

**OCCLUDED ARTERY TRIAL (OAT)**

**PROCEDURES MANUAL**

**FOR**

**OAT CLINICAL SITES**

**REVISED 3/29/04**

## TABLE OF CONTENTS

	PAGE
I. INTRODUCTION.....	1
II. START-UP PROCEDURES.....	1
III. REQUESTING TREATMENT ALLOCATIONS .....	2
A. Introduction.....	2
B. Practice Randomization for the Automated Telephone Response System (Required).....	3
C. How to Resolve Problems with the ATRS.....	4
IV. INSTRUCTIONS FOR USE OF OAT WEB SITE .....	5
A. Overview.....	5
B. Contents of the OAT Web Site .....	5
C. System Requirements To Access OAT Web Site.....	7
D. Site and User Applications.....	8
E. Printing Study Forms or Other Documents on the OAT Web Site.....	8
V. GENERAL INSTRUCTIONS FOR COMPLETING FORMS .....	8
A. Types of Study Forms .....	8
B. Obtaining Study Forms .....	10
VI. DEFINITIONS .....	11
A. Identifying Information.....	11
A.1 Patient Identification (ID) Number.....	11
A.2 Patient's Letter Code.....	11
B. Dates.....	11
C. Randomization Date (Study Entry Date) .....	12
D. Military Time .....	12
E. Period from Onset of Qualifying MI to Hospital Discharge .....	12
F. Missing Data.....	14

TABLE OF CONTENTS (Continued)

	PAGE
VII. INSTRUCTIONS FOR COMPLETING AND SUBMITTING OAT EVENT FORMS (OAT FORMS 14-21) .....	14
A. Introduction.....	14
B. Obtaining Required Supporting Documentation.....	15
C. Preparing Supporting Documentation for Submission with Event Forms.....	15
D. Mailing Forms and Other Materials to the Data Coordinating Center .....	16
VIII. PROCEDURES FOR DATA ENTRY .....	16
A. Introduction.....	16
B. Requirements for FAX ENTRY.....	17
C. Requirements for E-Mail Data Entry .....	18
D. Requirements for Internet Data Entry.....	18
IX. INSTRUCTIONS FOR COMPLETING FAX ENTRY FORMS .....	19
A. Completion of Each Item .....	19
B. Yes/No Items.....	20
C. Pre-coded Multiple-choice Items .....	20
D. Numeric Write-in Items .....	20
E. Alphabetic Write-in Items .....	20
F. Corrections .....	21
G. Transmittal List (OAT Form F).....	22
X. INSTRUCTIONS FOR E-MAIL DATA ENTRY.....	22
A. Start-Up Procedures and Test of Program .....	22
B. Regular Data Entry Session.....	23
B.1 Open Adobe Acrobat.....	23
B.2 Field Entry.....	23
B.3 Comment Items .....	23
B.4 Date Items .....	24
B.5 Completing and Sending the Data.....	24
B.6 Instructions for Saving a PDF File.....	25
B.7 Corrections .....	25
B.8 Review of E-mail Procedures.....	26
B.9 Receipt of E-Mail Forms.....	26

TABLE OF CONTENTS (Continued)

	PAGE
XI. INSTRUCTIONS FOR INTERNET DATA ENTRY .....	27
A. Start-Up Procedures and Test of Transmission.....	27
B. Selecting a Form.....	28
C. Entering Identification Information .....	28
D. Common Identifying Information Errors.....	29
E. Selecting a Function .....	29
F. Data Entry Form Screens.....	30
G. Skip Patterns .....	30
H. Data Not Available.....	30
I. Signature Fields .....	30
J. Menu Bar.....	30
K. Page Tabs .....	31
L. Navigation .....	31
M. Help .....	31
N. Saving Work .....	31
O. Interrupted Data Entry Session .....	32
P. Exiting Without Saving .....	32
Q. Printing Completed Form.....	32
XII. SPECIFIC INSTRUCTIONS FOR STUDY FORMS .....	33
A. ATRS Voice Response Worksheet - OAT Form B and ATRS Treatment Allocation - OAT Form C.....	33
A.1 Purpose of ATRS Voice Response Worksheet.....	33
A.2 Persons Responsible.....	33
A.3 Sources of Information.....	34
A.4 Time of Data Collection.....	34
A.5 Submission to Data Coordinating Center.....	34
A.6 Treatment Allocation Form.....	34
B. Randomized Patient Information Form - OAT Form 00 and Supplement to Form 00 - Form 0S .....	35
B.1 Purpose of Randomized Patient Information Form and Supplement.....	35
B.2 Time of Data Collection.....	35

TABLE OF CONTENTS (Continued)

	PAGE
C. Admission Forms - OAT Forms 01, 02, 03, 3A, and 04 and Inclusion and Exclusion Criteria Checklists - OAT Forms D and E .....	35
C.1 Purpose of These Forms .....	35
C.2 Submission to Data Coordinating Center .....	36
D. Fully Eligible, Non-Randomized Patient Form - OAT Form 25 and Supplement to Form 25 - Form 0S .....	36
D.1 Purpose of the Fully Eligible Non-Randomized Patient Form .....	36
D.2 Time of Data Collection .....	37
D.3 Submission to Data Coordinating Center .....	37
E. Protocol Percutaneous Coronary Intervention (PCI) Report Form - OAT Form 05 .....	37
E.1 Purpose of Protocol Percutaneous Coronary Intervention (PCI) Report Form .....	37
E.2 Submission to Data Coordinating Center .....	37
F. Complications Within 48 Hours of Study Entry Report - OAT Form 06 and Reinfarction Within 48 Hours of Study Entry Form - OAT Form 07 .....	37
F.1 Purpose of These Forms .....	38
F.1.1 All patients .....	38
F.1.2 PCI - Assigned Patients .....	38
F.2 Submission to Data Coordinating Center .....	38
G. Cardiac Serum Marker Results Form - OAT Form 8A, 8B and 8C, Medication Form - OAT Form 09, and Hospital Discharge or Outpatient Contact Form - OAT Form 10 .....	39
G.1 Purpose of the Hospital Discharge Forms .....	39
G.2 Hospitalizations > 30 Days .....	40
G.3 Submission to Data Coordinating Center .....	40
H. Follow-up Forms: Outcome Follow-up Form - OAT Form 11, Cardiovascular Status Outcome Follow-up Data Form - OAT Form 12, Medication Follow-up Form - OAT Form 13 .....	40

TABLE OF CONTENTS (Continued)

H.1	Purpose of Follow-up Forms.....	40
H.2	Time of Data Collection.....	41
H.3	Submission to Data Coordinating Center.....	41
I.	Cause of Death Form - OAT Form 14.....	42
I.1	Purpose of the Cause of Death Form.....	42
I.2	Submission to Data Coordinating Center .....	42
J.	Subsequent Hospitalization and Secondary Events Form - OAT Form 15.....	42
J.1	Purpose of the Subsequent Hospitalization and Secondary Events Form.....	42
J.2	Required Documentation.....	43
J.3	Submission to Data Coordinating Center .....	43
K.	Non-Protocol PCI Form - OAT Form 16.....	43
K.1	Purpose of the Non-Protocol PCI Form.....	43
K.2	Submission to Data Coordinating Center.....	44
L.	Myocardial Infarction Event Form - OAT Form 17, Congestive Heart Failure Event Form - OAT Form 18 and AICD Follow-Up Form - OAT Form 20.....	44
L.1	Purpose of These Forms .....	44
L.2	Submission to the Data Coordinating Center .....	45
M.	CABG Surgery Form - OAT Form 19 .....	45
M.1	Purpose of CABG Surgery Form .....	45
M.2	Submission to Data Coordinating Center .....	45
N.	Cardiac Serum Marker Results - OAT Form 21 .....	46
N.1	Purpose of the Cardiac Serum Marker Results .....	46
N.2	Submission to Data Coordinating Center.....	46
O.	Screening Log - OAT Form 26.....	46
P.	Angiography Transmittal Form - OAT Form 30.....	46
P.1	Purpose of Angiography Transmittal Form.....	46
P.2	Submission to Angiography Core Laboratory and Data Coordinating Center.....	46

Q.	Follow-up Angiography Form (TOSCA-2 Patients Only) - OAT Form 31 .....	47
Q.1	Purpose of Follow-up Angiography Form .....	47
Q.2	Submission to Angiography Core Laboratory and Data Coordinating Center .....	47
R.	OAT-EP Forms (for OAT-EP Patients only) .....	48
S.	OAT-NUC Forms (for OAT-NUC Patients only) .....	48
XIII.	STUDY MONITORING.....	49
A.	Checking Treatment Assignment.....	49
B.	Confirmation of ATRS Data .....	50
C.	Editing Data.....	50
C.1	Types of Problems Listed on Edit Statements .....	51
C.2	Format of Edit Statements.....	51
C.3	Instructions for Responding to Edit Statements .....	52
C.4	Missing Responses .....	53
C.5	Change an Item.....	53
C.6	Confirm Out-of-Range Values .....	53
C.7	Deletion of Page/Form .....	54
D.	Delinquent Listings.....	54
XIV.	EDUCATION ON PROTECTION OF HUMAN SUBJECT PARTICIPANTS .....	54
APPENDICES		
A	Sample PIN CARD .....	56
B	Home Page .....	57
C	Internet Site Application .....	59
D	Internet User Applicatioion.....	60
E	OAT Clinical Site Questionnaire on Site Resources .....	61
F	OAT Schedule of Measurements and Data Collection.....	62
G	Deadlines for Submission of Forms to the Data Coordinating Center .....	63
H	Guidelines for Completing Fax Entry Forms.....	64
I	Instructions for Saving a PDF File.....	65
J	Sample OAT Labels for ECGs and Stress Test Reports.....	68
K	OAT Follow-up Windows (Forms 11, 12, and 13).....	69
L	Appointment Schedule.....	70
M	Sample Edit Statement.....	71

## **I. INTRODUCTION**

The purpose of this Procedures Manual is to provide instructions for requesting treatment allocations and use of the OAT Web Site, general instructions for completing study forms, and a description of the requirements and procedures for the three alternative methods of transmitting study form data to the Data Coordinating Center (DCC) at the Maryland Medical Research Institute (MMRI). Several definitions that are common to all study forms are provided in this manual. Each of the study forms has specific instructions for completing each item on the form as well as definitions for certain items. These instructions are in the section for Study Forms in the OAT Binder. This binder contains the OAT Protocol, Consent Forms, Procedures Manual, study forms and, for Clinical Sites collecting quality of life data, the EQOL (Economics and Quality of Life) Manual. The OAT Binder should be retained for reference and updated as revised materials are distributed.

## **II. START-UP PROCEDURES**

The Clinical Coordinating Center has advised each of the Clinical Sites of the documents that are required before patient recruitment may be initiated. These documents are to be sent directly to the Clinical Coordinating Center. In addition, it is expected that one staff member will attend an OAT training session or have a conference call with DCC staff to review study procedures. The Principal Investigator of each Clinical Site should designate the individuals who should be authorized to request treatment allocations using the Automated Treatment Response System (ATRS) by submitting a completed application (OAT Form A) to the DCC. One staff member of each site should also be designated to perform a practice randomization. Clinical Site staff are asked to submit applications to use the OAT Web Site and to complete a survey to specify the preferred method of data entry. If a site plans to use E-mail or Internet Data Entry, a test session is required in order to assure that all of the programs are working satisfactorily before patient data are entered.

After Clinical Coordinating Center staff have notified the DCC that a Clinical Site is ready to begin enrollment, DCC staff send a start-up packet that includes the following materials.

- OAT Binder (current edition)
- Master set of Forms and Form Instructions
- Labels for ECGs and Stress Tests
- Test FAX Form
- All numbered memos issued prior to the date the start-up packet is mailed.



After the start-up materials are received, the first month of screening should be started and the Screening Log (OAT Form 26) completed for the next 30 days. At the end of the 30-day period the Screening Log should be mailed to the DCC.

For the first patient randomized in OAT in each Clinical Site, in addition to sending the forms to the DCC, all documentation and copies of the completed forms (01, 02, 03, 06, 07, 8A, 8B or 8C, and 10) should be sent to the Clinical Coordinating Center for review. The Clinical Coordinating Center will also need copies of the source documents to support the data on these forms. These materials should cover the period from the date of the onset of the index MI to hospital discharge or outpatient contact at 48 hours after study entry, whichever it later. (See Section VI E below and the instructions for Form 10.)

### **III. REQUESTING TREATMENT ALLOCATIONS**

#### **A. Introduction**

The DCC staff maintain an Automated Telephone Response System (ATRS) for Clinical Site staff to use to request treatment allocations as eligible patients are identified. The ATRS system is accessible only to study personnel who enter the password and identification number (PIN) for the Clinical Site. Staff at a Clinical Site can request treatment allocations for eligible patients after one staff member has practiced using the ATRS and the Clinical Coordinating Center has notified the Clinical Site that recruitment can be initiated.

Access to the ATRS is obtained by calling a toll-free telephone number at the DCC (see ATRS Worksheet OAT Form B). Clinical Sites outside the United States (U.S.) must first dial the U.S. AT&T Direct number (see Instructions for OAT Form B). This number is different for each country. The ATRS prompts authorized users by asking prerecorded questions; users respond by pressing keys on a touch-tone telephone. The prerecorded questions include confirmation that the patient meets all inclusion criteria and has no exclusion criteria and that the patient and the patient's physician have given informed consent for enrollment. Depending on the answers to these items, the next available treatment allocation is issued. The treatment allocation is given over the telephone by a prerecorded voice message and confirmed by fax transmission to the Clinical Site; a copy of the latter is sent to the Study Chair. The date and time of the completion of the call is the time of study entry for each patient. A computer record is maintained for each attempt to enroll a patient using the ATRS. If the Clinical Site fax machine is found to be inoperative after the call is completed, the investigator can call the ATRS again to request a second transmission of the allocation to the preprogrammed fax number or to another fax number at the Clinical Site. At the time of the second phone call, patient identifying information must be entered before the treatment allocation is transmitted. The ATRS also

announces the treatment allocation at the end of the second call. The ATRS should also be used to register each patient who is fully eligible for the trial but who does not consent to be randomized or the patient's physician does not give consent.

The steps required for a Clinical Site to be authorized to use the ATRS are:

1. Submit completed ATRS Hospital Application and Time Zone Form (OAT Form A) to the DCC.
2. DCC staff assign the hospital a Site number, a Hospital Identification Number (PIN) and a hospital password and issue PIN cards with this information for the ATRS (see Appendix A for sample PIN card). The PIN cards are sent to the Clinical Site with the instructions for a practice randomization using the ATRS.
3. At least one individual authorized to request allocations for a Clinical Site must complete a practice randomization prior to the hospital being able to randomize patients or enter patients in the OAT Registry.

#### **B. Practice Randomization for the Automated Telephone Response System (Required)**

DCC staff have designed a system to allow authorized personnel to practice a few allocations without actually entering a patient. The same procedures are used for this practice session as for an actual randomization except that: when you are requested to enter your Hospital password, enter 9999 rather than the Hospital Password that has been assigned to your Hospital. The phone allocation system identifies this call as a practice session. The steps to complete a practice session are described below.

1. Before you begin, prepare an ATRS Worksheet (OAT Form B) with practice information and have your Hospital PIN card on hand. Dial the toll-free number listed on the ATRS Worksheet. Users outside the U.S. should dial the U.S. AT&T Direct number before dialing the toll-free number (see Instructions for OAT Form B). As soon as the call is answered, you are requested to enter the Hospital Identification Number (PIN), and then the Hospital Password. When you enter 9999 as the Hospital Password, the ATRS identifies the call as a practice session.
2. Follow the ATRS voice instructions as if a patient were actually being randomized. The practice session should be performed during working hours at the DCC, weekdays 9:00 a.m. - 4:00 p.m. (EDT or EST) so that problems can be resolved if they occur.

