Prevention of Events with Angiotensin Converting Enzyme Inhibition (PEACE) Trial

Limited Access Data Set Documentation

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1 Overview of the Limited Access Data Set

This CD contains documentation and data comprising the Limited Access Data Set for the Prevention of Events with Angiotensin Converting Enzyme Inhibition (PEACE) trial.

This data release includes baseline and follow-up data collected from initiation of the trial November 1996 through the conclusion of the trial December 2003. Since the conclusion of the trial, additional ancillary data have become available, but are not part of this Limited Access Data Set. Separate limited access data releases for ancillary data will become available at later dates. The PEACE commercial purpose data set is the same as the non-commercial data set, so only one data set is provided.

2 PEACE Publications and Ancillary Studies Committee

The PEACE Publications and Ancillary Studies Committee plans to remain active and requests that investigators share their proposals/analysis plans with the Committee so that the Committee can encourage collaborations and avoid redundancies. Please send an e-mail to Drs. Eugene Braunwald, Marc Pfeffer and Bernard Gersh, expressing your interest in and your proposed use of the PEACE limited access data set. Their e-mail addresses are: EBraunwald@partners.org, MPfeffer@rics.bwh.harvard.edu, Gersh.Bernard@mayo.edu

3 Description of the Trial

3.1 Purpose

The goal of the PEACE trial was to test whether ACE-inhibitor therapy, when added to modern conventional therapy, would reduce the rate of nonfatal myocardial infarction, death from cardiovascular causes, or coronary revascularization in low-risk patients with stable coronary artery disease and normal or slightly reduced left ventricular function.

3.2 Overall Study Design

The trial was a double-blind, placebo-controlled study in which 8290 patients were randomly assigned to receive either trandolapril at a target dose of 4 mg per day (4158 patients) or matching placebo (4132 patients). Patients underwent randomization from November 1996 to June 2000 and were followed at six-month intervals for up to 7 years (median, 4.8 years), until December 31, 2003.

3.3 Inclusion criteria

- Age 50 years or older
- Coronary artery disease documented by at least one of the following:
  - Myocardial infarction at least 3 months before enrollment
  - Coronary-artery bypass grafting or percutaneous transluminal coronary angioplasty at least 3 months before enrollment
  - Obstruction of ≥50% of the luminal diameter of at least one native vessel on coronary angiography
- Left ventricular ejection fraction >40% on contrast or radionuclide ventriculography or echocardiography, a qualitatively normal left ventriculogram, or the absence of left

ventricular wall-motion abnormalities on echocardiography (a subgroup of echocardiograms was reviewed by a core laboratory to confirm eligibility)
- Toleration of the medication and successful completion of the run-in phase, with ≥80% compliance with the medication

3.4 Exclusion criteria

- Current use of or a current condition requiring use of an ACE inhibitor or a contraindication to ACE inhibitors
- Current use of an angiotensin II–receptor antagonist
- Hospitalization for unstable angina within the preceding 2 months
- Valvular heart disease deemed to require surgical intervention
- Coronary-artery bypass grafting or percutaneous transluminal angioplasty within the preceding 3 months
- Planned elective coronary revascularization
- Serum creatinine >2.0 mg/dl (177 μmol/liter)
- Serum potassium >5.5 mmol/liter
- Limited chance of 5-yr survival
- Psychosocial condition precluding long-term adherence
- Unable or unwilling to give consent
- Female sex and of childbearing potential and not using contraception
- Current use in a research trial of medication not approved by the U.S. Food and Drug Administration or the Health Protection Branch of the Canadian Department of National Health and Welfare

3.5 Study Organization

The PEACE trial was sponsored by the National Institutes of Health (NIH), National Heart, Lung, and Blood Institute (NHLBI). An independent data and safety monitoring board reviewed patient safety data and interim results. An executive committee and a steering committee provided scientific leadership and a clinical and statistical coordinating center coordinated all elements of the trial. An Italian coordinating center oversaw the data collection process in Italy. Patients were enrolled from 187 clinics in the United States (including Puerto Rico), Canada, and Italy. Study medication was distributed by a central pharmacy. All specimens went to a central laboratory and a morbidity and mortality review committee adjudicated outcomes. A publications and ancillary studies committee reviewed and approved proposals, manuscripts and presentations.

