Data Set Name: adacex.sas7bdat

Num	Variable	Type	Len	Format	Informat	Label
1	TRTINI	Char	20			Subject Initial Randomization (short term)
2	TRTW6	Char	20			Subject Randomization after six weeks visit (short term)
3	ACT_DURATION	Num	8	8.1		Total (Actual) Duration of Therapy (weeks)
4	TRTW6N	Num	8			Subject Randomization after six weeks visit (Numeric)
5	TRTP	Char	172			Subject Randomization after six weeks visit (long term)
6	ITT	Num	8			Intent-to-Treat Population
7	PP_FLG	Num	8			Per Protocol
8	DAYS	Num	8			Days between radiologic diagnosis and first dose
9	ACUTE	Num	8			Is days less than or equal to 7 days, 1=Yes 2=No
10	EACTXIP	Num	8	1.	1.	Anticoagulant Treatment(Numeric)
11	EACTXIPC	Char	51			Anticoagulant Treatment(Text)
12	EACTXIPOTHER	Char	127	$127.	$127.	Other Anticoagulant Treatment
13	EXTYPE	Num	8	1.	1.	Anticoagulant administered as
14	TARGETDATVAL	Num	8	3.	3.	Target monitoring value(Numeric)
15	TARGETDATVALC	Char	65			Target monitoring value(Text)
16	TARGETVALUE	Num	8	BEST4.	4.	Target monitoring level
17	LMWHEXDOS	Num	8	BEST6.	6.	Anticoagulant drug dose
18	ANTICOAGFREQ	Char	10	$10.	$10.	Anticoagulant frequency
19	ANTICOAGMISSEDDOS	Num	8	3.	3.	Number of missed doses of anticoagulant therapy during the trt period
20	DOAC	Num	8			Direct Oral Anticoagulant
21	RADIMG_DAYS	Num	8			Date of radiologic diagnosis (recode: number of days after consent)
22	EXST_DAYS	Num	8			Date of Anticoagulant drug Started (recode: number of days after consent)
23	EXEN_DAYS	Num	8			Date of anticoagulant drug discontinued (recode: number of days after consent)
24	TARGET_DAYS	Num	8			Date target monitoring level reached (recode: number of days after consent)
25	ANONID	Num	8			Anonymized version of original studyid SUBJECT

Data Set Name: adae.sas7bdat

Num	Variable	Type	Len	Format	Informat	Label
1	TRTINI	Char	20			Subject Initial Randomization (short term)
2	TRTW6	Char	20			Subject Randomization after six weeks visit (short term)
3	TRTW6N	Num	8			Subject Randomization after six weeks visit (Numeric)
4	TRTP	Char	172			Subject Randomization after six weeks visit (long term)
5	ITT	Num	8			Intent-to-Treat Population
6	AESPID	Num	8	2.	2.	Sponsor-Defined Identifier
7	AETERM_SOC_NAME	Char	67	$67.	$67.	Primary System Organ Class
8	AETERM_PT_NAME	Char	51	$51.	$51.	Preffered Term
9	AETERM	Char	136	$136.	$136.	Reported Term for the Adverse Event
10	AERECUR	Num	8	1.	1.	Recurrent Thrombosis Event
11	AEACN	Num	8	3.	3.	Action Taken with Study Treatmen
12	ALTEXNAME	Char	7	$7.	$7.	Changed Anticoagulant Name
13	AEREL	Num	8	3.	3.	Causality
14	AESEV	Num	8	3.	3.	Severity/Intensity
15	AESER	Num	8	3.	3.	Serious Event
16	AEOUT	Num	8	3.	3.	Outcome of Adverse Event
17	AECRNMBLEEDYN	Num	8	3.	3.	Event Related to Major or CRNM bleed
18	AEINFECTIONYN	Num	8	3.	3.	Was the event an infection
19	AETREATMENT	Num	8	3.	3.	Treatment required
20	SAEDTHCAUSE	Char	153	$153.	$153.	Cause of death
21	SAEDTHCERT	Num	8	1.	1.	Death Certificate Obtained
22	SAEAUTOPSYN	Num	8	1.	1.	Autopsy Performed
23	SAESERCRIT	Char	7	$7.	$7.	Serious Criteria
24	SAESERCRITDESC	Char	233	$233.	$233.	Important Medical Event Description
25	DEATH_DAYS	Num	8			Study Reference Death Day
26	ANL01FL	Char	1			Analysis Flag 01
27	ANL02FL	Char	1			Analysis Flag 02
28	ANL05FL	Char	1			Analysis Flag 05
29	ANL06FL	Char	1			Analysis Flag 06
30	ANL09FL	Char	1			Analysis Flag 09
31	ANL10FL	Char	1			Analysis Flag 10
32	AEENDAYS	Num	8			Analysis End Date (recode: number of days after consent)
33	AESTDAYS	Num	8			Analysis Start Date (recode: number of days after consent)
34	CUTOFFDAYS	Num	8			Data-cut date (recode: number of days after consent)
35	EXENDAYS	Num	8			Date of anticoagulant drug discontinued (recode: number of days after consent)
36	EXRSTDAYS	Num	8			Interrupted Event Date of Reintroduction (recode: number of days after consent)

Num	Variable	Type	Len	Format	Informat	Label
37	EXSTDAYS	Num	8			Date of Anticoagulant drug Started (recode: number of days after consent)
38	RADIMGDAYS	Num	8			Date of radiologic diagnosis (recode: number of days after consent)
39	SAEAEDAYSHDAYS	Num	8			Date of death (recode: number of days after consent)
40	SIXWKDAYS	Num	8			Date of Six Week Assessment (recode: number of days after consent)
41	SIXWKDAYS_IMP	Num	8			Six Weeks Imputed Date (recode: number of days after consent)
42	THRMONTHS_DAYS	Num	8			Three hundred days after randomization (recode: number of days after consent)
43	ANONID	Num	8			Anonymized version of original studyid SUBJECT

Data Set Name: adefceac_v2.sas7bdat

Num	Variable	Type	Len	Format	Informat	Label
1	TRTW6	Char	20			Subject Randomization after six weeks visit (short term)
2	TRTW6N	Num	8			Subject Randomization after six weeks visit (Numeric)
3	AGEGROUP2C	Char	7			Subject age group 2(text)
4	THROMTYPE	Num	8	1.	1.	Thrombosis type (Numeric)
5	THROMC	Char	50			Thrombosis type - text for reporting
6	ITT	Num	8			Intent-to-Treat Population
7	VTEYN	Num	8			Recurrent VTE level flag, 1=Yes, 2=No
8	BLDYN	Num	8			Bleeding event level flag, 1=Yes, 2=No
9	PTSDAY	Num	8			Days PTS assessments after VTE radiologic diagnosis
10	PTSYR1FL	Num	8			PTS by year 1 flag, 1=Yes
11	PTSYR2FL	Num	8			PTS by year 2 flag, 1=Yes
12	VTEFUDAY1	Num	8			Recurrent VTE follow-up days by year 1
13	VTEFUDAY2	Num	8			Recurrent VTE follow-up days by year 2
14	VTEFUMON1	Num	8			Recurrent VTE follow-up months by year 1
15	VTEFUMON2	Num	8			Recurrent VTE follow-up months by year 2
16	BLDFUDAY1	Num	8			Bleeding event follow-up days by year 1
17	BLDFUDAY2	Num	8			Bleeding event follow-up days by year 2
18	BLDFUMON1	Num	8			Bleeding event follow-up months by year 1
19	BLDFUMON2	Num	8			Bleeding event follow-up months by year 2
20	VTEPTSFUDAY1	Num	8			VTE or PTS event follow-up day by year 1
21	VTEPTSFUDAY2	Num	8			VTE or PTS event follow-up day by year 2
22	VTEPTSFUMON1	Num	8			VTE or PTS event follow-up Month by year 1
23	VTEPTSFUMON2	Num	8			VTE or PTS event follow-up Month by year 2
24	EPTSFLN	Num	8			Eligible for PTS assessment flag, 1=Yes
25	VYEAR1FL	Num	8			Recurrent VTE by year 1 event level flag, 1=Yes
26	VYEAR2FL	Num	8			Recurrent VTE by year 2 event level flag, 1=Yes
27	BYEAR1FL	Num	8			Bleeding by year 1 event level flag, 1=Yes
28	BYEAR2FL	Num	8			Bleeding by year 2 event level flag, 1=Yes
29	VTEPTSY1	Num	8			Recurrent VTE or PTS by year 1 event level flag, 1=Yes
30	VTEPTSY2	Num	8			Recurrent VTE or PTS by year 2 event level flag, 1=Yes
31	ITTSUBL	Num	8			ITT subject level flag, 1=Yes
32	EPTSFLNS	Num	8			Eligible for PTS assessment subject flag, 1=Yes, 2=No
33	VTEYNSL	Num	8			Recurrent VTE level subject flag, 1=Yes, 2=No
34	VYEAR1SL	Num	8			Recurrent VTE by year 1 subject flag, 1=Yes, 2=No
35	VYEAR2SL	Num	8			Recurrent VTE by year 2 subject flag, 1=Yes, 2=No
36	BLDYNSL	Num	8			Bleeding subject flag, 1=Yes, 2=No
37	BYEAR1SL	Num	8			Bleeding by year 1 subject flag, 1=Yes, 2=No

