General Notes

- Files
  - ReadMe PDF file
  - 28 dataset SAS files
  - Data dictionary and variable codes SAS files
  - 24 Case Report Forms PDF files
- Datasets
  - A complete listing of all variables, their description and their codes may be found in the datadictionary SAS file. Codes are detailed in the codelist SAS file.
  - There is a separate dataset for each included form, with the following exceptions:
    - Form09: Demographics is included in the subject dataset
    - Forms with child tables (Form03: Prior Medications, Form19: Study Drug Administration, Form25: Concomitant Medications, Form32: Additional Imaging) have 2 datasets: 1 with data from the child table (dataset ends in "c") and 1 with data from the remainder of the form. Exception: Form10c – only child table dataset included
  - Datasets can be merged using the SubjectID variable.
  - Forms that were collected only once during the study will have one row per subject. Forms collected multiple times per subject (Form06: GCS, Form07: Modified Rankin Scale, Form08: Labs, Form15: CT Scan & Central Reader CT Scan, Form18: Blood Sample Collection Sub-study, Form22: Vital Signs, Form23: Montreal Cognitive Assessment (MoCA) Scoring Summary, Form24: Stroke Impact Scale 16 (SIS-16), Form25: Concomitant Medications, Form26: Concomitant non-Drug Therapies, Form27: Adverse Events, Form30: Visual and Auditory Assessment Follow Up, Form32: Additional Imaging, Form43: NIH Stroke Scale) and child tables will have multiple rows per subject.
- Variable names
  - Except for the data from the subject enrollment form, data is named in the format F##Q##, where F## is the form number and Q## is the question number.
  - SubjectID and SiteID variables are included in all datasets. zVIsitNm is included in all datasets except the subject dataset.
- Dates and times
  - All dates and times are replaced with calculated time from randomization. If date and time are collected, the number of minutes from randomization is included. If only date is collected, the number of days from randomization is included.
  - If date and time are collected in separate questions on the CRF and 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

- Subject Enrollment Form
  - American Indian/Alaska Native (variable name zRaceM1) and Native Hawaiian/Other Pacific Islander (variable name zRaceM4) were coded as Other Race (variable name RaceOther) for de-identification purposes
  - Ages < 35 were replaced with 35 for de-identification purposes
  - Ethnicity (variable name f09q02) is included in this dataset
  - Inclusion in per protocol population indicated by variable PP_POP
- Form03c: Prior Medications child table
  - Medications (F03CQA) were categorized by the clinical PI (F03CzCategory2)
- Form09 – separate dataset not included; F09Q02 included in Subject Enrollment Form dataset (dataset name subject)
- Form12 – not included
- Form15

    - Merged with CT Scan Central Reader
    - Hematoma volume is calculated as total volume (Q04) – IVH volume (Q07)
    - Relative PHE is calculated as PHE volume (Q05)/hematoma volume
    - Hematoma location at screening based on CT scan and clinical PI review (variable name: HEMLOCSCR)
- Form23: Montreal Cognitive Assessment (MoCA) Scoring Summary – score calculated as sum of Q01-Q10
- Form24 – SIS-16 score is calculated as: ((sum of all questions-16)/64)*100
- Form25c: Concomitant Medications child table
    - Medications (F25CQA) were categorized by the clinical PI (F25CzCategory2)
- Form27: Adverse Events
    - MedDRA System Organ Class (SOC) and Preferred Term (PT) codes and names are included. SOCs with a frequency of one were combined and renamed 'Other System Organ Class'. PTs with a frequency of one were combined within each SOC by replacing the PT name with 'Other' *SOC name*. A list of these SOCs and PTs is below.
    - An indicator of ARDS based on the Medical Safety Monitor review of adverse events is included in this dataset (variable name: ARDS).
    - An indicator of symptomatic cerebral edema within 7 days/discharge based on clinical PI review is included in this dataset (variable name: EDEMA7DAY_AE)