3. At the end of the practice session, the system sends you a confirmation by FAX indicating the practice session came to a successful end. The FAX confirmation for the practice session clearly indicates that a patient has not been randomized. The receipt of this FAX shows that the accurate FAX number for your site is in the ATRS system.
4. The practice system will remain in place for the duration of the trial. If your staff periodically thinks that they need some practice using the system, or if new personnel have been assigned to request allocations, the practice system can be used for this purpose.
5. Each Clinical Site is expected to have at least one authorized individual perform a practice session prior to randomizing patients in the study or entering patients in the OAT Registry.

### **C. How to Resolve Problems with the ATRS**

If there is no answer when you call the toll-free number, make at least two more attempts. If there is no answer, call the DCC toll number. If there is no response at the toll number, call the ATRS beeper number or cellular phone number (see ATRS Worksheet - OAT Form B).

After entering your five-digit Hospital PIN number, if the system responds: "That is not a valid number," check the small laminated PIN card to confirm that you used the correct PIN number. Dial the ATRS and try the PIN number again. If the second attempt is not successful, contact DCC staff at the main number or if after hours, call the ATRS beeper number or cellular phone number (see ATRS Worksheet - OAT Form B).

If after entering your password the system responds: "I'm sorry, but you have not been certified for this application. To complete this requirement you must successfully complete the test procedure," staff at your Clinical Site have not performed a practice randomization. Perform a practice as described above in Section III B using your Hospital PIN number and the special password "9999."

If after entering your password the system responds "The selected application is not available for your Clinical Site at this time," your Clinical Site has not been authorized by the Clinical Coordinating Center to initiate patient recruitment. In this situation you should contact the Clinical Coordinating Center to determine what documents have not been received.

## **IV. INSTRUCTIONS FOR USE OF OAT WEB SITE**

### **A. Overview**

The OAT Web Site is available for use by all OAT Clinical Site and Central Unit staff. For questions about the Web Site, see the Contact Information page.

#### Web Access

To access the OAT Web Site, type <https://www.ctascstudies.com> into your browser's address window. Until you are assigned an individual log-on and password, use log-on = TOM and password = TERRIFIC. The home page is maintained by the Clinical Trials & Surveys Corp. (C-TASC), a subsidiary of the Maryland Medical Research Institute. Your connection to the OAT Web Site will be terminated after 20 minutes of inactivity. If that occurs, you will need to log back on the Web Site to continue.

#### Adobe Acrobat Reader and PDF files

Most documents available on the OAT Web Site are in Portable Document Format (PDF). Documents in PDF preserve the exact look and content of the originals. Adobe Acrobat Reader 4.0 is required to read and print the PDF documents. This product is free and is available from Adobe at <http://www.adobe.com/products/acrobat/readstep.html>. There is a link to Adobe on each of the OAT Web Site pages. When installing the program from the Adobe Web Site, follow the directions given on that Web Site. Click on the file name to open a PDF document with the Adobe Acrobat Reader.

### **B. Contents of the OAT Web Site**

The OAT Home Page (see Appendix B) identifies the categories of information available on the Web Site and provides links to those sections. To review the contents of each section, click on the section heading. The page for that section is then displayed. Each page lists the documents available in that section for the given category. The list can be quite long. To aid in finding documents in a section, a drop down list is provided to limit the list of documents to a smaller subset of that category.

#### Protocol/Manual

The Protocol, Procedures Manual, Ancillary study Protocols and related documents in PDF format, are accessible from the Protocol/Manual page.

### Memos

Important OAT study issues are distributed by numbered memos which are available in PDF format on the Memos page.

### Minutes

OAT does not post study minutes.

### Q & A

Frequently asked questions and answers about OAT Protocol or Procedures and Contact Information are available for browsing on the Q & A page.

### Forms

Study forms in PDF format are available for printing (see Section IV E below).

### Form QxQs

Instructions (Form QxQs) for each OAT Form provide specific details about each item on the form. These instructions are available in HTML (Hyper Text Mark-up Language) during Internet Data Entry or for browsing on the OAT Form QxQs page.

### Study Tools

Study schedules, time lines and other study management tools are available in PDF format on the OAT Study Tools page.

### News & Events

Announcements of upcoming events as well as the OAT Newsletters are available in PDF format on the OAT News & Events page.

### Presentations

The Powerpoint master slide set for conference presentation of background literature, overview of OAT Protocol, and data management training session slides are accessible from the OAT Presentations page. Click on the Powerpoint presentation name to open the presentation in

Powerpoint. If Powerpoint 97 or Powerpoint 2000 is not available on your computer, download the Powerpoint 97 viewer from the Internet at <http://office.microsoft.com/downloads/2000/Ppview97.aspx>. There is a link to this site on the OAT Presentations page.

### Reports

Study reports are available on the OAT Reports page.

### Publications

A list of study publications and presentations is on this page. Abstracts of published publications are in PDF format. Manuscripts in progress are available in MS WORD format on the OAT Publications page.

### Form Entry

Users must apply for “Data Entry and Content” and must test the system to have access to Form Entry on the OAT Web Site. This section heading will be listed on the OAT Home Page only for users who have completed these requirements.

## **C. System Requirements To Access OAT Web Site**

In order to use the Web Site, the user at the Clinical Site must have a computer that has the following configuration.

1. Connection to the Internet at 56 Kb or higher.
2. Pentium Class PC running Windows 95, Windows 98 or Windows NT.
3. Microsoft Internet Explorer 5 or greater or Netscape 4.5 or greater; Netscape 6 will not work for OAT data entry. The browser must be set to accept cookies. Internet Explorer 4 may work, but if there are problems it is suggested that the browser be upgraded.

Note: It is unlikely that a Macintosh computer will work for this system and the OAT Data Coordinating Center staff will not support a Macintosh configuration.

#### **D. Site and User Applications**

The Site Coordinator or Principal Investigator of each site should complete an Internet Site Application (OAT Form I, see Appendix C) and send this application to the OAT DCC by facsimile transmission. The e-mail address on this site application will be used to e-mail materials such as study memos, updates and edit messages to the Clinical Site on a regular basis.

Each staff member at the Clinical Site designated to use the Web Site must complete an Internet User Application (OAT Form J, see Appendix D) and send it to the OAT DCC by facsimile transmission. A user may request certification for “Content Only”; this allows the user to browse the Web Site content and print documents. A “Content Only” user does not have the authorization to enter, modify or view data. Users requesting “Content Only” receive a user log-on and password.

Clinical Site staff may request certification for “Data Entry and Content”; this allows the user to browse and print the Web Site content as well as to enter, modify and view data for patients enrolled in his/her Clinical Site. Before requesting “Data Entry and Content” use, the system requirements for Internet Data Entry should be reviewed (see Section VIII D). If the system requirements for Internet Data Entry are available, this is confirmed by submitting a completed Clinical Site Questionnaire on Site Resources (OAT Form K, see Appendix E) to the DCC. After receipt of completed Internet User Application (OAT Form I) and the completed Questionnaire on Site Resources (OAT Form K) at the DCC, the individual requesting “Data Entry and Content” is sent instructions for keying a test form. Upon successful completion of the entry of test form data, the user log-on and password are sent to the Clinical Site staff member.

#### **E. Printing Study Forms or Other Documents on the OAT Web Site**

Click on the file name to open a PDF document, the Adobe Acrobat Reader automatically opens and the document is displayed on the screen. The document can then be read on the screen or printed using the Adobe Acrobat menu.

### **V. GENERAL INSTRUCTIONS FOR COMPLETING FORMS**

#### **A. Types of Study Forms**

There are four types of Occluded Artery Trial (OAT) Forms: (1) forms which are completed and retained at the Clinical Site and are not sent to the Data Coordinating Center (DCC) at the Maryland Medical Research Institute; (2) forms which are designed to be sent to

the Data Coordinating Center by facsimile transmission or by e-mail or by Internet transmission; (3) forms which are to be sent to the Data Coordinating Center by mail; and (4) forms that are sent to the Economics and Quality of Life Coordinating Center. The list of study forms is given in the Section for Study Forms in the OAT Binder. The schedule of measurements and data collection is given in Appendix F. The deadlines for submission of all forms to the DCC are given in Appendix G.

The two OAT forms which are to be completed for each patient enrolled in the Randomized Trial or enrolled in the Registry and which are not to be submitted to the Data Coordinating Center (DCC) are the Patient Information Form (OAT Form 00) and the ATRS (Automated Telephone Response System) Voice Response Worksheet (OAT Form B).

OAT Forms 01 - 13 and Form 25 are designed to be sent to the Data Coordinating Center (DCC) at the Maryland Medical Research Institute (MMRI) by facsimile transmission (FAX) or by E-mail Data Entry or by Internet Data Entry using the OAT Web Site. The Lead Coordinator of each Clinical Site is asked to specify which data entry method will be used to submit forms by completing a Clinical Site Questionnaire on Site Resources (OAT Form K, see Appendix E). It is possible to switch from one system to the other by completing a new questionnaire (OAT Form K) and submitting it to the DCC.

Data submitted by FAX ENTRY are entered from the electronic fax image by a character recognition program. For this system to work well, a good quality fax machine, that is known to send clean copies, should be used to send the form and certain conventions for form completion must be followed. If FAX ENTRY is selected and problems with transmission are encountered, all OAT forms except Forms 01, 05, 06 and 07, may be submitted by mail.

The equipment requirements for e-mail and Internet transmissions are described in Section VIII.

OAT Forms 14-21 are Event Forms. These forms are to be submitted with other supporting documents; each form and required documents should be sent by mail to the DCC.

The OAT Screening Log (Form 26) will be completed for two one month periods as directed by the DCC (see Section XII O). The Screening Logs are sent by mail to the DCC.

The Quality of Life Forms are completed in Clinical Sites in the United States, Canada, New Zealand, Russia, Latvia, Poland, and Australia and these forms are sent to the Economics and Quality of Life Coordinating Center, DCRI Duke University. The instructions for completing these forms and the deadlines for submission of these forms are given in the



Procedures Manual for Economics and Quality of Life (EQOL) Forms section of the OAT Binder. Cost data are collected by the Economics and Quality of Life Coordinating Center for Clinical Sites in the United States. The instructions for completing these forms are given in the Procedures Manual for EQOL forms.

The qualifying angiograms and angiograms for documenting percutaneous coronary intervention for patients randomized to that treatment are sent directly to the Angiography Core Laboratory. Each film is to be sent with the Angiography Transmittal Form (Form 30). Instructions for completing the data collection forms are in Appendix 3 of the Protocol and also in Section XII P of this Procedures Manual.

The underlying principle in processing information in the DCC is to process the information as submitted without interpretation or second guessing what the recorder had intended. The providers of the data are requested to complete the forms as clearly and as legibly as possible, but also to follow certain conventions in reporting data to reduce the possibility of errors in processing the data collection forms. The conventions for completing the FAX ENTRY forms are described in Section IX, the procedures for E-mail Data Entry are described in Section X, and the procedures for Internet Data Entry in Section XI. The procedures for completing the event forms and preparing supporting documents are described in Section VII.

Before submitting the forms to the DCC, each form should be reviewed for completeness and accuracy. The person who collected the information is responsible for its accuracy, and he/she documents this by signing the form and providing his/her staff certification number (assigned by DCC). All completed forms should be filed in the patient's OAT records at the Clinical Site.

## **B. Obtaining Study Forms**

Copies of OAT Study Forms can be obtained by several different methods. Each Clinical Site should use the procedure that is most efficient based on available resources. For Clinical Sites using Fax entry, forms must be copied on 8 1/2 x 11 paper. The four ways of obtaining current OAT forms are:

1. Make photocopies of the new forms sent with the start-up materials or with the revised study procedures that will be distributed in December 2001.
2. Use the OAT Web Site and the free Adobe Acrobat Reader to print the required forms.

3. Clinical Sites that do not have access to the OAT Web Site may request that the Data Coordinating Center send PDF files of study forms by e-mail; these PDF files can be used with the free Adobe Acrobat Reader to print forms locally.
4. Complete an OAT Order Form (OAT Form G) and send it to the DCC.

## **VI. DEFINITIONS**

### **A. Identifying Information**

Each form has certain key items at the top which uniquely identify that form. These items must be filled in on all forms. These items include the patient's Identification (ID) Number and Letter Code and, on some forms, the date of the examination or telephone contact, procedure, or event. If this information is not completed correctly, the form cannot be processed in the DCC.

#### **A.1 Patient Identification (ID) Number**

Each patient is assigned an Identification Number by the DCC at the time the patient is enrolled in the ATRS. This Identification Number consists of six digits; the first three digits represent the Clinical Site number (assigned by the DCC before patient enrollment begins) and the next three digits identify the individual patient.

#### **A.2 Patient's Letter Code**

The patient's Letter Code are two letters chosen to identify the patient and may have no relationship to the patient's initials.

The patient's Letter Code is provided to the ATRS at the time of the call to request the treatment assignment or to enter the patient in the OAT Registry.

Once a patient's Letter Code and ID Number are entered, they should not be changed. The same Letter Code and ID Number must be used on all the patient's OAT Forms and correspondence about the patient's data. If the Letter Code is entered into the ATRS incorrectly, a note should be entered in the source document(s) explaining the discrepancy.

### **B. Dates**

As part of the identifying information a date is required, the appropriate date is the date of randomization, the date of the examination or telephone contact, or procedure, or the date of the

event that is being reported. All dates on OAT Forms (except on the ATRS Voice Response Worksheets) are to be recorded as a three-letter abbreviation of the month (first three letters), a two-digit date (a leading zero is to be used for dates 1-9), and the complete four-digit year. The following letters are to be used for each month: January = JAN, February = FEB, March = MAR, April = APR, May = MAY, June = JUN, July = JUL, August = AUG, September = SEP, October = OCT, November = NOV, December = DEC. Thus, June 1, 1999 would be JUN-01-1999 and November 10, 2000 would be NOV-10-2000.

On the ATRS Voice Response Worksheets, months are recorded as two digits, 01 for January, 02 for February, etc.

### **C. Randomization Date (Study Entry Date)**

The date at the Clinical Site when the call to DCC is made to request the treatment assignment is the study entry date for each patient (see Section III for description of these procedures). This date may be different than the date displayed on the Treatment Allocation Form which is the date in Baltimore, Maryland when the DCC issued the treatment assignment for each patient.

### **D. Military Time**

Times are to be recorded in local time at the site of data collection and recorded based on a 24-hour clock, which is referred to as military time. For example: 12 Noon = 12:00; 12 Midnight = 00:00; 12:01 am = 00:01; 10:15 am = 10:15; for pm time other than the period 12 Noon to 12:59 pm add 12 to convert to 24-hour recording, e.g., 2:30 pm = 14:30.

