Complete this form for:
• Age ≥ 18
• Confirmed diagnosis of a hematologic malignancy or aplasia
• Undergoing or planned chemotherapy, immunotherapy, or hematopoietic stem cell transplantation (includes CAR-T)

Screening Form

Form released: 2017-06-21
Version: 1.04.00

Case ID: To be assigned **Site Linking ID:**

1. Screening info

Hospital name: ---

Date started screening patient: ____-____-____

Date criteria reviewed: ____-____-____

Is this is a re-screen? ○ No ○ Yes

a. **Demographics**
   1. Ethnicity
      - ○ Hispanic/Latino
      - ○ Not Hispanic or Latino
      - ○ Unknown
   2. Race (check all that apply)
      - ☐ American-Indian/Alaska Native
      - ☐ Asian
      - ☐ Black/African-American
      - ☐ Native Hawaiian/Pacific Islander
      - ☐ White
      - ☐ Unknown

b. **Age:** ____ years

c. **Gender**
   ○ Male ○ Female

d. **Disease group (choose one)**
   - ○ Allogeneic transplant
   - ○ Autologous transplant
   - ○ Chemotherapy/immunotherapy without transplant

2. Inclusion Criteria:

Yes	No	
○	○	Age ≥ 18 years of age
○	○	Confirmed diagnosis of a hematologic malignancy or aplasia
○	○	Undergoing or planned chemotherapy, immunotherapy or hematopoietic stem cell transplantation (includes CAR-T)
○	○	Anticipated to have hypoproliferative thrombocytopenia resulting in a platelet count of ≤ 10,000/µl for ≥ 5 days
○	○	Able to provide informed consent and comply with treatment and monitoring, or having a Legally Authorized Representative (LAR)

3. Exclusion Criteria

Medical History Exclusions

Yes	No	Not Reviewed	
○	○	○	Diagnosis of acute promyelocytic leukemia undergoing induction chemotherapy
○	○	○	History of ITP, TTP or HUS

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Case ID: To be assigned **Site Linking ID:**

○	○	○	Past history or current diagnosis of arterial or venous thromboembolic disease including acute coronary syndrome, peripheral vascular disease and retinal arterial or venous thrombosis (except when a prior history of central line thrombosis has resolved) **If yes, indicate diagnosis →** ☐ Line occlusion ☐ DVT ☐ Central venous thrombosis ☐ PE ☐ CVA ☐ Myocardial Infarction ☐ VOD (SOS) ☐ Other → Specify:
○	○	○	Diagnosis/previous history of veno-occlusive disease (also called sinusoidal obstruction syndrome)
○	○	○	Known inherited or acquired bleeding disorder including, but not limited to: Acquired storage pool deficiency or Paraproteinemia with platelet inhibition
○	○	○	Known inherited or acquired prothrombotic disorders, including antiphospholipid syndrome. Those with lupus anticoagulant or positive antiphospholipid serology without thrombosis are not excluded.
○	○	○	DIC according to the patients physician
○	○	○	Pregnant or nursing or unwilling to use contraception during and for 30 days after taking the study drug (both males and females)
○	○	○	Known allergy to tranexamic acid
○	○	○	Known hypercoagulable state

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Case ID: To be assigned **Site Linking ID:**

Medication Exclusions			
Yes	**No**	**Not Reviewed**	
○	○	○	Receiving L-asparaginase as part of their current cycle of treatment
○	○	○	Receiving any pro-coagulant agents (e.g. DDAVP, recombinant Factor VIIa or Prothrombin Complex Concentrates (PCC)) and/or an antifibrinolytic agent within 48 hours of enrollment
○	○	○	Receiving anticoagulant therapy or anti-platelet therapy (except when receiving prophylactic anticoagulant or low dose aspirin therapy for prophylaxis only with a plan to discontinue when the platelet count falls below 50,000)

Renal Exclusions			
Yes	**No**	**Not Reviewed**	
○	○	○	Receiving dialysis treatments
○	○	○	Serum creatinine ≥ 5.7mg/dL
○	○	○	Anuria (defined as urine output < 10mls/hr over 24 hours)

Trial related exclusions			
Yes	**No**	**Not Reviewed**	
○	○	○	Enrolled in other trials involving platelet transfusions, anti-fibrinolytics, platelet growth factors or other pro-coagulant agents
○	○	○	Unwilling to accept blood or blood component transfusions
○	○	○	Prior randomization in this study at any stage of their treatment
○	○	○	MD refused patient participation → if refused, specify

