

NIH

Annotated Design For Trial: bridge

Protocol: BRIDGE

Generated By InForm Architect™

September 25, 2013 3:17PM

Time and Events Schedule For Study: bridge													
Assessment	CRF	STATUS (STATUS) [S]	SIGNATURE (SIGNAT) [U]	Conflict (Conflict) [U/R/D]	ENC10R2 (ENC10R2) [U/D]	ENC3 (ENC3) [U/D]	ENC4 (ENC4) [U/D]	ENC5 (ENC5) [U/D]	ENC6 (ENC6) [U/D]	ENC7 (ENC7) [U/D]	ENC8 (ENC8) [U/D]	ENC9 (ENC9) [U/D]	CAS (CAS) [U/D]
1 Status	STATUS	1											
2 SITE INVESTIGATOR SIGNATURE COMPLETION	SIGN		1										
3 Demographics	DEMOG				1								
4 Medical History Screening	SCMEDHX				2								
5 SCREENING LABS	SCRLAB				3								
6 SCREENING CONCOMITANT MEDICATIONS	SCRECON				4								
7 PROCEDURE OR SURGERY	PROCSURG				5		5						
8 Screening Serious Adverse Event Details	SCRSAE				6								
9 Screening Eligibility	SCRELG				7								
10 WARFARIN	WARFAR				8-RF-DF		4-RF-DF	5-RF-DF	5-RF-DF	5-RF-DF	4-RF-DF	4-RF-DF	
11 IXRS RANDOMIZATION	RAN					1							
12 ASSESSMENT	ASSESS					2	1	1	1	1	1	1	
13 LOCAL LABORATORY RESULTS	LAB					3-RF	2-RF	2-RF	2-RF	2-RF	2-RF	2-RF	
14 CONCOMITANT MEDICATIONS	CONMED					4	3	3	3	3	3	3	
15 MEDICATION ADMINISTRATION RECORD	MAR					5-RF-DF		4-RF-DF	4-RF-DF	4-RF-DF			
16 ASSESSMENT STROKE	ASSTRO					6-RF-DF	6-RF-DF	6-RF-DF	6-RF-DF	6-RF-DF	5-RF-DF	5-RF-DF	
17 ASSESSMENT TIA	ASTIA					7-RF-DF	7-RF-DF	7-RF-DF	7-RF-DF	7-RF-DF	6-RF-DF	6-RF-DF	
18 ASSESSMENT SYSTEMIC EMBOLISM	ASSEM					8-RF-DF	8-RF-DF	8-RF-DF	8-RF-DF	8-RF-DF	7-RF-DF	7-RF-DF	
19 FORM COMPLETION	FORMCOMP												1
20 Serious Adverse Event Details	SAE												2-RF-DF
21 BLEEDING	BLEED												3-RF-DF
22 STUDY COMPLETION	STUDYCOM												4-DF
23 WARMAR Log	WARMAR												5-RF

Key: [S] = Scheduled Visit [O] = Optional Visit [D] = Dynamic Visit [U] = Unscheduled Visit [R] = Repeating Visit
C = Common Form DF = Dynamic Form RF = Repeating Form

bridge : SYSTEM SCREENING (SCR)	
1. Site Number [<i>hidden</i>]	A3 (bridgecdd:SCR.SITENUM / Site Number)
2. System screening	(bridgecdd:SCR.chkScrClickforEnroll / Site enroll) [1] <input type="checkbox"/> Please click the checkbox to continue the system enrollment process

Item Design Notes:	
Item No.	Design Note
2.	InForm requires at least one enterable item on this form.

CDD: bridgecdd Table: SCR Key Type: PATIENTVISIT		
Column Name	Column Data Type	Design Note
SITENUM	STRING(3) - A3	
chkScrClickforEnroll	NUMERIC	

bridge : Enrollment (ENR)	
1. System enrollment	(bridgecdd:ENR.chkEnrClickforEnroll / Subject enroll) [?] <input type="checkbox"/> Please click the checkbox to continue the system enrollment process

Item Design Notes:	
Item No.	Design Note
1.	InForm requires at least one enterable item on this form.

CDD: bridgecdd Table: ENR Key Type: PATIENTVISIT		
Column Name	Column Data Type	Design Note
chkEnrClickforEnroll	NUMERIC	

bridge : Status (STATUS)		
Status		
1.	Date of Encounter	Req <input type="checkbox"/> / Req <input type="checkbox"/> / Req <input type="checkbox"/> (2009-2015) (bridgecdd:STATUS.STAENCDT / Status date of encounter)
2.	Patient screening completed	(bridgecdd:STATUS.SCREENST / Screening status) [1] <input type="radio"/> (bridgecdd:STATUS.NCDECISO / Non Screened decision) Non-consenting screen failure [1] <input type="radio"/> MD Decision [2] <input type="radio"/> Failed Inclusion/Exclusion Criteria [2] <input type="radio"/> Informed consent signed - Proceed with screening
3.*	SDV Status	(bridgecdd:STATUS.SDVSTAT / SDV Status) [1] <input type="radio"/> Not Applicable [2] <input type="radio"/> 100 % Full Review
* Item is not required		

Column Name	Column Data Type	Design Note
STAENCDT	DATE - DDMONYYYY	
SDVSTAT	NUMERIC	
NCDECISO	NUMERIC	
SCREENST	NUMERIC	

bridge : SITE INVESTIGATOR SIGNATURE COMPLETION (SIGN)		
.		
1.	Casebook Ready for Signature	(bridgecdd:SIGN.SIGNATUR / Casebook ready for signatur) [1] <input type="radio"/> Yes
2.*	SDV Status	(bridgecdd:SIGN.SDVSIGN / SDV Signature) [1] <input type="radio"/> Not Applicable [2] <input type="radio"/> 100 % Full Review
* Item is not required		

CDD: bridgecdd Table: SIGN Key Type: PATIENTVISIT		
Column Name	Column Data Type	Design Note
SDVSIGN	NUMERIC	
SIGNATUR	NUMERIC	

bridge : Demographics (DEMOG)		
Demographics		
1.	Patient Encounter	(bridgecdd:DEMOG.SCEMENC / Screen DEM encounter) [1] <input type="radio"/> 1 [2] <input type="radio"/> 2
2.	Date of Encounter	Req <input type="button" value="v"/> / Req <input type="button" value="v"/> / Req <input type="button" value="v"/> (2009-2015) (bridgecdd:DEMOG.DEMENCDT / Demog date of encounter)
3.	Date and Time of Consent	Req <input type="button" value="v"/> / Req <input type="button" value="v"/> / Req <input type="button" value="v"/> (2009-2015) (bridgecdd:DEMOG.CONDTM / Date of consent) Req <input type="button" value="v"/> : Req <input type="button" value="v"/> 24-hour clock
4.	Anticipated Date of Procedure	Req <input type="button" value="v"/> / Req <input type="button" value="v"/> / Req <input type="button" value="v"/> (2009-2015) (bridgecdd:DEMOG.ANPROCDT / Anticipated Date of proc)
5.	Date of Birth	Req <input type="button" value="v"/> / Req <input type="button" value="v"/> / Req <input type="button" value="v"/> (1900-1997) (bridgecdd:DEMOG.DEDOBDT / Date of Birth)
6.	Gender	(bridgecdd:DEMOG.DEGENDER / Gender) [1] <input type="radio"/> Male [2] <input type="radio"/> Female
7.	Weight	xxxxxxxx. lbs (bridgecdd:DEMOG.WT / Weight)
8.	Height	xxxxxxxx. in (bridgecdd:DEMOG.HT / Height)
	Study drug dosage amount [read-only]	xxxxxxxx. cc (bridgecdd:DEMOG.SDOSE / Study drug dose amounts)
9.	Is the patient of Hispanic or Latino Ethnicity?	(bridgecdd:DEMOG.ETHNIC / Ethnicity) [0] <input type="radio"/> No [1] <input type="radio"/> Yes
10.	Race (check only one):	(bridgecdd:DEMOG.RACE / Race) [1] <input type="radio"/> American Indian or Alaska Native [2] <input type="radio"/> Asian [3] <input type="radio"/> Black or African American [4] <input type="radio"/> Native Hawaiian or Other Pacific Islander [5] <input type="radio"/> White or Caucasian [6] <input type="radio"/> Mixed Race [7] <input type="radio"/> Refused to answer
11.*	SDV Status	(bridgecdd:DEMOG.SDVDEMOG / SDV Demog) [1] <input type="radio"/> Not Applicable [2] <input type="radio"/> 100 % Full Review
* Item is not required		

CDD: bridgecdd	Table: DEMOG	Key Type: PATIENTVISIT
Column Name	Column Data Type	Design Note
SDVDEMOG	NUMERIC	
RACE	NUMERIC	
SCEMENC	NUMERIC	
DEMENCDT	DATE - DDMONYYYY	
CONDTM	DATE - DDMONYYYY HHMM	
ANPROCDT	DATE - DDMONYYYY	
DEDOBDT	DATE - DDMONYYYY	
DEGENDER	NUMERIC	
WT	FLOAT - F9.0	
HT	FLOAT - F9.0	
SDOSE	FLOAT - F9.0	
ETHNIC	NUMERIC	

bridge : Medical History Screening (SCMEDHX)		
Medical Screening History		
1.	Patient Encounter	(bridgecdd:SCMEDHX.SCHXHENC / Screen MED HX encounter) [1] <input type="radio"/> 1 [2] <input type="radio"/> 2
2.	Date of Encounter	Req <input type="checkbox"/> / Req <input type="checkbox"/> / Req <input type="checkbox"/> (2009-2015) (bridgecdd:SCMEDHX.SCMENCDT / Scr M Hx date of encounter)
Does the patient have a history of the following?		
3.	Congestive Heart Failure or Left Ventricular Dysfunction	(bridgecdd:SCMEDHX.CHFLVHX / CHF or LV dysfunction) [1] <input type="radio"/> Yes [0] <input type="radio"/> No
4.	Hypertension	(bridgecdd:SCMEDHX.HYPHX / Hypertension) [1] <input type="radio"/> Yes [0] <input type="radio"/> No
5.	Diabetes	(bridgecdd:SCMEDHX.DIABHX / Diabetes) [1] <input type="radio"/> Yes [0] <input type="radio"/> No
6.	Stroke	(bridgecdd:SCMEDHX.STROKEHX / Stroke) [1] <input type="radio"/> Yes [0] <input type="radio"/> No
7.	TIA	(bridgecdd:SCMEDHX.TIAHX / TIA) [1] <input type="radio"/> Yes [0] <input type="radio"/> No
8.	Mitral Valve Disease	(bridgecdd:SCMEDHX.MIDIHX / Mitral Valve Disease) [1] <input type="radio"/> Yes [0] <input type="radio"/> No
9.	Mitral Valve Stenosis	(bridgecdd:SCMEDHX.MVSHX / Mitral Valve Stenosis) [1] <input type="radio"/> Yes [0] <input type="radio"/> No
10.	Mitral Valve Regurgitation	(bridgecdd:SCMEDHX.MVRHX / Mitral Valve Regurgitation) [1] <input type="radio"/> Yes [0] <input type="radio"/> No
11.	Mitral Valve Prolapse	(bridgecdd:SCMEDHX.MVPHX / Mitral Valve Prolapse) [1] <input type="radio"/> Yes [0] <input type="radio"/> No
12.	Gastrointestinal Bleed	(bridgecdd:SCMEDHX.GASBHX / Gastrointestinal Bleed) [1] <input type="radio"/> Yes [0] <input type="radio"/> No
13.	MI	(bridgecdd:SCMEDHX.MIHX / MI) [1] <input type="radio"/> Yes [0] <input type="radio"/> No
14.	AIDS	(bridgecdd:SCMEDHX.AIDSHX / AIDS) [1] <input type="radio"/> Yes [0] <input type="radio"/> No
15.	Dementia	(bridgecdd:SCMEDHX.DEMHX / Dementia) [1] <input type="radio"/> Yes [0] <input type="radio"/> No
16.	Hemiplegia	(bridgecdd:SCMEDHX.HEMIHX / Hemiplegia) [1] <input type="radio"/> Yes [0] <input type="radio"/> No
17.	Leukemia	(bridgecdd:SCMEDHX.LEUKHX / Leukemia) [1] <input type="radio"/> Yes [0] <input type="radio"/> No
18.	Malignant lymphoma	(bridgecdd:SCMEDHX.MALHX / Malignant lymphoma) [1] <input type="radio"/> Yes [0] <input type="radio"/> No
19.	Liver Disease	(bridgecdd:SCMEDHX.LIVDHX / Liver Disease) [1] <input type="radio"/> Yes [0] <input type="radio"/> No

20.	Renal Disease	(bridgecdd:SCMEDHX.RENALHX / Renal Disease) [1] <input type="radio"/> Yes [0] <input type="radio"/> No
21.	Malignant solid tumor	(bridgecdd:SCMEDHX.MALSTHX / Malignant solid tumor) [1] <input type="radio"/> Yes [0] <input type="radio"/> No
22.*	SDV Status	(bridgecdd:SCMEDHX.SDVSCRHX / SDV Med Hx) [1] <input type="radio"/> Not Applicable [2] <input type="radio"/> 100 % Full Review
* Item is not required		

