. Renal Diagnostic Angiography (COMPLETE REPEAT RENAL ANGIOGRAPHY FORM) | renangio (f, 5) | 26. Number of Stress Tests <u>with</u> Imaging: | stressw (f, 5) |
| 20. Renal Duplex Scan (excluding protocol required Duplex Scan) | us (f, 5) | 27. Number of nuclear imaging tests | nuclear (f, 5) |
| 21. Renal MRA | mra (f, 5) | 28. Hemodialysis | hemodial (f, 5) |
| 22. CT Angiography | ctang (f, 5) | 29. Peritoneal dialysis | peridial (f, 5) |
| 23. Coronary Diagnostic Angiography | corangio (f, 5) | 30. Other (specify) spec1 (vc, 50) | othval1 (f, 5) |
| 24. Number of Echo Procedures (excluding stress echo's): | echo (f, 5) | 31. Other (specify) spec2 (vc, 50) | othval2 (f, 5) |
| 25. Number of Stress Tests <u>without</u> Imaging | stresswo (f, 5) | 32. Other (specify) spec3 (vc, 50) | othval3 (f, 5) |

33. Is the subject currently receiving erythropoietin injections? (1) YES (2) NO erythro <yesno>

These questions should be answered via subject or proxy interview

34. Since last contact, please indicate the number of days spent:

| | |
|---|---|
| 34.1. At home with home health services (e.g. visiting nurses, home health aides, PT, OT): | dayshome (f, 5) |
| 34.2. At a rehabilitation hospital/facility: | daysrehb (f, 5) |
| 34.3. At a skilled nursing facility: | daysnurs (f, 5) |
| 34.4. At other chronic care facility: Specify type of facility: _____ | specoth (vc, 50) |

35. Since the last visit, please estimate the weekly number of hours spent in caregiving by family members: _____ famhrs (f, 5) hours/week

36. Since last visit, please estimate the number of work days missed by family caregivers: _____ famdays (f, 5)

37. Since last visit, please indicate the subject's work status:

(1) Retired (due to non-health reasons)
 (2) Not working because of his/her health
 (3) Currently working

↓

37.1. Number of work days missed since last visit due to health reasons: _____ workdays (f, 5)

| HCRI USE ONLY |
|---------------------------------|
| Received: _____ / _____ / _____ |
| By: _____ |

CORAL

Site ID: _____ Pt. No.: _____ Randomization #: _____

Contact Form

Time Interval: (1) 2 Week (2) 4 Week (3) 6 Week (4) 8 Week (5) 3 Mos
 (6) 6 Mos (7) 1 Year (8) 1 Yrs 6 Mos (9) 2 Years (10) 2 Yrs 6 Mos
 (11) 3 Years (12) 3 Yrs 6 Mos (13) 4 Years (14) 4 Yrs 6 Mos (15) 5 Years
 (16) Study Completion
 (99) Other, specify intoth (vc, 50)

timeptV2 <interval59>

PS: Fup4V2
PT: Fup4V2
Panel: Fup4

Outpatient Resource Utilization - Complete For All Contacts

| <u>Procedure</u> | <u>Quantity</u> | <u>Procedure</u> | <u>Quantity</u> |
|---|------------------------|---|------------------------|
| 19. Renal Diagnostic Angiography (COMPLETE REPEAT RENAL ANGIOGRAPHY FORM) | <u>renangio (f, 5)</u> | 26. Number of Stress Tests <u>with</u> Imaging: | <u>stressw (f, 5)</u> |
| 20. Renal Duplex Scan (EXCLUDING DUPLEX SUB-STUDY SCAN) | <u>us (f, 5)</u> | 27. Number of nuclear imaging tests | <u>nuclear (f, 5)</u> |
| 21. Renal MRA | <u>mra (f, 5)</u> | 28. Hemodialysis | <u>hemodial (f, 5)</u> |
| 22. CT Angiography | <u>ctang (f, 5)</u> | 29. Peritoneal dialysis | <u>peridial (f, 5)</u> |
| 23. Coronary Diagnostic Angiography | <u>corangio (f, 5)</u> | 30. Other (specify) <u>spec1 (vc, 50)</u> | <u>othval1 (f, 5)</u> |
| 24. Number of Echo Procedures (excluding stress echo's): | <u>echo (f, 5)</u> | 31. Other (specify) <u>spec2 (vc, 50)</u> | <u>othval2 (f, 5)</u> |
| 25. Number of Stress Tests <u>without</u> Imaging: | <u>stresswo (f, 5)</u> | 32. Other (specify) <u>spec3 (vc, 50)</u> | <u>othval3 (f, 5)</u> |

33. Is the subject currently receiving erythropoietin injections? (1) YES (2) NO erythro <yesno>

34. Since last contact, please indicate the number of days spent:

34.1. At home with home health services: dayshome (f, 5)

34.2. At a rehabilitation hospital/facility: daysrehb (f, 5)

34.3. At a skilled nursing facility: daysnurs (f, 5)

34.4. At other chronic care facility: daysothr (f, 5)
Specify type of facility: specoth (vc, 50)

HCRI USE ONLY
Received: _____ / _____ / _____
By: _____

CORAL

Site ID: _____ Pt. No.: _____ Randomization #: _____

Contact Form

Time Interval: (1) 2 Week (2) 4 Week (3) 6 Week (4) 8 Week (5) 3 Mos
 (6) 6 Mos (7) 1 Year (8) 1 Yrs 6 Mos (9) 2 Years (10) 2 Yrs 6 Mos
 (11) 3 Years (13) 4 Years (15) 5 Years
 (18) 6 Years (19) 7 Years (20) 8 Years (16) Study Completion
 (99) Other, specify _____

timeptV2 <interval59>

intoth (vc, 50)

PS: Fup4V5
PT: Fup4V5
Panel: Fup4

Outpatient Resource Utilization - Complete For All Contacts

| Procedure | Quantity | Procedure | Quantity |
|--|--|---|-------------------------------|
| 18. Renal Diagnostic Angiography (COMPLETE REPEAT RENAL ANGIOGRAPHY FORM) | renangio (f, 5) | 25. Number of Stress Tests <u>with</u> Imaging: | stressw (f, 5) |
| 19. Renal Duplex Scan (EXCLUDING DUPLEX SUB-STUDY SCAN) | us (f, 5) | 26. Number of nuclear imaging tests | nuclear (f, 5) |
| 20. Renal MRA | mra (f, 5) | 27. Hemodialysis | hemodial (f, 5) |
| 21. CT Angiography | ctang (f, 5) | 28. Peritoneal dialysis | peridial (f, 5) |
| 22. Coronary Diagnostic Angiography | corangio (f, 5) | 29. Other (specify) _____ | spec1 (vc, 50) othval1 (f, 5) |
| 23. Number of Echo Procedures (excluding stress echo's): | echo (f, 5) | 30. Other (specify) _____ | spec2 (vc, 50) othval2 (f, 5) |
| 24. Number of Stress Tests <u>without</u> Imaging: | stresswo (f, 5) | 31. Other (specify) _____ | spec3 (vc, 50) othval3 (f, 5) |
| 32. Is the subject currently receiving erythropoietin injections? | <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO | | erythro <yesno> |
| 33. Since last contact, please indicate the number of days spent: | | | |
| 33.1. At home with home health services: | | dayshome (f, 5) | daysrehb (f, 5) |
| 33.2. At a rehabilitation hospital/facility: | | | |
| 33.3. At a skilled nursing facility: | | daysnurs (f, 5) | |
| 33.4. At other chronic care facility: Specify type of facility: _____ | | | daysothr (f, 5) |
| | specoth (vc, 50) | | |

HCRI USE ONLY
 Received: _____ / _____ / _____
 By: _____

CORAL

Site ID: _____ Pt. No.: _____ Randomization #: _____

Supplemental Contact Form

Time Interval: (1) 2 Week (2) 4 Week (3) 6 Week (4) 8 Week (5) 3 Mos
 (6) 6 Mos (7) 1 Year (8) 1 Yrs 6 Mos (9) 2 Years (10) 2 Yrs 6 Mos
 (11) 3 Years (12) 3 Yrs 6 Mos (13) 4 Years (14) 4 Yrs 6 Mos (15) 5 Years
 (16) Study Completion
 (99) Other, specify intoth (vc, 50)

timeptV2 <interval59>

intoth (vc, 50)

PS: Fup5
PT: Fup5
Panel: Fup5

1. Date of form completion: formmm/formdd/formyy formdt() (mm/dd/yyyy)
 2. Date information collected: collmm/colldd/collyy colldt() (mm/dd/yyyy)

| 3. Endpoint Events | If YES, provide requested information and complete appropriate ENDPOINT DATA COLLECTION FORM |
|---|--|
| 3.1 Did subject die? <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO | Date of death: ____ / ____ <u>deathmm/deathdd/deathyy</u> <u>deathdt()</u> Was this death reported to HCRI as an SAE? <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO |
| 3.2 Has the subject experienced MI? <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO | Number of MIs: _____ <u>nummi (f, 5)</u> Were all events reported to HCRI as SAEs? <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO |
| 3.3 Has the subject been hospitalized for CHF? <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO | Number of hospitalizations: _____ <u>numhosp (f, 5)</u> Were all hospitalizations reported to HCRI? <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO |
| 3.4 Has the subject experienced a stroke? <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO | Number of strokes: _____ <u>numstroke (f, 5)</u> Were all strokes reported to HCRI as SAEs? <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO |
| 3.5 Does the report from the Biochem Core Lab indicate that the subject's Creatinine has doubled? <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO | Was an additional sample drawn and sent to Core Lab 60 days after initial sample? <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO Was this doubling reported to HCRI? <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO |
| 3.6 Did the patient undergo a renal replacement procedure for chronic renal failure? <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO | Please specify procedure: <input type="checkbox"/> Renal Transplant <input type="checkbox"/> Hemodialysis <input type="checkbox"/> Peritoneal dialysis Was this reported to HCRI? <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO |

die <yesno>

mi <yesno>

hospchf <yesno>

stroke <yesno>

creatdoub <yesno>

renalproc <yesno>

deathmm/deathdd/deathyy deathdt()

deathrep <yesno>

nummi (f, 5)

eventsrep <yesno>

numhosp (f, 5)

hosprep <yesno>

numstroke (f, 5)

strokerep <yesno>

addsample <yesno>

dblrep <yesno>

specproc <checked1>

procrep <yesno>

4. Has subject quit smoking since last contact? (1) YES (2) NO NA smoke <yesnona8>

4.1 Has subject been given materials on smoking cessation per protocol? (1) YES (2) NO smokecess <yesno>

HCRI USE ONLY
 Received: ____ / ____ / ____
 By: _____

CORAL

PANEL: Context
PS: Context

Site ID: _____ Pt. No.: _____ Randomization #: _____

Study Exit Form

P
PS: Term
PT: Term
Panel: Term

1. Date of final contact:

termmm/termdd/termy termdt()
(mm/dd/yyyy)

INDICATE THE REASON THIS SUBJECT IS EXITING THE STUDY (ANSWER ALL):

1.1. Subject withdrew consent to participate in the trial **before** treatment: (1) YES (2) NO pretx <yesno>

1.2. Subject withdrew consent to participate in the trial **after** treatment: (1) YES (2) NO posttx <yesno>

1.3. Subject completed all required follow-up for the trial: (1) YES (2) NO fucompl <yesno>

1.4. Subject lost to follow-up: (1) YES (2) NO lost <yesno>

1.4.1. Three phone calls without response: (1) YES (2) NO calls <yesno>
1.4.2. Sent registered letter: letter <yesno> (1) YES (2) NO

1.5. Death: (1) YES (2) NO death <yesno>

1.5.1. Date of death: deathmm/deathdd/deathy (mm/dd/yyyy) deathdt()

COMPLETE ENDPOINT DATA COLLECTION FORM

1.6. Other: (1) YES (2) NO other <yesno>

othtext (vc, 200)

I HAVE REVIEWED THE INFORMATION IN THIS CASE REPORT FORM AND ALL ATTACHED DOCUMENTS AND CERTIFY THAT THE INFORMATION CONTAINED HEREIN IS ACCURATE.

Plsig <yesno>

Plsigdt()

Signature of Investigator

Date (mm/dd/yyyy)

HCRI USE ONLY
Received: ____/____/____
By: _____

CORAL

Site ID: _____ Pt. No.: _____ Randomization #: _____

Study Exit Form

P
PS: Term
PT: Term
Panel: Term

1. Date of final contact:



termmm/termdd/termyy
_____/_____/_____

termdt()
(mm/dd/yyyy)

INDICATE THE REASON THIS SUBJECT IS EXITING THE STUDY (ANSWER ALL):

1.1. Subject withdrew consent to participate in the trial **before** treatment:

(1) YES

(2) NO

pretx <yesno>

1.2. Subject withdrew consent to participate in the trial **after** treatment:

(1) YES

(2) NO

posttx <yesno>

1.3. Subject completed all required follow-up for the trial:

(1) YES

(2) NO

fucompl <yesno>

1.4. Subject lost to follow-up:

(1) YES

(2) NO

lost <yesno>

1.4.1. Three phone calls without response:

(1) YES

(2) NO

calls <yesno>

1.4.2. Sent registered letter:

(1) YES

(2) NO

letter <yesno>

1.5. Death:

(1) YES

(2) NO

death <yesno>

1.5.1. Date of death:

deathmm/deathdd/deathyy
_____/_____/_____

(mm/dd/yyyy)

deathdt()
____/____/____

COMPLETE ENDPOINT DATA COLLECTION FORM, COMPLETE AND FAX SAE FORM

1.6. Other:

(1) YES

(2) NO

other <yesno>

othtext (vc, 200)

COMPLETE STUDY DRUG DISCONTINUATION FORM IF APPLICABLE

I HAVE REVIEWED THE INFORMATION IN THIS CASE REPORT FORM AND ALL ATTACHED DOCUMENTS AND CERTIFY THAT THE INFORMATION CONTAINED HEREIN IS ACCURATE.

Plsig <yesno>

Plsigdt()
____/____/____

Signature of Investigator

Date (mm/dd/yyyy)

HCRI USE ONLY
Received: ____/____/____
By: _____

CORAL

Site ID: _____ Pt. No.: _____ Randomization #: _____

PS: AELog
PT: AELog
Panel: AELog

Adverse Event Log

Page **pg1 (f, 5)** **pg2 (f, 5)**

| Line # | Adverse Event | startdt() startmm/ startdd/ Start Date (mm/dd/yyyy) | stopdt() stopmm/ stopdd/ Stop Date | sever <severity1 2> 1=mild 2=mod 3=severe | Relatedness to study drug 1=unlikely 2=possible or probable 3=no drug prescribed | Relatedness to study stent 1=unlikely 2=possible or probable 3=not used | Relatedness to Angioguard 1=unlikely 2=possible or probable 3=not used | Action Taken (circle all that apply) 1=intervention 2=other treatment 3=no action | Outcome 1=death 2=recovered 3=symptoms continue | Serious including Life Threat. 1=YES 2=NO |
|----------------|------------------------------------|---|---|--|--|--|---|---|---|--|
| lineno (vc, 5) | ae (vc, 50) | ___/___/___ | cont <checked1> | 1 2 3 | drugrel <relationship 11> | stntrel <relationship 12> | epdrel <relationship 12> | action (vc, 10) | 1 2 3 | serious <yesno> |
| | | ___/___/___ | <input type="checkbox"/> (1) Cont | 1 2 3 | | | | 1 2 3 | outcome <input type="checkbox"/> <outcome18> | 2 |
| | | ___/___/___ | <input type="checkbox"/> (1) Cont | 1 2 3 | 1 2 3 | 1 2 3 | 1 2 3 | 1 2 3 | | 2 |
| | PS: AEs PT: AELog Panel: AEs | ___/___/___ | <input type="checkbox"/> (1) Cont | 1 2 3 | 1 2 3 | 1 2 3 | 1 2 3 | 1 2 3 | 1 2 3 | DM: SAE recon: saarecon <checked1> |
| | | ___/___/___ | <input type="checkbox"/> (1) Cont | 1 2 3 | 1 2 3 | 1 2 3 | 1 2 3 | 1 2 3 | 1 2 3 | 1 2 |
| | | ___/___/___ | <input type="checkbox"/> (1) Cont | 1 2 3 | 1 2 3 | 1 2 3 | 1 2 3 | 1 2 3 | 1 2 3 | 1 2 |
| | | ___/___/___ | <input type="checkbox"/> (1) Cont | 1 2 3 | 1 2 3 | 1 2 3 | 1 2 3 | 1 2 3 | 1 2 3 | 1 2 |
| | | ___/___/___ | <input type="checkbox"/> (1) Cont | 1 2 3 | 1 2 3 | 1 2 3 | 1 2 3 | 1 2 3 | 1 2 3 | 1 2 |

Further details of adverse events

details (vc, 200)

PS: AELog1
PT: AELog
Panel: AELog

I HAVE REVIEWED THE INFORMATION IN THIS CASE REPORT FORM AND ALL ATTACHED DOCUMENTS AND CERTIFY THAT THE INFORMATION CONTAINED HEREIN IS ACCURATE.

Signature of Investigator _____

PSig <yesno>

Date (mm/dd/yyyy) _____

PSigdt()

CORAL

PANEL: Context
PS: Context

Site ID: _____ Pt. No.: _____ Randomization #: _____

Adverse Event Log

PS: AELogV2
PT: AELogV2
Panel: AELog

Time Interval: (1) 2 Week (2) 4 Week (3) 6 Week (4) 8 Week (5) 3 Mos (6) 6 Mos (7) 1 Year (8) 1 Yrs 6 Mos
 (9) 2 Years (10) 2 Yrs 6 Mos (11) 3 Years (12) 3 Yrs 6 Mos (13) 4 Years (14) 4 Yrs 6 Mos
 (15) 5 Years (16) Study Completion (99) Other, specify _____

timeptV2 <interval59>

othspec (vc, 50)

| # | Adverse Event | Start Date (mm/dd/yyyy) | Stop Date (mm/dd/yyyy) | Severity 1=mild 2=mod 3=severe | Relatedness to Atacand 1=unlikely 2=possible or probable 3=no drug prescribed | Relatedness to Caduet 1=unlikely 2=possible or probable 3=no drug prescribed | Relatedness to stent 1=unlikely 2=possible or probable 3=not used | Relatedness to Angioguard 1=unlikely 2=possible or probable 3=not used | Action Taken (circle all that apply) 1=intervention 2=other treatment 3=no action | Outcome 1=death 2=recovered 3=symptoms continue | Serious Inc. Life |
|---|---------------|---------------------------------|-----------------------------------|---|---|--|--|---|---|---|-------------------------|
| 1 | ae (vc, 50) | startmm/ startdd/ startyy | stopmm/ stopdd/ stopyy | sever <severity1> | atacrel <relationship11> | 1 2 3 | stntrel <relationship> | epdrel <relationship> | action (vc, 10) | outcome <outcome18> | 2 |
| | | | cont <checked1> | | cadrel <relationship11> | | | | 1 2 3 | DM: SAE recon: saarecon <checked1> | 2 |
| | | ___/___/___ | <input type="checkbox"/> (1) Cont | 1 2 3 | 1 2 3 | 1 2 3 | 1 2 3 | 1 2 3 | 1 2 3 | 1 2 3 | 1 2 |
| | | ___/___/___ | <input type="checkbox"/> (1) Cont | 1 2 3 | 1 2 3 | 1 2 3 | 1 2 3 | 1 2 3 | 1 2 3 | 1 2 3 | 1 2 |
| | | ___/___/___ | <input type="checkbox"/> (1) Cont | 1 2 3 | 1 2 3 | 1 2 3 | 1 2 3 | 1 2 3 | 1 2 3 | 1 2 3 | 1 2 |
| | | ___/___/___ | <input type="checkbox"/> (1) Cont | 1 2 3 | 1 2 3 | 1 2 3 | 1 2 3 | 1 2 3 | 1 2 3 | 1 2 3 | 1 2 |
| | | ___/___/___ | <input type="checkbox"/> (1) Cont | 1 2 3 | 1 2 3 | 1 2 3 | 1 2 3 | 1 2 3 | 1 2 3 | 1 2 3 | 1 2 |
| | | ___/___/___ | <input type="checkbox"/> (1) Cont | 1 2 3 | 1 2 3 | 1 2 3 | 1 2 3 | 1 2 3 | 1 2 3 | 1 2 3 | 1 2 |
| | | ___/___/___ | <input type="checkbox"/> (1) Cont | 1 2 3 | 1 2 3 | 1 2 3 | 1 2 3 | 1 2 3 | 1 2 3 | 1 2 3 | 1 2 |
| | | ___/___/___ | <input type="checkbox"/> (1) Cont | 1 2 3 | 1 2 3 | 1 2 3 | 1 2 3 | 1 2 3 | 1 2 3 | 1 2 3 | 1 2 |

serious <yesno>

DM: SAE recon:
saarecon <checked1>

PS: AEsV2
PT: AELogV2
Panel: AEs

I HAVE REVIEWED THE INFORMATION IN THIS CASE REPORT FORM AND ALL ATTACHED DOCUMENTS AND CERTIFY THAT THE INFORMATION CONTAINED HEREIN IS ACCURATE.

Signature of Investigator _____ PISig <yesno> Date (mm/dd/yyyy) _____ PISigdt() / _____

PS: AELog1V2
PT: AELogV2
Panel: AELog

HCRI USE ONLY

Received: _____ / _____ / _____

By: _____

CORAL

Site ID: _____ Pt. No.: _____ Randomization #: _____

Adverse Event Log

PS: AELogV2
PT: AELogV3
Panel: AELog

Time Interval: (1) 2 Week (2) 4 Week (3) 6 Week (4) 8 Week (5) 3 Mos (6) 6 Mos (7) 1 Year (8) 1 Yrs 6 M
 (9) 2 Years (10) 2 Yrs 6 Mos (11) 3 Years (12) 3 Yrs 6 Mos (13) 4 Years (14) 4 Yrs 6 Mos
 (15) 5 Years (16) Study Completion (99) Other, specify _____

timeptV2 <interval59>

othspec (vc, 50)

| Line # | Adverse Event | Start Date (mm/dd/yyyy) | Stop Date (mm/dd/yyyy) | Severity 1=mild 2=mod 3=severe | Relatedness to Atacand | Relatedness to Caduet | Relatedness to stent | Relatedness to EPD | Action Taken (circle all that apply) | Outcome | Serious Inc. Life |
|-------------|---------------------------------|------------------------------|-----------------------------------|---|--|--|--|--|--|--|--|
| | | | | | 1=unlikely 2=possible or probable 3=no drug prescribed | 1=unlikely 2=possible or probable 3=no drug prescribed | 1=unlikely 2=possible or probable 3=not used | 1=unlikely 2=possible or probable 3=not used | 1=intervention 2=other treatment 3=no action | 1=death 2=recovered 3=symptom continue | 1=NO 2=NO |
| ae (vc, 50) | startmm/ startdd/ startyy | stopmm/ stopdd/ stopyy | sever <severity1> | atacrel <relationship11> | 1 2 3 | stntrel <relationship> | epdrel <relationship> | action (vc, 10) | outcome <outcome18> | 2 | serious <yesno> |
| | | | cont <checked1> | | cadrel <relationship11> | | | | | | 2 |
| | | ___/___/___ | <input type="checkbox"/> (1) Cont | 1 2 3 | 1 2 3 | 1 2 3 | 1 2 3 | 1 2 3 | 1 2 3 | 1 2 3 | 1 2 |
| | | ___/___/___ | <input type="checkbox"/> (1) Cont | 1 2 3 | 1 2 3 | 1 2 3 | 1 2 3 | 1 2 3 | 1 2 3 | 1 2 3 | 1 2 |
| | | ___/___/___ | <input type="checkbox"/> (1) Cont | 1 2 3 | 1 2 3 | 1 2 3 | 1 2 3 | 1 2 3 | 1 2 3 | 1 2 3 | 1 2 |
| | | ___/___/___ | <input type="checkbox"/> (1) Cont | 1 2 3 | 1 2 3 | 1 2 3 | 1 2 3 | 1 2 3 | 1 2 3 | 1 2 3 | 1 2 |
| | | ___/___/___ | <input type="checkbox"/> (1) Cont | 1 2 3 | 1 2 3 | 1 2 3 | 1 2 3 | 1 2 3 | 1 2 3 | 1 2 | PS: AEsV3 PT: AELogV3 Panel: AEs |
| | | ___/___/___ | <input type="checkbox"/> (1) Cont | 1 2 3 | 1 2 3 | 1 2 3 | 1 2 3 | 1 2 3 | 1 2 3 | 1 2 3 | 1 2 |
| | | ___/___/___ | <input type="checkbox"/> (1) Cont | 1 2 3 | 1 2 3 | 1 2 3 | 1 2 3 | 1 2 3 | 1 2 3 | 1 2 3 | 1 2 |

PS: AEsV3
PT: AELogV3
Panel: AEs

I HAVE REVIEWED THE INFORMATION IN THIS CASE REPORT FORM AND ALL ATTACHED DOCUMENTS AND CERTIFY THAT THE INFORMATION CONTAINED HEREIN IS ACCURATE.

Signature of Investigator _____ PISig <yesno> _____ Date (mm/dd/yyyy) _____ PISigdt() _____

PS: AELog1V2
PT: AELogV3
Panel: AELog

HCRI USE ONLY
Received: ___/___/___
By: _____

CORAL

Site ID: _____ Pt. No.: _____ Randomization #: _____

PS: ConMed
PT: ConMed
Panel: ConMed

Concomitant Medication Log

| Line # | Generic Name | Given for: | | | Indication (if for Treatment of AE, enter Corresponding Adverse Event Line # from AE Log) | Date Started or Administered (mm/dd/yyyy) | | Date Stopped (mm/dd/yyyy) | | Continuing at end of study? 1 = YES 2 = NO | |
|----------------|-------------------|--------------------|---|---|--|--|-----------|------------------------------|----------|--|-----|
| | | 1 | 2 | 3 | | startmm/startdd/startyy | startdt() | stopmm/stopdd/stopyy | stopdt() | 1 | 2 |
| lineno (vc, 5) | cmedname (vc, 50) | given | | | indicat (vc, 50) | | | | | cont <yesno> | |
| | | <CONMED_GIVE N_AI> | | | | | | | | | 1 2 |
| | | | | | | | | | | | 1 2 |
| | | | | | | | | | | | 1 2 |
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| | | | | | | | | | | | 1 2 |
| | | | | | | | | | | | 1 2 |
| | | | | | | | | | | | 1 2 |
| | | | | | | | | | | | 1 2 |

PS: Meds
PT: ConMed
Panel: Meds

Signature of Investigator PISig <yesno>

PISigdt()
Date (mm/dd/yyyy)

PS: ConMed1
PT: ConMed
Panel: ConMed

| HCRI USE ONLY | |
|-----------------|-------|
| Received: _____ | _____ |
| By: _____ | _____ |

CORAL

PANEL: Context
PS: Context

Site ID: _____ Pt. No.: _____ Randomization #: _____

Concomitant Medication Log

PS: ConMedV2
PT: ConMedV2
Panel: ConMed

Time Interval: (1) 2 Week (2) 4 Week (3) 6 Week (4) 8 Week (5) 3 Mos (6) 6 Mos (7) 1 Year (8) 1 Yrs 6 M
 (9) 2 Years (10) 2 Yrs 6 Mos (11) 3 Years (12) 3 Yrs 6 Mos (13) 4 Years (14) 4 Yrs 6 Mos
 (15) 5 Years (16) Study Completion (99) Other, specify _____

timeptV2 <interval59>

othspec (vc, 50)

USE THIS LOG TO RECORD ALL NON-STUDY MEDICATIONS TAKEN BY SUBJECT

| Line # | Generic Name | Given for: 1= Existing Condition 2= Treatment of AE 3= Other | Indication (if for Treatment of AE, enter Corresponding Adverse Event Line # from AE Log) | Dose (with unit) | Frequency 1 = QD 2 = BID 3 = TID 4 = QID 5 = PRN 6 = Other (specify) | Date Started or Administered (mm/dd/yyyy) | Date Stopped (mm/dd/yyyy) | Continuing at end of study? 1 = YES 2 = NO |
|----------------|--------------------|---|--|---------------------|--|--|------------------------------|--|
| lineno (vc, 5) | cmedname (vc, 100) | given <CONMED_GIVE_N_AI> | indicat (vc, 50) | dose (vc, 20) | freq <freq6> | startdt() | stopdt() | cont <yesno> |
| | | 1 2 3 | | units (vc, 10) | freqoth (vc, 100) | startmm/startdd/startyy | stopmm/stopdd/stopyy | 1 2 |
| | | 1 2 3 | | | | ___/___/___ | ___/___/___ | 1 2 |
| | | 1 2 3 | | | | ___/___/___ | ___/___/___ | 1 2 |
| | | 1 2 3 | | | | ___/___/___ | ___/___/___ | 1 2 |
| | | 1 2 3 | | | | ___/___/___ | ___/___/___ | 1 2 |
| | | 1 2 3 | | | | ___/___/___ | ___/___/___ | 1 2 |
| | | 1 2 3 | | | | ___/___/___ | ___/___/___ | 1 2 |
| | | 1 2 3 | | | | ___/___/___ | ___/___/___ | 1 2 |
| | | 1 2 3 | | | | ___/___/___ | ___/___/___ | 1 2 |
| | | 1 2 3 | | | | ___/___/___ | ___/___/___ | 1 2 |
| | | 1 2 3 | | | | ___/___/___ | ___/___/___ | 1 2 |
| | | 1 2 3 | | | | ___/___/___ | ___/___/___ | 1 2 |
| | | 1 2 3 | | | | ___/___/___ | ___/___/___ | 1 2 |

PS: MedsV2
PT: ConMedV2
Panel: Meds

PISig <yesno>

PISigdt()

Signature of Investigator _____

Date (mm/dd/yyyy) _____

PS: ConMed1
PT: ConMedV2
Panel: ConMed

HCRI USE ONLY

Received: ___/___/___

By: _____

CORAL

PANEL: Context
PS: Context

Site ID: _____ Pt. No.: _____ Randomization #: _____

PS: RxDiscon
PT: RxDiscon
Panel: RxDiscon

Study Drug Discontinuation Form

1. Date of last dose of study drug: (mm/dd/yyyy)

INDICATE THE REASON THIS SUBJECT IS DISCONTINUING THE STUDY DRUG (CHECK ALL THAT APPLY):

- 1.1. Acute renal failure:
- 1.2. Chronic renal failure:
- 1.3. Hyperkalemia:
- 1.4. Syncope:
- 1.5. Symptomatic hypotension:
- 1.6. Allergic reaction:
- 1.7. Cough:
- 1.8. Angio edema:
- 1.9. Sexual dysfunction:
- 1.10. Subject refusal:
- 1.11. Other (specify):

2. Additional comments: _____

I HAVE REVIEWED THE INFORMATION IN THIS CASE REPORT FORM AND ALL ATTACHED DOCUMENTS AND CERTIFY THAT THE INFORMATION CONTAINED HEREIN IS ACCURATE.

/ _____
Signature of Investigator Date (mm/dd/yyyy)

HCRI USE ONLY
Received: ____ / ____ / ____
By: _____

CORAL

Site ID: _____ Pt. No.: _____ Randomization #: _____

Study Drug Discontinuation Form

PS: RxDisconV2
PT: RxDisconV2
Panel: RxDiscon

Study drug being discontinued: Atacand or Atacand/HCT Caduet

1. Date of last dose of study drug: (mm/dd/yyyy)

INDICATE THE REASON THIS SUBJECT IS DISCONTINUING THE STUDY DRUG (CHECK ALL THAT APPLY):

- | | | | |
|--------------------------|-------------------------------------|--|--------------------------|
| Acute renal failure* | <input checked="" type="checkbox"/> | Sexual dysfunction* | <input type="checkbox"/> |
| Chronic renal failure* | <input checked="" type="checkbox"/> | Peripheral edema* | <input type="checkbox"/> |
| Hyperkalemia* | <input checked="" type="checkbox"/> | Muscle cramps or pain* | <input type="checkbox"/> |
| Syncope* | <input checked="" type="checkbox"/> | CK elevations* | <input type="checkbox"/> |
| Symptomatic hypotension* | <input checked="" type="checkbox"/> | ABN liver function tests* | <input type="checkbox"/> |
| Allergic reaction* | <input checked="" type="checkbox"/> | Subject refusal | <input type="checkbox"/> |
| Cough* | <input checked="" type="checkbox"/> | Other (specify below) | <input type="checkbox"/> |
| Angio edema* | <input checked="" type="checkbox"/> | <input type="text" value="spec (vc, 50)"/> | |

***COMPLETE ADVERSE EVENT LOG FOR ALL EVENTS CHECKED**

2. Additional comments: _____

I HAVE REVIEWED THE INFORMATION IN THIS CASE REPORT FORM AND ALL ATTACHED DOCUMENTS AND CERTIFY THAT THE INFORMATION CONTAINED HEREIN IS ACCURATE.
 _____ / _____
Signature of Investigator Date (mm/dd/yyyy)

HCRI USE ONLY
Received: ____ / ____ / ____
By: _____

CORAL

PANEL: Context
PS: Context

Site ID: _____ Pt. No.: _____ Randomization #: _____

Protocol Deviation Form

PS: PDev
PT: PDev
Panel: PDev

Date and time of form completion: formmm/formdd/formyy (formdt() (mm/dd/yyyy)) formhr.formmn (24 hr.)

| Protocol Deviation Code* | Specify Deviation | Time of Occurrence (circle one) | | | Specify Contact Interval (if applicable) | Reason for Deviation (circle one) | | | | | | | |
|--------------------------|-------------------|------------------------------------|--|----------------------------------|---|--------------------------------------|-----------------------------|---------------------|-----------------|---------------|---|------------------------|---------------------------------|
| | | 1 = Baseline | 2 = Post-randomization prior to index visit completion | 3 = Follow-up contact, specify → | | 1 = Inadvertently not done | 2 = Done out of time window | 3 = Subject refused | 4 = MD decision | 5 = Lab error | 6 = Not consistent with hospital standard of care | 7 = Value out of range | 8 = Other (specify in Comments) |
| 1. | | 1 | 2 | 3 | | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 |
| 2. | | 1 | 2 | 3 | | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 |
| 3. | | 1 | 2 | 3 | | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 |
| 4. | | 1 | 2 | 3 | | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 |
| 5. | | 1 | 2 | 3 | | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 |
| 6. | | 1 | 2 | 3 | | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 |
| 7. | | 1 | 2 | 3 | | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 |
| 8. | | 1 | 2 | 3 | | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 |
| 9. | | 1 | 2 | 3 | | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 |
| 10. | | 1 | 2 | 3 | | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 |
| 11. | | 1 | 2 | 3 | | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 |
| 12. | | 1 | 2 | 3 | | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 |

Comments.

comments (vc, 200)

PS: PDev1
PT: PDev
Panel: PDev

***Protocol Deviation Codes:**

| | |
|--|---|
| <p><u>Inclusion/Exclusion Criteria</u> I1.-I2. Inclusion Criteria E1-E30. Exclusion Criteria</p> <p><u>Medications</u> 101. Aspirin 102. Clopidogrel 103. Ticlopidine 104. Heparin 105. Atacand 106. Atacand/HCT</p> <p><u>Treatment</u> 201. Study stent 202. Non-protocol device, specify 203. Angiocard 204. < 4 French pressure wire 205. Non-renal revascularization 206. Renal angiography</p> <p><u>Laboratory/Diagnostics</u> 301. Creatinine</p> | <p>302. K+</p> <p>303. Hgb</p> <p>304. HbA1c</p> <p>305. Lipids</p> <p>306. Urine dipstick</p> <p>307. ACT</p> <p>308. Pregnancy test, if applicable</p> <p>309. ECG</p> <p>310. Biochemistry Core Lab urine</p> <p>311. Biochemistry Core Lab serum</p> <p>312. Duplex scan</p> <p>313. Blood pressure assessment</p> <p>314. Physical exam</p> <p><u>Miscellaneous</u> 401. Follow-up contact 402. Pressure gradient 403. Physical exam 404. Other, specify</p> |
|--|---|

| |
|---------------------------------|
| HCRI USE ONLY |
| Received: _____ / _____ / _____ |
| By: _____ |

CORAL

Site ID: _____ Pt. No.: _____ Randomization #: _____

Protocol Deviation Form

PS: PDev
PT: PDevV2
Panel: PDev

Date and time of form completion: formmm/formdd/formyy (formdt()) formhr:formmn (24 hr.)

| Protocol Deviation Code* | IF OTHER Specify Deviation | Time of Occurrence (circle one) 1 = Baseline 2 = Post-randomization prior to index visit completion 3 = Follow-up contact, specify → | If Applicable Specify Contact Interval | Reason for Deviation (circle one) 1 = Inadvertently not done 2 = Done out of time window 3 = Subject refused 4 = MD decision 5 = Lab error 6 = Not consistent with hospital standard of care 7 = Value out of range 8 = Other (specify in Comments) |
|--------------------------|----------------------------|---|--|---|
| lineno (f, 5) | specify (vc, 50) | timept <tmocc> | intspec (vc, 50) | reason <pdevreas1> |
| pdcodeV2 <Coral_PDEV1> | | 1 2 3 | | 1 2 3 4 5 6 7 8 |
| | | 1 2 3 | | 1 2 3 4 5 6 7 8 |
| | | 1 2 3 | | 1 2 3 4 5 6 7 8 |
| | | 1 2 3 | | 1 2 3 4 5 6 7 8 |
| | | 1 2 3 | | 1 2 3 4 5 6 7 8 |
| | | 1 2 3 | | 1 2 3 4 5 6 7 8 |
| | | 1 2 3 | | 1 2 3 4 5 6 7 8 |
| | | 1 2 3 | | 1 2 3 4 5 6 7 8 |
| | | 1 2 3 | | 1 2 3 4 5 6 7 8 |
| | | 1 2 3 | | 1 2 3 4 5 6 7 8 |
| | | 1 2 3 | | 1 2 3 4 5 6 7 8 |
| | | 1 2 3 | | 1 2 3 4 5 6 7 8 |
| | | 1 2 3 | | 1 2 3 4 5 6 7 8 |

PS: DevsV2
PT: PDevV2
Panel: Devs

Comments:

_____ comments (vc, 200)

PS: PDev1
PT: PDevV2
Panel: PDev

***Protocol Deviation Codes:**

| | |
|--|--|
| <p><u>Inclusion/Exclusion Criteria</u> I1.-I2. Inclusion Criteria E1-E30. Exclusion Criteria</p> <p><u>Medications</u> 101. Aspirin 102. Clopidogrel 103. Ticlopidine 104. Heparin 105. Atacand 106. Atacand/HCT 107. Caduet</p> <p><u>Treatment</u> 201. Study stent 202. Non-protocol device, specify 203. Angioguard 204. < 4 French pressure wire 205. Non-renal revascularization 206. Renal angiography</p> | <p><u>Laboratory/Diagnostics</u> 301. Creatinine 302. K+ 303. Hgb 304. HbA1c 305. Lipids 306. Urine dipstick 307. ACT 308. Pregnancy test, if applicable 309. ECG 310. Biochemistry Core Lab urine 311. Biochemistry Core Lab serum 312. Duplex scan 313. Blood pressure assessment 314. Physical exam</p> <p><u>Miscellaneous</u> 401. Follow-up contact 403. Physical exam 404. Other, specify</p> |
|--|--|

HCRI USE ONLY
Received: _____ / _____ / _____
By: _____

CORAL

PANEL: Context
PS: Context

Site ID: _____ Pt. No.: _____ Randomization #: _____

Subsequent Hospitalization Form

PS: SubHosp1
PT: SubHosp1
Panel: SubHosp1

Date and time of form completion: () (24 hr.)