4. Consent signed

○ No → --- If other → specify:

○ Yes → Date signed: - -

Birth Date: - -

Complete this form for: Consented patients

Enrollment Form

Form released: 2017-06-21
Version: 1.04.00

Case ID: To be assigned **Site Linking ID:**

1. **Date of enrollment data review:** - -

2. **Does the patient still meet inclusion/exclusion criteria?**

- (•) No (If pre-randomization, stop here and complete 'End of Study' form, otherwise continue filling out form)
- ( ) Yes (Complete all required questions)

3. **Demographics**

a. Height ( ) in ( ) cm
b. Weight ( ) lbs ( ) kg

4. **Primary diagnosis**

A. **Disease (choose one)**

- ( ) Aplastic Anemia
- ( ) Acute Myeloid Leukemia
- ( ) Acute Lymphoblastic Leukemia
- ( ) Chronic Myelogenous Leukemia
- ( ) Chronic Lymphocytic Leukemia
- ( ) Hairy Cell Leukemia
- ( ) Non-Hodgkin's Lymphoma
- ( ) Hodgkin's Lymphoma
- ( ) Myelodysplastic Syndrome
- ( ) Myeloma
- ( ) Non-Hematopoietic Solid Tumor Malignancy
- ( ) Myelofibrosis
- ( ) Other → Specify:

B. **Treatment (check all that apply)**

- [ ] Targeted Immunotherapy (including, but not limited to CAR-T cells)
- [ ] Pre-Transplant Chemotherapy
- [ ] Radiation
- [ ] Chemotherapy → Start date - -
- [ ] Planned/previous Transplant → Date: - -

Other medications

- [ ] Estrogen → Start date - -
- [ ] Cytarabadine (AraC) → Start date - -
- [ ] Steroids → Start date - -
  - [ ] Systemic (IV/oral)
  - [ ] Ophthalmic
- [ ] Alteplase (Activase; Tissue Plasminogen Activator (TPA)) → Most recent dose: - -

5. **Patient blood type**

ABO Type:

( ) A ( ) B ( ) AB ( ) O

Rh Factor:

Complete this form for: Consented patients

Enrollment Form

Form released: 2017-06-21
Version: 1.04.00

Case ID: To be assigned **Site Linking ID:**

Rh Positive Rh Negative

6. Laboratory values

Lab	Date	Time	Modifier	Result	Unit Type					
					g/dL	%	mg/dL	THOU/µL	x10³/µL	x10⁹/L
Hemoglobin	- -	:	< >							
Hematocrit	- -	:	< >							
Serum creatinine	- -	:	< >							
White blood cell	- -	:	< >							
Neutrophil (if available)	- -	:	< >							
HLA PRA	- -	:	< >							

7. Platelet count (Provide all drawn within 48 hours)

#	Date	Time	Mod	Result	Unit		
					THOU/µL	x10³/µL	x10⁹/L
1	- -	:	< >				
2	- -	:	< >				
3	- -	:	< >				
4	- -	:	< >				
5	- -	:	< >				

All platelet counts entered:

8. Current adverse events

No pre-existing adverse events

	Adverse Event	Todays report		AE classification (DCC Only)	
		Grade	Seriousness	System Organ Class	PT
1		---	---	[]	[]

Complete this form for: Consented patients

Enrollment Form

Form released: 2017-06-21
Version: 1.04.00

Case ID: To be assigned **Site Linking ID:**

	Adverse Event	Todays report		AE classification (DCC Only)	
		Grade	Seriousness	System Organ Class	PT
2		---	---	[]	[]
3		---	---	[]	[]
4		---	---	[]	[]
5		---	---	[]	[]
6		---	---	[]	[]
7		---	---	[]	[]
8		---	---	[]	[]
9		---	---	[]	[]
10		---	---	[]	[]
11		---	---	[]	[]
12		---	---	[]	[]
13		---	---	[]	[]
14		---	---	[]	[]
15		---	---	[]	[]

AE Grades

- 1
- 2
- 3
- 4
- 5

AE Seriousness

- Prolonged hospitalization, or required hospitalization
- Life-threatening
- Fatal
- Led to permanent disability

Enrollment Form

Form released: 2017-06-21
Version: 1.04.00

Case ID: To be assigned **Site Linking ID:**

- Required intervention to prevent permanent disability
- Associated with congenital anomaly
- None of the above

