

## **The AASK COHORT Study Data Archive**

The AASK Cohort Study was a prospective, observational study that was an extension of the AASK Clinical Trial. AASK Trial and Cohort data are housed separately in the NIDDK Repository. Users interested in materials from both Trial and Cohort studies must explicitly request both archives.

The AASK Cohort Archive contains the Protocol, Manual of Operations, Forms, and Study data. The files are organized into the following subdirectories:

- \AASK Cohort\_documentation
- \AASK Cohort\_forms
- \AASK Cohort\_datasets
- \AASK Cohort\_DSIC

### **\AASK Cohort Documentation**

The AASK Cohort Documentation directory contains:

- 03252004 Cohort Protocol.pdf -- AASK Cohort Protocol
- AASK Cohort MOOP.pdf – AASK Cohort Manual of Operations.

### **\AASK Cohort Forms**

This subdirectory contains 59 annotated data collection forms in PDF format, with 51 associated forms (“raw”) SAS datasets which are in a separate subdirectory (\AASK Cohort\_datasets). Note that there are more forms than datasets because: 1.) some individual datasets are associated with multiple forms, and 2.) some forms, such as the Suicide Question Response Form #163, did not have associated datasets submitted to the Repository.

Table 1 on the next page shows the Form to Dataset mapping.

**Table 1. AASK Cohort Study: Form to Dataset Mapping (continues next page)**

<b>Form count</b>	<b>Study form</b>	<b>Description</b>	<b>Dataset count</b>	<b>Associated SAS dataset(s) and applicable notes</b>
1	form081	Cohort Enrollment form	1	c_enroll_rep
2	form082	Social Security Number form		n/a*
3	form083	Reasons why an active AASK randomized trial patient did not enroll in the cohort study form	2	c_reason_not_enroll_rep
4	form084	Demographic medical history form	3	c_demo_rep
5	form085	Exposures Data form	4	c_exposures_rep
6	form086	PCA order form	5	c_pca_order_rep
7	form105	Pill dispensing form	6	c_pill_dispense_rep
8	form109	Blood pressure aneroid calibration form	7	c_bp_calibrate_rep
9	form110	Blood Pressure form	8	c_bp_rep
10	form111	Visit/Missed visit form	9	c_visit_rep
11	form113	Local lab results: CBC	10	c_local_lab_rep
12	form114	Central ECG mailing form	11	c_ecg_rep
13	form115	Central ECG results report <sup>o</sup>	12	ecg_data_rep
14	form116	Local ECG form	13	c_local_ecg_rep
15	form117	Echo mailing form	14	c_echo_rep
16	form119	Central Echo reading results report <sup>o</sup>	15	echo_data_rep
17	form120	Genetics blood mailing form for cohort study patients	16	c_genetics_rep
18	form121	ESRD genetics blood mailing form	17	c_esrd_rep
19	form122	CBL serum and plasma mailing form	18	c_cbl_mailing_serum_rep
20	form123	CBL urine mailing form (24-hr urine)	19	c_cbl_mailing_urine_rep
21	form124	Central serum and plasma results <sup>o</sup>	20	c_cbl_result_serum_rep
22	form125	Central urine results <sup>o</sup>	21	c_cbl_result_urine_rep
23	form127	CBL dry ice mailing form	22	c_cbl_mailing_dryice_rep
24	form128	Renal failure form	23	c_renal_failure_notify_rep
25	form129	Follow-up for patients on dialysis or transplanted	24	c_dialysis_rep
26	form137	Cardiovascular outcome committee death review form	25	c_cardio_death_revw_rep
27	form138	Cardiovascular outcome committee hospitalization review form	26	c_cardio_hosp_revw_rep
28	form139	Reasons patients missed visits form	27	c_missed_visit_rsn_rep
29	form140	Medication form <sup>^</sup>	28, 29	c_med_improved_rep <sup>^</sup> ; c_med_list_improved_rep <sup>^</sup>
30	form141	ESRD patient hospitalization form	30	c_esrd_hospital_rep
31	form144	Hospital admission notification form	31	c_hospital_admission_rep
32	form145	Hospitalization form	32	c_hospital_rep
33	form146	Participant transfer form	33	c_transfer_rep
34	form148	Death notification form	34	c_cc_death_rep
35	form150	Diminished cognitive function form	35	c_dim_cog_rep
36	form159	Reasons why cohort patients are not on ace or arb	36	c_no_acearb_rep
37	form160	High blood pressure form		n/a*
38	form161	Local ECG response form		n/a*
39	form162	Echo alert response form		n/a*
40	form163	Suicide form		n/a*
41	form168	CBL nail clipping mailing form	37	c_nail_mailing_rep
42	form170	ABPM placement, calibration and initializing form	38	c_abpm_placement_rep
43	form171	ABPM downloading, copy scan and mailing form	39	c_abpm_mailing_rep
44	form172	ABPM calibration form	40	c_abpm_calib_rep
45	form173	Central ABPM data form <sup>o</sup>	41	c_abpm_mailing_data_rep
46	form174	Sleep questionnaire form	42	c_sleep_q_rep
47	form175	Health maintenance questionnaire	43	c_hmq_rep
48	form180	SF 36 short form	44	c_sf_36
49	form186	Jackson heart study approach to life-A form	45	c_qol_a
50	form187	Jackson heart study approach to life-B form	46	c_qol_b