Column Name	Column Data Type	Design Note
TIAHX	NUMERIC	
SDVSCRHX	NUMERIC	
RENALHX	NUMERIC	
MALHX	NUMERIC	
MALSTHX	NUMERIC	
DEMHX	NUMERIC	
HEMIHX	NUMERIC	
LEUKHX	NUMERIC	
LIVDHX	NUMERIC	
MIDIHX	NUMERIC	
MVSHX	NUMERIC	
MVRHX	NUMERIC	
MVPHX	NUMERIC	
GASBHX	NUMERIC	
MIHX	NUMERIC	
AIDSHX	NUMERIC	
SCHXHENC	NUMERIC	
SCMENCDT	DATE - DDMYYYY	
CHFLVHX	NUMERIC	
HYPHX	NUMERIC	
DIABHX	NUMERIC	
STROKEHX	NUMERIC	

bridge : SCREENING LABS (SCRLAB)		
Screening Labs		
1.	Patient Encounter	(bridgecdd:SCRLAB.SCLABENC / Screen lab encounter) [1] <input type="radio"/> 1 [2] <input type="radio"/> 2
2.	Date of Encounter	Req <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (2009-2015) (bridgecdd:SCRLAB.SCRLLENDT / Scr lab date of encounter)
3.	Serum Creatinine	xxxxxxx. (bridgecdd:SCRLAB.SCLABSCU / Scr lab text) (bridgecdd:SCRLAB.SCLSCUNI / Scr lab ser creat unit) [1] <input type="radio"/> μmol/L [2] <input type="radio"/> mg/dL Lab Draw Date and Time Req <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (2009-2015) (bridgecdd:SCRLAB.SCLSCDTM / Scr lab ser creat date time) Req <input type="text"/> : Req <input type="text"/> 24-hour clock
4.	GFR	xxxxxxx. mL/min (bridgecdd:SCRLAB.SCLABGFR / Screen lab GFR)
5.	Hemoglobin	xxxxxxx. (bridgecdd:SCRLAB.SCLHEUNT / Scr lab hemo text) (bridgecdd:SCRLAB.SCLHEMUN / Screen lab hemo unit) [1] <input type="radio"/> g/dL [2] <input type="radio"/> g/L Lab Draw Date and Time Req <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (2009-2015) (bridgecdd:SCRLAB.SCLHEDTM / Scr lab hemoglob date time) Req <input type="text"/> : Req <input type="text"/> 24-hour clock
6.	Platelets	xxxxxxx. x 10 ⁹ cells/L (bridgecdd:SCRLAB.SCLAPLUN / Scr lab plate text) Lab Draw Date and Time Req <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (2009-2015) (bridgecdd:SCRLAB.SCLPLDTM / Scr lab platelets date time) Req <input type="text"/> : Req <input type="text"/> 24-hour clock
7.	INR Results	xxxxxxx. (bridgecdd:SCRLAB.SCLINRUN / Scr lab INR text) Lab Draw Date and Time Req <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (2009-2015) (bridgecdd:SCRLAB.SCINRDTM / Screen lab INR date time) Req <input type="text"/> : Req <input type="text"/> 24-hour clock (bridgecdd:SCRLAB.SCINRPOC / Screen lab INR method) [1] <input type="radio"/> Point of Care Device [2] <input type="radio"/> Laboratory
8.*	SDV Status	(bridgecdd:SCRLAB.SDVSCRLB / SDV Screen Lab) [1] <input type="radio"/> Not Applicable [2] <input type="radio"/> 100 % Full Review
* Item is not required		

Column Name	Column Data Type	Design Note
SCINRDTM	DATE - DDMONYYYY HHMM	
SCINRPOC	NUMERIC	
SDVSCRLB	NUMERIC	
SCLINRUN	FLOAT - F9.0	
SCLABENC	NUMERIC	
SCLHEMUN	NUMERIC	
SCLABGFR	FLOAT - F9.0	
SCLSCDTM	DATE - DDMONYYYY HHMM	
SCLSCUNI	NUMERIC	
SCLABSCU	FLOAT - F9.0	
SCRLLENDT	DATE - DDMONYYYY	
SCLPLDTM	DATE - DDMONYYYY HHMM	
SCLHEUNT	FLOAT - F9.0	
SCLHEDTM	DATE - DDMONYYYY HHMM	

SCLAPLUN	FLOAT - F9.0	
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bridge : SCREENING CONCOMITANT MEDICATIONS (SCRECON)		
Screening Concomitant Medications		
1.	Patient Encounter	(bridgecdd:SCRECON.SCCONENC / Screen conmed encounter) [1] <input type="radio"/> 1 [2] <input type="radio"/> 2
2.	Date of Encounter	Req <input type="checkbox"/> / Req <input type="checkbox"/> / Req <input type="checkbox"/> (2009-2015) (bridgecdd:SCRECON.SCRCENDT / Scr Con date of encounter)
3.	Aspirin	(bridgecdd:SCRECON.SCONASPI / Scrcon aspirin) [1] <input type="radio"/> Yes [0] <input type="radio"/> No
4.	Clopidogrel (Plavix)	(bridgecdd:SCRECON.SCONCLOP / Scrcon clopidogrel) [1] <input type="radio"/> Yes [0] <input type="radio"/> No
5.	Ticlopidine (Ticlid)	(bridgecdd:SCRECON.SCONTICL / Scrcon Ticlopidine) [1] <input type="radio"/> Yes [0] <input type="radio"/> No
6.	Non-Steroidal Anti-Inflammatory Drugs	(bridgecdd:SCRECON.SCONNONS / Scrcon non-ster anti inflam) [1] <input type="radio"/> Yes [0] <input type="radio"/> No
7.	COX-2 Inhibitors	(bridgecdd:SCRECON.SCONCOX2 / Scrcon cox2 inhibitors) [1] <input type="radio"/> Yes [0] <input type="radio"/> No
8.	Dipyridamole	(bridgecdd:SCRECON.SCONDIPY / Scrcon dipyridamole) [1] <input type="radio"/> Yes [0] <input type="radio"/> No
9.	Dipyridamole with Aspirin (Aggrenox)	(bridgecdd:SCRECON.SCONDIPA / Scrcon dipyridamole w aggre) [1] <input type="radio"/> Yes [0] <input type="radio"/> No
10.	Pentoxifylline (Trental)	(bridgecdd:SCRECON.SCONPENT / Scrcon pentozifylline) [1] <input type="radio"/> Yes [0] <input type="radio"/> No
11.	Cilostazol (Pletal)	(bridgecdd:SCRECON.SCONCILO / Scrcon cilostazol) [1] <input type="radio"/> Yes [0] <input type="radio"/> No
12.	Ticagrelor (Brilinta)	(bridgecdd:SCRECON.SCONTICA / Scrcon ticagalar) [1] <input type="radio"/> Yes [0] <input type="radio"/> No
13.	Prasugrel (Effient)	(bridgecdd:SCRECON.SCONPRAS / Scrcon prasygrel) [1] <input type="radio"/> Yes [0] <input type="radio"/> No
14.*	SDV Status	(bridgecdd:SCRECON.SDVSCRCM / SDV Screen Con Med) [1] <input type="radio"/> Not Applicable [2] <input type="radio"/> 100 % Full Review
* Item is not required		

Column Name	Column Data Type	Design Note
SCONPENT	NUMERIC	
SCONDIPA	NUMERIC	
SCONDIPY	NUMERIC	
SCONCOX2	NUMERIC	
SCONNONS	NUMERIC	
SCONCLOP	NUMERIC	
SCONASPI	NUMERIC	
SCRCENDT	DATE - DDMONYYYY	
SCCONENC	NUMERIC	

SDVSCRCM	NUMERIC	
SCONTICL	NUMERIC	
SCONCILO	NUMERIC	
SCONTICA	NUMERIC	
SCONPRAS	NUMERIC	

bridge : PROCEDURE OR SURGERY (PROCSURG)		
Procedure or Surgery		
1.	Anticipated Date & Time of Procedure or Surgery	Req <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (2008-2015) (bridgecdd:PROCSURG.ACRODTM / Anti Procedure date time) Req <input type="text"/> : Req <input type="text"/> 24-hour clock
2.*	Actual Date & Time of Procedure or Surgery	(bridgecdd:PROCSURG.PROCND / Procedure not done) [1] <input type="radio"/> Req <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (2008-2015) (bridgecdd:PROCSURG.ANPRODTM / Actual procedure date time) Req <input type="text"/> : Req <input type="text"/> 24-hour clock (bridgecdd:PROCSURG.PROCTYPE / Procedure type) Procedure or Surgery Type: [1] <input type="radio"/> Minor [2] <input type="radio"/> Major (bridgecdd:PROCSURG.PROCOTHE / Procedure) [1] <input type="radio"/> Surgery code (4 or 6 digits) Please see InForm homepage, BRIDGE website or MOP for a listing of Procedure Codes. (bridgecdd:PROCSURG.PROCCODE / Surgery key code) A8 [12] <input type="radio"/> Other, specify: (bridgecdd:PROCSURG.OTHESPEC / Procedure other specify) A50 Anesthesia Type (bridgecdd:PROCSURG.ANESLOCA / Local anesthesia) [1] <input type="checkbox"/> Local or Conscious Sedation (bridgecdd:PROCSURG.ANESGEN / General anesthesia) [1] <input type="checkbox"/> General (bridgecdd:PROCSURG.ANESSEDA / Conscious sedation) [1] <input type="checkbox"/> Neuraxial (Spinal/Epidural) [97] <input type="radio"/> Not Done (bridgecdd:PROCSURG.PROCNDRE / Procedure cancelled) If Not Done, check all that apply: [1] <input type="checkbox"/> Patient cancelled (bridgecdd:PROCSURG.PROCSUCA / Surgeon cancelled) [1] <input type="checkbox"/> Surgeon cancelled (bridgecdd:PROCSURG.PROCREFC / Ref surgeon cancelled) [1] <input type="checkbox"/> Referring physician cancelled (bridgecdd:PROCSURG.PROCAE / Proc cancelled due to AE) [1] <input type="checkbox"/> Adverse event
3.*	Actual Date & Time of Procedure or Surgery	(bridgecdd:PROCSURG.PRXCND / Procedure not done) [1] <input type="radio"/> Req <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (2008-2015) (bridgecdd:PROCSURG.ANPRXDTM / Actual procedure date time) Req <input type="text"/> : Req <input type="text"/> 24-hour clock (bridgecdd:PROCSURG.PRXCTYPE / Procedure type) Procedure or Surgery Type: [1] <input type="radio"/> Minor [2] <input type="radio"/> Major (bridgecdd:PROCSURG.PRXCOTHE / Procedure) [1] <input type="radio"/> Surgery code (4 or 6 digits) Please see InForm homepage, BRIDGE website or MOP for a listing of Procedure Codes. A2 (bridgecdd:PROCSURG.PROC1 / Surgery key code 1) A4 (bridgecdd:PROCSURG.PROC2 / Surgery key code 2) [12] <input type="radio"/> Other, specify: (bridgecdd:PROCSURG.OTHXSPEC / Procedure other specify) A50 Anesthesia Type (bridgecdd:PROCSURG.ANESLXCA / Local anesthesia) [1] <input type="checkbox"/> Local or Conscious Sedation (bridgecdd:PROCSURG.ANESXEN / General anesthesia) [1] <input type="checkbox"/> General (bridgecdd:PROCSURG.ANESXEDA / Conscious sedation) [1] <input type="checkbox"/> Neuraxial (Spinal/Epidural) [97] <input type="radio"/> Not Done (bridgecdd:PROCSURG.PRXCNDRE / Procedure cancelled) If Not Done, check all that apply: [1] <input type="checkbox"/> Patient cancelled (bridgecdd:PROCSURG.PRXCSUCA / Surgeon cancelled) [1] <input type="checkbox"/> Surgeon cancelled (bridgecdd:PROCSURG.PRXCREFC / Ref surgeon cancelled) [1] <input type="checkbox"/> Referring physician cancelled (bridgecdd:PROCSURG.PRXCAE / Proc cancelled due to AE)

4.* SDV Status	<p>[1] <input type="checkbox"/> Adverse event</p> <p>(bridgecdd:PROCSURG.SDVPROC / SDV Procedure surgery)</p> <p>[1] <input type="radio"/> Not Applicable</p> <p>[2] <input type="radio"/> 100 % Full Review</p>
* Item is not required	

