**General Notes**

* Files
  + ReadMe PDF file
  + 24 dataset text files
  + Data dictionary excel file
  + Case Report Forms PDF file
* Datasets
  + A complete listing of all variables, their description and their codes may be found in the data dictionary excel file.
  + There is a separate dataset for each included form, with the following exceptions: Form 22 data are included in the CTCR dataset and Form 05 is separated into two datasets: Form05 and Form05C. The Form05C dataset is Q10 from Form 05 and has multiple records per subject. Note that Form 12 is not included in the Public Use Dataset.
  + Forms that were collected only once during the study will have one row per subject. Forms collected multiple times will have multiple rows per subject. A complete listing of which forms were collected at each study visit can be found in the data dictionary in the sheet called “Form List”.
* Variable names
  + Raw data is named in the format F##Q##, where F## is the form number and Q## is the question number.
  + Derived variables are included in some datasets, indicated below in Dataset Specific Notes.
* Dates and times
  + All dates and times are replaced with calculated time from randomization. Variables in the form F##Q##DAY indicate the number of days from randomization and F##Q##MIN indicate the number of minutes from randomization
  + If date is available but time is missing, 12:00 is used for calculating time from randomization and an indicator variable of the form F##Q##MIN\_impute (1=imputed, 0=not imputed) for missing time is included in the dataset.
  + Negative times indicate the event occurred before randomization.
* No text fields from the forms are included except MedDRA System Organ Class (SOC) and Preferred Term (PT) names.

**Dataset Specific Notes**

* Form01 – variable F01Q03M4 (Race: Native Hawaiian or Other Pacific Islander) was excluded and 1 subject was recoded as Other race
* Form05 - derived variables: PRIMARY\_TRTFAIL, SECONDARY\_TRTFAIL
* Form05C – Start (F05CQIMIN) and end (F05CQJMIN) times of infusion intervals should be equal to the time from randomization interval (F05CQA), but this is not always the case. In particular, SUBJECT\_IDs 1, 166, 240, 294, 948, 950 have interval times that are 2 or more hours off from the randomization interval.
* Form06 – Two self-evident changes have been made to the data:
  + F06ZFormDateDAY (Date of assessment, expressed as days from randomization) changed from -28 to 2 for subject\_id 197
  + F06ZFormDateDAY (Date of assessment, expressed as days from randomization) changed from -28 to 2 for subject\_id 766
* Form16 – derived variable: EQ\_INDEX
* Form20
  + MedDRA System Organ Class (SOC) and Preferred Term (PT) codes and names are included. PTs with a frequency of one were combined within each SOC by removing the PT code and replacing the PT name with ‘Other’ *SOC name*. A list of these PTs is below.
  + Results from the Independent Oversite Committee review of relatedness and expectedness of serious adverse events are included in this dataset.
  + Derived variables: RENAL\_AE, CARDIAC\_AE, INFARCT\_AE, HEMORRHAGE\_AE indicate groups of related events (events that represent the same condition of

interest by body system) classified using MedDRA terms. These groups were used in post-hoc analysis, presented in Supplementary Table 4 of the primary manuscript.

* + One self-evident change was made: F20Q11DAY (Date of AE Resolution, expressed as days from randomization) changed from 454 to 89 for subject\_id 249
* Form21
  + Derived variable: PRIMARYOUT – This variable is the primary study outcome, 90 day mRS 4-6 (0=mRS 0-3, 1=mRS 4-6). For subjects who died within 120 days of randomization, this variable is imputed as 1 (mRS 4-6). This variable is missing if the subject was alive and the assessment was not completed or if it was completed outside the 60-120 post-randomization window.
  + For subjects that were lost to follow-up, date of end of study (Q03) was imputed as the date of the last completed assessment.
* Form33
  + derived variables: RANDORDER, SITE\_ID, COUNTRY
  + Ages 19 to 30 years are represented by the value 30.
* CTCR
  + Only baseline and 24 hour CT scans are included
  + Date/time of CT was collected on Form22 (Imaging) and is included in this dataset.
  + Questions 15-17 on the CRF were not collected.

**Primary Analysis Notes**

* Table 1
  + Descriptive statistics for age calculated using the PUDS vary slightly since ages 19 to 30 are represented by the value 30 (see Form33 notes above).