3.6 Outcomes documentation and adjudication

The following outcomes were classified by centrally-trained, local staff and confirmed by outcomes staff at the coordinating center through review of medical records:

- Coronary-artery bypass grafting
- Percutaneous coronary intervention
- Hospitalization for unstable angina
- Peripheral vascular disease requiring angioplasty, bypass grafting, or aneurysm repair
- Hospitalization for congestive heart failure
- Hospitalization for cardiac arrhythmia

A morbidity and mortality review committee conducted a further review of medical records, and classified and adjudicated the following outcomes:

- Cardiovascular death
- Non-cardiovascular death
- Death from unknown causes
- Myocardial infarction

Further review of medical records by one of the morbidity and mortality review committee members was conducted for the following outcome:

- Stroke

All reviews were blinded to the study intervention.

The following outcome was ascertained by patient self-report:

- New-onset diabetes

4 Files and documents on the CD

4.1 Limited Access Data Set as SAS CPORT transport library

- *PEACEDAT.CPORT* (SAS CPORT transport library)
    - This transport library can be imported into any system (PC, Unix, Mainframe OS, etc.). For instructions on importing the files, please see Section 6 "***Installing the SAS Files.***" Conversion of the files using CIMPORT is required.

4.2 Limited Access Data Set as PC SAS datasets

- *Dataset LADS.PRERAND* *File name prerand.sas7bdat*
- *Dataset LADS.RAND* *File name rand.sas7bdat*
- *Dataset LADS.FOLLOWUP* *File name followup.sas7bdat*
- *Dataset LADS.OUTCOMES* *File name outcomes.sas7bdat*
    - For investigators that use PC SAS, these files can be read in directly by PC SAS versions 7, 8 and 9. No import program is necessary.

4.3 Import program

- *PEACE_Import.sas* (SAS program)

4.4 Readme document

- *PEACE Readme.pdf* (pdf document)

4.5 Protocol

- *PEACE Protocol.pdf* (pdf document)

4.6 Data Collection Forms with Variable Names

- *PEACE Screening Visit Form.pdf* (pdf document)
- *PEACE Pre Randomization Visit Form.pdf* (pdf document)
- *PEACE Randomization Visit Form.pdf* (pdf document)
- *PEACE Follow Up Visit Form.pdf* (pdf document)

4.7 Informed Consent Forms

- *PEACE Informed Consent Form Baseline.pdf* (pdf document)
- *PEACE Informed Consent Form Addendum.pdf* (pdf document)

4.8 List of Publications

- *PEACE List of Publications.pdf* (pdf document)

5 Description of System Requirements

- CD-ROM drive
- A working installation of the SAS system version 8 or later

6 Installing the SAS Files

6.1 PC SAS users:

- Copy the PC SAS datasets from the CD to a directory on the system running the SAS software. The PC SAS format files can be read in directly by PC SAS versions 7, 8 and 9. No import program is necessary.

6.2 All other users (Unix, Mainframe OS, etc.):

- Transfer the SAS CPORT transport library from the CD to a directory on the system running the SAS software. The transfer must be made using binary format.

- Execute a program such as the one below to read the transport library and convert it to a native SAS library format suitable for your operating system. Remember to change the directory and file names appropriately. This program is included on the CD, called "*PEACE_Import.sas*."

```
filename xin 'C:\Peace\SAS Data\peacedat.cport';
LIBNAME LADS 'C:\Peace\SAS Data';
PROC CIMPORT LIBRARY=LADS INFILE=XIN MEMTYPE=ALL;
run;
```

- The imported datasets are:
    - LADS.PRERAND (SAS data file)
    - LADS.RAND (SAS data file)
    - LADS.FOLLOWUP (SAS data file)
    - LADS.OUTCOMES (SAS data file)

7 Contents of the PEACE Limited Access Data Set

The next section lists all variables in the limited access dataset, which are organized by the data file from which they can be found. Each variable includes its name, descriptions of recoding if performed and other pertinent information.

Each data set file includes a participant ID that links all data set files. The IDs provided are not the original PEACE participants' IDs, but new random participant IDs ("NEW_ID") designed for use in the PEACE limited access data release. Merge data files by this variable.

7.1 Contents of LADS.PRERAND

The data in the LADS.PRERAND dataset correspond to the *PEACE Screening Visit* and the *PEACE Pre Randomization Visit* forms. The screening visit included a brief questionnaire to ascertain eligibility. The pre-randomization visit was then completed on all eligible patients who consented to the study. At the pre-randomization visit, patients were given active drug for a two-week run-in period. All measurements in this data set are pre-randomization and are pre-run-in to active treatment.