CDD: bridgecdd Table: PROCSURG Key Type: PATIENTVISIT		
Column Name	Column Data Type	Design Note
ACPRODTM	DATE - DDMONYYYY HHMM	
ANPRODTM	DATE - DDMONYYYY HHMM	
PROCTYPE	NUMERIC	
PROCOTHE	NUMERIC	
PROCCODE	STRING(8) - A8	
OTHESPEC	STRING(50) - A50	
ANESLOCA	NUMERIC	
ANESGEN	NUMERIC	
ANESSEDA	NUMERIC	
PROCND	NUMERIC	
PROCSUCA	NUMERIC	
PROCAE	NUMERIC	
SDVPROC	NUMERIC	
PROCNDRE	NUMERIC	
PROCREFC	NUMERIC	
ANPRXDTM	DATE - DDMONYYYY HHMM	
PRXCTYPE	NUMERIC	
PRXCOTHE	NUMERIC	
PROC1	STRING(2) - A2	
PROC2	STRING(4) - A4	
OTHXSPEC	STRING(50) - A50	
ANESLXCA	NUMERIC	
ANESXEN	NUMERIC	
ANESXEDA	NUMERIC	
PRXCND	NUMERIC	
PRXCAE	NUMERIC	
PRXCNDRE	NUMERIC	
PRXCREFC	NUMERIC	
PRXCSUCA	NUMERIC	

bridge : Screening Serious Adverse Event Details (SCRSAE)		
Serious Adverse Events		
Complete for all SAE's ocuring during screening to randomization		
1.	Patient Encounter	(bridgecdd:SCRSAE.SCRSAENC / Scr SAE encounter) [1] <input type="radio"/> 1 [2] <input type="radio"/> 2
2.	Date of Encounter	Req <input type="checkbox"/> / Req <input type="checkbox"/> / Req <input type="checkbox"/> (2009-2015) (bridgecdd:SCRSAE.SCRSAEDT / Scr lab date of encounter)
3.	SAE Event Term: (free text event for DCRI coding purposes)	A200 (bridgecdd:SCRSAE.SCSAETER / Scr SAE term)
4.	Onset Date:	Req <input type="checkbox"/> / Req <input type="checkbox"/> / Req <input type="checkbox"/> (2009-2015) (bridgecdd:SCRSAE.SCSAONDT / Scr SAE onset date)
5.	Causality	(bridgecdd:SCRSAE.SCSAECA / Scr SAE causality) [1] <input type="radio"/> Unlikely related to study drug [2] <input type="radio"/> Likely related to study drug
6.	Seriousness: (check all that apply)	(bridgecdd:SCRSAE.SCSAEHO / Scr SAE ser required hosp) [1] <input type="checkbox"/> Required or prolonged inpatient hospitalization specify hospital admission date: Req <input type="checkbox"/> / Req <input type="checkbox"/> / Req <input type="checkbox"/> (2009-2015) (bridgecdd:SCRSAE.SCSHOSDT / Scr SAE hospitalization dt) (bridgecdd:SCRSAE.SCSHOSSP / Scr SAE hospitalization spc) [1] <input type="radio"/> Prolonged Hospitalization [2] <input type="radio"/> Rehospitalization (bridgecdd:SCRSAE.SCSAEDEA / Scr SAE ser result in death) [1] <input type="checkbox"/> Resulted in death (bridgecdd:SCRSAE.SCSSELT / Scr SAE serious life threat) [1] <input type="checkbox"/> Life threatening (bridgecdd:SCRSAE.SCSSEPSD / Scr SAE seri per sig disabi) [1] <input type="checkbox"/> Persistent/significant disability (bridgecdd:SCRSAE.SCSSECAB / Scr SAE ser con ab birth) [1] <input type="checkbox"/> Congenital abnormality/birth defect (bridgecdd:SCRSAE.SCSSEOTH / Scr SAE ser other import) [1] <input type="checkbox"/> Other medically important condition
7.	Outcome Date:	Req <input type="checkbox"/> / Req <input type="checkbox"/> / Req <input type="checkbox"/> (2009-2015) (bridgecdd:SCRSAE.SCSOUTDT / Scr SAE outcome date)
8.	Outcome Details: (Check one only)	(bridgecdd:SCRSAE.SCSOUTCO / Scr SAE outcome) [1] <input type="radio"/> Resolved [2] <input type="radio"/> Resolved with Sequelae [3] <input type="radio"/> Unresolved [4] <input type="radio"/> Death
9.	Narrative of SAE:	A2000 (bridgecdd:SCRSAE.SCSANAR / Scr SAE narrative)
.		
10.*	SDV Status	(bridgecdd:SCRSAE.SDVSCRSA / SDV Screen SAE) [1] <input type="radio"/> Not Applicable [2] <input type="radio"/> 100 % Full Review
* Item is not required		

CDD: bridgecdd	Table: SCRSAE	Key Type: PATIENTVISIT
Column Name	Column Data Type	Design Note
SCSHOSSP	NUMERIC	
SDVSCRSA	NUMERIC	
SCSANAR	STRING(255) - A2000	
SCSOUTCO	NUMERIC	
SCRSAENC	NUMERIC	
SCRSAEDT	DATE - DDMONYYYY	

SCSAETER	STRING(200) - A200	
SCSOUTDT	DATE - DDMONYYYY	
SCSSECAB	NUMERIC	
SCSSEPSD	NUMERIC	
SCSSELT	NUMERIC	
SCSAEDEA	NUMERIC	
SCSAONDT	DATE - DDMONYYYY	
SCSAECA	NUMERIC	
SCSAEHO	NUMERIC	
SCSHOSDT	DATE - DDMONYYYY	
SCSSEOTH	STRING(255)	

bridge : Screening Eligibility (SCRELG)		
Screening		
1.	Did patient meet the eligibility criteria?	(bridgecdd:SCRELG.SCRELICR / Screen patient eligibility) [1] <input type="radio"/> Yes [0] <input type="radio"/> No
2.	Will the patient be randomized?	(bridgecdd:SCRELG.SCRRAND / Patient randomized) [1] <input type="radio"/> Yes [0] <input type="radio"/> (bridgecdd:SCRELG.SCRRANNO / Patient randomized no) No If No, please provide reason [1] <input type="radio"/> Patient Decision [2] <input type="radio"/> MD Decision
3.*	SDV Status	(bridgecdd:SCRELG.SDVSCREL / SDV Screen Elig) [1] <input type="radio"/> Not Applicable [2] <input type="radio"/> 100 % Full Review
* Item is not required		

Column Name	Column Data Type	Design Note
SCRRAND	NUMERIC	
SDVSCREL	NUMERIC	
SCRELICR	NUMERIC	
SCRRANNO	NUMERIC	

bridge : WARFARIN (WARFAR) - Repeating Form			
#		Warfarin Status	SDV Status
1	<input type="text"/>		

Warfarin Diary	
1.* Warfarin Status	(bridgecdd:WARFAR.WARSTAT / Warfarin Status) [1] <input type="radio"/> Stop [2] <input type="radio"/> Start Req <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (2009-2015) (bridgecdd:WARFAR.WARDIDTM / Warfarin diary date time) Req <input type="text"/> : Req <input type="text"/> 24-hour clock Amount xxxxxxxx. (bridgecdd:WARFAR.WARDIAAM / Warfarin diary amount)
2.* SDV Status	(bridgecdd:WARFAR.SDVWARFA / SDV Warfarin) [1] <input type="radio"/> Not Applicable [2] <input type="radio"/> 100 % Full Review

* Item is not required

Column Name	Column Data Type	Design Note
WARDIDTM	DATE - DDMONYYYY HHMM	
WARDIAAM	FLOAT - F9.0	
SDVWARFA	NUMERIC	
WARSTAT	NUMERIC	

bridge : IXRS RANDOMINZATION (RAN)	
Randomization	
1.	Patient Number: A20 (bridgecdd:RAN.SUBJNO / Subject number)
2.	Date and time of randomization Req <input type="checkbox"/> / Req <input type="checkbox"/> / Req <input type="checkbox"/> (2009-2015) (bridgecdd:RAN.RANDDTM / Date Time of Randomization) Req <input type="checkbox"/> : Req <input type="checkbox"/> 24-hour clock
3.	Date of Birth Req <input type="checkbox"/> / Req <input type="checkbox"/> / Req <input type="checkbox"/> (1900-2000) (bridgecdd:RAN.DOBBDT / Date of Birth)
4.	Gender (bridgecdd:RAN.GENDER / Gender) [1] <input type="radio"/> Male [2] <input type="radio"/> Female
5.	Kit Number A5 (bridgecdd:RAN.KITNUM / Kit number)
6.*	Additional Kit Number 1 (if applicable) A5 (bridgecdd:RAN.ADKITNU1 / Additional kit number 1)
7.*	Additional Kit Number 2 (if applicable) A5 (bridgecdd:RAN.ADKITNU2 / Additional kit number 2)
8.*	Additional Kit Number 3 (if applicable) A5 (bridgecdd:RAN.ADKITNU3 / Additional kit number 3)
9.*	SDV Status (bridgecdd:RAN.SDVVRAN / SDV Randomization) [1] <input type="radio"/> Not Applicable [2] <input type="radio"/> 100 % Full Review
* Item is not required	

CDD: bridgecdd	Table: RAN	Key Type: PATIENTVISIT
Column Name	Column Data Type	Design Note
SDVRAN	NUMERIC	
ADKITNU1	STRING(5) - A5	
GENDER	NUMERIC	
ADKITNU2	STRING(5) - A5	
ADKITNU3	STRING(5) - A5	
SUBJNO	STRING(20) - A20	
RANDDTM	DATE - DDMONYYYY HHMM	
DOBDT	DATE - DDMONYYYY	
KITNUM	STRING(5) - A5	

bridge : ASSESSMENT (ASSESS)	
Assessment	
Has the patient experienced any of the following events since last site contact?	
1.	Date of Encounter Req <input type="checkbox"/> / Req <input type="checkbox"/> / Req <input type="checkbox"/> (2009-2015) (bridgecdd:ASSESS.ASSESDT / Assessment encounter date)
2.	MI (bridgecdd:ASSESS.MI / Assess MI experience) [0] <input type="radio"/> No [1] <input type="radio"/> Yes Diagnosis Date Req <input type="checkbox"/> / Req <input type="checkbox"/> / Req <input type="checkbox"/> (2009-2015) (bridgecdd:ASSESS.MIDT / Assess MI date) (bridgecdd:ASSESS.MIRFBIO / Assess MI) Rise and fall of biochemical marker of myocardial necrosis (CK-MB, Troponin I, pr T) elevated to at least twice the upper limit of normal range. (cardiac troponin or CK-MB >2x ULN) [0] <input type="radio"/> No [1] <input type="radio"/> Yes Confirmed by at least one of the following: (bridgecdd:ASSESS.MICONDIS / Assess MI develop) [1] <input type="checkbox"/> Development of Ischemic Symptoms (bridgecdd:ASSESS.MICONECG / Assess MI ECG) [1] <input type="checkbox"/> ECG changes (bridgecdd:ASSESS.MICONCOR / Assess MI coronary) [1] <input type="checkbox"/> Coronary intervention (e.g. PTCA/CABG)
3.	Deep Vein Thrombosis (bridgecdd:ASSESS.DVT / Assess DVT) [0] <input type="radio"/> No [1] <input type="radio"/> Yes Diagnosis Date Req <input type="checkbox"/> / Req <input type="checkbox"/> / Req <input type="checkbox"/> (2009-2015) (bridgecdd:ASSESS.DVTDT / Assess DVT date) Symptomatic Venous Thrombosis verified by; check all that apply (bridgecdd:ASSESS.SVTVERUL / Assess DVT ultra) [1] <input type="checkbox"/> Ultrasound (bridgecdd:ASSESS.SVTVERIF / Assess DVT intralum) [1] <input type="checkbox"/> Intraluminal filling defect on CT/MR (bridgecdd:ASSESS.SVTVERVE / Assess DVT venog) [1] <input type="checkbox"/> Venography
4.	Pulmonary Embolism (bridgecdd:ASSESS.PULEMB / Assess pulmonary) [0] <input type="radio"/> No [1] <input type="radio"/> Yes Diagnosis Date Req <input type="checkbox"/> / Req <input type="checkbox"/> / Req <input type="checkbox"/> (2009-2015) (bridgecdd:ASSESS.PULEMBDT / Assess PUL date) Pulmonary Embolism verified by: (check all that apply) (bridgecdd:ASSESS.PEVERPLS / Assess PUL lung scan) [1] <input type="checkbox"/> Perfusion lung scan (bridgecdd:ASSESS.PEVERIFD / Assess PUL intralum) [1] <input type="checkbox"/> Intraluminal filling defect on CT/MR (bridgecdd:ASSESS.PEVERPA / Assess PUL angio) [1] <input type="checkbox"/> Pulmonary angiography
5.	Ischemic Stroke (bridgecdd:ASSESS.ISSTROKE / Assess Ischemic stroke) [0] <input type="radio"/> No [1] <input type="radio"/> Yes
6.*	CEC initiated Ischemic Stroke (bridgecdd:ASSESS.CECSTRF / CEC initiated stroke form) [1] <input type="radio"/> Yes
7.	Transient Ischemic Attack (TIA) (bridgecdd:ASSESS.TIA / Assess TIA) [0] <input type="radio"/> No [1] <input type="radio"/> Yes
8.*	CEC initiated TIA (bridgecdd:ASSESS.CECTIAF / CEC initiated TIA form) [1] <input type="radio"/> Yes
9.	Systemic Embolism (bridgecdd:ASSESS.SYMBOL / Assess systemic embo) [0] <input type="radio"/> No [1] <input type="radio"/> Yes
10.*	CEC initiated Systemic Embolism (bridgecdd:ASSESS.CECSEF / CEC initiated SE form) [1] <input type="radio"/> Yes
11.	Death (bridgecdd:ASSESS.DEATH)

