

Trans-Radial Education And Therapeutics (TREAT) IV: FDA, Silver Spring, MD

Monday, July 29, 2013 10.55 am

SAFE PCI FOR WOMEN: INVESTIGATOR VIEW

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Randomization Radial vs Femoral



No PCI

FFR

PCI

< 30 mins

< 45 mins

< 60 mins

Manual
Data Entry

Demographics
Medical Hx
Procedural Data
via site-specific
Custom Software



Auto
Populate
within 7 days

**ORACLE[®]
SAFE-PCI EDC**





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CRF History: 050:XXX:BA SE:PI

BASE CATH1 DISCHARGE FFR IVUS 30 DAY SIGN

PI INCEXC | VSPE | RAND | HIST2 | ACCDET | HEM

PATIENT INFORMATION Patient: XXX/050-0001

1.	Patient Number	<input type="text" value="050-0001"/>	
2.*	Date of Birth	Mar / 11 / 1958	
3.	NCDR Patient ID	<input type="text" value="856895"/>	
4.*	Hispanic or Latino Ethnicity	<input checked="" type="radio"/> No <input type="radio"/> Yes	
5.*	Date of Informed Consent	Apr / 2 / 2012	
6.*	Intend to use IIBIIIa inhibitors?	<input checked="" type="radio"/> No <input type="radio"/> Yes	
7.*	Did the patient undergo angioplasty or stenting?	<input checked="" type="radio"/> No <input type="radio"/> Yes	
8.	Did the patient undergo FFR, IVUS, or OCT?	<input type="radio"/> No <input checked="" type="radio"/> Yes	
9.*	Was the lab sample obtained?	<input type="radio"/> No <input checked="" type="radio"/> Yes	
10.*	Is the patient treated chronically with oral anticoagulants?	<input checked="" type="radio"/> No <input type="radio"/> Yes, agent: <input type="radio"/> Coumadin	

[Select Action] Apply Submit Return

BASE CATH1 DISCHARGE FFR IVUS 30 DAY SIGN

BASE CATH1 CATH2 CATH3 DISCHARGE 30 DAY SIGN

CLINEV | STRESS | PROC | ACC | CLOSURE | CATH | CATHDET | ANAT | PCI
PRDET | PMED | CMED | LESION | DEV | RLABS1 | RLABS2 | PROCEV

CLINICAL EVALUATION LEADING TO PROCEDURE

From NCDR




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CRF History:


- 050:XXX:CATH1:CLINEV
- 050:XXX:CATH1:ANAT
- 050:XXX:CATH1:CATH
- 050:XXX:CATH1:CATH

BASE CATH1 CATH2 CATH3 DISCHARGE 30 DAY SIGN








CLINEV | STRESS | PROC | ACC | CLOSURE | CATH | CATHDET | ANAT | PCI

PRDET | PMED | CMED | LESION | DEV | RLABS1 | RLABS2 | PROCEV

CLINICAL EVALUATION LEADING TO PROCEDURE Patient: XXX/050-0052

From NCDR 

Clinical Evaluation Leading to the Procedure

1.*	Arrival Date and Time	Mar/27/2013 06:17:00	
2.*	Procedure Date and Time	Mar/27/2013 09:12:00	
3.*	CAD Presentation (choose the worst status)	Unstable angina	
4.	If CAD Presentation is STEMI or Non-STEMI, Symptom Onset Date and Time		
5.	-----Symptom Time Estimated		
6.	-----Symptom Time Not Available		
7.	Received full dose thrombolytic therapy as an urgent treatment for STEMI		
8.*	Anginal Classification within 2 weeks	CCS IV	
9.*	Anti-Anginal medication within 2 Weeks (prior to Catheterization lab visit)	No	
10.*	Heart Failure within past 2 Weeks	No	
11.*	Cardiomyopathy or Left Ventricular Systolic Dysfunction	No	

[Select Action]



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