1. Date of admission to hospital: /dd/yyyy
2. Date of discharge: /yyyy
3. Hospital
 - (1) Same as enrolling hospital
 - (2) Different from enrolling hospital

3.1 If different from enrolling hospital, please specify:

(Name)

(City, State/Province)

(Country)

(Telephone Number)

4. Was subject transferred **to or from** another acute care hospital (1) YES (2) NO

COMPLETE A SECOND SUBSEQUENT HOSPITALIZATION FORM

5. Hospital Stay



PS: HospStay
PT: SubHosp1
Panel: HospStay

| Sequence of Stay | Check Type of Unit | | | Admission Date | Discharge/Transfer Date |
|------------------|--|---|--|---|--|
| | Med/Surg | ICU/CCU | Step-Down | | |
| 1. | <input checked="" type="checkbox"/> (1) <input type="checkbox"/> (2) <input type="text" value="medsurg <checked1>"/> | <input type="checkbox"/> (1) <input checked="" type="checkbox"/> (2) <input type="text" value="icuccu <checked1>"/> | <input type="checkbox"/> (1) <input checked="" type="checkbox"/> (2) <input type="checkbox"/> (3) <input type="text" value="stepdown <checked1>"/> | <input type="text" value="admmm/admdd/admyy"/> <input type="text" value="admdt()"/> | <input type="text" value="dischmm/dischdd/dischy"/> <input type="text" value="dischdt()"/> |
| 2. | <input type="checkbox"/> (1) <input type="checkbox"/> (2) <input type="checkbox"/> (3) | <input type="checkbox"/> (1) <input type="checkbox"/> (2) <input type="checkbox"/> (3) | <input type="checkbox"/> (1) <input type="checkbox"/> (2) <input type="checkbox"/> (3) | | |
| 3. | <input type="checkbox"/> (1) <input type="checkbox"/> (2) <input type="checkbox"/> (3) | <input type="checkbox"/> (1) <input type="checkbox"/> (2) <input type="checkbox"/> (3) | <input type="checkbox"/> (1) <input type="checkbox"/> (2) <input type="checkbox"/> (3) | | |
| 4. | <input type="checkbox"/> (1) <input type="checkbox"/> (2) <input type="checkbox"/> (3) | <input type="checkbox"/> (1) <input type="checkbox"/> (2) <input type="checkbox"/> (3) | <input type="checkbox"/> (1) <input type="checkbox"/> (2) <input type="checkbox"/> (3) | | |
| 5. | <input type="checkbox"/> (1) <input type="checkbox"/> (2) <input type="checkbox"/> (3) | <input type="checkbox"/> (1) <input type="checkbox"/> (2) <input type="checkbox"/> (3) | <input type="checkbox"/> (1) <input type="checkbox"/> (2) <input type="checkbox"/> (3) | | |
| 6. | <input type="checkbox"/> (1) <input type="checkbox"/> (2) <input type="checkbox"/> (3) | <input type="checkbox"/> (1) <input type="checkbox"/> (2) <input type="checkbox"/> (3) | <input type="checkbox"/> (1) <input type="checkbox"/> (2) <input type="checkbox"/> (3) | | |

6. Primary indication for hospitalization (check one and include discharge summary):

PS: SubHosp2
PT: SubHosp1
Panel: SubHosp1

- (1) Renal
- (2) Cardiac (e.g., MI, CHF, Arrhythmia, Chest pain)
- (3) Vascular (e.g., Stroke, TIA, etc.)
- (4) Bleeding (specify site)
- (5) Other (specify) _____

| HCRI USE ONLY |
|---------------------------------|
| Received: _____ / _____ / _____ |
| By: _____ |

CORAL

PANEL: Context
PS: Context

Site ID: _____ Pt. No.: _____ Randomization #: _____

Subsequent Hospitalization Form

PS: SubHosp3
PT: SubHosp2
Panel: SubHosp2

Date and time of form completion: formmm/formdd/formyy formdt() (yyyy) formhr:formmn 24 hr.)

7. Inpatient Procedure Log

Using the code list below*, indicate all procedures that were performed during this hospitalization

| Procedure Code | Date | Procedure Code | Date |
|---|---|----------------|-----------------------------|
| proccode <proccode> | procmm/procdd/procy /c procdt() | | ____/____/____ (mm/dd/yyyy) |
| | ____/____/____ (mm/dd/yyyy) | | ____/____/____ (mm/dd/yyyy) |
| | ____/____/____ (mm/dd/yyyy) | | ____/____/____ (mm/dd/yyyy) |
| | ____/____/____ (mm/dd/yyyy) | | ____/____/____ (mm/dd/yyyy) |
| | ____/____/____ (mm/dd/yyyy) | | ____/____/____ (mm/dd/yyyy) |

*Procedure Codes:

- | | |
|--|--|
| <ul style="list-style-type: none"> 1 = Renal Diagnostic Angiography without PCI 2 = Surgical Renal Revascularization 3 = Percutaneous Renal Revascularization 4 = Renal Duplex Scan (EXCLUDE PROTOCOL REQUIRED SCAN) 5 = Renal MRA 6 = CT angiography 7 = Renal transplant 8 = Hemodialysis 9 = Peritoneal dialysis 10 = Coronary Diagnostic Angiography 11 = Coronary PCI 12 = CABG operation 13 = Pacemaker placement 14 = Bi-ventricular pacemaker placement 15 = LVAD | <ul style="list-style-type: none"> 16 = ICD implant 17 = Heart transplant 18 = Surgical procedure for CHF (other than transplant or LVAD) 19 = Echo Procedures (EXCLUDING STRESS ECHO'S) 20 = Stress Tests <u>with</u> Imaging 21 = Stress Tests <u>without</u> Imaging 22 = Nuclear imaging tests 23 = PET scan 24 = Carotid stent 25 = Carotid endarterectomy 26 = Upper Endoscopy 27 = Colonoscopy 28 = Surgical vascular repair of vascular access site 29 = Vascular surgery, other |
|--|--|

PS: ProcLog
PT: SubHosp2
Panel: ProcLog

8. Record subject DRG:

(Obtain from Medical Records or Billing Office)

drg (vc 50)

PS: SubHosp4
PT: SubHosp2
Panel: SubHosp2

9. Principal Diagnosis (describe)

prindiag (vc, 200)

10. Did the subject sign the Medical Billing Release Form?

(1) YES

(2) NO

releasfrm <yesno>

10.1. Record Principal Diagnosis (ICD-9) Code:
(Obtain from Medical Records or Billing Office)

icd91 (vc 50)

10.2. Record secondary Diagnoses (ICD-9) Codes:

icd92 (vc 50)

icd921 (vc 50)

icd922 (vc 50)

icd923 (vc 50)

10.3. Record Principal Procedure (ICD-9) Code:

icd93 (vc 50)

10.4. Record Secondary Procedure (ICD-9) Codes:

icd941 (vc 50)

icd94 (vc 50)

icd942 (vc 50)

icd943 (vc 50)

CORAL

PANEL: Context
PS: Context

Site ID: _____ Pt. No.: _____ Randomization #: _____

Repeat Renal Angiography Form

PS: RepAngio1
PT: RepAngio1
Panel: RepAngio1

Date and time of form completion: (mm/dd/yyyy) (24 hr.)

1. Date of repeat angiography: (mm/dd/yyyy)

2. Time entered the procedure room: (24 Hour Format)

3. Reason for angiography: (Check only one)
 (1) Planned staged procedure
 (2) Elective
 (3) Emergency

4. Was a revascularization performed during this procedure? (1) YES (2) NO

SKIP TO ITEM 14 AND COMPLETE RENAL REVASCULARIZATION FORM

5. Time procedure began: (first xylocaine injection) (24 Hour Format)

6. Time of insertion of first renal angiography catheter: (24 hour format)

7. Time procedure ended: (last catheter removed) (24 Hour Format)

8. Was this procedure performed during an inpatient admission? (1) YES (2) NO

COMPLETE SUBSEQUENT HOSPITALIZATION FORM

9. Type and dose of contrast (Check all that apply)
 Ionic cc
 Non-Ionic cc
 Low Osmolar cc
 Isosmolar cc

10. Did the subject receive Fenoldopam? (1) YES (2) NO

11. Did the subject receive N-acetylcysteine? (1) YES (2) NO

HCRI USE ONLY
Received: _____ / _____ / _____
By: _____

CORAL

Site ID: _____ Pt. No.: _____ Randomization #: _____

Repeat Renal Angiography Form

PS: RptAng1
PT: RptAng1
Panel: RepAngio1

Date and time of form completion: (m) (24 hr.)

1. Date of repeat angiography: (yyy)

2. Time entered the procedure room: (24 Hour Format)

3. Reason for angiography: **(Check only one)**

(1) Planned staged procedure
 (2) Elective
 (3) Emergency

4. Was a revascularization performed during this procedure? (1) YES (2) NO

COMPLETE RENAL REVASCULARIZATION FORM OR ADDITIONAL LESION TREATMENT FORM AS APPLICABLE

4.1. Time procedure began: (24 hour format)
(first xylocaine injection)

4.2. Time of insertion of first renal angiography catheter: (24 hour format)

4.3. Time procedure ended: (24 hour format)
(last catheter removed)

4.4. Was this procedure performed during an inpatient admission? (1) YES (2) NO

COMPLETE SUBSEQUENT HOSPITALIZATION FORM

4.5. Total amount of contrast used: CC

HCRI USE ONLY
Received: _____ / _____ / _____
By: _____

CORAL

PANEL: Context
PS: Context

Site ID: _____ Pt. No.: _____ Randomization #: _____

Repeat Renal Angiography Form

Page 2 of 2

Date and time of form completion: formmm/formdd/formyy (formdt() (mm/dd/yyyy)) formhr:formmn 24 hr.)

PS: Repangio2
PT: Repangio2
Panel: Repangio2

12. Did the subject receive sodium bicarbonate? (1) YES (2) NO sodbicar <yesno>

12.1 Was subject considered high risk? (subjects with diabetes mellitus and/or serum creatinine \geq 1.4 mg/dL) (1) YES (2) NO hirisk <yesno>

12.1.1. Explain why no sodium bicarbonate was given: nosod (vc, 200)

13. Were any non-renal angiographies or revascularizations performed during this procedure? (1) YES (2) NO nonrenal <yesno>

13.1. Check all that apply:

- corangio <checked1> Coronary angiography
- carotang <checked1> Carotid angiography
- othangio <checked1> Other peripheral angiography, specify: othang (vc, 50)
- corevasc <checked1> Coronary revascularization
- carotrev <checked1> Carotid revascularization
- othrevas <checked1> Other revascularization, specify: othrev (vc, 50)

COMPLETE PROTOCOL

14. Right Kidney is present: (1) YES (2) NO RKidney <yesno>

| | | | | | |
|---|-----------------|--|--|--|--|
| colnum (f, 5) | Renal Site | rensite2 (vc, 5) | <input checked="" type="checkbox"/> kidna <checked1> | rensite (f, 5) | |
| 14.1. | Stenosis | stenosis (fl 6, 2) | _____ % | _____ % | PS: RARKidn PT: Repangio2 Panel: RARKidn |

15. Left Kidney is present: (1) YES (2) NO LKidney <yesno>

| | | | | | |
|---|-----------------|--|--|--|--|
| colnum (f, 5) | Renal Site | rensite2 (vc, 5) | <input checked="" type="checkbox"/> kidna <checked1> | rensite (f, 5) | |
| 15.1. | Stenosis | stenosis (fl 6, 2) | _____ % | _____ % | PS: RALKidn PT: Repangio2 Panel: RALKidn |

| |
|---------------------------------|
| HCRI USE ONLY |
| Received: _____ / _____ / _____ |
| By: _____ |

CORAL

Site ID: _____ Pt. No.: _____ Randomization #: _____

Repeat Renal Angiography Form

Date and time of form completion: (mm/dd/yyyy) 24 hr.)

PS: RptAng2
PT: RptAng2
Panel: Repangio2

5. Were any non-renal angiographies or revascularizations performed during this procedure? (1) YES (2) NO

5.1. Check all that apply:

Coronary angiography

Carotid angiography

Other peripheral angiography, specify:

Coronary revascularization

Carotid revascularization

Other revascularization, specify:

COMPLETE PROTOCOL

6. Was right kidney present? (1) YES (2) NO

7. Was left kidney is present: (1) YES (2) NO

8. Report all lesions ≥ 60% stenosed using the Renal Artery Site Map provided:

| <input type="text" value="colnum (f, 5)"/> | Renal Artery Site* | Percent Stenosis | Pressure Gradient |
|--|--|---|---|
| 1 | <input type="text" value="renlsite2 (vc, 5)"/> | <input type="text" value="stensign (vc, 3)"/> % <input type="text" value="stenosis (fl 6, 2)"/> | <input type="text" value="pressign (vc, 3)"/> mmHg <input type="text" value="press (fl 6, 2)"/> <input type="checkbox"/> ND <input type="text" value="pressND<checked1>"/> |
| 2 | | _____ % | _____ mmHg <input type="checkbox"/> ND |
| 3 | | _____ % | _____ mmHg <input type="checkbox"/> ND |
| 4 | | _____ % | _____ mmHg <input type="checkbox"/> ND |

*Please note: ALL Renal Artery Site codes contain a LETTER and a NUMBER.

PS: RAKidn
PT: RptAng2
Panel: RAKidn

HCRI USE ONLY
Received: _____ / _____ / _____
By: _____

CORAL

PANEL: Context
PS: Context

Site ID: _____ Pt. No.: _____ Randomization #: _____

Repeat Renal Revascularization Form

Page 1 of 2

Date and time of form completion: (24 hr.)

1. Was this a planned "staged" intervention? (1) YES (2) NO
2. Date of repeat procedure:
 - 2.1. Name of physician performing procedure: Last
3. Was this procedure performed during an inpatient admission? (1) YES (2) NO

PS: Revasc1
PT: Revasc1
Panel: Revasc1

COMPLETE SUBSEQUENT HOSPITALIZATION FORM

4. List ALL segments revascularized:

| | <input type="text" value="lesno (f, 5)"/> | 1 <input type="text" value="lesna <checked1>"/> | 2 <input type="checkbox"/> NA | Lesion 3 <input type="checkbox"/> NA | Lesion 4 <input type="checkbox"/> NA |
|----------------------------------|---|--|--|--|--|
| Kidney location | <input type="text" value="kidloc <rightleft>"/> | <input type="checkbox"/> Right <input type="checkbox"/> Left | <input type="checkbox"/> Right <input type="checkbox"/> Left | <input type="checkbox"/> Right <input type="checkbox"/> Left | <input type="checkbox"/> Right <input type="checkbox"/> Left |
| Renal artery site | <input type="text" value="rensite2 (vc, 5)"/> | <input type="text" value="rensite (f, 5)"/> | | | |
| Post-procedure residual stenosis | <input type="text" value="resid (f,1,6,2)"/> | _____ % | _____ % | _____ % | |

PS: Segmnt
PT: Revasc1
Panel: Segmnt

5. Revascularization anatomy (answer each):
 - 5.1. Involves target site: (1) YES (2) NO
 - 5.2. Involves target vessel: (1) YES (2) NO
 - 5.3. Involves non-target vessel: (1) YES (2) NO
6. Did the subject have a procedure-related adverse event? (1) YES (2) NO

PS: Revasc2
PT: Revasc1
Panel: Revasc1

COMPLETE THE ADVERSE EVENT LOG

7. Type of revascularization: (1) Percutaneous (2) Surgical

- 7.1. Time subject entered the procedure room:
 - 7.2. Time procedure began: (first xylocaine injection) (24 hour format)
 - 7.3. Time of insertion of first angio catheter: (24 hour format)
 - 7.4. Time procedure ended: (last catheter removed) (24 hour format)
 - 7.5. Was the revascularization successful? (1) YES (2) NO
 - 7.5.1. Emergency surgery required? (1) YES (2) NO
 - 7.5.2. ≥ 50% residual stenosis? (1) YES (2) NO

- 7.6. Indicate urgency of surgery: (1) Elective (2) Emergent
 - 7.7. Was surgical revascularization successful? (1) YES (2) NO
 - 7.8. Procedure duration: (Anesthesia start time) h: mm stop time)

Form Complete

| HCRI USE ONLY |
|---------------------------------|
| Received: _____ / _____ / _____ |
| By: _____ |

CORAL

Site ID: _____ Pt. No.: _____ Randomization #: _____

Repeat Renal Revascularization Form

Date and time of form completion: formmm/formdd/formyy formdt() formhr:formmn (24 hr.)

1. Date of repeat procedure:

rrmm/rrdd/rryy rrdt() (mm/dd/yyyy)

PS: Revasc1V2
PT: Revasc1V2
Panel: Revasc1

2. Name of physician performing procedure:

physfirs (vc, 50) physlast (vc, 50)
First Last

3. Was this procedure performed during an inpatient admission?

inpat <yesno> (1) YES (2) NO

COMPLETE SUBSEQUENT HOSPITALIZATION FORM

4. List ALL segments revascularized:

| <u>lesno (f, 5)</u> | Lesion 1 <u>lesna <checked1></u> | Lesion 2 <input type="checkbox"/> NA | Lesion 3 <input type="checkbox"/> NA | Lesion 4 <input type="checkbox"/> NA |
|----------------------------------|--|--|--|--|
| Kidney location | <u>kidloc <rightleft></u> | <input type="checkbox"/> Right <input type="checkbox"/> Left | <input type="checkbox"/> Right <input type="checkbox"/> Left | <input type="checkbox"/> Right <input type="checkbox"/> Left |
| Renal artery site | <u>renlsite2 (vc, 5)</u> | _____ | _____ | _____ |
| Post-procedure residual stenosis | <u>resid (f,1,6,2)</u> | _____ % | _____ % | _____ % |

PS: Segmnt
PT: Revasc1V2
Panel: Segmnt

5. Revascularization anatomy (answer each):

- 5.1. Involves target site: targsite <yesno> (1) YES (2) NO
- 5.2. Involves target vessel: (1) YES (2) NO targvess <yesno>
- 5.3. Involves non-target vessel: nontargv <yesno> (1) YES (2) NO

6. Did the subject have a procedure-related adverse event? (1) YES (2) NO

relaes <yesno>

PS: Revasc2V2
PT: Revasc1V2
Panel: Revasc1

COMPLETE THE ADVERSE EVENT LOG

7. Type of revascularization:

(1) Percutaneous revtype <revasc2> (2) Surgical

| | |
|---|--|
| <p>7.1. Was the revascularization successful?</p> <p><input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO <u>revasc <yesno></u></p> <p>7.1.1. Emergency surgery required?</p> <p><input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO <u>surgery <yesno></u></p> <p>7.1.2. ≥ 50% residual stenosis?</p> <p><input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO <u>residual <yesno></u></p> | <p>7.2. Indicate urgency of surgery:</p> <p><input type="checkbox"/> (1) Elective <input type="checkbox"/> (2) Emergent <u>urgency <reascabg1></u></p> <p>7.3. Was surgical revascularization successful?</p> <p><input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO <u>surgrev <yesno></u></p> |
|---|--|

Form Complete

Site ID: _____ Pt. No.: _____ Randomization #: _____

Repeat Renal Revascularization Form

Date and time of form completion: formmm/formdd/formyy (formdt()) y) formhr:formmn (4 hr.)

Please complete the following questions if a percutaneous revascularization was performed:

PS: Revasc3
PT: Revasc2
Panel: Revasc2

- 8. Type and dose of contrast (ionic <checked1> Ionic loval (f, 5) cc
(Check all that apply) nonionic <checked1> Non-Ionic nonval (f, 5) cc
lowosmo <checked1> Low Osmolar lowval (f, 5) cc
isosmol <checked1> Isosmolar isosval (f, 5) cc

- 9. Did the subject receive Fenoldopam? fenol <yesno> (1) YES (2) NO
10. Did the subject receive N-acetylcysteine? (1) YES (2) NO nacetyl <yesno>
11. Was subject given Bivalirudin? bival <yesno> (1) YES (2) NO

11.1 Bolus? bolus <yesno> (1) YES (2) NO
11.2 Infusion duration (hr:min): infushr:infusmn (1) YES (2) NO NA infusna <checked>

COMPLETE PROTOCOL

- 12. Did the subject receive sodium bicarbonate? (1) YES (2) NO sodbicar <yesno>

12.1 Was subject considered high risk? (subjects with diabetes mellitus and/or serum creatinine ≥ 1.4 mg/dL) (1) YES (2) NO hirisk <yesno>

12.1.1. Explain why no sodium bicarbonate was given nosod (vc, 200)

Device Utilization (if none, enter "0")

Number used

- 13. RADI Pressure Wire radi (f, 5)
14. Pressure Catheters press (f, 5)
15. Guidewires gdwire (f, 5)
16. Guiding Catheters gdcath (f, 5)
17. Angioplasty Balloons angball (f, 5)
18. Study stents studstnt (f, 5)
19. Study embolic protection devices studepd (f, 5)
20. Non-study Drug-eluting stents nsdrugel (f, 5)
21. Non-study Bare metal stents nsbare (f, 5)
22. Atherectomy devices ather (f, 5)
23. Other embolic protection devices nsepd (f, 5)
24. Other, specify othsp1 (vc, 100) oth1 (f, 5)
25. Other, specify othsp2 (vc, 100) oth2 (f, 5)

- 26. Were any non-renal angiographies or revascularizations performed during this procedure? (1) YES (2) NO nonrenal <yesno>

26.1. Check all that apply: corangio <checked1>
carotang <checked1> Coronary angiography
othangio <checked1> Carotid angiography othang (vc, 50)
corevasc <checked1> Other peripheral angiography, specify:
carotrev <checked1> Coronary revascularization
othrevas <checked1> Carotid revascularization
Other revascularization, specify: othrev (vc, 50)

HCRI USE ONLY
Received: ___/___/___
By: _____

CORAL

Site ID: _____ Pt. No.: _____ Randomization #: _____

Repeat Renal Revascularization Form

Date and time of form completion: (4 hr.)

Please complete the following questions if a percutaneous revascularization was performed:

PS: Revasc3V2
PT: Revasc2V2
Panel: Revasc2

8. Total amount of contrast used: cc

9. Was subject given Bivalirudin? (1) YES (2) NO

Device Utilization (if none, enter "0")

Number used

- | | |
|--|--|
| 10. RADI pressure wire: | <input type="text" value="radi (f, 5)"/> |
| 11. Pressure catheters: | <input type="text" value="press (f, 5)"/> |
| 12. Guidewires: | <input type="text" value="gdwire (f, 5)"/> |
| 13. Guiding catheters: | <input type="text" value="gdcath (f, 5)"/> |
| 14. Angioplasty balloons: | <input type="text" value="angball (f, 5)"/> |
| 15. Study stents: | <input type="text" value="studstnt (f, 5)"/> |
| 16. Study embolic protection devices: | <input type="text" value="studepd (f, 5)"/> |
| 17. Drug-eluting stents: | <input type="text" value="nsdrugel (f, 5)"/> |
| 18. Non-study bare metal stents: | <input type="text" value="nsbare (f, 5)"/> |
| 19. Atherectomy devices: | <input type="text" value="ather (f, 5)"/> |
| 20. Other embolic protection devices: | <input type="text" value="nsepd (f, 5)"/> |
| 21. Other, specify <input type="text" value="othsp1 (vc, 100)"/> | <input type="text" value="oth1 (f, 5)"/> |
| 22. Other, specify <input type="text" value="othsp2 (vc, 100)"/> | <input type="text" value="oth2 (f, 5)"/> |

23. Were any non-renal angiographies or revascularizations performed during this procedure? (1) YES (2) NO

23.1. Check all that apply:

| | | |
|-------------------------------------|--|--|
| <input checked="" type="checkbox"/> | Coronary angiography | <input type="text" value="corangio <checked1>"/> |
| <input checked="" type="checkbox"/> | Carotid angiography | |
| <input checked="" type="checkbox"/> | Other peripheral angiography, specify: | <input type="text" value="othang (vc, 50)"/> |
| <input checked="" type="checkbox"/> | Coronary revascularization | |
| <input checked="" type="checkbox"/> | Carotid revascularization | |
| <input checked="" type="checkbox"/> | Other revascularization, specify: | <input type="text" value="othrev (vc, 50)"/> |
| <input checked="" type="checkbox"/> | | |
| <input checked="" type="checkbox"/> | | |

COMPLETE PROTOCOL

HCRI USE ONLY
Received: _____ / _____ / _____
By: _____

CORAL

Site ID: _____ Pt. No.: _____ Randomization #: _____

Repeat Renal Revascularization Form

Date and time of form completion (formmm/formdd/formyy) (formdt()) (formhr:formmn) 4 hr.)

Please complete the following questions if a percutaneous revascularization was performed:

PS: Revasc3V3
PT: Revasc2V3
Panel: Revasc2

8. Total amount of contrast used: contrast (f 8, 2) cc

9. Was subject given Bivalirudin? bival <yesno> (1) YES (2) NO

Device Utilization (if none, enter "0")

Number used

- 10. RADI Pressure Wire radi (f, 5)
- 11. Pressure Catheters press (f, 5)
- 12. Guidewires gdwire (f, 5)
- 13. Guiding Catheters gdcath (f, 5)
- 14. Angioplasty Balloons angball (f, 5)
- 15. Study stents studstnt (f, 5)
- 16. Embolic protection devices epdv3 (f, 5)
- 17. Non-study Drug-eluting stents nsdrugel (f, 5)
- 18. Non-study Bare metal stents nsbare (f, 5)
- 19. Atherectomy devices ather (f, 5)
- 20. Other, specify othsp1 (vc, 100) oth1 (f, 5)
- 21. Other, specify othsp2 (vc, 100) oth2 (f, 5)



22. Were any non-renal angiographies or revascularizations performed during this procedure? (1) YES (2) NO nonrenal <yesno>

22.1. Check all that apply:

Corotang <checked1> Coronary angiography corangio <checked1>

othangio <checked1> Carotid angiography othang (vc, 50)

corevasc <checked1> Other peripheral angiography, specify:

carotrev <checked1> COMPLETE PROTOCOL Coronary revascularization

othrevas <checked1> Carotid revascularization othrev (vc, 50)

Other revascularization, specify:

HCRI USE ONLY

Received: _____ / _____ / _____

By: _____

CORAL

PANEL: Context
PS: Context

Site ID: _____ Pt. No.: _____ Randomization #: _____

Additional Diagnostic Angiography Form

PS: AdlAng1
PT: AdlAng1
Panel: AdlAng1

Date and time of form completion: formmm/formdd/formyy formdt() formhr:formmn (24 hr.)

1. This angiogram was performed at: angsite <angsite> Investigative site (1) Inpatient (2) Outside hospital
- 1.1. Name of physician performing angiogram: physfirs (vc, 50) physlast (vc, 50)
2. Date of procedure: procmm/procdd/procyy (mm/dd/yyyy) procdt()
3. Time subject arrived in procedure room: arrhr:armn (24 hour format)
4. Vascular access (sheath): (1) Femoral (2) Brachial (3) Radial sheath <accesssite1>
5. Was a renal intervention performed during this procedure? (1) YES (2) NO interven <yesno>

SKIP TO ITEM 15 AND COMPLETE INTERVENTION PROCEDURE FORM AND LESION TREATMENT FORM

6. Time procedure began: (first xylocaine injection) prochr:procmn (24 hour format)
7. Time of insertion of first renal angiography catheter: cathhr:cathmn (24 hour format)
8. Time procedure ended: (last catheter removed) endhr:endmn (24 hour format)
9. Type and dose of contrast: ionic <checked1> Ionic ioval (f, 5) cc
(Check all that apply) nonionic <checked1> Non-Ionic nonval (f, 5) cc
lowosmo <checked1> Low Osmolar lowval (f, 5) cc
isosmol <checked1> Isosmolar isosval (f, 5) cc
10. Did the subject receive Fenoldopam? fenol <yesno> (1) YES (2) NO
11. Did the subject receive N-acetylcysteine? (1) YES (2) NO nacetyl <yesno>
12. Did the subject receive sodium bicarbonate? (1) YES (2) NO sodbic <yesno>

12.1 Was subject considered high risk? (subjects with diabetes mellitus and/or serum creatinine ≥ 1.4 mg/dL) (1) YES (2) NO hirisk <yesno>

12.1.1. Explain why no sodium bicarbonate was given: nosod (vc, 200)

HCRI USE ONLY
Received: _____ / _____ / _____
By: _____

CORAL

PANEL: Context
PS: Context

Site ID: _____ Pt. No.: _____ Randomization #: _____

Additional Diagnostic Angiography Form

PS: AdIAng2
PT: AdIAng2
Panel: AdIAng2

Date and time of form completion: formmm/formdd/formyy formdt() formhr:formmn (24 hr.)

13. Were any non-renal angiographies or revascularizations performed during this procedure? (1) YES (2) NO nonrenal <yesno>

13.1. Check all that apply:

| | |
|---|---|
| <input checked="" type="checkbox"/> corangio <checked1> | <input type="checkbox"/> Coronary angiography |
| <input checked="" type="checkbox"/> carotang <checked1> | <input type="checkbox"/> Carotid angiography |
| <input checked="" type="checkbox"/> othangio <checked1> | <input type="checkbox"/> Other peripheral angiography, specify: othang (vc, 50) |
| <input checked="" type="checkbox"/> corevasc <checked1> | <input type="checkbox"/> Coronary revascularization |
| <input checked="" type="checkbox"/> carotrev <checked1> | <input type="checkbox"/> Carotid revascularization |
| <input checked="" type="checkbox"/> othrevas <checked1> | <input type="checkbox"/> Other revascularization, specify: othrev (vc, 50) |

COMPLETE PROTOCOL DEVIATION FORM IF < 80% STENOSIS AND PRESSURE GRADIENT NOT DONE

14. Right Kidney is present: (1) YES (2) NO rkidney <yesno>

| | | | | | |
|------|----------------------------------|---|--|---|------------------------------|
| | Renal Artery | renlsite2 (vc, 5) | <input checked="" type="checkbox"/> kidna <checked1> | renlsite (f, 5) | |
| | Stenosis | stensign (vc, 3) stenosis (fl 6, 2) | _____ % | _____ % | |
| 14.2 | Pressure Gradient | pressign (vc, 3) press (fl 6, 2) | _____ mmHg | _____ mmHg | _____ mmHg |
| | | pressND<checked1> | <input type="checkbox"/> ND* | <input type="checkbox"/> ND* | <input type="checkbox"/> ND* |
| 14.3 | Reference Vessel Diameter | refdiam (fl 6, 2) (mm) | refND<checked1> (mm) | _____ (mm) | _____ (mm) |
| 14.4 | Lesion Length | lesleng (fl 6, 2) (mm) | lenND<checked1> (mm) | _____ (mm) | _____ (mm) |

***COMPLETE PROTOCOL DEVIATION FORM IF < 80% STENOSIS AND PRESSURE GRADIENT NOT DONE**

15. Left Kidney is present: lkidney <yesno> (1) YES (2) NO

| | | | | | |
|------|----------------------------------|---|--|---|------------------------------|
| | Renal Artery | renlsite2 (vc, 5) | <input checked="" type="checkbox"/> kidna <checked1> | renlsite (f, 5) | |
| | Stenosis | stensign (vc, 3) stenosis (fl 6, 2) | _____ % | _____ % | |
| 15.2 | Pressure Gradient | pressign (vc, 3) press (fl 6, 2) | _____ mmHg | _____ mmHg | _____ mmHg |
| | | pressND<checked1> | <input type="checkbox"/> ND* | <input type="checkbox"/> ND* | <input type="checkbox"/> ND* |
| 15.3 | Reference Vessel Diameter | refdiam (fl 6, 2) (mm) | refND<checked1> (mm) | _____ (mm) | _____ (mm) |
| 15.4 | Lesion Length | lesleng (fl 6, 2) (mm) | lenND<checked1> (mm) | _____ (mm) | _____ (mm) |

***COMPLETE PROTOCOL DEVIATION FORM IF < 80% STENOSIS AND PRESSURE GRADIENT NOT DONE**

| |
|---------------------------------|
| HCRI USE ONLY |
| Received: _____ / _____ / _____ |
| By: _____ |

CORAL

Site ID: _____ Pt. No.: _____ Randomization #: _____

Additional Lesion Treatment Form

Date and time of form completion (formmm/formdd/formyy) (formdt()) (formhr:formmn) (24 hr.)

