

Biomarker Collection and Analysis in the Prevention of Serious Adverse Events Following Angiography (PRESERVE) Trial Cohort

The Biomarker Collection and Analysis sub-study collected, banked, and analyzed blood and urine of participants from the VA-funded PRESERVE trial. Blood and urine proteins and other markers may predict the development of contrast-induced acute kidney injury and diagnose the very early stages of this condition following angiography. In addition, these biomarkers may predict which participants that develop acute kidney injury following angiography are likely to experience serious longer-term complications such as death, need for dialysis, and/or progressive loss of kidney function.

Archive files are organized into the following directories:

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

Data

The PRESERVE Data directory contains the following datasets:

- AE_DATA_12192017.CSV
- ae_data_12192017.sas7bdat
- AE_MEDDRA_CODES_12192017.CSV
- ae_meddra_codes_12192017.sas7bdat
- CF13.CSV
- cf13.sas7bdat
- CSP578_ITT.CSV
- csp578_itt.sas7bdat
- CSP578_SAEFU.CSV
- csp578_saefu.sas7bdat
- F05_BIOMETRICS.CSV
- f05_biometrics.sas7bdat
- F06_PREPROCLABS.CSV
- f06_preproclabs.sas7bdat
- F07_DEMOGRAPHICS.CSV
- f07_demographics.sas7bdat
- F08_CMNAME.CSV
- f08_cmname.sas7bdat
- F09_MEDHIS.CSV
- f09_medhis.sas7bdat
- F10_PREPROCNSIV.CSV
- f10_preprocnsiv.sas7bdat
- F11_PROCEDURE.CSV

- f11_procedure.sas7bdat
- F12_STUDYIVFLUID.CSV
- f12_studyivfluid.sas7bdat
- F13_POSTURINEPH.CSV
- f13_posturineph.sas7bdat
- F14_12HRPOSTPROC.CSV
- f14_12hrpostproc.sas7bdat
- F15_96HRPOST.CSV
- f15_96hrpost.sas7bdat
- F16_DAY5.CSV
- f16_day5.sas7bdat
- F17_DAY35.CSV
- f17_day35.sas7bdat
- F18_DAY90.CSV
- f18_day90.sas7bdat
- F19_AE.CSV
- f19_ae.sas7bdat
- F20_ENDPOINTSAE_SAEFU.CSV
- f20_endpointsae_saefu.sas7bdat
- F22_EARLYWITH.CSV
- f22_earlywith.sas7bdat
- F23_PROTOCOLDEV.CSV
- f23_protocoldev.sas7bdat
- F24_STUDYBLOOD.CSV
- f24_studyblood.sas7bdat
- FORM02A.CSV
- form02a.sas7bdat
- FORM02B.CSV
- form02b.sas7bdat
- LOCAL_LAB_US_BL_082017.CSV
- local_lab_us_bl_082017.sas7bdat
- LOCAL_LAB_US_CON_082017.CSV
- local_lab_us_con_082017.sas7bdat
- LOCAL_LAB_US_D90_082017.CSV
- local_lab_us_d90_082017.sas7bdat
- NIDDK_DB_FINAL_9272017.CSV
- niddk_db_final_9272017.sas7bdat
- SAE_DATA_12192017.CSV
- sae_data_12192017.sas7bdat
- SAE_MEDDRA_CODES_12192017.CSV
- sae_meddra_codes_12192017.sas7bdat
- SUBPROTOCOL.CSV
- subprotocol.sas7bdat
- US_LOCAL_D90.CSV

- us_local_d90.sas7bdat
- V_CENTRAL_LAB_US.CSV
- v_central_lab_us.sas7bdat

Data/Contents

- CSP 578 Data Dictionary 2012_11_28.accdb

Documents

The PRESERVE Documents directory contains:

- CSP578 Operations Manual v2.0.pdf
- Protocol v1.8__eff 05.01.19.pdf

DSIC

The PRESERVE Dataset Integrity Check (DSIC) directory contains:

- PRESERVE_DSIC.pdf

Forms

The PRESERVE Forms directory contains:

- Form 04. Military History.pdf
- Form 05. Blood Pressure and Weight.pdf
- Form 06. Pre Procedure Laboratory Values.pdf
- Form 07. Demographics.pdf
- Form 08. Non-study Medications List.pdf
- Form 08. Pre Procedure Non-study Medications.pdf
- Form 09. Medical History.pdf
- Form 10. Pre Procedure Non-Study IV Fluid.pdf
- Form 11. Procedure Related Data.pdf
- Form 12. Study IV Fluid Administration.pdf
- Form 12. Study IV Fluid Workflow.pdf
- Form 13. Post Procedure Urine pH Results.pdf
- Form 14. 12 Hours Post Procedure.pdf
- Form 15. Hospitalizations Within 96 Hours Post Procedure.pdf
- Form 16. 5 Days Post Procedure.pdf
- Form 17. 35 Days Post Procedure.pdf
- Form 18. 90 Days Post Procedure.pdf
- Form 19. Adverse Event.pdf
- Form 20. Endpoint_SAE.pdf
- Form 21. Endpoint_SAE Follow-up.pdf
- Form 22. Early Participant Withdrawal.pdf

- Form 23. Protocol Deviation.pdf
- Form 24. Study Blood Specimens.pdf
- Form 25. Australian Local Scr Test Results.pdf