#	Variable	Type	Label	Comments
8	AGE	Num	AGE AT RANDOMIZATION	Units = years Recoded age > 80 = 83
2	DIABP	Num	SITTING DIASTOLIC BLOOD PRESSURE	Units = mmHg Recoded diastolic blood pressure < 57 = 53 Recoded diastolic blood pressure > 95 = 102
9	EGFR	Num		Units = $mL \cdot min^{-1} \cdot 1.73\ m^{-2}$ Calculated eGFR (estimated glomerular filtration rate) using the following 4-variable Modification of Diet in Renal Disease equation (Levey et al, *Ann Intern Med*. 1999;130:461- 470): eGFR = 186 X (serum creatinine in mg/dL)$^{-1.154}$ X (age in years)$^{-0.203}$ X (0.742 if female) X (1.21 if black) Recoded eGFR < 40 = 37 Recoded eGFR > 136 = 160
10	GENDER	Num	PATIENT GENDER	1 = female 2 = male
5	NEW_ID	Num	RANDOMLY CHOSEN ID	**Merge data files by this variable**
3	PHDIZZ	Num	PRIOR HISTORY OF DIZZINESS	1 = yes 2 = no
4	PHSYNC	Num	PRIOR HISTORY OF SYNCOPE	1 = yes 2 = no
6	SER_CHOL	Num	SERUM CHOLESTEROL	Units = mg/dL Recoded serum cholesterol < 135 = 122 Recoded serum cholesterol > 320 = 361
7	SER_POT	Num	SERUM POTASSIUM	Units = mEq/dL Recoded serum potassium < 3.5 = 3.3 Recoded serum potassium > 5.2 = 5.4
1	SYSBP	Num	SITTING SYSTOLIC BLOOD PRESSURE	Units = mmHg Recoded systolic blood pressure < 101 = 98 Recoded systolic blood pressure > 179 = 184

7.2 Contents of LADS.RAND

The data in the LADS.RAND dataset correspond to the *PEACE Randomization Visit* form. Patients returned 10-20 days following the pre-randomization visit for their randomization visit, in which side effects and compliance to the run-in period was assessed. Compliant patients willing to continue in the study were randomly assigned to active drug or to placebo. Data collected, and measurements obtained, at the randomization visit were collected following the two-week run-in period, when all patients were on active drug.

#	Variable	Type	Label	Comments
16	ANARRC	Num	USE OF ANTI-ARRHYTHMIC	1 = yes 2 = no
17	ANTICO	Num	USE OF ANTICOAGULANTS	1 = yes 2 = no
18	ASANT	Num	USE OF ASPIRIN OR ANTIPLATELET THERAPY	1 = yes 2 = no
12	BEBLOC	Num	USE OF BETA BLOCKER	1 = yes 2 = no
11	CALCBL	Num	USE OF CALCIUM CHANNEL BLOCKER	1 = yes 2 = no
9	CIGARE	Num	CIGARETTE USE	1 = current 2 = ever 3 = never
38	CMOTH	Num	USE OF OTHER CARDIAC MEDICATION	1 = yes 2 = no
7	COUGH	Num	COUGH	1 = yes 2 = no
45	DATEANGI_X	Num	DAYS SINCE RANDOMIZATION OF ANGIOGRAM	Units = days Calculated date of event - date of randomization = days since randomization
47	DATECABG_X	Num	DAYS SINCE RANDOMIZATION OF CABG	Units = days Calculated date of event - date of randomization = days since randomization
44	DATEMI_X	Num	DAYS SINCE RANDOMIZATION OF MOST RECENT MI	Units = days Calculated date of event - date of randomization = days since randomization
48	DATEODLV_X	Num	DAYS SINCE RANDOMIZATION OF LVE	Units = days Calculated date of event - date of randomization = days since randomization
46	DATEPTCA_X	Num	DAYS SINCE RANDOMIZATION OF PTCA	Units = days Calculated date of event - date of randomization = days since randomization