PS: AddIsn1
PT: AddIsn1
Panel: AddIsn1

COMPLETE FOR ALL LESIONS TREATED AFTER THE FIRST LESION (CAPTURED ON THE LESION TREATMENT FORM)

- Date of procedure: (procmm/procdd/procy) (procdt())
 - Time subject arrived in procedure room: (prochr:procmn) (24 hour)
- Name of physician performing intervention: (physfirs (vc, 50)) (physlast (vc, 50))
- Renal artery site treated (renlsite2 (vc, 5)) (renlsite (f, 5))

Angioguard

- Was Angioguard attempted? (attempt <yesno>)
 - (1) YES (2) NO → (1) anatomy <checked1> (landing <checked1>)
 - (2) Unfavorable landing zone (other <checked1>)
 - (99) Other: (othspec (vc, 50))

| No. | (4.2) Used in prior lesion treatment? | (4.3) Angioguard | | (4.4) Angioguard Basket Size (mm) | | (4.5) Package opened and used? | (4.6) Able to cross lesion? | (4.7) Successfully deployed? | (4.8) Protection achieved? | (4.9) Problem and/or complication with device treatment? | (4.10) (1) YES (2) NO |
|-----|--|------------------|-----------------|-----------------------------------|---------------------|--------------------------------|-----------------------------|------------------------------|-----------------------------------|---|-----------------------|
| | | (1) YES (2) NO | Lot # Cat # | 5 6 7 8 | 5 6 7 8 | (1) YES (2) NO | (1) YES (2) NO | (1) YES (2) NO | 1 = None 2 = Complete 3 = Partial | complic <yesno> | |
| 1 | (1) YES → Renal artery site: (renlsite2 (vc, 5)) | (1) YES (2) NO | lotnum (vc, 15) | catnum (vc, 15) | basket <basketsize> | pkgopen <yesno> | crosslen <yesno> | deployed <yesno> | protect <protection> | probcd1 <complicationcode> probcd2 <complicationcode> probcd3 <complicationcode> probcd4 <complicationcode> | (1) YES (2) NO |
| 2 | (1) YES → Renal artery site: _____ | (1) YES (2) NO | | | | (1) YES (2) NO | (1) YES (2) NO | (1) YES (2) NO | | | (1) YES (2) NO |
| 3 | (1) YES → Renal artery site: _____ | (1) YES (2) NO | | | | (1) YES (2) NO | (1) YES (2) NO | (1) YES (2) NO | | othspec (vc, 50) | (1) YES (2) NO |

PS: AddEPD
PT: AddIsn1
Panel: AddEPD

| | | | | | |
|--------|--------------------|-------------------------|---------------------------|--|--------------------|
| *Codes | 1 = Slow / No flow | 3 = Thrombus formation | 5 = Side branch occlusion | 7 = Angioguard entanglement with renal stent at time of device removal | 9 = Other, specify |
| | 2 = Abrupt Closure | 4 = Distal embolization | 6 = Spasm | 8 = Landing zone problems during placement | |

† Provide additional comments as needed on the Narrative Form.

HCRI USE ONLY
Received: ____/____/____
By: _____

CORAL

PANEL: Context
PS: Context

Site ID: _____ Pt. No.: _____ Randomization #: _____

Additional Lesion Treatment Form

Date and time of form completion formmm/formdd/formyy (mm/dd/yyyy) formdt() formhr:formmn (2 hr.)

PS: AddIsn1V2
PT: AddIsn1V2
Panel: AddIsn1

COMPLETE FOR ALL LESIONS TREATED AFTER THE FIRST LESION (CAPTURED ON THE LESION TREATMENT FORM)

Was this a planned "staged" intervention? staged <yesno> (1) YES (2) NO

1. Date of procedure: procmm/procdd/procy (mm/dd/yyyy) procdt()

2. Name of physician performing intervention: physfirs (vc, 50) physlast (vc, 50)
First Last

3. Renal artery site treated rensite2 (vc, 5) Percent stenosis: pctsten (vc, 5)

Protection Device

4. Was Angioguard attempted? attempt <yesno> (1) YES (2) NO → (1) Unfavorable anatomy anatomy <checked1>
 (2) Unfavorable landing zone landing <checked1>
 (99) Other: othspec (vc, 50)

PS: AddEPDV2
PT: AddIsn1V2
Panel: AddEPD

| (4.1) No. | (4.3) Angioguard | (4.4) Angioguard Basket Size (mm) | (4.5) Package opened and used? | (4.6) Able to cross lesion? | (4.7) Successfully deployed? | (4.8) Protection achieved? | (4.9) Problems and/or complications with device treatment? | (4.9.1.) Device used in treatment of a subsequent lesion? |
|--|--|--|--|---|--|---|--|---|
| lineno (vc, 5) | Lot # lotnum (vc, 15) Cat # catnum (vc, 15) | basket <basketsize> <input type="checkbox"/> 6 <input type="checkbox"/> 8 <input type="checkbox"/> 5 <input type="checkbox"/> 7 <input type="checkbox"/> 6 <input type="checkbox"/> 8 | NO, row is complete pkgopen <yesno> <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO | croslen <yesno> <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO | deployed <yesno> <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO | 1 = None 2 = Complete 3 = Partial protect <protection> <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO | probcode1 <complicationcode> probcode2 <complicationcode> probcode3 <complicationcode> probcode4 <complicationcode> othspec (vc, 50) <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO | othlesn <yesno> <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO |
| *Codes | | 1 = Slow / No flow 2 = Abrupt Closure | 3 = Thrombus formation 4 = Distal embolization | 5 = Side branch occlusion 6 = Spasm | 7 = Angioguard ent at time of dev 8 = Landing zone problems during placement | 9 = Other, specify: COMPLETE NARRATIVE FORM | | |

† Submit Narrative Form to provide details if only partial protection is achieved or to specify if code 9 (Other) is entered.

5. Was a protection device other than the Angioguard used? (1) YES (2) NO othEPD <yesno>

5.1. Device Manufacturer: manuf (vc, 50) 5.2. Device Name: devname (vc, 50)

5.3. Device size: devsize (vc, 15) 5.4. Why was this device used? reasused (vc, 100)

PS: AddIsn2V2
PT: AddIsn1V2
Panel: AddIsn1

HCRI USE ONLY

Received: _____ / _____ / _____

By: _____

CORAL

PANEL: Context
PS: Context

Site ID: _____ Pt. No.: _____ Randomization #: _____

Additional Lesion Treatment Form

Page 1 of _____

PS: Addlsn1V3
PT: Addlsn1V3
Panel: Addlsn1

Date and time of form completion formmm/formdd/formyy (formdt() (mm/dd/yyyy)) formhr:formmn (24 hr.)

COMPLETE FOR ALL LESIONS TREATED AFTER THE FIRST LESION (CAPTURED ON THE LESION TREATMENT FORM)

Was this a planned "staged" intervention? staged <yesno> (1) YES (2) NO

1. Date of procedure: procmm/procdd/procyy (mm/dd/yyyy) procdt()

2. Name of physician performing intervention: physfirs (vc, 50) physlast (vc, 50)
First Last

3. Renal artery site treated rensite2 (vc, 5)

Embollic Protection Device (EPD)

4. Was embolic protection attempted? attempt <yesno> (1) YES (2) NO → Skip to page 112

| No. | EPD used: | | | Size (mm) | Protection achieved? | Problems and/or complications with device / treatment? | If YES, indicate with code(s) *† (separate each code with <complicationcode1>) |
|-----|------------------|-----------------|-----------------|-----------------|----------------------|---|--|
| | Name | Lot # | Cat # | | | | |
| 1 | epdname (vc, 50) | lotnum (vc, 15) | catnum (vc, 15) | | protect <protection> | <input type="checkbox"/> (1) YES → <input type="checkbox"/> (2) NO | probcde1a <complicationcode1> probcde2a <complicationcode1> |
| 2 | | | | epdsz (fl 4, 2) | | <input type="checkbox"/> (1) YES → | probcde3a <complicationcode1> |
| 3 | | | | | | <input type="checkbox"/> (1) YES → <input type="checkbox"/> (2) NO | probcde4a <complicationcode1> |

| | | | | | |
|---------------|--------------------|-------------------------|---------------------------|---|---|
| *Codes | 1 = Slow / No flow | 3 = Thrombus formation | 5 = Side branch occlusion | 7 = Entanglement with renal stent at time of device removal | 9 = Other, specify: COMPLETE NARRATIVE FORM |
| | 2 = Abrupt Closure | 4 = Distal embolization | 6 = Spasm | 8 = Landing zone problems during placement | |

† Submit Narrative Form to specify if code 9 (Other) is entered.

| |
|---------------------------------|
| HCRI USE ONLY |
| Received: _____ / _____ / _____ |
| By: _____ |

PS: AddEPDV3
PT: Addlsn1V3
Panel: AddEPD

CORAL

PANEL: Context
PS: Context

Site ID: _____ Pt. No.: _____ Randomization #: _____

Additional Lesion Treatment Form

Page 2 of 2

Date and time of form completion: _____ (mm) _____ (mm) _____ (hr) _____ (24 hr.)

Target Lesion Study Stent Delivery Information

5. Was stent attempted? (1) YES (2) NO

PS: Addlsn2
PT: Addlsn2
Panel: Addlsn2

| (5.1) | (5.2) | (5.3) | (5.4) | (5.5) | (5.6) | | (5.7) | |
|------------------|---|-------------------------------------|---|-------------------|-------|-------------------------------|------------------------|---|
| Type of stent | Was lesion pre-dilated? | Max stent deployment pressure (ATM) | Was post-dilation performed? | If YES, | | Largest balloon diameter (mm) | Maximum pressure (ATM) | Procedure completed? |
| lineno (f, 5) | predil <yesno> | dplpress2 (fl 6, 2) | postdil <yesno> | maxdiam (fl 6, 2) | | maxpress2 (fl 6, 2) | | delvprob <yesno> |
| Name _____ | <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO | | <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO | | | | | <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO |
| Diameter _____mm | | | | | | | | |
| Length _____mm | | | | | | | | |
| 2 Name _____ | <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO | | <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO | | | | | <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO |
| Diameter _____mm | | | | | | | | |
| Length _____mm | | | | | | | | |

PS: Addstnt
PT: Addlsn2
Panel: Addstnt

Details of Target Lesion (Post All Treatments)

6. Total length of stent(s) placed: _____ mm

7. Final percent stenosis: _____ %

8. Pressure gradient: _____ mmHg ND

PS: Addlsn3
PT: Addlsn2
Panel: Addlsn2

Additional Treatments

9. Was an additional percutaneous treatment performed to another target lesion? (1) YES (2) NO

COMPLETE ADDITIONAL TREATMENT FORM

10. Were additional percutaneous treatment(s) performed to a non-target lesion? (1) YES (2) NO

COMPLETE PROTOCOL DEVIATION FORM

11. Were there complications that required additional treatment? (1) YES (2) NO

| | | | | |
|-------|--|----------------------------------|---------------------------------|--|
| 11.1. | Complication during pre-treatment: | <input type="checkbox"/> (1) YES | <input type="checkbox"/> (2) NO | |
| 11.2. | Never able to cross lesion with stent: | <input type="checkbox"/> (1) YES | <input type="checkbox"/> (2) NO | |
| 11.3. | Dissection beyond stented area: | <input type="checkbox"/> (1) YES | <input type="checkbox"/> (2) NO | |
| 11.4. | Complication in different segment: | <input type="checkbox"/> (1) YES | <input type="checkbox"/> (2) NO | |
| 11.5. | Complication in different vessel: | <input type="checkbox"/> (1) YES | <input type="checkbox"/> (2) NO | |
| 11.6. | Unplanned treatment of other lesion: | <input type="checkbox"/> (1) YES | <input type="checkbox"/> (2) NO | |

11.6.1 Specify: _____

11.7. Other: _____ (1) YES (2) NO

PROVIDE ADDITIONAL COMMENTS AS NEEDED ON NARRATIVE FORM

CORAL

Site ID: _____ Pt. No.: _____ Randomization #: _____

Additional Lesion Treatment Form

PS: Addlsn3aV2
PT: Addlsn2V2
Panel: Addlsn2

Estimated time of form completion: (mm) (24 hr.)

Lesion Study Stent Delivery Information

6. Was stent attempted? (1) YES (2) NO → Was stenosis less than 60%? (1) YES (2) NO

| (6.1) Stent # | (6.2) Stent Information | (6.3) Problem with / deployment of stent |
|--|---|--|
| <input type="checkbox"/> (1) Study <input type="checkbox"/> (2) Non-study ↓ 6.2.1 Why was non-study stent used? <input type="text" value="whyNSS (vc, 150)"/> (complete Narrative Form if more space is needed) | Manufacturer: <input type="text" value="manuf (vc, 50)"/> Name <input type="text" value="stent (vc, 50)"/> Lot # <input type="text" value="lotnum (vc, 10)"/> Diameter <input type="text" value="diam2 (fl 6, 2)"/> mm Length <input type="text" value="len (f, 5)"/> mm Delivery system length <input type="text" value="deliv (vc, 15)"/> mm | <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO COMPLETE NARRATIVE FORM <input type="text" value="delvprob <yesno>"/> |
| <input type="checkbox"/> (1) Study <input type="checkbox"/> (2) Non-study ↓ 6.2.1 Why was non-study stent used? _____ (complete Narrative Form if more space is needed) | Manufacturer: _____ Name _____ Lot # _____ Diameter _____ mm Length _____ mm Delivery system length _____ mm | <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO COMPLETE NARRATIVE FORM |

PS: AddstntV2
PT: Addlsn2V2
Panel: Addstnt

Details of Target Lesion (Post All Treatments)

7. Total length of stent(s) placed: mm

8. Final percent stenosis:

9. Pressure gradient: mmHg ND

PS: Addlsn3V2
PT: Addlsn2V2
Panel: Addlsn2

Additional Treatments

10. Was an additional percutaneous treatment performed to another target lesion? (1) YES (2) NO
 COMPLETE ADDITIONAL TREATMENT FORM

11. Were additional percutaneous treatment(s) performed to non-target lesion(s)? (1) YES (2) NO
 COMPLETE PROTOCOL DEVIATION FORM

12. Were there complications that required additional treatment? (1) YES (2) NO

| | | | |
|--|--|----------------------------------|---|
| 12.1. Complication during pre-treatment: | <input type="checkbox"/> (1) YES | <input type="checkbox"/> (2) NO | <input type="text" value="pretx <yesno>"/> |
| 12.2. Never able to cross lesion with stent: | <input type="text" value="nocross <yesno>"/> | <input type="checkbox"/> (1) YES | <input type="checkbox"/> (2) NO |
| 12.3. Dissection beyond stented area: | <input type="checkbox"/> (1) YES | <input type="checkbox"/> (2) NO | <input type="text" value="dissect <yesno>"/> |
| 12.4. Complication in different segment: | <input type="text" value="diffseg <yesno>"/> | <input type="checkbox"/> (1) YES | <input type="checkbox"/> (2) NO |
| 12.5. Complication in different vessel: | <input type="checkbox"/> (1) YES | <input type="checkbox"/> (2) NO | <input type="text" value="diffvess <yesno>"/> |
| 12.6. Unplanned treatment of other lesion: | <input type="text" value="unplan <yesno>"/> | <input type="checkbox"/> (1) YES | <input type="checkbox"/> (2) NO |

12.6.1 Specify:

12.7. Other: (1) YES (2) NO

PROVIDE ADDITIONAL COMMENTS AS NEEDED ON NARRATIVE FORM

HCRI USE ONLY

Received: _____ / _____ / _____

By: _____

CORAL

PANEL: Context
PS: Context

Site ID: _____ Pt. No.: _____ Randomization #: _____

Narrative Form

PS: Narr
PT: Narr
Panel: Narr

Time Interval:

- | | | | |
|--|---|---|---|
| <input type="checkbox"/> (1) Baseline | <input type="checkbox"/> (9) 6 Month | <input type="checkbox"/> (17) 2 Yr 6 Mo | <input type="checkbox"/> (25) 4 Yr 6 Mo |
| <input type="checkbox"/> (2) Post-randomization | <input type="checkbox"/> (10) 9 Month | <input type="checkbox"/> (18) 2 Yr 9 Mo | <input type="checkbox"/> (26) 4 Yr 9 Mo |
| <input type="checkbox"/> (3) Discharge | <input type="checkbox"/> (11) 1 Year | <input type="checkbox"/> (19) 3 Year | <input type="checkbox"/> (27) 5 Year |
| <input type="checkbox"/> (4) 2 Week | <input type="checkbox"/> (12) 1 Yr 3 Mo | <input type="checkbox"/> (20) 3 Yr 3 Mo | <input type="checkbox"/> (28) Termination |
| <input type="checkbox"/> (5) 4 Week | <input type="checkbox"/> (13) 1Yr 6 Mo | <input type="checkbox"/> (21) 3 Yr 6 Mo | |
| <input type="checkbox"/> (6) 6 Week | <input type="checkbox"/> (14) 1 Yr 9 Mo | <input type="checkbox"/> (22) 3 Yr 9 Mo | |
| <input type="checkbox"/> (7) 8 Week | <input type="checkbox"/> (15) 2 Year | <input type="checkbox"/> (23) 4 Year | |
| <input type="checkbox"/> (8) 3 Month | <input type="checkbox"/> (16) 2 Yr 3 Mo | <input type="checkbox"/> (24) 4 Yr 3 Mo | |
| <input type="checkbox"/> (99) Other, specify _____ | | | |

timept <interval44>

othspec (vc, 50)

Associated form(s):

- | | | | |
|--|--|--------------------------|---|
| 1. Inclusion/Exclusion Criteria Form | <input checked="" type="checkbox"/> IE <checked1> | <input type="checkbox"/> | <input checked="" type="checkbox"/> Blin <checked1> |
| 2. Baseline Form | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 3. Baseline Medical History Form | <input checked="" type="checkbox"/> BlinHx <checked1> | <input type="checkbox"/> | <input type="checkbox"/> |
| 4. Baseline Physical Exam Form | <input type="checkbox"/> | <input type="checkbox"/> | <input checked="" type="checkbox"/> BlinPhys <checked1> |
| 5. Baseline Diagnostic Angiography Form | <input checked="" type="checkbox"/> Blinang <checked1> | <input type="checkbox"/> | <input checked="" type="checkbox"/> proc <checked1> |
| 6. Intervention Procedure Form | <input checked="" type="checkbox"/> LesnTx <checked1> | <input type="checkbox"/> | <input type="checkbox"/> |
| 7. Lesion Treatment Form | <input type="checkbox"/> | <input type="checkbox"/> | <input checked="" type="checkbox"/> indexvis <checked1> |
| 8. Index Visit Completion Form | <input checked="" type="checkbox"/> contact <checked1> | <input type="checkbox"/> | <input checked="" type="checkbox"/> term <checked1> |
| 9. Contact Form | <input checked="" type="checkbox"/> aelog <checked1> | <input type="checkbox"/> | <input checked="" type="checkbox"/> conmed <checked1> |
| 10. Study Exit Form | <input checked="" type="checkbox"/> discnt <checked1> | <input type="checkbox"/> | <input checked="" type="checkbox"/> pdev <checked1> |
| 11. Adverse Event Log | <input checked="" type="checkbox"/> subhosp <checked1> | <input type="checkbox"/> | <input checked="" type="checkbox"/> ra <checked1> |
| 12. Concomitant Medication Log | <input type="checkbox"/> | <input type="checkbox"/> | <input checked="" type="checkbox"/> addldiag <checked1> |
| 13. Study Drug Discontinuation Form | <input checked="" type="checkbox"/> rr <checked1> | <input type="checkbox"/> | <input checked="" type="checkbox"/> addlesn <checked1> |
| 14. Protocol Deviation Form | <input checked="" type="checkbox"/> addlesn <checked1> | <input type="checkbox"/> | <input checked="" type="checkbox"/> other <checked1> |
| 15. Subsequent Hospitalization Form | <input type="checkbox"/> | <input type="checkbox"/> | |
| 16. Repeat Renal Angiography Form | | | |
| 17. Repeat Renal Revascularization Form | | | |
| 18. Additional Diagnostic Angiography Form | | | |
| 19. Additional Lesion Treatment Form | | | |
| 20. Other (specify) _____ | <input type="checkbox"/> othcrf (vc, 100) | <input type="checkbox"/> | |

narrtext (vc, 200)

text2 (vc, 200)

| |
|---------------------------------|
| HCRI USE ONLY |
| Received: _____ / _____ / _____ |
| By: _____ |

CORAL

Site ID: _____ Pt. No.: _____ Randomization #: _____

Narrative Form

Time Interval:

| | | | |
|--|---|---|---|
| <input type="checkbox"/> (1) Baseline | <input type="checkbox"/> (2) Post-randomization | <input type="checkbox"/> (3) Discharge | <input type="checkbox"/> (8) 3 Mos |
| <input type="checkbox"/> (4) 2 Week | <input type="checkbox"/> (5) 4 Week | <input type="checkbox"/> (6) 6 Week | <input type="checkbox"/> (7) 8 Week |
| <input type="checkbox"/> (9) 6 Mos | <input type="checkbox"/> (10) 1 Year | <input type="checkbox"/> (11) 1 Yrs 6 Mos | <input type="checkbox"/> (12) 2 Years |
| <input type="checkbox"/> (14) 3 Years | <input type="checkbox"/> (15) 3 Yrs 6 Mos | <input type="checkbox"/> (16) 4 Years | <input type="checkbox"/> (17) 4 Yrs 6 Mos |
| <input type="checkbox"/> (19) Study Completion | <input type="checkbox"/> (18) 5 Years | | |
| <input type="checkbox"/> (99) Other, specify _____ | <input type="checkbox"/> othspec (vc, 50) | | |

timeptV2 <interval60>

othspec (vc, 50)

PS: NarrV2
PT: NarrV2
Panel: Narr

Associated form(s):

- Randomization Form
- Baseline Form
- Baseline Lesion Diagnostic Form
- Intervention Procedure Form
- Lesion Treatment Form
- Index Visit Completion Form
- Contact Form
- Study Exit Form
- Adverse Event Log
- Concomitant Medication Logs
- Study Drug Discontinuation Form
- Protocol Deviation Form
- Subsequent Hospitalization Form
- Repeat Renal Angiography Form
- Repeat Renal Revascularization Form
- Additional Lesion Treatment Form
- Other (specify) _____

| | | |
|---------------------|-------------------------------------|---------------------|
| randomiz <checked1> | <input checked="" type="checkbox"/> | |
| Blinang <checked1> | <input checked="" type="checkbox"/> | Blin <checked1> |
| LesnTx <checked1> | <input checked="" type="checkbox"/> | proc <checked1> |
| contact <checked1> | <input checked="" type="checkbox"/> | indexvis <checked1> |
| aelog <checked1> | <input checked="" type="checkbox"/> | term <checked1> |
| discont <checked1> | <input checked="" type="checkbox"/> | conmed <checked1> |
| subhosp <checked1> | <input checked="" type="checkbox"/> | pdev <checked1> |
| rr <checked1> | <input checked="" type="checkbox"/> | ra <checked1> |
| other <checked1> | <input checked="" type="checkbox"/> | addlesn <checked1> |

othcrf (vc, 100)

narrtext (vc, 200)

text2 (vc, 200)

| | |
|----------------------|--------------------|
| HCRI USE ONLY | |
| Received: | ____ / ____ / ____ |
| By: | _____ |

CORAL

PANEL: Context
PS: Context

Site ID: _____ Pt. No.: _____ Randomization #: _____

Transfer of Patient Form

PS: Transfer
PT: Transfer
Panel: Transfer

Instructions: When a subject moves out of the original clinic area, the original clinic should notify HCRI. Together HCRI and the original clinic should determine if the subject can be transferred to another clinic.

Information from Original Clinic

- Date of last subject visit or contact: (mm/dd/yyyy)
- Print name of person completing this form:
- Date Transfer of Patient Form completed: (mm/dd/yyyy)
- Clinic Transferring to:
(Name and 3-digit Site ID)
- Forms and medical information forwarded to the new clinic? (1) YES (2) NO
(Confirm with HCRI the name and address of CORAL coordinator to send to)
- Date mailed: (mm/dd/yyyy)

Original clinic: Stop here.
Mail copy of this form with copies of other CORAL forms and medical records to new clinic.

Information from New Clinic

- Date of first visit: (mm/dd/yyyy)
(Complete appropriate forms and submit to HCRI as usual.)
- Date this form completed: (mm/dd/yyyy)
- Print name of person completing this form:

The new clinic is to FAX this completed form to HCRI along with the appropriate follow-up forms associated with the subject's first visit at the new clinic.

| |
|---------------------------------|
| HCRI USE ONLY |
| Received: _____ / _____ / _____ |
| By: _____ |

CORAL

IDE # G040181

Site ID: _____ Pt. No.: _____ Randomization #: _____

SERIOUS ADVERSE EVENT REPORTING FORM

PS: SAEfax
 PT: SAEfax
 Panel: SAEfax

Complete entire form. Fax to HCRI within 24 hours of knowledge of the event at 617 632-124

Date of form completion: Type of report: (2) Follow-up

- Principal Investigator (print full name):
- Report prepared by (print full name):
- Date of event:
- Adverse event:

4.1. Brief description of event:

COMPLETE ADVERSE EVENT LOG

- Relevant tests/procedures/laboratory data (include dates):
- Concomitant medications (taken at time of event):

7. Event details:

| Related to study drug? | Related to study stent? | Angioguard? | Expectedness | Severity of Event | Outcome of Event |
|---|--|--|--|--|--|
| <input type="checkbox"/> (1) Unlikely <input type="checkbox"/> (2) Possible or probable <input type="checkbox"/> (3) No drug <input type="text" value="drugrel <relationship11>"/> | <input type="checkbox"/> (1) Unlikely <input type="checkbox"/> (2) Possible or probable <input type="text" value="lotnum1 (vc, 15)"/> <input type="text" value="catnum1 (vc, 15)"/> | <input type="checkbox"/> (1) Unlikely <input type="checkbox"/> (2) Possible or probable <input type="text" value="lotnum2 (vc, 15)"/> <input type="text" value="catnum2 (vc, 15)"/> | <input type="checkbox"/> (1) Expected <input type="checkbox"/> (2) Not expected <input type="text" value="expect <expected>"/> | <input type="checkbox"/> (1) Mild <input type="text" value="sever <severity12>"/> | <input type="text" value="outcome <outcome18>"/> <input type="checkbox"/> (2) Recovered <input type="checkbox"/> (3) Symptoms continue |

- Criteria for SAE: (check all that apply)
 - death <checked1>
 - Congenital abnormality Hos Prolonged hospitaliz Other
 - medsig <checked1>
 - congen <checked1>
 - hosp <checked1>
 - prolhosp <checked1>
 - other <checked1>
 -

9. Treatment administered and follow-up plan:

10. Date this event was reported to IRB: /yyyy (1) Not reported irbnd <checked1>

I HAVE REVIEWED THE INFORMATION IN THIS CASE REPORT FORM AND ALL ATTACHED DOCUMENTS AND CERTIFY THAT THE INFORMATION CONTAINED HEREIN IS ACCURATE.

Signature of Investigator _____ Date (mm/dd/yyyy) _____

CORAL

PANEL: Context
PS: Context

Site ID: _____ Pt. No.: _____ Randomization #: _____

Crossover Form

Page 1 of 1

1. Date crossover request made: (mm/dd/yyyy)

2. Name of investigator requesting crossover: First Last

PS: Crossover
PT: Crossover
Panel: Crossover

2.1. Phone number of investigator: _____
(Area code)

3. Most recent laboratory data:

3.1. Most recent creatinine: mg/dl Date
(mm/dd/yyyy)
3.2. Most recent potassium: mg/dl Date
(mm/dd/yyyy)

4. Reason for crossover request:

4.1. Subject met a primary endpoint: (1) YES (2) NO
4.2. The subject presents with anuric acute renal failure: (1) YES (2) NO
4.3. Complete occlusion of all arteries to the one kidney if there is a solitary kidney or complete occlusion of all arteries to both kidneys if there are two kidneys documented angiographically: (1) YES (2) NO
4.4. There is at least one kidney distal to a complete occlusion that is greater than 8 cm in length: (1) YES (2) NO
4.5. Other reason: (1) YES (2) NO
Specify on Narrative Form (CRL 115)

5. Has the subject been hospitalized in the last 3 months? (1) YES (2) NO

5.1. Provide details. If more space is needed, list additional hospitalizations on Narrative Form.
Date: Diagnosis:
Date: _____/_____/_____ (mm/dd/yyyy) Diagnosis: _____
Date: _____/_____/_____ (mm/dd/yyyy) Diagnosis: _____

PS: Hosps
PT: Crossover
Panel: Hosps

6. List all hypertensive medications:

| Medication | Total Daily Dose | Medication | Total Daily Dose |
|--|--|---|------------------|
| <input type="text" value="med (vc, 100)"/> | <input type="text" value="dose (fl 8, 4)"/> <input type="text" value="dose1 (fl 8, 4)"/> | <input type="text" value="medunit (vc, 10)"/> | |
| | | | |
| | | | |

PS: Hypten
PT: Crossover
Panel: Hypten

Crossover Committee approval? (1) YES (2) NO

7. Date of Committee decision: (mm/dd/yyyy)

PS: Crossover1
PT: Crossover
Panel: Crossover

CORAL

Site ID: _____

Pt. No.: _____

Randomization #: _____

Non-Routine Follow-Up Notification

PS: NRFUNot
PT: NRFUNot
Panel: NRFUNot

Please FAX this form as soon as you are aware of a CORAL subject who will be undergoing non-routine follow-up. Fax to 617 307-5600; ATTN: INGRID ABRAHAMSEN

1. Date form completed:

formmm/formdd/formyy

____/____/____ (mm/dd/yyyy)

formdt()

2. Last subject routine contact:

lastctmm/lastctdd/lastctyy

____/____/____ (mm/dd/yyyy)

lastctdt()

Protocol contact interval (e.g., "6 Mo," "2 Year"):

interval (vc, 50)

3. Type of non-routine follow-up:

noncomp
<checked1>

Non-compliant subject

Please complete a Protocol Deviation Form for the subject's FIRST non-office follow-up contact and submit with the Contact Form.

You will receive a memo from the DCC for your records. Should the subject resume routine follow-up, please contact the DCC.

phone
<checked1>

Protocol-specified telephone-only follow-up, new In

newic1mm/newic1dd/newic1yy

newic1dt()

Date new Informed Consent signed:

____/____/____ (mm/dd/yyyy)

Please submit the Study Drug Discontinuation Form (*unless the subject has been prescribed Atacand or Caduet as standard of care*) and continue to report AEs and SAEs as you become aware of them. Contact Forms providing any additional data should also be submitted for each phone call.

tracking
<checked1>

Protocol-specified survival tracking only, new In

newic2mm/newic2dd/newic2yy

newic2dt()

Date new Informed Consent signed:

____/____/____ (mm/dd/yyyy)

Please submit the Study Drug Discontinuation Form. No further data on this subject is expected until study close-out, at which time a Study Exit Form should be submitted indicating the subject's survival status.

cccnotif
<checked1>

CCC notified to deactivate the voucher card number(s) for study drug(s).