		<p>[0] <input type="radio"/> No [1] <input type="radio"/> Yes</p> <p>Death Date & time Req [v] / Req [v] / Req [v] (2009-2015) (bridgecdd:ASSESS.DEATHDTM / Assess death date time) Req [v] : Req [v] 24-hour clock (bridgecdd:ASSESS.DEATHAUT / Assess death autopsy) Was an autopsy performed? [0] <input type="radio"/> No [1] <input type="radio"/> Yes (bridgecdd:ASSESS.DECAUSE / Assess death cause) Cause of Death [1] <input type="radio"/> CV [2] <input type="radio"/> Non CV [99] <input type="radio"/> Unknown</p>
12.	Did the patient experience any other event that meets the definition of Serious Adverse Event?	(bridgecdd:ASSESS.AEDEFINE / Assess SAE) [0] <input type="radio"/> No [1] <input type="radio"/> Yes
.		
13.*	Trigger #:	A20 (bridgecdd:ASSESS.DETRIGNU / Death trigger number)
14.*	Trigger Status:	Pull-down List 1 [v] (bridgecdd:ASSESS.DETRIGST / Death trigger status)
15.*	Review Type	(bridgecdd:ASSESS.DEREVTV / Death review type) [1] <input type="radio"/> Committee [2] <input type="radio"/> QC [3] <input type="radio"/> Re-review [4] <input type="radio"/> Adjudication
16.*	CEC Status Date	Req [v] / Req [v] / Req [v] (2009-2015) (bridgecdd:ASSESS.DESTATDT / CEC death Status date)
17.*	1st Reviewer Code	Pull-down List 2 [v] (bridgecdd:ASSESS.DEREV1CO / Death reviewer 1 code) Date returned Req [v] / Req [v] / Req [v] (2009-2015) (bridgecdd:ASSESS.DEREV1DT / Death reviewer 1 date)
18.*	2nd Reviewer Code	Pull-down List 3 [v] (bridgecdd:ASSESS.DEREV2CO / Death reviewer 2 code) Date returned Req [v] / Req [v] / Req [v] (2009-2015) (bridgecdd:ASSESS.DEREV2DT / Death reviewer 2 date)
19.*	Committee	(bridgecdd:ASSESS.DECOMM / Death to Committee) [1] <input type="radio"/> Yes [0] <input type="radio"/> No Date Returned NReq [v] / NReq [v] / NReq [v] (2009-2015) (bridgecdd:ASSESS.DECOMMDT / Death Committee date)
20.*	QC	(bridgecdd:ASSESS.DEATHQC / Death QC) [1] <input type="radio"/> Yes [0] <input type="radio"/> No Date Returned NReq [v] / NReq [v] / NReq [v] (2009-2015) (bridgecdd:ASSESS.DEQCCT / Death QC date)
CEC Death		
21.*	Date and time of death	Req [v] / Req [v] / Req [v] (2009-2015) (bridgecdd:ASSESS.CECDEDTM / CEC Death date time) Req [v] : Req [v] 24-hour clock
22.*	Primary cause of death (choose one):	(bridgecdd:ASSESS.CECDECAU / CEC cause if death) [1] <input type="radio"/> (bridgecdd:ASSESS.CECCARDI / CEC cardio death type) Cardiovascular [1] <input type="radio"/> (bridgecdd:ASSESS.CECDEWIT / CEC sudden death witness) Sudden Death [1] <input type="radio"/> Witnessed [2] <input type="radio"/> Unwitnessed [2] <input type="radio"/> Congestive Heart Failure/ Shock [3] <input type="radio"/> Fatal Arrhythmia [4] <input type="radio"/> Ischemic Stroke [5] <input type="radio"/> Systemic Embolism [6] <input type="radio"/> Fatal Myocardial Infarction [7] <input type="radio"/> Pulmonary Embolism [8] <input type="radio"/> Fatal Bleeding [98] <input type="radio"/> Other Specify: (bridgecdd:ASSESS.CECCAOSP / CEC cardio other specify)

		A25 [2] <input type="radio"/> (bridgecdd:ASSESS.CECNONCA / CEC non cardiac death type) Non-Cardiovascular [1] <input type="radio"/> Trauma [2] <input type="radio"/> Infection [3] <input type="radio"/> Malignancy [4] <input type="radio"/> Pulmonary [5] <input type="radio"/> Renal [98] <input type="radio"/> Other Specify: (bridgecdd:ASSESS.CECNCOSP / CEC non card other specify) A25 [99] <input type="radio"/> Unknown
23.*	SDV Status	(bridgecdd:ASSESS.SDVASSES / SDV Assess) [1] <input type="radio"/> Not Applicable [2] <input type="radio"/> 100 % Full Review

* Item is not required

Pulldown List 1:			
RefName	Display Text	Value	Design Note
ieTRGSTAT1	NEW	1	
ieTRGSTAT2	OUTSTANDING SOURCE DOCS	2	
ieTRGSTAT3	COMPLETE	3	
ieTRGSTAT4	PHASE 1	4	
ieTRGSTAT5	COMMITTEE	5	
ieTRGSTAT6	QC	6	
ieTRGSTAT7	NO ACTION NEEDED	7	
ieTRGSTAT8	HOLD	8	
ieTRGSTAT9	RE-REVIEW	9	

Pulldown List 2:			
RefName	Display Text	Value	Design Note
ieCECRE01	1	1	
ieCECRE02	2	2	
ieCECRE03	3	3	
ieCECRE04	4	4	
ieCECRE05	5	5	
ieCECRE06	6	6	
ieCECRE07	7	7	
ieCECRE08	8	8	
ieCECRE09	9	9	
ieCECRE10	10	10	
ieCECRE11	11	11	
ieCECRE12	12	12	
ieCECRE13	13	13	
ieCECRE14	14	14	
ieCECRE15	15	15	
ieCECRE16	16	16	
ieCECRE17	17	17	
ieCECRE18	18	18	
ieCECRE19	19	19	
ieCECRE20	20	20	

Pulldown List 3:			
RefName	Display Text	Value	Design Note

ieCECRE01	1	1
ieCECRE02	2	2
ieCECRE03	3	3
ieCECRE04	4	4
ieCECRE05	5	5
ieCECRE06	6	6
ieCECRE07	7	7
ieCECRE08	8	8
ieCECRE09	9	9
ieCECRE10	10	10
ieCECRE11	11	11
ieCECRE12	12	12
ieCECRE13	13	13
ieCECRE14	14	14
ieCECRE15	15	15
ieCECRE16	16	16
ieCECRE17	17	17
ieCECRE18	18	18
ieCECRE19	19	19
ieCECRE20	20	20

CDD: bridgecdd Table: ASSESS Key Type: PATIENTVISIT		
Column Name	Column Data Type	Design Note
MIDT	DATE - DDMONYYYY	
MICONDIS	NUMERIC	
DVT	NUMERIC	
MICONCOR	NUMERIC	
MICONECG	NUMERIC	
MIRFBIO	NUMERIC	
ASSESSDT	DATE - DDMONYYYY	
DVTDT	DATE - DDMONYYYY	
SVTVERUL	NUMERIC	
DEREV1DT	DATE - DDMONYYYY	
DEATHDTM	DATE - DDMONYYYY HHMM	
DECOMMDT	DATE - DDMONYYYY	
DEATHQC	NUMERIC	
CECTIAF	NUMERIC	
PEVERPA	NUMERIC	
PEVERIFD	NUMERIC	
DEREVTY	NUMERIC	
SVTVERVE	NUMERIC	
PULEMB	NUMERIC	
DEREV1CO	STRING(255) - 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20	
CECCARDI	NUMERIC	
PULEMBDT	DATE - DDMONYYYY	
DESTATDT	DATE - DDMONYYYY	
CECSEF	NUMERIC	
CECDEWIT	NUMERIC	
DEATH	NUMERIC	
DECAUSE	NUMERIC	
DEQCDT	DATE - DDMONYYYY	

DEATHAUT	NUMERIC	
ISSTROKE	NUMERIC	
TIA	NUMERIC	
DEREV2DT	DATE - DDMONYYYY	
DECOMM	NUMERIC	
PEVERPLS	NUMERIC	
CECSTRF	NUMERIC	
MI	NUMERIC	
SYMBOL	NUMERIC	
DETRIGST	STRING(255) - 1, 2, 3, 4, 5, 6, 7, 8, 9	
SVTVERIF	NUMERIC	
DEREV2CO	STRING(255) - 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20	
AEDEFINE	NUMERIC	
DETRIGNU	STRING(20) - A20	
CECDECAU	NUMERIC	
CECDEDTM	DATE - DDMONYYYY HHMM	
CECCAOSP	STRING(25) - A25	
CECNCOSP	STRING(25) - A25	
SDVASSES	NUMERIC	
CECNONCA	NUMERIC	

bridge : LOCAL LABORATORY RESULTS (LAB) - Repeating Form					
#		Hemoglobin	Platelets	INR Results	SDV Status
1	<input type="checkbox"/>				
Labs					
1.*	Hemoglobin	(bridgecdd:LAB.LABHEMOG / Lab hemo done) [97] <input type="radio"/> Not Done [1] <input type="radio"/> xxxxxxxx. (bridgecdd:LAB.LABHEMTX / Lab hemo value) (bridgecdd:LAB.LABHEMUN / Lab hemo unit) [1] <input type="radio"/> g/dL [2] <input type="radio"/> g/L Lab Draw Date and Time Req <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (2009-2015) (bridgecdd:LAB.LABHEDTM / Lab hemo date time) Req <input type="text"/> : Req <input type="text"/> 24-hour clock			
2.*	Platelets	(bridgecdd:LAB.LABPLATE / Lab platelets done) [97] <input type="radio"/> Not Done [1] <input type="radio"/> xxxxxxxx. x 10 ⁹ cells/L (bridgecdd:LAB.LABPLAND / Lab platelets value) Lab Draw Date and Time Req <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (2009-2015) (bridgecdd:LAB.LAPLADTM / Lab platelets date time) Req <input type="text"/> : Req <input type="text"/> 24-hour clock			
3.*	INR Results	(bridgecdd:LAB.LABINR / Lab INR done) [97] <input type="radio"/> Not Done [1] <input type="radio"/> xxxxxxxx. (bridgecdd:LAB.LABINRND / Lab INR value) Lab Draw Date and Time Req <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (2009-2015) (bridgecdd:LAB.LAINRDTM / Lab INR date time) Req <input type="text"/> : Req <input type="text"/> 24-hour clock (bridgecdd:LAB.LAINRPOC / Lab INR method) [1] <input type="radio"/> Point of Care Device [2] <input type="radio"/> Laboratory			
4.*	SDV Status	(bridgecdd:LAB.SDVLAB / SDV Lab) [1] <input type="radio"/> Not Applicable [2] <input type="radio"/> 100 % Full Review			
* Item is not required					

Column Name	Column Data Type	Design Note
LABINR	NUMERIC	
LAINRDTM	DATE - DDMONYYYY HHMM	
SDVLAB	NUMERIC	
LAINRPOC	NUMERIC	
LABHEMOG	NUMERIC	
LABHEMTX	FLOAT - F9.0	
LABHEMUN	NUMERIC	
LABHEDTM	DATE - DDMONYYYY HHMM	
LABPLATE	NUMERIC	
LABPLAND	FLOAT - F9.0	
LAPLADTM	DATE - DDMONYYYY HHMM	
LABINRND	FLOAT - F9.0	

		<p>Stop Date and Time Req/Unk <input type="button" value="v"/> / Req/Unk <input type="button" value="v"/> / Req <input type="button" value="v"/> (2007-2015) (bridgecdd:CONMED.PESTODTM / Con pent stop date time) Req/Unk <input type="button" value="v"/> : Req/Unk <input type="button" value="v"/> 24-hour clock</p> <p>Re-Start Date and Time Req/Unk <input type="button" value="v"/> / Req/Unk <input type="button" value="v"/> / Req <input type="button" value="v"/> (2007-2015) (bridgecdd:CONMED.PESTADTM / Con pent start date time) Req/Unk <input type="button" value="v"/> : Req/Unk <input type="button" value="v"/> 24-hour clock</p> <p>[0] <input type="radio"/> No</p>
9.	Cilostazol (Pletal)	<p>(bridgecdd:CONMED.CONCILO / Conmed cilostazol)</p> <p>[1] <input type="radio"/> Yes</p> <p>Stop Date and Time Req/Unk <input type="button" value="v"/> / Req/Unk <input type="button" value="v"/> / Req <input type="button" value="v"/> (2007-2015) (bridgecdd:CONMED.CISTODTM / Con cilo stop date time) Req/Unk <input type="button" value="v"/> : Req/Unk <input type="button" value="v"/> 24-hour clock</p> <p>Re-Start Date and Time Req/Unk <input type="button" value="v"/> / Req/Unk <input type="button" value="v"/> / Req <input type="button" value="v"/> (2007-2015) (bridgecdd:CONMED.CISTADTM / Con cilo start date time) Req/Unk <input type="button" value="v"/> : Req/Unk <input type="button" value="v"/> 24-hour clock</p> <p>[0] <input type="radio"/> No</p>
10.	Ticagrelor (Brilinta)	<p>(bridgecdd:CONMED.CONTICA / Conmed ticagalar)</p> <p>[1] <input type="radio"/> Yes</p> <p>Stop Date and Time Req/Unk <input type="button" value="v"/> / Req/Unk <input type="button" value="v"/> / Req <input type="button" value="v"/> (2007-2015) (bridgecdd:CONMED.TICAODTM / Con tica stop date time) Req/Unk <input type="button" value="v"/> : Req/Unk <input type="button" value="v"/> 24-hour clock</p> <p>Re-Start Date and Time Req/Unk <input type="button" value="v"/> / Req/Unk <input type="button" value="v"/> / Req <input type="button" value="v"/> (2007-2015) (bridgecdd:CONMED.TICARDTM / Con tica start date time) Req/Unk <input type="button" value="v"/> : Req/Unk <input type="button" value="v"/> 24-hour clock</p> <p>[0] <input type="radio"/> No</p>
11.	Prasugrel (Effient)	<p>(bridgecdd:CONMED.CONPRAS / Conmed prasugrel)</p> <p>[1] <input type="radio"/> Yes</p> <p>Stop Date and Time Req/Unk <input type="button" value="v"/> / Req/Unk <input type="button" value="v"/> / Req <input type="button" value="v"/> (2007-2015) (bridgecdd:CONMED.PRASODTM / Con pras stop date time) Req/Unk <input type="button" value="v"/> : Req/Unk <input type="button" value="v"/> 24-hour clock</p> <p>Re-Start Date and Time Req/Unk <input type="button" value="v"/> / Req/Unk <input type="button" value="v"/> / Req <input type="button" value="v"/> (2007-2015) (bridgecdd:CONMED.PRASADTM / Con pras start date time) Req/Unk <input type="button" value="v"/> : Req/Unk <input type="button" value="v"/> 24-hour clock</p> <p>[0] <input type="radio"/> No</p>
12.*	SDV Status	<p>(bridgecdd:CONMED.SDVCONMD / SDV Con med)</p> <p>[1] <input type="radio"/> Not Applicable</p> <p>[2] <input type="radio"/> 100 % Full Review</p>

