



Annotated: F01 Inclusion Exclusion Criteria

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doln

Form ID: 501 DB Table Name: F01 DB View Name: vF01

No.	Item Description	Data Value		
Q01	Date of signed informed consent DB Name: [Q01]	Complete		
Q02	Age DB Name: [Q02]	years old		
Q03	Diagnosis of ICH confirmed by brain CT scan DB Name: [Q03] Code Group: 51	○ 0 - No ○ 1 - Yes		
Q04	The first dose of the study drug is expected to be administered within 24h of ICH symptom onset DB Name: [Q04] Code Group: 51	○ 0 - No ○ 1 - Yes		
Q05	NIHSS score DB Name: [Q05] Code Group: 51	○ 0 - No ○ 1 - Yes		
Q06	Pre-ICH mRS DB Name: [Q06] Code Group: 584	○ 0 - (0) No symptoms at all ○ 1 - (1) No significant disability despite symptoms; able to carry out all usual duties and activities. ○ 2 - (2) Slight disability; unable to carry out all previous activities but able to look after own affairs without assistance. ○ 3 - (3) Moderate disability requiring some help, but able to walk without assistance. ○ 4 - (4) Moderately severe disability; unable to walk without assistance and unable to attend to own bodily needs without assistance. ○ 5 - (5) Severe disability; bedridden, incontinent, and requiring constant nursing care and attention.		
Q07	Previous chelation therapy or known hypersensitivity to DFO products DB Name: [Q07] Code Group: 51	○ 0 - No ○ 1 - Yes		
Q08	Known severe iron deficiency anemia DB Name: [Q08] Code Group: 51	○ 0 - No ○ 1 - Yes		
Q09	Abnormal renal functions DB Name: [Q09] Code Group: 51	○ 0 - No ○ 1 - Yes		
Q10	Planned surgical evacuation of ICH prior to administration of study drug DB Name: [Q10] Code Group: 51	○ 0 - No ○ 1 - Yes		
Q11	Suspected secondary ICH DB Name: [Q11] Code Group: 51	○ 0 - No ○ 1 - Yes		
Q12	Infratentorial hemorrhage DB Name: [Q12] Code Group: 51	○ 0 - No ○ 1 - Yes		
Q13	Irreversibly impaired brainstem function DB Name: [Q13] Code Group: 51	○ 0 - No ○ 1 - Yes		
Q14	Complete unconsciousness defined as a score of 3 on item 1a of the NIHSS DB Name: [Q14] Code Group: 51	○ 0 - No ○ 1 - Yes		
Q15	Coagulopathy DB Name: [Q15] Code Group: 51	○ 0 - No ○ 1 - Yes		
Q16	Confirmed aspiration, pneumonia, or evident bilateral pulmonary infiltrates DB Name: [Q16] Code Group: 51	○ 0 - No ○ 1 - Yes		
Q17	Significant respiratory disease DB Name: [Q17] Code Group: 51	○ 0 - No ○ 1 - Yes		
Q18	FiO2 DB Name: [Q18] Code Group: 51	○ 0 - No ○ 1 - Yes		

No.	Item Description	Data Value		
Q19	Sepsis DB Name: [Q19] Code Group: 51	○ 0 - No ○ 1 - Yes		
Q20	Taking iron supplements DB Name: [Q20] Code Group: 51	○ 0 - No ○ 1 - Yes		
Q21	Patients with heart failure DB Name: [Q21] Code Group: 51	○ 0 - No ○ 1 - Yes		
Q22	Known severe hearing loss DB Name: [Q22] Code Group: 51	○ 0 - No ○ 1 - Yes		
Q23	Known pregnancy DB Name: [Q23] Code Group: 51	○ 0 - No ○ 1 - Yes		
Q24	Positive drug screen DB Name: [Q24] Code Group: 51	○ 0 - No ○ 1 - Yes		
Q25	Patient is known or suspected of DB Name: [Q25] Code Group: 51	○ 0 - No ○ 1 - Yes		
Q26	Any condition DB Name: [Q26] Code Group: 51	○ 0 - No ○ 1 - Yes		
Q27	Life expectancy DB Name: [Q27] Code Group: 51	○ 0 - No ○ 1 - Yes		
Q28	Concurrent participation DB Name: [Q28] Code Group: 51	○ 0 - No ○ 1 - Yes		
Q29	Indication that a new DNR DB Name: [Q29] Code Group: 51	○ 0 - No ○ 1 - Yes		
Q30	Respiratory rate greater than 30 breaths/min DB Name: [Q30] Code Group: 51	○ 0 - No ○ 1 - Yes		
Q31	SpO ₂ level less than 95% DB Name: [Q31] Code Group: 51	○ 0 - No ○ 1 - Yes		
Q32	Estimated weight DB Name: [Q32]			
Q33	Estimated weight units DB Name: [Q33] Code Group: 573	○1 - lbs ○2 - kg		
Q34	Height DB Name: [Q34]			
Q35	Height units DB Name: [Q35] Code Group: 574	○1 - inches ○2 - cm		
Q36	Body Mass Index DB Name: [Q36] Code Group: 574			
Q37	Serum pH less than 7.35 pH DB Name: [Q37] Code Group: 503	○ 0 - No ○ 1 - Yes ○ 9998 - Unknown Reason:		
Q38	Serum Albumin DB Name: [Q38]	char.)		
	Code Group: 574 Serum Albumin units			
Q39	DB Name: [Q39] Code Group: 504	○1 - g/dL ○2 - g/L ○3 - umol/L		
Q40	Concurrent use of chemotherapy DB Name: [Q40] Code Group: 51	○ 0 - No ○ 1 - Yes		

No.	Item Description	Data Value	
Q42	Number of ARDS Modifiers DB Name: [CntRiskMod] Code Group: 574 SAS Name: [F01Q42]		
Q41	Is the subject participating in the iDEF sub-study? DB Name: [Q41] Code Group: 51	○ 0 - No ○ 1 - Yes	
Qc	General Comments DB Name: [zNotes]	(250 char.)	

When Q38 Is not null 0, Q39 is enabled.





Help

Annotated: F02 Randomization Form

Form ID: 502 DB Table Name: F02 DB View Name: vF02

No.	Item Description	Data Value
Q01	Is IVH present? DB Name: [Q01] Code Group: 51	○ 0 - No ○ 1 - Yes
Q02	Location of ICH DB Name: [Q02] Code Group: 506	○1 - Infratentorial ○2 - Supratentorial
Q03	Hematoma volume DB Name: [Q03] Code Group: 51	
Q04	Anticipated onset to treatment time DB Name: [Q04] Code Group: 505	_ 1 - ≤ 12 hours 2 - >12 and ≤ 24 hours
Q05	Was the subject using Warfarin DB Name: [Q05] Code Group: 503	○ 0 - No ○ 1 - Yes ○ 9998 - Unknown Reason: (200 char.)
Q06	Is the patient deemed eligible DB Name: [Q06] Code Group: 51	○ 0 - No ○ 1 - Yes
Qc	General Comments DB Name: [zNotes]	(250 char.)