4. Comments/Additional Information:

comments (vc, 200)

pageno (fl 6, 2)

visno (vc, 20)

subid (vc, 7)

pagerepeat (vc, 5)

visrepeat (vc, 5)

PANEL: Context
PS: Context

CORAL

CORAL

Site ID: Pt. No.: Randomization #:

Angiographic Core Lab Renal Angiography Case Report Form

PS: Angio1
PT: Angio1
Panel: Angio1

Angiographic Observation:

- (1) Baseline Diagnostic and post-pressure (if appropriate) angiograms (Medical RX arm)
- (2) Baseline Diagnostic and Intervention angiograms (Stent RX arm)
- (3) Follow-up angiogram → (1) Disease Progression Evaluation (Medical arm follow up) (2) Restenosis Evaluation (Stent RX arm follow up)

- Is subject at high risk for contrast induced nephropathy? (1) YES (2) NO
- Does the subject have only one kidney? (1) YES (2) NO

Date of angiogram: / / (mm / dd / yyyy)

Assessment of adherence to renal angiography methods

1. Does the angiogram comply with Renal Angiography Methods? (1) YES (2) NO

1.1. Select all applicable reasons:

- improper I.D. / labeling
- no pre Angioguard insertion image
- no pre Angioguard removal image
- no post Angioguard removal image
- technical aspects of image acquisition
- motion artifact
- improper angulation
- improper angiographic technique
- no flush aortogram or selective angiogram that shows entire kidneys in FOV
- no image without contrast of the calibrated marker or ≥ 6F catheter at the time of calibration
- no angiogram that profiles the ostia of all renal arteries
- no images of intra-renal vessels
- poor vessel opacification above and below renal arteries and renal arteries not opacified well
- no pressure tracings for 60-79% stenosis
- no post-pressure angiogram (Medical RX Arm)
- only "captured" images (and not entire study) sent

Assessment of Aortic Disease

2. Aortic disease:
- (1) none
 - (2) mild (minimal – scattered wall irregularities)
 - (3) moderate (vessel irregularity along both aortic walls with few "clean" regions)
 - (4) severe ("coral reef" appearance)

pageno (fl 6, 2)

visno (vc, 20)

subid (vc, 7)

pagerepeat (vc, 5)

visrepeat (vc, 5)

PANEL: Context
PS: Context

CORAL

Site ID: Pt. No.: Randomization #:

Angiographic Core Lab Renal Angiography Case Report Form

PS: V2Angio1
PT: V2Angio1
Panel: Angio1

Angiographic Observation:

- (1) Baseline Diagnostic and post-pressure (if appropriate) angiograms (Medical RX arm)
- (2) Baseline Diagnostic and Intervention angiograms (Stent RX arm)
- (3) Follow-up angiogram → (1) Disease Progression Evaluation (Medical arm follow up) (2) Restenosis Evaluation (Stent RX arm follow up)

Is subject at high risk for contrast induced nephropathy? (1) YES (2) NO

Does the subject have only one kidney? (1) YES (2) NO

Date of angiogram: / ____ / ____ (mm / dd / yyyy)

Assessment of adherence to renal angiography methods

1. Does the angiogram comply with Renal Angiography Methods? (1) YES (2) NO

1.1. Select all applicable reasons:

- improper I.D. / labeling
- no pre EPD insertion image (if applicable)
- no pre EPD removal image (if applicable)
- no post EPD removal image (if applicable)
- technical aspects of image acquisition
- motion artifact
- improper angulation
- improper angiographic technique
- no flush aortogram or selective angiogram that shows entire kidneys in FOV
- no image without contrast of the calibrated marker or ≥ 6F catheter reference calibration
- no angiogram that profiles the ostia of all renal arteries
- no images of intra-renal vessels
- poor vessel opacification above and below renal arteries and renal arteries not opacified well
- if pressures performed, no post-pressure angiogram (Stent RX Arm)
- only "captured" images (and not entire study) sent
- other, specify:

Assessment of Aortic Disease

2. Aortic disease:
- (1) none
 - (2) mild (minimal – scattered wall irregularities)
 - (3) moderate (vessel irregularity along both aortic walls with few "clean" regions)
 - (4) severe ("coral reef" appearance)

CORAL

Site ID: _____ **Pt. No.:** _____ **Randomization #:** _____

Date of angiogram: _____ angiodt() _____ (mm / dd / yyyy)

PS: Angio2
 PT: Angio2
 Panel: Angio2

3. Is the RIGHT kidney present? rtpres <yesno> YES (2) NO

3.1. RIGHT kidney size 1. rkidsz1 (fl 6, 2) 2. rkidsz2 (fl 6, 2) 3. rkidsz3 (fl 6, 2) Final rkidsz4 (fl 6, 2)

| | STENOTIC MAIN ARTERY #1 | STENOTIC MAIN ARTERY #2 | | | | | | | | | | | | | | | |
|---|---|---|-------------------|---|---|--------------------|---|---|-------------------|--|--|----------------|---|---|-------------------|--|---|
| 3.2. LESION LOCATION per Nomenclature | lesloc1 (vc, 5) | lesloc2 (vc, 5) | | | | | | | | | | | | | | | |
| 3.3. Minimum lumen Diameter (MLD) | 1. _____ mm mld1 (fl 6, 2) 2. _____ mm mld2 (fl 6, 2) 3. _____ mm mld3 (fl 6, 2) Final _____ mm mld4 (fl 6, 2) | 1. _____ mm mld5 (fl 6, 2) 2. _____ mm mld6 (fl 6, 2) 3. _____ mm mld7 (fl 6, 2) Final _____ mm mld8 (fl 6, 2) | | | | | | | | | | | | | | | |
| 3.4. Reference lumen Diameter (Ref) | 1. _____ mm ref1 (fl 6, 2) 2. _____ mm ref2 (fl 6, 2) 3. _____ mm ref3 (fl 6, 2) Final _____ mm ref4 (fl 6, 2) | 1. _____ mm ref5 (fl 6, 2) 2. _____ mm ref6 (fl 6, 2) 3. _____ mm ref7 (fl 6, 2) Final _____ mm ref8 (fl 6, 2) | | | | | | | | | | | | | | | |
| 3.5. % STENOSIS | sten1a (fl 6, 2) sten3a (fl 6, 2) sten2a (fl 6, 2) sten4a (fl 6, 2) | sten5a (fl 6, 2) sten7a (fl 6, 2) sten6a (fl 6, 2) sten8a (fl 6, 2) | | | | | | | | | | | | | | | |
| 3.6. Lesion Length | 1. _____ mm lesl1 (fl 6, 2) 2. _____ mm lesl2 (fl 6, 2) 3. _____ mm lesl3 (fl 6, 2) Final _____ mm lesl4 (fl 6, 2) | 1. _____ mm lesl5 (fl 6, 2) 2. _____ mm lesl6 (fl 6, 2) 3. _____ mm lesl7 (fl 6, 2) Final _____ mm lesl8 (fl 6, 2) | | | | | | | | | | | | | | | |
| 3.7. Distance from ostium to first renal artery branch | dist1 (fl 6, 2) mm | dist2 (fl 6, 2) mm | | | | | | | | | | | | | | | |
| 3.8. CHARACTERISTICS | <table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 33%;">3.8.1. Calcified?</td> <td style="width: 33%;">calc1 <yesno></td> <td style="width: 33%;">calc2 <yesno></td> </tr> <tr> <td>3.8.2. Concentric?</td> <td>conc1 <yesno></td> <td>conc2 <yesno></td> </tr> <tr> <td>3.8.3. Eccentric?</td> <td>ecc1 <yesno></td> <td>ecc2 <yesno></td> </tr> <tr> <td>3.8.4. Smooth?</td> <td>smth1 <yesno></td> <td>smth2 <yesno></td> </tr> <tr> <td>3.8.5. Ulcerated?</td> <td>ulc1 <yesno> <input type="checkbox"/> (2) NO</td> <td><input type="checkbox"/> (1) YES ulc2 <yesno></td> </tr> </table> | | 3.8.1. Calcified? | calc1 <yesno> | calc2 <yesno> | 3.8.2. Concentric? | conc1 <yesno> | conc2 <yesno> | 3.8.3. Eccentric? | ecc1 <yesno> | ecc2 <yesno> | 3.8.4. Smooth? | smth1 <yesno> | smth2 <yesno> | 3.8.5. Ulcerated? | ulc1 <yesno> <input type="checkbox"/> (2) NO | <input type="checkbox"/> (1) YES ulc2 <yesno> |
| 3.8.1. Calcified? | calc1 <yesno> | calc2 <yesno> | | | | | | | | | | | | | | | |
| 3.8.2. Concentric? | conc1 <yesno> | conc2 <yesno> | | | | | | | | | | | | | | | |
| 3.8.3. Eccentric? | ecc1 <yesno> | ecc2 <yesno> | | | | | | | | | | | | | | | |
| 3.8.4. Smooth? | smth1 <yesno> | smth2 <yesno> | | | | | | | | | | | | | | | |
| 3.8.5. Ulcerated? | ulc1 <yesno> <input type="checkbox"/> (2) NO | <input type="checkbox"/> (1) YES ulc2 <yesno> | | | | | | | | | | | | | | | |
| 3.9. TIMI FLOW PRE-pressure measurement | <input type="checkbox"/> 0 (no flow) <input type="checkbox"/> 1 (partial) <input type="checkbox"/> 2 (complete) <input checked="" type="checkbox"/> pretimi1 <timi> <input type="checkbox"/> CND | <input type="checkbox"/> 0 (no flow) <input type="checkbox"/> 1 (partial) <input type="checkbox"/> 2 (complete) <input type="checkbox"/> pretimi2 <timi> <input type="checkbox"/> CND | | | | | | | | | | | | | | | |
| 3.10. PRESSURE GRADIENTS (mm HG) | Aorta kidney gradient | Aorta kidney gradient | | | | | | | | | | | | | | | |
| 3.10.1. Peak Systolic | aorpk1 (fl 6, 2) kidpk1 (fl 6, 2) grapk1 (fl 6, 2) | aorpk2 (fl 6, 2) kidpk2 (fl 6, 2) grapk2 (fl 6, 2) | | | | | | | | | | | | | | | |
| 3.10.2. Mean Pressure | aormn1 (fl 6, 2) kidmn1 (fl 6, 2) gramn1 (fl 6, 2) | aormn2 (fl 6, 2) kidmn2 (fl 6, 2) gramn2 (fl 6, 2) | | | | | | | | | | | | | | | |
| 3.10.3. Diastolic | aordia1 (fl 6, 2) kiddia1 (fl 6, 2) gradia1 (fl 6, 2) | aordia2 (fl 6, 2) kiddia2 (fl 6, 2) gradia2 (fl 6, 2) | | | | | | | | | | | | | | | |
| 3.11. TIMI FLOW Medical Rx Arm ONLY POST-pressure measurement | <input type="checkbox"/> 0 (no flow) <input type="checkbox"/> 1 (partial) <input type="checkbox"/> 2 (complete) <input type="checkbox"/> posttimi1 <timi> <input type="checkbox"/> CND | <input type="checkbox"/> 0 (no flow) <input type="checkbox"/> 1 (partial) <input type="checkbox"/> 2 (complete) <input type="checkbox"/> posttimi2 <timi> <input type="checkbox"/> CND | | | | | | | | | | | | | | | |

- sten1 (f-5)
- sten2 (f-5)
- sten3 (f-5)
- sten4 (f-5)
- sten5 (f-5)
- sten6 (f-5)
- sten7 (f-5)
- sten8 (f-5)

Site ID: _____ Pt. No.: _____ Randomization #: _____

Date of angiogram: _____

angiodt() (mm / dd / yyyy)

PS: V2Angio2
 PT: V2Angio2
 Panel: Angio2

3. Is the RIGHT kidney present?

rtpres <yesnocnd> (1) YES (2) NO (3) CND

3.1. RICE cndQ31 <checked1> rkidsz1 (fl 6, 2) 2. rkidsz2 (fl 6, 2) 3. rkidsz3 (fl 6, 2) Final rkidsz4 (fl 6, 2)

Is a stenotic lesion present?
(>= 60% MINUS 1.8 SD)

(1) YES (2) NO → skip Rstenles <yesnocnd>

| | STENOTIC MAIN ARTERY #1 | STENOTIC MAIN ARTERY #2 |
|---|--|--|
| 3.2. LESION LOCATION per Nomenclature | lesloc1 (vc, 5) | lesloc2 (vc, 5) |
| 3.3. Minimum lumen Diameter (MLD) | 1. mld2 (fl 6, 2) mld1 (fl 6, 2) 2. mld4 (fl 6, 2) mld3 (fl 6, 2) Final | 1. mld5 (fl 6, 2) mld6 (fl 6, 2) 2. mld7 (fl 6, 2) mld8 (fl 6, 2) Final |
| 3.4. Reference lumen Diameter (Ref) | ref2 (fl 6, 2) ref1 (fl 6, 2) ref4 (fl 6, 2) ref3 (fl 6, 2) Final | 1. ref5 (fl 6, 2) ref6 (fl 6, 2) 2. ref7 (fl 6, 2) ref8 (fl 6, 2) Final |
| 3.5. % STENOSIS | sten1a (fl 6, 2) sten3a (fl 6, 2) sten2a (fl 6, 2) sten4a (fl 6, 2) Final | sten5a (fl 6, 2) sten7a (fl 6, 2) sten6a (fl 6, 2) sten8a (fl 6, 2) Final |
| 3.6. Lesion Length | 1. lesl2 (fl 6, 2) lesl1 (fl 6, 2) 2. lesl4 (fl 6, 2) lesl3 (fl 6, 2) 3. lesl5 (fl 6, 2) lesl6 (fl 6, 2) Final | 1. lesl5 (fl 6, 2) lesl6 (fl 6, 2) 2. lesl7 (fl 6, 2) lesl8 (fl 6, 2) 3. lesl9 (fl 6, 2) lesl10 (fl 6, 2) Final |
| 3.7. Distance from ostium to first renal artery branch | dist1 (fl 6, 2) mm | dist2 (fl 6, 2) mm |
| 3.8. CHARACTERISTICS | | |
| 3.8.1. Calcified? | calc1 <yesnocnd> <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO | calc2 <yesnocnd> <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO |
| 3.8.2. Concentric? | ecc1 <yesnocnd> <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO | conc2 <yesnocnd> <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO |
| 3.8.3. Eccentric? | ecc1 <yesnocnd> <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO | ecc2 <yesnocnd> <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO |
| 3.8.4. Smooth? | smth1 <yesnocnd> <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO | smth2 <yesnocnd> <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO |
| 3.8.5. Ulcerated? | ulc1 <yesnocnd> <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO | ulc2 <yesnocnd> <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO |
| 3.9. TIMI FLOW PRE-pressure measurement | <input type="checkbox"/> 0 (no flow) <input type="checkbox"/> 1 (partial) <input type="checkbox"/> 2 (complete) <input type="checkbox"/> CND pretimi1 <timi> | <input type="checkbox"/> 0 (no flow) <input type="checkbox"/> 1 (partial) <input type="checkbox"/> 2 (complete) <input type="checkbox"/> CND pretimi2 <timi> |
| 3.10. PRESSURE GRADIENTS (mm HG) | Aorta kidney gradient | Aorta kidney gradient |
| 3.10.1. Peak Systolic | aorpk1 (fl 6, 2) kidpk1 (fl 6, 2) grapk1 (fl 6, 2) | aorpk2 (fl 6, 2) kidpk2 (fl 6, 2) grapk2 (fl 6, 2) |
| 3.10.2. Mean Pressure | aormn1 (fl 6, 2) kidmn1 (fl 6, 2) gramn1 (fl 6, 2) | aormn2 (fl 6, 2) kidmn2 (fl 6, 2) gramn2 (fl 6, 2) |
| 3.10.3. Diastolic | aordia1 (fl 6, 2) kiddia1 (fl 6, 2) gradia1 (fl 6, 2) | aordia2 (fl 6, 2) kiddia2 (fl 6, 2) gradia2 (fl 6, 2) |
| 3.11. TIMI FLOW Medical Rx Arm ONLY POST-pressure measurement | <input type="checkbox"/> 0 (no flow) <input type="checkbox"/> 1 (partial) <input type="checkbox"/> 2 (complete) <input type="checkbox"/> CND posttimi1 <timi> | <input type="checkbox"/> 0 (no flow) <input type="checkbox"/> 1 (partial) <input type="checkbox"/> 2 (complete) <input type="checkbox"/> CND posttimi2 <timi> |

Site ID: _____ Pt. No.: _____ Randomization #: _____

Date of angiogram: _____ angiodt() _____ (mm / dd / yyyy)

PS: Angio3
 PT: Angio3
 Panel: Angio3

| | STENOTIC MAIN ARTERY #1 | STENOTIC MAIN ARTERY #2 | STENOTIC MAIN ARTERY #3 |
|---|-------------------------|-------------------------|-------------------------|
| 3.12. COMPLICATIONS | | | |
| <i>Medical Rx Arm only - post-procedure</i> | | | |
| 3.12.1. Dissection? | dissect1 <yesno> | dissect2 <yesno> | dissect3 <yesno> |
| 3.12.1.1. Flow limiting? | flow1 <yesno> | flow2 <yesno> | flow3 <yesno> |
| 3.12.2. Occlusion? | occl1 <yesno> | occl2 <yesno> | occl3 <yesno> |
| 3.12.2.1. Main RA? | main1 <yesno> | main2 <yesno> | main3 <yesno> |
| 3.12.2.2. Branch vessel? | bran1 <yesno> | bran2 <yesno> | bran3 <yesno> |
| 3.12.3. Embolus? | emb1 <yesno> | emb2 <yesno> | emb3 <yesno> |
| 3.12.4. Thrombus? | throm1 <yesno> | throm2 <yesno> | throm3 <yesno> |
| 3.12.5. Spasm? | spasm1 <yesno> | spasm2 <yesno> | spasm3 <yesno> |
| 3.12.6. Wire perforation? | wire1 <yesno> | wire2 <yesno> | wire3 <yesno> |
| 3.12.7. Vessel rupture? | rupt1 <yesno> | rupt2 <yesno> | rupt3 <yesno> |
| 3.12.8. Pseudoaneurysm? | paneur1 <yesno> | paneur2 <yesno> | paneur3 <yesno> |

Assessment of RIGHT RENAL ISCHEMIA

4. What is the total number of right renal arteries seen? _____

totrt (f, 5)

If more than one right renal artery, please define the status of all NON-TREATED arteries (not previously defined above).

*A main renal artery(s) is/are defined as a renal artery having a diameter of ≥ 3.5 mm and supplying ≥ 50% of kidney
 An accessory renal artery(s) is/are defined as a renal artery having a diameter of < 3.5 mm or supplying < 50% of kidney.*

| RENAL ARTERY LOCATION (refer to lesion identification nomenclature) | rmlart1 (vc, 5) | rmlart2 (vc, 5) | rmlart3 (vc, 5) |
|---|---|--|--|
| | stat1 <patenc> | | |
| 4.1. Patency Status | <input type="checkbox"/> (1) open (0 – 59% stenosis) <input type="checkbox"/> (2) narrowed (60 - 99% stenosis) <input type="checkbox"/> (3) totally occluded <input type="checkbox"/> (4) CND - why? cnd1 (vc, 100) | <input type="checkbox"/> (1) open (0 – 59% stenosis) <input type="checkbox"/> (2) stat2 <patenc> - 99% stenosis <input type="checkbox"/> (3) totally occluded <input type="checkbox"/> (4) CND - why? cnd2 (vc, 100) | <input type="checkbox"/> (1) open (0 – 59% stenosis) <input type="checkbox"/> (2) stat3 <patenc> - 99% stenosis <input type="checkbox"/> (3) totally occluded <input type="checkbox"/> (4) CND - why? cnd3 (vc, 100) |

4.2. Is the entire right kidney ischemic? cnd11<yesnocnd> (1) YES (2) NO (3) CND
where ischemia is defined as ALL renal arteries are narrowed by ≥ 60%

Why? _____
cnd4 (vc, 100)

Site ID: _____ Pt. No.: _____ Randomization #: _____

Date of angiogram: _____ angiodt() _____ (mm / dd / yyyy)

PS: V2Angio3
 PT: V2Angio3
 Panel: Angio3

| | STENOTIC MAIN ARTERY #1 | STENOTIC MAIN ARTERY #2 |
|---|--|--|
| 3.12. COMPLICATION cndQ312 <checked1> | | |
| 3.12.1. Dissection? | dissect1 <yesnocnd> | dissect2 <yesnocnd> |
| 3.12.1.1. Flow limiting? | flow1 <yesnocnd> | flow2 <yesnocnd> |
| 3.12.2. Occlusion? | occl1 <yesnocnd> | occl2 <yesnocnd> |
| 3.12.2.1. Main RA? | main1 <yesnocnd> | main2 <yesnocnd> |
| 3.12.2.2. Branch vessel? | bran1 <yesnocnd> | bran2 <yesnocnd> |
| 3.12.3. Embolus? | emb1 <yesnocnd> | emb2 <yesnocnd> |
| 3.12.4. Thrombus? | throm1 <yesnocnd> | throm2 <yesnocnd> |
| 3.12.5. Spasm? | spasm1 <yesnocnd> | spasm2 <yesnocnd> |
| 3.12.6. Wire perforation? | wire1 <yesnocnd> | wire2 <yesnocnd> |
| 3.12.7. Vessel rupture? | rupt1 <yesnocnd> | rupt2 <yesnocnd> |
| 3.12.8. Pseudoaneurysm? | paneur1 <yesnocnd> | paneur2 <yesnocnd> |

Assessment of RIGHT RENAL ISCHEMIA

4. What is the total number of right renal arteries seen? _____

totrt (f, 5)

If more than one right renal artery, please define the status of all NON-TREATED arteries (not previously defined above).

A main renal artery(s) is/are defined as a renal artery having a diameter of ≥ 3.5 mm and supplying $\geq 50\%$ of kidney
 An accessory renal artery(s) is/are defined as a renal artery having a diameter of < 3.5 mm or supplying $< 50\%$ of kidney.

| RENAL ARTERY LOCATION (refer to lesion identification nomenclature) | rlart1 (vc, 5) | rlart2 (vc, 5) | rlart3 (vc, 5) |
|---|---|---|---|
| 4.1. Patency Status | <input type="checkbox"/> (1) open (0 – 59% stenosis) <input checked="" type="checkbox"/> (2) stat1 <patenc> 99% stenosis <input type="checkbox"/> (3) totally occluded <input type="checkbox"/> (4) CND - why? cnd1 (vc, 100) | <input type="checkbox"/> (1) open (0 – 59% stenosis) <input checked="" type="checkbox"/> (2) stat2 <patenc> 99% stenosis <input type="checkbox"/> (3) totally occluded <input type="checkbox"/> (4) CND - why? cnd2 (vc, 100) | <input type="checkbox"/> (1) open (0 – 59% stenosis) <input checked="" type="checkbox"/> (2) stat3 <patenc> 99% stenosis <input type="checkbox"/> (3) totally occluded <input type="checkbox"/> (4) CND - why? cnd3 (vc, 100) |

4.2. Is the entire right kidney ischemic? cnd11 <yesnocnd> (1) YES (2) NO (3) CND

where ischemia is defined as ALL renal arteries are narrowed by $\geq 60\%$ MINUS 1.8 standard deviation (or 11.88%, i.e. $> 48.12\%$) and or a systolic translesion gradient ≥ 20 mmHg OR $\geq 70\%$ MINUS 1.8 SD (15.84%, i.e. $\geq 64.16\%$) with no pressures measured will be considered ischemic if only one renal artery to that side.

Why? cnd4 (vc, 100)

CORAL

Site ID: _____ Pt. No.: _____ Randomization #: _____

Date of angiogram: _____ / _____ (mm / dd / yyyy)

PS: Angio4
PT: Angio4
Panel: Angio4

5. Is the LEFT kidney present? (1) YES (2) NO

5.1. LEFT kidney size 1. _____ 2. _____ 3. _____ Final _____

| | STENOTIC MAIN ARTERY #1 | STENOTIC MAIN ARTERY #2 |
|---|--|--|
| 5.2. LESION LOCATION per Nomenclature | _____ | _____ |
| 5.3. Minimum lumen Diameter (MLD) | 1. _____ mm 2. _____ mm 3. _____ mm Final _____ mm | 1. _____ mm 2. _____ mm 3. _____ mm Final _____ mm |
| 5.4. Reference lumen Diameter (Ref) | 1. _____ mm 2. _____ mm 3. _____ mm Final _____ mm | 1. _____ mm 2. _____ mm 3. _____ mm Final _____ mm |
| 5.5. Lesion Length | 1. _____ mm 2. _____ mm 3. _____ mm Final _____ mm | 1. _____ mm 2. _____ mm 3. _____ mm Final _____ mm |
| 5.6. % Stenosis | 1. _____ % 2. _____ % 3. _____ % | 1. _____ % 2. _____ % 3. _____ % |
| 5.7. Distance from ostium to first renal artery branch | _____ mm | _____ mm |
| 5.8. CHARACTERISTICS | | |
| 5.8.1. Calcified? | <input type="checkbox"/> <input type="checkbox"/> | <input type="checkbox"/> <input type="checkbox"/> |
| 5.8.2. Concentric? | <input type="checkbox"/> <input type="checkbox"/> | <input type="checkbox"/> <input type="checkbox"/> |
| 5.8.3. Eccentric? | <input type="checkbox"/> <input type="checkbox"/> | <input type="checkbox"/> <input type="checkbox"/> |
| 5.8.4. Smooth? | <input type="checkbox"/> <input type="checkbox"/> | <input type="checkbox"/> <input type="checkbox"/> |
| 5.8.5. Ulcerated? | <input type="checkbox"/> (2) NO | <input type="checkbox"/> (1) YES |
| 5.9. TIMI FLOW PRE-pressure measurement | <input type="checkbox"/> 0 (no flow) <input type="checkbox"/> 2 (partial) <input type="checkbox"/> 1 (complete) <input type="checkbox"/> CND | <input type="checkbox"/> 0 (no flow) <input type="checkbox"/> 2 (partial) <input type="checkbox"/> 1 (complete) <input type="checkbox"/> CND |
| 5.10. PRESSURE GRADIENTS (mm HG) | Aorta kidney gradient | Aorta kidney gradient |
| 5.10.1. Peak Systolic | _____ | _____ |
| 5.10.2. Mean Pressure | _____ | _____ |
| 5.10.3. Diastolic | _____ | _____ |
| 5.11. TIMI FLOW Medical Rx Arm ONLY POST-pressure measurement | <input type="checkbox"/> 0 (no flow) <input type="checkbox"/> 2 (partial) <input type="checkbox"/> 1 (complete) <input type="checkbox"/> CND | <input type="checkbox"/> 0 (no flow) <input type="checkbox"/> 2 (partial) <input type="checkbox"/> 1 (complete) <input type="checkbox"/> CND |

- Isten1 (f-5)
- Isten2 (f-5)
- Isten3 (f-5)
- Isten4 (f-5)
- Isten5 (f-5)
- Isten6 (f-5)
- Isten7 (f-5)
- Isten8 (f-5)

Site ID: _____ Pt. No.: _____ Randomization #: _____

Date of angiogram: _____

angiodt() / _____ (mm / dd / yyyy)

PS: V2Angio4
 PT: V2Angio4
 Panel: Angio4

5. Is the LEFT kidney present?

ltpres <yesnocnd> (1) YES (2) NO (3) CND

5.1. LEF cndQ51 <checked1> lkidsz1 (fl 6, 2) 2. lkidsz2 (fl 6, 2) 3. lkidsz3 (fl 6, 2) Final lkidsz4 (fl 6, 2)

Is a stenotic lesion present?
(>= 60% MINUS 1.8 SD)

(1) YES (2) NO → skstenles <yesnocnd> lstenles <yesnocnd>

| | STENOTIC MAIN ARTERY #1 | STENOTIC MAIN ARTERY #2 |
|---|--|--|
| 5.2. LESION LOCATION per Nomenclature | <input type="checkbox"/> llesloc1 (vc, 5) | <input type="checkbox"/> llesloc2 (vc, 5) |
| 5.3. Minimum lumen Diameter (MLD) | 1. <input type="checkbox"/> lmlD1 (fl 6, 2) <input type="checkbox"/> lmlD2 (fl 6, 2) 2. <input type="checkbox"/> lmlD3 (fl 6, 2) <input type="checkbox"/> lmlD4 (fl 6, 2) Final <input type="checkbox"/> lmlD4 (fl 6, 2) | 1. <input type="checkbox"/> lmlD5 (fl 6, 2) <input type="checkbox"/> lmlD6 (fl 6, 2) 2. <input type="checkbox"/> lmlD7 (fl 6, 2) <input type="checkbox"/> lmlD8 (fl 6, 2) Final <input type="checkbox"/> lmlD8 (fl 6, 2) |
| 5.4. Reference lumen Diameter (Ref) | 1. <input type="checkbox"/> lref1 (fl 6, 2) <input type="checkbox"/> lref2 (fl 6, 2) 2. <input type="checkbox"/> lref3 (fl 6, 2) <input type="checkbox"/> lref4 (fl 6, 2) | 1. <input type="checkbox"/> lref5 (fl 6, 2) <input type="checkbox"/> lref6 (fl 6, 2) 2. <input type="checkbox"/> lref7 (fl 6, 2) <input type="checkbox"/> lref8 (fl 6, 2) |
| 5.5. Lesion Length | 1. <input type="checkbox"/> llesl1 (fl 6, 2) <input type="checkbox"/> llesl2 (fl 6, 2) 2. <input type="checkbox"/> llesl3 (fl 6, 2) <input type="checkbox"/> llesl4 (fl 6, 2) Final <input type="checkbox"/> llesl4 (fl 6, 2) | 1. <input type="checkbox"/> llesl5 (fl 6, 2) <input type="checkbox"/> llesl6 (fl 6, 2) 2. <input type="checkbox"/> llesl7 (fl 6, 2) <input type="checkbox"/> llesl8 (fl 6, 2) |
| 5.6. % Stenosis | 1. <input type="checkbox"/> lsten1a (fl 6, 2) <input type="checkbox"/> lsten2a (fl 6, 2) 2. <input type="checkbox"/> lsten3a (fl 6, 2) <input type="checkbox"/> lsten4a (fl 6, 2) Final <input type="checkbox"/> lsten4a (fl 6, 2) | 1. <input type="checkbox"/> lsten5a (fl 6, 2) <input type="checkbox"/> lsten6a (fl 6, 2) 2. <input type="checkbox"/> lsten7a (fl 6, 2) <input type="checkbox"/> lsten8a (fl 6, 2) |
| 5.7. Distance from ostium to first renal artery branch | <input type="checkbox"/> ldist1 (fl 6, 2) mm | <input type="checkbox"/> ldist2 (fl 6, 2) mm |
| 5.8. CHARACTERISTICS | | |
| 5.8.1. Calcified? | <input type="checkbox"/> lcalc1 <yesnocnd> | <input type="checkbox"/> lcalc2 <yesnocnd> |
| 5.8.2. Concentric? | <input type="checkbox"/> lconc1 <yesnocnd> | <input type="checkbox"/> lconc2 <yesnocnd> |
| 5.8.3. Eccentric? | <input type="checkbox"/> lecc1 <yesnocnd> | <input type="checkbox"/> lecc2 <yesnocnd> |
| 5.8.4. Smooth? | <input type="checkbox"/> lsmth1 <yesnocnd> | <input type="checkbox"/> lsmth2 <yesnocnd> |
| 5.8.5. Ulcerated? | <input type="checkbox"/> lulc1 <yesnocnd> | <input type="checkbox"/> lulc2 <yesnocnd> |
| 5.9. TIMI FLOW PRE-pressure measurement | <input type="checkbox"/> 0 (no flow) <input type="checkbox"/> 1 (partial) <input type="checkbox"/> 2 (complete) <input type="checkbox"/> 1 <input type="checkbox"/> lpretimi1 <timi> | <input type="checkbox"/> 0 (no flow) <input type="checkbox"/> 1 (partial) <input type="checkbox"/> 2 (complete) <input type="checkbox"/> 1 <input type="checkbox"/> lpretimi2 <timi> |
| 5.10. PRESSURE GRADIENTS (mm HG) | Aorta kidney gradient | Aorta kidney gradient |
| 5.10.1. Peak Systolic | <input type="checkbox"/> laorpk1 (fl 6, 2) <input type="checkbox"/> lkidpk1 (fl 6, 2) <input type="checkbox"/> lgrapk1 (fl 6, 2) | <input type="checkbox"/> laorpk2 (fl 6, 2) <input type="checkbox"/> lkidpk2 (fl 6, 2) <input type="checkbox"/> lgrapk2 (fl 6, 2) |
| 5.10.2. Mean Pressure | <input type="checkbox"/> laormn1 (fl 6, 2) <input type="checkbox"/> lkidmn1 (fl 6, 2) <input type="checkbox"/> lgramn1 (fl 6, 2) | <input type="checkbox"/> laormn2 (fl 6, 2) <input type="checkbox"/> lkidmn2 (fl 6, 2) <input type="checkbox"/> lgramn2 (fl 6, 2) |
| 5.10.3. Diastolic | <input type="checkbox"/> laordia1 (fl 6, 2) <input type="checkbox"/> lkiddia1 (fl 6, 2) <input type="checkbox"/> lgradia1 (fl 6, 2) | <input type="checkbox"/> laordia2 (fl 6, 2) <input type="checkbox"/> lkiddia2 (fl 6, 2) <input type="checkbox"/> lgradia2 (fl 6, 2) |
| 5.11. TIMI FLOW Medical Rx Arm ONLY POST-pressure measurement | <input type="checkbox"/> 0 (no flow) <input type="checkbox"/> 1 (partial) <input type="checkbox"/> 2 (complete) <input type="checkbox"/> 1 <input type="checkbox"/> lposttimi1 <timi> | <input type="checkbox"/> 0 (no flow) <input type="checkbox"/> 1 (partial) <input type="checkbox"/> 2 (complete) <input type="checkbox"/> 1 <input type="checkbox"/> lposttimi2 <timi> |

Site ID: _____ Pt. No.: _____ Randomization #: _____

Date of angiogram: _____ / angiodt() _____ (mm / dd / yyyy)

PS: Angio5
 PT: Angio5
 Panel: Angio5

| | STENOTIC MAIN ARTERY #1 | STENOTIC MAIN ARTERY #2 | STENOTIC MAIN ARTERY #3 |
|---|---|---|---|
| 5.12. COMPLICATIONS | | | |
| <i>Medical Rx Arm only - post-angiogram</i> | | | |
| 5.12.1. Dissection? | <input checked="" type="checkbox"/> ldissect1 <yesno> <input type="checkbox"/> NO | <input checked="" type="checkbox"/> ldissect2 <yesno> <input type="checkbox"/> NO | <input checked="" type="checkbox"/> ldissect3 <yesno> <input type="checkbox"/> NO |
| 5.12.1.1. Flow limiting? | <input checked="" type="checkbox"/> YES <input type="checkbox"/> NO | <input checked="" type="checkbox"/> YES <input type="checkbox"/> NO | <input checked="" type="checkbox"/> YES <input type="checkbox"/> NO |
| 5.12.2. Occlusion? | <input checked="" type="checkbox"/> loccl1 <yesno> <input type="checkbox"/> NO | <input checked="" type="checkbox"/> loccl2 <yesno> <input type="checkbox"/> NO | <input checked="" type="checkbox"/> loccl3 <yesno> <input type="checkbox"/> NO |
| 5.12.2.1. Main RA? | <input checked="" type="checkbox"/> YES <input type="checkbox"/> NO | <input checked="" type="checkbox"/> YES <input type="checkbox"/> NO | <input checked="" type="checkbox"/> YES <input type="checkbox"/> NO |
| 5.12.2.2. Branch vessel? | <input checked="" type="checkbox"/> lbran1 <yesno> <input type="checkbox"/> (2) NO | <input checked="" type="checkbox"/> lbran2 <yesno> <input type="checkbox"/> (2) NO | <input checked="" type="checkbox"/> lbran3 <yesno> <input type="checkbox"/> (2) NO |
| 5.12.3. Embolus? | <input checked="" type="checkbox"/> YES <input type="checkbox"/> NO | <input checked="" type="checkbox"/> YES <input type="checkbox"/> NO | <input checked="" type="checkbox"/> YES <input type="checkbox"/> NO |
| 5.12.4. Thrombus? | <input checked="" type="checkbox"/> lthrom1 <yesno> <input type="checkbox"/> NO | <input checked="" type="checkbox"/> lthrom2 <yesno> <input type="checkbox"/> NO | <input checked="" type="checkbox"/> lthrom3 <yesno> <input type="checkbox"/> NO |
| 5.12.5. Spasm? | <input checked="" type="checkbox"/> lspasm1 <yesno> <input type="checkbox"/> NO | <input checked="" type="checkbox"/> lspasm2 <yesno> <input type="checkbox"/> NO | <input checked="" type="checkbox"/> lspasm3 <yesno> <input type="checkbox"/> NO |
| 5.12.6. Wire perforation? | <input checked="" type="checkbox"/> lwire1 <yesno> <input type="checkbox"/> NO | <input checked="" type="checkbox"/> lwire2 <yesno> <input type="checkbox"/> NO | <input checked="" type="checkbox"/> lwire3 <yesno> <input type="checkbox"/> NO |
| 5.12.7. Vessel rupture? | <input checked="" type="checkbox"/> lrupt1 <yesno> <input type="checkbox"/> NO | <input checked="" type="checkbox"/> lrupt2 <yesno> <input type="checkbox"/> NO | <input checked="" type="checkbox"/> lrupt3 <yesno> <input type="checkbox"/> NO |
| 5.12.8. Pseudoaneurysm? | <input checked="" type="checkbox"/> lpaneur1 <yesno> <input type="checkbox"/> (2) NO | <input checked="" type="checkbox"/> lpaneur2 <yesno> <input type="checkbox"/> (2) NO | <input checked="" type="checkbox"/> lpaneur3 <yesno> <input type="checkbox"/> (2) NO |

Assessment of LEFT RENAL ISCHEMIA

6. What is the total number of left renal arteries seen? _____

ltotr (f, 5)

If more than one left renal artery, please define the status of all NON-TREATED arteries (not previously defined above).