#	Variable	Type	Label	Comments
21	DIABTC	Num	IS PATIENT KNOWN TO BE DIABETIC?	1 = yes 2 = no The variables DIABET and DIABTC from this data file can be used to establish patients with diabetes at baseline
24	DICONL	Num	USE OF DIET CONTROL	1 = yes
15	DIGITS	Num	USE OF DIGITALIS	1 = yes 2 = no
3	DIZZIN	Num	DIZZINESS	1 = yes 2 = no
6	HEADAC	Num	HEADACHE	1 = yes 2 = no
28	HIANGINA	Num	HISTORY OF ANGINA	1 = yes 2 = no
33	HIANGIOG	Num	ANGIOGRAPHIC CORONARY DISEASE	1 = yes 2 = no
35	HICCABG	Num	HISTORY OF CABG	1 = yes 2 = no
29	HICLAUDI	Num	HISTORY OF INTERMITTENT CLAUDICATION	1 = yes 2 = no
27	HIDIABET	Num	HISTORY OF DIABETES	1 = yes 2 = no The variables DIABET and DIABTC from this data file can be used to establish patients with diabetes at baseline
26	HIHYPERT	Num	HISTORY OF HYPERTENSION	1 = yes 2 = no
32	HIMI	Num	HISTORY OF DOCUMENTED MI	1 = yes 2 = no
34	HIPTCA	Num	HISTORY OF PTCA	1 = yes 2 = no
31	HISTROKE	Num	HISTORY OF STROKE	1 = yes 2 = no
30	HITIA	Num	HISTORY OF TIA	1 = yes 2 = no
19	HPREP	Num	USE OF HORMONE REPLACEMENT THERAPY	1 = yes 2 = no

#	Variable	Type	Label	Comments
42	HT_CM	Num		Units = cm In gender = 1 (female): Recoded height < 145 = 140 Recoded height 145-149 = 147 Recoded height 150-154 = 152 Recoded height 155-159 = 157 Recoded height 160-164 = 161 Recoded height 165-169 = 166 Recoded height 170-174 = 171 Recoded height > 174 = 179 In gender = 2 (male): Recoded height < 150 = 144 Recoded height 150-154 = 152 Recoded height 155-159 = 157 Recoded height 180-184 = 181 Recoded height 185-189 = 186 Recoded height 190-194 = 191 Recoded height > 194 = 198
22	INSLIN	Num	USE OF INSULIN	1 = yes
20	LIPLOW	Num	USE OF LIPID LOWERING THERAPY	1 = yes 2 = no
39	LVEDOC	Num	LEFT VENTRICULAR EVAL. DOCUMENTED BY	1 = contrast ventriculography 2 = radionuclide ventriculography 3 = echocardiogram
36	LVEEJF	Num	LEFT VENTRICULAR EJECTION FRACTION	Units = percent Recoded left ventricular ejection fraction < 45 = 42 Recoded left ventricular ejection fraction > 84 = 88
25	MOTHER	Num	USE OF OTHER NON-CARDIAC MEDICATION	1 = yes 2 = no
37	NEW_ID	Num	RANDOMLY CHOSEN ID	**Merge data files by this variable**
10	NSYANG	Num	CURR. CCS FUNCTIONAL CLASSIFICATION	1 = no symptoms of angina 2 = class I 3 = class II 4 = class III+ Recoded code 5 = 4
23	ORAGEN	Num	USE OF ORAL AGENTS	1 = yes
14	OTDIUR	Num	USE OF OTHER DIURETICS	1 = yes 2 = no
13	POSPDI	Num	USE OF POTASSIUM SPARING DIURETICS	1 = yes 2 = no
41	QUALAB	Num	LV FUNCTION QUALITATIVELY ABNORMAL	1 = yes 2 = no

#	Variable	Type	Label	Comments
40	QUANEF	Num	QUANTITATIVE EJECTION FRACTION AVAIL.	1 = yes 2 = no
2	SDIABP	Num	SITTING DIASTOLIC BLOOD PRESSURE	Units = mmHg Recoded diastolic blood pressure < 55 = 51 Recoded diastolic blood pressure > 93 = 99
5	SKINRA	Num	SKIN RASH	1 = yes 2 = no
1	SSYSBP	Num	SITTING SYSTOLIC BLOOD PRESSURE	Units = mmHg Recoded systolic blood pressure < 101 = 97 Recoded systolic blood pressure > 169 = 177
4	SYNCOP	Num	SYNCOPE	1 = yes 2 = no
43	TX	Num	TREATMENT GROUP	0 = placebo 1 = active drug, trandolapril
8	WT_KG	Num	WEIGHT KG	Units = kg In gender = 1 (female): Recoded weight < 50 = 45 Recoded weight 50-54 = 52 Recoded weight 80-84 = 82 Recoded weight 85-89 = 87 Recoded weight 90-94 = 92 Recoded weight 95-99 = 96 Recoded weight 100-104 = 101 Recoded weight 105-109 = 106 Recoded weight > 109 = 116 In gender = 2 (male): Recoded weight < 55 = 51 Recoded weight 55-59 = 57 Recoded weight 115-119 = 117 Recoded weight 120-124 = 122 Recoded weight 125-129 = 127 Recoded weight 130-134 = 131 Recoded weight > 134 = 143

7.3 Contents of LADS.FOLLOWUP

The data in the LADS.FOLLOWUP dataset correspond to the *PEACE Follow Up Visit* form. Follow-up visits were conducted every six months.