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Help

Annotated: F03 Prior Medications

	Form ID: 503 DB Table Name: F03 DB View Name: vF03			
No.	No. Item Description	Data Value		
Qa	Qa Data Collected? DB Name: [zDataCollected]	○1 - Yes		
Q01	Q01			
No.	A. Medication name (100 char.) DB Name: [QA]			
Qc	Qc General Comments DB Name: [zNotes]			





Annotated: F04 Screening Visual and Auditory Assessment Form ID: 504 DB Table Name: F04 DB View Name: vF04

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No.	Item Description	Data Value		
Qa	Data Collected? DB Name: [zDataCollected] Code Group: 51	○ 0 - No ○ 1 - Yes		
Qb	Date of assessment DB Name: [zFormDate]	(dd-mmm-yyyy) Complete		
Q01	Does the subject have cataracts? DB Name: [Q01] Code Group: 560	○ 0 - No ○ 1 - Yes ○ 3 - Unknown / Unable to assess		
Q02	Does the subject have visual loss or field cut? DB Name: [Q02] Code Group: 560	0 - No 1 - Yes 3 - Unknown / Unable to assess		
Q03	Is the subject color blind? DB Name: [Q03] Code Group: 560	○ 0 - No ○ 1 - Yes ○ 3 - Unknown / Unable to assess		
Q04	Does the subject have tinnitus? DB Name: [Q04] Code Group: 560	○ 0 - No ○ 1 - Yes ○ 3 - Unknown / Unable to assess		
Q05	Does the subject have hearing loss? DB Name: [Q05] Code Group: 560	○ 0 - No ○ 1 - Yes ○ 3 - Unknown / Unable to assess		
Q06	Other visual or auditory abnormalities/changes DB Name: [Q06]	(250 char.)		
Qc	General Comments DB Name: [zNotes]	(250 char.)		

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Help

Annotated: F05 Medical History Form

Form ID: 505 DB Table Name: F05 DB View Name: vF05

No.	Item Description	Data Value
Qa	Data Collected? DB Name: [zDataCollected] Code Group: 51	○ 0 - No ○ 1 - Yes
Q01	Date/time of ICH onset or last seen normal DB Name: [Q01]	$\boxed{\text{dd} \checkmark \text{mmm} \checkmark \text{yyyy} \checkmark \boxed{\text{m}} \text{hh} \checkmark : \text{mm} \checkmark \bigcirc \text{AM} \bigcirc \text{PM}}$
Q02	Date/time of presentation at ED of enrolling hospital DB Name: [Q02]	$\boxed{dd \boldsymbol{\vee} mmm \boldsymbol{\vee} yyyy \boldsymbol{\vee} \boxed{\hspace{-0.1cm}} hh \boldsymbol{\vee} : mm \boldsymbol{\vee} \bigcirc AM \bigcirc PM}$
Q03	Previous hemorrhage DB Name: [Q03] Code Group: 555	○ 0 - No ○ 1 - Yes ○ 96 - Unknown
Q04	Cognitive decline/dementia DB Name: [Q04] Code Group: 555	○ 0 - No ○ 1 - Yes ○ 96 - Unknown
Q05	Ischemic stroke/TIA DB Name: [Q05] Code Group: 555	○ 0 - No ○ 1 - Yes ○ 96 - Unknown
Q06	Specify any other nervous system disorders DB Name: [Q06]	(100 char.)
Q07	Hypertension DB Name: [Q07] Code Group: 555	○ 0 - No ○ 1 - Yes ○ 96 - Unknown
Q08	Hyperlipidemia DB Name: [Q08] Code Group: 555	○ 0 - No ○ 1 - Yes ○ 96 - Unknown
Q09	Congestive heart failure DB Name: [Q09] Code Group: 555	○ 0 - No ○ 1 - Yes ○ 96 - Unknown
Q10	Atrial fibrillation DB Name: [Q10] Code Group: 555	○ 0 - No ○ 1 - Yes ○ 96 - Unknown
Q11	Myocardial infarction DB Name: [Q11] Code Group: 555	○ 0 - No ○ 1 - Yes ○ 96 - Unknown
Q12	Peripheral vascular disease DB Name: [Q12] Code Group: 555	○ 0 - No ○ 1 - Yes ○ 96 - Unknown
Q13	Specify any other cardiovascular disorders DB Name: [Q13]	(100 char.)
Q14	COPD/Asthma DB Name: [Q14] Code Group: 555	○ 0 - No ○ 1 - Yes ○ 96 - Unknown
Q15	Specify any other respiratory disorders DB Name: [Q15]	(100 char.)
Q16	Diabetes mellitus DB Name: [Q16] Code Group: 555	○ 0 - No ○ 1 - Yes ○ 96 - Unknown
Q17	Specify any other endocrine disorders DB Name: [Q17]	(100 char.)
Q18	Immune system disorders DB Name: [Q18]	(100 char.)
Q19	Congenital and familial/genetic disorders DB Name: [Q19]	(100 char.)
Q20	Neoplasms (benign and malignant) DB Name: [Q20]	(100 char.)
Q21	Renal disorders DB Name: [Q21]	(100 char.)
Q22	Hepato-biliary disorders DB Name: [Q22]	(100 char.)
Q23	Hematologic disorders DB Name: [Q23]	(100 char.)

No.	Item Description	Data Value
Q24	Hearing disorders DB Name: [Q24]	(100 char.)
Q25	Visual disorders DB Name: [Q25]	(100 char.)
Q26	Neurosurgical procedures DB Name: [Q26]	(100 char.)
Q27	Other surgical or medical procedures DB Name: [Q27]	(100 char.)
Q28	Cigarettes or other tobacco products use DB Name: [Q28] Code Group: 608	○ 0 - No ○ 1 - Yes, current use ○ 2 - Yes, past use
Q29	Alcoholic drink DB Name: [Q29] Code Group: 608	○ 0 - No ○ 1 - Yes, current use ○ 2 - Yes, past use
Q30	Drug Use DB Name: [Q30] Code Group: 608	○ 0 - No ○ 1 - Yes, current use ○ 2 - Yes, past use
Qc	General Comments DB Name: [zNotes]	char.) (250

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Help

Annotated: F06 Glasgow Coma Scale

Form ID: 507 DB Table Name: F06 DB View Name: vF06

N.c.	Form ID: 50/ DB Table Name: F06 DB View Name: vF06		
No.	Item Description	Data Value	
Qa	Data Collected? DB Name: [zDataCollected] Code Group: 51	○ 0 - No ○ 1 - Yes	
Q01	Date/time of GCS assessment: DB Name: [Q01]	dd 🕶 mmm 🕶 yyyy 🕶 🗎 hh 🕶 : mm 🕶 🔾 AM 🔾 PM	
Q02	Was the study participant intubated at the time of assessment? DB Name: [Q02] Code Group: 51	○ 0 - No ○ 1 - Yes	
Q03	Best eye opening response DB Name: [Q03] Code Group: 585	○ 9998 - Unknown <i>Reason:</i> (200	
Q04	Best verbal response for non-intubated subjects DB Name: [Q04] Code Group: 601	char.) 1 - (1) None (no verbalization of any type) 2 - (2) Incomprehensible (moans/groans, no speech) 3 - (3) Inappropriate (intelligible, no sustained sentences) 4 - (4) Confused (converses but confused, disoriented) 5 - (5) Oriented (converses and oriented) 9998 - Unknown Reason:	
Q05	Predicted verbal response for intubated subjects DB Name: [Q05] Code Group: 601	char.) 1 - (1) None (no verbalization of any type) 2 - (2) Incomprehensible (moans/groans, no speech) 3 - (3) Inappropriate (intelligible, no sustained sentences) 4 - (4) Confused (converses but confused, disoriented) 5 - (5) Oriented (converses and oriented) 9998 - Unknown Reason:	
Q06	Best Motor Response DB Name: [Q06] Code Group: 602	char.) 1 - (1) None (to any pain; limbs remain flaccid) 2 - (2) Extension (shoulder adducted and shoulder and forearm internally rotated) 3 - (3) Flexor response (withdrawal response or assumption of hemiplegic posture) 4 - (4) Withdrawal (arm withdraws to pain, shoulder abducts) 5 - (5) Localizes Pain (arm attempts to remove from painful stimuli) 6 - (6) Obeys Commands (follows simple commands) 9998 - Unknown Reason:	
Q07	Total GCS score DB Name: [Q07]		
Qc	General Comments DB Name: [zNotes]		
T 71	One Faugl to 0. One is enabled	(250 char.)	

When Q02 Equal to 0, Q04 is enabled. When Q02 Equal to 1, Q05 is enabled.





