## **AASK Trial Analysis Files**

## June 12, 2006

As a supplement to the Oracle tables containing the contents of the AASK database, we are transmitting several SAS datasets containing key analysis files for the study. As with the Oracle tables, we are sending two sets of analysis files: One set associated with the database as of April 9, 2002, and the other with the current database. The analysis files corresponding to April 9, 2002 are contained in the archive AASK\_Analysis\_200249, and the analysis files corresponding to the current database are contained in the archive AASK\_Analysis\_Current.

Descriptions of the analysis files are as follows:

SAS Dataset	Description
Name	
demo	Contains 2802 records corresponding to the 2802 patients enrolled in the AASK trial, including both randomized and non-randomized participants. The file contains 102 fields corresponding to baseline characteristics and randomized treatment assignments. The baseline measurements were obtained primarily at one of three visits: SV2 = Main screening visit $G1 = 1^{st}$ GFR measurement visit $G2 = 2^{nd}$ GFR measurement visit The variable labels indicate the visits of the measurements used to define the different variables. For many variables, baseline values were defined as the value obtained at SV2 if the SV2 value was nonmissing, and as the value obtained at the G1 visit if the SV2 value was missing. Note that urine measurements were obtained once during baseline, at either the SV2 or the G1 visits.
basecov	Contains 1094 records providing values for selected baseline variables for the 1094 randomized patients. The baseline variables contained in this file were used for analyses relating baseline risk factors to outcomes observed during the follow-up period of the study. In a number of cases, measurements were averaged over two assessments. The variables grp1grp6 are indicators for randomized treatment assignment.
evnt_all	Contains information required for the conduct of time-to-event analyses related to the progression of kidney disease. Specifically, the file contains variables designating the duration of follow-up and 0-1 indicators for event status for each of the following outcomes: a) death prior to ESRD b) all reported deaths, prior to or following ESRD c) ESRD d) the composite of death and ESRD e) a confirmed GFR event (defined as a confirmed 50% reduction of 25

	<ul> <li>ml/min/1.73m2 decline in GFR from the mean of two baseline GFRs)</li> <li>f) the composite of dialysis or a GFR event,</li> <li>g) the composite of death, dialysis, or a GFR event.</li> <li>Note that in a number of cases the follow-up time variables</li> <li>corresponding to the above events are identical – for example, the</li> <li>follow-up time for ESRD or death is identical to the follow-up time for</li> <li>ESRD alone. Also note that in the AASK study, ESRD was always</li> <li>initiated by dialysis therapy, as no patients were transplanted without</li> <li>previously initiating dialysis.</li> </ul>
	This is the first of 3 time-to-event analysis files which treat the early termination of the CCB group in different ways. The file evnt_all censors all patients at the end of the trial unless they either were lost to follow-up, died, or reached ESRD prior to that date. For most patients, the end of the trial is defined as September 30, 2001. However, for several patients the administrative censoring data was extended to allow the patient to perform a confirmatory GFR for potential GFR events that were identified prior to September 30, 2001.
evt_0922	This time-to-event dataset is defined in the same way as evnt_all, except that the follow-up times for all patients are administratively censored on 9/22/2000 at the time that the CCB intervention was terminated unless the patient was lost to follow-up at an earlier date.
evnt_dat	This time-to-event dataset is defined similarly to evnt_all, except that follow-up time is censored at or near September 30, 2001 for patients randomized to the ACEi or BB groups, and as September 22, 2000 for patients randomized to the CCB groups.
gfr_scrp	This dataset contains longitudinal data including GFRs, serum measurements, and urine measurements for the 1094 randomized participants. The dataset also contains averages of blood pressure measurements over designated time periods, as well as selected baseline variables. The variables G_VIST, S_VIST and U_VIST designate the visit labels for GFR visits, serum visits and urine visits, respectively. Each one of these variables includes three components. The first component indicates the type of the visit, with S designating the primary screening visits, B designating baseline 24-Hr. Urines, G designating baseline GFR visits and F designating the follow-up visits. The second component designates the visit window number. The third component designates the visit sequence number within each visit window, with 0 indicating the protocol visit. The second and third components are separated by a period. For example, "G02.0" indicates the second baseline GFR visit and it is a protocol visit.

deviant from the remaining periods. The dataset gfr_scrp contains the
following GFR variables:
raw_gfrun = the original GFR prior to application of the above
algorithm, and expressed in ml/min without adjustment for body
surface area.
raw_gfrcv = the intra-test CV including each of the periods of the
original GFR.
gfrun = the corrected GFR in which extreme periods were deleted from
the computation, as noted above. Expressed without adjustment for
body surface, and expressed in ml/min.
gfrcv = intra-test CV of the GFR measurements used to compute
gfrun.
gfr_curbsa = gfrun adjusted to the patient's body surface area at the
time of the GFR measurement, expressed in ml/min/1.73m2.
gfr = gfrun adjusted to the patient's body surface area at baseline, and
expressed in ml/min/1.73m2. This was the GFR variable that was
used as the study's primary outcome.