

HALT Polycystic Kidney Disease Clinical Trials Network

ROADMAP

HALT-PKD Data Archive: Baseline and Follow-up Phase Data

The HALT-PKD trials are comprised of Study A and Study B with different participants in each study but with the same data at baseline and follow up visits. Study A uses a 2x2 factorial design testing low (systolic blood pressure 95-110 mmHg, diastolic 60-75 mmHg) versus standard blood pressure control (systolic 120-130 mmHg, diastolic 70-80 mmHg) and angiotensin-converting enzyme inhibitor (ACE-I) monotherapy to ACE and angiotensin receptor blocker (ARB) combination therapy in participants with polycystic kidney disease. Study B uses a standard parallel armed trial with participants randomized to ACE monotherapy or ACE/ARB combination therapy while having blood pressures controlled at one level for all (systolic blood pressure 110-130 mmHg; diastolic blood pressure 80 mmHg). The HALT-PKD data archive contains data collected during baseline and follow-up visits (5-8 years of follow up with 6-month clinic visits and 3 month telephone calls). In total, the HALT-PKD studies randomized n=1044 participants (Study A n=558 Study B n=486). The trials closed to efficacy and safety follow-up on August 31, 2014. This archive includes the study protocol, manual of procedures, data collection forms, statistical programs for the baseline manuscripts baseline publications, and study data for forms, data from lab tests, and publications.

The files in the archive are organized into the following directories:

- 1. Documentation Directory**
- 2. Forms Directory**
- 3. Data Directory**
- 4. DSIC Directory**

- 1. Documentation Directory**

- a. The HALT **Manual of Operations** is the final version of the HALT MOP (9/5/2013).
- b. The HALT **Protocol** is the final version of the HALT Protocol (5/3/2012).

2. Forms Directory

- a. A spreadsheet that links each of the Case Report Forms (CRFs) to its corresponding dataset.
- b. The set of data entry CRFs (in pdf format with and without variable names) with an indication of corresponding to data (see Table 1).

Table 1. Datasets and study forms used in data collection.

Form Number	Description	Dataset Name (.sas7bdat)	Visit (visit number) corresponding to CRF
1	Monthly Pre-Screening	No dataset to include	----
2	Contact Information	No dataset to include	----
3	Registration	form3	Screening
4	Clinical History	form4	Screening
5	Symptoms Checklist	form5	Baseline, every 3 months
6	Concomitant Medications	form6 form6_concmeds	Baseline, every 3 months
7	Physical Findings Screening	form7	Screening
8	Background Questionnaire	form8	Screening
9	Required Lab Results (PCC)	form9	Screening, Baseline, every 6 months
10	Enrollment	form10	Screening
12	Home Blood Pressure	form12_summary	Baseline, every 3 months
12A	Home Blood Pressure Instructions	No dataset to include	----
13	Serious Adverse Event Section I Event	form13_ae	Event driven
	Q15, Drug and non-drug therapies to treat event	form13_ae_treat	
	Q33, relevant diagnoses	form13_diag	
	Q32, relevant medications	form13_med	
	Section IV AKI	form13_section4	
13A	SAE Definitions and Guidelines	No dataset to include	----
13B	SAE Form 13 Instructions	No dataset to include	----

Form Number	Description	Dataset Name (.sas7bdat)	Visit (visit number) corresponding to CRF
14	Screen Failure	form14	Screening
15	Current Physical Findings	form15	Baseline, every 6 months
16	Urine Sample Collection	form16	Baseline, annual
17	Genetic Sample Collection	form17	
17A	NIDDK Phlebotomy	No dataset to include	----
17B	NIDDK Genetics Initiative Blood Sample	No dataset to include	----
18	Archived Blood Sample Collection	form18	Baseline, annual
19	Central Serum Creatinine Sample Collection	form19	Baseline, every 6 months
20	Randomization	form20_randform	Baseline
21	MRI Session	form21	Baseline, F24, F48, F60
	Q4 Adverse Event	form21_ae	
	Q3B Cardiac Series	form21_cseries	
	Q3A Renal Series	form21_rseries	
	Q3A Omitted Series	form21_rserieso	
21A	MR Scanning Procedure	No dataset to include	----
22	Renal Blood Flow	form22	Baseline, F24, F48, F60
	Series numbers (after Q4)	form22_series	
25	Missed Visit	form25	
26	Unmasking Drug	No unmasking/empty dataset	-----
27	Transfer	form27	Event driven
28	Modified Participation	form28	Event driven
29	Major Protocol Violation	Not included for data sharing	-----
30	Hospitalization	form30	Event driven
31	Death Notification	form31	Event driven
32	End Stage Renal Disease	form32	Event driven
33	eGFR Reduction	form33	Event driven but only at 6 month visits
34	BP Monitor Calibration Log PCC	No dataset to include	-----
35	Post-Closeout Follow-up (Study B)	form35	Event driven
36	Home Blood Pressure Monitor Calibration	No dataset to include	-----
37	24 Hour Urine Checklist	No dataset to include	-----
37A	Instructions for 24-Hour Urine Collection	No dataset to include	----
38	Quality of Life (<i>copyrighted</i>)	form38	Baseline, annual