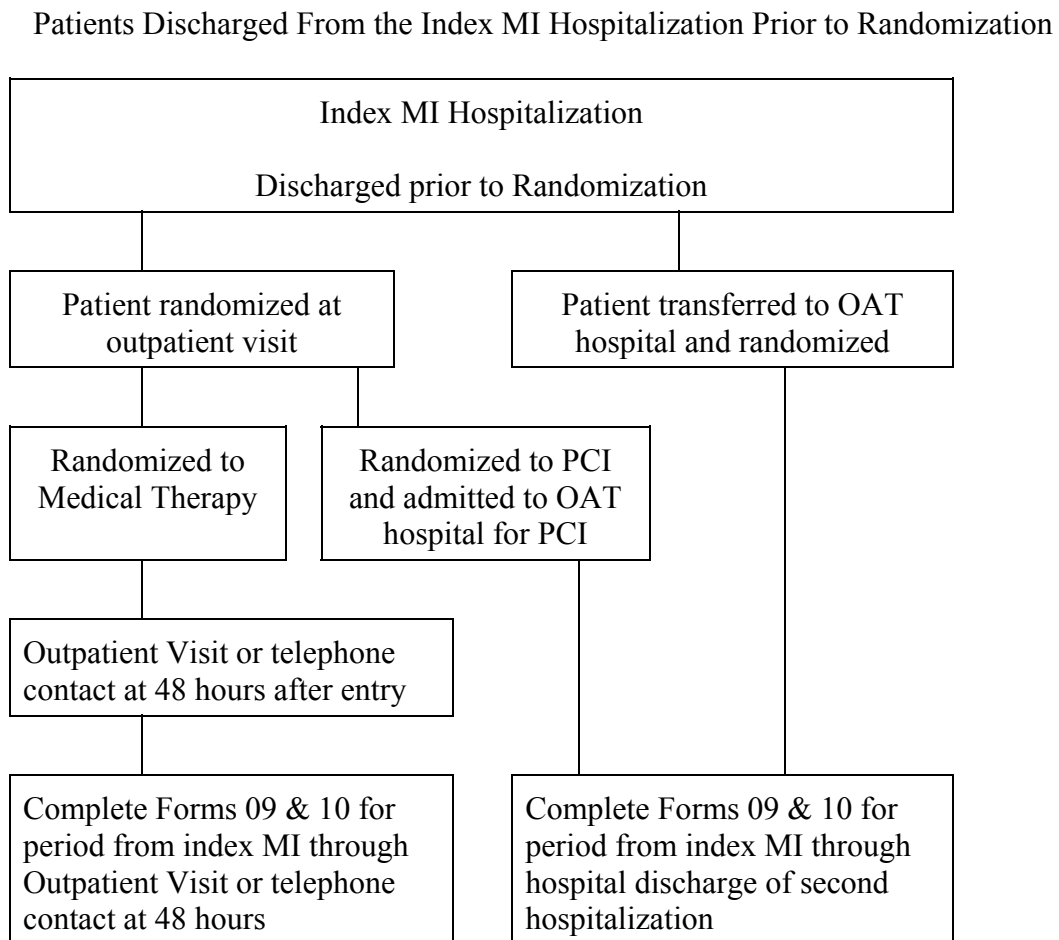
### **E. Period from Onset of Qualifying MI to Hospital Discharge**

OAT Forms 09 and 10 should contain data for events occurring during the period from onset of the qualifying index MI to hospital discharge or outpatient or telephone contact 48 hours after randomization (study entry) whichever is later. The time period covered may include one hospitalization for the index MI or two hospitalizations (the index MI hospitalization and hospitalization for OAT randomization and/or percutaneous coronary intervention in a different hospital after transfer from the index MI hospital). Report all events occurring during the first 48 hours after study entry including those which may have been reported on OAT Form 06 and OAT Form 07. Include outcomes or procedures during hospitalization for index MI if patient transferred to another OAT hospital for percutaneous coronary intervention. If randomization was performed at an outpatient visit or the patient was discharged before 48 hours after study entry and the patient was assigned to medical therapy, include outcomes or procedures for the

period from index MI through outpatient visit or telephone contact at 48 hours after study entry (randomization). See Figure 1 for description of possible sequence of OAT procedures for patients discharged from hospital prior to randomization.

A patient, who was not hospitalized for the index MI, may also be determined to be eligible at an outpatient visit. The time period for this patient is defined as date and time of onset of symptoms of index MI through the outpatient visit or telephone contact scheduled 48 hours after date and time of randomization. If a patient was not hospitalized for the index MI, was randomized as an outpatient and hospitalized for a procedure, the time period is defined as date and time of onset of symptoms of MI through hospital discharge.

Figure 1



## F. Missing Data

Answer all items. Some items may be blank, if there is a conditional skip (e.g., if ..., then skip to ...).

If information is unknown or not available:

Certain form items have choices for the responses “unknown” or “uncertain” or “not available”; these responses may be used if the information is not available.

Fill in other missing data with 9's followed by one 8 in the last space, e.g., if one space is available, fill in “8”, if three spaces are available for a numeric item, fill in “998.”

Consistent not available codes are used throughout all forms. Not available code is determined by the length of the field. Use the following codes for missing data:

Length of Field	Not Available Code
1	8
2	98 or 9.8
3	998 or 99.8 or 9.98
4	9998 or 999.8 or 99.98 or 9.998 etc.

If a date is completely unknown, enter DEC-31-9998. If a day is unknown, but the month and year are known, enter the 15th of the month. If day and month are unknown, but the year is known, enter Jun-15th and the appropriate year.

## VII. INSTRUCTIONS FOR COMPLETING AND SUBMITTING OAT EVENT FORMS (OAT FORMS 14-21)

### A. Introduction

OAT event forms are completed only when specified clinical events occur. Each event form should be completed using black ink. The conventions for completing FAX ENTRY Forms should be followed to complete these forms (see Section IX). Print clearly all written responses in the space provided. Do not use abbreviations unless absolutely necessary and then use only widely recognized abbreviations. A copy of each completed form should be retained for the Clinical Site files.

The first items to be completed on any patient data form are the patient's ID number and Letter Code. The sequence number is the actual count for each patient of this specific type of form submitted to the Data Coordinating Center. Next the date of the event is completed. The remaining sections of the form are completed by appropriately trained and certified OAT staff members. Supporting documents are required for deaths and all hospitalizations for cardiovascular events and pneumonia.

### **B. Obtaining Required Supporting Documentation**

The documentation of hospitalization and treatment at medical centers other than the OAT Clinical Site can require considerable staff effort to obtain release of medical records. We recommend that Clinical Site staff maintain a list of medical facilities regularly used by each enrolled patient. Obtain copies of medical record release forms from these facilities. Ask patients to sign release forms at the time of enrollment or prior to discharge for the hospitalization for the index MI. Some medical centers may accept forms only if they are signed after the clinical event. Keep blank forms on hand for patient completion as needed. On occasion it may be easier to travel to a nearby medical center to copy records than to deal with the medical center by telephone or mail. Obtaining copies of records from some medical centers is more difficult than from the treating physician's office. Take the more efficient approach to obtain copies of discharge summaries, electrocardiograms, etc.

### **C. Preparing Supporting Documentation for Submission with Event Forms**

Prepare documents for attachment to event forms by photocopying them; keep originals in permanent study file at the Clinical Site in case they are needed for later review. Identify each page of each copy with the patient's OAT ID number and Letter Code. Use black marker on the photocopy to obscure personal identifying information (e.g., patient's name) and information on OAT treatment assignment (e.g., "after performing study angioplasty" or "patient assigned to PCI"). Make good quality photocopies of the altered documents, attach these photocopies to the event forms for submission to the DCC and retain both the original of the altered document and the modified document in the patient's file. Clinical Site Coordinators and Principal Investigators should review these documents to assure that all related events are reported. For example, a Non-Protocol PCI report that makes reference to a recurrent myocardial infarction requires collection of the additional information to complete a Recurrent Myocardial Infarction Form (OAT Form 17). Attach OAT labels with the patient's OAT ID number and Letter Code to all ECGs and other test reports. A hospital discharge summary and/or a narrative summary should be prepared by the Site Coordinator or Principal Investigator; the narrative should describe pertinent clinical features, assessment and therapy for this admission. International sites should provide an English summary of narrative describing the event. If a patient has several

events during one hospitalization and all event forms are submitted at the same time, one copy of the hospital discharge summary for that hospitalization may be submitted with these event forms. If one or more of the forms for the events which occurred during one hospitalization are submitted separately, a copy of the hospital discharge summary should be submitted with each event form.

#### **D. Mailing Forms and Other Materials to the Data Coordinating Center**

The original of all event forms and photocopies of supporting documents are mailed to the Data Coordinating Center.

OAT Data Coordinating Center  
Maryland Medical Research Institute  
600 Wyndhurst Avenue  
Baltimore, Maryland 21210

Coronary angiograms and ventriculograms are sent directly to the Angiography Core Laboratory (see Section XII P).

Materials are usually sent to the DCC via first class mail. In rare situations in which rapid transmission of materials to the DCC is required, courier service or Federal Express may be used. Materials should not be mailed on Friday for overnight delivery to the DCC. Experience has shown that because the DCC is often not open for receipt of packages on Saturday, such deliveries are frequently delayed until late Monday afternoon.

### **VIII. PROCEDURES FOR DATA ENTRY**

#### **A. Introduction**

The OAT Data Coordinating Center staff have developed three systems for Clinical Site staff to use for the collection and transmission of study data to the Data Coordinating Center. Clinical Sites that started prior to 2001 were requested to complete what are referred to as FAX ENTRY forms and to send them to the Data Coordinating Center by facsimile transmission. Two alternate procedures are available for Clinical Site staff to select for routine submission of study data. One of these options is "E-mail Data Entry" and the other is "Internet Data Entry."

Both the E-mail and Internet Data Entry systems require that designated staff complete a short training session to become familiar with the program and to test that all required components of the system are working before patient data are keyed. The training session for the

keying and transmission of the form to be keyed (the form is provided by the OAT Data Coordinating Center) should require no more than 15 minutes for the E-mail Data Entry and 30 minutes for the Internet Data Entry.

Each of the three alternatives for data collection and submission of the form data to the Data Coordinating Center have advantages and disadvantages. The FAX ENTRY system requires a good quality facsimile machine and also requires that the forms be completed following specific conventions so that the data can be read by the computer system scanning the form. E-mail Data Entry requires that the data are keyed; after data entry, each page of the form should be printed to provide a copy of the information submitted to the Data Coordinating Center for the patient's file. The E-mail Data Entry should avoid the difficulties of poor quality images that are occasionally encountered with the facsimile transmission system. Keying the form may take a few minutes, but in general each form should require less than five minutes per page.

Internet Data Entry may take a little bit longer to key the information than for e-mail transmission. However, there are some built-in edit checks which should reduce the edit messages that are sent for the forms transmitted by either FAX ENTRY or e-mail. This is the main advantage to Internet Data Entry over the other two systems, since retrieving forms to verify or respond to edit queries is time consuming.

The Principal Investigator or Lead Coordinator of each Clinical Site is requested to advise the Data Coordinating Center whether staff at his or her Clinical Site plan to use FAX ENTRY or the E-mail or Internet Data Entry by submitting a completed OAT Clinical Site Questionnaire on Site Resources (see Appendix E). If forms initially submitted by FAX ENTRY require correction, the correction must be submitted using the FAX ENTRY or e-mail correction procedures. If forms initially submitted by e-mail require correction, the correction must be made using e-mail or FAX ENTRY procedures. If forms submitted by the Internet Data Entry require correction, the corrections must be sent using the Internet system.

Clinical Site staff who plan to transmit form data using E-mail Data Entry or Internet Data Entry, may print copies of the FAX ENTRY forms to use as worksheets to record the information for each item. Copies of these worksheets as well as the printed copy of the forms obtained at the end of data entry should be retained in the patient's OAT files.

## **B. Requirements for FAX ENTRY**

If FAX ENTRY is chosen as the method of data transmission, a Test FAX Form (OAT Form H) should be completed to supply contact information and to test the FAX ENTRY system. Complete and fax this test form to the DCC as soon as possible after receipt of the start-up



packet. The Principal Investigator or Lead Coordinator is contacted if this test indicates the facsimile machine is not of adequate quality for valid transmission.

### **C. Requirements for E-Mail Data Entry**

To use E-mail Data Entry you must have the following:

1. An e-mail address to send and receive forms and messages.
2. Ability to check your e-mail messages on a daily basis.
3. Full version of Adobe Acrobat Program 4.0 or 5.0 (not just the Reader which is free). If you have e-mail, meet the other requirements, and select E-mail Data Entry and do not have the Adobe Acrobat Program 4.0 or 5.0, the Data Coordinating Center will provide you with a license for the Adobe Acrobat Program 4.0 or 5.0 and will loan you a CD-ROM so that you may load the program on the appropriate computer. The CD-ROM is to be returned to the DCC as soon as you have completed the test of the system.
4. A laser jet printer or ink jet printer to print a copy of each form after the data have been entered using the e-mail system.

### **D. Requirements for Internet Data Entry**

To utilize the Internet Data Entry, the following must be available:

1. A Pentium PC which has Windows 95, Windows 98 or Windows NT; the PC must be at least 100 MHZ.
2. 32 MB (megabytes) of RAM or more.
3. Connection to the Internet at 56 KB or higher.
4. Microsoft Internet Explorer 5 or Netscape 4.5. Netscape 6 will not work. The browser must be set to accept cookies.
5. ORACLE J-Initiator.

6. A laser jet printer or ink jet printer to print a copy of each form after the data have been entered using the Internet Data Entry system.

If Internet Data Entry is chosen as the method for data transmission, an Internet Site Application (OAT Form I) and at least one Internet User Application (OAT Form J) for "Data Entry and Content" must be submitted (see Section IV D).

## **IX. INSTRUCTIONS FOR COMPLETING FAX ENTRY FORMS**

### **A. Completion of Each Item**

1. Use a black, felt tip pen, DO NOT use a ball point pen.
2. Completely darken the bubbles; do not check or X the bubbles.
3. Make sure to write inside the boxes. DO NOT TOUCH THE SIDES OF THE BOXES. However, do not write so small that the letters are unreadable.
4. Write all your letters in block capital letters.
5. Write all numerals clearly.
6. If you do not have a response, use the "Unknown" or "Unavailable" bubble if available. If a text field, do not fill the field with dashes.
7. Use leading 0's to fill in numerical fields, i.e., 0 0 9 1. If there is no value, do not fill the field with 0's or dashes. Use the missing data convention, i.e., 8, 98, 998, 9998, etc.
8. If you have a choice of responses, separated by "or" (see Form 02, page 1, Items 5 and 6) only fill in one response, leave the other field blank.
9. DO NOT copy and use the forms in the OAT BINDER. Use the forms sent to you with your start-up packet or print the forms locally (see Section V B) or request forms from the DCC. You may copy the forms but do not reduce them. Use paper size of 8 1/2 x 11. Do not use A4 paper size.
10. Time fields must be in military time (24-hour clock) as defined in Section VI D.

11. Use a Fax Form Transmittal list (OAT Form F) as your cover sheet when sending the completed FAX forms. This allows DCC staff to determine whether any forms are missing.

Do not write data or corrections on the form outside the spaces for answers -- these comments will not be recognized by the data entry program. See Appendix H "Guidelines for Completing FAX ENTRY Forms" for examples of how to fill out the spaces for data entry on these forms.

#### **B. Yes/No Items**

Answer Yes or No for every item, not just the "Yes" responses. Fill in each bubble completely, but do not leave marks outside the bubble.

#### **C. Pre-coded Multiple-choice Items**

Fill in only one bubble unless directed to "mark all that apply." Fill in each bubble completely, but do not extend marks outside the bubble.

#### **D. Numeric Write-in Items**

Write numerals legibly.

Be sure to write so that 1 can be distinguished from 7, and 4 from 9. Do not cross 7. Do not close top of 4.

Right justify numbers in the spaces provided, and fill in leading zeros, e.g., if the number 12 is the answer, and three spaces are available, write in 0 1 2.

If an item has a built-in decimal point for a numeric response, fill in the number to fit around the decimal and add zeros as needed to fill all spaces, e.g., write in 0 1 2 . 0, if that many spaces are provided around the decimal point. Do not use hyphens or dashes.

Fill in missing numeric data according to the missing data convention described above in Section VI F.

#### **E. Alphabetic Write-in Items**

Use clearly-written capital block letters.

Complete alphabetic write-in fields starting from the left. Leave blank spaces on the right if the response does not completely fill the spaces provided.

Separate words with blanks. Do not use hyphens or dashes. Avoid special characters.

If the entry is longer than the spaces allow, truncate at the last available space.

## **F. Corrections**

Do not use correction fluid.

Do not cross out and write over on the completed form.

To make a correction:

- a) If the form has not yet been sent in by FAX, fill out a new form with the correct data items.
- b) If the form has already been sent in by FAX:
  - 1) Complete a new form with the same revision number with the identifying information at the top (e.g., patient's ID Number, Letter Code, and appropriate date).
  - 2) Fill in the bubble marked "Correction" at the top of the form.
  - 3) Complete the item(s) to be corrected. Leave other data items blank. NOTE: All parts of a conditional item must be answered.
  - 4) Sign the corrected form, and fill in your certification number at the bottom of the form.
  - 5) FAX the correction page to the DCC.
  - 6) File the corrected page with the original (uncorrected) page in the patient's files.

## **G. Transmittal List (OAT Form F)**

A transmittal list should be prepared and sent as the cover sheet for the fax transmission each time forms are faxed to the DCC.