Randomization Form

Case ID: To be assigned **Site Linking ID:**

1. **Consent signed**

   - ○ No
   - ○ Yes → Signed date: ____-____-____

2. **Birth Date** ____-____-____

3. **Gender**

   ○ Male ○ Female

4. **Qualifying Platelet Count**

   Date: ____-____-____
   Time: ____:____
   Result: ____ Unit: THOU/µL ○ $x10^3$/µL ○ $x10^9$/L ○

5. **Does the patient still meet eligibility criteria?**

   - ○ No
   - ○ Yes

6. **Does the patient require a platelet transfusion threshold > 10,000/µl**

   - ○ No
   - ○ Yes

7. **Has the patient had WHO grade 2 bleeding in the past 48 hours?**

   - ○ No
   - ○ Yes

8. **Disease group (choose one)**

   - ○ Allogeneic transplant
   - ○ Autologous transplant
   - ○ Chemotherapy/immunotherapy without transplant

9. **Is the most recent pregnancy test within 7 days and the result is negative for pregnancy**

   - ○ Yes
   - ○ No
   - ○ NA - not of child bearing potential

10. **Is the most recent urinalysis within 72 hours and the result is negative for visible hematuria**

    - ○ Yes
    - ○ No

Remember to contact your IDS with the appropriate patient identifiers via your approved methods

Complete this form for: Enrolled patients

Daily Form

Reason: Daily Form
Form released: 2018-03-28
Version: 1.09.00

Case ID: **Site Linking ID:** [ ]

1. Location of patient at start of day

- ○ Inpatient → If discharged, time: :
- ○ Outpatient → If readmitted, time: :

2. Does the patient still meet inclusion/exclusion criteria? (Not required after activation)

- ○ No (If pre-randomization, stop here and complete 'End of Study' form, otherwise continue filling out required daily forms)
- ○ Yes (Complete all required questions)

3. Indicate changes in patient status

☐ Activation
Pharmacy notified date: - - Time: :
First dose date: - - Time: :

☐ Study dose treatment ended
Reason: ---
Additional Details

Study dose treatment ended - Reason

- Platelet recovery per protocol section 6.3.2 or 6.3.3
- 30 days post activation
- Open label antifibrinolytic or procoagulant
- Anticoagulant or antiplatelet therapy
- Visible hematuria
- Thrombosis or recurrent central line occlusion
- Sinusoidal obstructive syndrome (SOS or VOD)
- Pregnancy
- Death
- Other physician decision (specify)
- Patient decision (specify)

4. Study medication doses

☐ All study medication dose info unknown → Specify:
☐ All study medication doses on hold → Specify:

Dose	No dose	1 pills	2 pills	IV dose	Unknown	Other	Explain if non-standard dose given	Source of study drug: Pharmacy Stock	Source of study drug: Patient Bottle
1st	○	○	○	○	○	○		○	○
2nd	○	○	○	○	○	○		○	○
3rd	○	○	○	○	○	○		○	○

If day of outpatient visit **Or** day of activation and bottle issued → Number of pills in
Bottle 1 Count: ID:
Bottle 2 Count: ID:

5. Current Treatment

☐ Transplant today
Transplant Type ---
If allogeneic transplant

Donor ABO Type:

○ A ○ B ○ AB ○ O

Donor Rh Factor:

○ Rh Positive ○ Rh Negative

Transplant Types

- ○ Myeloablative allo - related
- ○ Myeloablative allo - unrelated
- ○ Non-Myeloablative - related
- ○ Non-Myeloablative - unrelated

Case ID: **Site Linking ID:** [ ]

- Myeloablative syngeneic
- Auto
- Cord

- ☐ Cytarabine (AraC)
- ☐ Steroids
  - ☐ Systemic (IV/oral)
  - ☐ Ophthalmic

- ☐ Alteplase (Activase; Tissue Plasminogen Activator (tPA))
  Given for:
  - ○ Less than all lumens occluded, sluggish, difficult to access
  - ○ All lumens occluded, sluggish, difficult to access
  - ○ Other → specify:
- ☐ None of the above

6. **Laboratory values** (Must be drawn prior to 1st dose of study drug on first day study drug given)