  + Race corresponds to PUDS variables F01Q03M1-F01Q03M7, categorized as:
    - F01Q03M2 (Race: Asian)=1 (Yes) and F01Q03M2 (Race: American Indian or Alaska Native)=0 (No) and F01Q03M3 (Race: Black or African American)=0 (No) and F01Q03M5 (Race: White)=0 (No) as Asian
    - F01Q03M3 (Race: Black or African American)=1 (Yes) and F01Q03M2 (Race: American Indian or Alaska Native)=0 (No) and F01Q03M2 (Race: Asian)=0 (No) and F01Q03M5 (Race: White)=0 (No) as Black
    - F01Q03M5 (Race: White)=1 (Yes) F01Q03M2 (Race: American Indian or Alaska Native)=0 (No) and F01Q03M2 (Race: Asian)=0 (No) and F01Q03M3 (Race: Black or African American)=0 (No) as White
    - Subjects not meeting the criteria above as Other or unknown
  + Glasgow Coma Score corresponds to PUDS variable F33Q04 (baseline GCS)
  + Intracerebral hematoma volume, intraventricular hemorrhage, and location of hemorrhage use only CT scans at or before randomization with non-missing times
    - Intracerebral hematoma volume corresponds to PUDS variable CTCRQ12 [Volume of the intraparenchymal component (IPH volume) (mm3)], converted to cm3
    - Intraventricular hemorrhage corresponds to PUDS variable CTCRQ13 [Volume of the intraventricular component (IVH volume) (mm^3)], dichotomized to 0=Yes, >0=No
    - Location of hemorrhage corresponds to PUDS variable CTCRQ05 (Primary location of parenchymal hemorrhage), recategorized as 2 (R Basal ganglia) or 5 (L Basal ganglia)=Basal ganglia, 1 (R Thalamus) or 4 (L Thalamus)=Thalamus, 3 (R Lobar) or 6 (L Lobar)=Lobar, 7 (Pons) or 8 (Cerebellum)=Cerebellum
  + NIHSS score uses only assessments at or before randomization with non-missing times
* Table 2
  + Results based on multiple imputation may differ due to seed selected for random number generation, sort order, and/or ages <30 represented as 30 in the PUDS. Glasgow Coma Scale at 24 hours was included in the imputation model and is defined as assessments completed between 1080 and 1800 minutes post-randomization with non-missing time. Additional details regarding the multiple imputation method can be found in the Supplementary Appendix of the primary manuscript.
  + Hematoma expansion is calculated using baseline (at or before randomization with non-missing time) and 24 hour (between 1080 and 1800 minutes post-randomization with non-missing time) CT scans.
  + Neurological deterioration within 24 hr is defined as an adverse event causing neurological deterioration (F20Q02=2) occurring within 24.4 hours (1464 minutes) post-randomization (F20Q08MIN)
  + Treatment-related serious adverse events within 72 hr is defined as serious (F20Q07=1) adverse event possibly, probably, or definitely related to study treatment (F20Q12=3,4, or 5) occurring within 80.4 hours (4824 minutes) post-randomization (F20Q08MIN)
  + Hypotension within 72 hr is defined as an adverse event with MedDRA Preferred Term name (PTNAME) = “Hypotension” occurring within 72.4 hours (4344 minutes) post-randomization (F20Q08MIN)
  + Adjusted analysis uses site IVH (F33Q03) if the central reader determination of IVH (derived from variable CTCRQ13 as described above) is missing.
* Figure 2 uses the mRS assessment collected between 60 and 120 days post-randomization that is closest to 90 days for each subject. If the subject died within 120 days post-randomization, the mRS score is imputed as 6.
* Figure 3
  + Subjects with unknown Hispanic or Latino ethnicity are included in the ‘No’ subgroup.
* Additional analysis in manuscript
  + For each subject, the mean minimum systolic blood pressure during the first 2 hours is calculated as the mean of F05CQC (Lowest SBP) during the 2nd hour post-randomization (F05CQA=5) and the minimum of the four lowest SBP during the 1st hour post-randomization (F05CQA=1, 2, 3, and 4).
* Supplemental Table 1
  + History of coronary artery disease is defined as F03Q06 (Previous CABG / Ischemic Heart Disease / Angina Pectoris / PTCA).