Help

Annotated: F07 Modified Rankin Scale

Form ID: 508 DB Table Name: F07 DB View Name: vF07

No.	Item Description	Data Value
Qa	Data Collected? DB Name: [zDataCollected] Code Group: 51	○ 0 - No ○ 1 - Yes
Qb	Date of assessment DB Name: [zFormDate]	(dd-mmm-yyyy) Complete
Q01	Modified Rankin Scale DB Name: [Q01] Code Group: 584	 0 - (0) No symptoms at all 1 - (1) No significant disability despite symptoms; able to carry out all usual duties and activities. 2 - (2) Slight disability; unable to carry out all previous activities but able to look after own affairs without assistance. 3 - (3) Moderate disability requiring some help, but able to walk without assistance. 4 - (4) Moderately severe disability; unable to walk without assistance and unable to attend to own bodily needs without assistance. 5 - (5) Severe disability; bedridden, incontinent, and requiring constant nursing care and attention.
Q02	Who provided the information on this form? DB Name: [Q02] Code Group: 561	1 - Subject 2 - Proxy 3 - Both subject and proxy 9998 - Unknown Reason: (200
Q03	First/Given name DB Name: [Q03]	(50 char.)
Q04	Last/Family name DB Name: [Q04]	(50 char.)
Qc	General Comments DB Name: [zNotes]	(250 char.)

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Q19

Q20

Q21





Annotated: F08 Labs

Help

No.	Item Description	Data Value
Qa	Data Collected? DB Name: [zDataCollected] Code Group: 51	○ 0 - No ○ 1 - Yes
Q01	Date of blood draw DB Name: [Q01]	(dd-mmm-yyyy) Complete
Q02	Time of blood draw DB Name: [Q02]	hh → : mm → (24hr clock) Complete Time
Q03	WBC DB Name: [Q03]	
Q04	WBC units DB Name: [Q04] Code Group: 562	\bigcirc 1 - x 10 ³ /mm ³ (x 10 ³ /mcL) \bigcirc 2 - x 10 ⁹ /L (K/mcL, μ L)
Q05	Are the WBC results abnormal and clinically significant? DB Name: [Q05] Code Group: 51	○ 0 - No ○ 1 - Yes
Q06	Monocytes DB Name: [Q06]	%
Q07	Neutrophil DB Name: [Q07]	%
Q08	RBC DB Name: [Q08]	
Q09	RBC units DB Name: [Q09] Code Group: 563	○2 - x 10 ⁶ /mm ³ (x 10 ⁶ /mcL) ○3 - x 10 ¹² /L
Q10	Are the RBC results abnormal and clinically significant? DB Name: [Q10] Code Group: 51	○ 0 - No ○ 1 - Yes
Q11	Platelet count DB Name: [Q11]	
Q12	Platelet count units DB Name: [Q12] Code Group: 613	○1 - x 10 ³ /mm ³ (x 10 ³ /mcL) ○2 - x 10 ⁹ /L
Q13	Are the platelet count results abnormal and clinically significant? DB Name: [Q13] Code Group: 51	○ 0 - No ○ 1 - Yes
Q14	Hemoglobin DB Name: [Q14]	
Q15	Hemoglobin units DB Name: [Q15] Code Group: 564	◯1 - gm/dL ◯2 - gm/L
Q16	Are the hemoglobin results abnormal and clinically significant? DB Name: [Q16] Code Group: 51	○ 0 - No ○ 1 - Yes
Q17	Hematocrit DB Name: [Q17]	%
Q18	Are the hematocrit results abnormal and clinically significant? DB Name: [Q18] Code Group: 51	○ 0 - No ○ 1 - Yes

Q22	clinically significant? DB Name: [Q22] Code Group: 51	○ 0 - No	○1 - Yes
Q23	Sodium DB Name: [Q23]		mmol/L (mEq / L)

○0 - No ○1 - Yes

Are the International Normalized Ratio results abnormal and

Activated Partial Thromboplastin Time

abnormal and clinically significant?

International Normalized Ratio

Are the Activated Partial Thromboplastin Time results

DB Name: [Q19]

DB Name: [Q20] Code Group: 51

DB Name: [Q21]

No.	Item Description	Data Value
Q24	Are the Sodium results abnormal and clinically significant? DB Name: [Q24] Code Group: 51	○ 0 - No ○ 1 - Yes
Q25	Glucose DB Name: [Q25]	
Q26	Glucose units DB Name: [Q26] Code Group: 565	○1 - mg/dL ○2 - mmol/L
Q27	Are the Glucose results abnormal and clinically significant? DB Name: [Q27] Code Group: 51	○ 0 - No ○ 1 - Yes
Q28	Potassium DB Name: [Q28]	mmol/L (mEq / L)
Q29	Are the Potassium results abnormal and clinically significant? DB Name: [Q29] Code Group: 51	○ 0 - No ○ 1 - Yes
Q30	Creatinine Result DB Name: [Q30]	
Q31	Creatinine units DB Name: [Q31] Code Group: 566	○1 - mg/dL ○2 - umol/L
Q32	Are the Creatinine results abnormal and clinically significant? DB Name: [Q32] Code Group: 51	○ 0 - No ○ 1 - Yes
Q33	Blood Urea Nitrogen (BUN) Result DB Name: [Q33]	
Q34	Blood Urea Nitrogen (BUN) units DB Name: [Q34] Code Group: 565	◯1 - mg/dL
Q35	Are the Blood Urea Nitrogen results abnormal and clinically significant? DB Name: [Q35] Code Group: 51	○0 - No ○1 - Yes
Q36	Alanine transaminase (ALT) Result DB Name: [Q36]	U/L (IU/L)
Q37	Are the ALT results abnormal and clinically significant? DB Name: [Q37] Code Group: 51	○ 0 - No ○ 1 - Yes
Q38	Aspartate Aminotransferase (AST) Result DB Name: [Q38]	U/L (IU/L)
Q39	Are the AST results abnormal and clinically significant? DB Name: [Q39] Code Group: 51	○ 0 - No ○ 1 - Yes
Q40	Alkaline Phosphatase (ALK PHOS) Result DB Name: [Q40]	U/L (IU/L)
Q41	Are the ALK PHOS results abnormal and clinically significant? DB Name: [Q41] Code Group: 51	○ 0 - No ○ 1 - Yes
Q42	Date/time urine sample DB Name: [Q42]	dd • mmm • yyyy • the hh • : mm • OAM OPM
Q43	Urine Bilirubin DB Name: [Q43] Code Group: 567	0 - Negative 1 - Positive 9998 - Unknown Reason: (200
Q44	Are the urine bilirubin results abnormal and clinically significant? DB Name: [Q44] Code Group: 51	○ 0 - No ○ 1 - Yes
Q45	Urine Specific Gravity DB Name: [Q45]	
Q46	Are the urine specific gravity results abnormal and clinically significant? DB Name: [Q46] Code Group: 51	○ 0 - No ○ 1 - Yes

No.	Item Description	Data Value	
Q47	Urine Blood DB Name: [Q47] Code Group: 567	○ 0 - Negative ○ 1 - Positive ○ 9998 - Unknown Reason: (200 char.))
Q48	Are the urine blood results abnormal and clinically significant? DB Name: [Q48] Code Group: 51	○ 0 - No ○ 1 - Yes	
Q49	Urine pH Result DB Name: [Q49]		
Q50	Are the urine pH results abnormal and clinically significant? DB Name: [Q50] Code Group: 51	○ 0 - No ○ 1 - Yes	
Q51	Urine Nitrite Result DB Name: [Q51] Code Group: 567	○ 0 - Negative ○ 1 - Positive ○ 9998 - Unknown Reason:)
		char.)	
Q52	Are the urine nitrate results abnormal and clinically significant? DB Name: [Q52] Code Group: 51	○ 0 - No ○ 1 - Yes	
Q53	Urine Leukocytes Result DB Name: [Q53] Code Group: 567	0 - Negative 1 - Positive 9998 - Unknown Reason: (200)
Q54	Are the urine leukocytes results abnormal and clinically significant? DB Name: [Q54] Code Group: 51	○ 0 - No ○ 1 - Yes	
Q55	Is the urine sample colorless? DB Name: [Q55] Code Group: 51	○ 0 - No ○ 1 - Yes	
Q56	Urine color DB Name: [Q56]	(25 char.)	
Qc	General Comments DB Name: [zNotes]	(250 char)	1

When Q55 Equal to 0, Q56 is enabled.