#	Variable	Type	Label	Comments
31	ACE	Num	USE OF OPEN LABEL ACE INHIBITOR	1 = yes 2 = no Earlier versions of the follow-up form did not have this variable During the first few years of the study, this variable was optional at semi-annual (odd numbered) follow-up visits
26	AGENTS	Num	USE OF ORAL AGENTS	1 = yes During the first few years of the study, this variable was optional at semi-annual (odd numbered) follow-up visits
19	ANARHY	Num	USE OF ANTI-ARRHYTHMICS	1 = yes 2 = no During the first few years of the study, this variable was optional at semi-annual (odd numbered) follow-up visits
20	ANTICO	Num	USE OF ANTICOAGULANTS	1 = yes 2 = no During the first few years of the study, this variable was optional at semi-annual (odd numbered) follow-up visits Earlier versions of this form had this variable; later versions had “Use of warfarin or coumadin”
32	ARB	Num	USE OF ANGIOTENSIN II RECEPTOR BLOCKER -	1 = yes 2 = no Earlier versions of the follow-up form did not have this variable
21	ASPANT	Num	USE OF ASPIRIN OR ANTIPLATELET THERAPY	1 = yes 2 = no During the first few years of the study, this variable was optional at semi-annual (odd numbered) follow-up visits Earlier versions of this form had this variable; later versions had “Use of aspirin” and “Use of other antiplatelet agents”
34	ASPIR	Num	USE OF ASPRIN	1 = yes 2 = no Later versions of this form had this variable; earlier versions had “Use of aspirin or other antiplatelet therapy”

#	Variable	Type	Label	Comments
15	BEBLOC	Num	USE OF BETA BLOCKER	1 = yes 2 = no During the first few years of the study, this variable was optional at semi-annual (odd numbered) follow-up visits
14	CALCBL	Num	USE OF CALCIUM CHANNEL BLOCKER	1 = yes 2 = no During the first few years of the study, this variable was optional at semi-annual (odd numbered) follow-up visits
12	CIGARE	Num	CIGARETTE USE	1 = current 2 = ever 3 = never During the first few years of the study, this variable was optional at semi-annual (odd numbered) follow-up visits
8	COUGH	Num	PATIENT EXPERIENCED COUGH	1 = yes 2 = no
24	DIABTC	Num	PATIENT KNOWN TO BE DIABETIC	1 = yes 2 = no During the first few years of the study, this variable was optional at semi-annual (odd numbered) follow-up visits This variable from this data file was used to establish the outcome of new-onset diabetes
27	DIETCT	Num	USE OF DIET CONTROL	1 = yes During the first few years of the study, this variable was optional at semi-annual (odd numbered) follow-up visits
18	DIGITS	Num	USE OF DIGITALIS	1 = yes 2 = no During the first few years of the study, this variable was optional at semi-annual (odd numbered) follow-up visits
4	DIZZI	Num	PATIENT EXPERIENCED DIZZINESS	1 = yes 2 = no
30	FATGUE	Num	PATIENT EXPERIENCED FATIGUE	1 = yes 2 = no Earlier versions of the follow-up form did not have this variable
10	FORMDATE_FOLLOWUP	Num	DAYS SINCE RANDOMIZATION	Units = days Calculated date of follow-up visit - date of randomization = days since randomization
7	HEADCH	Num	PATIENT EXPERIENCED HEADACHE	1 = yes 2 = no
22	HORREP	Num	USE OF HORMONE REPLACEMENT THERAPY	1 = yes 2 = no During the first few years of the study, this variable was optional at semi-annual (odd numbered) follow-up visits