* Supplemental Tables 2-3 – Since PTs with a frequency of one were renamed ‘Other’ *SOC name* in the PUDS (see Form20 dataset notes above), these table cannot exactly replicated using the PUDS.
* Supplemental Table 4 –
  + AEs within 7 days are defined as those occurring within 7.4 days (10656 minutes)
  + Adjusted relative risks calculated using the PUDS vary slightly since age is included as a covariate in the models and ages 19 to 30 are represented by the value 30 (see Form33 notes above).

**MedDRA Preferred Terms with Frequency=1, presented alphabetically by System Organ Class**

| **SOCCode** | **SOCName** | **PTCode** | **PTName** |
| --- | --- | --- | --- |
| 10005329 | Blood and lymphatic system disorders | 10024384 | Leukopenia |
| 10007541 | Cardiac disorders | 10003673 | Atrioventricular block complete |
| 10007541 | Cardiac disorders | 10003677 | Atrioventricular block second degree |
| 10007541 | Cardiac disorders | 10006580 | Bundle branch block left |
| 10007541 | Cardiac disorders | 10007556 | Cardiac failure acute |
| 10007541 | Cardiac disorders | 10015856 | Extrasystoles |
| 10007541 | Cardiac disorders | 10028600 | Myocardial ischaemia |
| 10007541 | Cardiac disorders | 10040741 | Sinus bradycardia |
| 10007541 | Cardiac disorders | 10047295 | Ventricular hypertrophy |
| 10007541 | Cardiac disorders | 10049773 | Left ventricular hypertrophy |
| 10007541 | Cardiac disorders | 10051093 | Cardiopulmonary failure |
| 10007541 | Cardiac disorders | 10051592 | Acute coronary syndrome |
| 10007541 | Cardiac disorders | 10052337 | Diastolic dysfunction |
| 10007541 | Cardiac disorders | 10058151 | Pulseless electrical activity |
| 10013993 | Ear and labyrinth disorders | 10047340 | Vertigo |
| 10013993 | Ear and labyrinth disorders | 10048812 | Deafness unilateral |
| 10015919 | Eye disorders | 10025415 | Macular oedema |
| 10015919 | Eye disorders | 10038845 | Retinal degeneration |
| 10015919 | Eye disorders | 10038926 | Retinopathy hypertensive |
| 10015919 | Eye disorders | 10047513 | Vision blurred |
| 10015919 | Eye disorders | 10057431 | Scleral oedema |
| 10017947 | Gastrointestinal disorders | 10000059 | Abdominal discomfort |
| 10017947 | Gastrointestinal disorders | 10016766 | Flatulence |
| 10017947 | Gastrointestinal disorders | 10033645 | Pancreatitis |
| 10017947 | Gastrointestinal disorders | 10041101 | Small intestinal obstruction |
| 10017947 | Gastrointestinal disorders | 10043967 | Tongue oedema |
| 10017947 | Gastrointestinal disorders | 10051606 | Necrotising colitis |
| 10018065 | General disorders and administration site conditions | 10001315 | Administration site reaction |
| 10018065 | General disorders and administration site conditions | 10003549 | Asthenia |
| 10018065 | General disorders and administration site conditions | 10013754 | Drug withdrawal syndrome |
| 10018065 | General disorders and administration site conditions | 10016256 | Fatigue |
| 10018065 | General disorders and administration site conditions | 10052268 | Catheter site pain |
| 10019805 | Hepatobiliary disorders | 10019641 | Hepatic cirrhosis |
| 10019805 | Hepatobiliary disorders | 10019646 | Hepatic cyst |
| 10019805 | Hepatobiliary disorders | 10019708 | Hepatic steatosis |
| 10019805 | Hepatobiliary disorders | 10020578 | Hyperbilirubinaemia |
| 10021881 | Infections and infestations | 10000311 | Abscess oral |
| 10021881 | Infections and infestations | 10006469 | Bronchopneumonia |
| 10021881 | Infections and infestations | 10009657 | Clostridium difficile colitis |
| 10021881 | Infections and infestations | 10011844 | Dacryocystitis |
| 10021881 | Infections and infestations | 10015145 | Erysipelas |
| 10021881 | Infections and infestations | 10021789 | Infection |
| 10021881 | Infections and infestations | 10030963 | Oral candidiasis |