Help

Annotated: F09 Demographics

	Form ID: 510 DB Table	Name: F09 DB View Name: VF09
No.	Item Description	Data Value
Q01	Gender DB Name: [Q01] Code Group: 568	Male Female
Q02	Ethnicity DB Name: [Q02] Code Group: 569	○1 - Hispanic or Latino ○2 - Not Hispanic or Latino ○98 - Unknown
Q03	Race	□ American Indian or Alaska Native □ Asian □ Black or African American □ Native Hawaiian or Other Pacific Islander □ White □ Unknown □ Not reported
Qc	General Comments DB Name: [zNotes]	(250 char.)





Help

Annotated: F10 Subject Intubation Log

		Form ID: 512 DB Table Name: F10 DB View Name: vF10					
No.	Item Description Data Value						
Qa	Data Collected? DB Name: [zDataCollected Code Group: 51		ollected]	○0 - No ○1 - Yes			
Q01							
No.	A. Reason for assessment? DB Name: [QA]	B. Date/time of intubation/worsening DB Name: [QB]	C. PaO ₂ /FiO ₂ ratio (If PaO ₂ /FiO ₂ is less than 30 mmHg, chest xray is required) (mmHg) DB Name: [QC]		D. Plateau pressure (cm H ₂ O) DB Name: [QD	E. Peak pressure (cm H ₂ O) DB Name: [QE	F. Mode of ventilation (100 char.) DB Name: [QF]
Qc		General Com DB Name: [zNo		(250 char.)			//

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Help

Annotated: F11 Hospital Discharge

Form ID: 528 DB Table Name: F11 DB View Name: vF11

No.	Item Description	Data Value		
Q01	Date of hospital discharge DB Name: [Q01]	~	(dd-mmm-yyyy) Complete	
Q02	Subject was discharged to: DB Name: [Q02] Code Group: 600	2 - Acute rei types, multidisc 3 - Sub-acut that does not re 4 - Long-ten that require inte days)) 5 - Skilled n only be done b 6 - Assisted live independer 7 - Nursing enough to need	home care (usually long-term) of patients who are not sick d hospital care, but are not able to remain at home Funeral home (Death-Complete End of Study form) independent) r Specify:	
Q03	Based on available clinical and imaging data, what is the most likely cause for ICH? DB Name: [Q03] Code Group: 508	1 - Hyperter 2 - Amyloid 9996 - Othe char.) 9998 - Unkr	angiopathy r <i>Specify:</i> (200	
Qc	General Comments DB Name: [zNotes]	(250 char.)	//	







Help

Annotated: F12 Treatment Confirmation

Form ID: 549 DB Table Name: F12

No.	Item Description	Data Value
Q01	Is this subject a post-randomization screen failure? DB Name: [Q01] Code Group: 51	○ 0 - No ○ 1 - Yes
Q02	Was study drug prepared for this subject at the site pharmacy? DB Name: [Q02] Code Group: 51	○ 0 - No ○ 1 - Yes
Qc	General Comments DB Name: [zNotes]	(250 char.)

When Q01 Equal to 1, Q02 is enabled.





Help

Annotated: F15 CT Scan

Form ID: 511 DB Table Name: F15 DB View Name: vF15

No. Item Description Data Value Qa DB Name: [zDataCollected] Code Group: 51 0 - No	
Qa DB Name: [zDataCollected] Code Group: 51 0 - No	
DB Name: [Q01]	
Q02 DB Name:	
Code Group: 51	
Is cerebral hemorrhage present? DB Name: [Q03] Code Group: 51	
Q04M1 - Thalamus Q04M2 - Caudate Q04M3 - Putamen Q04M4 - Pallidum Q04M5 - Internal Capsule Q04M6 - External Capsule Q04M7 - Lobar Q04M8 - Midbrain Q04M9 - Pons Q04M10 - Cerebellum Q04M96 - Other Specify: char.) Q04M98 - Unknown Reason:	(200
Subarachnoid hemorrhage: DB Name: [Q05] Code Group: 555	
Intraventricular hemorrhage: Q06 DB Name: [Q06] Code Group: 555	
Hydrocephalus: DB Name: [Q07] Code Group: 555	
Q08 Image tracking number DB Name: [CTTrackingNb]	
Qc General Comments DB Name: [zNotes] (250 char.)	

When Q03 Equal to 1, Q04 is enabled.

When Q03 Equal to 1, Q06 is enabled.

When Q03 Equal to 1, Q05 is enabled.

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Annotated: F18 Blood Sample Collection Substudy Form ID: 513 DB Table Name: F18 DB View Name: vF18

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No.	Item Description	Data Value
Qa	Data Collected? DB Name: [zDataCollected] Code Group: 51	
Q01	Date/time of blood sample collection DB Name: [Q01]	dd • mmm • yyyy • the hh • : mm • AM OPM
Qc	General Comments DB Name: [zNotes]	(250 char.)

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Help

Annotated: F19 Study Drug Administration

Form ID: 514 DB Table Name: F19 DB View Name: vF19 **Item Description Data Value** No. ∩ 1 - Study drug was administered in full Administration of IV DFO Q01 DB Name: [Q01] ○2 - Study drug was administered, but the intended dosage or duration was not Code Group: 571 received ∩ 1 - Severe allergic reaction ○ 2 - Significant worsening of neurological status 3 - Significant worsening of renal function tests 4 - Administration of prohibited medication/therapy Reason 'Study drug was administered, but the ○5 - ARDS intended dosage or duration was not received' _ 6 - Discharge Q02 DB Name: [Q02] Code Group: 572 ○ 8 - Death 9 - Other AE 9996 - Other Specify: (200 char.) CRF ID of the adverse event Q03 DB Name: [Q03] (100 char.) Weight used for initial dose calculation Q04 DB Name: [F01Q32] Estimated weight units for initial dose calculation Q05 DB Name: [F01Q33] Ibs _ kg Code Group: 573 Actual weight as measured within 24 hours of Q06 randomization DB Name: [Q06] Weight units for actual weight ○1 - lbs _2 - kg Q07 DB Name: [Q07] Code Group: 573 □ Q08M0 - None Q08M1 - Pharmacy mixing/dosing error □ Q08M2 - Failure to follow criteria for premature discontinuation of study drug Study drug administration errors Q08 ☐ Q08M3 - Infusion pump malfunction/error Q08M98 - Other Specify: (200 char.) Q09 C. A. Rate of infusion Start date/time of infusion Stop date/time of infusion No. (cc/hr) DB Name: [QA] DB Name: [QB] DB Name: [QC] **General Comments** Qc DB Name: [zNotes] (500 char.)

When **O01** Equal to 2, **O02** is enabled.

When Q02 Equal to 1, Q03 is enabled.

When Q02 Equal to 2, Q03 is enabled.

When Q02 Equal to 3, Q03 is enabled.

When Q02 Equal to 4, Q03 is enabled.

When Q02 Equal to 5, Q03 is enabled.

When O02 Equal to 7. O03 is enabled.

When **O02 Equal to 8**, **O03** is enabled.

When Q02 Equal to 9, Q03 is enabled.