Num	Variable	Type	Len	Format	Informat	Label
38	BYEAR2SL	Num	8			Bleeding by year 2 subject flag, 1=Yes, 2=No
39	VTPTY1SL	Num	8			Recurrent VTE or PTS by year 1 subject flag, 1=Yes, 2=No
40	VTPTY2SL	Num	8			Recurrent VTE or PTS by year 2 subject flag, 1=Yes, 2=No
41	PP_FLG	Num	8			Per Protocol
42	SAF_FLG	Num	8			Safety Population
43	PTSFUDAY1	Num	8			PTS event follow-up day by year 1
44	PTSFUDAY2	Num	8			PTS event follow-up day by year 2
45	PTSFUMON1	Num	8			PTS event follow-up month by year 1
46	PTSFUMON2	Num	8			PTS event follow-up month by year 2
47	PTSYR1SL	Num	8			Recurrent PTS by year 1 subject flag, 1=Yes, 2=No
48	PTSYR2SL	Num	8			Recurrent PTS by year 2 subject flag, 1=Yes, 2=No
49	BANY1FL	Num	8			Any Bleeding by Year 1 event level flag, 1=Yes
50	BANY2FL	Num	8			Any Bleeding by Year 1 event level flag, 1=Yes
51	BANY1SL	Num	8			Subject level flag for any bleed by 1 year post diagnosis
52	BANY2SL	Num	8			Subject level flag for any bleed by 2 year post diagnosis
53	RADIMGDAYS	Num	8			Date of radiologic diagnosis (recode: number of days after consent)
54	VTEDAYS	Num	8			Date of recurrent VTE (recode: number of days after consent)
55	BLDSTDAYS	Num	8			Date of bleeding (recode: number of days after consent)
56	PTSDAYS	Num	8			Date of PTS (recode: number of days after consent)
57	VTEPTSCENDAYS1	Num	8			PTS censor date by year 1 (recode: number of days after consent)
58	VTEPTSCENDAYS2	Num	8			PTS censor date by year 2 (recode: number of days after consent)
59	DMDAYS	Num	8			Date of last visit (recode: number of days after consent)
60	DSETDAYS	Num	8			Date of withdrew (recode: number of days after consent)
61	YR1WIND_DAYS	Num	8			Date of year 1 window after VTE radiologic diagnosis (recode: number of days after consent)
62	YR2WIND_DAYS	Num	8			Date of year 2 window after VTE radiologic diagnosis (recode: number of days after consent)
63	VTECENDAYS1	Num	8			Recurrent VTE censor date by year 1 (recode: number of days after consent)
64	VTECENDAYS2	Num	8			Recurrent VTE censor date by year 2 (recode: number of days after consent)
65	BLDCENDAYS1	Num	8			Bleeding censor date by year 1 (recode: number of days after consent)
66	BLDCENDAYS2	Num	8			Bleeding censor date by year 2 (recode: number of days after consent)
67	DEATHDAYS	Num	8			Date of Death (Adjudicated or Disposition or SAE) (recode: number of days after consent)
68	SIXWKDAYS	Num	8			Date of Six Week Assessment (recode: number of days after consent)
69	PTSCENDAYS1	Num	8			PTS censor date by year 1 (recode: number of days after consent)
70	PTSCENDAYS2	Num	8			PTS censor date by year 2 (recode: number of days after consent)
71	ANONID	Num	8			Anonymized version of original studyid SUBJECT

Data Set Name: adefceac_v3.sas7bdat

Num	Variable	Type	Len	Format	Informat	Label
1	TRTW6	Char	20			Subject Randomization after six weeks visit (short term)
2	TRTW6N	Num	8			Subject Randomization after six weeks visit (Numeric)
3	AGEGROUP2C	Char	7			Subject age group 2(text)
4	THROMTYPE	Num	8	1.	1.	Thrombosis type (Numeric)
5	THROMC	Char	50			Thrombosis type - text for reporting
6	ITT	Num	8			Intent-to-Treat Population
7	VTEYN	Num	8			Recurrent VTE level flag, 1=Yes, 2=No
8	BLDYN	Num	8			Bleeding event level flag, 1=Yes, 2=No
9	VTEFUDAY1	Num	8			Recurrent VTE follow-up days by year 1
10	VTEFUDAY2	Num	8			Recurrent VTE follow-up days by year 2
11	VTEFUMON1	Num	8			Recurrent VTE follow-up months by year 1
12	VTEFUMON2	Num	8			Recurrent VTE follow-up months by year 2
13	BLDFUDAY1	Num	8			Bleeding event follow-up days by year 1
14	BLDFUDAY2	Num	8			Bleeding event follow-up days by year 2
15	BLDFUMON1	Num	8			Bleeding event follow-up months by year 1
16	BLDFUMON2	Num	8			Bleeding event follow-up months by year 2
17	VYEAR1FL	Num	8			Recurrent VTE by year 1 event level flag, 1=Yes
18	VYEAR2FL	Num	8			Recurrent VTE by year 2 event level flag, 1=Yes
19	BYEAR1FL	Num	8			Bleeding by year 1 event level flag, 1=Yes
20	BYEAR2FL	Num	8			Bleeding by year 2 event level flag, 1=Yes
21	ITTSUBL	Num	8			ITT subject level flag, 1=Yes
22	VTEYNSL	Num	8			Recurrent VTE level subject flag, 1=Yes, 2=No
23	VYEAR1SL	Num	8			Recurrent VTE by year 1 subject flag, 1=Yes, 2=No
24	VYEAR2SL	Num	8			Recurrent VTE by year 2 subject flag, 1=Yes, 2=No
25	BLDYNSL	Num	8			Bleeding subject flag, 1=Yes, 2=No
26	BYEAR1SL	Num	8			Bleeding by year 1 subject flag, 1=Yes, 2=No
27	BYEAR2SL	Num	8			Bleeding by year 2 subject flag, 1=Yes, 2=No
28	PP_FLG	Num	8			Per Protocol
29	SAF_FLG	Num	8			Safety Population
30	BANY1FL	Num	8			Any Bleeding by Year 1 event level flag, 1=Yes
31	BANY2FL	Num	8			Any Bleeding by Year 1 event level flag, 1=Yes
32	BANY1SL	Num	8			Subject level flag for any bleed by 1 year post diagnosis
33	BANY2SL	Num	8			Subject level flag for any bleed by 2 year post diagnosis
34	RADIMGDAYS	Num	8			Date of radiologic diagnosis (recode: number of days after consent)
35	VTEDAYS	Num	8			Date of recurrent VTE (recode: number of days after consent)
36	BLDSTDAYS	Num	8			Date of bleeding (recode: number of days after consent)
37	DMDAYS	Num	8			Date of last visit (recode: number of days after consent)

Num	Variable	Type	Len	Format	Informat	Label
38	DSETDAYS	Num	8			Date of withdrew (recode: number of days after consent)
39	YR1WIND_DAYS	Num	8			Date of year 1 window after VTE radiologic diagnosis (recode: number of days after consent)
40	YR2WIND_DAYS	Num	8			Date of year 2 window after VTE radiologic diagnosis (recode: number of days after consent)
41	VTECENDAYS1	Num	8			Recurrent VTE censor date by year 1 (recode: number of days after consent)
42	VTECENDAYS2	Num	8			Recurrent VTE censor date by year 2 (recode: number of days after consent)
43	BLDCENDAYS1	Num	8			Bleeding censor date by year 1 (recode: number of days after consent)
44	BLDCENDAYS2	Num	8			Bleeding censor date by year 2 (recode: number of days after consent)
45	DEATHDAYS	Num	8			Date of Death (Adjudicated or Disposition or SAE) (recode: number of days after consent)
46	SIXWKDAYS	Num	8			Date of Six Week Assessment (recode: number of days after consent)
47	ANONID	Num	8			Anonymized version of original studyid SUBJECT