#	Variable	Type	Label	Comments
25	INSULN	Num	USE OF INSULIN	1 = yes During the first few years of the study, this variable was optional at semi-annual (odd numbered) follow-up visits
23	LIPLOW	Num	USE OF LIPID-LOWERING THERAPY	1 = yes 2 = no During the first few years of the study, this variable was optional at semi-annual (odd numbered) follow-up visits
9	NEW_ID	Num	RANDOMLY CHOSEN ID	**Merge data files by this variable**
33	NITRO	Num	USE OF NITRO	1 = yes 2 = no Earlier versions of the follow-up form did not have this variable
28	NONCAR	Num	OTHER NON-CARDIAC MEDICATION	1 = yes 2 = no During the first few years of the study, this variable was optional at semi-annual (odd numbered) follow-up visits
13	NSYANG	Num	CURR. CCS FUNCTIONAL CLASSIFICATION	1 = no symptoms of angina 2 = class I 3 = class II+ Recoded codes 4-5 = 3 During the first few years of the study, this variable was optional at semi-annual (odd numbered) follow-up visits
17	OTDIUR	Num	USE OF OTHER DIURETICS	1 = yes 2 = no During the first few years of the study, this variable was optional at semi-annual (odd numbered) follow-up visits
29	OTHCAR	Num	OTHER CARDIAC MEDICATION	1 = yes 2 = no During the first few years of the study, this variable was optional at semi-annual (odd numbered) follow-up visits
37	OXID	Num	USE OF ANY ANTIOXIDANTS	1 = yes 2 = no Earlier versions of the follow-up form did not have this variable
35	PLATE	Num	USE OF OTHER ANTIPLATELET AGENTS	1 = yes 2 = no Later versions of this form had this variable; earlier versions had “Use of aspirin or other antiplatelet therapy”
16	POSPDI	Num	USE OF POTASSIUM-SPARING DIURETICS	1 = yes 2 = no During the first few years of the study, this variable was optional at semi-annual (odd numbered) follow-up visits

#	Variable	Type	Label	Comments
3	SDIABP	Num	SITTING DIASTOLIC BLOOD PRESSURE	Units = mmHg Recoded diastolic blood pressure < 55 = 51 Recoded diastolic blood pressure > 93 = 99
6	SKRASH	Num	PATIENT EXPERIENCED SKIN RASH	1 = yes 2 = no
2	SSYSBP	Num	SITTING SYSTOLIC BLOOD PRESSURE	Units = mmHg Recoded systolic blood pressure < 101 = 97 Recoded systolic blood pressure > 169 = 177
39	STRENGTH	Num	DOSAGE	1 = 1 mg 2 = 2 mg 3 = 4 mg 4 = off
5	SYSCPE	Num	PATIENT EXPERIENCED SYNCOPE	1 = yes 2 = no
1	VISIT	Num	PEACE VISIT NUMBER	Visit number 1 was conducted approximately 6 months after randomization; visit number 2 was conducted approximately 1 year after randomization; visit number 3 was conducted approximately 1.5 years after randomization, etc
38	VITMIN	Num	USE OF OTHER VITAMINS BEYOND MULTIVITAMI	1 = yes 2 = no Earlier versions of the follow-up form did not have this variable

#	Variable	Type	Label	Comments
36	WARF	Num	USE OF WARFARIN OR COUMADIN	1 = yes 2 = no Later versions of this form had this variable; earlier versions had “Use of anticoagulants”
11	WT_KG	Num	WEIGHT KG	Units = kg In gender = 1 (female): Recoded weight < 50 = 45 Recoded weight 50-54 = 52 Recoded weight 80-84 = 82 Recoded weight 85-89 = 87 Recoded weight 90-94 = 92 Recoded weight 95-99 = 96 Recoded weight 100-104 = 101 Recoded weight 105-109 = 106 Recoded weight > 109 = 116 In gender = 2 (male): Recoded weight < 55 = 51 Recoded weight 55-59 = 57 Recoded weight 115-119 = 117 Recoded weight 120-124 = 122 Recoded weight 125-129 = 127 Recoded weight 130-134 = 131 Recoded weight > 134 = 143 During the first few years of the study, this variable was optional at semi-annual (odd numbered) follow-up visits

7.4 Contents of LADS.OUTCOMES

The data in the LADS.OUTCOMES dataset includes data on outcomes, days since randomization for these outcomes, and total days of follow-up. Please see Section 3.6 "***Outcomes documentation and adjudication***" regarding the adjudication process for the outcomes.