Annotated: F22 Vital Signs (BP & Pulse)

Help

	Form ID: 515 DB Table	Name: F22 DB View Name: vF22
No.	Item Description	Data Value
Qa	Data Collected? DB Name: [zDataCollected] Code Group: 51	○ 0 - No ○ 1 - Yes
Q01	Date/time of assessment DB Name: [Q01]	dd ✔ mmm ✔ yyyy ✔ 🛗 hh ✔ : mm ✔ ○AM ○PM
Q04	Temperature DB Name: [Q04]	
Q05	Temperature units DB Name: [Q05] Code Group: 575	○1-°C ○2-°F
Q06	Heart rate DB Name: [Q06]	beats/min
Q07	Systolic blood pressure DB Name: [Q07]	mm Hg
Q08	Diastolic blood pressure DB Name: [Q08]	mm Hg
Q09	Respiratory rate DB Name: [Q09]	breaths/min
Qc	General Comments DB Name: [zNotes]	(250 char.)





Help

Annotated: F23 MoCA Scoring Summary

Form ID: 516 DB Table Name: F23 DB View Name: vF23

No.	Item Description	Data Value
Qa	Data Collected? DB Name: [zDataCollected] Code Group: 51	○ 0 - No ○ 1 - Yes
Qb	Date of assessment DB Name: [zFormDate]	(dd-mmm-yyyy) Complete
Q01	Visuospatial / Executive Score: DB Name: [Q01]	(0—5)
Q02	Naming Score: DB Name: [Q02]	(0—3)
Q03	Digits Attention Score: DB Name: [Q03]	(0—2)
Q04	Letters Attention Score: DB Name: [Q04]	(0—1)
Q05	Subtraction Attention Score: DB Name: [Q05]	(0—3)
Q06	Language Repeat Score: DB Name: [Q06]	(0—2)
Q07	Language Fluency Score: DB Name: [Q07]	(0—1)
Q08	Abstraction Score: DB Name: [Q08]	(0—2)
Q09	Delayed Recall Score: DB Name: [Q09]	(0—5)
Q10	Orientation Score: DB Name: [Q10]	(0—6)
Q11	Trail 1 Memory Score: DB Name: [Q11]	correct (0—5)
Q12	Trail 2 Memory Score: DB Name: [Q12]	correct (0—5)
Qc	General Comments DB Name: [zNotes]	(250 char.)



Annotated: F24 Stroke Impact Scale-16

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Help

Form ID: 517 DB Table Name: F24 DB View Name: vF24

-		Name: F24 DB View Name: vF24
No.	Item Description	Data Value
Qa	Data Collected? DB Name: [zDataCollected] Code Group: 51	○ 0 - No ○ 1 - Yes
Qb	Date of assessment DB Name: [zFormDate]	(dd-mmm-yyyy) Complete
Q01	Dress the top part of your body? DB Name: [Q01] Code Group: 576	 5 - 5 = Not difficult at all 4 - 4 = A little difficult 3 - 3 = Somewhat difficult 2 - 2 = Very difficult 1 - 1 = Could not do at all
Q02	Bathe yourself? DB Name: [Q02] Code Group: 576	 5 - 5 = Not difficult at all 4 - 4 = A little difficult 3 - 3 = Somewhat difficult 2 - 2 = Very difficult 1 - 1 = Could not do at all
Q03	Get to the toilet on time? DB Name: [Q03] Code Group: 576	 5 - 5 = Not difficult at all 4 - 4 = A little difficult 3 - 3 = Somewhat difficult 2 - 2 = Very difficult 1 - 1 = Could not do at all
Q04	Control your bladder (not have an accident)? DB Name: [Q04] Code Group: 576	 5 - 5 = Not difficult at all 4 - 4 = A little difficult 3 - 3 = Somewhat difficult 2 - 2 = Very difficult 1 - 1 = Could not do at all
Q05	Control your bowels (not have an accident)? DB Name: [Q05] Code Group: 576	 5 - 5 = Not difficult at all 4 - 4 = A little difficult 3 - 3 = Somewhat difficult 2 - 2 = Very difficult 1 - 1 = Could not do at all
Q06	Stand without losing balance? DB Name: [Q06] Code Group: 576	 5 - 5 = Not difficult at all 4 - 4 = A little difficult 3 - 3 = Somewhat difficult 2 - 2 = Very difficult 1 - 1 = Could not do at all
Q07	Go shopping? DB Name: [Q07] Code Group: 576	 5 - 5 = Not difficult at all 4 - 4 = A little difficult 3 - 3 = Somewhat difficult 2 - 2 = Very difficult 1 - 1 = Could not do at all
Q08	Do heavy household chores? DB Name: [Q08] Code Group: 576	 5 - 5 = Not difficult at all 4 - 4 = A little difficult 3 - 3 = Somewhat difficult 2 - 2 = Very difficult 1 - 1 = Could not do at all
Q09	Stay sitting without losing your balance? DB Name: [Q09] Code Group: 576	 5 - 5 = Not difficult at all 4 - 4 = A little difficult 3 - 3 = Somewhat difficult 2 - 2 = Very difficult 1 - 1 = Could not do at all
Q10	Walk without losing your balance? DB Name: [Q10] Code Group: 576	 5 - 5 = Not difficult at all 4 - 4 = A little difficult 3 - 3 = Somewhat difficult 2 - 2 = Very difficult 1 - 1 = Could not do at all
Q11	Move from a bed to a chair? DB Name: [Q11] Code Group: 576	 5 - 5 = Not difficult at all 4 - 4 = A little difficult 3 - 3 = Somewhat difficult 2 - 2 = Very difficult 1 - 1 = Could not do at all

No.	Item Description	Data Value
Q12	Walk fast? DB Name: [Q12] Code Group: 576	 5 - 5 = Not difficult at all 4 - 4 = A little difficult 3 - 3 = Somewhat difficult 2 - 2 = Very difficult 1 - 1 = Could not do at all
Q13	Climb one flight of stairs? DB Name: [Q13] Code Group: 576	 5 - 5 = Not difficult at all 4 - 4 = A little difficult 3 - 3 = Somewhat difficult 2 - 2 = Very difficult 1 - 1 = Could not do at all
Q14	Walk one block? DB Name: [Q14] Code Group: 576	 5 - 5 = Not difficult at all 4 - 4 = A little difficult 3 - 3 = Somewhat difficult 2 - 2 = Very difficult 1 - 1 = Could not do at all
Q15	Get in and out of a car? DB Name: [Q15] Code Group: 576	 5 - 5 = Not difficult at all 4 - 4 = A little difficult 3 - 3 = Somewhat difficult 2 - 2 = Very difficult 1 - 1 = Could not do at all
Q16	Carry heavy objects (e.g. bag of groceries) with your affected hand? DB Name: [Q16] Code Group: 576	 5 - 5 = Not difficult at all 4 - 4 = A little difficult 3 - 3 = Somewhat difficult 2 - 2 = Very difficult 1 - 1 = Could not do at all
Q17	Who provided the information on this form? DB Name: [Q17] Code Group: 561	1 - Subject 2 - Proxy 3 - Both subject and proxy 9998 - Unknown Reason: (200
Qc	General Comments DB Name: [zNotes]	(250 char.)





Annotated: F25 Concomitant Medications R Table Name: F25 DR Vie

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Help

	Form ID: 518 DB Table N	rame: F25 DB view Name: vF25
No.	Item Description	Data Value
Qa	Data Collected? DB Name: [zDataCollected] Code Group: 51	○ 0 - No ○ 1 - Yes
Qb	Date of assessment DB Name: [zFormDate]	(dd-mmm-yyyy) Complete
Q01		
No.	A. Medication name (100 char.) DB Name: [QA]	
Qc	General Comments DB Name: [zNotes]	(250 char.)