The form is filled out with the Clinical Site number, the date the fax is being sent, the total number of pages in the transmission, and the OAT patient's ID number. Place a check mark next to the form(s) and/or pages being sent for the patient. Also indicate the follow-up visit number for Forms 11, 12 and 13.

When received at the DCC the bottom section is filled out indicating if there were any problems with the forms. Any forms to be resent are circled and a note written to indicate the problem. The annotated transmittal form is sent back to the Clinical Site by FAX to acknowledge receipt of the forms.

## **X. INSTRUCTIONS FOR E-MAIL DATA ENTRY**

### **A. Start-Up Procedures and Test of Program**

Each Clinical Site that has selected E-mail Data Entry and is approved to initiate patient recruitment is sent a CD-ROM which contains a copy of the full Adobe Acrobat Program 4.0 or 5.0 by DCC staff. This is the full Adobe Acrobat Program, not just the Reader, and is necessary for keying the study forms. The license number for the program is listed in the memorandum accompanying the CD-ROM. The DCC staff sends by e-mail a completed test form and a blank data entry form. After you have installed the CD ROM, follow the instructions below for regular data entry sessions to key the test Form 01; this is necessary to assure that all components of the system are working properly.

Once the two pages of the test form has been received at the DCC, PDF files for each study form for the data entry program are sent to you via e-mail. A specific directory should be created on your computer hard drive for these PDF files. If there is a problem and a new PDF file is required, request DCC staff send a new PDF file to you.

## **B. Regular Data Entry Session**

### **B.1 Open Adobe Acrobat**

Begin the data entry session by opening up the Adobe Acrobat Program. Open up the appropriate form page that you plan to data enter. The file names reflect the form and page number, i.e., OAT0101.PDF is Form 01, Rev. 0, page 1.

### **B.2 Field Entry**

1. Use tab to move from field to field, or use the mouse to click on the field you want to key.
2. The date items are actually three fields, the month, the day and the year, therefore, use the tab after each field.
3. Clicking on a bubble will select that bubble and fill it.
4. When entering a question that will accept only one answer, tab to move from bubble to bubble, or click with the mouse on the answer. If you click on the “Yes” bubble, it will darken the bubble; if you click on the “No” bubble, the “No” bubble will darken and the “Yes” bubble will clear.

### **B.3 Comment Items**

1. When typing into a Comment field, the appearance on the screen will not show each letter inside of each box until you hit the Enter or Tab key to leave the field. When you hit Enter or Tab, the letters go into the boxes.
2. The Comment fields will not allow you to enter more letters than the 20 boxes available.

#### B.4 Date Items

1. The dates are entered as a three-letter abbreviation for each month, a two-digit number for the day, and a four-digit number for the year. For example, September 2, 2000 should be entered as shown below.

S	E	P		0	2		2	0	0	0
mmm				dd			yyyy			

#### B.5 Completing and Sending the Data

1. After completing all data on a page, review the header information, (the patient's ID number and Letter Code) for accuracy.
2. Click on the button at the bottom of the page called "Email to MMRI." The page will be forwarded either automatically to MMRI or forwarded to your e-mail outbox. If during the test of the e-mail system you determined that this step did not work for your site, you should save the file in a file folder and send it to [sfick@mmri.org](mailto:sfick@mmri.org) as an e-mail attachment.
3. Print and sign the form for your hard copy file; a copy of each completed form is to be kept in the patient's file at the Clinical Site.
4. Save the page as a separate pdf file (see Section B.6 below and Appendix I) giving it the name of the patient ID number, form number, and page number (i.e., 01001fm03pg2.pdf) would be patient 01001, form 03, page 2.
5. Clear the page by clicking the "Clear Page" button on the top left hand corner of the page.
6. After completing these steps for all form pages data entered at a given time, check your outbox to make sure all pages were sent. If there are still pages in your outbox, select "Send All Messages" and the forms will be sent to MMRI.

## B.6 Instructions for Saving a PDF File

1. If you have keyed the patient data into the form and have not created a *Patient ID subdirectory* for this patient, you may create the *Patient ID subdirectories* from this “Save As” Window as follows:
2. Click on the “Folder Icon” with the arrow that points up; until you see the Drive letter where your *OAT Email Forms* directory resides.
3. Double click on the OAT Email Forms directory to open it.
4. Create a new *Patient ID subdirectory*:
  - Click on the “Folder Icon” (image), normally the third icon from the “Save in:” window. When moving the mouse cursor over the icon it will say “Create New Folder”.
  - Click on “Create New Folder”
  - A new folder appears in the window labeled “New Folder”.
  - Change the name to the Patient’s ID number, Example: “999-001” by typing over the words “New Folder”.
  - Then press the enter key.
  - Double click on the new Patient ID sub-directory you just created.
5. To name the File:
  - In the “Save As” window
  - The 3<sup>rd</sup> white box from the top is “File name:”
  - Create a file name: It is suggested that you use the patient ID number, form number and page number, (i.e. *999001fm03pg2.pdf*) or use visit number when saving a multi-visit form, (i.e. *999001fm11v08.pdf*).
  - Type the name in the File name box.
  - Click “Save”
6. You may then clear the page to enter data for another patient or you may close this form page.

## B.7 Corrections

Follow the same instructions as described in Section IX F for FAX ENTRY forms, but submit the correction using E-mail Data Entry.



## **B.8 Review of E-mail Procedures**

In summary, below are the e-mail procedures for sending pages/forms:

### **SENDING DIRECTLY TO MMRI PC:**

Open the pdf file for the page, type in the patient information, hit the “send to MMRI” button at the bottom of the page. Print and sign the page and keep this in the patient’s file at your site. Save the page to a folder in your PC and then clear the page. Repeat this procedure for each form page to be data entered. At the end of the data entry session, send an e-mail message to [sfick@mmri.org](mailto:sfick@mmri.org) with a transmittal list indicating all the forms sent to the MMRI PC. An e-mail message will be sent to the site coordinator within 24-36 hours confirming receipt of all forms or listing any problems with receiving the forms.

### **SENDING AS AN ATTACHMENT TO [sfick@mmri.org](mailto:sfick@mmri.org)**

Open the pdf file, type in the patient information. Print and sign the page and keep this in the patient’s file at your site. Save the page to a folder in your PC and then clear the page. Attach the form page(s) to an e-mail and send to [sfick@mmri.org](mailto:sfick@mmri.org). At the end of the data entry session, send a separate e-mail message to [sfick@mmri.org](mailto:sfick@mmri.org) with a transmittal list indicating which forms have been sent. An e-mail message will be sent within 24-36 hours confirming receipt of all forms, or listing any problems with receiving the forms.

## **B.9 Receipt of E-Mail Forms**

Each Clinical Site using E-mail Data Entry should send a transmittal list by separate e-mail message to [sfick@mmri.org](mailto:sfick@mmri.org) at the time the pages are being e-mailed. A “Word” version of the transmittal list will be sent to you at the time the pdf files of OAT forms are sent to you via e-mail. After receipt of the e-mail transmittal list, DCC staff will verify that pages/forms have been received and send a message back to the site within 24-36 hours.

## **XI. INSTRUCTIONS FOR INTERNET DATA ENTRY**

### **A. Start-Up Procedures and Test of Transmission**

Clinical Site staff who have submitted Internet User Applications (OAT Form J) for “Data Entry and Content” are sent an e-mail message by the DCC Internet Administrator after the Clinical Site has been approved to initiate patient recruitment and the DCC has received the completed Clinical Site Questionnaire on Site Resources (OAT Form K). If review of the completed OAT Form K indicates that the Clinical Site does not have adequate resources, the individual is notified of this problem. If review of OAT Form K confirms that the Clinical Site has the required resources to perform Internet Data Entry, the individual submitting the Internet User Application is notified of the procedures to install the ORACLE J-Initiator and how to perform the test of the system by keying the data for a completed OAT Form 01 supplied by the DCC. After the test is completed successfully, the individual is sent a log-on and password to use for OAT Internet Data Entry. Clinical Site staff who are considering testing the Internet Data Entry should view the Power Point Presentation on the OAT Web Site in the Presentations section in the document “Web System –Internet Entry.”

The OAT Web Site Presentations page contains a Power Point presentation with instructions for forms entry.

Entry of study data is accomplished using ORACLE Forms through the ORACLE Forms Server. This requires the ORACLE J-Initiator. The ORACLE J-Initiator is an ORACLE version of a Java Plug-in which delivers a browser-independent Java Runtime Environment.

**Installation of the ORACLE J-Initiator is required** to run the Form Entry portion of the system on Windows based systems.

The ORACLE J-Initiator is available at the OAT Web Study Tools section, select JINIT File – J-Initiator Download page. The ORACLE J-Initiator must be **installed** after downloading.

The ORACLE J-Initiator functions as an Active-X object in Microsoft Internet Explorer and as a plug-in in Netscape Navigator. ***If you are using Netscape Navigator as your browser, you should install the J-Initiator in the Netscape plug-ins directory.*** If you are using Internet Explorer, the default destination will work.

The ORACLE Forms Server connects to your PC by talking to the TCP/IP socket. Socket mode makes a direct connection between your machine and the forms server through port 9000. If your machine is behind a firewall, there may be problems establishing the connection. Your

Information Technology department or staff responsible for the system may have to “open a hole” in the firewall.

The first time you select Form Entry from the OAT Home Page, you will be presented with the Data Entry Set Up page. Select “Sockets” as your connection mode. Once your connection mode has been established, it is written to your computer as a cookie.

When Form Entry is selected, a Java Applet starts to load. This may take a few moments. Please be patient. If J-Initiator has not already been installed, or a newer version of J-Initiator becomes available, the system will attempt to download it to you. This may take a long time. Please be very patient!

## **B. Selecting a Form**

The Form Process Selection screen is the first screen to be displayed. This screen allows selection of the OAT Form to be entered or updated. You may use the mouse or the up and down arrows to highlight a form.

OAT Form **01** must be the **first** form entered for each participating patient. For registry patients, the OAT Form **25** is the **first and only** form entered.

Highlight the selected form and either double click on the form or click on the OK button.

## **C. Entering Identification Information**

Enter the identifying information: the patient’s six-digit ID is entered in two fields as the Clinical Site Number and the Patient Identification Number, the Patient’s Letter Code, the Study Visit and Visit Date from the top of the paper forms are entered in the appropriate fields. This date is the first date listed on the paper form, this may be the date of Randomization, as on the Form 01-Medical History Form, the date of the confirmed MI, as on the Form 03 Documentation of Qualifying MI or some other date related to the information on the form. This is not the date that the form is being entered. Note also that the date must be entered using the format MON-DD-YYYY, including the dashes, where MON is the three-letter abbreviation for Month, DD is the two-digit day of the month and YYYY is the four-digit year.

Each of these identifying items is validated. If the item does not meet the validation criteria, a message will appear in either an alert box or in the gray message line at the bottom of the screen. (Be sure to position your entry screen in the browser so that the message line is visible!) If an alert box appears, you must “dismiss” it by pressing enter or clicking on the OK

button before correcting the item. The cursor will not move from an item that is failing validation. The item must be corrected before continuing.

#### **D. Common Identifying Information Errors**

Patient does not exist in the system. - OAT Form 01 must be the first form entered for each patient.

Wrong Letter Code. - The two letters must match those entered for Form 01 and match those used to randomize the patient in the ATRS.

Incorrect visit. - Visit is out of acceptable time window. The visit time windows are based on time from the enrollment date and are shown for each patient on the patient's Appointment Schedule (see Section XIII A). The Appointment Schedule is based on the date of randomization, that is, the local date and time the treatment assignment was made.

Form not expected at this visit.

Visit date more than one year ago. - A warning message will appear, but will allow you to continue.

Visit date greater than today. - The visit date cannot be in the future.

#### **E. Selecting a Function**

Choose the function to be performed. For the initial entry of data into the system the Entry button should be selected. For updates to data, the Correction button should be selected. After entering the identifying information and selecting the function, click on the OK button. Some additional checks are performed at this time. After the identifying information has been completely validated, the data entry form screen is displayed.

The identifying information entered on this screen cannot be changed by you once the form has been saved. Be certain of this information **before** saving the form. The Letter Code entered for a patient on the ATRS follow the patient throughout the study.

## **F. Data Entry Form Screens**

The data entry form screens are designed to look like the OAT forms. Use the mouse to click on the answer to each coded question. Select "Clear Item" to remove an answer. Use the keyboard to enter write-in responses.

## **G. Skip Patterns**

Some questions on a form are to be answered based on the answer to another question. To skip over an item that is meant to be blank, press the <TAB> key or position the mouse cursor over the next item to be answered.

## **H. Data Not Available**

The values of some data may not be available. If that is the case, fill the field in the correct format with 9's and one 8 in the last position on the right or click on the "Unavailable" or "Unknown" response if this response is shown on the screen.

## **I. Signature Fields**

Some fields on the forms are areas for signatures. Do not try to key the signature, click on the check box if the signature exists, or leave the check box un-clicked if no signature exists.

## **J. Menu Bar**

The menu bar is at the top of the screen. The individual menu items are Action, Field, Window, and Help. The commands for each item and their description are given below. Depending on the function chosen, some menu items may be grayed out. The menu actions can be performed by clicking on the menu item or by using the alternative key strokes shown in parenthesis.

- a. Action ( <ALT><A> )
  - Save: Saves the form ( <S> )
  - Clear All: Clears all values in the data entry area ( <C> )
  - Print: Prints a copy of the screen ( <P> )
  - Exit: Exits the data entry screen without saving changes. ( <E> )

- b. Field
  - Previous: Moves the cursor to the previous item. ( <SHIFT><TAB> )
  - Next: Moves the cursor to the next item. ( <TAB> )
  - Clear: Clears the current item.
  
- c. Help
  - List: Lists allowable values if a list of values exists.
  - Display Error: Displays the current error.

## **K. Page Tabs**

Each screen is a page of the form. On forms with multiple pages, there are page tabs that are located on the left hand side of the screen; these tabs can be used to move directly to a given page. The page number is displayed above the page tabs.

## **L. Navigation**

During form entry the cursor automatically moves from one write-in field to the next field when a field is **completely** filled.

During form update the cursor does not automatically move from one write-in field to the next. Press <ENTER> after changing the data in a field.

Press the <TAB> key, <ENTER> key or use the mouse to move from one field to the next for write -in items that do not completely fill the field.

To move backward through items press the <SHIFT><TAB> keys simultaneously or use the mouse.

## **M. Help**

Form instructions are available during data entry by clicking on the ? button located on the lower left side of the screen. The instructions will display in another window in HTML format.

## **N. Saving Work**

One additional item has been added at the end of each form to indicate if the form is completed and ready for edit.

Once all items have been entered, the form must be saved to the database even if it is not ready for edit. The steps are as follows:

Click on Action in the Menu Bar, or press <ALT><A> to activate the Action menu.

Choose Save by clicking on it, or press <S> and then <ENTER>.

A message will appear in an Alert Box suggesting that the form be reviewed.

After reviewing the form, once again click on Action in the Menu Bar, or press <ALT><A> to activate the Action menu.

Choose Save by clicking on it, or press <S> and then <ENTER>.

**DO NOT SELECT EXIT --- THE DATA WILL NOT BE SAVED!**

After saving the form, the Form Process Selection screen will be re-displayed. And the Form Status item will now display “Keyed”.

#### **O. Interrupted Data Entry Session**

If you are performing data entry and must stop before you have completed the form, the steps outlined for saving your work should be implemented because after 20 minutes of inactivity the data for the form that was started will not be posted and the data for the form must be reentered.

#### **P. Exiting Without Saving**

The form may be exited without saving the data or changes. The steps are as follows:

Click on Action in the Menu Bar, or press <ALT><A> to activate the Action menu.

Choose Exit by clicking on it, or press <E> and then <ENTER>.

#### **Q. Printing Completed Form**

After saving or exiting the form, an alert box appears asking if you want to print the form. Select Yes. A PDF version of the form is generated and displayed to your browser. You must

have Adobe Acrobat Reader for the form to be displayed and printed. The form will be encrypted and password protected. To open the form enter the password OAT. The form can be printed from Adobe Acrobat Reader. Each OAT Form should be printed after the form is completed and the question: "Is the form ready for edit" is answered "Yes." The printed form should be signed, staff number recorded and the form placed in the patient's OAT files.

