

OCCLUDED ARTERY TRIAL (OAT) PCI Related Adverse Event Form

OAT Form 52
Rev 1
07/08/2004
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13243

Please Use Black Pen To Fill Out Form.

Patient's ID Number: - Letter Code: Seq. No. Correction

1. Date of reported adverse event:
mmm dd yyyy

2. Event description:

3. Is this a PCI related complication? Yes No Unknown **pcicomp**

4. Was the mechanism of this complication a result of the following:

A. Coronary artery intervention? Yes No N/A* **pcintrvt**

If Yes, answer 1-6.

1. Abrupt closure: **pclosure**

If Yes, answer a-c.

a. Thrombosis **pcthrmb**
 b. Distal embolism **pcdembo**
 c. Dissection **pcdisst**

2. No reflow **pcreflow**

3. Coronary artery perforation? **pcper**

If Yes, answer a-d.

a. Effusion **pceffus**
 b. Tamponade **pctamp**
 c. Pericardiocentesis performed **pcperi**
 d. Silent (asymptomatic) **pcsiln**

4. Air embolism **pcair**

5. Side branch occlusion **pcocclu**

6. Reperfusion injury** **pcreper**

5. Initials of MMCC reviewer:

6. Signature of MMCC Reviewer _____

Item 4 (mechanism of complication) continued:

B. Arrhythmia Yes No N/A* **parrhyth**

C. Cardiac arrest Yes No N/A* **pcarda**

D. Myocardial rupture Yes No N/A* **pmyorupt**

E. Non-cardiac events Yes No N/A* **pncevt**

If Yes, answer 1-3.

1. Vascular access disturbance Yes No N/A* **pncvascu**

If Yes, answer a-f.

a. Hemorrhage Yes No N/A* **pncchemor**
 b. Thrombosis Yes No N/A* **pncthrmb**
 c. Embolism Yes No N/A* **pncembo**
 d. Dissection Yes No N/A* **pncdisst**
 e. Occlusion Yes No N/A* **pncocclu**
 f. Other, specify: Yes No N/A* **pncoth**

2. Anaphylaxis Yes No N/A* **pncanap**

3. Renal failure Yes No N/A* **pncrenal**

If Yes, answer a.

a. Transient or Permanent **pncrtype**

4. Other, specify: Yes No N/A* **pncotr**

*N/A = Not applicable

**Arrhythmia, myocardial rupture, cardiogenic shock or other complication occurring directly following revascularization.