| 10021881 | Infections and infestations | 10034835 | Pharyngitis |
| 10021881 | Infections and infestations | 10035728 | Pneumonia pneumococcal |
| 10021881 | Infections and infestations | 10035734 | Pneumonia staphylococcal |
| 10021881 | Infections and infestations | 10037601 | Pyelonephritis chronic |
| 10021881 | Infections and infestations | 10040070 | Septic shock |
| 10021881 | Infections and infestations | 10040753 | Sinusitis |
| 10021881 | Infections and infestations | 10044008 | Tonsillitis |
| 10021881 | Infections and infestations | 10044314 | Tracheobronchitis |
| 10021881 | Infections and infestations | 10046306 | Upper respiratory tract infection |
| 10021881 | Infections and infestations | 10049059 | Urinary tract infection fungal |
| 10021881 | Infections and infestations | 10050473 | Abscess limb |
| 10021881 | Infections and infestations | 10058080 | Staphylococcal infection |
| 10021881 | Infections and infestations | 10058839 | Enteritis infectious |
| 10021881 | Infections and infestations | 10060921 | Abdominal abscess |
| 10021881 | Infections and infestations | 10061841 | Enterocolitis viral |
| 10021881 | Infections and infestations | 10062352 | Respiratory tract infection |
| 10021881 | Infections and infestations | 10062631 | Cholecystitis infective |
| 10021881 | Infections and infestations | 10064687 | Device related infection |
| 10022117 | Injury, poisoning and procedural complications | 10016450 | Femoral neck fracture |
| 10022117 | Injury, poisoning and procedural complications | 10035765 | Pneumothorax traumatic |
| 10022117 | Injury, poisoning and procedural complications | 10042361 | Subdural haematoma |
| 10022117 | Injury, poisoning and procedural complications | 10050584 | Contusion |
| 10022117 | Injury, poisoning and procedural complications | 10072265 | Post transfusion purpura |
| 10022891 | Investigations | 10000636 | Activated partial thromboplastin time prolonged |
| 10022891 | Investigations | 10005364 | Blood bilirubin increased |
| 10022891 | Investigations | 10005395 | Blood calcium decreased |
| 10022891 | Investigations | 10005417 | Blood chloride abnormal |
| 10022891 | Investigations | 10005425 | Blood cholesterol increased |
| 10022891 | Investigations | 10005481 | Blood creatinine abnormal |
| 10022891 | Investigations | 10005482 | Blood creatinine decreased |
| 10022891 | Investigations | 10005630 | Blood lactate dehydrogenase increased |
| 10022891 | Investigations | 10005734 | Blood pressure decreased |
| 10022891 | Investigations | 10005739 | Blood pressure diastolic increased |
| 10022891 | Investigations | 10005750 | Blood pressure increased |
| 10022891 | Investigations | 10005803 | Blood sodium increased |
| 10022891 | Investigations | 10005850 | Blood urea decreased |
| 10022891 | Investigations | 10005911 | Body temperature increased |
| 10022891 | Investigations | 10006825 | C-reactive protein increased |
| 10022891 | Investigations | 10007586 | Cardiac murmur |
| 10022891 | Investigations | 10011734 | Cyst aspiration |
| 10022891 | Investigations | 10014391 | Electrocardiogram ST segment depression |
| 10022891 | Investigations | 10018359 | Glomerular filtration rate increased |
| 10022891 | Investigations | 10018484 | Glycosylated haemoglobin increased |
| 10022891 | Investigations | 10018838 | Haematocrit decreased |
| 10022891 | Investigations | 10018870 | Blood urine present |
| 10022891 | Investigations | 10027880 | Monocyte count increased |
| 10022891 | Investigations | 10029368 | Neutrophil count increased |
| 10022891 | Investigations | 10035528 | Platelet count decreased |
| 10022891 | Investigations | 10035768 | PO2 decreased |
| 10022891 | Investigations | 10038712 | Respiratory rate increased |