## **XII. SPECIFIC INSTRUCTIONS FOR STUDY FORMS**

Form instructions are available on the Web Site for on-line browsing. On the OAT Home Page click on "Form QxQs" section.

Certified Research Coordinators and Study Investigators are responsible for screening and enrolling patients and contacting patients to obtain follow-up information.

The required information for each form is obtained by interview of the patient, family members, and/or study physicians and review of appropriate medical records.

It is important for the DCC to receive Forms 01, 05, 06, and 07 in a timely manner. Please submit by FAX ENTRY, E-mail or Internet Data Entry promptly. **If you are using FAX ENTRY and are having difficulty submitting forms by fax, the other forms can be sent by regular mail.**

### **A. ATRS Voice Response Worksheet - OAT Form B and ATRS Treatment Allocation - OAT Form C**

#### **A.1 Purpose of ATRS Voice Response Worksheet**

The purpose of the ATRS Voice Response Worksheet (OAT Form B) is to confirm that all major eligibility criteria have been met before a treatment allocation is requested for a patient eligible for the randomized trial. This system is also used to register a patient who meets all of the eligibility criteria, but the patient, or the patient's physician, did not give consent to participate in the trial or the patient will not participate for other reasons. During the screening process complete the Inclusion and Exclusion Checklists (OAT Forms D and E) to keep in the patient's folder.

#### **A.2 Persons Responsible**

The ATRS Voice Response Worksheet (OAT Form B) should be completed by the OAT Clinical Site staff (investigators and coordinators) who have been designated to request treatment



allocations using the Automated Telephone Response System (ATRS) in the Clinical Sites (hospitals) that have been assigned a site identification number to utilize the ATRS.

### **A.3 Sources of Information**

The summary information on eligibility should be obtained from the patient and the patient's medical records; appropriate items of OAT Study Forms 01, 02, 03, 3A, and 04 may be completed to use as the source for completing the ATRS Voice Response Worksheet.

### **A.4 Time of Data Collection**

The ATRS Voice Response Worksheet should be completed as soon as the screening of the patient has been completed, the informed consent form has been signed by the patient and the patient's physician has agreed to the patient's participation.

### **A.5 Submission to Data Coordinating Center**

The information on the ATRS Voice Response Worksheet (OAT Form B) is transferred to the DCC by calling the Automated Telephone Response System (ATRS) at the DCC. During the call the patient's identification (ID) number and treatment assignment are issued and are to be recorded on the bottom of the patient's Voice Response Worksheet. The local date and time of the call are also to be recorded on the Voice Response Worksheet.

At the end of the call the Treatment Allocation Form for the patient is sent by facsimile transmission to the designated FAX number at the Clinical Site. The Voice Response Worksheet (OAT Form B) is kept in the patient's files in the Clinical Site.

### **A.6 Treatment Allocation Form**

The bottom portion of the Treatment Allocation Form (OAT Form C) is completed to record the local date and time of randomization (as recorded on the Voice Response Worksheet) and to indicate whether the patient received PCI of the IRA within 32 hours of study entry. The 32-hour time period is measured from the local time of the call for randomization. A copy of this form is to be returned by FAX to the DCC within one working day of receipt of the Treatment Allocation (OAT Form C). The completed form is kept in the patient's files.

After the DCC staff check the local date and time and the treatment assignment, an appointment schedule for the patient is sent to the site (see Section XIII A).

**B. Randomized Patient Information Form - OAT Form 00 and Supplement to Form 00 - Form 0S**

**B.1 Purpose of Randomized Patient Information Form and Supplement**

The purpose of the Randomized Patient Information Form (OAT Form 00) is to provide patient contacts who may help the Clinical Site Coordinator locate and maintain contact with randomized patients. The information on this form is strictly confidential and it is not transmitted to the DCC.

The purpose of the Supplement (OAT Form 0S) is to record information required to utilize the National Death Index for patients enrolled in the United States or equivalent government agency in other countries, if necessary.

**B.2 Time of Data Collection**

The Patient Information Form and the Supplement should be completed after Clinical Site staff have confirmed that the patient is eligible and is willing to participate in the randomized trial.

**C. Admission Forms - OAT Forms 01, 02, 03, 3A, and 04 and Inclusion and Exclusion Criteria Checklists - OAT Forms D and E**

**C.1 Purpose of These Forms**

The purpose of OAT Forms 01, 02, 03, 3A, and 04 and Inclusion and Exclusion Criteria Checklists (OAT Forms D and E) is to guide the Coordinators and Study Investigators through the screening process. The Inclusion and Exclusion Criteria Checklists (Forms D and E) should be completed first to establish eligibility; these forms are not submitted to the DCC but should be retained in the patient's files. The information on these forms confirms that the patient meets all inclusion criteria and does not have any of the exclusion criteria. OAT Forms 01, 02, 03, 3A, and 04 provide final documentation that the patient is eligible and agrees to participate in the randomized trial. As part of the screening process all available ECGs taken after presentation at the hospital for the index MI and/or obtained prior to the time of entry into OAT should be reviewed and OAT Form 3A completed. Report the most severe abnormalities on Form 3A. If

the ECGs are to be centrally read, all patient identifying information on the ECGs should be masked. A label (see Appendix J) with the patient's ID and Letter Code, as well as date and time the ECG was obtained should be completed for each ECG to be submitted to document the qualifying index MI. Affix a completed label to each sheet of ECGs being submitted for central reading. When stress test and/or viability test results are readily available, copies of the reports (these are not required) should be labeled. All patient identifying information on the report should be masked. Complete the label with patient's ID and Letter Code, as well as date and time the stress test or viability test was performed. Affix the labels to the test results being submitted for central review and mail to the DCC. Submission of these reports is requested, but is optional.

These forms should be completed during the period of screening and before completing the ATRS Voice Response Worksheet (OAT Form B).

## **C.2 Submission to Data Coordinating Center**

The completed Form 01 should be submitted by FAX ENTRY or E-mail or Internet Data Entry to the DCC within 72 hours of randomization. The other completed forms (Forms 02, 03, 3A, if appropriate, and 04) should be submitted to the DCC within seven days of randomization. The ECGs, that are to be centrally read, and stress test on viability test reports are to be sent to the DCC by mail.

## **D. Fully Eligible, Non-Randomized Patient Form - OAT Form 25 and Supplement to Form 25 - Form 0S**

### **D.1 Purpose of the Fully Eligible Non-Randomized Patient Form**

The purpose of the fully Eligible Non-Randomized Patient Form (OAT Form 25) is to provide demographic data on the patients who were clinically and angiographically eligible, but were not randomized into the trial. It is also used to provide information concerning planned revascularization procedures during the hospitalization for these patients.

The purpose of the Supplement (OAT Form 0S) is to record the information required to utilize the National Death Index or equivalent.

## **D.2 Time of Data Collection**

Form 25 and Form 0S should be completed as soon as the screening of the patient has been completed, that is, the patient has been identified as being eligible and the patient or the referring physician declines to give consent for the patient to participate in the trial. OAT Forms 01 through 04 can be used as worksheets. The required information for each registry patient is recorded on Form 25 as soon as possible after screening of the patient has been completed.

## **D.3 Submission to Data Coordinating Center**

OAT Form 25 is submitted to the DCC within one month of screening. OAT Forms 01 through 04 and Form 0S for patients who were eligible but not randomized are not submitted to the DCC; these forms should be kept on file at the Clinical Site.

## **E. Protocol Percutaneous Coronary Intervention (PCI) Report Form - OAT Form 05**

### **E.1 Purpose of Protocol Percutaneous Coronary Intervention (PCI) Report Form**

OAT Form 05 is to be completed only for patients who are randomly assigned to have percutaneous coronary intervention (PCI). The form is used to record data relevant to the PCI procedure or to report the reasons PCI was not attempted. It also provides information on the immediate results of the procedure and other aspects of the procedure concerning placement of stents and use of Gp IIb/IIIa antagonists. This form should be completed immediately after the performance of PCI or the decision not to perform PCI.

### **E.2 Submission to Data Coordinating Center**

The completed form should be submitted to the DCC within 72 hours of PCI or the decision not to perform PCI.

## **F. Complications Within 48 Hours of Study Entry Report - OAT Form 06 and Reinfarction Within 48 Hours of Study Entry Form - OAT Form 07**

Call the Clinical Coordinating Center to report any serious complications that occur in the cath lab.

## **F.1 Purpose of These Forms**

### **F.1.1 All patients**

The purpose of OAT Form 06 is to report all serious clinical complications that occur within 48 hours of study entry (randomization) for all patients who are enrolled in the randomized trial. The purpose of OAT Form 07 is to report whether or not reinfarction occurred within 48 hours of study entry.

These forms should be completed as soon as possible after 48 hours from study entry has elapsed, but no later than 72 hours after the time of study entry.

If the patient is discharged before 48 hours from study entry, the patient should be seen at an outpatient visit or contacted by phone 48 hours after study entry.

### **F.1.2 PCI – Assigned Patients**

If Protocol PCI was performed within 32 hours of randomization, OAT Form 06 and OAT Form 07 should include the 24-hour period after performance of the PCI procedure. If Protocol PCI was performed more than 32 hours after randomization, complete OAT Form 06 and OAT Form 07 to report on the complications that occur in the first 48 hours after study entry and complete OAT Form 6A (Complications of Delayed Protocol PCI) to cover the period from 48 hours post randomization through 24 hours after PCI.

For patients who have Protocol PCI performed more than 32 hours after randomization, Call or e-mail the Clinical Coordinating Center to report any serious complications that occur within 24 hours of the PCI procedure and report these events on OAT Form 6A (Complications of PCI for Patients with Delayed PCI). These events should also be reported on OAT Form 10 (Hospital Discharge Form).

The new Form 6A and the instructions for this form were distributed with OAT Memo 042.

## **F.2 Submission to Data Coordinating Center**

The completed OAT Forms 06 and 07 should be submitted to the DCC within 72 hours of study entry. OAT Form 6A should be submitted within 48 hours of the performance of Protocol PCI.

**G. Cardiac Serum Marker Results Form - OAT Form 8A, 8B and 8C, Medication Form - OAT Form 09, and Hospital Discharge or Outpatient Contact Form - OAT Form 10**

**G.1 Purpose of the Hospital Discharge Forms**

Cardiac Serum Marker Results Form 8A is to document the peak cardiac serum marker levels at the time of the qualifying index MI. The purpose of the Cardiac Serum Marker Results Form (OAT Forms 8B or 8C) is to record the cardiac serum marker levels which are obtained every eight hours during the first 48 hours of the date and time of study entry. CPK-MB measurement after enrollment constitutes a special case. In order to capture potentially important CPK-MB increases after PTCA/stent, CPK-MB is to be obtained pre and at 8, 16 and 24 hours post-PTCA. To avoid bias in endpoint ascertainment between the two groups, the medical therapy group is to have CPK-MB obtained within 24 hours after randomization and 8, 16 and 24 hours thereafter. All patients assigned to medical therapy, even if randomized as an outpatient, should have at least two cardiac serum marker measurements, one at time of randomization and one at 48 hours after randomization; the measurements for each time period are to be recorded on a Form 8B. As PTCA should occur within 24 hours of randomization for the intervention group, these cardiac serum marker measurements will be within the same time frame for the two groups. If protocol PCI is performed within 32 hours of randomization, complete a Form 8B with cardiac serum marker levels for each time period with measurements. If protocol PCI could not be performed within 32 hours of randomization, complete a Form 8C instead of Form 8B for each time period with measurements.

The purpose of the Medication Form (OAT Form 09) is to record the information concerning the medications prescribed during the period of hospitalization as well as at discharge. The time period for Form 09 is the same as for Form 10 unless the patient is in hospital for more than 30 days (see below).

The purpose of the Hospital Discharge or Outpatient Contact Form (OAT Form 10) is to identify the procedures and/major events that occurred during the period from qualifying index MI to hospital discharge or through 48 hours after randomization if patient was not in hospital at 48 hours after randomization and to provide information concerning the disposition of the patient at discharge or at 48 hours after study entry, whichever is later. All events occurring during the first 48 hours after study entry including those which may have been reported on OAT Form 06 and OAT Form 07 should be reported. For each outcome indicate whether the event occurred before or after study entry (randomization). If the event occurred before study entry and also

after study entry, report the first event as the one before study entry. The appropriate OAT event forms should be completed for both of these events.

These forms are to be completed after the patient has been discharged from the hospital or 48 hours after study entry, whichever is later, if the patient is discharged within 30 days of randomization.

## **G.2 Hospitalizations > 30 Days**

If patient remains in hospital at 30 days from randomization, complete Form 10 to cover the period from the index MI to 30 days after randomization. Record the date at 30 days after randomization. Item 3, disposition, is recorded as "Still in hospital 30 days after randomization." When the patient is discharged from the extended hospitalization complete a second Form 10. Events recorded on this form cover the period from the first Form 10 (30 days after randomization to hospital discharge).

Complete Forms 8A and 8B or 8C and submit with the first Form 10 for patients who are still in the hospital 30 days after randomization.

Complete one Form 09 to cover the entire hospitalization period after a patient is discharged from the extended hospitalization.

## **G.3 Submission to Data Coordinating Center**

The completed forms should be submitted to the DCC within one month of the date the patient was discharged from the hospital or date of second outpatient visit or telephone contact at 48 hours after study entry if patient discharged prior to randomization or within 60 days of randomization if patient is still in hospital 30 days after randomization.

## **H. Follow-up Forms: Outcome Follow-up Form - OAT Form 11, Cardiovascular Status Outcome Follow-up Data Form - OAT Form 12, Medication Follow-up Form - OAT Form 13**

### **H.1 Purpose of Follow-up Forms**

The purpose of the follow-up forms is to record clinical information which characterizes the patient's health status at each follow-up contact and to record information on medical history since the last follow-up contact. These forms are completed on the basis of a telephone interview with the patient and/or family member or if Clinical Site personnel or the patient

prefer, the patient may return to the Clinical Site and this information may be obtained by personal interview.

## **H.2 Time of Data Collection**

OAT Form 11 should be completed every four months based on the date of study entry. The contact may be scheduled within plus or minus two weeks of the ideal date (see Appendix K). If the patient cannot be contacted within this time period for a four-month contact, the form should be completed and it should be noted that the contact was not done. Even if contact with patient is not obtained, submit OAT Form 11 within three weeks of the target contact date. If contact is not made, continue an effort to make contact and send an updated form with contact information as soon as possible.

If the patient has died, complete the Outcome Follow-up Form (OAT Form 11) for the appropriate four-month period based on patient's date of death. Record the date this Outcome Follow-up Form is completed as the date of contact. If you learn of a patient's death after you have submitted the Outcome Follow-up Form for a four-month time period and the window for the next four-month period has not opened, complete a corrected Outcome Follow-up Form for this four-month period, record date of death as the date of contact, complete Item 1, sign the form and record OAT staff ID number.

The first Follow-up Forms cover the period from hospital discharge (or the outpatient visit or telephone contact at 48-hours if patient was discharged prior to 48 hours after study entry) to four months from study entry. The events recorded on all subsequent forms are all events which have occurred since the last Outcome Follow-up Form was completed. Only the first occurrence of each event in the specified period is reported on Form 11. Each event (including multiple events in a period) is documented by completion and submission of the appropriate event form (OAT Forms 14 to 19).

OAT Forms 12 and 13 should be completed at four months and at annual intervals after study entry.

## **H.3 Submission to Data Coordinating Center**

These forms are sent to the DCC as soon as they are completed and should be submitted no later than three weeks from the ideal date for contacting the patient for the telephone interview.



## **I. Cause of Death Form - OAT Form 14**

### **I.1 Purpose of the Cause of Death Form**

The purpose of this form is to provide information concerning the immediate and underlying causes of death and the basis for the information supporting the classification of the cause(s) of death.

The death certificate, autopsy report, and if available, hospital discharge summary and physician summary should be utilized to complete the form.