Data Set Name: adsl.sas7bdat

Num	Variable	Type	Len	Format	Informat	Label
1	WORKGROUPNAME	Char	8	$8.	$8.	Work Group Name
2	INCEXCYN	Num	8	1.	1.	Incl/Excl criteria met:1=Yes 2=No
3	RANDPREV	Num	8	1.	1.	Has the patient previously been randomized? 1=Yes 2=No
4	RANDPREVYES	Char	49	$49.	$49.	If Yes, select initial randomization assignment
5	EXTREATMENT	Char	49	$49.	$49.	Randomization Assignment
6	RANDAGEGROUP	Num	8	3.	3.	Select the subject’s age group
7	RANDCLOTTYPE	Num	8	3.	3.	Select the subject’s Thrombus type
8	EXTXDISPLAY	Char	49	$49.	$49.	This subject’s initial randomization assignment
9	EXTREATMENT2	Num	8	1.	1.	Parallel cohort assignment after Visit 6
10	TRTINI	Char	20			Subject Initial Randomization (short term)
11	TRTW6	Char	20			Subject Randomization after six weeks visit (short term)
12	TRTW6N	Num	8			Subject Randomization after six weeks visit (Numeric)
13	TRTP	Char	172			Subject Randomization after six weeks visit (long term)
14	AGEGROUP2	Num	8			Subject age group 2(numeric)
15	AGEGROUP2C	Char	7			Subject age group 2(text)
16	SEX	Num	8	1.	1.	Gender 1=Male 2=Female
17	WEIGHT	Num	8	BEST15.	15.	Weight(kg)
18	HEIGHT	Num	8	BEST6.	6.	Height(cm)
19	BMI	Num	8			BMI(kg/m2)
20	MHFAMBLEED	Num	8	3.	3.	Does the patient have a family history of bleeding disorder?
21	MHPATBLEED	Num	8	3.	3.	Does the patient have a personal history of abnormal bleeding?
22	THROMTYPE	Num	8	1.	1.	Thrombosis type (Numeric)
23	THROMTYPEC	Char	30			Thrombosis type (text)
24	THROMC	Char	50			Thrombosis type - text for reporting
25	THROMSITE	Num	8	2.	2.	Thrombosis site (Numeric)
26	THROMSITEC	Char	59			Thrombosis site (text)
27	THROMSIDE	Num	8	1.	1.	Affected side (Numeric)
28	THROMSIDEC	Char	5			Affected side (text)
29	THROMOCLD	Num	8	1.	1.	Complete occlusion of an entire venous segment 1=Yes 2=No 3=Unknown
30	THROMINVOLVE	Num	8	1.	1.	Does thrombus currently involve any one of the following venous segments 1=Yes 2=No
31	ITT	Num	8			Intent-to-Treat Population
32	VTETOICDT	Num	8			Days from qualifying VTE to Informed Consent
33	PP_FLG	Num	8			Per Protocol
34	COMPLIANCE	Num	8	8.4		Percent Compliance
35	FLG_6MO	Num	8			Completed 6 month visit by phone or in person
36	CRITERIA_FLAG	Num	8			Eligibility criteria violations

Num	Variable	Type	Len	Format	Informat	Label
37	ACT_DURATION	Num	8	8.1		Total (Actual) Duration of Therapy (weeks)
38	SAF_FLG	Num	8			Safety Population
39	AGE_GROUP	Num	8			Age (Age Floored/Tenth Floored)
40	RACECRF_GROUP	Char	50			Race - text for reporting (grouped)
41	ETHNICCRF_GROUP	Char	50			Ethnicity - text for reporting (grouped)
42	SCREENDAYS	Num	8			Date of screening (recode: number of days after consent)
43	SIXWKDAYS	Num	8			Date of Six Week Assessment (recode: number of days after consent)
44	SXONDAYS	Num	8			SXONDAT (recode: number of days after consent)
45	RADIMGDAYS	Num	8			Date of radiologic diagnosis (recode: number of days after consent)
46	DEATHDAYS	Num	8			Date of Death (Adjudicated or Disposition or SAE) (recode: number of days after consent)
47	DTHDAYS	Num	8			Date of Death (Adjudicated) (recode: number of days after consent)
48	DSDTHDAYS	Num	8			Date of Death (Disposition) (recode: number of days after consent)
49	SAEAEDTHDAYS	Num	8			Date of Death (SAE) (recode: number of days after consent)
50	DSETDAYS	Num	8			Date of Withdrawal (recode: number of days after consent)
51	ANONID	Num	8			Anonymized version of original studyid SUBJECT

Data Set Name: allvisits.sas7bdat

Num	Variable	Type	Len	Format	Informat	Label
1	TRTINI	Char	20			Subject Initial Randomization (short term)
2	TRTW6	Char	20			Subject Randomization after six weeks visit (short term)
3	TRTW6N	Num	8			Subject Randomization after six weeks visit (Numeric)
4	TRTP	Char	172			Subject Randomization after six weeks visit (long term)
5	AGEGROUP2	Num	8			Subject age group 2(numeric)
6	AGEGROUP2C	Char	7			Subject age group 2(text)
7	THROMC	Char	50			Thrombosis type - text for reporting
8	THROMSIDE	Num	8	1.	1.	Affected side (Numeric)
9	ITT	Num	8			Intent-to-Treat Population
10	VISITNAME	Char	27	$27.	$27.	Visit Name
11	VISITCOMPLETEYN	Num	8	3.	3.	Was this visit completed? 1=Yes 2=No
12	RECURTHROM	Num	8	1.	1.	Has the patient had a recurrent thromboembolism?
13	MAJORBLEEDYN	Num	8	1.	1.	Patient experience either a major or a clinically relevant non-major (CRNM) bleed?
14	PTSPEORRES	Char	13	$13.	$13.	Physical exam findings
15	PTSPAINREST	Num	8	3.	3.	Rating of the pain experienced on the affected limb when at rest
16	PTSPAINADL	Num	8	3.	3.	Rating for pain on the affected limb when performing age appropriate Activities of Daily Living(ADL)
17	PTSPAINAEROBIC	Num	8	3.	3.	Rating for pain experienced on the affected limb with age-appropriate aerobic exercise
18	PTCPAINWONGYN	Num	8	3.	3.	Does the patient have pain in the limb where the clot was diagnosed?
19	BYPHONE	Num	8			Conducted by phone = 1
20	V_SEQ	Num	8			Visit Sequence Number
21	ELIGIBLE	Num	8			Eligible for analysis? 1=Yes, 0=No, 99=died before elig
22	ELDAYS	Num	8			Days between first image date and [DSMB closed (Days) or date of death]
23	INWINDOW	Num	8			In window for visit = 1
24	PTSFL	Num	8			PTS flag, yes=1
25	PTSCSFL	Num	8			Clinical Significant of PTS flag, yes=1
26	DEATHDAYS	Num	8			Date of Death (Adjudicated or Disposition or SAE) (recode: number of days after consent)
27	DSMB_CLOSE_DAYS	Num	8			DSMB Close Date (recode: number of days after consent)
28	DSETDAYS	Num	8			Date of Withdrawal (recode: number of days after consent)
29	RADIMGDAYS	Num	8			Date of Radiological Diagnosis (recode: number of days after consent)
30	DMDAYS	Num	8			Date of Visit for Visits>=6 months (recode: number of days after consent)
31	ANONID	Num	8			Anonymized version of original studyid SUBJECT

Data Set Name: bleinvest.sas7bdat

Num	Variable	Type	Len	Format	Informat	Label
1	TRTW6N	Num	8			Subject Randomization after six weeks visit (Numeric)
2	BLEFL	Num	8	1.	1.	Bleed, yes=1
3	BLE_DAYS	Num	8			Days to Bleed
4	BLECR	Num	8	1.	1.	Bleed Clinically Relevant
5	BLEMAJYN	Num	8	1.	1.	Bleed Major/Non
6	BYYR1	Num	8			Bleed by Year 1
7	BYYR2	Num	8			Bleed by Year 2
8	WITHIN2Y	Num	8			Bleed by 2year adj window
9	RADIMGDAYS	Num	8			Date of Radiological Diagnosis (recode: number of days after consent)
10	BLESTDAYS	Num	8			Start Date or Bleed (recode: number of days after consent)
11	BLEENDAYS	Num	8			End Date or Bleed (recode: number of days after consent)
12	ANONID	Num	8			Anonymized version of original studyid SUBJECT

Data Set Name: hc_bld.sas7bdat

Num	Variable	Type	Len	Format	Informat	Label
1	BLDREL	Num	8			What was the relationship to the anticoagulant?
2	BLDCR	Num	8			Was the bleed event clinically-relevant?
3	BLDYN	Num	8			Does the event meet criteria as an anticoagulant associated, clinically-relevant bleeding event?
4	BLDMAJYN	Num	8			If yes, was the bleeding event major or non-major?
5	BLDFATAL	Num	8			Was the bleeding event fatal?
6	BLDSTDAYS	Num	8			Bleed start date (dd/MMM/yyyy): (recode: number of days after consent)
7	BLDENDAYS	Num	8			Bleed end date (dd/MMM/yyyy): (recode: number of days after consent)
8	ANONID	Num	8			Anonymized version of original studyid SUBJECT

Data Set Name: vteinvest.sas7bdat

Num	Variable	Type	Len	Format	Informat	Label
1	TRTW6N	Num	8			Subject Randomization after six weeks visit (Numeric)
2	VTEFL	Num	8			Recurrent VTE, yes=1
3	VTERECURR_DAYS	Num	8			Days to Recurrent VTE
4	VTERECURR_TYPE	Num	8	3.	3.	Recurrent VTE Catheter Related
5	VTERECURR_SITE	Num	8	3.	3.	Recurrent VTE Site
6	VTERECURR_OCLD	Num	8	3.	3.	Recurrent VTE Occlusion
7	BYYR1	Num	8			Recurrent VTE by Year 1
8	BYYR2	Num	8			Recurrent VTE by Year 2
9	WITHIN6W_2Y	Num	8			Recurrent VTE within 6week-2year adj window
10	RADIMGDAYS	Num	8			Date of Radiological Diagnosis (recode: number of days after consent)
11	SIXWKDAYS	Num	8			Set SWDCW.DMDAT and SWDCW_NEW.DMDAT. Merge on RETHROM (where VTEFL=1) by subject (recode: number of days after consent)
12	ANONID	Num	8			Anonymized version of original studyid SUBJECT

