README File
PROMISE Final Analysis Database
28MAR2016

Overview of data

The data for the PROMISE trial was collected and entered into an electronic CRF database then converted into SAS files. A process of redaction/summarization was performed to protect the privacy of study participants. The PROMISE trial CRF database contains 54 different datasets which correspond to the CRF annotation document where variables and code list decodes are given. 18 analysis datasets for the primary analysis are provided. The randomization assignment decodes are provided in the analysis dataset DEM. All variables ending "DT" are date variables and all variables ending with "TM" are date/time variables. All dates have been imputed with days from randomization. All date/time variables have been imputed with minutes from randomization. The analysis datasets contain the time event variables and are named with the leading "T2".

InForm Database (CRF database): All data collected in the PROMISE trial is contained in the InForm database. In the following sections the InForm database will be summarized with panel names and short data descriptions.

Randomization/Baseline data

InForm Panel Names	*Data Description*
DEMOG	This dataset contains data related patient demographics
ELIG	This dataset contains data related to the patient eligibility criteria.
RAND	This dataset contains data related to pre-randomization and randomization selections.
RAND1	This dataset contains data related to randomization arm and diagnostic test conducted
PREG	This dataset contains pregnancy test result data.
VITALS	This dataset contains vital signs collected at baseline.
CRDRSK	This dataset contains cardiac risk factors data at baseline.
PAPR	This dataset contains provider assessment of risk data at baseline.
PS1, PS2	This dataset contains presenting symptoms data.
DXLAB	This dataset contains diagnostic laboratory testing data.
ECG	This dataset contains ECG data.
PSQ	This dataset contains patient satisfaction questionnaire data.
MTLC	This dataset contains medical therapy and lifestyle counseling data.

Diagnostic test related and revascularization data

InForm Panel Names	*Data Description*
CTA, CTA2, CTA_CL	The data collected for the CTA diagnostic test which includes test results and radiation,.
ECHO1, ECHO2, ECHO_C	The data collected for the stress echo diagnostic test which include stress test results
EEST, EEST_CL	The data collected for the exercise ECG diagnostic test which include stress test results. Also includes ECG portion of stress echo and stress nuclear studies.

NUC1, NUC1_2, NUC2, NUC_CL	The data collected for the stress nuclear diagnostic test which include stress test results and radiation.
VPST VPST_2	The procedural data collected for the VASODILATOR PHARMACOLOGIC stress.
DBST	The procedural data collected for the DOBUTAMINE stress.
CC	The data collected for the diagnostic catheterizations which include stenosis results.
REVASC, REVASC1	These datasets contain revascularization procedure data

Visit Data

InForm Panel Names	*Data Description*
VISIT, DOV	These datasets contain patient visit date data.
TERM, FU. FU2	These datasets contain patient follow-status and clinical event review triggering data.
FU2_2	This dataset contains post 60 day diagnostic test data.
PTSTATUS	This dataset contains patient follow-up status.
STATUS	This dataset contains form tracking data from INFORM system.
CONMED, CM_CODING	These datasets contain the concomitant medication names and dictionary coding data.

Event/CEC Data

InForm Panel Names	*Data Description*
ANAPHY	This dataset contains CEC anaphylaxis event review data
ANGINA	This dataset contains CEC unstable angina event review data
BLEED	This dataset contains CEC bleeding event review data
CECINCAD, INCAD	These datasets contain CEC obstructive disease (OD) review data
DEATH	This dataset contains CEC cause of death data
STROKE	This dataset contains CEC stroke event review data
RENAL	This dataset contains CEC renal event review data
MI	This dataset contains CEC MI event review data
HOSPER	This dataset contains patient hospitalization and procedure follow-up data

Blood bio repository Data

InForm Panel Names	*Data Description*
BMKGEN, BMKGEN_2	Blood and genetic sample collection data

Primary Analysis Datasets: For the primary analysis a set of analysis datasets were derived and validated. In the following sections the analysis datasets will be summarized with dataset names and a short description.