Primary Analysis Notes

- Subjects were included in the modified Intent To Treat (mITT) population if study drug was administered (F29Q02 ≠3)
- Race corresponds to PUDS variables zRaceM1-zRaceM5 and zRaceM98. Race was categorized as unknown if zRaceM98 (Race: Unknown/Not Reported)=1 (Yes) or if more than one of zRaceM1-zRaceM5=1 (Yes).
- Medication use
    - Previous medication use data is from Form03: Prior Medications and post-ICH medication use data is from Form 25: Concomitant Medications
    - Antiplatelet agents – defined as subjects with medication categories of "Antiplatelet" or "Antiplatelet (aspirin)"
    - Warfarin– defined as subjects using warfarin at the time of ICH onset (F02Q05=1 (Yes))
    - Antihypertensives– defined as subjects with medication categories of "Acetyl Choline Esterase Inhibitor", "Antihypertensive", "Antihypertensive (ACE Inhibitor)", "Antihypertensive (B blocker)", "Antihypertensive (B Blocker)", "Antihypertensive (B Clocker)", "Antihypertensive (Calcium blocker)", "Antihypertensive (Vasodilator)", "Antihypertensive (alpha agonist)", "Antihypertensive (diuretic)", "Antihypertentive (diuretic)", "Antihypertensive (alpha adrenergic blocker)", "Antihypertensive (aplha adrenergic blocker)", "Coronary Vasodilator", "Coronary vasodilator", or "Diuretic"
    - Statins– defined as subjects with medication category of "Statin"
    - Antiedema agents– defined as subjects with medication categories of 'Anti-edema' 'Anti-edema agent'
    - Antiepileptics– defined as subjects with medication categories of 'Anti-epileptic' 'Antiepileptic'
- Subjects with post-infusion CT scan performed before the end of the last infusion were excluded from CT-related analysis (subjectID 1072, 1046)
- mRS was imputed as 6 (death) if the mRS assessment was missing and the death date (F26Q06) was on or before the expected visit (i.e. on/before 30 days post-randomization for the 30 day mRS)
- Timeliness – assessments were considered in-window according to the definitions below

Visit	**In-window definition**
7 day	No window applied
30 day	30±7 days post-randomization
60 day	60±14 days post-randomization
90 day	90±30 days post-randomization

180 day	180±30 days post-randomization

- Primary outcome defined as 90 day mRS assessed within window, dichotomized to ≤2 (mRS=0, 1, or 2) v. >2 (mRS=3, 4, 5, or 6)
- Withdrawal of care for a subject was defined as having an AE with MedDRA Preferred Term='Withdrawal of life support' or if withdrawal of care was instituted within 72 hours of randomization (F27Q52=Yes).

MedDRA System Organ Classes wiith Frequency=1, presented alphabetically

SOCName	PTName
Congenital, familial and genetic disorders	Colour blindness
Hepatobiliary disorders	Acute hepatic failure
Immune system disorders	Hypersensitivity
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Metastatic malignant melanoma

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

SOCName	PTName
Blood and lymphatic system disorders	Coagulopathy
Blood and lymphatic system disorders	Thrombocytopenia
Cardiac disorders	Extrasystoles
Cardiac disorders	Myocardial ischaemia
Cardiac disorders	Nodal rhythm
Cardiac disorders	Sinus arrhythmia
Cardiac disorders	Sinus bradycardia
Cardiac disorders	Sinus tachycardia
Cardiac disorders	Supraventricular extrasystoles
Cardiac disorders	Tachycardia
Cardiac disorders	Ventricular tachycardia
Ear and labyrinth disorders	Ear pain
Ear and labyrinth disorders	Tinnitus
Endocrine disorders	Goitre
Endocrine disorders	Inappropriate antidiuretic hormone secretion
Eye disorders	Blindness
Eye disorders	Diplopia
Eye disorders	Eye pain
Eye disorders	Gaze palsy
Eye disorders	Scleral oedema