A main renal artery(s) is/are defined as a renal artery having a diameter of ≥ 3.5 mm and supplying $\geq 50\%$ of kidney
 An accessory renal artery(s) is/are defined as a renal artery having a diameter of < 3.5 mm or supplying $< 50\%$ of kidney.

| RENAL ARTERY LOCATION (refer to lesion identification nomenclature) | lrnlart1 (vc, 5) | lrnlart2 (vc, 5) | lrnlart3 (vc, 5) |
|---|--|--|--|
| 6.1. Patency Status | <input type="checkbox"/> (1) open (0 – 59% stenosis) <input type="checkbox"/> (2) narrowed (60 - 99% stenosis) <input type="checkbox"/> (3) totally occluded <input type="checkbox"/> (4) CND - why? _____ lcnd1 (vc, 100) | <input type="checkbox"/> (1) open (0 – 59% stenosis) <input checked="" type="checkbox"/> (2) lstat2 <patenc> 99% stenosis <input type="checkbox"/> (3) totally occluded <input type="checkbox"/> (4) CND - why? _____ lcnd2 (vc, 100) | <input type="checkbox"/> (1) open (0 – 59% stenosis) <input checked="" type="checkbox"/> (2) lstat3 <patenc> 99% stenosis <input type="checkbox"/> (3) totally occluded <input type="checkbox"/> (4) CND - why? _____ lcnd3 (vc, 100) |

6.3. Is the entire left kidney ischemic? lcnd11<yesnocnd> (1) YES (2) NO (3) CND
 where ischemia is defined as ALL renal arteries are narrowed by $\geq 60\%$

Why? _____
lcnd4 (vc, 100)

Site ID: _____ Pt. No.: _____ Randomization #: _____

Date of angiogram: _____ / angiodt() _____ (mm / dd / yyyy)

PS: V2Angio5
 PT: V2Angio5
 Panel: Angio5

| | STENOTIC MAIN ARTERY #1 | STENOTIC MAIN ARTERY #2 | |
|--|---|---|---|
| 5.12. COMPLICATIONS cndQ512 <checked1> | | | |
| <i>Medical Rx Arm only - post-contrast</i> | | | |
| 5.12.1. Dissection? | ldissect1 <yesnocnd> | ldissect2 <yesnocnd> | NO |
| 5.12.1.1. Flow limiting? | lflow1 <yesnocnd> | lflow2 <yesnocnd> | NO |
| 5.12.2. Occlusion? | loccl1 <yesnocnd> | loccl2 <yesnocnd> | NO |
| 5.12.2.1. Main RA? | lmain1 <yesnocnd> | lmain2 <yesnocnd> | NO |
| 5.12.2.2. Branch vessel? | lbran1 <yesnocnd> | lbran2 <yesnocnd> | NO |
| 5.12.3. Embolus? | lthrom1 <yesnocnd> | lthrom2 <yesnocnd> | NO |
| 5.12.4. Thrombus? | lthrom1 <yesnocnd> | lthrom2 <yesnocnd> | NO |
| 5.12.5. Spasm? | lspasm1 <yesnocnd> | lspasm2 <yesnocnd> | NO |
| 5.12.6. Wire perforation? | lwire1 <yesnocnd> | lwire2 <yesnocnd> | NO |
| 5.12.7. Vessel rupture? | lrupt1 <yesnocnd> | lrupt2 <yesnocnd> | NO |
| 5.12.8. Pseudoaneurysm? | lpaneur1 <yesnocnd> | lpaneur2 <yesnocnd> | NO |

Assessment of LEFT RENAL ISCHEMIA

6. What is the total number of left renal arteries seen? itotr (f, 5)

If more than one left renal artery, please define the status of all NON-TREATED arteries (not previously defined above).

*A main renal artery(s) is/are defined as a renal artery having a diameter of ≥ 3.5 mm and supplying ≥ 50% of kidney
 An accessory renal artery(s) is/are defined as a renal artery having a diameter of < 3.5 mm or supplying < 50% of kidney.*

| RENAL ARTERY LOCATION (refer to lesion identification nomenclature) | lrlart1 (vc, 5) | lrlart2 (vc, 5) | lrlart3 (vc, 5) |
|---|---|--|--|
| 6.1. Patency Status | <input type="checkbox"/> (1) open (0 – 59% stenosis) <input type="checkbox"/> (2) narrowed (60 - 99% stenosis) <input type="checkbox"/> (3) totally occluded <input type="checkbox"/> (4) CND - why? lstat1 <patenc> | <input type="checkbox"/> (1) open (0 – 59% stenosis) <input type="checkbox"/> (2) lstat2 <patenc> 99% stenosis <input type="checkbox"/> (3) totally occluded <input type="checkbox"/> (4) CND - why? lcnd1 (vc, 100) | <input type="checkbox"/> (1) open (0 – 59% stenosis) <input type="checkbox"/> (2) lstat3 <patenc> 99% stenosis <input type="checkbox"/> (3) totally occluded <input type="checkbox"/> (4) CND - why? lcnd3 (vc, 100) |

6.3. Is the entire left kidney ischemic? lcnd11 <yesnocnd> (1) YES (2) NO (3) CND

where ischemia is defined as ALL renal arteries are narrowed by ≥ 60% MINUS 1.8 standard deviation (or 11.88%, i.e. > 48.12%) and or a systolic translesion gradient ≥/ = 20mmHg OR ≥/ = 70% MINUS 1.8 SD (15.84%, i.e. ≥/ = 64.16%) with no pressures measured will be considered ischemic if only one renal artery to that side.

Why? lcnd4 (vc, 100)

Site ID: _____ Pt. No.: _____ Randomization #: _____

Date of angiogram: _____ / angiodt() _____ (mm / dd / yyyy)

PS: Angio6
 PT: Angio6
 Panel: Angio6

POST INTERVENTION Target Lesion Evaluation - RIGHT KIDNEY

Refer to the following definitions when evaluating for location of the stent device:

- ^ where a value of "0" is assigned for a stent positioned flush with the junction of the renal artery with the aorta.
- where a (-) number is # mm of stent protruding into the aorta
- where a (+) number is # mm of proximal renal artery not covered by stent
- * Proximal stent location # mm from renal artery ostium ("0")
- ** Distal stent location # mm (+) from renal artery ostium ("0")

| | STENOTIC MAIN ARTERY #1 | STENOTIC MAIN ARTERY #2 |
|--|--|--|
| 7. LESION LOCATION per nomenclature | lesn1 (vc, 5) | lesn2 (vc, 5) |
| 8. Is protection device visible radiographically? | <input type="checkbox"/> (1) YES vis1 <yesnocnd> CND | <input type="checkbox"/> (1) vis2 <yesnocnd> (3) CND |
| 8.1. If protection device NOT visible, based upon anatomy, could a device have been used (i.e. main renal artery length ≥ 45mm)? | <input type="checkbox"/> (1) YES noepd1 <yesnocnd> ND | <input type="checkbox"/> noepd2 <yesnocnd> (3) CND |
| 9. Is there good wall apposition of device? | <input type="checkbox"/> (1) appos1 <yesnocnd> CND | <input type="checkbox"/> appos2 <yesnocnd> (3) CND |
| 10. Describe the percentage of protection: | <input type="checkbox"/> (1) 100% <input type="checkbox"/> (2) >50% but < 100% <input type="checkbox"/> (3) 1 – 49% protect1 <percentage> <input type="checkbox"/> (4) 0% | <input type="checkbox"/> (1) 100% <input type="checkbox"/> (2) protect2 <percentage> <input type="checkbox"/> (3) <input type="checkbox"/> (4) 0% |
| 11. TIMI FLOW with Angioguard present: | <input type="checkbox"/> 0 (no flow) <input type="checkbox"/> 2 (partial) <input type="checkbox"/> 1 flow1 <timi> <input type="checkbox"/> 3 (complete) <input type="checkbox"/> CND | <input type="checkbox"/> 0 (no flow) <input type="checkbox"/> 2 (partial) <input type="checkbox"/> flow2 <timi> <input type="checkbox"/> 3 (complete) <input type="checkbox"/> CND |
| 12. Is there evidence to suggest a potential adverse finding related to the protection device? | <input type="checkbox"/> ae1 <yesnocnd> <input type="checkbox"/> (3) CND | <input type="checkbox"/> ae2 <yesnocnd> <input type="checkbox"/> (3) CND |
| 12.1. Dissection? | dissect1 <yesno> <input type="checkbox"/> (2) NO | dissect2 <yesno> <input type="checkbox"/> (2) NO |
| 12.1.1. Flow limiting? | <input type="checkbox"/> (1) YES <input type="checkbox"/> flowlim1 <yesno> | <input type="checkbox"/> (1) YES <input type="checkbox"/> flowlim2 <yesno> |
| 12.2. Occlusion? | occlus1 <yesno> <input type="checkbox"/> (2) NO | occlus2 <yesno> <input type="checkbox"/> (2) NO |
| 12.2.1. Main RA? | <input type="checkbox"/> (1) YES <input type="checkbox"/> mainra1 <yesno> | <input type="checkbox"/> (1) YES <input type="checkbox"/> mainra2 <yesno> |
| 12.2.2. Branch vessel? | branch1 <yesno> <input type="checkbox"/> (2) NO | branch2 <yesno> <input type="checkbox"/> (2) NO |
| 12.3. Embolus? | <input type="checkbox"/> (1) YES <input type="checkbox"/> embol1 <yesno> | <input type="checkbox"/> (1) YES <input type="checkbox"/> embol2 <yesno> |
| 12.4. Thrombus? | thromb1 <yesno> <input type="checkbox"/> (2) NO | thromb2 <yesno> <input type="checkbox"/> (2) NO |
| 12.5. Spasm? | <input type="checkbox"/> (1) YES <input type="checkbox"/> spas1 <yesno> | <input type="checkbox"/> (1) YES <input type="checkbox"/> spas2 <yesno> |
| 12.6. Wire perforation? | perfor1 <yesno> <input type="checkbox"/> (2) NO | perfor2 <yesno> <input type="checkbox"/> (2) NO |
| 12.7. Vessel rupture? | <input type="checkbox"/> (1) YES <input type="checkbox"/> vess1 <yesno> | <input type="checkbox"/> (1) YES <input type="checkbox"/> vess2 <yesno> |
| 12.8. Pseudoaneurysm? | pseudo1 <yesno> <input type="checkbox"/> (2) NO | pseudo2 <yesno> <input type="checkbox"/> (2) NO |
| 12.9. Incomplete or mal-deployment of angioguard? | <input type="checkbox"/> (1) YES <input type="checkbox"/> maldepl1 <yesno> | <input type="checkbox"/> (1) YES <input type="checkbox"/> maldepl2 <yesno> |

Site ID: _____ Pt. No.: _____ Randomization #: _____

Date of angiogram: _____ / angiodt() _____ (mm / dd / yyyy)

PS: V2Angio6
 PT: V2Angio6
 Panel: Angio6

POST INTERVENTION Target Lesion Evaluation - RIGHT KIDNEY

Refer to the following definitions when evaluating for location of the stent device:

- ^ where a value of "0" is assigned for a stent positioned flush with the junction of the renal artery with the aorta.
- where a (-) number is # mm of stent protruding into the aorta
- where a (+) number is # mm of proximal renal artery not covered by stent
- * Proximal stent location # mm from renal artery ostium ("0")
- ** Distal stent location # mm (+) from renal artery ostium ("0")

| | STENOTIC MAIN ARTERY #1 | STENOTIC MAIN ARTERY #2 |
|--|---|---|
| 7. LESION LOCATION per nomenclature | lesn1 (vc, 5) | lesn2 (vc, 5) |
| Was EPD used? | <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO <input type="checkbox"/> (3) UNK Repdusd1 <yesnounk2> | <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO <input type="checkbox"/> (3) UNK Repdusd2 <yesnounk2> |
| If NO or UNK, skip to item 13 | Device: Repddev1 (vc, 100) | Device: Repddev2 (vc, 100) |
| 8. Is protection device visible radiographically? | <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO <input type="checkbox"/> (3) CND vis1 <yesnocnd> | <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO <input type="checkbox"/> (3) CND vis2 <yesnocnd> |
| 8.1. If protection device NOT visible, based upon anatomy, could a device have been used (i.e. main renal artery length ≥ 45mm)? | <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO <input type="checkbox"/> (3) CND noepd1 <yesnocnd> | <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO <input type="checkbox"/> (3) CND noepd2 <yesnocnd> |
| 9. Is there good wall apposition of device? | <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO <input type="checkbox"/> (3) CND appos1 <yesnocnd> | <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO <input type="checkbox"/> (3) CND appos2 <yesnocnd> |
| 10. Describe the percentage of protection: | <input type="checkbox"/> (1) 100% <input type="checkbox"/> (2) protect1 <percentage> <input type="checkbox"/> (3) 0% <input type="checkbox"/> (4) 0% | <input type="checkbox"/> (1) 100% <input type="checkbox"/> (2) protect2 <percentage> <input type="checkbox"/> (3) 0% <input type="checkbox"/> (4) 0% |
| 11. TIMI FLOW with EPD present: | <input type="checkbox"/> (1) flow1 <timi> <input type="checkbox"/> 2 (partial) <input type="checkbox"/> (2) flow1 <timi> <input type="checkbox"/> 3 (complete) <input type="checkbox"/> (3) CND | <input type="checkbox"/> (1) flow2 <timi> <input type="checkbox"/> 2 (partial) <input type="checkbox"/> (2) flow2 <timi> <input type="checkbox"/> 3 (complete) <input type="checkbox"/> (3) CND |
| 12. Is there evidence to suggest a potential adverse finding related to the protection device? | <input type="checkbox"/> (1) ae1 <yesnocnd> <input type="checkbox"/> (2) NO <input type="checkbox"/> (3) CND <input type="checkbox"/> (4) YES | <input type="checkbox"/> (1) ae2 <yesnocnd> <input type="checkbox"/> (2) NO <input type="checkbox"/> (3) CND <input type="checkbox"/> (4) YES |
| 12.1. Dissection? | <input type="checkbox"/> (1) dissect1 <yesno> <input type="checkbox"/> (2) NO <input type="checkbox"/> (3) YES | <input type="checkbox"/> (1) dissect2 <yesno> <input type="checkbox"/> (2) NO <input type="checkbox"/> (3) YES |
| 12.1.1. Flow limiting? | <input type="checkbox"/> (1) flowlim1 <yesno> <input type="checkbox"/> (2) NO <input type="checkbox"/> (3) YES | <input type="checkbox"/> (1) flowlim2 <yesno> <input type="checkbox"/> (2) NO <input type="checkbox"/> (3) YES |
| 12.2. Occlusion? | <input type="checkbox"/> (1) occlus1 <yesno> <input type="checkbox"/> (2) NO <input type="checkbox"/> (3) YES | <input type="checkbox"/> (1) occlus2 <yesno> <input type="checkbox"/> (2) NO <input type="checkbox"/> (3) YES |
| 12.2.1. Main RA? | <input type="checkbox"/> (1) mainra1 <yesno> <input type="checkbox"/> (2) NO <input type="checkbox"/> (3) YES | <input type="checkbox"/> (1) mainra2 <yesno> <input type="checkbox"/> (2) NO <input type="checkbox"/> (3) YES |
| 12.2.2. Branch vessel? | <input type="checkbox"/> (1) branch1 <yesno> <input type="checkbox"/> (2) NO <input type="checkbox"/> (3) YES | <input type="checkbox"/> (1) branch2 <yesno> <input type="checkbox"/> (2) NO <input type="checkbox"/> (3) YES |
| 12.3. Embolus? | <input type="checkbox"/> (1) embol1 <yesno> <input type="checkbox"/> (2) NO <input type="checkbox"/> (3) YES | <input type="checkbox"/> (1) embol2 <yesno> <input type="checkbox"/> (2) NO <input type="checkbox"/> (3) YES |
| 12.4. Thrombus? | <input type="checkbox"/> (1) thromb1 <yesno> <input type="checkbox"/> (2) NO <input type="checkbox"/> (3) YES | <input type="checkbox"/> (1) thromb2 <yesno> <input type="checkbox"/> (2) NO <input type="checkbox"/> (3) YES |
| 12.5. Spasm? | <input type="checkbox"/> (1) spas1 <yesno> <input type="checkbox"/> (2) NO <input type="checkbox"/> (3) YES | <input type="checkbox"/> (1) spas2 <yesno> <input type="checkbox"/> (2) NO <input type="checkbox"/> (3) YES |
| 12.6. Wire perforation? | <input type="checkbox"/> (1) perfor1 <yesno> <input type="checkbox"/> (2) NO <input type="checkbox"/> (3) YES | <input type="checkbox"/> (1) perfor2 <yesno> <input type="checkbox"/> (2) NO <input type="checkbox"/> (3) YES |
| 12.7. Vessel rupture? | <input type="checkbox"/> (1) vess1 <yesno> <input type="checkbox"/> (2) NO <input type="checkbox"/> (3) YES | <input type="checkbox"/> (1) vess2 <yesno> <input type="checkbox"/> (2) NO <input type="checkbox"/> (3) YES |
| 12.8. Pseudoaneurysm? | <input type="checkbox"/> (1) pseudo1 <yesno> <input type="checkbox"/> (2) NO <input type="checkbox"/> (3) YES | <input type="checkbox"/> (1) pseudo2 <yesno> <input type="checkbox"/> (2) NO <input type="checkbox"/> (3) YES |
| 12.9. Incomplete or mal-deployment of EPD? | <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO <input type="checkbox"/> (3) YES maldepl1 <yesno> | <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO <input type="checkbox"/> (3) YES maldepl2 <yesno> |

CORAL

Site ID: _____ Pt. No.: _____ Randomization #: _____

Date of angiogram: _____ angiodt() _____ (mm / dd / yyyy)

PS: Angio7
PT: Angio7
Panel: Angio7

- psten1 (f-5)
- psten2 (f-5)
- psten3 (f-5)
- psten4 (f-5)
- psten5 (f-5)
- psten6 (f-5)
- psten7 (f-5)
- psten8 (f-5)

| 13. Lesion Assessment | STENOTIC MAIN ARTERY #1 | STENOTIC MAIN ARTERY #2 |
|--|--|--|
| 13.1. LESION LOCATION per Nomenclature | plesloc1 (vc, 5) | plesloc2 (vc, 5) |
| 13.2. Minimum lumen Diameter (MLD) | 1. pmlD2 (fl 6, 2) 2. pmlD3 (fl 6, 2) 3. pmlD4 (fl 6, 2) Final _____ mm | 1. pmlD5 (fl 6, 2) 2. pmlD6 (fl 6, 2) 3. pmlD7 (fl 6, 2) 4. pmlD8 (fl 6, 2) Final _____ mm |
| 13.3. Reference lumen Diameter (Ref) | 1. pref2 (fl 6, 2) 2. pref1 (fl 6, 2) 3. pref3 (fl 6, 2) Final _____ mm | 1. pref5 (fl 6, 2) 2. pref6 (fl 6, 2) 3. pref7 (fl 6, 2) 4. pref8 (fl 6, 2) Final _____ mm |
| 13.4. Lesion Length | 1. plesl2 (fl 6, 2) 2. plesl1 (fl 6, 2) 3. plesl3 (fl 6, 2) Final _____ mm | 1. plesl5 (fl 6, 2) 2. plesl6 (fl 6, 2) 3. plesl7 (fl 6, 2) 4. plesl8 (fl 6, 2) Final _____ mm |
| 13.5. % STENOSIS | 1. psten2a (fl 6, 2) 2. psten1a (fl 6, 2) 3. psten4a (fl 6, 2) Final _____ % | 1. psten5a (fl 6, 2) 2. psten6a (fl 6, 2) 3. psten7a (fl 6, 2) 4. psten8a (fl 6, 2) Final _____ % |
| 13.6. Stent Location ^ | | |
| 13.6.1 Proximal end * | prox1 (fl 6, 2) prox3 (fl 6, 2) Final _____ mm | prox2 (fl 6, 2) prox4 (fl 6, 2) prox5 (fl 6, 2) prox6 (fl 6, 2) prox7 (fl 6, 2) prox8 (fl 6, 2) Final _____ mm |
| 13.6.1 Distal end ** | dist1 (fl 6, 2) dist3 (fl 6, 2) Final _____ mm | dist2 (fl 6, 2) dist4 (fl 6, 2) dist5 (fl 6, 2) dist7 (fl 6, 2) dist6 (fl 6, 2) dist8 (fl 6, 2) Final _____ mm |
| 13.7. TIMI FLOW POST – Angioguard removal | <input type="checkbox"/> 0 (no flow) <input type="checkbox"/> 1 (partial) <input type="checkbox"/> 2 (partial) <input type="checkbox"/> 3 (complete) <input type="checkbox"/> CND | <input type="checkbox"/> 0 (no flow) <input type="checkbox"/> 1 (partial) <input type="checkbox"/> 2 (partial) <input type="checkbox"/> 3 (complete) <input type="checkbox"/> CND |
| 13.8. COMPLICATIONS | | |
| 13.8.1. Dissection? | pdissect3 <yesno> <input type="checkbox"/> (2) NO | dissect3 <yesno> <input type="checkbox"/> (2) NO |
| 13.8.1.1. Flow limiting? | pflow3 <yesno> <input type="checkbox"/> (1) YES | flow31 <yesno> <input type="checkbox"/> (2) NO |
| 13.8.2. Occlusion? | poccl3 <yesno> <input type="checkbox"/> (1) YES | occl3 <yesno> <input type="checkbox"/> (2) NO |
| 13.8.2.1. Main RA? | <input type="checkbox"/> (1) YES | main3 <yesno> <input type="checkbox"/> (2) NO |
| 13.8.2.2. Branch vessel? | pbran3 <yesno> <input type="checkbox"/> (2) NO | bran3 <yesno> <input type="checkbox"/> (2) NO |
| 13.8.3. Embolus? | <input type="checkbox"/> (1) YES | pemb3 <yesno> <input type="checkbox"/> (4) YES <input type="checkbox"/> (2) NO |
| 13.8.4. Thrombus? | pthrom3 <yesno> <input type="checkbox"/> (2) NO | throm3 <yesno> <input type="checkbox"/> (2) NO |
| 13.8.5. Spasm? | <input type="checkbox"/> (1) YES | pspasm3 <yesno> <input type="checkbox"/> (4) YES <input type="checkbox"/> (2) NO |
| 13.8.6. Wire perforation? | pwire3 <yesno> <input type="checkbox"/> (2) NO | wire3 <yesno> <input type="checkbox"/> (2) NO |
| 13.8.7. Vessel rupture? | <input type="checkbox"/> (1) YES | prupt3 <yesno> <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO |
| 13.8.8. Pseudoaneurysm? | ppaneur3 <yesno> <input type="checkbox"/> (2) NO | paneur3 <yesno> <input type="checkbox"/> (2) NO |
| 13.8.9 Incomplete or mal-deployment of angioguard? | <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO | maldepl4 <yesno> <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO |

Site ID: _____ Pt. No.: _____ Randomization #: _____

Date of angiogram: _____ angiodt() _____ (mm / dd / yyyy)

PS: V2Angio7
 PT: V2Angio7
 Panel: Angio7

| 13. Lesion Assessment | STENOTIC MAIN ARTERY #1 | STENOTIC MAIN ARTERY #2 |
|---|---|---|
| 13.1. LESION LOCATION per Nomenclature | plesloc1 (vc, 5) | plesloc2 (vc, 5) |
| 13.2. Minimum lumen Diameter (MLD) | 1. pml2 (fl 6, 2) 2. pml1 (fl 6, 2) 3. pml4 (fl 6, 2) Final _____ mm | 1. pml5 (fl 6, 2) pml6 (fl 6, 2) 2. pml3 (fl 6, 2) 3. pml7 (fl 6, 2) pml8 (fl 6, 2) Final _____ mm |
| 13.3. Reference lumen Diameter (Ref) | 1. pref2 (fl 6, 2) pref1 (fl 6, 2) 2. _____ mm pref3 (fl 6, 2) 3. _____ mm Final _____ mm | 1. pref5 (fl 6, 2) pref6 (fl 6, 2) 2. _____ mm pref7 (fl 6, 2) 3. _____ mm pref8 (fl 6, 2) Final _____ mm |
| 13.4. Lesion Length | 1. ples2 (fl 6, 2) ples1 (fl 6, 2) 2. _____ mm ples3 (fl 6, 2) 3. ples4 (fl 6, 2) _____ mm Final _____ mm | 1. ples5 (fl 6, 2) ples6 (fl 6, 2) 2. _____ mm ples7 (fl 6, 2) 3. ples8 (fl 6, 2) _____ mm Final _____ mm |
| 13.5. % STENOSIS | 1. psten2a (fl 6, 2) psten1a (fl 6, 2) 2. _____ % psten3a (fl 6, 2) 3. psten4a (fl 6, 2) _____ % Final _____ % | 1. psten5a (fl 6, 2) psten6a (fl 6, 2) 2. _____ % psten7a (fl 6, 2) 3. psten8a (fl 6, 2) _____ % Final _____ % |
| 13.6. Stent Location ^ | | |
| 13.6.1 Proximal end * | prox1 (fl 6, 2) prox2 (fl 6, 2) prox5 (fl 6, 2) prox6 (fl 6, 2) prox3 (fl 6, 2) prox4 (fl 6, 2) prox7 (fl 6, 2) prox8 (fl 6, 2) Final _____ mm | prox5 (fl 6, 2) prox6 (fl 6, 2) prox7 (fl 6, 2) prox8 (fl 6, 2) Final _____ mm |
| 13.6.1 Distal end ** | dist1 (fl 6, 2) dist2 (fl 6, 2) dist5 (fl 6, 2) dist6 (fl 6, 2) dist3 (fl 6, 2) dist4 (fl 6, 2) dist7 (fl 6, 2) dist8 (fl 6, 2) Final _____ mm | dist5 (fl 6, 2) dist6 (fl 6, 2) dist7 (fl 6, 2) dist8 (fl 6, 2) Final _____ mm |
| 13.7. TIMI FLOW POST –stent and post-EPD removal (if used) | <input type="checkbox"/> 0 (no flow) <input type="checkbox"/> 2 (partial) <input type="checkbox"/> 1 (reduced) <input type="checkbox"/> 3 (complete) <input type="checkbox"/> CND <input type="checkbox"/> No EPD flow3 <timi> _____ | <input type="checkbox"/> 0 (no flow) <input type="checkbox"/> 2 (partial) <input type="checkbox"/> 1 (reduced) <input type="checkbox"/> 3 (complete) <input type="checkbox"/> CND <input type="checkbox"/> No EPD flow4 <timi> _____ |
| 13.8. COMPLICATIONS | | |
| 13.8.1. Dissection? | pdissect3 <yesno> _____ <input type="checkbox"/> (2) NO | dissect3 <yesno> _____ <input type="checkbox"/> (2) NO |
| 13.8.1.1. Flow limiting? | pflow3 <yesno> _____ <input type="checkbox"/> (4) YES | flow31 <yesno> _____ <input type="checkbox"/> (2) NO |
| 13.8.2. Occlusion? | poccl3 <yesno> _____ <input type="checkbox"/> (2) NO | occl3 <yesno> _____ <input type="checkbox"/> (2) NO |
| 13.8.2.1. Main RA? | <input type="checkbox"/> (1) YES pmain3 <yesno> _____ <input type="checkbox"/> (2) NO | <input type="checkbox"/> (1) YES main3 <yesno> _____ <input type="checkbox"/> (2) NO |
| 13.8.2.2. Branch vessel? | pbran3 <yesno> _____ <input type="checkbox"/> (2) NO | bran3 <yesno> _____ <input type="checkbox"/> (2) NO |
| 13.8.3. Embolus? | <input type="checkbox"/> (4) YES pemb3 <yesno> _____ <input type="checkbox"/> (2) NO | <input type="checkbox"/> (4) YES emb3 <yesno> _____ <input type="checkbox"/> (2) NO |
| 13.8.4. Thrombus? | pthrom3 <yesno> _____ <input type="checkbox"/> (2) NO | throm3 <yesno> _____ <input type="checkbox"/> (2) NO |
| 13.8.5. Spasm? | <input type="checkbox"/> (1) YES pspasm3 <yesno> _____ <input type="checkbox"/> (2) NO | <input type="checkbox"/> (4) YES spasm3 <yesno> _____ <input type="checkbox"/> (2) NO |
| 13.8.6. Wire perforation? | pwire3 <yesno> _____ <input type="checkbox"/> (2) NO | wire3 <yesno> _____ <input type="checkbox"/> (2) NO |
| 13.8.7. Vessel rupture? | <input type="checkbox"/> (1) YES prupt3 <yesno> _____ <input type="checkbox"/> (2) NO | <input type="checkbox"/> (1) YES rupt3 <yesno> _____ <input type="checkbox"/> (2) NO |
| 13.8.8. Pseudoaneurysm? | ppneur3 <yesno> _____ <input type="checkbox"/> (2) NO | paneur3 <yesno> _____ <input type="checkbox"/> (2) NO |
| 13.8.9 Incomplete or mal-deployment of stent? | <input type="checkbox"/> (1) YES maldepl3 <yesno> _____ <input type="checkbox"/> (2) NO | <input type="checkbox"/> (1) YES maldepl4 <yesno> _____ <input type="checkbox"/> (2) NO |

Site ID: _____ Pt. No.: _____ Randomization #: _____

Date of angiogram: _____ angiodt() _____ (mm / dd / yyyy)

PS: Angio8
 PT: Angio8
 Panel: Angio8

POST INTERVENTION Target Lesion Evaluation - LEFT KIDNEY

Refer to the following definitions when evaluating for location of the stent device:

- ^ where a value of "0" is assigned for a stent positioned flush with the junction of the renal artery with the aorta.
- where a (-) number is # mm of stent protruding into the aorta
- where a (+) number is # mm of proximal renal artery not covered by stent
- * Proximal stent location # mm from renal artery ostium ("0")
- ** Distal stent location # mm (+) from renal artery ostium ("0")

| | STENOTIC MAIN ARTERY #1 | STENOTIC MAIN ARTERY #2 |
|---|---|---|
| 14. LESION LOCATION per nomenclature | llesn1 (vc, 5) | llesn2 (vc, 5) |
| 15. Is protection device visible radiographically? | <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO <input type="checkbox"/> (3) CND lvis1 <yesnocnd> | <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO <input type="checkbox"/> (3) CND lvis2 <yesnocnd> |
| 15.1. If protection device NOT visible, based upon anatomy, could a device have been used (i.e. main renal artery length ≥ 45mm)? | <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO <input type="checkbox"/> (3) CND lnoepd1 <yesnocnd> | <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO <input type="checkbox"/> (3) CND lnoepd2 <yesnocnd> |
| 16. Is there good wall apposition of device? | <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO <input type="checkbox"/> (3) CND lappos1 <yesnocnd> | <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO <input type="checkbox"/> (3) CND lappos2 <yesnocnd> |
| 17. Describe the percentage of protection: | <input type="checkbox"/> (1) 100% <input type="checkbox"/> (2) >50% but <100% <input type="checkbox"/> (3) protect3 <percentage> <input type="checkbox"/> (4) 0% | <input type="checkbox"/> (1) 100% <input type="checkbox"/> (2) >50% but <100% <input type="checkbox"/> (3) protect4 <percentage> <input type="checkbox"/> (4) 0% |
| 18. TIMI FLOW with Angioguard present: | <input type="checkbox"/> 0 (no flow) <input type="checkbox"/> 2 (partial) <input type="checkbox"/> 1 (partial) <input type="checkbox"/> 3 (complete) lflow1 <timi> | <input type="checkbox"/> 0 (no flow) <input type="checkbox"/> 2 (partial) <input type="checkbox"/> 1 (partial) <input type="checkbox"/> 3 (complete) lflow2 <timi> |
| 19. Is there evidence to suggest a potential adverse finding related to the protection device? | <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO <input type="checkbox"/> (3) CND lae1 <yesnocnd> | <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO <input type="checkbox"/> (3) CND lae2 <yesnocnd> |
| 19.1. Dissection? | <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO ldissect1 <yesno> | <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO ldissect2 <yesno> |
| 19.1.1. Flow limiting? | <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO lflowlim1 <yesno> | <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO lflowlim2 <yesno> |
| 19.2. Occlusion? | <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO locclus1 <yesno> | <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO locclus2 <yesno> |
| 19.2.1. Main RA? | <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO lmainra1 <yesno> | <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO lmainra2 <yesno> |
| 19.2.2. Branch vessel? | <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO lbranch1 <yesno> | <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO lbranch2 <yesno> |
| 19.3. Embolus? | <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO lembol1 <yesno> | <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO lembol2 <yesno> |
| 19.4. Thrombus? | <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO lthromb1 <yesno> | <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO lthromb2 <yesno> |
| 19.5. Spasm? | <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO lspas1 <yesno> | <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO lspas2 <yesno> |
| 19.6. Wire perforation? | <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO lperfor1 <yesno> | <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO lperfor2 <yesno> |
| 19.7. Vessel rupture? | <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO lvess1 <yesno> | <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO lvess2 <yesno> |
| 19.8. Pseudoaneurysm? | <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO lpseudo1 <yesno> | <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO lpseudo2 <yesno> |
| 19.9. Incomplete or mal-deployment of angioguard? | <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO lmaldepl1 <yesno> | <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO lmaldepl2 <yesno> |

Site ID: _____ Pt. No.: _____ Randomization #: _____

Date of angiogram: _____ angiodt() _____ (mm / dd / yyyy)

PS: V2Angio8
 PT: V2Angio8
 Panel: Angio8

POST INTERVENTION Target Lesion Evaluation - LEFT KIDNEY

Refer to the following definitions when evaluating for location of the stent device:

- ^ where a value of "0" is assigned for a stent positioned flush with the junction of the renal artery with the aorta.
- where a (-) number is # mm of stent protruding into the aorta
- where a (+) number is # mm of proximal renal artery not covered by stent
- * Proximal stent location # mm from renal artery ostium ("0")
- ** Distal stent location # mm (+) from renal artery ostium ("0")

| | STENOTIC MAIN ARTERY #1 | STENOTIC MAIN ARTERY #2 |
|---|--|--|
| 14. LESION LOCATION per nomenclature | llesn1 (vc, 5) | llesn2 (vc, 5) |
| Was EPD used? | Lepdusd1 <yesnunk2> <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO <input type="checkbox"/> (3) UNK | <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO <input type="checkbox"/> (3) UNK ↓ Lepdusd2 <yesnunk2> |
| If NO or UNK, skip to item 20 | Device: Lepddev1 (vc, 100) | Device: Lepddev2 (vc, 100) |
| 15. Is protection device visible radiographically? | <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO <input type="checkbox"/> (3) CND lvis1 <yesnocnd> | <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO <input type="checkbox"/> (3) CND lvis2 <yesnocnd> |
| 15.1. If protection device NOT visible, based upon anatomy, could a device have been used (i.e. main renal artery length ≥ 45mm)? | <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO <input type="checkbox"/> (3) CND lnoepd1 <yesnocnd> | <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO <input type="checkbox"/> (3) CND lnoepd2 <yesnocnd> |
| 16. Is there good wall apposition of device? | <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO <input type="checkbox"/> (3) CND lappos1 <yesnocnd> | <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO <input type="checkbox"/> (3) CND lappos2 <yesnocnd> |
| 17. Describe the percentage of protection: | <input type="checkbox"/> (1) 100% <input type="checkbox"/> (2) _____ <input type="checkbox"/> (3) _____ <input type="checkbox"/> (4) 0% protect3 <percentage> | <input type="checkbox"/> (1) 100% <input type="checkbox"/> (2) _____ <input type="checkbox"/> (3) _____ <input type="checkbox"/> (4) 0% protect4 <percentage> |
| 18. TIMI FLOW with EPD present: | <input type="checkbox"/> (1) _____ <input type="checkbox"/> 2 (partial) <input type="checkbox"/> (2) _____ <input type="checkbox"/> 3 (complete) <input type="checkbox"/> CND lflow1 <timi> | <input type="checkbox"/> (1) _____ <input type="checkbox"/> 2 (partial) <input type="checkbox"/> (2) _____ <input type="checkbox"/> 3 (complete) <input type="checkbox"/> CND lflow2 <timi> |
| 19. Is there evidence to suggest a potential adverse finding related to the protection device? | ↓ <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO <input type="checkbox"/> (3) CND lae1 <yesnocnd> | ↓ <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO <input type="checkbox"/> (3) CND lae2 <yesnocnd> |
| 19.1. Dissection? | ldissect1 <yesno> <input type="checkbox"/> (2) NO | ldissect2 <yesno> <input type="checkbox"/> (2) NO |
| 19.1.1. Flow limiting? | <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO <input type="checkbox"/> (3) CND lflowlim1 <yesno> | <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO <input type="checkbox"/> (3) CND lflowlim2 <yesno> |
| 19.2. Occlusion? | locclus1 <yesno> <input type="checkbox"/> (2) NO | locclus2 <yesno> <input type="checkbox"/> (2) NO |
| 19.2.1. Main RA? | <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO <input type="checkbox"/> (3) CND lmainra1 <yesno> | <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO <input type="checkbox"/> (3) CND lmainra2 <yesno> |
| 19.2.2. Branch vessel? | lbranch1 <yesno> <input type="checkbox"/> (2) NO | lbranch2 <yesno> <input type="checkbox"/> (2) NO |
| 19.3. Embolus? | <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO <input type="checkbox"/> (3) CND lembol1 <yesno> | <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO <input type="checkbox"/> (3) CND lembol2 <yesno> |
| 19.4. Thrombus? | lthromb1 <yesno> <input type="checkbox"/> (2) NO | lthromb2 <yesno> <input type="checkbox"/> (2) NO |
| 19.5. Spasm? | <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO <input type="checkbox"/> (3) CND lspas1 <yesno> | <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO <input type="checkbox"/> (3) CND lspas2 <yesno> |
| 19.6. Wire perforation? | lperfor1 <yesno> <input type="checkbox"/> (2) NO | lperfor2 <yesno> <input type="checkbox"/> (2) NO |
| 19.7. Vessel rupture? | <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO <input type="checkbox"/> (3) CND lvess1 <yesno> | <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO <input type="checkbox"/> (3) CND lvess2 <yesno> |
| 19.8. Pseudoaneurysm? | lpseudo1 <yesno> <input type="checkbox"/> (2) NO | lpseudo2 <yesno> <input type="checkbox"/> (2) NO |
| 19.9. Incomplete or mal-deployment of device? | <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO <input type="checkbox"/> (3) CND lmaldepl1 <yesno> | <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO <input type="checkbox"/> (3) CND lmaldepl2 <yesno> |

CORAL

Site ID: _____ Pt. No.: _____ Randomization #: _____

Date of angiogram: _____ / angiodt() _____ (mm / dd / yyyy)

PS: Angio9
PT: Angio9
Panel: Angio9

- plsten1 (f-5)
- plsten2 (f-5)
- plsten3 (f-5)
- plsten4 (f-5)
- plsten5 (f-5)
- plsten6 (f-5)
- plsten7 (f-5)
- plsten8 (f-5)

| 20. Lesion Assessment | STENOTIC MAIN ARTERY #1 | STENOTIC MAIN ARTERY #2 |
|--|---|---|
| 20.1. LESION LOCATION per Nomenclature | pllesloc1 (vc, 5) | pllesloc2 (vc, 5) |
| 20.2. Minimum lumen Diameter (MLD) | 1. plmld1 (fl 6, 2) 2. plmld2 (fl 6, 2) 3. plmld3 (fl 6, 2) Final plmld4 (fl 6, 2) | 1. plmld5 (fl 6, 2) 2. plmld6 (fl 6, 2) 3. plmld7 (fl 6, 2) Final plmld8 (fl 6, 2) |
| 20.3. Reference lumen Diameter (Ref) | 1. plref1 (fl 6, 2) 2. plref2 (fl 6, 2) 3. plref3 (fl 6, 2) Final plref4 (fl 6, 2) | 1. plref5 (fl 6, 2) 2. plref6 (fl 6, 2) 3. plref7 (fl 6, 2) Final plref8 (fl 6, 2) |
| 20.4. Lesion Length | 1. pllesl2 (fl 6, 2) 2. pllesl1 (fl 6, 2) 3. pllesl4 (fl 6, 2) Final pllesl3 (fl 6, 2) | 1. pllesl5 (fl 6, 2) 2. pllesl6 (fl 6, 2) 3. pllesl7 (fl 6, 2) Final pllesl8 (fl 6, 2) |
| 20.5. % STENOSIS | plsten2a (fl 6, 2) plsten1a (fl 6, 2) plsten4a (fl 6, 2) plsten3a (fl 6, 2) | plsten5a (fl 6, 2) plsten6a (fl 6, 2) plsten7a (fl 6, 2) plsten8a (fl 6, 2) |
| 20.6. Stent Location ^ | | |
| 20.6.1 Proximal end * | lprox1 (fl 6, 2) lprox2 (fl 6, 2) lprox3 (fl 6, 2) lprox4 (fl 6, 2) | lprox5 (fl 6, 2) lprox6 (fl 6, 2) lprox7 (fl 6, 2) lprox8 (fl 6, 2) |
| 20.6.1 Distal end ** | ldist1 (fl 6, 2) ldist2 (fl 6, 2) ldist3 (fl 6, 2) ldist4 (fl 6, 2) | ldist5 (fl 6, 2) ldist6 (fl 6, 2) ldist7 (fl 6, 2) ldist8 (fl 6, 2) |
| 20.7. TIMI FLOW POST – Angioguard removal | <input type="checkbox"/> 0 (no flow) <input type="checkbox"/> 2 (partial) <input type="checkbox"/> 1 (minimal) <input type="checkbox"/> 3 (complete) <input type="checkbox"/> CND lflow3 <timi> | <input type="checkbox"/> 0 (no flow) <input type="checkbox"/> 2 (partial) <input type="checkbox"/> 1 (minimal) <input type="checkbox"/> 3 (complete) <input type="checkbox"/> CND lflow4 <timi> |
| 20.8. COMPLICATIONS | | |
| 20.8.1. Dissection? | pldissect3 <yesno> <input type="checkbox"/> (2) NO | ldissect3 <yesno> <input type="checkbox"/> (2) NO |
| 20.8.1.1. Flow limiting? | plflow3 <yesno> <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO | lflow31 <yesno> <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO |
| 20.8.2. Occlusion? | ploccl3 <yesno> <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO | loccl3 <yesno> <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO |
| 20.8.2.1. Main RA? | plmain3 <yesno> <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO | lmain3 <yesno> <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO |
| 20.8.2.2. Branch vessel? | plbran3 <yesno> <input type="checkbox"/> (2) NO | lbran3 <yesno> <input type="checkbox"/> (2) NO |
| 20.8.3. Embolus? | plemb3 <yesno> <input type="checkbox"/> (4) YES <input type="checkbox"/> (2) NO | lemb3 <yesno> <input type="checkbox"/> (4) YES <input type="checkbox"/> (2) NO |
| 20.8.4. Thrombus? | plthrom3 <yesno> <input type="checkbox"/> (2) NO | lthrom3 <yesno> <input type="checkbox"/> (2) NO |
| 20.8.5. Spasm? | plspasm3 <yesno> <input type="checkbox"/> (4) YES <input type="checkbox"/> (2) NO | lspasm3 <yesno> <input type="checkbox"/> (4) YES <input type="checkbox"/> (2) NO |
| 20.8.6. Wire perforation? | plwire3 <yesno> <input type="checkbox"/> (2) NO | lwire3 <yesno> <input type="checkbox"/> (2) NO |
| 20.8.7. Vessel rupture? | plrupt3 <yesno> <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO | lrupt3 <yesno> <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO |
| 20.8.8. Pseudoaneurysm? | plpaneur3 <yesno> <input type="checkbox"/> (2) NO | lpaneur3 <yesno> <input type="checkbox"/> (2) NO |
| 20.8.9 Incomplete or mal-deployment of angioguard? | <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO maldepl1 <yesno> | <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO maldepl2 <yesno> |

Site ID: _____ **Pt. No.:** _____ **Randomization #:** _____

Date of angiogram: _____ / angiodt() _____ (mm / dd / yyyy)

PS: V2Angio9
PT: V2Angio9
Panel: Angio9

| 20. Lesion Assessment | STENOTIC MAIN ARTERY #1 | STENOTIC MAIN ARTERY #2 |
|--|--|--|
| 20.1. LESION LOCATION per Nomenclature | pllesloc1 (vc, 5) | pllesloc2 (vc, 5) |
| 20.2. Minimum lumen Diameter (MLD) | 1. plmld1 (fl 6, 2) 2. plmld2 (fl 6, 2) 3. plmld3 (fl 6, 2) Final plmld4 (fl 6, 2) mm | 1. plmld5 (fl 6, 2) 2. plmld6 (fl 6, 2) 3. plmld7 (fl 6, 2) Final plmld8 (fl 6, 2) mm |
| 20.3. Reference lumen Diameter (Ref) | 1. plref1 (fl 6, 2) 2. plref2 (fl 6, 2) 3. plref3 (fl 6, 2) Final plref4 (fl 6, 2) mm | 1. plref5 (fl 6, 2) 2. plref6 (fl 6, 2) 3. plref7 (fl 6, 2) Final plref8 (fl 6, 2) mm |
| 20.4. Lesion Length | 1. pllesl2 (fl 6, 2) 2. pllesl1 (fl 6, 2) 3. pllesl3 (fl 6, 2) Final pllesl4 (fl 6, 2) mm | 1. pllesl5 (fl 6, 2) 2. pllesl6 (fl 6, 2) 3. pllesl7 (fl 6, 2) Final pllesl8 (fl 6, 2) mm |
| 20.5. % STENOSIS | plsten2a (fl 6, 2) plsten1a (fl 6, 2) plsten4a (fl 6, 2) plsten3a (fl 6, 2) | plsten5a (fl 6, 2) plsten6a (fl 6, 2) plsten7a (fl 6, 2) plsten8a (fl 6, 2) |
| 20.6. Stent Location ^ | | |
| 20.6.1 Proximal end * | lprox1 (fl 6, 2) lprox3 (fl 6, 2) | lprox2 (fl 6, 2) lprox4 (fl 6, 2) lprox5 (fl 6, 2) lprox6 (fl 6, 2) lprox7 (fl 6, 2) lprox8 (fl 6, 2) |
| 20.6.1 Distal end ** | ldist1 (fl 6, 2) ldist3 (fl 6, 2) | ldist2 (fl 6, 2) ldist4 (fl 6, 2) ldist5 (fl 6, 2) ldist6 (fl 6, 2) ldist7 (fl 6, 2) ldist8 (fl 6, 2) |
| 20.7. TIMI FLOW POST – stent and post-EPD removal (if used) | <input type="checkbox"/> 0 (no flow) <input type="checkbox"/> 1 (minimal) <input type="checkbox"/> 2 (partial) <input type="checkbox"/> 3 (complete) <input type="checkbox"/> 3 lflow3 <timi> <input type="checkbox"/> NO EPD <input type="checkbox"/> CND | <input type="checkbox"/> 0 (no flow) <input type="checkbox"/> 1 (minimal) <input type="checkbox"/> 2 (partial) <input type="checkbox"/> 3 (complete) <input type="checkbox"/> 3 lflow4 <timi> <input type="checkbox"/> NO EPD <input type="checkbox"/> CND |
| 20.8. COMPLICATIONS | | |
| 20.8.1. Dissection? | pldissect3 <yesno> | pldissect3 <yesno> |
| 20.8.1.1. Flow limiting? | plflow3 <yesno> | plflow3 <yesno> |
| 20.8.2. Occlusion? | plocc3 <yesno> | plocc3 <yesno> |
| 20.8.2.1. Main RA? | <input type="checkbox"/> (1) YES | <input type="checkbox"/> (1) YES |
| 20.8.2.2. Branch vessel? | plbran3 <yesno> | plbran3 <yesno> |
| 20.8.3. Embolus? | plthrom3 <yesno> | plthrom3 <yesno> |
| 20.8.4. Thrombus? | plthrom3 <yesno> | plthrom3 <yesno> |
| 20.8.5. Spasm? | plspasm3 <yesno> | plspasm3 <yesno> |
| 20.8.6. Wire perforation? | plwire3 <yesno> | plwire3 <yesno> |
| 20.8.7. Vessel rupture? | plrupt3 <yesno> | plrupt3 <yesno> |
| 20.8.8. Pseudoaneurysm? | planeur3 <yesno> | planeur3 <yesno> |
| 20.8.9 Incomplete or mal-deployment of stent? | <input type="checkbox"/> (1) YES maldepl1 <yesno> | <input type="checkbox"/> (1) YES maldepl2 <yesno> |

CORAL

PANEL: Context
PS: Context

UVA CORAL

Site ID: _____ Pt. No.: _____ Randomization #: _____

Date of angiogram: _____ / _____ (mm / dd / yyyy)

PS: Angio10
PT: Angio10
Panel: Angio10

21. Is there global ischemia? (1) YES (2) NO (3) CND
(ALL renal arteries are \geq 60% stenotic)

Why?

22. Miscellaneous Observations: _____



23. Evidence for Potential Adverse Finding/s? (1) YES (2) NO (3) CND

23.1. If YES, describe:

23.2. If CND, WHY:

23.3. Notification of CCC: Person Notified / _____ (mm / dd / yyyy)

Interpretation

Core Lab Technologist: _____
PRINT NAME

Date of Interpretation: / _____
(mm / dd / yyyy)

Interpreting Physician: _____
PRINT NAME

Date of Interpretation: / _____
(mm / dd / yyyy)

Signatures

Core Lab Technologist: _____ Date _____
(mm / dd / yyyy)

Interpreting Physician: _____ Date _____
(mm / dd / yyyy)

CORAL

PANEL: Context
PS: Context

UVA CORAL

Site ID: _____ Pt. No.: _____ Randomization #: _____

PS: V2Angio10
PT: V2Angio10
Panel: Angio10

Date of angiogram: _____ / _____ (mm / dd / yyyy)

21. Is there global ischemia? (1) YES (2) NO (3) CND
(ALL renal arteries are $\geq 60\%$ stenotic)

Why? _____

22. Miscellaneous Observations: _____

23. Evidence for Potential Adverse Finding (1) YES (2) NO (3) CND
23.1. If YES, describe:

23.2. If CND, WHY:

23.3. Notification of CCC: _____ ified _____ / _____
(mm / dd / yyyy)

Interpretation

Core Lab Technologist: _____ _____
NT NAME

Date of Interpretation: _____ _____ / _____
(yy)

Interpreting Physician: _____ _____
NAME

Date of Interpretation: _____ _____ / _____
(yyyy)

Signatures

Core Lab Technologist: _____ _____ Date _____ _____
(yy)

Interpreting Physician: _____ _____ Date _____ _____
(yy)

CORAL Hospitalization for CHF Adjudication Form

PANEL: Context
PS: Context

Site ID: _____ Pt. No. _____ Randomization #: _____

Unique Event Number: _____ Site Reported Date: ____/____/____ strptdt ()
DAY MONTH YEAR

evntno (f, 10)

strptdd/strptmmm/strptyyyy

admit <yesno>

NO YES

1. Was the patient admitted (ie met the protocol definition for hospitalization) for the management of new or worsening heart failure?

PS: CHF Hosp
PT: CHF Hosp
Panel: CHF Hosp

newhf <yesno>

NO YES

2a. Was there documented evidence for new or worsening heart failure?

If Yes →

b. If yes, evidence for new or worsening heart failure was determined by (at least one of the following):

- dysp <checked1> Increasing dyspnea on exertion
- orth <checked1> Orthopnea
- noctdys <checked1> Paroxysmal Nocturnal dyspnea
- edema <checked1> Increasing peripheral edema
- incrfatg <checked1> Increasing fatigue/decreasing exercise tolerance
- hypoperf <checked1> Renal hypoperfusion (decreased renal function)
- pulmed <checked1> Pulmonary edema
- jugular <checked1> Elevated jugular venous pressure
- radio <checked1> Radiological signs of CHF

NO YES

ivther <yesno>

3. Did the patient require IV therapy with either vasodilators, diuretics, or inotropes?

NO YES

MIset <yesno>

4. Did the worsening heart failure occur in the setting of a MI?

chfhosp <checked1>

chfhosp2 <checked1>

- CORAL HF criteria met under the Old Definition MI
- CORAL HF criteria met under the New Definition MI
- CORAL HF criteria NOT met under the Old Definition MI
- CORAL HF criteria NOT met under the New Definition MI

nochfhosp <checked1>

nochfhosp2 <checked1>

ADJUDICATED DATE OF EVENT (check one of the following)

___ Site reported Date of Event as Above siterpt <checked1>

___ CEC Adjudicated Date of Event ____/____/____ cecadjdt ()
Day mon year
cecadj <checked1> cecadjdd/cecadjmmm/cecadjyyyy

Comments: _____ comments (vc, 200) single entry

Physician Reviewer Signature: _____ MDsig <yesno>

Date: _____ MDsigdd/MDsigmmm/MDsigyyyy
day month year

CEC Administrative Signature: _____ CECsig <yesno>

Date: _____ CECsigdd/CECsigmmm/CECsigyyyy
CECsigdt ()

duplicat <checked1>

CORAL MI Adjudication Form

PANEL: Context
PS: Context

Site ID: _____ Pt. No. _____ Randomization #: _____
Unique Event Number: Site Reported Date:

YES **1. Ischemic Symptoms:** clinical presentation consistent with myocardial infarction?
 YES **2. ECG changes** consistent with myocardial infarction ?

Non-Procedural MI:
new significant Q waves (or R waves in V1-V2) in two contiguous leads in the absence of previous LVH or conduction abnormalities evolving ST-segment / T-wave changes in two or more contiguous leads development of new left bundle branch block ST segment elevation requiring thrombolytics or PCI

Post-CABG MI:
new pathological Q waves that are persistent at discharge documentation of new wall motion abnormality (other than septal)

PS: MIAdj
PT: MIAdj
Panel: MIAdj

Old Definition

3. Cardiac Marker criteria met for this event? NO Yes

Non-Procedural MI:
Troponin drawn:
Troponin is > 2x ULN (necrosis range)
Troponin not > 2x ULN (necrosis range)
Troponin not drawn:
CK and CKMB or only CKMB drawn, serial CK changes of $\geq 2x$ ULN
only CK drawn, serial CK changes of $\geq 2x$ ULN

Post-PCI MI:
Troponin drawn:
Troponin $\geq 3x$ ULN (necrosis range)
Troponin not $\geq 3x$ ULN (necrosis range)
Troponin not drawn:
CK and CKMB or only CKMB drawn, serial CK changes of $\geq 2x$ ULN
only CK drawn, serial CK changes of $\geq 2x$ ULN

Post-CABG MI:
CKMB $\geq 5x$ ULN and > 50% above last measurement if last measure > ULN

New Definition

3. Cardiac Marker criteria met No Yes

Non-Procedural MI:
Troponin drawn:
Troponin is > 1x ULN (necrosis range)
Troponin not > 1x ULN (necrosis range)
Troponin not drawn:
CK and CKMB or only CKMB drawn, serial CK changes of $\geq 2x$ ULN
only CK drawn, serial CK changes of $\geq 2x$ ULN

Post-PCI MI:
Troponin drawn:
Troponin $\geq 3x$ ULN (necrosis range)
Troponin not $\geq 3x$ ULN (necrosis range)
Troponin not drawn:
CK and CKMB or only CKMB drawn, serial CK changes of $\geq 2x$ ULN
only CK drawn, serial CK changes of $\geq 2x$ ULN

Post-CABG MI:
CKMB > 5x ULN and new Q wave or wall motion abnormalities

4. CORAL MI Criteria Met (please check one below)

nonproc periproc pericabg
 noMlcrit

4. CORAL MI Criteria Met (please check one below)

nonproc2 periproc2 pericabg2
 noMlcrit2

5. Date of event if MI Criteria met
 Site Reported Date:

CEC Adjudicated Date of Event: _____ / _____ / _____
Day Month Year

Comments:

Physician Reviewer Signature: Date:

CEC Administrative Signature: Date:

duplicat

CORAL Renal Replacement Therapy Adjudication Form

Site ID: _____ Pt. No. _____ Randomization #: _____

Unique Event Number: Site Reported Date:

PS: Renrep
PT: Renrep
Panel: Renrep

CORAL Renal Replacement Therapy Criteria Met:
(at least one must be checked)

repl <checked1>

___ a. renal transplant trans <checked1>

___ b. hemodialysis hemo <checked1>

___ c. physician rrt <checked1> and patient refused

___ d. patient died within 30 days after the initiation of dialysis for chronic renal failure death <checked1>

Adjudicated Date of Event (check one of the following):

___ SITE REPORTED DATE OF EVENT AS ABOVE siterpt <checked1>

___ CEC ADJUDICATED DATE OF EVENT

OR

CORAL Renal Replacement Therapy Criteria NOT Met
Explain

Comments:

Physician Reviewer Signature: Date:

CEC Administrative Signature: Date:

CORAL Stroke Adjudication Form

Site ID: _____ Pt. No. _____ Randomization #: _____

Unique Event Number: _____ Site Reported Date: _____

evntno (f, 10) strptdd/strptmmm/strptyyyy strptdt ()

NO YES focal <yesno>

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)?

PS: Stroke
PT: Stroke
Panel: Stroke

NO YES revers <yesno>

2. Were symptoms reversible within 24 hours?

NO YES UNKNOWN

3a. Was an imaging study performed?

imag <yesnunk7>

If yes →

b.If yes, Is there documentation of:

NO YES - New hemorrhage? newhem <yesno>

NO YES - New infarction? newinfa <yesno>

Old Definition

stroke <checked1>

CORAL Stroke Criteria Met

___ Hemorrhagic Stroke hemstroke <checked1>

___ Non-Hemorrhagic Stroke nonhemstroke <checked1>

CORAL TIA Criteria Met

tia <checked1>

New Definition

stroke2 <checked1>

CORAL Stroke Criteria Met

___ Ischemic Stroke ischstroke <checked1>

___ Ischemic Stroke w/ Hemorrhagic ischstrokehem <checked1>

___ Primary Intracranial Hemorrhage primhem <checked1>

___ Unknown unk <checked1>

CORAL TIA Criteria Met

tia2 <checked1>

Adjudicated Date: siterpt <checked1> the following):

___ SITE REPORTED DATE OF EVENT AS ABOVE

___ CEC ADJUDICATED DATE OF EVENT cecadjdd/cecadjmmm/cecadjyyy

cecadj <checked1>

Adjudicated Date: siterpt2 <checked1> one of the following):

___ SITE REPORTED DATE OF EVENT

___ CEC ADJUDICATED DATE OF EVENT cecadj2dd/cecadj2mmm/cecadj2yyy

cecadj2 <checked1> EVENT / / cecadjdt2 ()

day month year

CORAL Criteria NOT Met, NO EVENT

Explain expl (vc, 200) SINGLE ENTRY

CORAL Criteria NOT Met, NO EVENT

Explain expl2 (vc, 200) SINGLE ENTRY

Comments: comments (vc, 200) SINGLE ENTRY

Physician Reviewer Signature: MDsig <yesno> Date: MDsigdd/MDsigmmm/MDsigyyy MDsigdt ()

CEC Administrative Signature: CECsig <yesno> Date: CECsigdd/CECsigmmm/CECsigyyy CECsigdt ()

duplicat <checked1>

CORAL Progressive Renal Insufficiency Adjudication Form (New Definition)

PANEL: Context
PS: Context

| | | |
|---|--|---|
| Site ID: _____ | Pt. No.: _____ | Randomization #: _____ |
| Unique Event Number: <input type="text" value="evntno (f, 10)"/> | Site Reported Date: <input type="text" value="strptdd/strptmmm/strptyyyy"/> | <input type="text" value="strptdt ()"/> |

PS:
RenAdjnew
PT:
RenAdjnew
Panel:
RenAdjnew

1.) Did the patient experience a 30% decline in GFR from baseline on 2 measurement separated by \geq 60 days?

Yes No

CORAL Progressive Renal Insufficiency Criteria Met

Adjudicated Date of Event (check one of the following):

___ SITE REPORTED DATE OF EVENT AS ABOVE

___ CEC ADJUDICATED DATE OF EVENT

OR

CORAL Progressive Renal Insufficiency Criteria NOT Met
Explain

Core Lab Values Only

Core Labs and Local Labs

Local Lab Values Only

| | |
|--|--|
| Comments: <input type="text" value="comments (vc, 200) single entry"/> | |
| Physician Reviewer Signature: <input type="text" value="MDsig <yesno>"/> | Date: <input type="text" value="MDsigdd/MDsigmmm/MDsigyyyy"/> <input type="text" value="MDsigdt ()"/> |
| CEC Administrative Signature: <input type="text" value="CECsig <yesno>"/> | Date: <input type="text" value="CECsigdd/CECsigmmm/CECsigyyyy"/> <input type="text" value="CECsigdt ()"/> |

CORAL Silent MI Adjudication Form

PANEL: Context
PS: Context

Patient ID: _____ Patient Initials: _____ Site No. _____

Unique Event Number:

Site Reported Date: ____/____/____

DAY MONTH YEAR

PS: Silentmi
PT: Silentmi
Panel: Silentmi

NO YES

1. Were there new pathologic Q waves in two or more contiguous leads in the absence of corresponding symptoms?

CORAL Silent MI Criteria Met

Adjudicated Date of Event (check one of the following):

SITE REPORTED DATE OF EVENT AS ABOVE

CEC ADJUDICATED DATE OF EVENT ____/____/____

CORAL Criteria NOT Met, NO EVENT

Explain _____

Comments: _____

Physician Reviewer Signature: _____

Date: _____

day month year

CEC Administrative Signature: _____

Date: _____

day month year

Site ID: _____ Pt. No.: _____ Randomization #: _____

Pre-randomization MR Angiography Data Form

PS: MRA
PT: MRA
Panel: MRA

MRA number:

1. This MR angiogram was performed at: (1) Investigative site (2) Outside hospital

1.1. Name of radiologist supervising MRA: First Last

2. Date of MRA: (mm/dd/yyyy)

3. Contrast Agent: Contrast dose: Contrast injection rate: NA

4. Bolus timing method:

5. Manufacturer:

6. Field strength:

7. Coil:

8. 3D Gd MRA: Not done

8.1. FOV: cm Matrix:

8.2. Slice thickness: mm

8.3. TR: TE: flip: bandwidth:

8.4. Parallel factor:

8.5. Partial Fourier factor:

8.6. Scan duration (s):

9. 3D phase contrast: Not done

9.1. FOV: cm Matrix:

9.2. Slice thickness: mm

9.3. TR: TE: flip: bandwidth:

9.4. Parallel factor:

9.5. Partial Fourier factor:

9.6. Scan duration (s):

10. Additional sequences:

11. On-site post processing:

11.1. Total number of post-processed MRA images:

11.2. Sub-volume MIPs of right renal artery:

11.3. Sub-volume MIPs of left renal artery:

Site ID: _____ Pt. No.: _____ Randomization #: _____

Pre-randomization MR Angiography Data Form

PS: MRA
PT: MRA
Panel: MRA

MRA number:

1. This MR angiogram was performed at: (1) Investigative site (2) Outside hospital

1.1. Name of radiologist supervising MRA:
First Last

2. Date of MRA: (mm/dd/yyyy)

3. Contrast Agent: Contrast dose: Contrast injection rate: NA

4. Bolus timing method:

5. Manufacturer:

6. Field strength:

7. Coil:

8. 3D Gd MRA: Not done

8.1. FOV: cm Matrix:

8.2. Slice thickness: mm

8.3. TR: TE: flip: bandwidth:

8.4. Parallel factor:

8.5. Partial Fourier factor:

8.6. Scan duration (s):

9. 3D phase contrast: Not done

9.1. FOV: cm Matrix:

9.2. Slice thickness: mm

9.3. TR: TE: flip: bandwidth:

9.4. Parallel factor:

9.5. Partial Fourier factor:

9.6. Scan duration (s):

10. Additional sequences:

11. On-site post processing:

11.1. Total number of post-processed MRA images:

11.2. Sub-volume MIPs of right renal artery:

11.3. Sub-volume MIPs of left renal artery:

Site ID: _____ Pt. No.: _____ Randomization #: _____

Pre-randomization MR Angiography Data Form

MRA number: mranum (f, 10)

PS: MRA1
PT: MRA1
Panel: MRA1

12. MRA Image Quality: MRAImg <diaginterv1> (1) Diagnostic (2) Non-diagnostic

13. Anatomic coverage of 3D coronal volume

- a. from origin of celiac trunk down to common iliac arteries (1) YES (2) NO trunk <yesno>
- b. entire aorta anteriorly and at least to mid-kidney posteriorly (1) YES (2) NO midkid <yesno>
- c. Aorta and renal arteries free of wrap-around artifact (1) YES (2) NO artif <yesno>

14. Bolus timing and enhancement

- a. Dark inferior vena cava (1) YES (2) NO darkinf <yesno>
- b. Minimal ringing artifact (1) YES (2) NO minring <yesno>
- c. Homogeneous arterial signal (1) YES (2) NO artsig <yesno>

15. Resolution

- a. Visualization of renal arteries with branching to renal hilum (1) YES (2) NO hilum <yesno>
- b. Slice thickness less than 3mm before interpolation (1) YES (2) NO slice <yesno>
- c. Frequency and Phase dimensions less than 2mm (1) YES (2) NO freqphz <yesno>

16. Minimal artifact

- a. Sharp outline of kidney and renal arteries (1) YES (2) NO shrpkid <yesno>
- b. Free of metal artifact (1) YES (2) NO freemetl <yesno>

17. Post-processing

- a. At least two subvolume MIPs for each renal artery (0) Core Lab (1) YES (2) NO subvol <CLyesno>
- b. MIPS free of bright structure overlap (0) Core Lab (1) YES (2) NO overlap <CLyesno>

Site ID: _____ Pt. No.: _____ Randomization #: _____

Pre-randomization MR Angiography Data Form

MRA number: **mranum (f, 10)**

PS: MRA2
PT: MRA2
Panel: MRA2

18. Right Kidney is present: (1) YES (2) NO **rkid <yesno>**

Right Kidney size (SI x AP x RL): **SI1 (fl 6, 2)** **AP1 (fl 6, 2)** **RL1 (fl 6, 2)** Volume: **vol1 (fl 6, 2)** **volunt1 (vc, 5)**

Cortical thickness: **cort1 (fl 6, 2)** mm

| colnum (f, 5) | Right Renal Artery Site | renart (vc, 5) | | | |
|----------------------|---------------------------------|---|--|--|--|
| 18.1 | Stenosis | stensgn (vc, 2) | stenos (fl 6, 2) % | % | |
| 18.2 | Spin dephasing on 3D PC | <input type="checkbox"/> spin <yesnoND7> <input type="checkbox"/> (2) NO <input type="checkbox"/> Not Done | <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO <input type="checkbox"/> Not Done | <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO <input type="checkbox"/> Not Done | <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO <input type="checkbox"/> Not Done |
| 18.3 | Post-stenotic dilatation | <input type="checkbox"/> dilat <yesno> <input type="checkbox"/> (2) NO | <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO | <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO | <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO |
| 18.4 | Delayed peak on cine PC | <input type="checkbox"/> (1) YES cinepc <yesnoND7> <input type="checkbox"/> Not Done | <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO <input type="checkbox"/> Not Done | <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO <input type="checkbox"/> Not Done | <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO <input type="checkbox"/> Not Done |

PS: RtKid
PT: MRA2
Panel: RtKid

19. Left Kidney is present: (1) YES (2) NO **lkid <yesno>**

Left Kidney size (SI x AP x RL): **SI2 (fl 6, 2)** **AP2 (fl 6, 2)** **RL2 (fl 6, 2)** Volume: **vol2 (fl 6, 2)** **volunt2 (vc, 5)**

Cortical thickness: **cort2 (fl 6, 2)** mm

PS: MRA3
PT: MRA2
Panel: MRA2

| colnum (f, 5) | Left Renal Artery Site | renart (vc, 5) | | | |
|----------------------|---------------------------------|---|--|--|--|
| | Stenosis | stensgn (vc, 2) | stenos (fl 6, 2) % | % | |
| 19.2 | Spin dephasing on 3D PC | <input type="checkbox"/> (1) YES spin <yesnoND7> <input type="checkbox"/> Not Done | <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO <input type="checkbox"/> Not Done | <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO <input type="checkbox"/> Not Done | <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO <input type="checkbox"/> Not Done |
| 19.3 | Post-stenotic dilatation | <input type="checkbox"/> (1) YES dilat <yesno> <input type="checkbox"/> (2) NO | <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO | <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO | <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO |
| 19.4 | Delayed peak on cine PC | <input type="checkbox"/> (1) YES cinepc <yesnoND7> <input type="checkbox"/> Not Done | <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO <input type="checkbox"/> Not Done | <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO <input type="checkbox"/> Not Done | <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO <input type="checkbox"/> Not Done |

PS: LeftKid
PT: MRA2
Panel: LeftKid

20. If stenosis is unilateral: (1) Right (2) Left (3) No, bilateral **unilat <nobilat>**

Ischemic kidney enhances less on arterial phase. (1) YES (2) NO **enhances <yesno>**

Ischemic kidney has delayed Gd excretion. (1) YES (2) NO **delayed <yesno>**

Ischemic kidney hyper-concentrates the urine. (1) YES (2) NO **hypercon <yesno>**

21. Severe aortic atherosclerosis (1) YES (2) NO **atheros <yesno>**

PS: MRA4
PT: MRA2
Panel: MRA3

Site ID: _____ Pt. No.: _____ Randomization #: _____

Pre-randomization MR Angiography Data Form

MRA number: **mranum (f, 10)**

PS: MRA2
PT: MRA2
Panel: MRA2

18. Right Kidney is present: (1) YES (2) NO **rkid <yesno>**
Right Kidney size (SI x AP x RL): **SI1 (fl 6, 2)** **AP1 (fl 6, 2)** **RL1 (fl 6, 2)** Volume: **vol1 (fl 6, 2)** **volunt1 (vc, 5)**
Cortical thickness: **cort1 (fl 6, 2)** mm

| colnum (f, 5) | Right Renal Artery Site | renart (vc, 20) | | | |
|----------------------|---------------------------------|--|--|--|--|
| 18.1 | Stenosis | stensgn (vc, 2) | stenos (fl 6, 2) % | % | |
| 18.2 | Spin dephasing on 3D PC | <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO <input type="checkbox"/> Not Done spin <yesnoND7> | <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO <input type="checkbox"/> Not Done | <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO <input type="checkbox"/> Not Done | <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO <input type="checkbox"/> Not Done |
| 18.3 | Post-stenotic dilatation | <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO dilat <yesno> | <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO | <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO | <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO |
| 18.4 | Delayed peak on cine PC | <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO <input type="checkbox"/> Not Done cinepc <yesnoND7> | <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO <input type="checkbox"/> Not Done | <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO <input type="checkbox"/> Not Done | <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO <input type="checkbox"/> Not Done |

PS: RtKid
PT: MRA2
Panel: RtKid

19. Left Kidney is present: (1) YES (2) NO **lkid <yesno>**
Left Kidney size (SI x AP x RL): **SI2 (fl 6, 2)** **AP2 (fl 6, 2)** **RL2 (fl 6, 2)** Volume: **vol2 (fl 6, 2)** **volunt2 (vc, 5)**
Cortical thickness: **cort2 (fl 6, 2)** mm