#	Variable	Type	Label	Comments
22	ARR	Num	CARDIAC ARRYTHMIA REQUIRING HOSPITALIZATION	This is a non-fatal outcome
21	ARRDT	Num	CARDIAC ARRYTHMIA REQUIRING HOSPITALIZATION DATE	Units = days Calculated date of event - date of randomization = days since randomization
16	CABG	Num	CABG	This is a non-fatal outcome
17	CABGDT	Num	CABG DATE;	Units = days Calculated date of event - date of randomization = days since randomization
10	CHF	Num	CHF(HOSP)	This is a non-fatal outcome
11	CHFDT	Num	CHF(HOSP) DATE	Units = days Calculated date of event - date of randomization = days since randomization
3	CVDEATH	Num	CARDIOVASCULAR DEATH	This is deaths due to cardiovascular causes
29	CVDEATHDT	Num	CARDIOVASCULAR DEATH DATE	Units = days Calculated date of event - date of randomization = days since randomization
31	DAYSSINCERAND	Num	DAYS FOLLOWUP	Units = days Calculated date of last visit - date of randomization = days since randomization
5	DEATH	Num	DEATH	This is all deaths
18	DEATHDT	Num	DEATH DATE	Units = days Calculated date of event - date of randomization = days since randomization
7	MI	Num	MYOCARDIAL INFARCTION (NON-FATAL)	This is a non-fatal outcome
6	MIDT	Num	MYOCARDIAL INFARCTION (NON-FATAL) DATE	Units = days Calculated date of event - date of randomization = days since randomization
28	NEWDM	Num	NEW DIABETES	This is a non-fatal outcome This is new-onset diabetes; the variable DIABTC from the LADS.FOLLOWUP data file was used to establish new-onset diabetes; those with diabetes at baseline were not at risk for his outcome; the variables DIABET and DIABTC from the LADS.RAND data file can be used to establish patients with diabetes at baseline

#	Variable	Type	Label	Comments
27	NEWDMDT	Num	NEW DIABETES DATE	Units = days Calculated date of visit in which patient self-repotted diabetes - date of randomization = days since randomization
1	NEW_ID	Num	RANDOMLY CHOSEN ID	**Merge data files by this variable**
25	ORIGINAL	Num	ORIGINAL PEACE OUTCOME	This is a composite outcome of death from cardiovascular causes or non-fatal MI
26	ORIGINALDT	Num	ORIGINAL PEACE OUTCOME DATE	Units = days Calculated date of event - date of randomization = days since randomization
4	OTHERDEATH	Num	DEATHS FROM NON-CV OR UNKNOWN CAUSES	This is deaths due to non-cardiovascular or unknown causes
30	OTHERDEATHDT	Num	DEATHS FROM NON-CV OR UNKNOWN CAUSES DATE	Units = days Calculated date of event - date of randomization = days since randomization
23	PRIMARY	Num	PRIMARY PEACE OUTCOME	This is a composite outcome of death from cardiovascular causes, non-fatal MI, CABG or PTCA
24	PRIMRYDT	Num	PRIMARY PEACE OUTCOME DATE	Units = days Calculated date of event - date of randomization = days since randomization
8	PTCA	Num	PTCA	This is a non-fatal outcome
9	PTCADT	Num	PTCA DATE	Units = days Calculated date of event - date of randomization = days since randomization
12	PVASC	Num	PERIPHERAL VASCULAR DISEASE	This is a non-fatal outcome
13	PVASCDT	Num	PERIPHERAL VASCULAR DISEASE DATE	Units = days Calculated date of event - date of randomization = days since randomization
20	STROKE	Num	NON-FATAL STROKE	This is a non-fatal outcome
19	STROKEDT	Num	NON FATAL STROKE DATE	Units = days Calculated date of event - date of randomization = days since randomization
14	UA	Num	UNSTABLE ANGINA	This is a non-fatal outcome
15	UADT	Num	UNSTABLE ANGINA DATE	Units = days Calculated date of event - date of randomization = days since randomization
2	VISIT	Num	PEACE VISIT NUMBER	Visit number 1 was conducted approximately 6 months after randomization; visit number 2 was conducted approximately 1 year after randomization; visit number 3 was conducted approximately 1.5 years after randomization, etc

