

HALT Progression of Polycystic Kidney Disease (HALT PKD)

The HALT Progression of Polycystic Kidney Disease (HALT PKD) studies were two simultaneous multicenter clinical trials designed to test the efficacy of interruption of the renin-angiotensin-aldosterone system (RAAS) on the progression of cystic disease and the decline in renal function in autosomal dominant polycystic kidney disease (ADPKD). Specifically, the studies assessed the effects of ACE-I/ARB combination therapy as compared to ACE-I monotherapy in hypertensive ADPKD subjects.

Archive files are organized into the following directories:

- Data
- Documents
- Dataset Integrity Check (DSIC)
- Forms

Data

The HALT PKD Data directory contains the following files:

- HALT PKD_DataDictionary_20150220.xlsx

Data/Form Data

- FORM10.CSV
- form10.sas7bdat
- FORM121.CSV
- form121.sas7bdat
- FORM125_WIDE.CSV
- form125_wide.sas7bdat
- FORM12_SUMMARY.CSV
- form12_summary.sas7bdat
- FORM130_131.CSV
- form130_131.sas7bdat
- FORM13_AE.CSV
- form13_ae.sas7bdat
- FORM13_AE_TREAT.CSV
- form13_ae_treat.sas7bdat
- FORM13_DIAG.CSV
- form13_diag.sas7bdat
- FORM13_MED.CSV
- form13_med.sas7bdat
- FORM13_SECTION4.CSV
- form13_section4.sas7bdat
- FORM14.CSV
- form14.sas7bdat
- FORM15.CSV

- form15.sas7bdat
- FORM16.CSV
- form16.sas7bdat
- FORM17.CSV
- form17.sas7bdat
- FORM18.CSV
- form18.sas7bdat
- FORM19.CSV
- form19.sas7bdat
- FORM20_RANDFORM.CSV
- form20_randform.sas7bdat
- FORM21.CSV
- form21.sas7bdat
- FORM21_AE.CSV
- form21_ae.sas7bdat
- FORM21_CSERIES.CSV
- form21_cseries.sas7bdat
- FORM21_RSERIES.CSV
- form21_rseries.sas7bdat
- FORM21_RSERIESO.CSV
- form21_rserieso.sas7bdat
- FORM22.CSV
- form22.sas7bdat
- FORM22_SERIES.CSV
- form22_series.sas7bdat
- FORM25.CSV
- form25.sas7bdat
- FORM27.CSV
- form27.sas7bdat
- FORM28.CSV
- form28.sas7bdat
- FORM3.CSV
- form3.sas7bdat
- FORM30.CSV
- form30.sas7bdat
- FORM31.CSV
- form31.sas7bdat
- FORM32.CSV
- form32.sas7bdat
- FORM33.CSV
- form33.sas7bdat
- FORM35.CSV
- form35.sas7bdat
- FORM38.CSV

- form38.sas7bdat
- FORM39.CSV
- form39.sas7bdat
- FORM4.CSV
- form4.sas7bdat
- FORM5.CSV
- form5.sas7bdat
- FORM51.CSV
- form51.sas7bdat
- FORM52.CSV
- form52.sas7bdat
- FORM56.CSV
- form56.sas7bdat
- FORM6.CSV
- form6.sas7bdat
- FORM62.CSV
- form62.sas7bdat
- FORM62_CARDS.CSV
- form62_cards.sas7bdat
- FORM63.CSV
- form63.sas7bdat
- FORM6_CONCMEDS.CSV
- form6_concmeds.sas7bdat
- FORM7.CSV
- form7.sas7bdat
- FORM8.CSV
- form8.sas7bdat
- FORM9.CSV
- form9.sas7bdat
- FORM90.CSV
- form90.sas7bdat
- TBLTIMEPOINTS.CSV
- tbltimepoints.sas7bdat
- TBLVISITRECORDS.CSV
- tblvisitrecords.sas7bdat

Data/Non-CRF data

- GENETYPE09022014.CSV
- genotype09022014.sas7bdat
- HALT_PKD_IDS_GENETIC_DATA.CSV
- halt_pkd_ids_genetic_data.sas7bdat
- SAFETY.CSV
- safety.sas7bdat

Data/Non-CRF_Data/Imaging_Data

- DBO_TBLNONLABACCN.CSV
- dbo_tblnonlabaccn.sas7bdat
- TBLMRIMEASURES.CSV
- tblmrimeasures.sas7bdat

Data/Non-CRF_Data/Lab_Data

- ACCNUSE_ACCNTEST.CSV
- accnuse_accntest.sas7bdat
- Sample Accession Number and Value Handling Methods.docx

Data/Primary_Paper_Analysis_Data/Final SAS programs

- Contents_Baseline.doc
- Contents_Endpoints.docx
- Contents_Longitudinal.doc
- HALT_Baseline.sas
- HALT_format.sas
- HALT_Longitudinal.sas
- PrimaryPaper_StudyA.sas
- PrimaryPaper_StudyB.sas

Data/Primary_Paper_Analysis_Data/Final SAS datasets

- ENDPOINTS_SEP2014.CSV
- endpoints_sep2014.sas7bdat
- HALT_BASELINE.CSV
- halt_baseline.sas7bdat
- HALT_LONGITUDINAL.CSV
- halt_longitudinal.sas7bdat

Documents

The HALT PKD Documents directory contains:

- MOP.pdf
- Protocol.pdf

DSIC

The HALT PKD Dataset Integrity Check (DSIC) directory contains:

- DSIC_Baseline.doc
- DSIC_Followup.pdf
- HALT_PKD_Allele_DSIC.pdf

Forms

The HALT PKD Forms directory contains:

- CRF and Dataset name list.xlsx

Forms/Forms with var names

- F1 Monthly Pre-Screening Activity Report Form.pdf
- F10 Enrollment Form.pdf
- F12 Home BP Form.pdf
- F121 Assessment of Quality of Radiologic Studies.pdf
- F125 MD FORM for adjudication on web.pdf
- F12A Home Blood Pressure Form 12 Instructions.pdf
- F13 SeriousAdverse Event.pdf
- F130 Participant penult questionnaire.pdf
- F131 Participant penult questionnaire.pdf
- F13A SAE Definitions and Guidelines.pdf
- F13B SAE Form 13 Instructions.pdf
- F14 ScreenFailureForm.pdf
- F15 Current Physical Findings.pdf
- F16 Urine Sample Collection.pdf
- F17 Genetic Sample Collection.pdf
- F17A NIDDK Phlebotomy Form.pdf
- F17B NIDDK Genetics Initiative Blood Sample Collection Flow Sheet.pdf
- F18 Archived Blood Sample Collection.pdf
- F19 Central Serum Creatinine.pdf
- F2 Contact information.pdf
- F20 Randomization Form.pdf
- F21 MRI Session form.pdf
- F21A MR Scanning Procedure.pdf
- F22 Renal Blood FLOW (MRA).pdf
- F25 Missed Visit Form.pdf
- F26 Unmasking Drug.pdf
- F27 Transfer Form.pdf
- F28 Modified Participation Form.pdf
- F29 Major Protocol Violation Form.pdf
- F3 Registration Form.pdf
- F30 Hospitalization Form.pdf
- F31 Death Notification Form.pdf
- F32 End Stage Renal Disease Form (ESRD).pdf
- F33 eGFR Reduction Form.pdf
- F34 BP Monitor Calibration Log PCC.pdf
- F35 Post-Closeout Follow-Up (Study B).pdf
- F36 Home Blood Pressure Monitor Calibration Log.pdf

- F37 24 Hour Urine Checklist.pdf
- F37A Instructions for 24-Hour Urine Collection.pdf
- F39 Pain Questionnaire.pdf
- F4 Clinical History Form.pdf
- F40 Halt PKD Visit Tracking Form.pdf
- F5 Symptoms Checklist.pdf
- F50 Hormonal Birth Control Form.pdf
- F51 Required Safety Lab Results.pdf
- F52 Post-Closeout Follow-Up (Study A).pdf
- F56 Therapy confirmation.pdf
- F6 Concomitant Medications form.pdf
- F62 Drug Card Assignment Form.pdf
- F62A Instructions for Drug Card Assignment Form 62.pdf
- F63 Study Medication Form.pdf
- F63A Instructions for Study Medication Form 63.pdf
- F7 Physical Findings Form Screening.pdf
- F8 Background Questionnaire.pdf
- F81 Shipping Manifest CL-CCF.pdf
- F82 Shipping Manifest CL-DLF.pdf
- F83 Shipping Manifest Repository Genetic Sample.pdf
- F84 Shipping Manifest Repository Serum Plasma.pdf
- F85 Shipping Manifest Repository Urine.pdf
- F86 Relatedness Form.pdf
- F9 Required Lab Results.pdf
- F90 Quest Visit.pdf
- F96A Definition of Modified Participation.pdf
- F96B Modified Participation Checklist for Form 96.pdf

Forms/Forms without var names

- F10 Enrollment Form.pdf
- F12 Home BP Form.pdf
- F121 Assessment of Quality of Radiologic Studies.pdf
- F125 MD FORM for adjudication on web.pdf
- F13 SeriousAdverse Event.pdf
- F130 Participant penult questionnaire.pdf
- F131 Participant penult questionnaire.pdf
- F14 ScreenFailureForm.pdf
- F15 Current Physical Findings.pdf
- F16 Urine Sample Collection.pdf
- F17 Genetic Sample Collection.pdf
- F18 Archived Blood Sample Collection.pdf
- F19 Central Serum Creatinine.pdf
- F2 Contact information.pdf
- F20 Randomization Form.pdf

- F21 MRI Session form.pdf
- F22 Renal Blood Flow.pdf
- F25 Missed Visit Form.pdf
- F26 Unmasking Drug.pdf
- F27 Transfer Form.pdf
- F28 Modified Participation Form.pdf
- F29 Major Protocol Violation Form.pdf
- F3 Registration Form.pdf
- F30 Hospitalization Form.pdf
- F31 Death Notification Form.pdf
- F32 End Stage Renal Disease Form.pdf
- F33 eGFR Reduction Form.pdf
- F35 Post-Closeout Follow-Up (Study B).pdf
- F36 Home Blood Pressure Monitor Calibration Log.pdf
- F39 Pain Questionnaire.pdf
- F4 Clinical History Form.pdf
- F40 Halt PKD Visit Tracking Form.pdf
- F5 Symptoms Checklist.pdf
- F51 Required Safety Lab Results.pdf
- F52 Post-Closeout Follow-Up (Study A).pdf
- F6 Concomitant Medications form.pdf
- F62 Drug Card Assignment Form.pdf
- F63 Study Medication Form.pdf
- F7 Physical Findings Form Screening.pdf
- F8 Background Questionnaire.pdf
- F81 Shipping Manifest CL-CCF.pdf
- F82 Shipping Manifest CL-DLF.pdf
- F83 Shipping Manifest Repository Genetic Sample.pdf
- F84 Shipping Manifest Repository Serum Plasma.pdf
- F85 Shipping Manifest Repository Urine.pdf
- F86 Relatedness Form.pdf
- F9 Required Lab Results.pdf
- F90 Quest Visit.pdf