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Annotated: F26 Concomitant Non-Drug Therapies Form ID: 519 DB Table Name: F26 DB View Name: vF26

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No.	Item Description	Data Value	
Qa	Data Collected? DB Name: [zDataCollected] Code Group: 51	○ 0 - No ○ 1 - Yes	
Qb	Date of assessment DB Name: [zFormDate]	(dd-mmm-yyyy) Complete	
Q01	EVD Placement DB Name: [Q01] Code Group: 503	0 - No 1 - Yes 9998 - Unknown Reason: (200	
Q02	Date of EVD placement DB Name: [Q02]	(dd-mmm-yyyy) Day Optional	
Q03	Date of EVD removal DB Name: [Q03]	(dd-mmm-yyyy) Day Optional	
Q04	PEG Placement DB Name: [Q04] Code Group: 503	0 - No 1 - Yes 9998 - Unknown Reason:	
Q05	Date of PEG placement DB Name: [Q05]	(dd-mmm-yyyy) Day Optional	
Q06	Date of PEG removal DB Name: [Q06]	(dd-mmm-yyyy) Day Optional	
Q07	Tracheostomy DB Name: [Q07] Code Group: 503	0 - No 1 - Yes 9998 - Unknown Reason:	
Q08	Date of tracheostomy placement DB Name: [Q08]	(dd-mmm-yyyy) Day Optional	
Q09	Date of tracheostomy removal DB Name: [Q09]	(dd-mmm-yyyy) Day Optional	
Q10	Number of days of physical therapy DB Name: [Q10]	day(s)	
Q11	Number of days of occupational therapy DB Name: [Q11]	day(s)	
Q12	Number of days of speech therapy DB Name: [Q12]	day(s)	
Q13			
No.		A. Name of procedure/therapy (250 char.) DB Name: [QA]	
Qc	General Comments DB Name: [zNotes]	(250 char.)	

When Q01 Equal to 1, Q02 is enabled.

When Q01 Equal to 1, Q03 is enabled.

When Q04 Equal to 1, Q05 is enabled.

When Q04 Equal to 1, Q06 is enabled.

When Q07 Equal to 1, Q08 is enabled.

When Q07 Equal to 1, Q09 is enabled.





Help

Annotated: F27 Adverse Events

Form ID: 521 DB Table Name: FAE DB View Name: vFAE

No.	Item Description	B Table Name: FAE DB View Name: vFAE Data Value
NO.	Adverse Event Name	Data Value
Q01	DB Name: [AEName] CDE ID: [C02307]	(100 char.)
Q02	Adverse event category DB Name: [Q02] Code Group: 577	 1 - Allergic/anaphylactic reaction 2 - Unexplained hypotension requiring medical intervention 3 - Unexplained Visual and/or auditory changes 4 - Respiratory compromise 96 - None of the above
Q03	Severity DB Name: [Q03] Code Group: 603 CDE ID: [C02305]	1 - Mild 4 - Life threatening / Disabling 2 - Moderate 5 - Fatal 3 - Severe
Q04	Related to ICH DB Name: [Q04] Code Group: 51	○ 0 - No ○ 1 - Yes
Q05	Serious? DB Name: [Q05] Code Group: 51 CDE ID: [C02309]	○ 0 - No ○ 1 - Yes
Q06	Date of AE onset DB Name: [Q06] CDE ID: [C02306]	(dd-mmm-yyyy) Complete
Q07	Time of AE onset: DB Name: [Q07]	hh ∶ mm (24hr clock) Complete Time
Q08	Did the AE occur during study drug infusion? DB Name: [Q08] Code Group: 51 CDE ID: [C02308]	○ 0 - No ○ 1 - Yes
Q09	Outcome DB Name: [Q09] Code Group: 578 CDE ID: [C02303]	 1 - Resolved 2 - Resolved w/ sequellae 3 - Continuing (Follow up is required) 4 - Continuing at end of study (No follow up is required) 5 - Continuing at time of death
Q10	Date of AE resolution DB Name: [Q10] CDE ID: [C02301]	(dd-mmm-yyyy) Complete
Q11	Relationship of the AE to the study intervention DB Name: [Q11] Code Group: 579 CDE ID: [C02304]	 1 - Unrelated 2 - Unlikely 3 - Possible 4 - Probably 5 - Definitely
Q12	Actions taken for this event	□ Q12M0 - None □ Q12M1 - Medication / medication change □ Q12M2 - Surgery □ Q12M3 - New hospitalization / prolonged hospitalization □ Q12M4 - Intubation □ Q12M5 - Discontinuation of study drug □ Q12M96 - Other Specify:
Q13	Describe event or problem DB Name: [Q13]	(200 char.)
Q14	Relevant Tests/ Laboratory Data DB Name: [Q14]	char.) (3000

No.	Item Description	Data Value	
Q15	Other Relevant History DB Name: [Q15]		(3000
Q16	Last name of reporting site investigator	(50 char.)	
Q17	DB Name: [Q16] Date of reporting site investigator signature	(dd-mmm-yyyy) Complete	
Q18	DB Name: [Q17] Suspected cause of respiratory compromise	□ Q18M1 - Neurogenic pulmonary edema □ Q18M2 - Cardiogenic pulmonary edema/ MI/ arrhythmia □ Q18M3 - Aspiration pneumonitis □ Q18M4 - Pneumonia □ Q18M5 - Pulmonary embolus □ Q18M6 - ARDS without any of the above evident causes □ Q18M96 - Other Specify: □ Q18M98 - Unknown Reason: (200 char.)	
Q19	Severity of respiratory symptoms DB Name: [Q19] Code Group: 509	$ 1 - O_2 \text{ by NC} \le 4 \text{ L/min} $ $ 2 - \text{Mild, } O_2 \text{ by NC} > 4 \text{ L/min but not non-rebreather} $ $ 3 - \text{Moderate, } O_2 \text{ by non-rebreather} $ $ 4 - \text{Severe, } O_2 \text{ by non-invasive mechanical ventilation (e.g. BiPAP)} $ $ 5 - \text{Intubated - Hypoxic respiratory failure} $ $ 9996 - \text{Other} \text{Specify:} $ $ 9998 - \text{Unknown} \text{Reason:} $ $ (200 \text{ char.}) $,
Q20	Lowest PaO ₂ /FiO ₂ ratio DB Name: [Q20]	mmHg	
Q21	Total fluid intake since admission DB Name: [Q21]	L	
Q22	Total fluid output since admission DB Name: [Q22]	L	
Q23	Results of baseline and subsequent chest x-rays DB Name: [Q23]	char.)	(500
Q24	Was echocardiography done? DB Name: [Q24] Code Group: 51	○0 - No ○1 - Yes	
Q25	Date of echocardiography DB Name: [Q25]	(dd-mmm-yyyy) Complete	
Q26	Results of echocardiography DB Name: [Q26]	char.)	(500
Q27	Were there results from other monitoring devices? DB Name: [Q27] Code Group: 51	○ 0 - No ○ 1 - Yes	
Q28	Results of other monitoring devices, for example PICCO if applicable DB Name: [Q28]	char.)	(500
Q29	Date of results DB Name: [Q29]	(dd-mmm-yyyy) Complete	
Q30	Was blood culture done? DB Name: [Q30] Code Group: 51	○ 0 - No ○ 1 - Yes	
Q31	Date of blood culture DB Name: [Q31]	(dd-mmm-yyyy) Complete	
Q32	Blood culture results DB Name: [Q32]	char.)	(500

No.	Item Description	Data Value	
Q33	Was sputum culture done? DB Name: [Q33] Code Group: 51	3] ○ 0 - No ○ 1 - Yes	
Q34	Date of sputum culture DB Name: [Q34]		
Q35	Sputum culture results DB Name: [Q35]		(500
Q36	Was bronchoalveolar lavage culture done? DB Name: [Q36] Code Group: 51	[3]	
Q37	Date of bronchoalveolar lavage culture DB Name: [Q37]		
Q38	Bronchoalveolar lavage culture results DB Name: [Q38]		(500
Q39	Were troponin levels checked? DB Name: [Q39] Code Group: 51	0]	
Q40	Date of first troponin test DB Name: [Q40]		
Q41	Results of first troponin test DB Name: [Q41]		
Q42	Date of second troponin test DB Name: [Q42]		
Q43	Results of second troponin test DB Name: [Q43]		
Q44	Date of third troponin test DB Name: [Q44]		
Q45	Results of third troponin test DB Name: [Q45]		
Q46	Were blood products transfused? DB Name: [Q46] Code Group: 51	[] 0 - No 1 - Yes	
Q47	Date of blood products transfusion DB Name: [Q47]		
Q48	Volume of blood products transfused and type DB Name: [Q48]		
Q49	Oxygen delivery system in non-ventilated subjects DB Name: [Q49]		
Q51	Hemicraniectomy or surgical evacuation of the hematoma performed before all 3 doses of the study drug was administered in full DB Name: [Q51] Code Group: 51	y	
Q52	Withdrawal of care instituted within 72 hours of randomization DB Name: [Q52] Code Group: 51	0 - No 1 - Yes	
Q50	File Upload DB Name: [Q50]		
Qc	General Comments DB Name: [zNotes]		(250
	File Upload: Choos	ose File No file chosen Upload File	

When Q03 Equal to 5, Q04 is enabled.