This form should be completed as soon as the required documentation which will be available has been received after the Clinical Site personnel were made aware of the death of the patient.

### **I.2 Submission to Data Coordinating Center**

The completed form and the required documentation are submitted by mail to the DCC as soon as all of the materials are available.

## **J. Subsequent Hospitalization and Secondary Events Form - OAT Form 15**

### **J.1 Purpose of the Subsequent Hospitalization and Secondary Events Form**

The purpose of this form is to report reasons for each hospitalization for cardiovascular events and pneumonia after the initial hospitalization during which the patient was entered into the trial and any events or procedures including stroke, ventricular arrhythmia, and placement of automatic implantable cardiac defibrillator (AICD) which required hospitalization or occurred during a hospitalization. Number the forms for each patient consecutively starting with 01, 02, etc. and record in space for sequence in the header of the form. Clinical Sites in the United States are to report all other hospitalizations by completing Page 1 of OAT Form 15.

This form should be started at the time study personnel are made aware of a rehospitalization or the occurrence of a secondary event and the form should be completed upon receipt of the appropriate hospital records and required documentation.

## **J.2 Required Documentation**

Required documentation for stroke includes a narrative summary, consultation report or discharge summary completely describing the stroke onset and course, and imaging study (CT scan, MRI/MRA, or cerebral angiography) report(s).

Required documentation for a ventricular arrhythmia event includes rhythm strips, electrocardiograms, emergency medical service records, hospital records, narrative and discharge summaries.

Required documentation of AICD implantation and the indication includes electrocardiograms, electrophysiological study reports, operative reports and hospital discharge summary and narrative summary.

## **J.3 Submission to Data Coordinating Center**

The completed forms and required documentation are to be sent by mail to the DCC within 30 days of the Hospital Discharge or Outpatient Contact Form (OAT Form 10) or Outcome Follow-up Form (OAT Form 11) which identified the occurrence of the hospitalization or secondary event or as soon as all materials are available. Mail to DCC within 24 hours of receipt of supporting documentation.

## **K. Non-Protocol PCI Form - OAT Form 16**

### **K.1 Purpose of the Non-Protocol PCI Form**

The purpose of this form is to collect the data relevant to non-protocol percutaneous coronary intervention (PCI). Non-protocol PCI includes all PCI procedures performed on any artery in either treatment group (except for the protocol PCI which is performed on the infarct-related artery immediately after randomization in the patients assigned to percutaneous coronary intervention). PCI prior to randomization is considered a non-protocol PCI. Number the non-protocol PCI procedures for each patient consecutively starting with 01, 02, etc. and record in space for sequence in the header of the form. This form should be completed as soon as possible after the performance of the non-protocol procedure.

## **K.2 Submission to Data Coordinating Center**

This form is sent by mail to the DCC within 24 hours of receipt of supporting documentation.

### **L. Myocardial Infarction Event Form - OAT Form 17, Congestive Heart Failure Event Form - OAT Form 18 and AICD Follow-up Form – OAT Form 20**

#### **L.1 Purpose of These Forms**

The purpose of the Recurrent Myocardial Infarction Event Form is to document each myocardial infarction which occurs after the myocardial infarction which made the patient eligible for OAT, that is, after the qualifying index myocardial infarction (MI). Number the recurrent MI events for each patient consecutively starting with 01, 02, etc. and record in space for sequence in the header of the form. The required documentation includes ECGs, cardiac serum marker results, narrative summary and angiography report (if angiography was performed). If the MI occurred after the index MI and prior to randomization, the documentation is not required.

ECGs that are obtained during the three periods: “Pre-ischemic,” “During the ischemic event” and “After ischemic event” should be submitted. “Pre- ischemic” event ECGs may be from anytime the patient has been clinically stable continuously up to the time of the onset of symptoms or signs at the beginning of the reported event. “During the ischemic event” refers to the acute period of event occurrence (e.g., during the time the patient is symptomatic or receiving therapy for acute symptoms). The ECGs “after the ischemic event” may be recorded up to 7 days after the event, so long as there are no further intervening ischemic events. All patient identifying information on the ECG should be masked. OAT Event ECG labels (see Appendix I) should be used for ECGs being submitted with an Event Form. Complete each label with patient’s ID and Letter Code, as well as date and time ECG was obtained. Indicate when ECG was obtained by placing a check mark (✓) or X in the appropriate parentheses.

Complete the Congestive Heart Failure Event Form for the first Class III event and first Class IV event and for all hospitalizations or emergency department or short stay unit admissions for congestive heart failure (CHF). Complete this form for any hospitalization (including hospitalization for index MI) during which congestive heart failure (CHF) was diagnosed, whether or not the primary admitting diagnosis was congestive heart failure. Also, complete this form for outpatient visits for IV diuretic therapy for CHF and for any new onset CHF Class III or CHF Class IV even if it did not result in hospitalization or use of a CHF specialized treatment

unit. Number the congestive heart failure events for each patient consecutively starting with 01, 02, etc. and record in space for sequence in the header of the form. These forms should be completed after notification of the occurrence of the event and after the required documentation has been received. The required documentation includes narrative summary and chest X-ray report. If the CHF event occurred after the index MI but before randomization, this documentation is not required.

For patients with AICD placement, complete Form 20 when AICD is first reported and at each 4-month contact until the first discharge for ventricular arrhythmia (documented or presumed) has been answered "Yes." Discharge means AICD delivers electric shock or attempts electroconversion, unless it is known that this occurred as a test or as an inappropriate discharge, e.g., supraventricular arrhythmia.

## **L.2 Submission to the Data Coordinating Center**

The completed forms and required documentation are to be sent by mail to the DCC within 30 days of the Hospital Discharge or Outpatient Contact Form (OAT Form 10) or Outcome Follow-up Form (OAT Form 11) which identified the occurrence of these events. Mail to DCC within 24 hours of receipt of supporting documentation.

## **M. CABG Surgery Form - OAT Form 19**

### **M.1 Purpose of CABG Surgery Form**

The purpose of this form is to document the performance of coronary artery bypass graft (CABG) surgery. Number the CABG surgical procedures for each patient consecutively starting with 01, 02, etc. and record in space for sequence in the header of the form. This form should be completed as soon as possible after knowledge of performance of CABG surgery is received and after required documentation has been received.

### **M.2 Submission to Data Coordinating Center**

The completed forms and required documentation are to be sent by mail to the DCC within 30 days of the Hospital Discharge or Outpatient Contact Form (OAT Form 10) or Outcome Follow-up Form (OAT Form 11) which identified the occurrence of these events. Mail to DCC within 24 hours of receipt of supporting documentation.

## **N. Cardiac Serum Marker Results - OAT Form 21**

### **N.1 Purpose of the Cardiac Serum Marker Results**

The purpose of the Cardiac Serum Marker Results (OAT Form 21) is to record the cardiac serum marker levels which are obtained in conjunction with an event. For multiple events or procedures during the same hospitalization, complete a Form 21 for each serum marker result, numbering them sequentially beginning with sequence number 01. These forms are to be completed after the patient has been discharged from the hospital.

### **N.2 Submission to Data Coordinating Center**

The completed forms and required documentation are to be sent by mail to the DCC within 30 days of the Hospital Discharge or Outpatient Contact Form (OAT Form 10) or Outcome Follow-up Form (OAT Form 11) which identified the occurrence of these events. Mail to DCC within 24 hours of receipt of supporting documentation.

## **O. Screening Log - OAT Form 26**

This form is completed in each Clinical Site during the first 30 days of the initiation of patient recruitment; this form should include data for all acute MI admissions who are not randomized into the trial. The required information for each patient is recorded on this form as soon as possible after the patient has been screened and it is known whether PTCA of the infarct-related artery (IRA) is planned during the period of hospitalization. The completed form is sent by mail to the DCC. This form will be completed in each Clinical Site for another 30-day period designated by the DCC.

## **P. Angiography Transmittal Form - OAT Form 30**

### **P.1 Purpose of Angiography Transmittal Form**

This form is completed for qualifying angiography and protocol PCI procedures. This form should be completed immediately after the performance of angiography and/or PCI.

### **P.2 Submission to Angiography Core Laboratory and Data Coordinating Center**

All qualifying and Protocol interventional procedure cineangiographic films or CD-ROM discs with the completed Angiography Transmittal Forms should be sent by registered or certified mail or any inexpensive traceable method to the Angiography Core Laboratory within

30 days of patient discharge. Films that need to be returned to the site quickly should be sent by Federal Express and marked "Urgent." Films and discs should be clearly and securely labeled with the unique OAT patient identification (ID) number, patient's Letter Code and Clinical Site number, and packaged in impact resistant cases to prevent damage during shipment.

The address for shipment to the Angiographic Core Lab can be found on the contact information page and the form instructions.

For participating centers outside Canada it is vital to label the package as follows to avoid delays in Canada Customs at the border. Significant delays may result if the films are not labeled as follows: **Patient X-Rays for Medical Research only, No commercial Value.** The declared value should be less than \$5.00 US.

A copy of each Angiography Transmittal Form (OAT Form 30) is mailed to the DCC.

#### **Q. Follow-up Angiography Form (TOSCA-2 Patients Only) - OAT Form 31**

The Total Occlusion Study of Canada-2 (TOSCA-2) is an ancillary study of OAT; approximately 30 Clinical Sites are participating.

##### **Q.1 Purpose of Follow-up Angiography Form**

This form is completed to provide the details of the one-year angiography performed on TOSCA-2 patients and to report any serious clinical complications which occur within 24 hours of the procedure. If any serious complications occur in the cath lab, call the Clinical Coordinating Center. The form should be completed 24 hours after the performance of the one-year angiography or after the decision to not perform angiography is made.

##### **Q.2 Submission to Angiography Core Laboratory and Data Coordinating Center**

All one-year angiographic procedure cineangiographic films or CD-ROM discs with the completed Angiography Transmittal Forms should be sent by registered or certified mail or any inexpensive traceable method to the Angiography Core Laboratory within 30 days of patient discharge. Films that need to be returned to the site quickly should be sent by Federal Express and marked "Urgent." Films and discs should be clearly and securely labeled with the unique OAT patient identification (ID) number, patient's Letter Code and Clinical Site number, and packaged in impact resistant cases to prevent damage during shipment.

The address for shipment to the Angiographic Core Lab can be found on the contact information page and the form instructions.

For participating centers outside Canada it is vital to label the package as follows to avoid delays in Canada Customs at the border. Significant delays may result if the films are not labeled as follows: **Patient X-Rays for Medical Research only, No commercial Value.** The declared value should be less than \$5.00 US.

**R. OAT-EP Forms (for OAT-EP Patients only)**

OAT-EP is an ancillary study of OAT with expected enrollment of 300 patients in approximately 45 Clinical Sites. EP Enrollment Form (Form 32) should be completed for patients who have given consent for OAT-EP. The Holter recording is obtained after OAT and OAT-EP consent but before OAT randomization. Holter Monitoring Form (Form 33) should be completed on the date of entry (Holter performance) in the OAT-EP study, 30 days and 1 year after enrollment into the OAT-EP study. Complete instructions for the six-lead Holter recording are in the OAT-EP Ancillary Study Instructions for the Holter Recording (sent by the OAT-EP Holter Core Laboratory with each recording card).

**S. OAT NUC Forms (for OAT-NUC Patients only)**

OAT-NUC is an ancillary study of OAT with expected enrollment of 200 patients in approximately 25 Clinical Sites. OAT-NUC Enrollment Form (Form 34) should be completed for patients who have given consent for OAT-NUC. SPECT Imaging Form (Form 35) should be completed on the date of SPECT Imaging for the OAT-NUC Study. SPECT Imaging is required at entry and at 1 year after enrollment. Complete instructions for the SPECT Imaging are in the OAT-NUC Ancillary Study Instructions for the SPECT Imaging (sent by the OAT-NUC Core Laboratory).

OAT-NUC Biomarker Study Enrollment Form (Form 36) should be completed on patients who have given consent for OAT-NUC Biomarker study. Biomarker Blood Specimen Form 37 should be completed on the date of blood specimen collection at entry and at 1 year after enrollment.

SPECT Imaging for Patients Not Randomized Form 38 is completed for each patient who had SPECT Imaging completed, but was later found to be ineligible for OAT and not randomized to OAT.

### **XIII. STUDY MONITORING**

#### **A. Checking Treatment Assignment**

After the bottom section of the Treatment Allocation Form is received in the DCC, the following items are checked:

1. Local date and time are checked against the time that the randomization was issued as recorded in the ATRS database.
2. Treatment received is checked against treatment assignment.

If date and time reported on the form do not agree with date and time in the database, a query is sent to the Clinical Site. If the information is concordant, an appointment schedule is generated (see Appendix L) and mailed to the site.

If the treatment received does not match the treatment assignment, one of the following messages is sent to the site.

- a. If PCI of IRA was assigned and not performed within 32 hours, the following message is sent: "Patient did not receive assigned treatment within 32 hours. If PCI of IRA was performed between 32 and 72 hours of randomization, please notify the DCC of the date and time PCI of IRA was performed by sending a reply to this message by e-mail or by recording the date and time on the bottom of this message and sending this message back to the DCC by fax. If PCI of IRA was not performed within 72 hours of randomization, send narrative by fax to Dr. Hochman at the CCC and Dr. Knatterud at the DCC to explain why PCI of IRA was not performed."
- b. If Medical Therapy was assigned and PCI of IRA was performed within 32 hours, the following message is sent: "Patient did not receive assigned treatment. Please send narrative by fax to Dr. Hochman at the CCC and Dr. Knatterud at the DCC to explain why PCI of IRA was performed. Complete a Non-Protocol PCI Form."



**B. Confirmation of ATRS Data**

After the OAT Form 01 has been received at the DCC, the data specified below are compared to the data entered during the ATRS randomization telephone call.

ATRS Voice Response Worksheet		Source of Information	
<u>Item</u>		<u>Form</u>	<u>Item(s)</u>
7	Gender	01	1
8	Date of birth	01	2
9	Ethnic origin	01	3

If any discrepancies are noted, the Clinical Site is notified.

**C. Editing Data**

In spite of earnest attempts by all members of the Clinical Site staff, items on the data collection forms are sometimes overlooked, information is sometimes recorded in the wrong format, or items are answered inconsistently. In order to identify such problems and other errors which may have occurred during processing in the DCC and to retrieve as much information as possible, all forms received at the DCC are subjected to computer edit to detect missing or improbable answers to every item.

Problems detected by the special computerized edit procedure trigger printed "Edit Statements" which are sent to the Clinical Site staff for resolution. Because of the need to identify a broad range of possible problems, items that have been answered correctly are sometimes identified as questionable. An attempt has been made to provide clear, concise edit messages, but sometimes the problem is not obvious. The DCC staff should be contacted by telephone or in writing to resolve any unusual problems that result in edit messages. A description of edit procedures and the routine procedures for dealing with edit messages follows.

## **C.1 Types of Problems Listed on Edit Statements**

### 1. Inconsistencies

Within a form, the responses to different parts of an item are checked for consistency. For example, if certain parts of the item are to be answered only if the first part of the item is answered "YES," a message is generated for each item that is answered if the first part is answered "NO." A message is also generated for each item which is left unanswered if the first part is answered "YES." All parts of the item should be examined to determine whether the first part of the item was answered correctly and based on that response determine whether the subitems should be answered.

### 2. Out-of-Range Values

The DCC has specific upper and lower ranges for all numeric items and an out-of-range value must be verified by the OAT Clinical Site staff. Any values outside of these ranges are indicated on the edit statement with a comment "This response is out-of-range."

### 3. Unanswered Items

All non-valid unanswered items are identified on the edit statement as "This response is missing."

An edit message is printed for each error identified during the computer edit.

## **C.2 Format of Edit Statements**

The format of the Edit Statement is designed to limit the work required to "correct" the item in question, as well as to limit the possibility of additional "errors" in processing the corrections at the Clinical Sites. The Edit Statement consists of basic patient identifying information, the edit messages (a description of problems) and the general instructions for correcting edit messages.

Each Edit Statement page is for a specific form for a given patient. The upper section of the Edit Statement identifies the Form, the form Revision number, the Site number and patient's ID, the patient's Letter Code and the visit date. For some forms you may also have a visit period or a time period or a sequence number.