| 10022891 | Investigations | 10049471 | Blood phosphorus decreased |
| 10022891 | Investigations | 10051612 | Sputum culture positive |
| 10022891 | Investigations | 10061480 | Renal function test abnormal |
| 10022891 | Investigations | 10061880 | Occult blood positive |
| 10022891 | Investigations | 10067081 | Procalcitonin increased |
| 10022891 | Investigations | 10067855 | Gastric occult blood positive |
| 10022891 | Investigations | 10069709 | Coma scale abnormal |
| 10022891 | Investigations | 10070055 | Streptococcus test positive |
| 10027433 | Metabolism and nutrition disorders | 10001680 | Alkalosis |
| 10027433 | Metabolism and nutrition disorders | 10016803 | Fluid overload |
| 10027433 | Metabolism and nutrition disorders | 10020919 | Hypervolaemia |
| 10027433 | Metabolism and nutrition disorders | 10021083 | Hypoproteinaemia |
| 10027433 | Metabolism and nutrition disorders | 10021137 | Hypovolaemia |
| 10027433 | Metabolism and nutrition disorders | 10047609 | Vitamin B12 deficiency |
| 10028395 | Musculoskeletal and connective tissue disorders | 10036030 | Polyarthritis |
| 10028395 | Musculoskeletal and connective tissue disorders | 10039073 | Rheumatoid arthritis |
| 10029104 | Neoplasms benign, malignant and unspecified (incl cysts and polyps) | 10005003 | Bladder cancer |
| 10029104 | Neoplasms benign, malignant and unspecified (incl cysts and polyps) | 10006187 | Breast cancer |
| 10029104 | Neoplasms benign, malignant and unspecified (incl cysts and polyps) | 10038038 | Rectal cancer |
| 10029104 | Neoplasms benign, malignant and unspecified (incl cysts and polyps) | 10062194 | Metastasis |
| 10029205 | Nervous system disorders | 10001854 | Altered state of consciousness |
| 10029205 | Nervous system disorders | 10002948 | Aphasia |
| 10029205 | Nervous system disorders | 10006147 | Brain stem infarction |
| 10029205 | Nervous system disorders | 10008196 | Cerebrovascular disorder |
| 10029205 | Nervous system disorders | 10009719 | CNS ventriculitis |
| 10029205 | Nervous system disorders | 10010071 | Coma |
| 10029205 | Nervous system disorders | 10013573 | Dizziness |
| 10029205 | Nervous system disorders | 10014498 | Embolic stroke |
| 10029205 | Nervous system disorders | 10019016 | Haemorrhagic stroke |
| 10029205 | Nervous system disorders | 10019468 | Hemiplegia |
| 10029205 | Nervous system disorders | 10021283 | IIIrd nerve paralysis |
| 10029205 | Nervous system disorders | 10022758 | Intracranial aneurysm |
| 10029205 | Nervous system disorders | 10024264 | Lethargy |
| 10029205 | Nervous system disorders | 10024855 | Loss of consciousness |
| 10029205 | Nervous system disorders | 10033775 | Paraesthesia |
| 10029205 | Nervous system disorders | 10041466 | Speech disorder |
| 10029205 | Nervous system disorders | 10042316 | Subarachnoid haemorrhage |
| 10029205 | Nervous system disorders | 10044390 | Transient ischaemic attack |
| 10029205 | Nervous system disorders | 10048626 | Subdural hygroma |
| 10029205 | Nervous system disorders | 10057668 | Cognitive disorder |
| 10029205 | Nervous system disorders | 10060839 | Embolic cerebral infarction |
| 10029205 | Nervous system disorders | 10060840 | Ischaemic cerebral infarction |
| 10029205 | Nervous system disorders | 10060860 | Neurological symptom |
| 10029205 | Nervous system disorders | 10067275 | Vasogenic cerebral oedema |
| 10029205 | Nervous system disorders | 10071048 | Seizure like phenomena |
| 10037175 | Psychiatric disorders | 10012225 | Delirium tremens |
| 10037175 | Psychiatric disorders | 10012374 | Depressed mood |
| 10037175 | Psychiatric disorders | 10039639 | Schizophrenia, paranoid type |
| 10037175 | Psychiatric disorders | 10061920 | Psychotic disorder |
| 10038359 | Renal and urinary disorders | 10020524 | Hydronephrosis |