Data Set Name: bld.sas7bdat

Num	Variable	Type	Len	Format	Informat	Label
1	BLDREL	Num	8	1.	1.	What was the relationship to the anticoagulant?
2	BLDCR	Num	8	1.	1.	Was the bleed event clinically-relevant?
3	BLDMAJYN	Num	8	1.	1.	If yes, was the bleeding event major or non-major?
4	BLDFATAL	Num	8	1.	1.	Was the bleeding event fatal?
5	BLDCOM	Char	226	$226.	$226.	Comments or Rationale:
6	BLDYN	Num	8	1.	1.	Does the event meet criteria as an anticoagulant associated, clinically-relevant bleeding event?
7	BLDSTDAYS	Num	8			Bleed start date (dd/MMM/yyyy): (recode: number of days after consent)
8	BLDENDAYS	Num	8			Bleed end date (dd/MMM/yyyy): (recode: number of days after consent)
9	ANONID	Num	8			Anonymized version of original studyid SUBJECT

Data Set Name: dth.sas7bdat

Num	Variable	Type	Len	Format	Informat	Label
1	DTHCAUS	Num	8	1.	1.	Cause of death:
2	DTHOTH	Char	33	$33.	$33.	If Other, specify:
3	DTHCOM	Char	111	$111.	$111.	Comments and Rationale (text field)
4	DTHDAYS	Num	8			Date of Death (dd/MMM/yyyy): (recode: number of days after consent)
5	ANONID	Num	8			Anonymized version of original studyid SUBJECT

Data Set Name: vte.sas7bdat

Num	Variable	Type	Len	Format	Informat	Label
1	VTESITE	Char	2	$2.	$2.	Thrombosis site (select all that apply):
2	VTESIDE	Num	8	1.	1.	Affected side (select one):
3	VTERAD	Num	8	1.	1.	Radiologic image type (select one):
4	VTERADOT	Char	21	$21.	$21.	If Other, please specify:
5	VTESYMP	Char	7	$7.	$7.	Associated signs/symptoms (select all that apply):
6	VTESYMPO	Char	86	$86.	$86.	If Other, please specify:
7	VTEYN	Num	8	1.	1.	Does the event meet criteria as a recurrent VTE?
8	VTESYMPY	Num	8	1.	1.	If yes, was the recurrent VTE symptomatic or asymptomatic?
9	VTEFATAL	Num	8	1.	1.	Was the VTE fatal?
10	VTECOM	Char	405	$405.	$405.	Comments or Rationale:
11	VTEDAYS	Num	8			Recurrent Venous Thromboembolism Date (recode: number of days after consent)
12	ANONID	Num	8			Anonymized version of original studyid SUBJECT

Data Set Name: acex.sas7bdat

Num	Variable	Type	Len	Format	Informat	Label
1	EACTXIP	Num	8	1.	1.	Anticoagulation Treatment (select 1):
2	EACTXIPOTHER	Char	127	$127.	$127.	If Other, please specify:
3	EXTYPE	Num	8	1.	1.	Was this anticoagulant administered at a therapeutic or prophylactic dose?
4	TARGETDATVAL	Num	8	3.	3.	Target monitoring value on date above
5	TARGETVALUE	Num	8	BEST4.	4.	Enter the target monitoring level (numeric value):
6	LMWHEXDOS	Num	8	BEST6.	6.	For all anticoagulant drugs except those administered by continuous infusion, please provide dose (in mg/kg of body weight for warfarin or enoxaparin or in U/kg of body weight for dalteparin) that achieved the target monitoring level:
7	ANTICOAGFREQ	Char	10	$10.	$10.	Anticoagulant frequency:
8	ANTICOAGMISSEDDOS	Num	8	3.	3.	Enter the number of missed doses of anticoagulant therapy during the treatment period.
9	EXSTDAYS	Num	8			This specific anticoagulant drug was started on (dd/MMM/yyyy): (recode: number of days after consent)
10	EXENDAYS	Num	8			This specific anticoagulant drug was discontinued (if applicable) on (dd/MMM/yyyy): (recode: number of days after consent)
11	TARGETDAYS	Num	8			Date target monitoring level reached: (dd/MMM/yyyy): (recode: number of days after consent)
12	ANONID	Num	8			Anonymized version of original studyid SUBJECT

Data Set Name: ae.sas7bdat

Num	Variable	Type	Len	Format	Informat	Label
1	AESPID	Num	8	2.	2.	Adverse Event Number:
2	AETERM	Char	136	$136.	$136.	Adverse Event term:
3	AETERM_STATUS	Char	8	$8.	$8.	Indicates AE term coding (using MEDDRA and Medical Safety Officer review) was completed
4	AETERM_APPROVED	Char	8	$8.	$8.	Indicates AE term has been reviewed and approved by Medical Safety Officer
5	AETERM_LLT	Char	8	$8.	$8.	Lowest level term Lowest Level Term (MEDDRA code)
6	AETERM_LLT_NAME	Char	44	$44.	$44.	Lowest Level Term (text)
7	AETERM_PT	Char	8	$8.	$8.	Preferred Term Preferred Term (MEDDRA code)
8	AETERM_PT_NAME	Char	51	$51.	$51.	Preferred Term (text)
9	AETERM_HLT	Char	8	$8.	$8.	High Level Term High Level Term (MEDDRA code)
10	AETERM_HLT_NAME	Char	65	$65.	$65.	High Level Term (text)
11	AETERM_HLGT	Char	8	$8.	$8.	High Level Group Term High Level Group Term (MEDDRA code)
12	AETERM_HLGT_NAME	Char	66	$66.	$66.	High Level Group Term (text)
13	AETERM_SOC	Char	8	$8.	$8.	System Organ Class System Organ Class (MEDDRA code)
14	AETERM_SOC_NAME	Char	67	$67.	$67.	System Organ Class (text)
15	AERECUR	Num	8	1.	1.	Is this event a recurrent thrombosis (if yes, remember to enter the event into the Recurrent Thrombosis Form)?
16	AEACN	Num	8	3.	3.	Action taken with anticoagulant:
17	ALTEXNAME	Char	7	$7.	$7.	"If permanently discontinued and changed to another anticoagulant, name of anticoagulant:"
18	AEREL	Num	8	3.	3.	Relationship to study anticoagulant:
19	AESEV	Num	8	3.	3.	Severity:
20	AESER	Num	8	3.	3.	Serious Event?
21	AEOUT	Num	8	3.	3.	Outcome:
22	AECRNMBLEEDYN	Num	8	3.	3.	Is this event related to a major bleed or to a clinicallyrelevant non-major (CRNM) bleed?
23	AESUPORRES	Num	8	3.	3.	Is this a supratherapeutic anticoagulant monitoring test value?
24	AEINFECTIONYN	Num	8	3.	3.	Was the event an infection?
25	AETREATMENT	Num	8	3.	3.	Treatment required?
26	EXRSTDAYS	Num	8			If temporarily interrupted, date of reintroduction: (recode: number of days after consent)
27	AESTDAYS	Num	8			AE start date (dd/MMM/yyyy): (recode: number of days after consent)
28	AEENDAYS	Num	8			AE stop date (dd/MMM/yyyy): (recode: number of days after consent)
29	ANONID	Num	8			Anonymized version of original studyid SUBJECT

Data Set Name: apex.sas7bdat

Num	Variable	Type	Len	Format	Informat	Label
1	APTERM	Num	8	1.	1.	Antiplatelet Treatment (select 1):
2	APDOS	Num	8	BEST5.	5.	Please provide dose (mg/kg):
3	APSTDAYS	Num	8			This specific antiplatelet drug was started on (dd/MMM/yyyy): (recode: number of days after consent)
4	APENDAYS	Num	8			This specific antiplatelet drug was discontinued (if applicable) on (dd/MMM/yyyy): (recode: number of days after consent)
5	ANONID	Num	8			Anonymized version of original studyid SUBJECT

Data Set Name: ble.sas7bdat

Num	Variable	Type	Len	Format	Informat	Label
1	BLECR	Num	8	1.	1.	Was the bleed event clinically-relevant?
2	BLEMAJYN	Num	8	1.	1.	Was the bleeding event major or non-major?
3	BLEEX	Num	8	1.	1.	Did the bleeding event occur while taking anticoagulant therapy?
4	BLEREL	Num	8	1.	1.	If yes, what was the relationship to the anticoagulant?
5	BLESTDAYS	Num	8			Bleed start date (dd/MMM/yyyy): (recode: number of days after consent)
6	BLEENDAYS	Num	8			Bleed end date (dd/MMM/yyyy): (recode: number of days after consent)
7	ANONID	Num	8			Anonymized version of original studyid SUBJECT