The bottom section of the Edit Statement consists of four columns which identify the following information:

Column 1: Page number.

Column 2: Item number.

Column 3: Description of the item in question and the query statement.

Column 4: Old Value.

The value given in this column is:

- a. The value or data recorded on the form, for write-in responses, or
- b. The precoded number and response chosen for precoded bubble items, or
- c. Blank for an answer which is illegible or missing.

A sample edit statement and the OAT Form with the correction in response to this edit statement are given in Appendix M.

### **C.3 Instructions for Responding to Edit Statements**

The Edit Statement should be compared to the original form/page for the patient. All the items on the Edit Statement that require correction should be addressed. Those items that are correct do not need to be changed; restatement of items that are out of range will serve as verification. A copy of the Edit Statement should be retained in the patient's file at the Clinical Site. Corrections to FAX ENTRY forms and forms transmitted by E-mail Data Entry are made by sending the corrected items on a form with the "Correction" bubble filled. Corrections to forms transmitted by Internet Data Entry can be made using the "correction" function in the Internet Data Entry program.

If it is impossible to "correct" every item listed on the Edit Statement, as many items as possible should be corrected. The corrections should be posted as soon as feasible.

Prepare a new form with the patient's OAT ID number and Letter Code (header information) and darken the correction bubble. Because you must use the same version of the form you used to submit the data initially, a copy of the Fax image and a blank form to be used for each statement will be sent with the edit statement for edit messages if the form edited was not the current revision of the form. The DCC staff will complete the header information for these messages. Complete only the item(s) to be corrected or verified. Sign the bottom of the form and fill in your OAT staff ID number. The form should be sent to the DCC in the appropriate manner, i.e., fax forms should be faxed to the number at the bottom of the form. The bottom of each edit page indicates which form of data entry was used for this patient form, either Fax or E-mail or Internet. The first two are interchangeable, therefore you can do a correction form as an e-mail form even if the original form was a FAX ENTRY form or vice versa. Internet Data Entry is NOT interchangeable with FAX ENTRY or E-mail Data Entry.

All form corrections should be noted on the edit statement as documentation of the action taken. A copy of the correction form and the actual edit statement should be kept in the patient's files.

#### **C.4 Missing Responses**

If a missing response is unavailable, prepare a correction form as indicated above and use the missing data convention for the OAT study and fill in the missing response only. Numeric or character responses are coded as a series of 9's, ending with an 8, i.e., "8", "98", "998", "99.8", etc. Do not write NA, or UNK, or any other comment into character or numeric fields, use only the missing data convention.

#### **C.5 Change an Item**

If you need to change the value of an item, prepare a correction form for the patient as described above (i.e., complete the header information on the appropriate form) and complete only the item that is to be changed. All responses to a conditional item must be completed even if some of the original responses were correct. The corrected page should be sent to the DCC to be posted to the database. Please note that it is important to submit corrections on the same revision of the form that was used to submit the data initially for each patient.

#### **C.6 Confirm Out-of-Range Values**

Values identified as "out-of-range" that are correct are confirmed by submitting a correction form. On the correction form complete the header information and complete only the item(s) identified as out-of-range with the same values as recorded on the original form.

### **C.7 Deletion of Page/Form**

To delete a page or form from the data entry system, an OAT Form/Page Deletion Form (OAT Form 099) must be completed and sent to the DCC for each form in question. The patient's identifying information and the OAT form number and page number(s) should be completed. Sign the form and fill in your staff ID number, either mail or fax the form to the DCC.

During the editing and correction process, if you wish to delete a form or page that is not listed on the edit statement, complete the OAT Form 099. If you wish to correct information not listed on the edit statement, prepare a correction form as described above and transmit to the DCC by fax, e-mail or Internet.

### **D. Delinquent Listings**

Study forms are inventoried as they are received in the DCC and once a month the inventory of received forms is compared with the forms expected. The forms expected are based on submission time specified in Appendix G. No matter how far in advance appointments are scheduled or how often patients are reminded, there are occasional instances in which a patient does not have a follow-up contact by the last possible date as indicated in the Patient Appointment Schedule. If a patient is not contacted within the appropriate time window, the Outcome Follow-up Form (OAT Form 11) with the appropriate header information and the NOT DONE bubble darkened, should be submitted to the DCC. If an Outcome Follow-up Form is not submitted, the form for this follow-up contact will appear on the Delinquent Forms List generated every month at the DCC. Forms are listed as delinquent if more than two weeks have passed since the last date of the follow-up contact time window.

## **XIV. EDUCATION ON PROTECTION OF HUMAN SUBJECT PARTICIPANTS**

A new National Institutes of Health (NIH) policy became effective October 1, 2000. This policy requires education on the protection of human subject participants for all investigators and "key personnel" who are responsible for the design and conduct of research under the NIH grant and contract awards for the research involving human subjects.

Since OAT is an NIH trial, the investigators and coordinators of all participating sites are required to comply with this new policy. Most academic institutions have already developed educational programs on the protection of research participants and have made attendance at such programs a requirement for their investigators. If your institution has not provided this

training, an educational program can be accessed on the NIH web at <http://cme.nci.nih.gov>. This takes 30-60 minutes, and you receive a certificate at the end. This training module was originally developed for NIH staff, but it can be used by your personnel to meet training requirements. The program is simple and you are asked to answer only two questions after two cases. Please fax documentation of this education or a copy of the certificate obtained from the Internet training for each Clinical Site staff member identified as key personnel.

The NIH describes key personnel as anyone involved in the design or conduct of the research. This would include anyone who obtains informed consent, enrolls, and conducts follow-up with a patient. At a minimum you should consider the Principal Investigator (PI), the lead coordinator and any other staff member who consents, enrolls and follows patients to be key personnel and consequently should provide documentation of their training. It is up to the discretion of the PI to determine whether other study staff (co-investigators, other coordinators) would be considered key personnel at his/her site. It is not necessary to document training of non-key personnel. An example of non-key personnel is an interventional cardiologist who has been certified to perform PCI on OAT patients but does not obtain informed consent, enroll or follow OAT patients for research purposes.

APPENDIX A  
SAMPLE PIN CARD

<p>Occluded Artery Trial (OAT)</p> <hr/> <p>Clinical Site 999 University Hospital</p> <p>Hospital Identification # (PIN): XXXXX</p> <p>Hospital Password: XXXX</p> <p style="text-align: right;">1/18/00</p> <hr/> <p>Maryland Medical Research Institute</p>
---

## APPENDIX B

### OAT HOME PAGE



Tue, 17  
Feb 2004  
17:00:29 UTC

# WEB STUDY Welcome!

# OAT

- Home
- Protocol / Manual
- Memos
- Minutes
- Q & A
- Forms
- Form QxQs
- Study Tools
- News & Events
- Presentations
- Publications
- Reports

## ▶ Protocol/Manual

Study Protocol and Manual, Ancillary Study Protocols and other related documents.

## ▶ Memos

Numbered memos.

## ▶ Minutes

Minutes for meetings and conference calls (if applicable).

## ▶ Q & A

Frequently asked questions and answers, and people to contact.

## ▶ Forms

Current study forms.

## ▶ Form QxQs

Form instructions - Addressed question by question.

## ▶ Study Tools

Schedules, time lines, applications, [SAE reporting procedure](#) and other study management tools.

## ▶ News & Events

Meetings, conference calls, events and newsletters.

## ▶ Presentations

Power Point slide presentations.

## ▶ Publications

Published publications as well as manuscripts in progress.

## ▶ Reports

Recruitment, performance and other study reports.



APPENDIX B (Continued)  
 CONTENTS OF A SECTION ON OAT HOME PAGE

https://www.ctascstudies.com/news.asp - Microsoft Internet Explorer  
 Tue, 17 Feb 2004 16:41:52 UTC

**WEBSTUDY NEWS & EVENTS**

All documents | Select Subset

Description	Document Date	Size, Bytes
Update - 1/12/01	7/6/01	49611
<a href="#">NEWS022001</a> Update - 2/01	7/6/01	37792
<a href="#">News012000</a> OAT Newsletter - October 2000	10/1/00	104626
<a href="#">News012002</a> Newsletter - January 2002	1/11/02	95367
<a href="#">News012003</a> Newsletter - January 2003	3/11/03	83849
<a href="#">News022003</a> Newsletter - February 2003	2/11/03	107900
<a href="#">News032001</a> Newsletter - April 2001	5/4/01	101799
<a href="#">News032002</a> OAT Newsletter - March 2002	3/7/02	91426
<a href="#">News032003</a> Newsletter - March 2003	3/11/03	70882
<a href="#">News042001</a> Newsletter - May 17, 2001	5/23/01	217057

https://www.ctascstudies.com/news.asp - Microsoft Internet Explorer  
 Tue, 17 Feb 2004 16:47:14 UTC

**WEBSTUDY NEWS & EVENTS**

New 2004 | Select Subset

Document	Description	Document Date	Size, Bytes
<a href="#">News200401</a>	Newletter - January 2004	1/12/04	373427
<a href="#">News200402</a>	Newletter - February 2004	2/10/04	416149

APPENDIX C

INTERNET SITE APPLICATION



OAT Form I  
05/04/2001

**OAT INTERNET SITE APPLICATION**

Complete one form per site.  
Please type or print clearly.  
FAX to MMRI (410) 323-8622

Date: \_\_\_\_\_

Site Number: \_\_\_\_\_

Site Name: \_\_\_\_\_

Principal Investigator: \_\_\_\_\_

Site Address: \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

Site e-mail (required): \_\_\_\_\_

Site Phone Number: area/country code (\_\_\_\_)

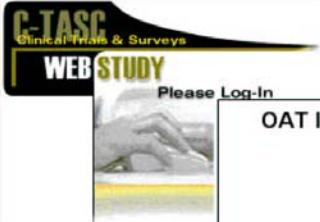
**For Computer Services Use Only!**

Date Completed: \_\_\_\_\_

Completed by: \_\_\_\_\_

APPENDIX D

INTERNET USER APPLICATION



OAT Form J  
05/04/2001

**OAT INTERNET USER APPLICATION**

**Complete one form per user.**  
**Please type or print clearly.**  
**FAX to MMRI (410) 323-8622**

Date: \_\_\_\_\_

Site Number/Name: \_\_\_\_\_

User Name: \_\_\_\_\_

User e-mail: \_\_\_\_\_

User Phone Number: area/country code ( ) \_\_\_\_\_

Computer / Operating System: \_\_\_\_\_

Browser / Version: \_\_\_\_\_

Certification Requested:  Content Only – The user may browse web site content such as manuals and forms, but may *not* enter, modify or view data.  
 (Select One)  Data Entry and Content - The user may browse web site content such as manuals and forms, and *may* enter, modify and view data.

For Computer Services Use Only!	
Test IDs: _____	Comments: _____
Passed Comparison: _____	_____
Date Certified: _____	_____
Completed by: _____	_____
USER LOGON Assigned: _____	_____
USER PASSWORD Assigned: _____	_____
USER NUMBER Assigned: _____	_____

APPENDIX E

OAT Form K  
 5/12/2001

OAT Clinical Site Questionnaire on Site Resources

Please answer all questions in each section.

**Site Information:** Site Number: \_\_\_\_\_ Site Coordinator: \_\_\_\_\_

**A. FAX ENTRY**

1. Clinical Site staff plan to continue with FAX-ENTRY?  Yes  No
2. Clinical Site staff would like to test:
- E-mail?  Yes  No
- Internet?  Yes  No

**B. E-Mail**

1. Do you have e-mail capability?  Yes  No
2. Is your e-mail checked on a daily basis?  Yes  No
3. Do you have the full version of Adobe Acrobat 4.0 or 5.0?  Yes  No
- If No, can you obtain the Adobe Acrobat 4.0 or 5.0?  Yes  No
4. Do you have a laser or ink jet printer?  Yes  No

**C. Internet**

1. Do you have a Pentium Class PC (at least 100 MHZ) with Windows 95, Windows 98 or Windows NT?  Win 95  Win N/T
- (Check as many as apply.)  Win 98  Other, please specify below
- 
2. Do you have 32 MB (megabytes) of RAM or more?  Yes  No
3. Do you have Internet access at 56 KB or higher?  Yes  No
4. Do you connect to the Internet through a hospital or institution network?  Yes  No
- If Yes, are you able to do the following:
- Download software from Web sites?  Yes  No
- Set you browser to accept cookies?  Yes  No
5. Do you connect to the Internet through a modem?  Yes  No
- If Yes, what is your modem speed?  28 K  33 K or 58 K
6. Do you have?
- Microsoft IE 5.0 or better?  Yes  No
- Netscape Navigator 4.5 or better?  Yes  No
- Adobe Acrobat Reader 4.0?  Yes  No
7. Do you have a laser or ink jet printer?  Yes  No

APPENDIX F  
 OCCLUDED ARTERY TRIAL (OAT)  
 SCHEDULE OF MEASUREMENTS AND DATA COLLECTION

TIMES OF DATA COLLECTION

	BASELINE	48 HOURS	HOSPITAL DISCHARGE	MONTHS 4-60 EVERY 4 MONTHS	MONTH 4 AND YEARLY
Demographics and Eligibility (ATRS Form)	X				
Medical History (OAT Form 01)	X				
Physical Examination (OAT Form 02)	X				
Documentation of Qualifying MI (OAT Form 03 and 3A)	X				
Qualifying Angiography, Stress Test, and Ejection Fraction (OAT Form 04) and (OAT Form 30)	X				
QOL Baseline Summary and Questionnaire	X				
Percutaneous Coronary Intervention Report (OAT Form 05) and (OAT Form 30)		X			
Complications within 48 Hours of Study Entry (OAT Form 06)		X			
Reinfarction within 48 Hours of Study Entry (OAT Form 07)		X			
Cardiac Serum Marker Results (OAT Form 8A and 8B or 8C)	X	X			
Medication (OAT Form 09)			X		
Hospital Discharge or Outpatient Contact (OAT Form 10)			X		
Outcome Follow-up (OAT Form 11)				X	
Cardiovascular Status Outcome Follow-up (OAT Form 12)					X
Medication Follow-up (OAT Form 13)					X
QOL Follow-up Summary and Questionnaire					X
Cause of Death (OAT Form 14)			X	X	
Subsequent Hospitalization and Secondary Event (OAT Form 15)			X	X	
Non-Protocol PCI (OAT Form 16)			X	X	
Recurrent Myocardial Infarction Event (OAT Form 17)			X	X	
Congestive Heart Failure Event (OAT Form 18)			X	X	
CABG Surgery (OAT Form 19)			X	X	
Cardiac Serum Marker Results (OAT Form 21)			X	X	
Fully Eligible, Non-Randomized Patient (OAT Form 25)	X				

APPENDIX G  
DEADLINES FOR SUBMISSION OF FORMS TO THE DATA COORDINATING CENTER

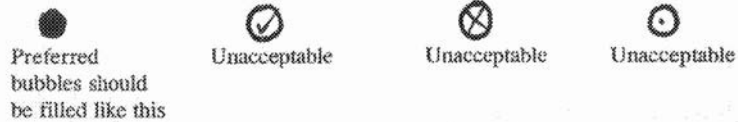
- a. ATRS Voice Response Worksheet - Complete before randomization call. File at site.
- b. Treatment Allocation  
Received from DCC by fax. To be completed and faxed back to DCC within one day.
- c. Form 00 - Keep at site.  
Form 0S - Keep at site.
- d. Form 01 - Submit to DCC within 72 hours of randomization.
- e. Form 02 - Submit to DCC within 7 days of randomization.
- f. Form 03 - Submit to DCC within 7 days of randomization.
- g. Form 04 - Submit to DCC within 7 days of randomization.
- h. Form 05 - Submit to DCC within 72 hours of randomization.
- i. Form 06 - Submit to DCC within 72 hours of randomization.
- j. Form 07 - Submit to DCC within 72 hours of randomization.
- k. Form 8A and 8B or 8C - Submit to DCC within 1 month of discharge.
- l. Form 09 - Submit to DCC within 1 month of discharge.
- m. Form 10 - Submit to DCC within 1 month of discharge.
- n. Form 11 - Submit to DCC within 3 weeks of contact.
- o. Form 12 - Submit to DCC within 3 weeks of contact.
- p. Form 13 - Submit to DCC within 3 weeks of contact.
- q. Form 14 - Mail to DCC when all materials are available.
- r. Form 15 - Mail to DCC when all materials are available. DCC would like to have this within 30 days of a hospitalization noted on a follow-up contact form.
- s. Form 16 - Mail to DCC within 24 hours of receipt of supporting documentation.
- t. Form 17 - Mail to DCC within 24 hours of receipt of supporting documentation.
- u. Form 18 - Mail to DCC within 24 hours of receipt of supporting documentation.
- v. Form 19 - Mail to DCC when all materials are available. DCC would like to have this within 30 days of a hospitalization noted on a follow-up contact form.
- w. Form 21 - Mail to DCC along with other event forms.
- x. Form 25 - Submit to DCC within 1 month of screening.  
Form 0S - Keep at site.
- y. Form 26 - Screening Log - Mail to DCC.
- z. Form 30 - Traceable method of delivery to Angiography Core Laboratory within 30 days of patient discharge. Mail copy to DCC.