SOCName	PTName
Gastrointestinal disorders	Abdominal distension
Gastrointestinal disorders	Abdominal pain
Gastrointestinal disorders	Anorectal disorder
Gastrointestinal disorders	Dry mouth
Gastrointestinal disorders	Dysphagia
Gastrointestinal disorders	Ileus paralytic
Gastrointestinal disorders	Lip swelling
Gastrointestinal disorders	Oedema mouth
Gastrointestinal disorders	Reflux gastritis
Gastrointestinal disorders	Retroperitoneal haemorrhage
Gastrointestinal disorders	Swollen tongue
Gastrointestinal disorders	Upper gastrointestinal haemorrhage
General disorders and administration site conditions	Discomfort
General disorders and administration site conditions	Fatigue
General disorders and administration site conditions	Inflammation
General disorders and administration site conditions	Injection site irritation
General disorders and administration site conditions	Injection site reaction
General disorders and administration site conditions	Nodule
General disorders and administration site conditions	Oedema
General disorders and administration site conditions	Oedema peripheral
General disorders and administration site conditions	Pain
Infections and infestations	Clostridium difficile colitis
Infections and infestations	Lobar pneumonia

SOCName	PTName
Infections and infestations	Otitis media
Infections and infestations	Septic shock
Infections and infestations	Skin candida
Infections and infestations	Tinea pedis
Injury, poisoning and procedural complications	Anaphylactic transfusion reaction
Injury, poisoning and procedural complications	Rib fracture
Injury, poisoning and procedural complications	Wound decomposition
Investigations	Activated partial thromboplastin time prolonged
Investigations	Blood glucose increased
Investigations	Blood potassium decreased
Investigations	Cardiac enzymes increased
Investigations	Hepatic enzyme increased
Investigations	International normalised ratio increased
Investigations	Monocyte count
Investigations	Prothrombin time prolonged
Investigations	Rubulavirus test positive
Investigations	Transaminases increased
Investigations	Urine output decreased
Metabolism and nutrition disorders	Fluid retention
Metabolism and nutrition disorders	Hyperphosphataemia
Metabolism and nutrition disorders	Hypoalbuminaemia
Metabolism and nutrition disorders	Hypovolaemia
Musculoskeletal and connective tissue disorders	Arthralgia
Musculoskeletal and connective tissue disorders	Back pain
Musculoskeletal and connective tissue disorders	Chondrocalcinosis pyrophosphate
Musculoskeletal and connective tissue disorders	Joint effusion
Musculoskeletal and connective tissue disorders	Joint swelling
Musculoskeletal and connective tissue disorders	Limb discomfort

SOCName	PTName
Musculoskeletal and connective tissue disorders	Pain in jaw
Nervous system disorders	Autonomic nervous system imbalance
Nervous system disorders	Encephalopathy
Nervous system disorders	Hemianopia
Nervous system disorders	Hemiparesis
Nervous system disorders	Hemiplegia
Nervous system disorders	Hypoaesthesia
Nervous system disorders	Intracranial aneurysm
Nervous system disorders	Lethargy
Nervous system disorders	Paraesthesia
Nervous system disorders	Partial seizures
Nervous system disorders	Sensory loss
Nervous system disorders	Subarachnoid haemorrhage
Nervous system disorders	Tremor
Psychiatric disorders	Confusional state
Psychiatric disorders	Depression
Psychiatric disorders	Mental status changes
Renal and urinary disorders	Dysuria
Renal and urinary disorders	Incontinence
Renal and urinary disorders	Nephropathy
Renal and urinary disorders	Pyuria
Renal and urinary disorders	Renal failure chronic
Renal and urinary disorders	Renal tubular necrosis
Reproductive system and breast disorders	Breast mass
Reproductive system and breast disorders	Pelvic pain
Respiratory, thoracic and mediastinal disorders	Bronchial obstruction
Respiratory, thoracic and mediastinal disorders	Lung consolidation
Respiratory, thoracic and mediastinal disorders	Pulmonary hypertension
Respiratory, thoracic and mediastinal disorders	Respiratory arrest

SOCName	PTName
Respiratory, thoracic and mediastinal disorders	Tachypnoea
Respiratory, thoracic and mediastinal disorders	Wheezing
Skin and subcutaneous tissue disorders	Hyperhidrosis
Vascular disorders	Haematoma
Vascular disorders	Neurogenic shock
Vascular disorders	Thrombophlebitis superficial