* Item is not required

Column Name	Column Data Type	Design Note
DASTODTM	DATE - DDMONYYYY HHMM	
PESTADTM	DATE - DDMONYYYY HHMM	
CONASPI	NUMERIC	
ASSTODTM	DATE - DDMONYYYY HHMM	
ASSTADTM	DATE - DDMONYYYY HHMM	
CONCLOP	NUMERIC	
CLSTODTM	DATE - DDMONYYYY HHMM	
CLSTADTM	DATE - DDMONYYYY HHMM	
CONTICL	NUMERIC	
TISTODTM	DATE - DDMONYYYY HHMM	
TISTADTM	DATE - DDMONYYYY HHMM	
CONNONS	NUMERIC	
NSSTODTM	DATE - DDMONYYYY HHMM	
CONCOX2	NUMERIC	
NSSTADTM	DATE - DDMONYYYY HHMM	
CXSTADTM	DATE - DDMONYYYY HHMM	
CXSTODTM	DATE - DDMONYYYY HHMM	
CONDIPY	NUMERIC	
DISTODTM	DATE - DDMONYYYY HHMM	

DISTADTM	DATE - DDMONYYYY HHMM	
CONDIPA	NUMERIC	
CONCILO	NUMERIC	
CISTODTM	DATE - DDMONYYYY HHMM	
CISTADTM	DATE - DDMONYYYY HHMM	
SDVCONMD	NUMERIC	
CONTICA	NUMERIC	
DASTADTM	DATE - DDMONYYYY HHMM	
CONPENT	NUMERIC	
PESTODTM	DATE - DDMONYYYY HHMM	
TICAODTM	DATE - DDMONYYYY HHMM	
TICARDTM	DATE - DDMONYYYY HHMM	
CONPRAS	NUMERIC	
PRASODTM	DATE - DDMONYYYY HHMM	
PRASADTM	DATE - DDMONYYYY HHMM	

bridge : MEDICATION ADMINISTRATION RECORD (MAR) - Repeating Form				
#	Study Drug Administration	Vitamin K	SDV Status	
1				
Medication Administration Record				
1.*	Study Drug Administration	(bridgecdd:MAR.SDADMIN / Study drug administration) [97] <input type="radio"/> Not Given [1] <input type="radio"/> Stop [2] <input type="radio"/> Start Req <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (2009-2015) (bridgecdd:MAR.SDASTATM / Study drug admin date time) Req <input type="text"/> : Req <input type="text"/> 24-hour clock Amount xxxxxxxx. (bridgecdd:MAR.MARSTAAM / Study drug amount)		
2.*	Vitamin K	(bridgecdd:MAR.MARVKNG / Vitamin K not given) [97] <input type="radio"/> Not Given [1] <input type="radio"/> Req <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (2009-2015) (bridgecdd:MAR.MARVKDTM / Vitamin K date time) Req <input type="text"/> : Req <input type="text"/> 24-hour clock Amount xxxxxxxx. (bridgecdd:MAR.MARVKAMO / Vitamin K amount) (bridgecdd:MAR.VITKROUT / Vitamin K route given) Route [1] <input type="radio"/> Oral mg [2] <input type="radio"/> SC or IV mg		
3.*	SDV Status	(bridgecdd:MAR.SDVMMAR / SDV Mar) [1] <input type="radio"/> Not Applicable [2] <input type="radio"/> 100 % Full Review		
* Item is not required				

Column Name	Column Data Type	Design Note
SDVMAR	NUMERIC	
SDADMIN	NUMERIC	
MARSTAAM	FLOAT - F9.0	
MARVKNG	NUMERIC	
MARVKDTM	DATE - DDMONYYYY HHMM	
VITKROUT	NUMERIC	
MARVKAMO	FLOAT - F9.0	
SDASTATM	DATE - DDMONYYYY HHMM	

bridge : ASSESSMENT STROKE (ASSTRO) - Repeating Form											
#	Ischemic Stroke	Trigger #:	Trigger Status:	Review Type	CEC Status Date	1st Reviewer Code	2nd Reviewer Code	Committee	QC	Did the patient experience an Ischemic stroke?	SDV Status
1	<input type="checkbox"/>										
Assessment											
1.	Ischemic Stroke					(bridgecdd:ASSTRO.STROINIT / Stroke Initiated by) [1] <input type="radio"/> CEC Initiated [2] <input type="radio"/> Site Symptom Onset date & time Req <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (2008-2015) (bridgecdd:ASSTRO.ISSYSDTM / Assess IS sym date time) Req <input type="text"/> : Req <input type="text"/> 24-hour clock Diagnosis Date Req <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (2008-2015) (bridgecdd:ASSTRO.ISDIADT / Assess IS dia date time) (bridgecdd:ASSTRO.ISDURAT / Assess IS sym duration) Symptom Duration [1] <input type="radio"/> < 24 Hours [2] <input type="radio"/> >= 24 Hours Method of diagnosis: (check all that apply) (bridgecdd:ASSTRO.ISMODCT / Assess IS CT) [1] <input type="checkbox"/> CT (bridgecdd:ASSTRO.ISMODMRI / Assess IS MRI) [1] <input type="checkbox"/> MRI (bridgecdd:ASSTRO.ISMODNEU / Assess IS neuro eval) [1] <input type="checkbox"/> Neurologic Evaluation					
2.*	Trigger #:					A20 (bridgecdd:ASSTRO.STTRIGNU / Stroke trigger number)					
3.*	Trigger Status:					Pulldown List 1 <input type="text"/> (bridgecdd:ASSTRO.STTRIGST / Stroke trigger status)					
4.*	Review Type					(bridgecdd:ASSTRO.STREVTY / Stroke review type) [1] <input type="radio"/> Committee [2] <input type="radio"/> QC [3] <input type="radio"/> Re-review [4] <input type="radio"/> Adjudication					
5.*	CEC Status Date					Req <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (2009-2015) (bridgecdd:ASSTRO.STSTATDT / Stroke Status date)					
6.*	1st Reviewer Code					Pulldown List 2 <input type="text"/> (bridgecdd:ASSTRO.STREV1CO / Stroke reviewer 1 code) Date returned Req <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (2009-2015) (bridgecdd:ASSTRO.STREV1DT / Stroke reviewer 1 date)					
7.*	2nd Reviewer Code					Pulldown List 3 <input type="text"/> (bridgecdd:ASSTRO.STREV2CO / Stroke reviewer 2 code) Date returned Req <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (2009-2015) (bridgecdd:ASSTRO.STREV2DT / Stroke reviewer 2 date)					
8.*	Committee					(bridgecdd:ASSTRO.STCOMM / Stroke to Committee) [1] <input type="radio"/> Yes [0] <input type="radio"/> No Date Returned NReq <input type="text"/> / NReq <input type="text"/> / NReq <input type="text"/> (2009-2015) (bridgecdd:ASSTRO.STCOMMDT / Stroke Committee date)					
9.*	QC					(bridgecdd:ASSTRO.STROKEQC / Stroke QC) [1] <input type="radio"/> Yes [0] <input type="radio"/> No Date Returned NReq <input type="text"/> / NReq <input type="text"/> / NReq <input type="text"/> (2009-2015) (bridgecdd:ASSTRO.STQCDDT / Stroke QC date)					
CEC Stroke											
10.*	Did the patient experience an Ischemic stroke?					(bridgecdd:ASSTRO.CECSTROK / CEC Ischemic stroke) [0] <input type="radio"/> No [99] <input type="radio"/> Unknown [1] <input type="radio"/> Yes Datetime Req <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (2009-2015) (bridgecdd:ASSTRO.CECSTDTM / CEC Isch stroke date time) Req <input type="text"/> : Req <input type="text"/> 24-hour clock					
11.*	SDV Status					(bridgecdd:ASSTRO.SDVASSTR / SDV Assess Stroke) [1] <input type="radio"/> Not Applicable [2] <input type="radio"/> 100 % Full Review					

* Item is not required

Pulldown List 1:			
RefName	Display Text	Value	Design Note
ieTRGSTAT1	NEW	1	
ieTRGSTAT2	OUTSTANDING SOURCE DOCS	2	
ieTRGSTAT3	COMPLETE	3	
ieTRGSTAT4	PHASE 1	4	
ieTRGSTAT5	COMMITTEE	5	
ieTRGSTAT6	QC	6	
ieTRGSTAT7	NO ACTION NEEDED	7	
ieTRGSTAT8	HOLD	8	
ieTRGSTAT9	RE-REVIEW	9	

Pulldown List 2:			
RefName	Display Text	Value	Design Note
ieCECRE01	1	1	
ieCECRE02	2	2	
ieCECRE03	3	3	
ieCECRE04	4	4	
ieCECRE05	5	5	
ieCECRE06	6	6	
ieCECRE07	7	7	
ieCECRE08	8	8	
ieCECRE09	9	9	
ieCECRE10	10	10	
ieCECRE11	11	11	
ieCECRE12	12	12	
ieCECRE13	13	13	
ieCECRE14	14	14	
ieCECRE15	15	15	
ieCECRE16	16	16	
ieCECRE17	17	17	
ieCECRE18	18	18	
ieCECRE19	19	19	
ieCECRE20	20	20	

Pulldown List 3:			
RefName	Display Text	Value	Design Note
ieCECRE01	1	1	
ieCECRE02	2	2	
ieCECRE03	3	3	
ieCECRE04	4	4	
ieCECRE05	5	5	
ieCECRE06	6	6	
ieCECRE07	7	7	
ieCECRE08	8	8	
ieCECRE09	9	9	
ieCECRE10	10	10	
ieCECRE11	11	11	

ieCECRE12	12	12	
ieCECRE13	13	13	
ieCECRE14	14	14	
ieCECRE15	15	15	
ieCECRE16	16	16	
ieCECRE17	17	17	
ieCECRE18	18	18	
ieCECRE19	19	19	
ieCECRE20	20	20	

CDD: bridgecdd Table: ASSTRO Key Type: PATIENTVISIT		
Column Name	Column Data Type	Design Note
STTRIGST	STRING(255) - 1, 2, 3, 4, 5, 6, 7, 8, 9	
STCOMM	NUMERIC	
ISSYSDTM	DATE - DDMONYYYY HHMM	
CECSTDTM	DATE - DDMONYYYY HHMM	
ISMODNEU	NUMERIC	
ISDIADT	DATE - DDMONYYYY	
STSTATDT	DATE - DDMONYYYY	
STCOMMDT	DATE - DDMONYYYY	
STREVTY	NUMERIC	
STROINIT	NUMERIC	
STREV1CO	STRING(255) - 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20	
ISMODCT	NUMERIC	
STROKEQC	NUMERIC	
ISMODMRI	NUMERIC	
STREV2DT	DATE - DDMONYYYY	
ISDURAT	NUMERIC	
STREV1DT	DATE - DDMONYYYY	
SDVASSTR	NUMERIC	
STQCDT	DATE - DDMONYYYY	
CECSTROK	NUMERIC	
STTRIGNU	STRING(20) - A20	
STREV2CO	STRING(255) - 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20	

bridge : ASSESSMENT TIA (ASTIA) - Repeating Form											
#	Transient Ischemic Attack (TIA)	Trigger Number:	Trigger Status	Review Type	CEC Status Date	1st Reviewer Code	2nd Reviewer Code	Committee	QC	Did the patient experience a TIA?	SDV Status
1											
Assessment											
1.	Transient Ischemic Attack (TIA)		(bridgecdd:ASTIA.TIAINIT / TIA initiated by) [1] <input type="radio"/> CEC Initiated [2] <input type="radio"/> Site Symptom Onset date & time Req [v] / Req [v] / Req [v] (2009-2015) (bridgecdd:ASTIA.TIADTM / Assess TIA sym date time) Req [v] : Req [v] 24-hour clock (bridgecdd:ASTIA.TIADURAT / Assess TIA duration) Symptom Duration [1] <input type="radio"/> <24 [2] <input type="radio"/> ≥24 (bridgecdd:ASTIA.TIAMODCT / Assess TIA CT) Method of diagnosis: (check all that apply) [1] <input type="checkbox"/> CT (bridgecdd:ASTIA.TIAMODMR / Assess TIA MRI) [1] <input type="checkbox"/> MRI (bridgecdd:ASTIA.TIAMODNE / Assess TIA neuro eva) [1] <input type="checkbox"/> Neurologic Evaluation								
2.*	Trigger Number:	A20 (bridgecdd:ASTIA.TITRIGNU / TIA trigger number)									
3.*	Trigger Status:	Pulldown List 1 [v] (bridgecdd:ASTIA.TITRIGST / TIA trigger status)									
4.*	Review Type	(bridgecdd:ASTIA.TIREVTY / TIA review type) [1] <input type="radio"/> Committee [2] <input type="radio"/> QC [3] <input type="radio"/> Re-review [4] <input type="radio"/> Adjudication									
5.*	CEC Status Date	Req [v] / Req [v] / Req [v] (2009-2015) (bridgecdd:ASTIA.TISTATDT / TIA Status date)									
6.*	1st Reviewer Code	Pulldown List 2 [v] (bridgecdd:ASTIA.TIREV1CO / TIA reviewer 1 code) Date returned Req [v] / Req [v] / Req [v] (2009-2015) (bridgecdd:ASTIA.TIREV1DT / TIA reviewer 1 date)									
7.*	2nd Reviewer Code	Pulldown List 3 [v] (bridgecdd:ASTIA.TIREV2CO / TIA reviewer 2 code) Date returned Req [v] / Req [v] / Req [v] (2009-2015) (bridgecdd:ASTIA.TIREV2DT / TIA reviewer 2 date)									
8.*	Committee	(bridgecdd:ASTIA.TICOMM / TIA to Committee) [1] <input type="radio"/> Yes [0] <input type="radio"/> No Date Returned NReq [v] / NReq [v] / NReq [v] (2009-2015) (bridgecdd:ASTIA.TICOMMDT / TIA Committee date)									
9.*	QC	(bridgecdd:ASTIA.TIROKEQC / TIA QC) [1] <input type="radio"/> Yes [0] <input type="radio"/> No Date Returned NReq [v] / NReq [v] / NReq [v] (2009-2015) (bridgecdd:ASTIA.TIQCDT / TIA QC date)									
CEC TIA											
10.*	Did the patient experience a TIA?	(bridgecdd:ASTIA.CECTIA / CEC TIA) [0] <input type="radio"/> No [1] <input type="radio"/> Yes Datetime Req [v] / Req [v] / Req [v] (2009-2015) (bridgecdd:ASTIA.CECTIDTM / CEC TIA date time) Req [v] : Req [v] 24-hour clock									
11.*	SDV Status	(bridgecdd:ASTIA.SDVASTIA / SDV Assess TIA) [1] <input type="radio"/> Not Applicable [2] <input type="radio"/> 100 % Full Review									
* Item is not required											