Data Set Name: ds.sas7bdat

Num	Variable	Type	Len	Format	Informat	Label
1	DSCOMPYN	Num	8	3.	3.	Did subject complete study?
2	DSCOMPYN_A	Num	8	3.	3.	Did subject complete study?
3	DSDECOD	Num	8	1.	1.	Reason for withdrawal:
4	DSDECOTH	Char	249	$249.	$249.	If other, please specify.
5	DSCOMPDAYS	Num	8			If completed, enter study completion date (dd/MMM/yyyy): (recode: number of days after consent)
6	DSETDAYS	Num	8			If not completed, enter withdrawal Date (dd/MMM/yyyy): (recode: number of days after consent)
7	DSDTHDAYS	Num	8			Date of death (dd/MMM/yyyy): (recode: number of days after consent)
8	ANONID	Num	8			Anonymized version of original studyid SUBJECT

Data Set Name: dv.sas7bdat

Num	Variable	Type	Len	Format	Informat	Label
1	DVDECOD	Num	8	1.	1.	Type of deviation:
2	DVSPEC	Char	433	$433.	$433.	If Other, please specify type of deviation:
3	VSINVOLVED	Num	8	3.	3.	Visit involved:
4	DVPREVYN	Num	8	1.	1.	Has this type of deviation occurred previously? (If yes, please describe below)
5	DVPREVY	Char	176	$176.	$176.	If Yes, please describe.
6	DEVIRBRT	Num	8	1.	1.	Is this deviation reportable to your IRB (based on your IRB guidelines)?
7	DVSTDAYS	Num	8			Date deviation discovered (dd/MMM/yyyy): (recode: number of days after consent)
8	ANONID	Num	8			Anonymized version of original studyid SUBJECT

Data Set Name: gcs.sas7bdat

Num	Variable	Type	Len	Format	Informat	Label
1	GCSYN	Num	8	1.	1.	Was the patient prescribed Graduated Compression Stockings?
2	GCSEX	Num	8	1.	1.	Extremity prescribed for:
3	GCSCS	Num	8	1.	1.	Compression strength of Graduated Compression Stockings:
4	GCSCSO	Char	67	$67.	$67.	If other, specify:
5	GCSFREQ	Num	8	1.	1.	Regimen Graduated Compression Stockings to be worn:
6	GCSFREQO	Char	37	$37.	$37.	If other, specify:
7	GCSSTDAYS	Num	8			Date Graduated Compression Stockings prescribed: (recode: number of days after consent)
8	GCSENDAYS	Num	8			Date Graduated Compression Stockings Discontinued: (recode: number of days after consent)
9	ANONID	Num	8			Anonymized version of original studyid SUBJECT

Data Set Name: idcw.sas7bdat

Num	Variable	Type	Len	Format	Informat	Label
1	SEX	Num	8	1.	1.	Gender:
2	WEIGHT	Num	8	BEST15.	15.	Weight (kg):
3	HEIGHT	Num	8	BEST6.	6.	Height (cm):
4	MHFAMBLEED	Num	8	3.	3.	Does the patient have a family history of bleeding disorder?
5	MHPATBLEED	Num	8	3.	3.	Does the patient have a personal history of abnormal bleeding?
6	THROMTYPE	Num	8	1.	1.	Thrombosis type:
7	THROMSITE	Num	8	2.	2.	Thrombosis site (select 1):
8	THROMSIDE	Num	8	1.	1.	Affected side (select 1):
9	THROMOCLD	Num	8	1.	1.	"Complete occlusion of an entire venous segment (e.g., entire femoral vein; if thrombus limited to right atrium, select "no)
10	THROMINVOLVE	Num	8	1.	1.	Does thrombus currently involve any one of the following venous segments: femoral; iliac; IVC; brachial; basilic half way or more above elbow; subclavian; brachiocephalic; innominate; axillary; SVC:
11	RADIMGTYPE	Num	8	1.	1.	Radiologic image type (select 1):
12	RADIMGTYPEOTH	Char	66	$66.	$66.	If Other, please specify:
13	LBATXRES	Num	8	1.	1.	Text result:
14	LBATRES	Num	8	BEST5.	5.	Numeric result (U/dL or %):
15	LBDTXRES	Num	8	1.	1.	Text result:
16	LBDNUMRES	Char	6	$6.	$6.	Numeric result (e.g. XX, X, or XX.X):
17	LBDNUMRESUNIT	Num	8	1.	1.	Units of measurement:
18	LBDNUMRESOTHER	Char	28	$28.	$28.	If Other, please specify:
19	LBFLTXRES	Num	8	1.	1.	Text result:
20	LBFVTXRES	Num	8	1.	1.	Text result:
21	LBFVNUMRES	Num	8	BEST6.	6.	Numeric result (U/dL or %):
22	LBHCYTXRES	Num	8	1.	1.	Text result:
23	LBHCYNUMRES	Num	8	BEST5.	5.	Numeric result (Î¼mol/L):
24	LBPCTXRES	Num	8	1.	1.	Text result:
25	LBPCNUMRES	Num	8	BEST5.	5.	Numeric result (U/dL or %):
26	LBPSTXRES	Num	8	1.	1.	Text result:
27	LBPSNUMRES	Num	8	BEST5.	5.	Numeric result (U/dL or %):
28	LBPTTXRES	Num	8	1.	1.	Text result:
29	LNACATXRES	Num	8	3.	3.	Text result:
30	LBACANUMRES	Char	54	$54.	$54.	Numeric result:
31	LBBGTXRES	Num	8	3.	3.	Text result:
32	LBBGNUMRES	Char	54	$54.	$54.	Numeric result:
33	LBIGMNUMRES	Char	54	$54.	$54.	Numeric result:
34	LBIGMTXRES	Num	8	3.	3.	Text result:
35	LBVTTXRES	Num	8	1.	1.	Text result for LA1 (screen):

Num	Variable	Type	Len	Format	Informat	Label
36	LBVTNUMRES	Num	8	BEST4.	4.	Numeric result for LA1/LA2 (screen/confirm) ratio:(not applicable if screen is Normal/negative)
37	LBVTRATIO	Num	8	3.	3.	Text result for LA1/LA2 (screen/confirm) ratio:(notapplicable if screen is Normal/negative)
38	LBHPTXRES	Num	8	1.	1.	Text result:
39	LBHPNUMRES	Num	8	BEST5.	5.	Numeric result:
40	LBSPTXRES	Num	8	1.	1.	Text result:
41	LBSPNUMRES	Num	8	BEST5.	5.	Numeric result:
42	RACECRF_GROUP	Char	50			Race - text for reporting (grouped)
43	ETHNICCRF_GROUP	Char	50			Ethnicity - text for reporting (grouped)
44	SXONDAYS	Num	8			SXONDAT (recode: number of days after consent)
45	RADIMGDAYS	Num	8			Date of radiologic diagnosis (dd/MMM/yyyy): (recode: number of days after consent)
46	LBATDAYS	Num	8			Date of antithrombin activity (dd/MMM/yyyy): (recode: number of days after consent)
47	LBDDAYS	Num	8			Date of D-Dimer (dd/MMM/yyyy): (recode: number of days after consent)
48	LBFLDAYS	Num	8			Date of Factor V Leiden (mutation) (dd/MMM/yyyy): (recode: number of days after consent)
49	LBFVDAYS	Num	8			Date of Factor VIII (dd/MMM/yyyy): (recode: number of days after consent)
50	LBHCYDAYS	Num	8			Date of Homocysteine (dd/MMM/yyyy): (recode: number of days after consent)
51	LBPCDAYS	Num	8			Date of Protein C activity (dd/MMM/yyyy): (recode: number of days after consent)
52	LBPSDAYS	Num	8			Date of Protein S (dd/MMM/yyyy): (recode: number of days after consent)
53	LBPTDAYS	Num	8			Date of Prothrombin G20210A (Prothrombin mutation) (dd/MMM/yyyy): (recode: number of days after consent)
54	LBACADAYS	Num	8			Date of Anti-cardiolipin (cardiolipin antibody) IgM (dd/MMM/yyyy): (recode: number of days after consent)
55	LBBGDAYS	Num	8			Date of Anti-Beta-2-Glycoprotein-I (Beta-2-Glycoprotein-I Antibody) IgG (dd/MMM/yyyy): (recode: number of days after consent)
56	LBIGMDAYS	Num	8			Date of Anti-Beta-2-Glycoprotein-I (Beta-2-Glycoprotein-I Antibody) IgM (dd/MMM/yyyy): (recode: number of days after consent)
57	LBVTDAYS	Num	8			Date of dRVVT (dd/MMM/yyyy): (recode: number of days after consent)
58	LBHPDAYS	Num	8			Date of aPTT-based, Hexagonal Phospholipid ('StaClotLA' or other) (dd/MMM/yyyy): (recode: number of days after consent)
59	LBSPDAYS	Num	8			Date of aPTT-based, Non-hexagonal Phospholipid ('HemosIL Silica Clotting Time' or other) (dd/MMM/yyyy): (recode: number of days after consent)
60	ANONID	Num	8			Anonymized version of original studyid SUBJECT