Form Number	Description	Dataset Name (.sas7bdat)	Visit (visit number) corresponding to CRF
39	Pain Questionnaire	form39	Baseline, annual
40	HALT PKD Visit Tracking Visit key codes	Tblvisitrecords tbltimepoints	All time points
50	History of Hormonal Birth Control	No dataset to include	-----
51	Required Safety Lab Results	form51	Event driven
52	Post-Closeout Follow-up (Study A)	form52	Event driven
56	Therapy Confirmation	form56	F5
62	Drug Card Assignment	form62	Baseline, between visits (BV), any F* visit
	Unique drug cards assigned	form62_cards	
62A	Instructions for Drug Card Assignment	No dataset to include	----
63	Study Medication	form63	Baseline, between visits (BV), any F* visit
63A	Instructions for Study Medication Form	No dataset to include	----
81	Shipping Manifest for Creatinines	No dataset to include	-----
82	Shipping Manifest Urine	No dataset to include	-----
83	Shipping Manifest Repository Genetic Sample	No dataset to include	-----
84	Shipping Manifest Repository Serum Plasma	No dataset to include	-----
85	Shipping Manifest Repository Urine	No dataset to include	-----
86	Relatedness	Not included due to potentially identifiable information	-----
90	Quest Visit	form90	Baseline, any 6 month visit, and BV
96A	Definition of Modified Participation	No dataset to include	----
96B	Modified Participation Checklist	No dataset to include	----
121	Assessment of Quality of Radiologic Studies	form121	Baseline, F24, F48, F60
125	Hospital Adjudication	form125_wide	Event driven
130	Participant penultimate visit questionnaire (all notification options available)	form130_131	Next to last PCC visit

Form Number	Description	Dataset Name (.sas7bdat)	Visit (visit number) corresponding to CRF
131	Participant penultimate visit questionnaire (no notification options available)	Form130_131	Next to last PCC visit

3. Data Directory

The **Data Directory** contains the following files and folders:

- **Form Data** folder contains each of the CRF data sets in .sas7bdat format.
- **Non-CRF Study Data** folder contains a folder for imaging data (tblmrimeasures.sas7bdat) and a folder for laboratory data (serum and urine in accnuse_accntest.sas7bdat). The genetic data are also in the Non-CRF Study Data folder (genotype09022014.sas7bdat).

The **Primary Paper Analysis Data** Subdirectory includes folders

- Final SAS datasets: contains baseline and longitudinal datasets for primary publications for Study A and Study B, as well as the endpoints dataset
- Final SAS programs: contains programs to create baseline and longitudinal datasets, programs for primary analyses for each study, a formats file, and PROC CONTENTS for each dataset

Reference tables and figures for the programs can be found in the *NEJM* articles (Torres, et al, 2014, 'Angiotensin Blockade in Late Autosomal Dominant Polycystic Kidney Disease' and Schrier, et al, 2014 'Blood Pressure in Early Autosomal Dominant Polycystic Kidney Disease').

(Submitted in March 2014, not included in March 2015 submission)

The **Baseline** Subdirectory includes folders

- *Final SAS datasets*
- *Final SAS programs*
- *Final Tables for the baseline manuscript (Torres, et al, 2012, 'Analysis of baseline parameters in the HALT polycystic kidney disease trials', Kidney International) and 4 documents*

- *Description of SAS files for HALT baseline repository transfer.doc' contains detailed information about the files*
- *Dictionary for baseline paper data.doc contains a PROC CONTENTS of the baseline paper data*
- *Dictionary for current baseline data.doc contains a PROC CONTENTS of the current baseline data*
- *Discrepancies between baseline paper and current baseline results contains information about the data differences between the baseline paper (published in 2012) results and the current baseline data (as of March 2014).*

4. DSIC Directory

The **DSIC Directory** contains the following files and folders:

- The **DSIC Baseline** document contains an analysis performed to duplicate the results for the data published in "Analysis of baseline parameters in the HALT polycystic kidney disease trials".
- The **DSIC Follow-up** document contains analyses performed to duplicate the results for the data published in 2 papers: "Blood Pressure in Early Autosomal Dominant Polycystic Kidney Disease" and "Angiotensin Blockade in Late Autosomal Dominant Polycystic Kidney Disease".