Pulldown List 1:			
RefName	Display Text	Value	Design Note
ieTRGSTAT1	NEW	1	
ieTRGSTAT2	OUTSTANDING SOURCE DOCS	2	
ieTRGSTAT3	COMPLETE	3	
ieTRGSTAT4	PHASE 1	4	
ieTRGSTAT5	COMMITTEE	5	
ieTRGSTAT6	QC	6	
ieTRGSTAT7	NO ACTION NEEDED	7	
ieTRGSTAT8	HOLD	8	
ieTRGSTAT9	RE-REVIEW	9	

Pulldown List 2:			
RefName	Display Text	Value	Design Note
ieCECRE01	1	1	
ieCECRE02	2	2	
ieCECRE03	3	3	
ieCECRE04	4	4	
ieCECRE05	5	5	
ieCECRE06	6	6	
ieCECRE07	7	7	
ieCECRE08	8	8	
ieCECRE09	9	9	
ieCECRE10	10	10	
ieCECRE11	11	11	
ieCECRE12	12	12	
ieCECRE13	13	13	
ieCECRE14	14	14	
ieCECRE15	15	15	
ieCECRE16	16	16	
ieCECRE17	17	17	
ieCECRE18	18	18	
ieCECRE19	19	19	
ieCECRE20	20	20	

Pulldown List 3:			
RefName	Display Text	Value	Design Note
ieCECRE01	1	1	
ieCECRE02	2	2	
ieCECRE03	3	3	
ieCECRE04	4	4	
ieCECRE05	5	5	
ieCECRE06	6	6	
ieCECRE07	7	7	
ieCECRE08	8	8	
ieCECRE09	9	9	
ieCECRE10	10	10	
ieCECRE11	11	11	
ieCECRE12	12	12	
ieCECRE13	13	13	
ieCECRE14	14	14	

ieCECRE15	15	15	
ieCECRE16	16	16	
ieCECRE17	17	17	
ieCECRE18	18	18	
ieCECRE19	19	19	
ieCECRE20	20	20	

CDD: bridgecdd Table: ASTIA Key Type: PATIENTVISIT		
Column Name	Column Data Type	Design Note
TIREV1DT	DATE - DDMONYYYY	
TIADTM	DATE - DDMONYYYY HHMM	
TIAMODMR	NUMERIC	
TICOMM	NUMERIC	
TIAMODCT	NUMERIC	
TITRIGNU	STRING(20) - A20	
TISTATDT	DATE - DDMONYYYY	
TIAINIT	NUMERIC	
TIREV2DT	DATE - DDMONYYYY	
TITRIGST	STRING(255) - 1, 2, 3, 4, 5, 6, 7, 8, 9	
SDVASTIA	NUMERIC	
CECTIDTM	DATE - DDMONYYYY HHMM	
TIROKEQC	NUMERIC	
TICOMMDT	DATE - DDMONYYYY	
CECTIA	NUMERIC	
TIQCDT	DATE - DDMONYYYY	
TIADURAT	NUMERIC	
TIREV1CO	STRING(255) - 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20	
TIREVTY	NUMERIC	
TIAMODNE	NUMERIC	
TIREV2CO	STRING(255) - 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20	

bridge : ASSESSMENT SYSTEMIC EMBOLISM (ASSEM) - Repeating Form												
#	Systemic Embolism	Trigger Number:	Trigger Status	Review Type	CEC Status Date	1st Reviewer Code	2nd Reviewer Code	Committee	QC	Did the patient experience a systemic embolism?	If Yes, specify location of systemic embolism:	SDV Status
1												

Assessment

1. Systemic Embolism

(bridgecdd:ASSEM.SEMINIT / Sys embo initiated by)
 [1] CEC Initiated
 [2] Site
 Symptom Onset date & time
 Req [v] / Req [v] / Req [v] (2009-2015) (bridgecdd:ASSEM.SYSEMDTM / Assess sys embo date time)
 Req [v] : Req [v] 24-hour clock
 (bridgecdd:ASSEM.SYSLOCUE / Assess sys embo upper)
 Location: check all that apply
 [1] upper extremity
 (bridgecdd:ASSEM.SYSLOCLE / Assess sys embo lower)
 [1] lower extremity
 (bridgecdd:ASSEM.SYSLOCAV / Assess sys embo avo)
 [1] abdominal visceral organ (check all that apply)
 (bridgecdd:ASSEM.SYSAVOSP / Assess sys embo avo splen)
 [1] Splenic
 (bridgecdd:ASSEM.SYSAVOKI / Assess sys embo avo kid)
 [1] Kidney
 (bridgecdd:ASSEM.SYSAVOBO / Assess sys embo avo bowel)
 [1] Bowel
 (bridgecdd:ASSEM.SYSAVOOT / Assess sys embo avo other)
 [1] Other
 (bridgecdd:ASSEM.SYSMODCT / Assess sys embo CT scan)
 Method of diagnosis: (check all that apply)
 [1] CT scan
 (bridgecdd:ASSEM.SYSMODAN / Assess sys embo angio)
 [1] Angiography
 (bridgecdd:ASSEM.SYSMODMR / Assess sys embo MRI)
 [1] MRI/MRA
 (bridgecdd:ASSEM.SYSMODUL / Assess sys embo ultra)
 [1] Ultrasound
 (bridgecdd:ASSEM.SYSMODIN / Assess sys embo intra)
 [1] Intraoperative

2.* Trigger Number: | A20 | (bridgecdd:ASSEM.SETRIGNU / Sys embo trigger number)

3.* Trigger Status: | Pulldown List 1 [v] | (bridgecdd:ASSEM.SETRIGST / Sys embo trigger status)

4.* Review Type
 (bridgecdd:ASSEM.SEREVTY / Sys embo review type)
 [1] Committee
 [2] QC
 [3] Re-review
 [4] Adjudication

5.* CEC Status Date
 Req [v] / Req [v] / Req [v] (2009-2015) (bridgecdd:ASSEM.SESTATDT / Sys embo status date)

6.* 1st Reviewer Code
 Pulldown List 2 [v] (bridgecdd:ASSEM.SEREV1CO / Sys embo reviewer 1 code)
 Date returned Req [v] / Req [v] / Req [v] (2009-2015) (bridgecdd:ASSEM.SEREV1DT / Sys embo reviewer 1 date)

7.* 2nd Reviewer Code
 Pulldown List 3 [v] (bridgecdd:ASSEM.SEREV2CO / Sys embo reviewer 2 code)
 Date returned Req [v] / Req [v] / Req [v] (2009-2015) (bridgecdd:ASSEM.SEREV2DT / Sys embo reviewer 2 date)

8.* Committee
 (bridgecdd:ASSEM.SECOMM / Sys embo to Committee)
 [1] Yes
 [0] No
 Date Returned |NReq [v] / |NReq [v] / |NReq [v] (2009-2015) (bridgecdd:ASSEM.SECOMMDT / Sys embo committee date)

9.* QC
 (bridgecdd:ASSEM.SEROKEQC / Sys embo QC)
 [1] Yes
 [0] No

		Date Returned NReq [v] / NReq [v] / NReq [v] (2009-2015) (bridgecdd:ASSEM.SEQCDDT / Sys embo QC date)
CEC Systemic embolism		
10.*	Did the patient experience a systemic embolism?	(bridgecdd:ASSEM.CECSYSEM / CEC Systemic embolism) [0] <input type="radio"/> No [1] <input type="radio"/> Yes Date/time Req [v] / Req [v] / Req [v] (2009-2015) (bridgecdd:ASSEM.CECSYDTM / CEC Systemic embo date time) Req [v] : Req [v] 24-hour clock
11.*	If Yes, specify location of systemic embolism:	(bridgecdd:ASSEM.CECSYLOC / CEC Sys embolism location) [1] <input type="radio"/> Upper extremity [2] <input type="radio"/> Lower extremity [3] <input type="radio"/> Abdominal visceral organ, specify: (bridgecdd:ASSEM.CECSYSSP / CEC Systemic AVO splenic) [1] <input type="checkbox"/> Splenic (bridgecdd:ASSEM.CECSYSKI / CEC Systemic AVO kidney) [1] <input type="checkbox"/> Kidney (bridgecdd:ASSEM.CECSYSBO / CEC Systemic AVO bowel) [1] <input type="checkbox"/> Bowel (bridgecdd:ASSEM.CECSYSOT / CEC Systemic AVO other) [1] <input type="checkbox"/> Other Specify: A25 (bridgecdd:ASSEM.BLORSPEC / Bleed organ specify)
12.*	SDV Status	(bridgecdd:ASSEM.SDVASSEM / SDV Assess Sys Embo) [1] <input type="radio"/> Not Applicable [2] <input type="radio"/> 100 % Full Review
* Item is not required		

Pulldown List 1:

RefName	Display Text	Value	Design Note
ieTRGSTAT1	NEW	1	
ieTRGSTAT2	OUTSTANDING SOURCE DOCS	2	
ieTRGSTAT3	COMPLETE	3	
ieTRGSTAT4	PHASE 1	4	
ieTRGSTAT5	COMMITTEE	5	
ieTRGSTAT6	QC	6	
ieTRGSTAT7	NO ACTION NEEDED	7	
ieTRGSTAT8	HOLD	8	
ieTRGSTAT9	RE-REVIEW	9	

Pulldown List 2:

RefName	Display Text	Value	Design Note
ieCECRE01	1	1	
ieCECRE02	2	2	
ieCECRE03	3	3	
ieCECRE04	4	4	
ieCECRE05	5	5	
ieCECRE06	6	6	
ieCECRE07	7	7	
ieCECRE08	8	8	
ieCECRE09	9	9	
ieCECRE10	10	10	
ieCECRE11	11	11	
ieCECRE12	12	12	
ieCECRE13	13	13	
ieCECRE14	14	14	

ieCECRE15	15	15	
ieCECRE16	16	16	
ieCECRE17	17	17	
ieCECRE18	18	18	
ieCECRE19	19	19	
ieCECRE20	20	20	

Pulldown List 3:			
RefName	Display Text	Value	Design Note
ieCECRE01	1	1	
ieCECRE02	2	2	
ieCECRE03	3	3	
ieCECRE04	4	4	
ieCECRE05	5	5	
ieCECRE06	6	6	
ieCECRE07	7	7	
ieCECRE08	8	8	
ieCECRE09	9	9	
ieCECRE10	10	10	
ieCECRE11	11	11	
ieCECRE12	12	12	
ieCECRE13	13	13	
ieCECRE14	14	14	
ieCECRE15	15	15	
ieCECRE16	16	16	
ieCECRE17	17	17	
ieCECRE18	18	18	
ieCECRE19	19	19	
ieCECRE20	20	20	

CDD: bridgecdd Table: ASSEM Key Type: PATIENTVISIT		
Column Name	Column Data Type	Design Note
SEMINIT	NUMERIC	
SYSEMDTM	DATE - DDMONYYYY HHMM	
SYSLOCLE	NUMERIC	
SYSLOCUE	NUMERIC	
SYSAVOSP	NUMERIC	
SYSAVOBO	NUMERIC	
SYSLOCAV	NUMERIC	
SYSMODUL	NUMERIC	
SYSMODCT	NUMERIC	
SYSMODAN	NUMERIC	
SYSAVOKI	NUMERIC	
SYSMODMR	NUMERIC	
SYSAVOOT	NUMERIC	
SEREV2DT	DATE - DDMONYYYY	
SETRIGNU	STRING(20) - A20	
SYSMODIN	NUMERIC	
SETRIGST	STRING(255) - 1, 2, 3, 4, 5, 6, 7, 8, 9	
SEREV1CO	STRING(255) - 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20	
SEREVTY	NUMERIC	