| 10038359 | Renal and urinary disorders | 10029151 | Nephropathy |
| 10038359 | Renal and urinary disorders | 10029279 | Neurogenic bladder |
| 10038359 | Renal and urinary disorders | 10030302 | Oliguria |
| 10038359 | Renal and urinary disorders | 10036018 | Pollakiuria |
| 10038359 | Renal and urinary disorders | 10038423 | Renal cyst |
| 10038359 | Renal and urinary disorders | 10038444 | Renal failure chronic |
| 10038359 | Renal and urinary disorders | 10046543 | Urinary incontinence |
| 10038359 | Renal and urinary disorders | 10061481 | Renal injury |
| 10038359 | Renal and urinary disorders | 10065584 | Urethral stenosis |
| 10038604 | Reproductive system and breast disorders | 10004446 | Benign prostatic hyperplasia |
| 10038604 | Reproductive system and breast disorders | 10006272 | Breast mass |
| 10038604 | Reproductive system and breast disorders | 10013935 | Dysmenorrhoea |
| 10038604 | Reproductive system and breast disorders | 10033132 | Ovarian cyst |
| 10038738 | Respiratory, thoracic and mediastinal disorders | 10001029 | Acute pulmonary oedema |
| 10038738 | Respiratory, thoracic and mediastinal disorders | 10001052 | Acute respiratory distress syndrome |
| 10038738 | Respiratory, thoracic and mediastinal disorders | 10011224 | Cough |
| 10038738 | Respiratory, thoracic and mediastinal disorders | 10015090 | Epistaxis |
| 10038738 | Respiratory, thoracic and mediastinal disorders | 10020591 | Hypercapnia |
| 10038738 | Respiratory, thoracic and mediastinal disorders | 10028735 | Nasal congestion |
| 10038738 | Respiratory, thoracic and mediastinal disorders | 10037368 | Pulmonary congestion |
| 10038738 | Respiratory, thoracic and mediastinal disorders | 10038669 | Respiratory arrest |
| 10038738 | Respiratory, thoracic and mediastinal disorders | 10041812 | Sputum increased |
| 10038738 | Respiratory, thoracic and mediastinal disorders | 10043089 | Tachypnoea |
| 10040785 | Skin and subcutaneous tissue disorders | 10002424 | Angioedema |
| 10040785 | Skin and subcutaneous tissue disorders | 10005191 | Blister |
| 10040785 | Skin and subcutaneous tissue disorders | 10013786 | Dry skin |
| 10040785 | Skin and subcutaneous tissue disorders | 10014184 | Eczema |
| 10040785 | Skin and subcutaneous tissue disorders | 10015150 | Erythema |
| 10040785 | Skin and subcutaneous tissue disorders | 10037087 | Pruritus |
| 10040785 | Skin and subcutaneous tissue disorders | 10037867 | Rash macular |
| 10040785 | Skin and subcutaneous tissue disorders | 10040831 | Skin disorder |
| 10040785 | Skin and subcutaneous tissue disorders | 10040849 | Skin fissures |
| 10040785 | Skin and subcutaneous tissue disorders | 10046735 | Urticaria |
| 10040785 | Skin and subcutaneous tissue disorders | 10051576 | Generalised erythema |
| 10042613 | Surgical and medical procedures | 10011322 | Craniotomy |
| 10042613 | Surgical and medical procedures | 10042363 | Subdural haematoma evacuation |
| 10042613 | Surgical and medical procedures | 10052592 | Gastrostomy tube insertion |
| 10042613 | Surgical and medical procedures | 10066143 | Stereotactic surgery |
| 10042613 | Surgical and medical procedures | 10067450 | Endotracheal intubation |
| 10047065 | Vascular disorders | 10002906 | Aortic stenosis |
| 10047065 | Vascular disorders | 10003210 | Arteriosclerosis |
| 10047065 | Vascular disorders | 10003880 | Axillary vein thrombosis |
| 10047065 | Vascular disorders | 10018852 | Haematoma |
| 10047065 | Vascular disorders | 10019013 | Haemorrhagic infarction |
| 10047065 | Vascular disorders | 10020802 | Hypertensive crisis |
| 10047065 | Vascular disorders | 10047195 | Vena cava thrombosis |
| 10047065 | Vascular disorders | 10058179 | Hypertensive emergency |
| 10047065 | Vascular disorders | 10059245 | Angiopathy |
| 10047065 | Vascular disorders | 10061255 | Ischaemia |