Data Set Name: ie.sas7bdat

Num	Variable	Type	Len	Format	Informat	Label
1	INC1A	Num	8	1.	1.	1a. Is the patient less than 21 years old?
2	INC1B	Num	8	1.	1.	1b. Was the patient enrolled within 30 days of radiologically confirmed acute venous thrombosis diagnosis?
3	INC2	Num	8	1.	1.	2. Was the venous thrombosis non-spontaneous (provoked)
4	INC2PF	Char	7	$7.	$7.	If yes, specify provoking factor (select all that apply):
5	INC2PFO	Char	23	$23.	$23.	If other, specify factor:
6	EXC1	Num	8	1.	1.	1. Does the patient have a prior episode of VTE?
7	EXC2	Num	8	1.	1.	2. Does the patient have presence of or a history of cancer?
8	EXC3	Num	8	1.	1.	3. Does the patient have systemic lupus erythematosus?
9	EXC4	Num	8	1.	1.	4. Does the patient have a known Pulmonary Embolism?
10	EXC5	Num	8	1.	1.	5. Has the treating Physician used or intends to use thrombolytic therapy?
11	EXC6	Num	8	1.	1.	6. Does the patient have congenital cardiac disease involving a single or hypoplastic ventricle or otherwise require an intracardiac shunt?
12	EXC7	Num	8	1.	1.	7. Does the patient have moderate/severe anticoagulant deficiency defined by one of the following?
13	EXC7A	Num	8	1.	1.	7a. Protein C < 20 IU/dL if patient is greater than or equal to 3 months of age or protein C below lower limit of detection if patient is less than 3 months of age?
14	EXC7B	Num	8	1.	1.	7b. Antithrombin < 30 IU/dL if patient is greater than or equal to 3 months of age, or Antithrombin below lower limit detection if patient is less than 3 months of age?
15	EXC7C	Num	8	1.	1.	7c. Protein S (free antigen or activity) less than 20 IU/dL: label
16	ANONID	Num	8			Anonymized version of original studyid SUBJECT

Data Set Name: ie_a.sas7bdat

Num	Variable	Type	Len	Format	Informat	Label
1	INC1A	Num	8	1.	1.	1a. Is the patient less than 21 years old?
2	INC1B	Num	8	1.	1.	1b. Was the patient enrolled within 30 days of radiologically confirmed acute venous thrombosis diagnosis?
3	INC2	Num	8	1.	1.	2. Was the venous thrombosis non-spontaneous (provoked)
4	INC2PF	Char	10	$10.	$10.	If yes, specify provoking factor (select all that apply):
5	INC2PFO	Char	42	$42.	$42.	If other, specify factor:
6	EXC1	Num	8	1.	1.	1. Does the patient have a prior episode of VTE?
7	EXC2	Num	8	1.	1.	2. Does the patient have presence of or a history of cancer?
8	EXC2A	Num	8	1.	1.	2a. If yes, does the patient have a malignancy that, in the opinion of the treating oncologist, is not in remission, or for which chronic anticoagulation is being administered/anticipated to be initiated within 6 months?
9	EXC3	Num	8	1.	1.	3. Does the patient have systemic lupus erythematosus?
10	EXC4	Num	8	1.	1.	4. Does the patient have a known Pulmonary Embolism?
11	EXC4A	Num	8	1.	1.	4a. If yes, does the patient have a pulmonary embolism that is not accompanied by DVT or is more proximal than segmental branches of the pulmonary artery?
12	EXC5	Num	8	1.	1.	5. Has the treating Physician used or intends to use thrombolytic therapy?
13	EXC6	Num	8	1.	1.	6. Does the patient have congenital cardiac disease involving a single or hypoplastic ventricle or otherwise require an intracardiac shunt?
14	EXC6A	Num	8	1.	1.	6a. If yes, is chronic anticoagulation being administered/anticipated to be initiated within 6 months (e.g., for select patients or centers, in the setting of a single or hypoplastic ventricle or surgically-established cardiac shunt)?
15	EXC7	Num	8	1.	1.	7. Does the patient have moderate/severe anticoagulant deficiency defined by one of the following?
16	EXC7A	Num	8	1.	1.	7a. Protein C < 20 IU/dL if patient is greater than or equal to 3 months of age or protein C below lower limit of detection if patient is less than 3 months of age?
17	EXC7B	Num	8	1.	1.	7b. Antithrombin < 30 IU/dL if patient is greater than or equal to 3 months of age, or Antithrombin below lower limit detection if patient is less than 3 months of age?
18	EXC7C	Num	8	1.	1.	7c. Protein S (free antigen or activity) less than 20 IU/dL: label
19	ANONID	Num	8			Anonymized version of original studyid SUBJECT

Data Set Name: ie_b.sas7bdat

Num	Variable	Type	Len	Format	Informat	Label
1	INC1A	Num	8	1.	1.	1a. Is the patient less than 21 years old?
2	INC1B	Num	8	1.	1.	1b. Was the patient enrolled within 30 days of radiologically confirmed acute venous thrombosis diagnosis?
3	INC2	Num	8	1.	1.	2. Was the venous thrombosis non-spontaneous (provoked)
4	INC2PF	Char	7	$7.	$7.	If yes, specify provoking factor (select all that apply):
5	EXC1	Num	8	1.	1.	1. Does the patient have a prior episode of VTE?
6	EXC2	Num	8	1.	1.	2. Does the patient have presence of or a history of cancer?
7	EXC3	Num	8	1.	1.	3. Does the patient have systemic lupus erythematosus?
8	EXC4	Num	8	1.	1.	4. Does the patient have a known Pulmonary Embolism?
9	EXC4A	Num	8	1.	1.	4a. If yes, does the patient have a pulmonary embolism that is not accompanied by DVT or is more proximal than segmental branches of the pulmonary artery?
10	EXC5	Num	8	1.	1.	5. Has the treating Physician used or intends to use thrombolytic therapy?
11	EXC6B	Num	8	1.	1.	6. Is chronic anticoagulant at prophylactic dosing being administered or will be administered beyond 6 months post VTE diagnosis?
12	EXC7	Num	8	1.	1.	7. Does the patient have moderate/severe anticoagulant deficiency defined by one of the following?
13	EXC7A	Num	8	1.	1.	7a. Protein C < 20 IU/dL if patient is greater than or equal to 3 months of age or protein C below lower limit of detection if patient is less than 3 months of age?
14	EXC7B	Num	8	1.	1.	7b. Antithrombin < 30 IU/dL if patient is greater than or equal to 3 months of age, or Antithrombin below lower limit detection if patient is less than 3 months of age?
15	EXC7C	Num	8	1.	1.	7c. Protein S (free antigen or activity) less than 20 IU/dL:
16	ANONID	Num	8			Anonymized version of original studyid SUBJECT

Data Set Name: lrdcw.sas7bdat

Num	Variable	Type	Len	Format	Informat	Label
1	LRDCSUMMARYYN	Num	8	3.	3.	Did the patient complete the Long Range Study Visit (6 month or annual post diagnosis follow-up visits)?
2	VITALSTAT	Num	8	1.	1.	What is the subject's vital status at this visit?
3	RECURTHROM	Num	8	1.	1.	Has the patient had a recurrent thromboembolism?
4	MAJORBLEEDYN	Num	8	1.	1.	Did the patient experience either a major bleed or a clinically relevant non-major (CRNM) bleed?
5	LRDCPCYN	Num	8	1.	1.	Was this visit completed by telephone?
6	PTSPEORRES	Char	13	$13.	$13.	Please indicate physical exam findings. Select all that apply.
7	PTSCALFR	Num	8	BEST6.	6.	Enter the Calf measurements for both the right and left sides. Right side (cm):
8	PTSCALFL	Num	8	BEST6.	6.	Left side (cm):
9	PTSTHIGHR	Num	8	BEST6.	6.	Enter the Thigh measurements for both the right and left sides. Right side (cm):
10	PTSTHIGHL	Num	8	BEST6.	6.	Left side (cm):
11	PTSFOREARMR	Num	8	BEST6.	6.	Enter the Forearm measurements for both the right and left sides. Right side (cm):
12	PTSFOREARML	Num	8	BEST6.	6.	Left side (cm):
13	PTSUPPERARMR	Num	8	BEST5.	5.	Enter the Upper arm measurements for both the right and left sides. Right (cm):
14	PTSUPPERARML	Num	8	BEST6.	6.	Left side (cm):
15	PTSPAINREST	Num	8	3.	3.	Select the rating which best describes the pain experienced on the affected limb when at rest:
16	PTSPAINADL	Num	8	3.	3.	Select the rating which best describes the pain experienced on the affected limb when performing age appropriate Activities of Daily Living(ADL):
17	PTSPAINAEROBIC	Num	8	3.	3.	Select the rating which best describes the pain experienced on the affected limb with age-appropriate aerobic exercise:
18	PTSPAINASSESS	Num	8	1.	1.	Based on the Basic CEAP exam part of the PTS assessment, does the patient have any phys findings of PTS? (for SVC clots, answer for findings in arms, or head/face/neck swelling of SVC syndrome; for IVC clots, answer for findings in legs)
19	PTCPAINWONGYN	Num	8	3.	3.	Based on the Wong-Baker 'Faces' component of the PTS assessment, does the patient have pain in the limb where the clot was diagnosed? (for SVC clots, answer for pain in either arm; for IVC clots, answer for pain in either leg)
20	DMDAYS	Num	8			Date of assessment (dd/MMM/yyyy): (recode: number of days after consent)
21	ANONID	Num	8			Anonymized version of original studyid SUBJECT