SESTATDT	DATE - DDMONYYYY	
SEREV1DT	DATE - DDMONYYYY	
SEREV2CO	STRING(255) - 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20	
SECOMM	NUMERIC	
SECOMMDT	DATE - DDMONYYYY	
SEROKEQC	NUMERIC	
SEQCDT	DATE - DDMONYYYY	
CECSYSOT	NUMERIC	
CECSYSEM	NUMERIC	
CECSYDTM	DATE - DDMONYYYY HHMM	
CECSYLOC	NUMERIC	
CECSYSSP	NUMERIC	
CECSYSKI	NUMERIC	
CECSYSBO	NUMERIC	
BLORSPEC	STRING(25) - A25	
SDVASSEM	NUMERIC	

bridge : FORM COMPLETION (FORMCOMP)	
Forms Completion	
1.* Which of the following forms need completion?	(bridgecdd:FORMCOMP.FORMSC / Form study completion) [1] <input type="checkbox"/> Study Completion (bridgecdd:FORMCOMP.FORMBLEE / Form bleed) [1] <input type="checkbox"/> Bleed
2.* SDV Status	(bridgecdd:FORMCOMP.SDVFORM / SDV Form completion) [1] <input type="radio"/> Not Applicable [2] <input type="radio"/> 100 % Full Review
* Item is not required	

CDD: bridgecdd Table: FORMCOMP Key Type: PATIENTVISIT		
Column Name	Column Data Type	Design Note
SDVFORM	NUMERIC	
FORMSC	NUMERIC	
FORMBLEE	NUMERIC	

bridge : Serious Adverse Event Details (SAE) - Repeating Form									
#	SAE Encounter	SAE Event Term	Onset Date	Causality	Seriousness	Outcome Date	Outcome Details	Narrative of SAE	SDV Status
1	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Serious Adverse Events - Complete for all events noted "Yes" on the assessment page									
1.	SAE Encounter		Pulldown List 1 <input type="text"/> (bridgecdd:SAE.SAEENC / SAE Encounter)						
2.	SAE Event Term: (free text event for DCRI coding purposes)		A200 (bridgecdd:SAE.SAETERM / SAE term)						
3.	Onset Date:		Req <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (2009-2015) (bridgecdd:SAE.SAEONDT / SAE onset date)						
4.	Causality:		(bridgecdd:SAE.SAECAUS / SAE causality) [1] <input type="radio"/> Unlikely related to study drug [2] <input type="radio"/> Likely related to study drug						
5.	Seriousness: (check all that apply)		(bridgecdd:SAE.SAESEHOS / SAE serious required hosp) [1] <input type="checkbox"/> Required or prolonged inpatient hospitalization specify hospital admission date: Req <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (2009-2015) (bridgecdd:SAE.SAEHOSDT / SAE hospitalization date) (bridgecdd:SAE.SAEHOSSP / SAE hospitalization spcific) [1] <input type="radio"/> Prolonged Hospitalization [2] <input type="radio"/> Rehospitalization (bridgecdd:SAE.SAESEDEA / SAE serious result in death) [1] <input type="checkbox"/> Resulted in death (bridgecdd:SAE.SAESELT / SAE serious life threat) [1] <input type="checkbox"/> Life threatening (bridgecdd:SAE.SAESEPSD / SAE serious pers sig disabi) [1] <input type="checkbox"/> Persistent/significant disability (bridgecdd:SAE.SAESECAB / SAE serious con ab birth) [1] <input type="checkbox"/> Congenital abnormality/birth defect (bridgecdd:SAE.SAESEOTH / SAE serious other import) [1] <input type="checkbox"/> Other medically important condition (bridgecdd:SAE.SAECRINO / SAE criteria not meet) [1] <input type="checkbox"/> Did not meet SAE criteria						
6.	Outcome Date:		Req <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (2009-2015) (bridgecdd:SAE.SAEOUTDT / SAE outcome date)						
7.	Outcome Details: (Check one only)		(bridgecdd:SAE.SAEOUTCO / SAE outcome) [1] <input type="radio"/> Resolved [2] <input type="radio"/> Resolved with Sequelae [3] <input type="radio"/> Unresolved [4] <input type="radio"/> Death						
8.	Narrative of SAE:		A2000 (bridgecdd:SAE.SAENAR / SAE narrative)						
9.*	SDV Status		(bridgecdd:SAE.SDVSAE / SDV SAE) [1] <input type="radio"/> Not Applicable [2] <input type="radio"/> 100 % Full Review						
* Item is not required									

Pulldown List 1:			
RefName	Display Text	Value	Design Note
ieCECRE03	3	3	
ieCECRE04	4	4	
ieCECRE05	5	5	
ieCECRE06	6	6	
ieCECRE07	7	7	

ieCECRE08	8	8	
ieCECRE09	9	9	

CDD: bridgecdd Table: SAE Key Type: PATIENTVISIT		
Column Name	Column Data Type	Design Note
SAESEHOS	NUMERIC	
SAEHOSDT	DATE - DDMONYYYY	
SAEOUTCO	NUMERIC	
SAESE CAB	NUMERIC	
SAEHOSSP	NUMERIC	
SAESEDEA	NUMERIC	
SAESEL T	NUMERIC	
SAESEPSD	NUMERIC	
SAESEOTH	NUMERIC	
SAE CRINO	NUMERIC	
SAEOUTDT	DATE - DDMONYYYY	
SAENAR	STRING(255) - A2000	
SDVSAE	NUMERIC	
SAECAUS	NUMERIC	
SAEENC	STRING(255) - 3, 4, 5, 6, 7, 8, 9	
SAETERM	STRING(200) - A200	
SAEONDT	DATE - DDMONYYYY	

bridge : BLEEDING (BLEED) - Repeating Form												
#	Is the bleed symptomatic or clinically overt?	If the patient has not had one of the above-listed bleeds, has the patient had a bleed characterized by one or more of the following criteria?	Trigger #:	Trigger Status:	Review Type	CEC Status Date	1st Reviewer Code	2nd Reviewer Code	Committee	QC	Did the patient experience major bleeding?	SDV Status
1	<input type="checkbox"/>											

CLINICAL OUTCOMES

1.	Is the bleed symptomatic or clinically overt?	<p>(bridgecdd:BLEED.BLEEDSYM / Bleed sympt or clin overt) [0] <input type="radio"/> No [1] <input type="radio"/> Yes</p> <p>(bridgecdd:BLEED.BLEINIT / Bleed initiated by) [1] <input type="radio"/> CEC Initiated [2] <input type="radio"/> Site</p> <p>Bleed Encounter Pulldown List 1 <input type="button" value="v"/> (bridgecdd:BLEED.BLEEDENC / Bleeding encounter) Date & Time: Req <input type="button" value="v"/> / Req <input type="button" value="v"/> / Req <input type="button" value="v"/> (2009-2015) (bridgecdd:BLEED.BLEEDDTM / Bleed date and time) Req <input type="button" value="v"/> : Req <input type="button" value="v"/> 24-hour clock</p> <p>(bridgecdd:BLEED.BSYMTRAN / Bleed need tranfusion) Has the patient had a bleed characterized by one or more of the following criteria (please check all that apply): [1] <input type="checkbox"/> need for transfusion of > or = 2 units heterologous packed red blood cells or whole blood (bridgecdd:BLEED.BSYMDECR / Bleed decrease in hemoglobin) [1] <input type="checkbox"/> decrease in hemoglobin level >20 g/L (>2 g/dL) (bridgecdd:BLEED.BSYMREOP / Bleed need for reop) [1] <input type="checkbox"/> need for re-operation or invasive intervention (e.g., evacuation of wound hematoma) (bridgecdd:BLEED.BSYMLOCA / Bleed location) For any of the above that are checked, please specify the location of the bleed: [1] <input type="radio"/> surgery or procedure site [2] <input type="radio"/> respiratory tract [3] <input type="radio"/> upper gastrointestinal tract [4] <input type="radio"/> lower gastrointestinal tract [5] <input type="radio"/> urinary tract [6] <input type="radio"/> genital tract</p> <p>(bridgecdd:BLEED.BSYMINTR / Bleed intracranial) [1] <input type="checkbox"/> (bridgecdd:BLEED.BSYSINLO / Bleed intracranial location) intracranial bleed [1] <input type="radio"/> subdural or epidural [2] <input type="radio"/> intracerebral [3] <input type="radio"/> subarachnoid [4] <input type="radio"/> intraventricular</p> <p>(bridgecdd:BLEED.BSYMSPIN / Bleed intraspinal) [1] <input type="checkbox"/> intraspinal bleed</p> <p>(bridgecdd:BLEED.BSYMOCUL / Bleed intraocular) [1] <input type="checkbox"/> intraocular bleed</p> <p>(bridgecdd:BLEED.BSYMRETR / Bleed retroperitoneal) [1] <input type="checkbox"/> retroperitoneal bleed</p> <p>(bridgecdd:BLEED.BSYMARTI / Bleed intraarticular) [1] <input type="checkbox"/> intra-articular bleed</p> <p>(bridgecdd:BLEED.BSYMPERI / Bleed pericardial) [1] <input type="checkbox"/> pericardial bleed</p> <p>(bridgecdd:BLEED.BSYMUSC / Bleed intramuscular) [1] <input type="checkbox"/> intramuscular bleed with compartment syndrome</p>
2.*	If the patient has not had one of the above-listed bleeds, has the patient had a bleed characterized by one or more of the following criteria?	<p>(bridgecdd:BLEED.NOBLEED / Other bleed) [0] <input type="radio"/> No [1] <input type="radio"/> Yes</p> <p>Date: Req <input type="button" value="v"/> / Req <input type="button" value="v"/> / Req <input type="button" value="v"/> (2009-2015) (bridgecdd:BLEED.NOBLEDT / Other bleed date time) (bridgecdd:BLEED.NBSITEBR / Other bleed surgery site) Please check all that apply from the following list: [1] <input type="checkbox"/> surgery/procedure site bruising or bleeding that is greater than expected</p> <p>(bridgecdd:BLEED.NBHEMA / Other bleed subcutaneous) [1] <input type="checkbox"/> (bridgecdd:BLEED.NBHEMA5 / Other bleed subcut size) subcutaneous (study drug) injection hematoma [1] <input type="radio"/> measures < 5cm in diameter [2] <input type="radio"/> >= 5cm in diameter</p> <p>(bridgecdd:BLEED.NBGINGIV / Other bleed gingival)</p>

		<p>[1] <input type="checkbox"/> (bridgecdd:BLEED.NBGING5 / Other bleed gingival dur) gingival bleed <i>[1]</i> <input type="radio"/> lasting <5 minutes <i>[2]</i> <input type="radio"/> >= 5 minutes</p> <p>(bridgecdd:BLEED.NBEPISTA / Other bleed epistaxis) [1] <input type="checkbox"/> (bridgecdd:BLEED.NBEPI5 / Other bleed epistaxis dur) epistaxis <i>[1]</i> <input type="radio"/> lasting <5 minutes <i>[2]</i> <input type="radio"/> >= 5 minutes</p> <p>(bridgecdd:BLEED.NBHEMO / Other bleed hemoptysis) [1] <input type="checkbox"/> (bridgecdd:BLEED.NBHEMO1 / Other bleed hemoptysis amo) hemoptysis <i>[1]</i> <input type="radio"/> amount is <1 teaspoon <i>[2]</i> <input type="radio"/> >= 1 teaspoon</p> <p>(bridgecdd:BLEED.NBUPGAS / Other bleed upper gas) <i>[1]</i> <input type="checkbox"/> upper gastrointestinal bleed with melena and positive hemocult test</p> <p>(bridgecdd:BLEED.NBROID / Other bleed hemorrhoidal) [1] <input type="checkbox"/> (bridgecdd:BLEED.NBROID5 / Other bleed hemorrhoid dur) hemorrhoidal bleed <i>[1]</i> <input type="radio"/> lasting <5 minutes <i>[2]</i> <input type="radio"/> >= 5 minutes</p> <p>(bridgecdd:BLEED.NBTURIA / Other bleed hematuria) [1] <input type="checkbox"/> (bridgecdd:BLEED.NBTUR5 / Other bleed hematuria dur) hematuria related to instrumentation <i>[1]</i> <input type="radio"/> lasting <24 hours <i>[2]</i> <input type="radio"/> >= 24 hours</p> <p>(bridgecdd:BLEED.NBMUSC / Other bleed intramuscular) [1] <input type="checkbox"/> (bridgecdd:BLEED.NBMUSDO / Other bleed intramusc docu) intramuscular hematoma <i>[1]</i> <input type="radio"/> documented by imaging studies (US, CT, MR) <i>[2]</i> <input type="radio"/> based on clinical findings alone</p> <p>(bridgecdd:BLEED.NBNEED / Other bleed medical atten) <i>[1]</i> <input type="checkbox"/> need for medical attention (e.g., visit to emergency room or doctors office)</p> <p>(bridgecdd:BLEED.NBOTHER / Other bleed other) [1] <input type="checkbox"/> other bleed</p> <p style="text-align: right;">Specify: A100 (bridgecdd:BLEED.NBOTSPEC / Other bleed specify)</p>
.		
3.*	Trigger #:	A20 (bridgecdd:BLEED.BLTRIGNU / Bleed trigger number)
4.*	Trigger Status:	Pulldown List 2 (bridgecdd:BLEED.BLTRIGST / Bleed trigger status)
5.*	Review Type	(bridgecdd:BLEED.BLREVTY / Bleed review type) <i>[1]</i> <input type="radio"/> Committee <i>[2]</i> <input type="radio"/> QC <i>[3]</i> <input type="radio"/> Re-review <i>[4]</i> <input type="radio"/> Adjudication
6.*	CEC Status Date	Req / Req / Req (2009-2015) (bridgecdd:BLEED.BLSTATDT / Bleed status date)
7.*	1st Reviewer Code	Pulldown List 3 (bridgecdd:BLEED.BLREV1CO / Bleed reviewer 1 code) Date returned Req / Req / Req (2009-2015) (bridgecdd:BLEED.BLREV1DT / Bleed reviewer 1 date)
8.*	2nd Reviewer Code	Pulldown List 4 (bridgecdd:BLEED.BLREV2CO / Bleed reviewer 2 code) Date returned Req / Req / Req (2009-2015) (bridgecdd:BLEED.BLREV2DT / Bleed reviewer 2 date)
9.*	Committee	(bridgecdd:BLEED.BLCOMM / Bleed to Committee) <i>[1]</i> <input type="radio"/> Yes <i>[0]</i> <input type="radio"/> No Date Returned NReq / NReq / NReq (2009-2015) (bridgecdd:BLEED.BLCOMMDT / Bleed committee date)
10.*	QC	(bridgecdd:BLEED.BLROKEQC / Bleed QC) <i>[1]</i> <input type="radio"/> Yes <i>[0]</i> <input type="radio"/> No Date Returned NReq / NReq / NReq (2009-2015) (bridgecdd:BLEED.BLQCDT / Bleed QC date)
CEC Bleed		
	Did the patient experience major bleeding?	(bridgecdd:BLEED.CECBLEED / CEC Bleed)