Randomization

Analysis Dataset Name	*Data Description*
DEM	This dataset contains the demographic and randomization assignment variables. One observation per patient.

Primary and Secondary Time to Event data

Analysis Dataset Name	*Data Description*
ENDPTS	This dataset contains the time to event primary and secondary endpoints variables and component variables. One observation per patient.

Intermediate Event data

Analysis Dataset Name	*Data Description*
ANAL_COM	This dataset contains major complications event variables, suspected and CEC adjudicated. Multiple observations per patient are possible.
ANAL_MI	This dataset contains myocardial infraction event variables, suspected and CEC adjudicated. Multiple observations per patient are possible.
ANAL_UA	This dataset contains unstable angina event variables, suspected and CEC adjudicated. Multiple observations per patient are possible.

Follow-up data

Analysis Dataset Name	*Data Description*
CONMEDS	This dataset contains the concomitant medications variables. Multiple observations per patient.
FUSUM	This dataset contains the variables related to visits and follow-up. Multiple observations per patient.

Health Procedures and Episodes data

Analysis Dataset Name	*Data Description*
HOSPER	This dataset contains the variables related to hospital or ER visits in follow-up. Multiple observations per patient are possible.
REVASC	This dataset contains the variables related to revascularization (CABG and PCI) in follow-up. Multiple observations per patient are possible.

Baseline and Patient Characteristics

Analysis Dataset Name	*Data Description*
BASELINE	This dataset contains physical exam, ECG findings, cardiac risk factors, provider assessment of patient risks, primary symptoms, labs, risk score related variables, and symptoms variables at baseline. One observation per patient.
RISKSCR	This dataset contains a set of derived risk score variables at baseline. One observation per patient.

Diagnostic testing and radiation data

Analysis Dataset Name	*Data Description*
DIAGTST	This dataset contains the detailed data collected for the diagnostic test results (for exercise ECG, stress echo, stress nuclear, CTA, and catheterizations) along with safety and incidental findings. Primary derived data: Diagnostic test results Multiple observations for a patient are possible.
DIAGTST2	This dataset contains the data collected for the diagnostic test occurrences (for exercise ECG, stress echo, stress nuclear, CTA, and catheterizations) in follow-up. Multiple observations per patient are possible.
DIAGTSTR	This dataset contains the 1st diagnostic test result results. One observation per patient.
RADCAL	This dataset contains the radiation exposure data for individual tests (within 90 days). Multiple observations for a patient are possible.
RADCUM	This dataset contains the radiation exposure data for the 1st test and cumulative radiation exposure (within 90 days). One observation per patient.

Blood repository Data

Analysis Dataset Name	*Data Description*
ESOTERIX	Blood and genetic sample collection data
SUBSAMPLE	Blood and genetic sample collection data

Brief description of study

The PROMISE Trial - **PRO**spective **M**ulticenter **I**maging **S**tudy for **E**valuation of Chest Pain

The PROMISE Trial was a pragmatic randomized trial of clinical effectiveness of diagnostic testing strategies for CAD, performed in outpatient settings, including urgent care, primary care, and cardiology offices. Qualifying patients presenting with new or worsening symptoms suspicious for clinically significant CAD who require diagnostic testing and have not been previously evaluated for this episode of symptoms were randomized to an initial strategy of either anatomic or functional testing. All subsequent decisions regarding additional testing, medications, and/or procedures were at the discretion of the responsible clinical care team.
Within the functional testing arm, the subject's care team selected the specific test to be performed (exercise electrocardiogram, stress nuclear imaging, or stress echocardiogram) consistent with "usual care" in that practice setting. The subject's care team were provided with "Information sheets" summarizing current standards for test interpretation and preventive care, but specific medical treatment will not be mandated by the trial.
Primary Hypothesis: An initial anatomic testing strategy will provide information that will result in superior long-term health outcomes as compared with an initial functional testing strategy.
Primary Study Objective: To determine whether an initial noninvasive anatomic imaging strategy with coronary computed tomographic angiography (CTA) will improve clinical outcomes in subjects with symptoms concerning for CAD relative to an initial functional testing strategy.
Secondary Endpoints:

- Death or MI or unstable angina hospitalization
- Death or MI
- Major complications from cardiovascular procedures and testing (stroke, major bleeding, anaphylaxis, and renal failure requiring dialysis)
- Composite endpoint of the primary endpoint or invasive catheterization without obstructive CAD
- Invasive catheterization without obstructive CAD (Defined as no stenosis >= 50% in any major epicardial vessel including side branches ≥ 2 mm in diameter, on the first cath performed <= 60 days after randomization))
- Medical costs, resource use, and incremental cost effectiveness
- Health-related quality of life (QOL)

Secondary Safety Endpoint: Cumulative radiation exposure
Number of Subjects: 10,003 subjects were enrolled.
Number of Sites: 193
Enrollment period: July 27, 2010 to September 19, 2013
Last follow visit: October 31, 2014

Major Study Publications

Primary Manuscript

Douglas PS, Hoffmann U, Patel MR, Mark DB, Al-Khalidi HR, Cavanaugh B, Cole J, Dolor RJ, Fordyce CB, Huang M, Khan MA, Kosinski AS, Krucoff MW, Malhotra V, Picard MH, Udelson JE, Velazquez EJ, Yow E, Cooper LS, Lee KL; PROMISE Investigators. Outcomes of anatomical versus functional testing for coronary artery disease. N Engl J Med 2015;372:1291–1300

Listing of all files provided

- Protocol
  - PROMISE amendment 2_version 30 April 2013_Final.pdf
- Statistical Analysis Plan
  - PROMISE SAP Final.pdf
- Case Report Form Annotation
  - PROMISE CRF ANNO.xls
  - PROMISE_SASDATA_PROC_CONTENTS.pdf
- Analysis Datasets
  - PROMISE_Analysis_Datasets.pdf
  - PROMISE_SASDATA_PROC_CONTENTS.pdf
- SAS Transport files
  - PROMISE_SASDATA.xpt
  - PROMISE_ANALDATA.xpt

System requirements

SAS v9.4 has been used in all data manipulation and analyses. Earlier versions may work but have not been tested.

SAS code to convert from transfer files

Use the following SAS code to convert the transport files to SAS datasets.

```
libname out  "<<location where you want to output your SAS datasets>>";
filename trans "<<location of where your transport files are located/transport
file.xpt>>"

proc cimport infile=trans lib=out;
run;
```

Frequencies for selected key variables

The following table summarizes selected key variables:

Parameter Statistic	Anatomic Testing (N=4996)	Functional Testing (N=5007)
Age (years)		
N	4996	5007
Median (25^{th}, 75^{th})	59.8 (54.3, 65.9)	60.2 (54.6, 66.0)
Mean ± Std. Dev	60.7 ± 8.3	60.9 ± 8.3
Female	2595 (51.9%)	2675 (53.4%)
Weight (lb)		
N	4987	4996
Median (25^{th}, 75^{th})	189.0 (162.0, 219.0)	190.0 (162.0, 220.4)
Mean ± Std. Dev	193.4 ± 44.0	193.9 ± 44.2
Ethnicity (Hispanic or Latino)	393 (7.9%)	374 (7.5%)
Race		
White	4139 (83.6%)	4232 (85.3%)
Black or African American	563 (11.4%)	533 (10.7%)
Asian	139 (2.8%)	114 (2.3%)
American Indian/Alaska Native	38 (0.8%)	33 (0.7%)
Native Hawaiian or other Pacific Islander	11 (0.2%)	19 (0.4%)
More than one race	62 (1.3%)	33 (0.7%)