8 Frequency Distribution for Selected Key Variables

8.1 Frequency Distribution for Selected Baseline Variables

Variable	Dataset	Description	Mean ± SD	Percent
AGE	LADS.PRERAND	Age at randomization	64 ± 8	
GENDER	LADS.PRERAND	Gender		18 (female)
SYSBP	LADS.PRERAND	Pre-randomization (pre-run-in) systolic blood pressure	133 ± 17	
DIABP	LADS.PRERAND	Pre-randomization (pre-run-in) diastolic blood pressure	78 ± 10	
EGFR	LADS.PRERAND	Estimated glomerular filtration rate	78 ± 19	
SER_CHOL	LADS.PRERAND	Serum cholesterol	192 ± 39	
LVEEJF	LADS.RAND	Left ventricular ejection fraction	58 ± 9	
CIGARE	LADS.RAND	Cigarette use		14 (current) 61 (ever) 24 (never)
HIMI	LADS.RAND	History of documented myocardial infarction		55
HIANGIOG	LADS.RAND	History of angiographic coronary disease		61
HIANGINA	LADS.RAND	History of angina		71
NSYANG	LADS.RAND	Canadian Cardiovascular Society functional classification of angina		72 (no symptoms) 18 (Class 1) 9 (Class 2) 1 (Class 3+)
HIPTCA	LADS.RAND	History of percutaneous coronary intervention		42
HICCABG	LADS.RAND	History of coronary-artery bypass grafting		39
HIHYPERT	LADS.RAND	History of hypertension		45
HISTROKE	LADS.RAND	History of stroke		4
HITIA	LADS.RAND	History of transient ischemic attack		3
DIABTC or HIDIABET	LADS.RAND	History of diabetes		17
CALCBL	LADS.RAND	Use of calcium channel blocker		35
BEBLOC	LADS.RAND	Use of beta blocker		60
ASANT	LADS.RAND	Use of aspirin or antiplatelet therapy		91
LIPLOW	LADS.RAND	Use of lipid lowering therapy		70
POSPDI	LADS.RAND	Use of potassium sparing diuretic		3
OTDIUR	LADS.RAND	Use of other diuretic		10
DIGITS	LADS.RAND	Use of digitalis		4
ANARRC	LADS.RAND	Use of anti-arrhythmic		2
ANTICO	LADS.RAND	Use of anticoagulant		5
INSLIN	LADS.RAND	Use of insulin		4
TX	LADS.RAND	Randomized treatment group		50/50

8.2 Number of outcomes

LADS.OUTCOMES Dataset	Outcome	N
ARR	Hospitalization for cardiac arrhythmia, non-fatal (2 have missing dates of cardiac arrhythmia)	393
CABG	Coronary-artery bypass grafting	565
CHF	Hospitalization for congestive heart failure, non-fatal	239
CVDEATH	Death from cardiovascular causes	298
DEATH	Death from all causes (3 have missing dates of death)	633
MI	Myocardial infarction, non-fatal	442
NEWDM	New-onset diabetes (self-reported)	734
ORIGINAL	Original PEACE outcome, a composite of death from cardiovascular causes or non-fatal MI	696
OTHERDEATH	Death from non-cardiovascular or unknown causes (3 have missing dates of death)	335
PRIMARY	Primary PEACE outcome, a composite of death from cardiovascular causes, non-fatal MI, CABG or PTCA	1838
PTCA	Percutaneous coronary intervention	1012
PVASC	Peripheral vascular disease requiring angioplasty, bypass grafting, or aneurysm repair, non-fatal	303
STROKE	Stroke, non-fatal	130
UA	Hospitalization for unstable angina, non-fatal	1010

Prevention of Events with Angiotensin Converting Enzyme Inhibition (PEACE) Trial

Limited Access Data Set Documentation Addendum

Version March 17, 2008

Table of Contents

1 Overview of the Addendum

During the course of investigators using the Limited Access Data Set for the Prevention of Events with Angiotensin Converting Enzyme Inhibition (PEACE) trial, questions often come up. This addendum provides clarification to one question raised.

2 Visit numbers out of order

Each visit (VISIT) has a corresponding days since randomization (FORMDATE_FOLLOWUP). There are four cases in which the patient appears to have a duplicate visit number. These are not duplicate visits, but rather incorrectly coded visit numbers. If you plan to use the visit number variable (VISIT) in any of your analyses, you should re-number the visits for these four cases. The four cases are summarized below.

NEW_ID	FORMDATE_FOLLOWUP	VISIT	VISIT recode
11262	172	01	
11262	364	02	
11262	571	03	
11262	717	04	
11262	914	05	
11262	1134	06	
11262	1250	07	
11262	1442	08	
11262	1644	09	
11262	1810	10	
11262	2012	11	
11262	2201	11	12
26959	175	01	
26959	287	02	
26959	377	03	
26959	571	04	
26959	762	05	
26959	951	06	
26959	1126	06	07
26959	1327	07	08
26959	1504	08	09
71700	174	01	
71700	372	02	
71700	553	03	

NEW_ID	FORMDATE_FOLLOWUP	VISIT	Suggested VISIT recode
71700	727	04	
71700	918	05	
71700	1092	06	
71700	1286	07	
71700	1489	08	
71700	1611	09	
71700	1801	10	
71700	1997	10	11
84311	193	01	
84311	311	02	
84311	549	03	
84311	743	04	
84311	921	05	
84311	1110	06	
84311	1267	07	
84311	1459	08	
84311	1659	09	
84311	1803	09	10
84311	1990	11	