When Q09 Equal to 1, Q10 is enabled.

When Q09 Equal to 2, Q10 is enabled.

When Q02 Equal to 4, Q18 is enabled.

When Q02 Equal to 4, Q19 is enabled.

When Q02 Equal to 4, Q20 is enabled.

When Q02 Equal to 4, Q21 is enabled.

When Q02 Equal to 4, Q22 is enabled.

When Q02 Equal to 4, Q23 is enabled.

When Q02 Equal to 4, Q24 is enabled.

When Q24 Equal to 1, Q26 is enabled.

When Q27 Equal to 1, Q28 is enabled. When Q02 Equal to 4, Q27 is enabled. When Q24 Equal to 1, Q25 is enabled. When Q02 Equal to 4, Q30 is enabled. When Q27 Equal to 1, Q29 is enabled. When Q02 Equal to 4, Q33 is enabled. When Q02 Equal to 4, Q36 is enabled. When Q02 Equal to 4, Q39 is enabled. When Q02 Equal to 4, Q46 is enabled. When Q30 Equal to 1, Q31 is enabled. When Q30 Equal to 1, Q32 is enabled. When Q33 Equal to 1, Q34 is enabled. When Q33 Equal to 1, Q35 is enabled. When Q36 Equal to 1, Q37 is enabled. When Q36 Equal to 1, Q38 is enabled. When Q39 Equal to 1, Q40 is enabled. When Q39 Equal to 1, Q41 is enabled. When Q39 Equal to 1, Q42 is enabled. When Q39 Equal to 1, Q43 is enabled. When Q39 Equal to 1, Q44 is enabled. When Q39 Equal to 1, Q45 is enabled. When Q46 Equal to 1, Q47 is enabled. When Q46 Equal to 1, Q48 is enabled. When Q02 Equal to 4, Q49 is enabled. When Q02 Less than 3, Q08 is enabled. When Q02 Equal to 4, Q50 is enabled. When Q12M2 Equal to 1, Q51 is enabled.

When Q03 Equal to 5, Q52 is enabled.





Help

Annotated: F29 End of Study

Form ID: 522 DB Table Name: F29 DB View Name: vF29

	Form ID: 522 DB Table	Name: F29 DB View Name: vF29
No.	Item Description	Data Value
Q01	Did the subject prematurely terminate the study? DB Name: [Q01] Code Group: 51	○ 0 - No ○ 1 - Yes
Q02	Primary reason for premature study termination DB Name: [Q02] Code Group: 580	1 - Withdrawal of consent 2 - Lost to follow up 3 - Study drug not administered 4 - Death 9996 - Other Specify:
		char.)
Q03	Date of withdrawal of consent DB Name: [Q03]	✓ (dd-mmm-yyyy) Complete
Q04	Reason for withdrawal of consent DB Name: [Q04]	(250 char.)
Q05	Date subject was last known to be alive DB Name: [Q05]	✓ (dd-mmm-yyyy) Complete
Q06	Date of death DB Name: [Q06]	(dd-mmm-yyyy) Complete
Q07	Last name of reviewing site PI DB Name: [Q07]	(50 char.)
Q08	Date of site PI review and affirmation DB Name: [Q08]	✓ (dd-mmm-yyyy) Complete
Qc	General Comments DB Name: [zNotes]	(250 char.)

When Q01 Equal to 1, Q02 is enabled.

When Q02 Equal to 1, Q03 is enabled.

When Q02 Equal to 1, Q04 is enabled.

When Q02 Equal to 2, Q05 is enabled.

When Q02 Equal to 4, Q06 is enabled.





Annotated: F30 Visual and Auditory Assessment Follow Up Form ID: 523 DB Table Name: F30 DB View Name: vF30

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Help

No.	Item Description			Data Value
Qa	Data Collected? DB Name: [zDataCollected] Code Group: 51	○0 - No	_1 - Yes	
Qb	Date of assessment DB Name: [zFormDate]		•	(dd-mmm-yyyy) Complete
Q01	Has the subject developed cataracts since last assessment? DB Name: [Q01] Code Group: 560	○0 - No	_1 - Yes	○ 3 - Unknown / Unable to assess
Q02	Has the subject developed visual loss or field cut since last assessment? DB Name: [Q02] Code Group: 560	○0 - No	○1 - Yes	○3 - Unknown / Unable to assess
Q03	Has the subject developed color blindness since last assessment? DB Name: [Q03] Code Group: 560	○0 - No	○1 - Yes	○ 3 - Unknown / Unable to assess
Q04	Has the subject developed tinnitus since last assessment? DB Name: [Q04] Code Group: 560	○0 - No	○1 - Yes	○ 3 - Unknown / Unable to assess
Q05	Has the subject developed hearing loss since last assessment? DB Name: [Q05] Code Group: 560	○ 0 - No	○1 - Yes	○ 3 - Unknown / Unable to assess
Q06	Specify any other visual or auditory abnormalities/changes developed since last assessment: DB Name: [Q06]	(250 char.)		
Qc	General Comments DB Name: [zNotes]	(250 char.)		





Annotated: F32 Additional Imaging

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Help

Form ID: 529 DB Table Name: F32 DB View Name: vF32

	1 Olim 1B. 329 Bi	5 Table IN	ame. F32 DB view Name. v	132
No.	Item Description			Data Value
Qa	Data Co DB Name: [zDataCo Code Gr	ollected]	○ 0 - No ○ 1 - Yes	
Q01	Child Table			
No.	A. Date/time of imaging DB Name: [QA]		B. Type of imaging DB Name: [QB]	C. Specify, if Other (50 char.) DB Name: [QC]
Qc	General Com DB Name: [zNo		(250 char.)	

When Child Field **QB Equal to 96**, **QC** is enabled.