Data Set Name: mvs.sas7bdat

Num	Variable	Type	Len	Format	Informat	Label
1	MVSYN	Num	8	3.	3.	Was a Modified Villalta Scale completed for this patient?
2	MVSQ1	Num	8	1.	1.	Change in skin color
3	MVSQ2	Num	8	3.	3.	Increased limb circumference >3% compared with contralateral side:
4	MVSQ3	Num	8	1.	1.	Pitting edema:
5	MVSQ4	Num	8	1.	1.	Venous collaterals on skin:
6	MVSQ5	Num	8	1.	1.	Pigmentation of skin:
7	MVSQ6	Num	8	1.	1.	Tenderness on palpation:
8	MVSQ7	Num	8	1.	1.	Varicosities:
9	MVSQ8	Num	8	1.	1.	Head swelling:
10	MVSQ9	Num	8	1.	1.	Ulceration:
11	MVSDAYS	Num	8			Date completed: (recode: number of days after consent)
12	ANONID	Num	8			Anonymized version of original studyid SUBJECT

Data Set Name: phone.sas7bdat

Num	Variable	Type	Len	Format	Informat	Label
1	PHCONTYN	Num	8	1.	1.	Was patient contacted for follow up?
2	PHTIMEPOINT	Num	8	1.	1.	For which visit was the phone interview conducted?
3	VITALSTAT	Num	8	1.	1.	What is the subject's vital status at this visit?
4	RECURTHROM	Num	8	1.	1.	Has the patient had a recurrent thromboembolism?
5	MAJORBLEEDYN	Num	8	3.	3.	Did the patient experience either a major bleed or a clinically relevant non-major (CRNM) bleed? label
6	NEWAEYN	Num	8	1.	1.	Did the patient experience any new adverse events or changes in those previously experienced?
7	PHCALLDAYS	Num	8			Date of phone call (dd/MMM/yyyy): (recode: number of days after consent)
8	ANONID	Num	8			Anonymized version of original studyid SUBJECT

Data Set Name: rand.sas7bdat

Num	Variable	Type	Len	Format	Informat	Label
1	RANDAGEGROUP	Num	8	3.	3.	Select the subject's age group at the time of radiologic diagnosis of VTE:
2	RANDCLOTTYPE	Num	8	3.	3.	Select the subject's Thrombus type:
3	INCEXCYN	Num	8	1.	1.	Randomization criteria met?
4	EXTREATMENT	Char	49	$49.	$49.	Randomization Assignment:
5	ANONID	Num	8			Anonymized version of original studyid SUBJECT

Data Set Name: reg.sas7bdat

Num	Variable	Type	Len	Format	Informat	Label
1	INCEXCYN	Num	8	1.	1.	Randomization criteria met?
2	RANDPREV	Num	8	1.	1.	Has the patient previously been randomized? (Patients within the primary database)
3	RANDPREVYES	Char	49	$49.	$49.	If Yes, select initial randomization assignment: label
4	EXTREATMENT	Char	49	$49.	$49.	Randomization Assignment:
5	SCREENDAYS	Num	8			Date of screening (dd/MMM/yyyy): (recode: number of days after consent)
6	ANONID	Num	8			Anonymized version of original studyid SUBJECT

Data Set Name: reg_new.sas7bdat

Num	Variable	Type	Len	Format	Informat	Label
1	SCREENDAYS	Num	8			Date of screening (dd/MMM/yyyy): (recode: number of days after consent)
2	ANONID	Num	8			Anonymized version of original studyid SUBJECT

Data Set Name: rethrom.sas7bdat

Num	Variable	Type	Len	Format	Informat	Label
1	THROMTYPE	Num	8	3.	3.	Thrombosis type:
2	THROMSITE	Num	8	3.	3.	Thrombosis site (select 1):
3	THROMSIDE	Num	8	3.	3.	Affected side (select 1):
4	THROMOCLD	Num	8	3.	3.	Complete occlusion of an entire venous segment (e.g., entire femoral vein; if thrombus limited to right atrium, select 'no')
5	RADIMGTYPE	Num	8	3.	3.	Radiologic image type (select 1):
6	RADIMGTYPEOTH	Char	15	$15.	$15.	If Other, please specify:
7	THROMSX	Char	10	$10.	$10.	Signs/symptoms associated with the recurrent thromboembolism (select all that apply):
8	THROMSXOTHER	Char	61	$61.	$61.	If Other, please specify:
9	RADIMGDAYS	Num	8			Date of radiologic diagnosis (dd/MMM/yyyy): (recode: number of days after consent)
10	ANONID	Num	8			Anonymized version of original studyid SUBJECT

Data Set Name: sae.sas7bdat

Num	Variable	Type	Len	Format	Informat	Label
1	AERPTTYPE	Num	8	1.	1.	Type of report:
2	AEFUNUM	Num	8	1.	1.	Follow-up #:
3	AECONSETCYN	Num	8	1.	1.	At the time of the AE onset, was the subject receiving anticoagulation for the study-qualifying thrombotic event? (If yes, complete Section 1 below. If no, complete Section 2 below)
4	EXPREVTRTY	Char	10	$10.	$10.	If Yes, Anticoagulant used:
5	EXDOSU	Char	23	$23.	$23.	Most recent dose (e.g. # mg/kg, # units/kg, etc.):
6	EXDOSFRQ	Char	4	$4.	$4.	Frequency (qd, bid, etc.):
7	EXROUTEY	Char	12	$12.	$12.	Route (e.g. po, subcutaneous, etc.):
8	EXPREVTRTN	Char	53	$53.	$53.	If No, Anticoagulant previously used to treat initial thrombosis:
9	EXLSTDOS	Char	15	$15.	$15.	Last dose (e.g. # mg/kg, # units/kg, etc.):
10	EXDOSFRQN	Char	14	$14.	$14.	Frequency (qd, bid, etc.):
11	EXROUTEN	Char	13	$13.	$13.	Route (e.g. po, subcutaneous, etc.):
12	SAESERCRIT	Char	7	$7.	$7.	Serious criteria (Check all that apply):
13	SAESERCRITDESC	Char	233	$233.	$233.	Important medical event description (Intervention required to prevent permanent impairment or damage):
14	SAEABATE	Num	8	1.	1.	Did the SAE abate after stopping anticoagulant treatment?
15	SAEREAPPEAR	Num	8	1.	1.	Did the SAE reappear after reintroduction of the anticoagulant?
16	SAEALTCAUSE	Num	8	1.	1.	If the SAE is not related to anticoagulant, provide alternate cause:
17	SAEALTCAUSEOTH	Char	198	$198.	$198.	Alternate cause of 'Other' was selected, please specify:
18	SAEALTCAUSECM	Char	88	$88.	$88.	Alternate cause of 'Concomitant medication' was selected. Please specify medication name, dose, route, and frequency of administration:
19	SAEDTHCAUSE	Char	153	$153.	$153.	Cause of death:
20	SAEDTHCERT	Num	8	1.	1.	Was death certificate obtained?
21	SAEAUTOPSYN	Num	8	1.	1.	Was autopsy performed?
22	AERPTDAYS	Num	8			Date of report (dd/MMM/yyyy): (recode: number of days after consent)
23	EXSTDAYS	Num	8			Date of first dose (dd/MMM/yyyy): (recode: number of days after consent)
24	AEEXRECDAYS	Num	8			Date of most recent dose (dd/MMM/yyyy): (recode: number of days after consent)
25	EXENDAYS	Num	8			This specific anticoagulant drug was discontinued (if applicable) on (dd/MMM/yyyy): (recode: number of days after consent)
26	SAEAEDTHDAYS	Num	8			Date of death (dd/MMM/yyyy): (recode: number of days after consent)
27	ANONID	Num	8			Anonymized version of original studyid SUBJECT