PS: MRA3
PT: MRA2
Panel: MRA2

| colnum (f, 5) | Left Renal Artery Site | renart (vc, 20) | | | |
|----------------------|---------------------------------|--|--|--|--|
| | Stenosis | stensgn (vc, 2) | stenos (fl 6, 2) % | % | |
| 19.2 | Spin dephasing on 3D PC | <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO <input type="checkbox"/> Not Done spin <yesnoND7> | <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO <input type="checkbox"/> Not Done | <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO <input type="checkbox"/> Not Done | <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO <input type="checkbox"/> Not Done |
| 19.3 | Post-stenotic dilatation | <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO dilat <yesno> | <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO | <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO | <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO |
| 19.4 | Delayed peak on cine PC | <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO <input type="checkbox"/> Not Done cinepc <yesnoND7> | <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO <input type="checkbox"/> Not Done | <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO <input type="checkbox"/> Not Done | <input type="checkbox"/> (1) YES <input type="checkbox"/> (2) NO <input type="checkbox"/> Not Done |

PS: LeftKid
PT: MRA2
Panel: LeftKid

20. If stenosis is unilateral: (1) Right (2) Left (3) No, bilateral **unilat <nobilat>**
Ischemic kidney enhances less on arterial phase. (1) YES (2) NO **enhances <yesno>**
Ischemic kidney has delayed Gd excretion. (1) YES (2) NO **delayed <yesno>**
Ischemic kidney hyper-concentrates the urine. (1) YES (2) NO **hypercon <yesno>**

21. Severe aortic atherosclerosis (1) YES (2) NO **atheros <yesno>**

PS: MRA4
PT: MRA2
Panel: MRA3

CORAL Trial

Vascular Core Lab Final Report Form

Screen Exam

RENAL DUPLEX ULTRASOUND FINDINGS SCREEN EXAM

Clinical Site # Date of Exam
MM/DD/YYYY

Pat Randomizati VL

Patient # **SPONSOR REPORT**

Renal Parenchymal Evaluation

PS: ScrnUSa
PT: ScrnUSa
Panel: ScrnUSa

Right

Hillar Analysis msec Hillar Analysis; Supports Stenosis Yes No NA UNK

(AT) Upper Pole PSV cm/sec EDV cm/sec

Lower Pole PSV cm/sec EDV cm/sec

Cortical Thickness cm Average: RI

Average Pole to Pole Kidney Measurement cm

Left

Hillar Analysis msec Hillar Analysis; Supports Stenosis Yes No NA UNK

(AT) Upper Pole PSV cm/sec EDV cm/sec

Lower Pole PSV cm/sec EDV cm/sec

Cortical Thickness cm Average: RI

Average Pole to Pole Kidney Measurement cm

Comments

Reviewer Gail Hadley, RN, RVT Sandra M. Kim, RVT, RDMS Michael Jaff, DO Other

Review Date Overread Yes No

MM/DD/YYYY

Vascore of Massachusetts General
62 Staniford Street
Boston, MA 02114

CORAL Trial

Vascular Core Lab Final Report Form

Post Treatment Scans

PS: Context
Panel: Context

RENAL DUPLEX ULTRASOUND FINDINGS

Clinical Site #

Date of Exam
MM/DD/YYYY

VU PS: Ultra1
PT: PostUS1a
Panel: Ultra1

Patient Randomization #

Patient #

SPONSOR REPORT

PS: PostUS1a
PT: PostUS1a
Panel: PostUS1a

| | PSV | EDV | cm/sec | |
|------------------------|---|---|--------|---|
| Aorta | <input type="text" value="psv1 (f 5)"/> | <input type="text" value="edv1 (f 5)"/> | | |
| RIGHT RENAL PRA | <input type="text" value="psv2 (f 5)"/> | <input type="text" value="edv2 (f 5)"/> | sec | <input type="radio"/> proximal to stent <input type="radio"/> intrastent <input type="radio"/> distal to stent <input type="radio"/> unk <input type="radio"/> NA |
| MRA | <input type="text" value="psv3 (f 5)"/> | <input type="text" value="edv3 (f 5)"/> | /sec | <input type="radio"/> proximal to stent <input type="radio"/> intrastent <input type="radio"/> distal to stent <input type="radio"/> unk <input type="radio"/> NA |
| DRA | <input type="text" value="psv4 (f 5)"/> | <input type="text" value="edv4 (f 5)"/> | sec | <input type="radio"/> proximal to stent <input type="radio"/> intrastent <input type="radio"/> distal to stent <input type="radio"/> unk <input type="radio"/> NA |
| Pstent | <input type="text" value="psv5 (f 5)"/> | <input type="text" value="edv5 (f 5)"/> | sec | |
| Mstent | <input type="text" value="psv6 (f 5)"/> | <input type="text" value="edv6 (f 5)"/> | sec | |
| Dstent | <input type="text" value="psv7 (f 5)"/> | <input type="text" value="edv7 (f 5)"/> | sec | |

Renal Aortic Ratio: $\frac{\text{Renal PSV}}{\text{Aorta PSV}} = \text{result (fl 4, 2)}$

÷ =

STENT 2: if applicable

| | | | | |
|--|-------------|----------------------|--------|--|
| <input type="text" value="psv8 (f 5)"/> | P-IS | <input type="text"/> | cm/sec | <input type="text" value="edv8 (f 5)"/> |
| <input type="text" value="psv9 (f 5)"/> | M-IS | <input type="text"/> | cm/sec | <input type="text" value="edv9 (f 5)"/> |
| <input type="text" value="psv10 (f 5)"/> | D-IS | <input type="text"/> | cm/sec | <input type="text" value="edv10 (f 5)"/> |

Right Renal Parenchymal Evaluation

Upper Pole PSV /sec

Lower Pole PSV /sec

Cortical Thickness cm

Average: RI

Hilar Analysis sec

Hilar Analysis; Supports Stenosis Yes No NA UNK

Average Pole to Pole Kidney Length Measurements cm

Indirect Findings Positive Yes No NA UNK

PST

Right Diagnostic Impression

Normal Occluded 1-59% stenosis Insufficient direct findings to determine status of renal artery >=60-99% stenosis

Right Final Impression determined using:

RAR Absolute PSV>200cm/sec NO PST NA Absolute PSV>200cm/sec+PST Deviated from Criteria

PS: Context
Panel: Context

RENAL DUPLEX ULTRASOUND FINDINGS

Clinical Site #

Date of Exam

VUCL LABEL

PS: Ultra1
PT: PostUS2a
Panel: Ultra1

Patient #

Patient Randomization #

Left Renal

| | | | | | | | | |
|--------|--|--|-------|---|--|--|---------------------------|--------------------------|
| PRA | <input type="text" value="psv11 (f 5)"/> | <input type="text" value="edv11 (f 5)"/> | m/sec | <input type="radio"/> proximal | <input type="text" value="relatn4 <relation4>"/> | <input type="radio"/> distal to stent | <input type="radio"/> unk | <input type="radio"/> NA |
| MRA | <input type="text" value="psv12 (f 5)"/> | <input type="text" value="edv12 (f 5)"/> | m/sec | <input type="radio"/> proximal to stent | <input type="radio"/> intrastent | <input type="text" value="relatn5 <relation4>"/> | <input type="radio"/> unk | <input type="radio"/> NA |
| DRA | <input type="text" value="psv13 (f 5)"/> | <input type="text" value="edv13 (f 5)"/> | m/sec | <input type="radio"/> proximal | <input type="text" value="relatn6 <relation4>"/> | <input type="radio"/> distal to stent | <input type="radio"/> unk | <input type="radio"/> NA |
| Pstent | <input type="text" value="psv14 (f 5)"/> | <input type="text" value="edv14 (f 5)"/> | m/sec | | | | | |
| Mstent | <input type="text" value="psv15 (f 5)"/> | <input type="text" value="edv15 (f 5)"/> | m/sec | | | | | |
| Dstent | <input type="text" value="psv16 (f 5)"/> | <input type="text" value="edv16 (f 5)"/> | m/sec | | | | | |

PS: PostUS2a
PT: PostUS2a
Panel: PostUS2a

Renal PSV Aorta PSV

Renal Aortic Ratio

STENT 2: if applicable
PSV EDV

| | | | |
|------|--|--|-------|
| P-IS | <input type="text" value="psv17 (f 5)"/> | <input type="text" value="edv17 (f 5)"/> | m/sec |
| M-IS | <input type="text" value="psv18 (f 5)"/> | <input type="text" value="edv18 (f 5)"/> | m/sec |
| D-IS | <input type="text" value="psv19 (f 5)"/> | <input type="text" value="edv19 (f 5)"/> | m/sec |

Left Renal Parenchymal Evaluation

Upper Pole PSV m/sec Lower Pole PSV m/sec

Cortical Thickness Average: RI

Hilar Analysis m/sec Hilar Analysis; Supports Stenosis Yes No NA UNK

Average Pole to Pole Kidney Length Measurement

PST Indirect Findings Positive Yes No NA UNK

Left Diagnostic Impression 99% stenosis Insufficient direct findings to determine status of renal artery

Left Final Impression determined using: RAR Absolute PSV Absolute PSV >200cm/sec NO PST NA Deviated from Criteria

Interval Change Yes No NA UNK

Comments

Reviewer Gail Sandager, RN, RVT Sandra M. Kim, RVT, RDMS Shirley Morgan, RN, RVT Michael R. Jaff, DO, RVT Other...

Overread

Vascore of

Boston, MA 02114

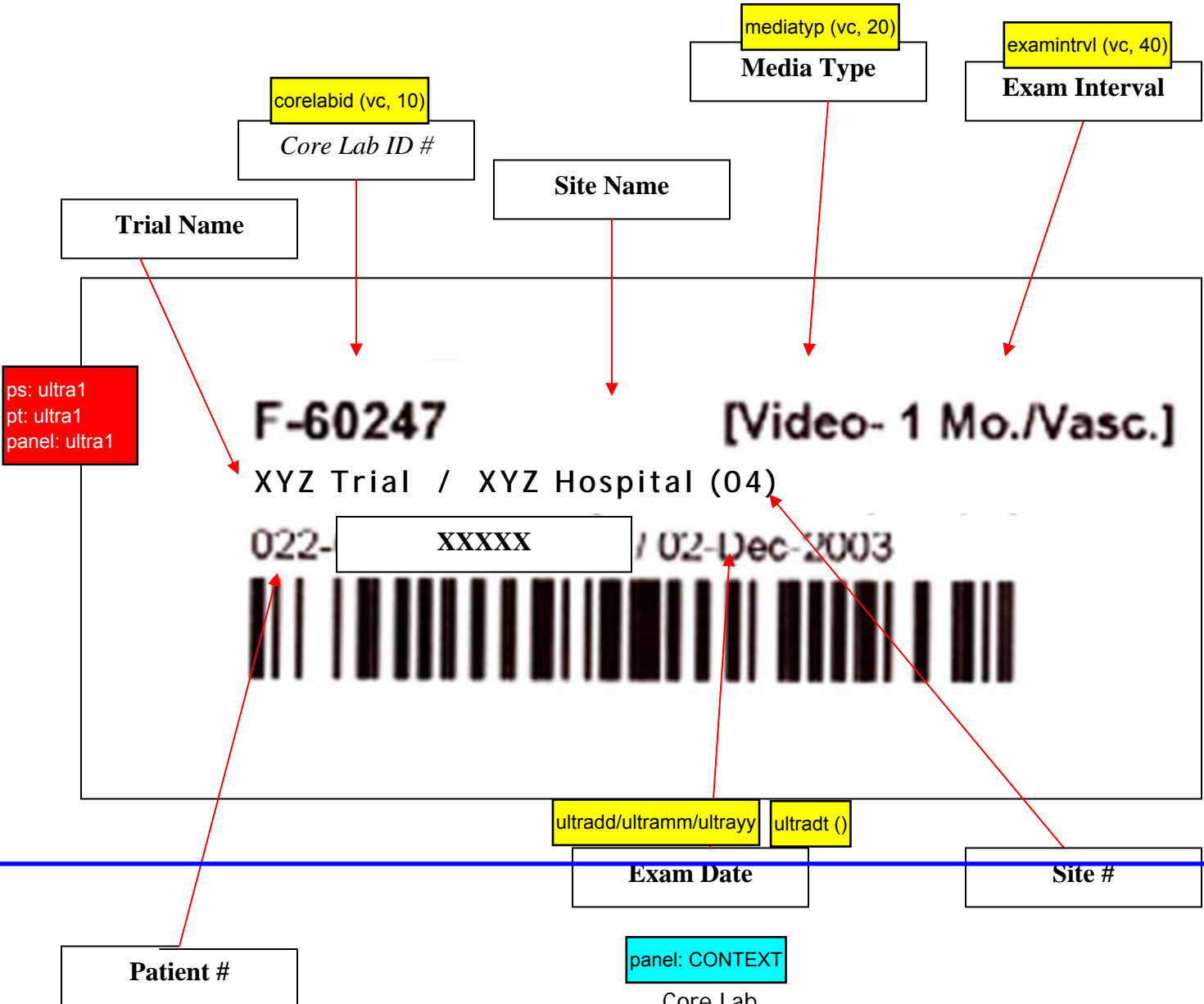
rev. 03/21/2006 v.2

Page 2 of 2



EXAMPLE BARCODE LABEL

Barcode labels are sometimes placed on Feedback forms and other documents from the Core Lab.
Below is an example of how to read the labels.



Vascular Core Lab Final Report Form

SCREEN DUPLEX RANDOMIZATION

Clinical **Patient Randomization #**

PS: Context
Panel: Context

Date of Exam

MM/DD/YYYY

Study Side Left Right UNK

Non-Diagnostic Yes No

PS: Ultra1
PT: RandUS
Panel: Ultra1

PS: RandUS
PT: RandUS
Panel: RandUS

SCREEN DUPLEX RANDOMIZATION

PRA

MRA

DRA

PST Yes No NA UNK

Renal Artery Stenosis Yes No NA UNK

If RAS Yes < 60% >= 60 - 99% Occluded NA UNK

Meets Duplex Randomization Criteria Yes No UNK

Comments

Reviewer Gail Hadley, RN, RVT Sandra Croteau, RN, RVT Victoria Sova, RN, RVT Other

Review Date

Vascore of

CORAL

Patient Functioning and Quality of Life Questionnaire:

Baseline

Instructions

This questionnaire asks for your views about your health. This information will help keep track of how you feel and how well you are able to do your usual activities.

Any information that would permit you to be identified as a member of the study will be regarded as strictly confidential and will be used only for this study.

Please answer every question by marking one box. If you are unsure about how to answer, please give the best answer you can.

The Research Coordinator will hand you this Questionnaire. Please complete to the best of your ability since the Research Coordinator is not permitted to answer any questions during your completion time.

pageno (f, 5)

visno (vc, 20)

subid (vc, 20)

PS: Context
Panel: Context

To be completed by the Research Coordinator:

Site ID

Site

Date of Survey

survmm/survdd/surveyy

survdt()

Patient No.

Patient

Before start of treatment?

 (1) YES

Randomization No.

PTRando

pretx <yesno>

 (2) NOThis form was completed: (1) By the Patient

formcmpl<contact3>

 (2) By Research Coordinator via interview (3) By Proxy

PS: QOLBas01
PT: QOLBas01
Panel: QOLBas01

Questions on Health Perception

The following questions are about your health. Think about how you have been feeling recently and then answer each question below. Please circle the number of the answer that most closely fits you. If you are unsure about how to answer a question, please give the best answer that you can.

PS: QOLBas02
PT: QOLBas02
Panel: QOLBas02

1. First, in general, would you say your health is:

- Excellent 1 health <health1>
- Very Good 2
- Good 3
- Fair 4
- Poor 5

2. Compared to one year ago, how would you rate your health in general now?

- Much better than one year ago 1 hxhealth <health2>
- Somewhat better than one year ago 2
- About the same 3
- Somewhat worse now than one year ago 4
- Much worse now than one year ago 5

Current Daily Activities

PS: QOLBas03
PT: QOLBas03
Panel: QOLBas03

1. The following questions are about activities you might do during a typical day. I would like to know if your health limited you in each of these activities during the past month. If so, how much?

(Please circle the appropriate answer)

| DURING THE PAST MONTH, DID YOUR HEALTH LIMIT YOU IN ... | YES, LIMITED A LOT | YES, LIMITED A LITTLE | NO, NOT LIMITED AT ALL |
|--|--------------------|-----------------------|---|
| a. Vigorous activities , such as running, lifting heavy objects, or strenuous sports | 1 | 2 | 3 <input type="text" value="vigactv <limit>"/> |
| b. Moderate activities , such as moving a table, pushing a vacuum cleaner, bowling, or playing golf | 1 | 2 | 3 <input type="text" value="modactv <limit>"/> |
| c. Lifting or carrying groceries | 1 | 2 | 3 <input type="text" value="groactv <limit>"/> |
| d. Climbing several flights of stairs | 1 | 2 | 3 <input type="text" value="sevstair <limit>"/> |
| e. Climbing one flight of stairs | 1 | 2 | 3 <input type="text" value="onestair <limit>"/> |
| f. Bending, kneeling, or stooping | 1 | 2 | 3 <input type="text" value="stoop <limit>"/> |
| g. Walking more than one mile | 1 | 2 | 3 <input type="text" value="grtmile <limit>"/> |
| h. Walking several blocks | 1 | 2 | 3 <input type="text" value="sevblock <limit>"/> |
| i. Walking one block | 1 | 2 | 3 <input type="text" value="oneblock <limit>"/> |
| j. Bathing and dressing yourself | 1 | 2 | 3 <input type="text" value="dressing <limit>"/> |

2. During the past month, have you had any of the following problems with your work or regular activities as a result of your physical health?

PS: QOLBas04
PT: QOLBas04
Panel: QOLBas04

(Please circle the appropriate answer)

| AS A RESULT OF YOUR PHYSICAL HEALTH, HAVE YOU ... | YES | NO | |
|--|-----|----|------------------|
| a. Cut down on the amount of time you spend on work or other activities | 1 | 2 | phyredct <yesno> |
| b. Accomplished less than you would like | 1 | 2 | phyaccmp <yesno> |
| c. Been limited in the kind of work or other activities | 1 | 2 | physkind <yesno> |
| d. Had difficulty performing work or other activities (for example, it took extra effort) | 1 | 2 | physdiff <yesno> |

3. During the past month, have you had any of the following problems with your work or regular activities as a result of any emotional problems (such as feeling depressed or anxious)?

(Please circle the appropriate answer)

| AS A RESULT EMOTIONAL PROBLEMS, HAVE YOU ... | YES | NO | |
|---|-----|----|------------------|
| a. Cut down on the amount of time you spend on work or other activities? | 1 | 2 | emoredct <yesno> |
| b. Accomplished less than you would like? | 1 | 2 | emoaccmp <yesno> |
| c. Didn't do work or other activities as carefully as usual? | 1 | 2 | emotcare <yesno> |

4. During the past month, to what extent have health problems interfered with your normal social activities with family, friends, neighbors, or groups? (Circle one)

PS: QOLBas05
PT: QOLBas05
Panel: QOLBas05

- Not at all..... 1
- Slightly 2
- Moderately 3
- Quite a bit..... 4
- Extremely 5

health <problems>

5. How much bodily pain have you had during the past month? (Circle one)

- None 1
- Very mild 2
- Mild 3
- Moderate 4
- Severe..... 5
- Very severe 6

bodypain <pain1>

6. During the past month, how much did pain interfere with your normal work (including both work outside the home and housework)? (Circle one)

- Not at all..... 1
- A little bit 2
- Moderately 3
- Quite a bit..... 4
- Extremely 5

workpain <pain2>

Current Well-Being

PS: QOLBas06
 PT: QOLBas06
 Panel: QOLBas06

1. These next questions are about how you feel and how things have been with you during the past month. For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past month . . .

| DURING THE PAST MONTH, HOW MUCH OF THE TIME.... | All of the time | Most of the time | A good bit of the time | Some of the time | A little of the time | None of the time |
|--|-----------------|------------------|------------------------|------------------|----------------------|------------------|
| a. Did you feel full of life? | 1 | 2 | 3 | 4 | 5 | 6 |
| b. Were you lifefull <QOLstate> nervous person? | 1 | 2 | 3 | 4 | 5 | 6 |
| c. Did you feel so nervous <QOLstate> down like the dumps that nothing could cheer you up? | 1 | 2 | 3 | 4 | 5 | 6 |
| d. Did you feel calm and peaceful? depress <QOLstate> | 1 | 2 | 3 | 4 | 5 | 6 |
| e. Did you have peace <QOLstate> energy? | 1 | 2 | 3 | 4 | 5 | 6 |
| f. Did you feel energy <QOLstate> downhearted and low? | 1 | 2 | 3 | 4 | 5 | 6 |
| g. Did you feel worn out? down <QOLstate> | 1 | 2 | 3 | 4 | 5 | 6 |
| h. Were you a wornout <QOLstate> happy person? happy <QOLstate> | 1 | 2 | 3 | 4 | 5 | 6 |
| i. Did you feel tired? tired <QOLstate> | 1 | 2 | 3 | 4 | 5 | 6 |

2. During the past month, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives, etc.)? (Circle one answer)

PS: QOLBas07
PT: QOLBas07
Panel: QOLBas07

- social <active> All of the time 1
- Most of the time..... 2
- Some of the time 3
- A little bit of the time..... 4
- None of the time..... 5

3. How TRUE or FALSE is each of the following statements for you?

(Circle one number on each line)

| How TRUE or FALSE is each statement for you? | Definitely true | Mostly true | Don't know | Mostly false | Definitely false |
|--|-----------------|-------------|------------|--------------|------------------|
| a. I seem to get ill more easily than other people. illness <truth> | 1 | 2 | 3 | 4 | 5 |
| b. I am as healthy as anybody I know. healthy <truth> | 1 | 2 | 3 | 4 | 5 |
| c. I expect my health to get worse. worse <truth> | 1 | 2 | 3 | 4 | 5 |
| d. My health is excellent. excellnt <truth> | 1 | 2 | 3 | 4 | 5 |

Questions on Health Perception

By circling one number in each group below, please indicate which statements best describe your own health state today.

1. Mobility (Circle one) mobility <qolwalk>

- I have no problems in walking about..... 1
- I have some problems in walking about..... 2
- I am confined to bed..... 3

2. Self-Care (Circle one) selfcare <qolselfcare>

- I have no problems with self-care..... 1
- I have some problems washing or dressing myself..... 2
- I am unable to wash or dress myself..... 3

3. Usual Activities (Circle one) uslactv <qolactiv>
(e.g. work, study, housework, family or social activities)

- I have no problems with performing my usual activities..... 1
- I have some problems with performing my usual activities..... 2
- I am unable to perform my usual activities..... 3

4. Pain/Discomfort (Circle one) discmfrt <discom>

- I have no pain or discomfort..... 1
- I have moderate pain or discomfort..... 2
- I have extreme pain or discomfort..... 3

5. Anxiety/Depression (Circle one) anxiety <anx>

- I am not anxious or depressed..... 1
- I am moderately anxious or depressed..... 2
- I am extremely anxious or depressed..... 3

To help people say how good or bad a health state is, we have drawn a scale (rather like a thermometer) on which the best state you can imagine is marked 100 and the worst state you can imagine is marked 0.

We would like you to indicate on this scale how good or bad your own health is today, in your opinion. Please do this by drawing a line from the box below to whichever point on the scale indicates how good or bad your health state is today.

Your own health state today

Best imaginable health state

PS: QOLBas09
PT: QOLBas09
Panel: QOLBas09



Worst imaginable health state

Employment

PS: QOLBas10
 PT: QOLBas10
 Panel: QOLBas10

1. Which term best describes your most recent main job? *(Circle one)*

employ <employ>

- Professional or technical (lawyer, teacher, social worker, scientist, nurse, doctor, state police, computer programmer)..... 1
- Clerical worker (secretary, receptionist, data entry, cashier)..... 2
- Service worker (janitor, cook, waitress/waiter, nurse’s aide, security guard, driver, road crew worker, subway conductor)..... 3
- Craftsman or tradesman (carpenter, electrician, mechanic) 4
- Other (please describe) employsp (vc, 200) 5

2. What was your total family income last year before taxes? *(Circle one)*

income <income>

- Less than \$10,000 1
- \$10,000 to \$20,000..... 2
- \$20,000 to \$40,000..... 3
- \$40,000 to \$60,000..... 4
- \$60,000 to \$80,000..... 5
- \$80,000 to \$100,000..... 6
- more than \$100,000 7

3. Which of the following statements best describes your work situation for the past month? *(Circle one)*

worksitn <situation>

- Working 1
- Unemployed (but seeking work) 2
- On disability..... 3
- Retired 4
- On sick leave..... 5

Personal Information

PS: QOLBas11
PT: QOLBas11
Panel: QOLBas11

4. What is the highest grade of school you completed? *(Circle one)*

schling <schooling>

- Grade eight or less 1
- Some high school 2
- Graduated from high school 3
- Some college or did not attend college, but
had additional special training 4
- Graduated from college 5
- Post-graduate work 6

5. How many people, including yourself, live in your household? hshold (f, 5) people

hshold (f, 5)

6. Are you presently: *(Circle one)*

marital <marital>

- Married or living as married 1
- Divorced or separated 2
- Widowed 3
- Never Married 4



INSTRUCTIONS

A list of symptoms appears down the left side of the page. For each one, please think whether **YOU HAVE EVER HAD** this symptom during the **PAST MONTH**.

If not, **FILL IN THE CIRCLE 'N'**, and go on to the next symptom.

If you have had it or think you have had it – even if only once, and only very mildly—then **FILL IN THE CIRCLE 'Y'** and go on to answer **HOW OFTEN** you have had this symptom, filling in the appropriate circle. Then answer **HOW DISTRESSING** this symptom has been to you, again filling in the appropriate circle.

SAMPLE QUESTIONS

| <p>DURING THE PAST MONTH, HAVE YOU EXPERIENCED THIS SYMPTOM OR FEELING?</p> <p>Please mark: Y = Yes N = No If YES, then answer →</p> | <p>HOW OFTEN?</p> <p>1 = Once or twice 2 = Once or twice a week 3 = Often each week 4 = Almost daily</p> | <p>HOW DISTRESSING HAS IT BEEN?</p> <p>0 = Not at all 1 = Somewhat 2 = Moderately 3 = Very Much 4 = Extremely</p> |
|--|--|--|
| <p>1. Dryness of mouth <input type="radio"/> Y <input type="radio"/> N</p> <p>2. General Weakness <input type="radio"/> Y <input type="radio"/> N</p> <p>3. Confusion <input type="radio"/> Y <input type="radio"/> N</p> | <p><input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> 4</p> <p><input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> 4</p> <p><input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> 4</p> | <p><input type="radio"/> 0 <input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> 4</p> <p><input type="radio"/> 0 <input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> 4</p> <p><input type="radio"/> 0 <input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> 4</p> |

| <p>DURING THE PAST MONTH, HAVE YOU EXPERIENCED THIS SYMPTOM OR FEELING?</p> <p>Please mark: Y = Yes N = No If YES, then answer →</p> | <p>HOW OFTEN?</p> <p>1 = Once or twice 2 = Once or twice a week 3 = Often each week 4 = Almost daily</p> | <p>HOW DISTRESSING HAS IT BEEN?</p> <p>0 = Not at all 1 = Somewhat 2 = Moderately 3 = Very Much 4 = Extremely</p> |
|--|---|--|
| <p>1. Dryness of mouth (Y) (N)</p> <p>2. General weakness (Y) (N)</p> <p>3. Confusion (Y) (N)</p> <p>4. Heartburn (Y) (N)</p> <p>5. Itching (Y) (N)</p> | <p>(1) (2) (3) (4)</p> <p>(1) (2) (3) (4)</p> <p>(1) (2) (3) (4)</p> <p>(1) (2) (3) (4)</p> <p>(1) (2) (3) (4)</p> | <p>(0) (1) (2) (3) (4)</p> <p>(0) (1) (2) (3) (4)</p> <p>(0) (1) (2) (3) (4)</p> <p>(0) (1) (2) (3) (4)</p> <p>(0) (1) (2) (3) (4)</p> |
| <p>6. Shortness of breath (Y) (N)</p> <p>7. Unable to sleep, insomnia (Y) (N)</p> <p>8. Mood swings (Y) (N)</p> <p>9. Difficulty remembering things (Y) (N)</p> <p>10. Blurry vision (Y) (N)</p> | <p>(1) (2) (3) (4)</p> <p>(1) (2) (3) (4)</p> <p>(1) (2) (3) (4)</p> <p>(1) (2) (3) (4)</p> <p>(1) (2) (3) (4)</p> | <p>(0) (1) (2) (3) (4)</p> <p>(0) (1) (2) (3) (4)</p> <p>(0) (1) (2) (3) (4)</p> <p>(0) (1) (2) (3) (4)</p> <p>(0) (1) (2) (3) (4)</p> |
| <p>11. Wheezing, difficulty breathing (Y) (N)</p> <p>12. Hives or swelling of body or facial areas (Y) (N)</p> <p>13. Extreme thirst (Y) (N)</p> <p>14. Lethargy, no energy to do things (Y) (N)</p> <p>15. Difficulty thinking (Y) (N)</p> | <p>(1) (2) (3) (4)</p> <p>(1) (2) (3) (4)</p> <p>(1) (2) (3) (4)</p> <p>(1) (2) (3) (4)</p> <p>(1) (2) (3) (4)</p> | <p>(0) (1) (2) (3) (4)</p> <p>(0) (1) (2) (3) (4)</p> <p>(0) (1) (2) (3) (4)</p> <p>(0) (1) (2) (3) (4)</p> <p>(0) (1) (2) (3) (4)</p> |

| <p>DURING THE PAST MONTH, HAVE YOU EXPERIENCED THIS SYMPTOM OR FEELING?</p> <p>Please mark: Y = Yes N = No If YES, then answer →</p> | <p>HOW OFTEN?</p> <p>1 = Once or twice 2 = Once or twice a week 3 = Often each week 4 = Almost daily</p> | <p>HOW DISTRESSING HAS IT BEEN?</p> <p>0 = Not at all 1 = Somewhat 2 = Moderately 3 = Very Much 4 = Extremely</p> |
|---|--|--|
| <p>16. Diarrhea <input type="radio"/> Y <input type="radio"/> N</p> <p>17. Cloudy thinking <input type="radio"/> Y <input type="radio"/> N</p> <p>18. Hair loss <input type="radio"/> Y <input type="radio"/> N</p> <p>19. Double vision <input type="radio"/> Y <input type="radio"/> N</p> <p>20. Lightheadedness <input type="radio"/> Y <input type="radio"/> N</p> | <p><input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> 4</p> <p><input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> 4</p> <p><input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> 4</p> <p><input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> 4</p> <p><input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> 4</p> | <p><input type="radio"/> 0 <input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> 4</p> <p><input type="radio"/> 0 <input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> 4</p> <p><input type="radio"/> 0 <input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> 4</p> <p><input type="radio"/> 0 <input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> 4</p> <p><input type="radio"/> 0 <input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> 4</p> |
| <p>21. Tiredness, feeling weary <input type="radio"/> Y <input type="radio"/> N</p> <p>22. Constipation <input type="radio"/> Y <input type="radio"/> N</p> <p>23. Rapid heartbeat or palpitations <input type="radio"/> Y <input type="radio"/> N</p> <p>24. Numbness or tingling of hands <input type="radio"/> Y <input type="radio"/> N</p> <p>25. Fatigue <input type="radio"/> Y <input type="radio"/> N</p> | <p><input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> 4</p> <p><input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> 4</p> <p><input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> 4</p> <p><input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> 4</p> <p><input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> 4</p> | <p><input type="radio"/> 0 <input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> 4</p> <p><input type="radio"/> 0 <input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> 4</p> <p><input type="radio"/> 0 <input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> 4</p> <p><input type="radio"/> 0 <input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> 4</p> <p><input type="radio"/> 0 <input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> 4</p> |
| <p>26. Reduced awareness of what's going on <input type="radio"/> Y <input type="radio"/> N</p> <p>27. Body aches and pains <input type="radio"/> Y <input type="radio"/> N</p> <p>28. Dizziness when standing up <input type="radio"/> Y <input type="radio"/> N</p> | <p><input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> 4</p> <p><input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> 4</p> <p><input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> 4</p> | <p><input type="radio"/> 0 <input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> 4</p> <p><input type="radio"/> 0 <input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> 4</p> <p><input type="radio"/> 0 <input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> 4</p> |

CORAL Patient Functioning and Quality of Life Questionnaire:

Follow-Up

Instructions

This questionnaire asks for your views about your health. This information will help keep track of how you feel and how well you are able to do your usual activities.

Any information that would permit you to be identified as a member of the study will be regarded as strictly confidential and will be used only for this study.

Please answer every question by marking one box. If you are unsure about how to answer, please give the best answer you can.

Please complete PS: Context
Panel: Context our ability.

pageno (f, 5) visno (vc, 20) subid (vc, 20)

To be completed by HCRI

| | | | |
|-------------------|---|-----------------|---|
| Site ID | Site _____ | Date of Survey: | survmm/survdd/survy |
| Patient No. | Patient _____ | | survdt() |
| Randomization No. | PTRando _____ | | |

PS: QOLAnn01
 PT: QOLAnn01
 Panel: QOLAnn01

| | | | | |
|---|---------|--------|--------|--------|
| Time Point (circle one) | 6 month | 1 year | 2 year | 3 year |
| timept <interval45> | | | | |

Who was contacted? contact <contact1>
 (1) Patient (2) Proxy

Questions on Health Perception

PS: QOLAnn02
PT: QOLAnn02
Panel: QOLAnn02

The following questions are about your health. Think about how you have been feeling recently and then answer each question below. Please circle the number of the answer that most closely fits you. If you are unsure about how to answer a question, please give the best answer that you can.

1. First, in general, would you say your health is:

- Excellent 1
- Very Good 2
- Good 3
- Fair 4
- Poor 5

health <health1>

2. Compared to one year ago, how would you rate your health in general now?

- Much better than one year ago 1
- Somewhat better than one year ago 2
- About the same 3
- Somewhat worse now than one year ago 4
- Much worse now than one year ago 5

hxhealth <health2>

Current Daily Activities

PS: QOLAnn03
PT: QOLAnn03
Panel: QOLAnn03

1. The following questions are about activities you might do during a typical day. We would like to know if your health limited you in each of these activities during the past month. If so, how much?

(Please circle the appropriate answer)

| DURING THE PAST MONTH, DID YOUR HEALTH LIMIT YOU IN ... | YES, LIMITED A LOT | YES, LIMITED A LITTLE | NO, NOT LIMITED AT ALL |
|--|--------------------|-----------------------|---------------------------------------|
| a. Vigorous activities , such as running, lifting heavy objects, or strenuous sports | 1 | 2 | 3 vigactv <limit> |
| b. Moderate activities , such as moving a table, pushing a vacuum cleaner, bowling, or playing golf | 1 | 2 | 3 modactv <limit> |
| c. Lifting or carrying groceries | 1 | 2 | 3 grocactv <limit> |
| d. Climbing several flights of stairs | 1 | 2 | 3 sevstair <limit> |
| e. Climbing one flight of stairs | 1 | 2 | 3 onestair <limit> |
| f. Bending, kneeling, or stooping | 1 | 2 | 3 stoop <limit> |
| g. Walking more than one mile | 1 | 2 | 3 grtmile <limit> |
| h. Walking several blocks | 1 | 2 | 3 sevblock <limit> |
| i. Walking one block | 1 | 2 | 3 oneblock <limit> |
| j. Bathing and dressing yourself | 1 | 2 | 3 dressing <limit> |

2. During the past month, have you had any of the following problems with your work or regular activities as a result of your physical health?