<b>Form count</b>	<b>Study form</b>	<b>Description</b>	<b>Dataset count</b>	<b>Associated SAS dataset(s) and applicable notes</b>
	<b>(form190)<sup>Δ</sup></b>	Beck Depression Inventory-II form	47	c_beck_rep
51	<b>form191</b>	Diener satisfaction of life	48	c_diener_rep
52	<b>form192</b>	CBL serum report template for clinical centers		n/a, report is populated by data in form124
53	<b>form193</b>	CBL urine report template for clinical centers		n/a, report is populated by data in form125
54	<b>form195</b>	Patient ABPM report	49	mean_abpm_data_rep
55	<b>form196</b>	Central ECG results report <sup>ο</sup>		n/a, this form is a revision to <b>form115</b> . Associated data are included in the aforementioned <b>ecg_data_rep</b> dataset.
56	<b>form197</b>	Central Echo reading results report <sup>ο</sup>		n/a, this form is a <b>revision to form119</b> . Associated data are included in the aforementioned <b>echo_data_rep</b> dataset.
57	<b>form197b</b>	Central Echo reading results report <sup>ο</sup>		n/a, this form is a revision to <b>form119/197</b> . Associated data are included in the <b>echo_data_rep</b> dataset mentioned above.
58	<b>form198</b>	Close out form	50	c_close_out_rep
59	<b>form199</b>	Post close out form	51	c_post_close_out_rep

\* n/a; data not submitted for this form.

<sup>Δ</sup> E-Mail communication from the data coordinating center: "the c\_med\_improved file is a one record per patient, per visit file; the c\_med\_list\_improved has one record per patient, per visit, per medication." Every patient-visit in c\_med\_list\_improved has a corresponding record in c\_med\_improved. The reverse is not true, because a small number of patients were not on any meds at a given visit.

<sup>Δ</sup> Due to copyright issues, the Beck Depression Inventory-II form is excluded from the Archive. The associated dataset is included. All remaining forms are either in the public domain, or were devised by the AASK Cohort study group and submitted to the Archive. (This was verified in E-mail communication exchanged between the DCC and the Repository communications group on 10/17/2011.)

<sup>ο</sup> Completed by Core Lab / Central Biochemistry Lab

## \AASK Cohort datasets

The AASK Cohort data directory contains the following datasets in *PC-SAS*, v.7-8-9 format, in the following subdirectories. (The user may find that the AASK Cohort datasets have more value when analyzed together with the AASK Trial datasets; both data archives must be explicitly requested. Datasets from AASK Trial and Cohort periods may be linked via the unique masked participant ID, <pid>.)

### AASK Cohort datasets\analysis dataset

cohort\_analysis.sas7bdat – This dataset contains key outcome variables, such as time to ESRD, extending from Trial to Cohort periods. It does not contain covariate data, which must be merged in from the forms data.

### AASK Cohort datasets/forms datasets

This directory contains 51 forms (raw) datasets in SAS format, corresponding with the forms described in Table 1. See Table 1 to see how datasets match to forms. Table 2 below is a simple alphabetical listing of the forms datasets.

**Table 2. Alphabetical listing of datasets derived from forms (continues next page)**

<b>#</b>	<b>SAS Dataset</b>
1	c_abpm_calib_rep
2	c_abpm_mailing_data_rep
3	c_abpm_mailing_rep
4	c_abpm_placement_rep
5	c_beck_rep
6	c_bp_calibrate_rep
7	c_bp_rep
8	c_cardio_death_revw_rep
9	c_cardio_hosp_revw_rep
10	c_cbl_mailing_dryice_rep
11	c_cbl_mailing_serum_rep
12	c_cbl_mailing_urine_rep
13	c_cbl_result_serum_rep
14	c_cbl_result_urine_rep
15	c_cc_death_rep
16	c_close_out_rep
17	c_demo_rep
18	c_dialysis_rep
19	c_diener_rep
20	c_dim_cog_rep

<b>#</b>	<b><u>SAS Dataset</u></b>
21	c_ecg_rep
22	c_echo_rep
23	c_enroll_rep
24	c_esrd_hospital_rep
25	c_esrd_rep
26	c_exposures_rep
27	c_genetics_rep
28	c_hmq_rep
29	c_hospital_admission_rep
30	c_hospital_rep
31	c_local_ecg_rep
32	c_local_lab_rep
33	c_med_improved_rep
34	c_med_list_improved_rep
35	c_missed_visit_rsn_rep
36	c_nail_mailing_rep
37	c_no_acearb_rep
38	c_pca_order_rep
39	c_pill_dispense_rep
40	c_post_close_out_rep
41	c_qol_a_rep
42	c_qol_b_rep
43	c_reason_not_enroll_rep
44	c_renal_failure_notify_rep
45	c_sf_36_rep
46	c_sleep_q_rep
47	c_transfer_rep
48	c_visit_rep
49	ecg_data_rep
50	echo_data_rep
51	mean_abpm_data_rep

## **AASK Cohort DSIC**

The AASK Cohort Data Integrity Check (DSIC) directory contains a report of an examination of the repository for completeness by statisticians and quality control specialists at the Repository. Datasets were checked for completeness. The published data from the AASK Cohort study were compared to values recalculated from the AASK Cohort data in the NIDDK repository.

## **AASK Cohort Biosamples**

In addition to the aforementioned study components, there are also biosamples available in the Repository.

See <https://www.niddkrepository.org/> for further details on these biosamples.

In summary, biosamples currently available from the AASK Cohort Study: Serum, Plasma, Frozen Plasma, Urine.

No other biosamples are expected.