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Help

Annotated: F43 NIH Stroke Scale

Form ID: 506 DB Table Name: F43 DB View Name: vF43

No.	Item Description	B Table Name: F43 DB View Name: VF43 Data Value
Qa	Data Collected DB Name: [zDataCollected]	○ 0 - No ○ 1 - Yes
Qa	Code Group: 51	
Q01	Date/time of assessment DB Name: [Q01]	dd ✔ mmm ✔ yyyy ✔ 🛗 hh ✔ : mm ✔ ○AM ○PM
Q02	(1a) Level of Consciousness DB Name: [Q02] Code Group: 587 CDE ID: [C13232]	 ○ 0 - 0=Alert; keenly responsive ○ 1 - 1=Not alert, but arousable by minor stimulation to obey, answer or respond ○ 2 - 2=Not alert, requires repeated stimulation to attend, or is obtunded and requires strong or painful stimulation to make movements (not stereotyped) ○ 3 - 3=Responds only with reflex motor or autonomic effects or totally unresponsive, flaccid, and flexic. (Complete form using coma scoring) ○ 98 - Unknown
Q03	(1b) LOC Questions DB Name: [Q03] Code Group: 588 CDE ID: [C13233]	 0 - 0=Answers both questions correctly 1 - 1=Answers one question correctly 2 - 2=Answers neither question correctly 98 - Unknown
Q04	(1c) LOC Commands DB Name: [Q04] Code Group: 589 CDE ID: [C13234]	 0 - 0=Performs both tasks correctly 1 - 1=Performs one task correctly 2 - 2=Performs neither task correctly 98 - Unknown
Q05	(2) Best Gaze DB Name: [Q05] Code Group: 590 CDE ID: [C13235]	 0 - 0=Normal 1 - 1=Partial gaze palsy; gaze is abnormal in one or both eyes, but forced deviation or total gaze paresis is not present 2 - 2=Forced deviation, or total gaze paresis not overcome by the oculocephalic maneuver 98 - Unknown
Q06	(3) Visual DB Name: [Q06] Code Group: 591 CDE ID: [C13236]	 ○ 0 - 0=No visual loss ○ 1 - 1=Partial hemianopia ○ 2 - 2=Complete hemianopia ○ 3 - 3=Bilateral hemianopia (blind including cortical blindness) ○ 98 - Unknown
Q07	(4) Facial Palsy DB Name: [Q07] Code Group: 592 CDE ID: [C13237]	 0 - 0=Normal symmetrical movement 1 - 1=Minor paralysis (flattened nasolabial fold, asymmetry on smiling) 2 - 2=Partial paralysis (total or near total paralysis of lower face) 3 - 3=Complete paralysis of one or both sides (absence of facial movement in the upper and lower face) 98 - Unknown
Q08	(5a) Motor Arm Left DB Name: [Q08] Code Group: 593 CDE ID: [C13238_L]	 0 - 0=No drift, limb holds 90 (or 45) degrees for full 10 seconds. 1 - 1=Drift, limb holds 90 (or 45) degrees, but drifts down before full 10 seconds; does not hit bed or other support 2 - 2=Some effort against gravity, limb cannot get to or maintain (if cued) 90 (or 45) degrees, drifts down to bed, but has some effort against gravity 3 - 3=No effort against gravity, limb falls 4 - 4=No movement 9 - UN=Amputation, joint fusion 98 - Unknown
Q09	Explain if amputation or joint fusion (Motor Arm Left) DB Name: [Q09] CDE ID: [C13238_LUN]	(100 char.)
Q10	(5b) Motor Arm Right DB Name: [Q10] Code Group: 593 CDE ID: [C13238_R]	○ 0 - 0=No drift, limb holds 90 (or 45) degrees for full 10 seconds. ○ 1 - 1=Drift, limb holds 90 (or 45) degrees, but drifts down before full 10 seconds; does not hit bed or other support ○ 2 - 2=Some effort against gravity, limb cannot get to or maintain (if cued) 90 (or 45) degrees, drifts down to bed, but has some effort against gravity ○ 3 - 3=No effort against gravity, limb falls ○ 4 - 4=No movement ○ 9 - UN=Amputation, joint fusion ○ 98 - Unknown
Q11	Explain if amputation or joint fusion (Motor Arm Right) DB Name: [Q11] CDE ID: [C13238_RUN]	(100 char.)

No.	Item Description	Data Value
Q12	(6a) Motor Leg Left DB Name: [Q12] Code Group: 594 CDE ID: [C13239_L]	0 - 0=No drift, leg holds 30 degrees position for full 5 seconds 1 - 1=Drift, leg falls by the end of the 5 second period but does not hit bed 2 - 2=Some effort against gravity; leg falls to bed by 5 seconds, but has some effort against gravity 3 - 3=No effort against gravity; leg falls to bed immediately 4 - 4=No movement 9 - UN=Amputation, joint fusion 98 - Unknown
Q13	Explain if amputation or joint fusion (Motor Leg Left) DB Name: [Q13] CDE ID: [C13239_LUN]	(100 char.)
Q14	(6b) Motor Leg Right DB Name: [Q14] Code Group: 594 CDE ID: [C13239_R]	0 - 0=No drift, leg holds 30 degrees position for full 5 seconds 1 - 1=Drift, leg falls by the end of the 5 second period but does not hit bed 2 - 2=Some effort against gravity; leg falls to bed by 5 seconds, but has some effort against gravity 3 - 3=No effort against gravity; leg falls to bed immediately 4 - 4=No movement 9 - UN=Amputation, joint fusion 98 - Unknown
Q15	Explain if amputation or joint fusion (Motor Leg Right) DB Name: [Q15] CDE ID: [C13239_RUN]	(100 char.)
Q16	(7) Limb Ataxia DB Name: [Q16] Code Group: 595 CDE ID: [C13240]	○ 0 - 0=Absent ○ 1 - 1=Present in one limb ○ 2 - 2=Present in two limbs ○ 9 - UN=Amputation, joint fusion ○ 98 - Unknown
Q17	Explain if amputation or joint fusion (Limb Ataxia) DB Name: [Q17] CDE ID: [C13240_UN]	(100 char.)
Q18	(8) Sensory DB Name: [Q18] Code Group: 596 CDE ID: [C13241]	0 - 0=Normal; no sensory loss 1 - 1=Mild to moderate sensory loss; patient feels pinprick is less sharp or is dull on the affected side; or there is a loss of superficial pain with pinprick, but patient is aware of being touched 2 - 2=Severe to total sensory loss; patient is not aware of being touched in the face, arm & leg 98 - Unknown
Q19	(9) Best Language DB Name: [Q19] Code Group: 597 CDE ID: [C13242]	○ 0 - 0=No aphasia, normal ○ 1 - 1=Mild to moderate aphasia; some obvious loss of fluency or facility of comprehension, without significant limitation on ideas expressed or form of expression. Reduction of speech and/or comprehension, however, makes conversation about provided materials difficult or impossible. For example, in conversation about provided materials, examiner can identify picture or naming card content from patient's response ○ 2 - 2=Severe aphasia; all communication is through fragmentary expression; great need for inference, questioning, and guessing by the listener. Range of information that can be exchanged is limited; listener carries burden of communication. Examiner cannot identify materials provided from patient response ○ 3 - 3=Mute, global aphasia; no usable speech or auditory comprehension ○ 98 - Unknown
Q20	(10) Dysarthria DB Name: [Q20] Code Group: 598 CDE ID: [C13243]	0 - 0=Normal 1 - 1=Mild to moderate dysarthria; patient slurs at least some words and, at worst, can be understood with some difficulty 2 - 2=Severe dysarthria; patient's speech is so slurred as to be unintelligible in the absence of or out of proportion to any dysphasia, or is mute/anarthric 9 - UN=Intubated or other physical barrier 98 - Unknown
Q21	Explain if intubated or other physical barrier (Dysarthria) DB Name: [Q21] CDE ID: [C13243_UN]	(100 char.)
Q22	(11) Extinction and Inattention (formerly Neglect) DB Name: [Q22] Code Group: 599 CDE ID: [C13244]	 ○ 0 - 0=No abnormality ○ 1 - 1=Visual, tactile, auditory, spatial, or personal inattention or extinction to bilateral simultaneous stimulation in one of the sensory modalities ○ 2 - 2=Profound hemi-inattention or extinction to more than one modality; does not recognize own hand or orients to only one side of space ○ 98 - Unknown
Q23	NIH Stroke Scale score DB Name: [Q23] CDE ID: [C13245]	(0-42)

No.	Item Description	Data Value
Q24	First/Given name DB Name: [Q24]	(50 char.)
Q25	Last/Family name DB Name: [Q25]	(50 char.)
Qc	General Comments DB Name: [zNotes]	char.) (250

When Q08 Equal to 9, Q09 is enabled.

When Q10 Equal to 9, Q11 is enabled.

When Q12 Equal to 9, Q13 is enabled.

When Q14 Equal to 9, Q15 is enabled.

When Q16 Equal to 9, Q17 is enabled.

When Q20 Equal to 9, Q21 is enabled.

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