PS: QOLAnn04
PT: QOLAnn04
Panel: QOLAnn04

(Please circle the appropriate answer)

| AS A RESULT OF YOUR PHYSICAL HEALTH, HAVE YOU ... | YES | NO | |
|--|-----|----|------------------|
| a. Cut down on the amount of time you spend on work or other activities | 1 | 2 | phyredct <yesno> |
| b. Accomplished less than you would like | 1 | 2 | phyaccmp <yesno> |
| c. Been limited in the kind of work or other activities | 1 | 2 | physkind <yesno> |
| d. Had difficulty performing work or other activities (for example, it took extra effort) | 1 | 2 | physdiff <yesno> |

3. During the past month, have you had any of the following problems with your work or regular activities as a result of any emotional problems (such as feeling depressed or anxious)?

(Please circle the appropriate answer)

| AS A RESULT EMOTIONAL PROBLEMS, HAVE YOU ... | YES | NO | |
|---|-----|----|------------------|
| a. Cut down on the amount of time you spend on work or other activities? | 1 | 2 | emoredct <yesno> |
| b. Accomplished less than you would like? | 1 | 2 | emoaccmp <yesno> |
| c. Didn't do work or other activities as carefully as usual? | 1 | 2 | emotcare <yesno> |

4. During the past month, to what extent have health problems interfered with your normal social activities with family, friends, neighbors, or groups? (Circle one)

- Not at all..... 1
- Slightly 2
- Moderately 3
- Quite a bit..... 4
- Extremely 5

health <problems>

5. How much bodily pain have you had during the past month? (Circle one)

- None 1
- Very mild 2
- Mild 3
- Moderate 4
- Severe..... 5
- Very severe 6

bodypain <pain1>

6. During the past month, how much did pain interfere with your normal work (including both work outside the home and housework)? (Circle one)

- Not at all..... 1
- A little bit 2
- Moderately 3
- Quite a bit..... 4
- Extremely 5

workpain <pain2>

Current Well-Being

1. These next questions are about how you feel and how things have been with you during the past month. For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past month . . .

| DURING THE PAST MONTH, HOW MUCH OF THE TIME.... | All of the time | Most of the time | A good bit of the time | Some of the time | A little of the time | None of the time |
|--|-----------------|------------------|------------------------|------------------|----------------------|------------------|
| a. Did you feel full lifelike <QOLstate> | 1 | 2 | 3 | 4 | 5 | 6 |
| b. Were you a very nervous person? nervous <QOLstate> | 1 | 2 | 3 | 4 | 5 | 6 |
| c. Did you feel so down in the dumps that nothing could cheer you up? depress <QOLstate> | 1 | 2 | 3 | 4 | 5 | 6 |
| d. Did you feel calm and peaceful? peace <QOLstate> | 1 | 2 | 3 | 4 | 5 | 6 |
| e. Did you have a lot of energy? energy <QOLstate> | 1 | 2 | 3 | 4 | 5 | 6 |
| f. Did you feel downhearted and low? down <QOLstate> | 1 | 2 | 3 | 4 | 5 | 6 |
| g. Did you feel worn out? wornout <QOLstate> | 1 | 2 | 3 | 4 | 5 | 6 |
| h. Were you a happy person? happy <QOLstate> | 1 | 2 | 3 | 4 | 5 | 6 |
| i. Did you feel tired? tired <QOLstate> | 1 | 2 | 3 | 4 | 5 | 6 |

2. During the past month, how much of the time have your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives, etc.)? (Circle one answer)

- social <active>** All of the time 1
- Most of the time..... 2
- Some of the time 3
- A little bit of the time..... 4
- None of the time..... 5

3. How TRUE or FALSE is each of the following statements for you?

(Circle one number on each line)

| How TRUE or FALSE is each statement for you? | Definitely true | Mostly true | Don't know | Mostly false | Definitely false |
|--|-----------------|-------------|------------|--------------|------------------|
| a. I seem to get ill more easily than other people. illness <truth> | 1 | 2 | 3 | 4 | 5 |
| b. I am as healthy as anybody I know. healthy <truth> | 1 | 2 | 3 | 4 | 5 |
| c. I expect my health to get worse. worse <truth> | 1 | 2 | 3 | 4 | 5 |
| d. My health is excellent excellnt <truth> | 1 | 2 | 3 | 4 | 5 |

Questions on Health Perception

By circling one number in each group below, please indicate which statements best describe your own health state today.

1. Mobility (Circle one) mobility <qolwalk>

- I have no problems in walking about..... 1
- I have some problems in walking about..... 2
- I am confined to bed..... 3

2. Self-Care (Circle one) selfcare <qolselfcare>

- I have no problems with self-care..... 1
- I have some problems washing or dressing myself..... 2
- I am unable to wash or dress myself..... 3

3. Usual Activities (Circle one) uslactv <qolactiv>
(e.g. work, study, housework, family or leisure activities)

- I have no problems with performing my usual activities..... 1
- I have some problems with performing my usual activities..... 2
- I am unable to perform my usual activities..... 3

4. Pain/Discomfort (Circle one) discmfrt <discom>

- I have no pain or discomfort..... 1
- I have moderate pain or discomfort..... 2
- I have extreme pain or discomfort..... 3

5. Anxiety/Depression (Circle one) anxiety <anx>

- I am not anxious or depressed.....1
- I am moderately anxious or depressed.....2
- I am extremely anxious or depressed.....3

Best imaginable health state

PS: QOLAnn09
PT: QOLAnn09
Panel: QOLAnn09

To help people say how good or bad a health state is, we have drawn a scale (rather like a thermometer) on which the best state you can imagine is marked 100 and the worst state you can imagine is marked 0.

We would like you to indicate on this scale how good or bad your own health is today, in your opinion. Please do this by drawing a line from the box below to whichever point on the scale indicates how good or bad your health state is today.

Your own health state today



Worst imaginable health state

SID: _____

Pt. No. _____

Randomization No. _____

PS: QOLAnn10
PT: QOLAnn10
Panel: QOLAnn10

INSTRUCTIONS

A list of symptoms appears down the left side of the page. For each one, please think whether YOU HAVE EVER HAD this symptom during the PAST MONTH.

If not, FILL IN THE CIRCLE 'N', and go on to the next symptom.

If you have had it or think you have had it – even if only once, and only very mildly— then FILL IN THE CIRCLE 'Y' and go on to answer HOW OFTEN you have had this symptom, filling in the appropriate circle. Then answer HOW DISTRESSING this symptom has been to you, again filling in the appropriate circle.

SAMPLE QUESTIONS

| <p>DURING THE PAST MONTH, HAVE YOU EXPERIENCED THIS SYMPTOM OR FEELING?</p> <p>Please mark: Y = Yes N = No If YES, then answer →</p> | <p>HOW OFTEN?</p> <p>1 = Once or twice 2 = Once or twice a week 3 = Often each week 4 = Almost daily</p> | <p>HOW DISTRESSING HAS IT BEEN?</p> <p>0 = Not at all 1 = Somewhat 2 = Moderately 3 = Very Much 4 = Extremely</p> |
|---|---|--|
| <p>1. Dryness of mouth (Y) (N)</p> | <p>(1) (2) (3) (4)</p> | <p>(0) (1) (2) (3) (4)</p> |
| <p>2. General Weakness (Y) (N)</p> | <p>(1) (2) (3) (4)</p> | <p>(0) (1) (2) (3) (4)</p> |
| <p>3. Confusion (Y) (N)</p> | <p>(1) (2) (3) (4)</p> | <p>(0) (1) (2) (3) (4)</p> |

Site ID: _____

Pt. No. _____

Randomization No. _____

PS: QOLAnn11
PT: QOLAnn11
Panel: QOLAnn11

| <p>DURING THE PAST MONTH, HAVE YOU EXPERIENCED THIS SYMPTOM OR FEELING?</p> <p>Please mark: Y = Yes N = No If YES, then answer →</p> | <p>HOW OFTEN?</p> <p>1 = Once or twice 2 = Once or twice a week 3 = Often each week 4 = Almost daily</p> | <p>HOW DISTRESSED HAS IT BEEN</p> <p>0 = Not at all 1 = Somewhat 2 = Moderately 3 = Very Much 4 = Extremely</p> |
|--|---|--|
| <p>1. Dryness of mouth (Y) (N)</p> <p>2. General weakness (Y) (N)</p> <p>3. Confusion (Y) (N)</p> <p>4. Heartburn (Y) (N)</p> <p>5. Itching (Y) (N)</p> | <p>(1) (2) (3) (4)</p> <p>(1) (2) (3) (4)</p> <p>(1) (2) (3) (4)</p> <p>(1) (2) (3) (4)</p> <p>(1) (2) (3) (4)</p> | <p>(0) (1) (2) (3) (4)</p> <p>(0) (1) (2) (3) (4)</p> <p>(0) (1) (2) (3) (4)</p> <p>(0) (1) (2) (3) (4)</p> <p>(0) (1) (2) (3) (4)</p> |
| <p>6. Shortness of breath (Y) (N)</p> <p>7. Unable to sleep, insomnia (Y) (N)</p> <p>8. Mood swings (Y) (N)</p> <p>9. Difficulty remembering things (Y) (N)</p> <p>10. Blurry vision (Y) (N)</p> | <p>(1) (2) (3) (4)</p> <p>(1) (2) (3) (4)</p> <p>(1) (2) (3) (4)</p> <p>(1) (2) (3) (4)</p> <p>(1) (2) (3) (4)</p> | <p>(0) (1) (2) (3) (4)</p> <p>(0) (1) (2) (3) (4)</p> <p>(0) (1) (2) (3) (4)</p> <p>(0) (1) (2) (3) (4)</p> <p>(0) (1) (2) (3) (4)</p> |
| <p>11. Wheezing, difficulty breathing (Y) (N)</p> <p>12. Hives or swelling of body or facial areas (Y) (N)</p> <p>13. Extreme thirst (Y) (N)</p> <p>14. Lethargy, no energy to do things (Y) (N)</p> <p>15. Difficulty thinking (Y) (N)</p> | <p>(1) (2) (3) (4)</p> <p>(1) (2) (3) (4)</p> <p>(1) (2) (3) (4)</p> <p>(1) (2) (3) (4)</p> <p>(1) (2) (3) (4)</p> | <p>(0) (1) (2) (3) (4)</p> <p>(0) (1) (2) (3) (4)</p> <p>(0) (1) (2) (3) (4)</p> <p>(0) (1) (2) (3) (4)</p> <p>(0) (1) (2) (3) (4)</p> |

Site ID: _____ Pt. No. _____ Randomization No. _____

PS: QOLAnn12
 PT: QOLAnn12
 Panel: QOLAnn12

| <p>DURING THE PAST MONTH, HAVE YOU EXPERIENCED THIS SYMPTOM OR FEELING?</p> <p>Please mark: Y = Yes N = No If YES, then answer →</p> | <p>HOW OFTEN?</p> <p>1 = Once or twice 2 = Once or twice a week 3 = Often each week 4 = Almost daily</p> | <p>HOW DISTRESSING HAS IT BEEN?</p> <p>0 = Not at all 1 = Somewhat 2 = Moderately 3 = Very Much 4 = Extremely</p> |
|---|--|--|
| 16. Diarrhea (Y) (N) | (1) (2) (3) (4) | (0) (1) (2) (3) (4) |
| 17. Cloudy thinking (Y) (N) | (1) (2) (3) (4) | (0) (1) (2) (3) (4) |
| 18. Hair loss (Y) (N) | (1) (2) (3) (4) | (0) (1) (2) (3) (4) |
| 19. Double vision (Y) (N) | (1) (2) (3) (4) | (0) (1) (2) (3) (4) |
| 20. Lightheadedness (Y) (N) | (1) (2) (3) (4) | (0) (1) (2) (3) (4) |
| 21. Tiredness, feeling weary (Y) (N) | (1) (2) (3) (4) | (0) (1) (2) (3) (4) |
| 22. Constipation (Y) (N) | (1) (2) (3) (4) | (0) (1) (2) (3) (4) |
| 23. Rapid heartbeat or palpitations (Y) (N) | (1) (2) (3) (4) | (0) (1) (2) (3) (4) |
| 24. Numbness or tingling of hands (Y) (N) | (1) (2) (3) (4) | (0) (1) (2) (3) (4) |
| 25. Fatigue (Y) (N) | (1) (2) (3) (4) | (0) (1) (2) (3) (4) |
| 26. Reduced awareness of what's going on (Y) (N) | (1) (2) (3) (4) | (0) (1) (2) (3) (4) |
| 27. Body aches and pains (Y) (N) | (1) (2) (3) (4) | (0) (1) (2) (3) (4) |
| 28. Dizziness when standing up (Y) (N) | (1) (2) (3) (4) | (0) (1) (2) (3) (4) |

CORAL Patient Functioning and Quality of Life Questionnaire:

Study Close-Out

Instructions

This questionnaire asks for your views about your health. This information will help keep track of how you feel and how well you are able to do your usual activities.

Any information that would permit you to be identified as a member of the study will be regarded as strictly confidential and will be used only for this study.

Please answer every question by marking one box. If you are unsure about how to answer, please give the best answer you can.

The Research Coordinator will hand you this Questionnaire. Please complete to the best of your ability since the Research Coordinator is not permitted to answer any questions during your completion time.

pageno (f, 5) visno (vc, 20) subid (vc, 20)

PS: Context
Panel: Context

To be completed by the Research Coordinator:

Site ID Date of Survey

Patient No.

Randomization No.

This form was completed: (1) By the Patient

(2) By Research Coordinator via interview

(3) By Proxy

PS: QOLEx01
PT: QOLEx01
Panel: QOLEx01

Questions on Health Perception

PS: QOLEx02
PT: QOLEx02
Panel: QOLEx02

The following questions are about your health. Think about how you have been feeling recently and then answer each question below. Please circle the number of the answer that most closely fits you. If you are unsure about how to answer a question, please give the best answer that you can.

1. First, in general, would you say your health is:

- | | |
|-----------------|---|
| Excellent | 1 |
| Very Good | 2 |
| Good | 3 |
| Fair | 4 |
| Poor | 5 |

health <health1>

2. Compared to one year ago, how would you rate your health in general now?

- | | |
|--|---|
| Much better than one year ago | 1 |
| Somewhat better than one year ago | 2 |
| About the same | 3 |
| Somewhat worse now than one year ago | 4 |
| Much worse now than one year ago | 5 |

hxhealth <health2>

Current Daily Activities

PS: QOLEX03
PT: QOLEX03
Panel: QOLEX03

1. The following questions are about activities you might do during a typical day. We would like to know if your health limited you in each of these activities during the past month. If so, how much?

(Please circle the appropriate answer)

| DURING THE PAST MONTH, DID YOUR HEALTH LIMIT YOU IN ... | YES, LIMITED A LOT | YES, LIMITED A LITTLE | NO, NOT LIMITED AT ALL |
|--|--------------------|-----------------------|---------------------------------------|
| a. Vigorous activities , such as running, lifting heavy objects, or strenuous sports | 1 | 2 | 3 vigactv <limit> |
| b. Moderate activities , such as moving a table, pushing a vacuum cleaner, bowling, or playing golf | 1 | 2 | 3 modactv <limit> |
| c. Lifting or carrying groceries | 1 | 2 | 3 grocactv <limit> |
| d. Climbing several flights of stairs | 1 | 2 | 3 sevstair <limit> |
| e. Climbing one flight of stairs | 1 | 2 | 3 onestair <limit> |
| f. Bending, kneeling, or stooping | 1 | 2 | 3 stoop <limit> |
| g. Walking more than one mile | 1 | 2 | 3 grtmile <limit> |
| h. Walking several blocks | 1 | 2 | 3 sevblock <limit> |
| i. Walking one block | 1 | 2 | 3 oneblock <limit> |
| j. Bathing and dressing yourself | 1 | 2 | 3 dressing <limit> |

2. During the past month, have you had any of the following problems with your work or regular activities as a result of your physical health?

PS: QOLEX04
PT: QOLEX04
Panel: QOLEX04

(Please circle the appropriate answer)

| AS A RESULT OF YOUR PHYSICAL HEALTH, HAVE YOU ... | YES | NO | |
|--|-----|----|------------------|
| a. Cut down on the amount of time you spend on work or other activities | 1 | 2 | phyredct <yesno> |
| b. Accomplished less than you would like | 1 | 2 | phyaccmp <yesno> |
| c. Been limited in the kind of work or other activities | 1 | 2 | physkind <yesno> |
| d. Had difficulty performing work or other activities (for example, it took extra effort) | 1 | 2 | physdiff <yesno> |

3. During the past month, have you had any of the following problems with your work or regular activities as a result of any emotional problems (such as feeling depressed or anxious)?

(Please circle the appropriate answer)

| AS A RESULT EMOTIONAL PROBLEMS, HAVE YOU ... | YES | NO | |
|---|-----|----|------------------|
| a. Cut down on the amount of time you spend on work or other activities? | 1 | 2 | emoredct <yesno> |
| b. Accomplished less than you would like? | 1 | 2 | emoaccmp <yesno> |
| c. Didn't do work or other activities as carefully as usual? | 1 | 2 | emotcare <yesno> |

4. During the past month, to what extent have health problems interfered with your normal social activities with family, friends, neighbors, or groups? (Circle one)

PS: QOLEx05
PT: QOLEx05
Panel: QOLEx05

Not at all..... 1
Slightly 2
Moderately 3
Quite a bit..... 4
Extremely 5

health <problems>

5. How much bodily pain have you had during the past month? (Circle one)

None 1
Very mild 2
Mild 3
Moderate 4
Severe 5
Very severe 6

bodypain <pain1>

6. During the past month, how much did pain interfere with your normal work (including both work outside the home and housework)? (Circle one)

Not at all..... 1
A little bit 2
Moderately 3
Quite a bit..... 4
Extremely 5

workpain <pain2>

Current Well-Being

PS: QOLEx06
PT: QOLEx06
Panel: QOLEx06

1. These next questions are about how you feel and how things have been with you during the past month. For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past month . . .

| DURING THE PAST MONTH, HOW MUCH OF THE TIME.... | All of the time | Most of the time | A good bit of the time | Some of the time | A little of the time | None of the time |
|--|-----------------|------------------|------------------------|------------------|----------------------|------------------|
| a. Did you feel full of life? lifefull <QOLstate> | 1 | 2 | 3 | 4 | 5 | 6 |
| b. Were you a very nervous person? nervous <QOLstate> | | 2 | 3 | 4 | 5 | 6 |
| c. Did you feel so down in the dumps that nothing could cheer you up? depress <QOLstate> | 1 | 2 | 3 | 4 | 5 | 6 |
| d. Did you feel calm and peaceful? peace <QOLstate> | 1 | 2 | 3 | 4 | 5 | 6 |
| e. Did you have a lot of energy? energy <QOLstate> | 1 | 2 | 3 | 4 | 5 | 6 |
| f. Did you feel downhearted and low? down <QOLstate> | | 2 | 3 | 4 | 5 | 6 |
| g. Did you feel worn out? wornout <QOLstate> | 1 | 2 | 3 | 4 | 5 | 6 |
| h. Were you a happy person? happy <QOLstate> | | 2 | 3 | 4 | 5 | 6 |
| i. Did you feel tired? tired <QOLstate> | 1 | 2 | 3 | 4 | 5 | 6 |

2. During the past month, how much of the time have your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives, etc.)? (Circle one answer)

social <active>

- All of the time 1
- Most of the time..... 2
- Some of the time 3
- A little bit of the time..... 4
- None of the time..... 5

3. How TRUE or FALSE is each of the following statements for you?

(Circle one number on each line)

| How TRUE or FALSE is each statement for you? | Definitely true | Mostly true | Don't know | Mostly false | Definitely false |
|--|-----------------|-------------|------------|--------------|------------------|
| a. I seem to get ill more easily than other people. illness <truth> | 1 | 2 | 3 | 4 | 5 |
| b. I am as healthy as anybody I know. healthy <truth> | 1 | 2 | 3 | 4 | 5 |
| c. I expect my health to get worse. worse <truth> | 1 | 2 | 3 | 4 | 5 |
| d. My health is excellent excellnt <truth> | 1 | 2 | 3 | 4 | 5 |

Questions on Health Perception

By circling one number in each group below, please indicate which statements best describe your own health state today.

1. Mobility (Circle one) mobility <qolwalk>

- I have no problems in walking about..... 1
- I have some problems in walking about..... 2
- I am confined to bed..... 3

2. Self-Care (Circle one) selfcare <qolselfcare>

- I have no problems with self-care..... 1
- I have some problems washing or dressing myself..... 2
- I am unable to wash or dress myself..... 3

3. Usual Activities (Circle one) uslactv <qolactiv>
(e.g. work, study, housework, family or leisure activities)

- I have no problems with performing my usual activities..... 1
- I have some problems with performing my usual activities..... 2
- I am unable to perform my usual activities..... 3

4. Pain/Discomfort (Circle one) discmfrt <discom>

- I have no pain or discomfort..... 1
- I have moderate pain or discomfort..... 2
- I have extreme pain or discomfort..... 3

5. Anxiety/Depression (Circle one) anxiety <anx>

- I am not anxious or depressed..... 1
- I am moderately anxious or depressed..... 2
- I am extremely anxious or depressed..... 3

Best imaginable health state

PS: QOLEx09
PT: QOLEx09
Panel: QOLEx09

To help people say how good or bad a health state is, we have drawn a scale (rather like a thermometer) on which the best state you can imagine is marked 100 and the worst state you can imagine is marked 0.

We would like you to indicate on this scale how good or bad your own health is today, in your opinion. Please do this by drawing a line from the box below to whichever point on the scale indicates how good or bad your health state is today.

Your own health state today



Worst imaginable health state

Site ID: _____ Pt. No. _____ Randomization No. _____



PS: QOLEx10
PT: QOLEx10
Panel: QOLEx10

INSTRUCTIONS

A list of symptoms appears down the left side of the page. For each one, please think whether YOU HAVE EVER HAD this symptom during the PAST MONTH.

If not, FILL IN THE CIRCLE 'N', and go on to the next symptom.

If you have had it or think you have had it – even if only once, and only very mildly— then FILL IN THE CIRCLE 'Y' and go on to answer HOW OFTEN you have had this symptom, filling in the appropriate circle. Then answer HOW DISTRESSING this symptom has been to you, again filling in the appropriate circle.

SAMPLE QUESTIONS

| <p>DURING THE PAST MONTH, HAVE YOU EXPERIENCED THIS SYMPTOM OR FEELING?</p> <p>Please mark: Y = Yes N = No If YES, then answer →</p> | <p>HOW OFTEN?</p> <p>1 = Once or twice 2 = Once or twice a week 3 = Often each week 4 = Almost daily</p> | <p>HOW DISTRESSING HAS IT BEEN?</p> <p>0 = Not at all 1 = Somewhat 2 = Moderately 3 = Very Much 4 = Extremely</p> |
|---|---|--|
| <p>1. Dryness of mouth <input type="radio"/> Y <input type="radio"/> N</p> | <p><input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> 4</p> | <p><input type="radio"/> 0 <input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> 4</p> |
| <p>2. General Weakness <input type="radio"/> Y <input type="radio"/> N</p> | <p><input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> 4</p> | <p><input type="radio"/> 0 <input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> 4</p> |
| <p>3. Confusion <input type="radio"/> Y <input type="radio"/> N</p> | <p><input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> 4</p> | <p><input type="radio"/> 0 <input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> 4</p> |

Site ID: _____ Pt. No. _____ Randomization No. _____

PS: QOLEx11
 PT: QOLEx11
 Panel: QOLEx11


| <p>DURING THE PAST MONTH, HAVE YOU EXPERIENCED THIS SYMPTOM OR FEELING?</p> <p>Please mark: Y = Yes N = No If YES, then answer →</p> | <p>HOW OFTEN?</p> <p>1 = Once or twice 2 = Once or twice a week 3 = Often each week 4 = Almost daily</p> | <p>HOW DISTRESSED HAS IT BEEN?</p> <p>0 = Not at all 1 = Somewhat 2 = Moderately 3 = Very Much 4 = Extremely</p> |
|---|--|---|
| 1. Dryness of mouth (Y) (N) | (1) (2) (3) (4) | (0) (1) (2) (3) (4) |
| 2. General weakness (Y) (N) | (1) (2) (3) (4) | (0) (1) (2) (3) (4) |
| 3. Confusion (Y) (N) | (1) (2) (3) (4) | (0) (1) (2) (3) (4) |
| 4. Heartburn (Y) (N) | (1) (2) (3) (4) | (0) (1) (2) (3) (4) |
| 5. Itching (Y) (N) | (1) (2) (3) (4) | (0) (1) (2) (3) (4) |
| 6. Shortness of breath (Y) (N) | (1) (2) (3) (4) | (0) (1) (2) (3) (4) |
| 7. Unable to sleep, insomnia (Y) (N) | (1) (2) (3) (4) | (0) (1) (2) (3) (4) |
| 8. Mood swings (Y) (N) | (1) (2) (3) (4) | (0) (1) (2) (3) (4) |
| 9. Difficulty remembering things (Y) (N) | (1) (2) (3) (4) | (0) (1) (2) (3) (4) |
| 10. Blurry vision (Y) (N) | (1) (2) (3) (4) | (0) (1) (2) (3) (4) |
| 11. Wheezing, difficulty breathing (Y) (N) | (1) (2) (3) (4) | (0) (1) (2) (3) (4) |
| 12. Hives or swelling of body or facial areas (Y) (N) | (1) (2) (3) (4) | (0) (1) (2) (3) (4) |
| 13. Extreme thirst (Y) (N) | (1) (2) (3) (4) | (0) (1) (2) (3) (4) |
| 14. Lethargy, no energy to do things (Y) (N) | (1) (2) (3) (4) | (0) (1) (2) (3) (4) |
| 15. Difficulty thinking (Y) (N) | (1) (2) (3) (4) | (0) (1) (2) (3) (4) |

Site ID: _____ Pt. No. _____ Randomization No. _____

PS: QOLEx12
PT: QOLEx12
Panel: QOLEx12

| <p>DURING THE PAST MONTH, HAVE YOU EXPERIENCED THIS SYMPTOM OR FEELING?</p> <p>Please mark: Y = Yes N = No If YES, then answer →</p> | <p>HOW OFTEN?</p> <p>1 = Once or twice 2 = Once or twice a week 3 = Often each week 4 = Almost daily</p> | <p>HOW DISTRESSED HAS IT BEEN?</p> <p>0 = Not at all 1 = Somewhat 2 = Moderately 3 = Very Much 4 = Extremely</p> |
|---|---|---|
| <p>16. Diarrhea <input type="radio"/> Y <input type="radio"/> N</p> | <p><input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> 4</p> | <p><input type="radio"/> 0 <input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> 4</p> |
| <p>17. Cloudy thinking <input type="radio"/> Y <input type="radio"/> N</p> | <p><input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> 4</p> | <p><input type="radio"/> 0 <input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> 4</p> |
| <p>18. Hair loss <input type="radio"/> Y <input type="radio"/> N</p> | <p><input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> 4</p> | <p><input type="radio"/> 0 <input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> 4</p> |
| <p>19. Double vision <input type="radio"/> Y <input type="radio"/> N</p> | <p><input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> 4</p> | <p><input type="radio"/> 0 <input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> 4</p> |
| <p>20. Lightheadedness <input type="radio"/> Y <input type="radio"/> N</p> | <p><input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> 4</p> | <p><input type="radio"/> 0 <input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> 4</p> |
| <p>21. Tiredness, feeling weary <input type="radio"/> Y <input type="radio"/> N</p> | <p><input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> 4</p> | <p><input type="radio"/> 0 <input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> 4</p> |
| <p>22. Constipation <input type="radio"/> Y <input type="radio"/> N</p> | <p><input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> 4</p> | <p><input type="radio"/> 0 <input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> 4</p> |
| <p>23. Rapid heartbeat or palpitations <input type="radio"/> Y <input type="radio"/> N</p> | <p><input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> 4</p> | <p><input type="radio"/> 0 <input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> 4</p> |
| <p>24. Numbness or tingling of hands <input type="radio"/> Y <input type="radio"/> N</p> | <p><input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> 4</p> | <p><input type="radio"/> 0 <input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> 4</p> |
| <p>25. Fatigue <input type="radio"/> Y <input type="radio"/> N</p> | <p><input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> 4</p> | <p><input type="radio"/> 0 <input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> 4</p> |
| <p>26. Reduced awareness of what's going on <input type="radio"/> Y <input type="radio"/> N</p> | <p><input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> 4</p> | <p><input type="radio"/> 0 <input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> 4</p> |
| <p>27. Body aches and pains <input type="radio"/> Y <input type="radio"/> N</p> | <p><input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> 4</p> | <p><input type="radio"/> 0 <input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> 4</p> |
| <p>28. Dizziness when standing up <input type="radio"/> Y <input type="radio"/> N</p> | <p><input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> 4</p> | <p><input type="radio"/> 0 <input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> 4</p> |

PS: BIOCHEM
 PT: BIOCHEM
 Panel: BIOCHEM

| Field Seq # | Sunquest Field Name and Content | Max Field Size | Field Description - Comments |
|-------------|--|----------------|---|
| 1 | HMO-ID ptid (vc, 12)  | 12 | This field contains the number assigned as the patient ID by the Study or Project. If client-assigned combinations of alpha and numeric are not compatible with our Lab computer system, an assigned number is used. |
| 2 | Specimen # Pre-assigned accession # or Lab ID # spec (vc, 10) SQ: Specimen Comment Field | 10 | This field is the Specimen Number or "Accession Number" pre-assigned to the study/project. If there is no pre-assigned number, the system will assign a number. This number, in combination with the date should be unique. |
| 3 | Performed Test-Code testcode (vc, 10) | 10 | This field contains the 'performed test' code. |
| 4 | Result Name/Code resname (vc, 10) | 10 | This field contains the 'Result Name' code. |
| 5 | Specimen Collection Date and Time specdtm () | 16 | This field contains the Collection Date of the Specimen. The date format is DD/YYYY HH:MI, where HH is 00-23. For Months and Days that are less than 10, the characters include a leading zero. |
| 6 | Test Status teststat (vc, 1) | 1 | Indicates the status of the test in question (e.g. F = verified/final, C = corrected). |
| 7 | Result Verify Date and Time resldtm () | 16 | This field contains the verify date of the result. The date format is MM/DD/YYYY HH:MI, where HH is 00-23. For Months and Days that are less than 10, the characters include a leading zero. |

| Field Seq # | Sunquest Field Name and Content | Max Field Size | Field Description - Comments |
|-------------|--|----------------|---|
| 8 | Result Type restype (vc, 1) | 1 | This data item will indicate the type of result record (N = Numeric, C = Comment, and F = Free Text, S = String-not strictly numeric). Test comments will generate additional, separate data records. |
| 9 | Result Units | 20 | resunit (vc, 20) n contains the Units the result is being reported in. |
| 10 | Result-Value SQ: Modifiers Field resval (vc, 80) | 80 | This data field is used for the result value, and could contain up to 80 Characters for Alpha Numeric test results or comments. If the result record includes a Comment or is Free Text (see field # 8), this information will also be stored here as a separate record with the same demographics as the numeric test result record. |
| 11 | Visit Number SQ: Order Comment Field visnum (vc, 15) | 15 | This field has contained a "Visit Number" or related designation for the patient. The actual numeric 'Visit' or 'Year' text label will precede the numeric information in the field. |
| 12 | Patient ID Code: acrostic or Initials nmfld (vc, 60) SQ: Name Field | 60 | This field has been used for a patient's initials or an acrostic code. |
| 13 | Patient Type Code pttype (vc, 3) | 3 | This data item indicates the Patient Type code (e.g. OS). |
| 14 | Site-Code (DR#-client-cd) sitecode (vc, 8) | 8 | This data item is the "Study ID code" (Patient Location Code – e.g. U007A). |

| Field Seq # | Sunquest Field Name and Content | Max Field Size | Field Description - Comments |
|-------------|--|----------------|--|
| 15 | <u>Ordered Test Code</u> ordtest (vc, 10) | 10 | This field contains the 'Ordered Test' code. |
| 16 | <u>Specimen Receipt Date and Time</u> recptdtm () | 16 | This field contains the specimen receipt date. The date format is MM/DD/YYYY HH:MI, where HH is 00-23. For Months and Days that are less than 10, the characters include a leading zero. |
| 17 | <u>Patient Birth Date</u> -STF SQ: Study patient BDates will be entered as 01/01/1900 when not provided dobdt() | 10 | This data item is the Patient Birth Date expressed as MM/DD/YYYY. The patient Birth Date is typically not known for research study/project specimens and the field. For Months and Days that are less than 10, the characters include a leading zero. For Study patients that do not have specified birth dates, a value of 01/01/1900 will be entered and reported (required field). |
| 18 | <u>SQ: Lab assigned Accession #</u> accession (vc, 14) | 14 | This field contains the computer-assigned specimen accession number. This accession number is our lab internal number. It will usually differ from the assigned accession # or Lab ID # that is used in field # 2. |

| Field Seq # | Sunquest Field Name and Content | Max Field Size | Field Description - Comments |
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| 1 | HMO-ID ptid (vc, 12) | 12 | This field contains the number assigned as the patient ID by the Study or Project. If client-assigned combinations of alpha and numeric are not compatible with our Lab computer system, an assigned number is used. |
| 2 | Specimen # Pre-assigned accession # or Lab ID # spec (vc, 10) SQ: Specimen Comment Field | 10 | This field is the Specimen Number or "Accession Number" pre-assigned to the study/project. If there is no pre-assigned number, the system will assign a number. This number, in combination with the date should be unique. |
| 3 | Performed Test-Code testcode (vc, 10) | 10 | This field contains the 'performed test' code. |
| 4 | Result Name/Code resname (vc, 10) | 10 | This field contains the 'Result Name' code. |
| 5 | Specimen Collection Date and Time specdtm () | 16 | This field contains the Collection Date of the Specimen. The date format is MM/DD/YYYY HH:MI, where HH is 00-23. For Months and Days that are less than 10, the characters include a leading zero. |
| 6 | Test Status teststat (vc, 1) | 1 | Indicates the status of the test in question (e.g. F = verified/final, C = corrected). |
| 7 | Result Verify Date and Time resldtm () | 16 | This field contains the verify date of the result. The date format is MM/DD/YYYY HH:MI, where HH is 00-23. For Months and Days that are less than 10, the characters include a leading zero. |

| Field Seq # | Sunquest Field Name and Content | Max Field Size | Field Description - Comments |
|-------------|--|----------------|---|
| 8 | Result Type restype (vc, 1) | 1 | This data item will indicate the type of result record (N = Numeric, C = Comment, and F = Free Text, S = String-not strictly numeric). Test comments will generate additional, separate data records. |
| 9 | Result Units | 20 | resunit (vc, 20) n contains the Units the result is being reported in. |
| 10 | Result-Value SQ: Modifiers Field resval (vc, 80) | 80 | This data field is used for the result value, and could contain up to 80 Characters for Alpha Numeric test results or comments. If the result record includes a Comment or is Free Text (see field # 8), this information will also be stored here as a separate record with the same demographics as the numeric test result record. |
| 11 | Visit Number SQ: Order Comment Field visnum (vc, 15) | 15 | This field has contained a "Visit Number" or related designation for the patient. The actual numeric 'Visit' or 'Year' text label will precede the numeric information in the field. |
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