11.*		<p>[0] <input type="radio"/> No [1] <input type="radio"/> Yes</p> <p>Datetime Req <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (2008-2015) (bridgecdd:BLEED.CECBLDTM / CEC Bleed date time) Req <input type="text"/> : Req <input type="text"/> 24-hour clock (bridgecdd:BLEED.CECBL01 / CEC bleed location site) Specify location of major bleeding: (check all that apply) [1] <input type="checkbox"/> surgery or procedure site (bridgecdd:BLEED.CECBL02 / CEC bleed location resp) [1] <input type="checkbox"/> respiratory tract (bridgecdd:BLEED.CECBL03 / CEC bleed location up gas) [1] <input type="checkbox"/> upper gastrointestinal tract (bridgecdd:BLEED.CECBL04 / CEC bleed location low gas) [1] <input type="checkbox"/> lower gastrointestinal tract (bridgecdd:BLEED.CECBL05 / CEC bleed location urinary) [1] <input type="checkbox"/> urinary tract (bridgecdd:BLEED.CECBL06 / CEC bleed location genital) [1] <input type="checkbox"/> genital tract (bridgecdd:BLEED.CECBL07 / CEC bleed location inspi) [1] <input type="checkbox"/> intraspinal bleed (bridgecdd:BLEED.CECBL08 / CEC bleed location inoc) [1] <input type="checkbox"/> intraocular bleed (bridgecdd:BLEED.CECBL09 / CEC bleed location retro) [1] <input type="checkbox"/> retroperitoneal bleed (bridgecdd:BLEED.CECBL10 / CEC bleed location intra) [1] <input type="checkbox"/> intra-articular bleed (bridgecdd:BLEED.CECBL11 / CEC bleed location peri) [1] <input type="checkbox"/> pericardial bleed (bridgecdd:BLEED.CECBL12 / CEC bleed location inmusc) [1] <input type="checkbox"/> intramuscular bleed with compartment syndrome (bridgecdd:BLEED.CECBL13 / CEC bleed location incran) [1] <input type="checkbox"/> (bridgecdd:BLEED.CECHBLOC / CEC head bleed location) intracranial bleed [1] <input type="radio"/> subdural or epidural [2] <input type="radio"/> intracerebral [3] <input type="radio"/> subarachnoid [4] <input type="radio"/> Intraventricular</p>
12.*	SDV Status	(bridgecdd:BLEED.SDVBLEED / SDV Bleed) [1] <input type="radio"/> Not Applicable [2] <input type="radio"/> 100 % Full Review

* Item is not required

Pulldown List 1:

RefName	Display Text	Value	Design Note
ieCECRE03	3	3	
ieCECRE04	4	4	
ieCECRE05	5	5	
ieCECRE06	6	6	
ieCECRE07	7	7	
ieCECRE08	8	8	
ieCECRE09	9	9	

Pulldown List 2:

RefName	Display Text	Value	Design Note
ieTRGSTAT1	NEW	1	
ieTRGSTAT2	OUTSTANDING SOURCE DOCS	2	
ieTRGSTAT3	COMPLETE	3	
ieTRGSTAT4	PHASE 1	4	
ieTRGSTAT5	COMMITTEE	5	
ieTRGSTAT6	QC	6	

ieTRGSTAT7	NO ACTION NEEDED	7	
ieTRGSTAT8	HOLD	8	
ieTRGSTAT9	RE-REVIEW	9	

Pulldown List 3:			
RefName	Display Text	Value	Design Note
ieCECRE01	1	1	
ieCECRE02	2	2	
ieCECRE03	3	3	
ieCECRE04	4	4	
ieCECRE05	5	5	
ieCECRE06	6	6	
ieCECRE07	7	7	
ieCECRE08	8	8	
ieCECRE09	9	9	
ieCECRE10	10	10	
ieCECRE11	11	11	
ieCECRE12	12	12	
ieCECRE13	13	13	
ieCECRE14	14	14	
ieCECRE15	15	15	
ieCECRE16	16	16	
ieCECRE17	17	17	
ieCECRE18	18	18	
ieCECRE19	19	19	
ieCECRE20	20	20	

Pulldown List 4:			
RefName	Display Text	Value	Design Note
ieCECRE01	1	1	
ieCECRE02	2	2	
ieCECRE03	3	3	
ieCECRE04	4	4	
ieCECRE05	5	5	
ieCECRE06	6	6	
ieCECRE07	7	7	
ieCECRE08	8	8	
ieCECRE09	9	9	
ieCECRE10	10	10	
ieCECRE11	11	11	
ieCECRE12	12	12	
ieCECRE13	13	13	
ieCECRE14	14	14	
ieCECRE15	15	15	
ieCECRE16	16	16	
ieCECRE17	17	17	
ieCECRE18	18	18	
ieCECRE19	19	19	
ieCECRE20	20	20	

CDD: bridgecd	Table: BLEED	Key Type: PATIENTVISIT
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Column Name	Column Data Type	Design Note
BLEINIT	NUMERIC	
BLEEDSYM	NUMERIC	
BLEEDENC	STRING(255) - 3, 4, 5, 6, 7, 8, 9	
NOBLEDT	DATE - DDMONYYYY	
NBGINGIV	NUMERIC	
NBSITEBR	NUMERIC	
NBHEMA	NUMERIC	
NBHEMA5	NUMERIC	
NBGING5	NUMERIC	
NBEPISTA	NUMERIC	
NBEPIS5	NUMERIC	
NBHEMO	NUMERIC	
NBHEMO1	NUMERIC	
NBMUSC	NUMERIC	
NBTUR5	NUMERIC	
NBTURIA	NUMERIC	
NBROID5	NUMERIC	
NBUPGAS	NUMERIC	
NBROID	NUMERIC	
BSYMDECR	NUMERIC	
BSYMTRAN	NUMERIC	
BLEEDDTM	DATE - DDMONYYYY HHMM	
BSYMRETR	NUMERIC	
BSYSINLO	NUMERIC	
BSYMLOCA	NUMERIC	
BSYMREOP	NUMERIC	
BSYMOCUL	NUMERIC	
BSYMARTI	NUMERIC	
BSYMPERI	NUMERIC	
BSYMINTR	NUMERIC	
NOBLEED	NUMERIC	
BSYMMUSC	NUMERIC	
BLTRIGST	STRING(255) - 1, 2, 3, 4, 5, 6, 7, 8, 9	
BLTRIGNU	STRING(20) - A20	
NBOTSPEC	STRING(100) - A100	
NBMUSDO	NUMERIC	
NBNEED	NUMERIC	
NBOTHER	NUMERIC	
BLSTATDT	DATE - DDMONYYYY	
BSYMSPIN	NUMERIC	
BLREV2DT	DATE - DDMONYYYY	
BLREV2CO	STRING(255) - 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20	
BLREV1DT	DATE - DDMONYYYY	
BLCOMM	NUMERIC	
BLCOMMDT	DATE - DDMONYYYY	
BLROKEQC	NUMERIC	
BLQCDT	DATE - DDMONYYYY	
CECBLEED	NUMERIC	
CECBLDTM	DATE - DDMONYYYY HHMM	
BLREVTY	NUMERIC	
BLREV1CO		

	STRING(255) - 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20	
CECBL12	NUMERIC	
CECBL13	NUMERIC	
CECHBLOC	NUMERIC	
CECBL04	NUMERIC	
CECBL08	NUMERIC	
CECBL11	NUMERIC	
SDVBLEED	NUMERIC	
CECBL06	NUMERIC	
CECBL07	NUMERIC	
CECBL09	NUMERIC	
CECBL10	NUMERIC	
CECBL03	NUMERIC	
CECBL02	NUMERIC	
CECBL01	NUMERIC	
CECBL05	NUMERIC	

bridge : STUDY COMPLETION (STUDYCOM)		
Study Completion/Early Withdrawal		
1.	Has the patient completed the study through Encounter 9?	(bridgecdd:STUDYCOM.SCENCOUN / Encounter thru 9 comp) [1] <input type="radio"/> Date of Completion Req <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (2009-2015) (bridgecdd:STUDYCOM.SCCOMPDT / Study Completion Date) [0] <input type="radio"/> (bridgecdd:STUDYCOM.SCWITHST / Subject withdrawal reason) No If no, [1] <input type="radio"/> Subject Withdrew consent Date consent withdrawn Req <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (2009-2015) (bridgecdd:STUDYCOM.SCWITHDT / Date consent withdrawn) [2] <input type="radio"/> Subject lost to Follow-up Date of Last Contact Req <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (2009-2015) (bridgecdd:STUDYCOM.SCLASTDT / Date of last contact) [3] <input type="radio"/> Subject died (Complete SAE eCRF) [4] <input type="radio"/> PI decision [5] <input type="radio"/> Other-Specify A25 (bridgecdd:STUDYCOM.SCOTSPEC / Did not complete other spec)
2.	Has all the study medication been collected?	(bridgecdd:STUDYCOM.SCMEDCOL / Study medication collected) [1] <input type="radio"/> Yes [0] <input type="radio"/> No If no, A50 (bridgecdd:STUDYCOM.NOMEDSPEC / Reason stu med not collect)
3.	Patient Status Study Information Obtained From	(bridgecdd:STUDYCOM.STINFOBT / Study Info Obtained From) [1] <input type="radio"/> Patient [2] <input type="radio"/> Relative [3] <input type="radio"/> Local Newspaper [4] <input type="radio"/> Death Index [5] <input type="radio"/> Other
4.*	SDV Status	(bridgecdd:STUDYCOM.SDVSTUCO / SDV Study Completion) [1] <input type="radio"/> Not Applicable [2] <input type="radio"/> 100 % Full Review
* Item is not required		

Column Name	Column Data Type	Design Note
SCMEDCOL	NUMERIC	
SCWITHST	NUMERIC	
SCWITHDT	DATE - DDMONYYYY	
SCLASTDT	DATE - DDMONYYYY	
SCOTSPEC	STRING(25) - A25	
NOMEDSPEC	STRING(50) - A50	
SDVSTUCO	NUMERIC	
SCENCOUN	NUMERIC	
SCCOMPDT	DATE - DDMONYYYY	
STINFOBT	NUMERIC	

bridge : WARMAR Log (WARMAR) - Repeating Form					
#	Date	Study Drug	Warfarin	Vitamin K	
1	<input type="text"/>				
-					
1.	Date	Req <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (2008-2015) (bridgecdd:WARMAR.WARMARDT / WARMARDate)			
2.	Study Drug	(bridgecdd:WARMAR.STDRG / WARMAR Study Drug) [2] <input type="radio"/> Not Taken [3] <input type="radio"/> Unknown [1] <input type="radio"/> Yes (check all that apply) (bridgecdd:WARMAR.STDRGAM / Vitamin K AM) [1] <input type="checkbox"/> Morning (bridgecdd:WARMAR.STDRGPM / Vitamin K PM) [1] <input type="checkbox"/> Evening			
3.	Warfarin	(bridgecdd:WARMAR.WARST / Warfarin) [1] <input type="radio"/> Yes [2] <input type="radio"/> Not Taken [3] <input type="radio"/> Unknown			
4.	Vitamin K	(bridgecdd:WARMAR.VITKSTAT / Vitamin K) [2] <input type="radio"/> Not Taken [1] <input type="radio"/> Taken Time Req <input type="text"/> : Req <input type="text"/> 24-hour clock (bridgecdd:WARMAR.VITKTM / Vitamin K Time) Amount <input type="text" value="A50"/> (bridgecdd:WARMAR.VITKAMT / Vitamin K Amount) Route (bridgecdd:WARMAR.VITKRTE / Vitamin K Route) [1] <input type="radio"/> Oral MG [2] <input type="radio"/> SC or IV mg			

Column Name	Column Data Type	Design Note
STDRG	NUMERIC	
WARMARDT	DATE - DDMONYYYY	
STDRGAM	NUMERIC	
STDRGPM	NUMERIC	
WARST	NUMERIC	
VITKSTAT	NUMERIC	
VITKTM	DATE - HHMM	
VITKAMT	STRING(50) - A50	
VITKRTE	NUMERIC	

CRB Electronic Signature Affidavit

By my dated signature below, I, [*First Name*] [*Last Name*], verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this patient.

Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that I intend that this electronic signature is to be the legally binding equivalent of my handwritten signature.

To this I do attest by supplying my user name and password and clicking the button marked **Submit** below.

CRF Electronic Signature Affidavit

By my dated signature below, I, [*First Name*] [*Last Name*], verify that this case report form accurately displays the results of the examinations, tests, evaluations and treatments noted within.

Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that I intend that this electronic signature is to be the legally binding equivalent of my handwritten signature.

To this I do attest by supplying my user name and password and clicking the button marked **Submit** below.