APPENDIX H

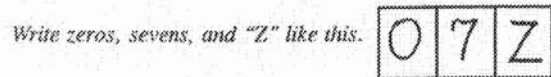
GUIDELINES FOR COMPLETING FAX ENTRY FORMS

**Using the Right Pen** Use a black fine felt-tip pen; this type of pen works best because it leaves solid line segments. Some ball-point pens create broken line segments that introduce greater possibility of recognition error. Some facsimile (FAX) machines transmit colors differently. Light blue, in particular, is not picked up by many fax machines and may cause interruption errors.

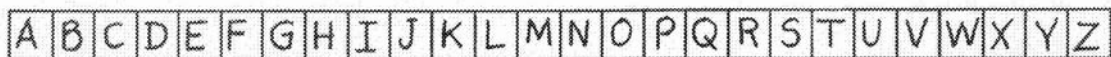
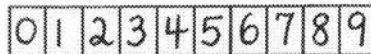
**Filling in bubbles** The best results are obtained when bubbles are completely darkened. Bubbles should never be circled because Teleform does not look outside the circle for marking information.



**Filling in Letters and numbers:** When you print letters and numbers, use capital block letters. Be sure to print only one character per box, keeping the character's lines completely inside the box and avoiding the edge of the box. Zero, seven, and "Z" should not be crossed.



EXAMPLES OF NUMBERS AND LETTERS ARE GIVEN BELOW



## APPENDIX I

### INSTRUCTIONS FOR SAVING A PDF FILE

#### **PART A: Set-up File Directory Before Data Entry**

Before keying data for OAT forms using the email system perform the following steps.

1. Set-up a File Directory
  - Open Windows Explorer  
To open Windows Explorer: Click on the Start Icon>Programs>Windows Explorer
  - Determine where on your network or local computer drive you want to set-up a directory folder to retain the data for each form page. Click on that Drive Letter (Example: C:\).
  - On the menu bar of Windows Explorer: Click on File>New>Folder.
  - A new folder appears in the window labeled “New Folder”.
  - Change the name to “OAT Email Forms” by typing over the words “New Folder”.
  - Then press the enter key.
  - Double click on the new directory you just created - *OAT Email Forms*
2. Create Sub-directories for each Patient ID as follows:
  - On the menu bar of Windows Explorer: Click on File>New>Folder.
  - A new folder appears in the window labeled “New Folder”.
  - Change the name to the Patient’s ID number, Example: “999-001” by typing over the words “New Folder”.
  - Then press the enter key.
  - Before repeating Step 2 to create another Patient ID sub-directory, Click on the folder *OAT Email Forms* in the Directory window on the left. Always click on the *OAT Email Forms* directory first before creating a new Patient ID sub-directory.
3. When finished setting up the directories, close Windows Explorer by clicking on the “X” in the upper right corner of the screen.

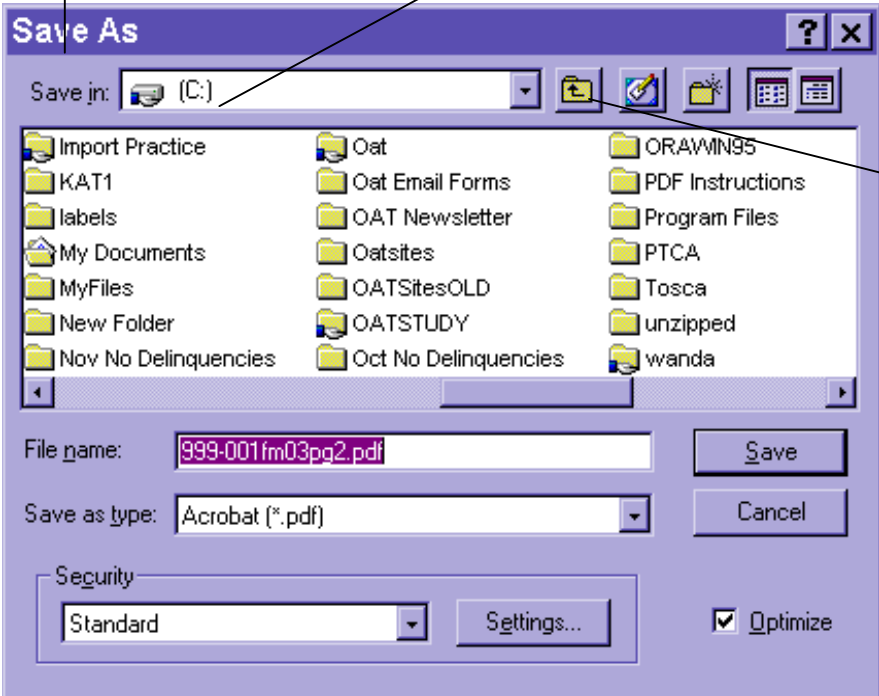


APPENDIX I (Continued)

4. After keying the patient data into the form, go to the menu bar of your Adobe Acrobat:
  - Click on File
  - Click on “Save As”

A directory window appears: “Save As”

Look at the “Save in” Window box to see if you are on the correct drive.



If the appropriate drive or folder does not appear move to that drive as follows:

Click on the “Folder Icon” with the arrow that points up; continue to click on this icon until you see the Drive letter where your OAT Email directory resides. *Example: (C:).*

5. Open the *OAT Email Forms Directory* by double clicking on it.
6. Open the appropriate Patient ID sub-directory by double clicking on it.
7. Name the File:
  - ▶ In the “File name:” window
  - ▶ Create a file name: It is suggested that you use the patient ID number, form number and page number, (i.e. *999001fm03pg2.pdf*) or use visit number when saving a multi-visit form, (i.e. *999001fm11v08.pdf*).
  - ▶ Type the name in the “File name:” box.
  - ▶ Click Save
8. You may then clear the page to enter data for another patient or you may close this form page.

APPENDIX I (Continued)

**PART B: Set-up File Directory After Data Entry**

1. If you have keyed the patient data into the form and have not created a *Patient ID subdirectory* for this patient, you may create the *Patient ID subdirectories* from this “Save As” Window as follows:
  1. Click on the “Folder Icon” with the arrow that points up; until you see the Drive letter where your *OAT Email Forms* directory resides.
  2. Double click on the OAT Email Forms directory to open it.
  4. Create a new *Patient ID subdirectory*:
    - Click on the “Folder Icon” (image), normally the third icon from the “Save in:” window. When moving the mouse cursor over the icon it will say “Create New Folder”.
    - Click on “Create New Folder”
    - A new folder appears in the window labeled “New Folder”.
    - Change the name to the Patient’s ID number, Example: “999-001” by typing over the words “New Folder”.
    - Then press the enter key.
    - Double click on the new Patient ID sub-directory you just created.
  5. To name the File:
    - In the “Save As” window
    - The 3<sup>rd</sup> white box from the top is “File name:”
    - Create a file name: It is suggested that you use the patient ID number, form number and page number, (i.e. *999001fm03pg2.pdf*) or use visit number when saving a multi-visit form, (i.e. *999001fm11v08.pdf*).
    - Type the name in the File name box.
    - Click “Save”
  6. You may then clear the page to enter data for another patient or you may close this form page.

APPENDIX J

SAMPLE OAT LABELS FOR ECGS AND STRESS TEST REPORTS

OAT QUALIFYING EVENT ECG

OAT QUALIFYING ECG					
ID	_____	-	_____	Letter Code	_____
_____	-	_____	-	_____	_____
Month	Day	Year		Hr.	Min.

OAT EVENT ECG

OAT EVENT ECG					
ID	_____	-	_____	Letter Code	_____
_____	-	_____	-	_____	_____
Month	Day	Year		Hr.	Min.
Ischemic Event: Pre ( ) During ( ) After ( )					

OAT STRESS AND/OR VIABILITY TEST REPORT

OAT STRESS AND/OR VIABILITY TEST REPORT					
ID	_____	-	_____	Letter Code	_____
_____	-	_____	-	_____	_____
Month	Day	Year		Hr.	Min.

APPENDIX K

OAT FOLLOW-UP WINDOWS (FOR FORMS 11, 12, and 13)

MONTH	START IDEAL	CLOSE IDEAL	CLOSE ACCEPTABLE
4*	3.5 mo (110 days)	4.5 mo (138 days)	7.5 mo (233 days)
8	7.5 mo (234 days)	8.5 mo (262 days)	11.5 mo (357 days)
12*	11.5 mo (358 days)	12.5 mo (386 days)	15.5 mo (481 days)
16	15.5 mo (482 days)	16.5 mo (510 days)	19.5 mo (605 days)
20	19.5 mo (606 days)	20.5 mo (634 days)	23.5 mo (729 days)
24*	23.5 mo (730 days)	24.5 mo (758 days)	27.5 mo (853 days)
28	27.5 mo (854 days)	28.5 mo (882 days)	31.5 mo (977 days)
32	31.5 mo (978 days)	32.5 mo (1006 days)	35.5 mo (1101 days)
36*	35.5 mo (1102 days)	36.5 mo (1130 days)	39.5 mo (1225 days)
40	39.5 mo (1226 days)	40.5 mo (1254 days)	43.5 mo (1349 days)
44	43.5 mo (1350 days)	44.5 mo (1378 days)	47.5 mo (1473 days)
48*	47.5 mo (1474 days)	48.5 mo (1502 days)	51.5 mo (1597 days)
52	51.5 mo (1598 days)	52.5 mo (1626 days)	55.5 mo (1721 days)
56	55.5 mo (1722 days)	56.5 mo (1750 days)	59.5 mo (1845 days)
60*	59.5 mo (1846 days)	60.5 mo (1874 days)	63.5 mo (1969 days)

\*Applicable for Forms 12 and 13.

APPENDIX L  
 APPOINTMENT SCHEDULE

Occluded Artery Trial

09/16/2003

Patient Schedule

Clinic:

ID:                      Letter Code:                      Study Entry Date and Time: Sep/16/2003 12:27

Month	START IDEAL	CLOSE IDEAL	ACTUAL CONTACT DATE	CLOSE ACCEPTABLE
4	Jan/02/2004	Jan/30/2004	-----	May/01/2004
8	May/02/2004	May/30/2004	-----	Sep/01/2004
12	Sep/02/2004	Sep/30/2004	-----	Jan/01/2005
16	Jan/02/2005	Jan/30/2005	-----	May/01/2005
20	May/02/2005	May/30/2005	-----	Sep/01/2005
24	Sep/02/2005	Sep/30/2005	-----	Jan/01/2006
28	Jan/02/2006	Jan/30/2006	-----	May/01/2006
32	May/02/2006	May/30/2006	-----	Sep/01/2006
36	Sep/02/2006	Sep/30/2006	-----	Jan/01/2007
40	Jan/02/2007	Jan/30/2007	-----	May/01/2007
44	May/02/2007	May/30/2007	-----	Sep/01/2007
48	Sep/02/2007	Sep/30/2007	-----	Jan/01/2008

Record dates of event forms below.

Hospitalization (Oat Form 15)		Non-Protocol PCI (Oat Form 16)		Recurrent MI (Oat Form 17)	
	Date		Date		Date
HP01	-----	NP01	-----	MI01	-----
HP02	-----	NP02	-----	MI02	-----
HP03	-----	NP03	-----	MI03	-----
HP04	-----	NP04	-----	MI04	-----
HP05	-----	NP05	-----	MI05	-----
HP06	-----				
HP07	-----				
HP08	-----				
HP09	-----				
HP10	-----				

Congestive Heart Failure (Oat Form 18) CABG Surgery (Oat Form 19)

Congestive Heart Failure (Oat Form 18)		CABG Surgery (Oat Form 19)	
	Date		Date
HF01	-----	CG01	-----
HF02	-----	CG02	-----
HF03	-----	CG03	-----
HF04	-----	CG04	-----
HF05	-----	CG05	-----

APPENDIX M  
 SAMPLE EDIT STATEMENT

OAT Edit Query  
 Sep. 8, 2003

Page 1

Form / Rev : 12 / 1  
 Site - ID :  
 Letter Code :

Visit Period: 04  
 Visit Date: AUG-08-2003  
 Enrollment Period: B

Page	Item	Description	Old Value
<u>This (These) response(s)</u>			
1	2	DIAGNOSED OR TREATED FOR CHF IN PAST 4 MONTHS	<input type="text" value="(2)No"/>
<u>is (are) inconsistent with some or all of the following responses</u>			
1	2A	RATE PATIENT'S MOST SEVERE HEART FAIL PAST 4 MON	<input type="text" value="(1)Class I"/>
1	2B	IS THIS THE FIRST EPISODE OF CHF SINCE STUDY ENTRY	<input type="text"/>

Entry Mode: FAX

APPENDIX M (Continued)  
 CORRECTION IN RESPONSE TO EDIT STATEMENT

**OCCLUDED ARTERY TRIAL (OAT)**  
**Cardiovascular Status Outcome**  
**Follow-Up Form**

OAT Form 12  
 Rev 1  
 04/14/2003  
 1 of 1 Page

24469

Please Use Black Pen To Fill Out Form.

Patient's ID Number:  -  Letter Code:  Correction ●

Date of Follow-Up:  -  -   Not Done  
mmm dd yyyy

Period: 4 mo  12 mo  24mo  36 mo  48 mo  60 mo

---

1. Have you had angina pectoris or an anginal equivalent during the past four months?  Yes  No  Uncertain  
 If Yes, answer A.

A. Rate the patient's anginal status (Canadian Cardiovascular Society Classification).

Ordinary physical activity, such as walking and climbing stairs, does not cause angina. Angina results from strenuous or rapid or prolonged exertion at work or recreation.  Class I

Slight limitation of ordinary activity. Angina results from walking or climbing stairs rapidly, walking uphill, walking or stair climbing after meals, in cold, in wind, or when under emotional stress, or only during the few hours after awakening. Walking more than two blocks on the level and more than one flight of stairs at a normal pace and under normal conditions results in angina.  Class II

Marked limitation of ordinary physical activity. Angina results from walking one or two blocks on the level and climbing one flight under normal conditions.  Class III

Inability to carry on any physical activity without discomfort, anginal syndrome may be present at rest.  Class IV

2. Have you been diagnosed or treated for congestive heart failure in the past four months?  Yes  No  Uncertain  
 If Yes, answer A and B.

A. Rate the patient's most severe heart failure in the past four months using the following functional classification (New York Heart Association Function Classification):

No symptoms with ordinary physical exertion.  Class I

Symptoms with ordinary activity (activities of daily living). Slight limitation of activity.  Class II

Symptoms with less than ordinary activity. Marked limitation of activity.  Class III (Complete Form 18)

Symptoms with any physical activity or even at rest.  Class IV (Complete Form 18)

B. Is this the first episode of CHF since study entry? (i.e. CHF has not previously been diagnosed after randomization)  Yes  No  Uncertain

Signature: Your signature  -   
OAT Staff Number

**FAX to MMRI (410) 323 - 4729**