Data Set Name: swdcw.sas7bdat

Num	Variable	Type	Len	Format	Informat	Label
1	VISITCOMPLETEYN	Num	8	1.	1.	Was this visit completed?
2	FUIMAGETYPE	Num	8	1.	1.	Follow-up imaging type (select 1):
3	OTHERIMAGE	Char	23	$23.	$23.	If Other, please specify:
4	FUIMAGEORRES	Num	8	1.	1.	Follow-up imaging result (select 1):
5	THROMOCLD	Num	8	1.	1.	Complete occlusion of an entire venous segment (e.g., entire femoral vein; if thrombus limited to right atrium, select 'no')
6	RECURTHROM	Num	8	1.	1.	Has the patient had a recurrent thromboembolism?
7	MAJORBLEEDYN	Num	8	1.	1.	Did the patient experience either a major bleed or a clinically relevant non-major (CRNM) bleed?
8	LNACATXRES	Num	8	1.	1.	Text result:
9	LBACANUMRES	Char	3	$3.	$3.	Numeric result:
10	LBBGTXRES	Num	8	1.	1.	Text result:
11	LBBGNUMRES	Char	3	$3.	$3.	Numeric result:
12	LBIGMNUMRES	Char	3	$3.	$3.	Numeric result:
13	LBIGMTXRES	Num	8	1.	1.	Text result:
14	LBVTTXRES	Num	8	3.	3.	Text result for LA1 (screen):
15	LBVTNUMRES	Num	8	BEST4.	4.	Numeric result for LA1/LA2 (screen/confirm) ratio:(not applicable if screen is Normal/negative)
16	LBVTRATIO	Num	8	1.	1.	Text result for LA1/LA2 (screen/confirm) ratio:(notapplicable if screen is Normal/negative)
17	LBHPTXRES	Num	8	1.	1.	Text result:
18	LBHPNUMRES	Num	8	BEST3.	3.	Numeric result:
19	LBSPTXRES	Num	8	1.	1.	Text result:
20	LBSPNUMRES	Num	8	BEST4.	4.	Numeric result:
21	LBPROT	Num	8	1.	1.	Was the research blood sample collected and the tracking form completed?
22	EXTXDISPLAY	Char	49	$49.	$49.	This subject's initial randomization assignment is:
23	EXTREATMENT2	Num	8	1.	1.	If the subject meets the protocol defined criteria below, select appropriate parallel cohort assignment. Note, this will change the randomization assignment for all future visits. Persistent Occlusive Thrombosis OR Persistent APA
24	DMDAYS	Num	8			Date of assessment (dd/MMM/yyyy): (recode: number of days after consent)
25	FUIMAGEDAYS	Num	8			Date of follow-up imaging (dd/MMM/yyyy): (recode: number of days after consent)
26	LBACADAYS	Num	8			Date of Anti-cardiolipin (cardiolipin antibody) IgM (dd/MMM/yyyy): (recode: number of days after consent)
27	LBBGDAYS	Num	8			Date of Anti-Beta-2-Glycoprotein-I (Beta-2-Glycoprotein-I Antibody) IgG (dd/MMM/yyyy): (recode: number of days after consent)
28	LBIGMDAYS	Num	8			Date of Anti-Beta-2-Glycoprotein-I (Beta-2-Glycoprotein-I Antibody) IgM (dd/MMM/yyyy): (recode: number of days after consent)

Num	Variable	Type	Len	Format	Informat	Label
29	LBVTDAYS	Num	8			Date of dRVVT (dd/MMM/yyyy): (recode: number of days after consent)
30	LBHPDAYS	Num	8			Date of aPTT-based, Hexagonal Phospholipid ('StaClotLA' or other) (dd/MMM/yyyy): (recode: number of days after consent)
31	LBSPDAYS	Num	8			Date of aPTT-based, Non-hexagonal Phospholipid ('HemosIL Silica Clotting Time' or other) (dd/MMM/yyyy): (recode: number of days after consent)
32	ANONID	Num	8			Anonymized version of original studyid SUBJECT

Data Set Name: swdcw_new.sas7bdat

Num	Variable	Type	Len	Format	Informat	Label
1	VISITCOMPLETEYN	Num	8	1.	1.	Was this visit completed?
2	FUIMAGETYPE	Num	8	3.	3.	Follow-up imaging type (select 1):
3	OTHERIMAGE	Char	41	$41.	$41.	If Other, please specify:
4	FUIMAGEORRES	Num	8	3.	3.	Follow-up imaging result (select 1):
5	THROMOCLD	Num	8	3.	3.	Complete occlusion of an entire venous segment (e.g., entire femoral vein; if thrombus limited to right atrium, select 'no')
6	RECURTHROM	Num	8	1.	1.	Has the patient had a recurrent thromboembolism?
7	MAJORBLEEDYN	Num	8	1.	1.	Did the patient experience either a major bleed or a clinically relevant non-major (CRNM) bleed?
8	LNACATXRES	Num	8	3.	3.	Text result:
9	LBACANUMRES	Char	32	$32.	$32.	Numeric result:
10	LBBGTXRES	Num	8	3.	3.	Text result:
11	LBBGNUMRES	Char	19	$19.	$19.	Numeric result:
12	LBIGMNUMRES	Char	19	$19.	$19.	Numeric result:
13	LBIGMTXRES	Num	8	1.	1.	Text result:
14	LBVTTXRES	Num	8	1.	1.	Text result for LA1 (screen):
15	LBVTNUMRES	Num	8	BEST4.	4.	Numeric result for LA1/LA2 (screen/confirm) ratio:(not applicable if screen is Normal/negative)
16	LBVTRATIO	Num	8	3.	3.	Text result for LA1/LA2 (screen/confirm) ratio:(notapplicable if screen is Normal/negative)
17	LBHPTXRES	Num	8	1.	1.	Text result:
18	LBHPNUMRES	Num	8	BEST4.	4.	Numeric result:
19	LBSPTXRES	Num	8	1.	1.	Text result:
20	LBSPNUMRES	Num	8	BEST5.	5.	Numeric result:
21	LBPROT	Num	8	1.	1.	Was the research blood sample collected and the tracking form completed?
22	EXTREATMENT2	Num	8	3.	3.	If the subject meets the protocol defined criteria below, select appropriate parallel cohort assignment. Note, this will change the randomization assignment for all future visits. Persistent Occlusive Thrombosis OR Persistent APA
23	DMDAYS	Num	8			Date of assessment (dd/MMM/yyyy): (recode: number of days after consent)
24	FUIMAGEDAYS	Num	8			Date of follow-up imaging (dd/MMM/yyyy): (recode: number of days after consent)
25	LBACADAYS	Num	8			Date of Anti-cardiolipin (cardiolipin antibody) IgM (dd/MMM/yyyy): (recode: number of days after consent)
26	LBBGDAYS	Num	8			Date of Anti-Beta-2-Glycoprotein-I (Beta-2-Glycoprotein-I Antibody) IgG (dd/MMM/yyyy): (recode: number of days after consent)
27	LBIGMDAYS	Num	8			Date of Anti-Beta-2-Glycoprotein-I (Beta-2-Glycoprotein-I Antibody) IgM (dd/MMM/yyyy): (recode: number of days after consent)
28	LBVTDAYS	Num	8			Date of dRVVT (dd/MMM/yyyy): (recode: number of days after consent)

Num	Variable	Type	Len	Format	Informat	Label
29	LBHPDAYS	Num	8			Date of aPTT-based, Hexagonal Phospholipid ('StaClotLA' or other) (dd/MMM/yyyy): (recode: number of days after consent)
30	LBSPDAYS	Num	8			Date of aPTT-based, Non-hexagonal Phospholipid ('HemosIL Silica Clotting Time' or other) (dd/MMM/yyyy): (recode: number of days after consent)
31	ANONID	Num	8			Anonymized version of original studyid SUBJECT

Data Set Name: threemdcw.sas7bdat

Num	Variable	Type	Len	Format	Informat	Label
1	VISITCOMPLETEYN	Num	8	1.	1.	Was this visit completed?
2	VITALSTAT	Num	8	1.	1.	What is the subject's vital status at this visit?
3	UPGIBLEED	Num	8	1.	1.	Number of minor upper GI bleeds:
4	LOGIBLEED	Num	8	1.	1.	Number of minor lower GI bleeds:
5	UTBLEED	Num	8	1.	1.	Number of minor urinary tract bleeds:
6	LUNGBLEED	Num	8	1.	1.	Number of minor lung bleeds:
7	NASOBLEED	Num	8	2.	2.	Number of minor nasopharynx bleeds:
8	WOUNDBLEED	Num	8	1.	1.	Number of minor wound bleeds:
9	OTHERBLEED	Num	8	1.	1.	Number of other minor bleeds:
10	BLEEDOTH	Char	76	$76.	$76.	Please describe any "other minor bleeds":
11	LBPROT	Num	8	1.	1.	Was the research blood sample collected and the tracking form completed?
12	RECURTHROM	Num	8	1.	1.	Has the patient had a recurrent thromboembolism?
13	MAJORBLEEDYN	Num	8	1.	1.	Did the patient experience either a major bleed or a clinically relevant non-major (CRNM) bleed?
14	DMDAYS	Num	8			Date of assessment (dd/MMM/yyyy): (recode: number of days after consent)
15	ANONID	Num	8			Anonymized version of original studyid SUBJECT