☐ No labs drawn

	Date	Time	Modifier	Result	Unit
Hemoglobin	- -	:	< >		g/dL
Hematocrit	- -	:	< >		%
Serum Creatinine	- -	:	< >		mg/dL
PT	- -	:	< >		seconds
INR	- -	:	< >		NA
PTT	- -	:	< >		seconds
Fibrinogen	- -	:	< >		mg/dL
D-dimer	- -	:	< >		○ µg/mL ○ ng/mL
D-dimer, QN	- -	:	< >		○ µg/mL ○ ng/mL
Thrombin time	- -	:	< >		seconds
Billirubin	- -	:	< >		mg/dL
White blood cell	- -	:	< >		○ THOU/µL ○ $x10^3$/µL ○ $x10^9$/L
Neutrophil (if available)	- -	:	< >		○ THOU/µL ○ $x10^3$/µL ○ $x10^9$/L
☐ All lab data entered					

Urinalysis

Date: - - Time: :
Amount of RBCs: < >
Interpretation: (+)
OR

Case ID: **Site Linking ID:** [ ]

Dipstick: ◯ Positive
◯ Negative

Child bearing potential:

Pregnancy test: ◯ No ◯ Yes → Date: ____-__-__ Time: __:__
Result: ◯ Positive ◯ Negative
Source ◯ Serum ◯ Urine

7. Platelet count (provide all drawn)

☐ No platelets drawn

	Time	Modifier	Result	Unit		
				THOU/µL	$x10^3/µL$	$x10^9/L$
▾	__:__	< > 🗑		◯	◯	◯
All platelet counts entered: ☐						

8. Transfusions

◯ Not reviewed
◯ No transfusions
◯ Yes
☐ Granulocyte Transfusion
☐ Platelet Transfusion

		Platelet Source		Platelet additive solution		Pathogen inactivation		HLA Compatible		Cross-match compatible		Reason for transfusion						
Time	Unknown	Apheresis	Whole blood derived	Yes	No	Yes	No	Yes	No	Yes	No	Met Threshold	Invasive Procedure	Active Bleeding	Risk of Significant Bleeding	Scheduling/patient convenience	Other	If Other, Specify
__:__	☐	◯	◯	◯	◯	◯	◯	◯	◯	◯	◯	◯	◯	◯	◯	◯	◯	
__:__	☐	◯	◯	◯	◯	◯	◯	◯	◯	◯	◯	◯	◯	◯	◯	◯	◯	
__:__	☐	◯	◯	◯	◯	◯	◯	◯	◯	◯	◯	◯	◯	◯	◯	◯	◯	
__:__	☐	◯	◯	◯	◯	◯	◯	◯	◯	◯	◯	◯	◯	◯	◯	◯	◯	

Case ID: **Site Linking ID:** [ ]

Time	Unknown	Platelet Source		Platelet additive solution		Pathogen inactivation		HLA Compatible		Cross-match compatible		Reason for transfusion						
		Apheresis	Whole blood derived	Yes	No	Yes	No	Yes	No	Yes	No	Met Threshold	Invasive Procedure	Active Bleeding	Risk of Significant Bleeding	Scheduling/patient convenience	Other	If Other, Specify
:																		

Red Blood Cell Transfusion
Number of units transfused:
Reason for transfusion
- Met Threshold
- Invasive Procedure
- Active Bleeding
- Risk of Significant Bleeding
- Other→ Specify

9. Ocular assessment

Assessment not done

Assessment done:
- With patient corrective lenses
- With study coordinator corrective lenses
- No corrective lenses

Right Eye:

a. Snellen eye chart: Results: /

b. Amsler grid:
- Normal
- Abnormal → Quadrant: Upper left Upper right Center Lower Left Lower Right

c. Ishihara test - colorblindness was:
- Not found
- Found → Which plates:
  01 03 04 07 08 10
  12 14 16 22 25

Left Eye:

a. Snellen eye chart: Results: /

b. Amsler grid:
- Normal
- Abnormal → Quadrant: Upper left Upper right Center Lower Left Lower Right

Case ID: **Site Linking ID:** [ ]

c. Ishihara test - colorblindness was:
- ○ Not found
- ○ Found → Which plates:
  - ☐ 01 ☐ 03 ☐ 04 ☐ 07 ☐ 08 ☐ 10
  - ☐ 12 ☐ 14 ☐ 16 ☐ 22 ☐ 25

10. Any thrombosis or thrombotic/occlusive events identified

- ○ No
- ○ Not reviewed
- ○ Yes → Location: [ ]

Date of onset symptoms per patient: [ ]-[ ]-[ ]

Diagnosis
- ☐ Line occlusion (all lumens occluded)
- ☐ DVT
- ☐ Central venous thrombosis
- ☐ PE
- ☐ CVA
- ☐ Myocardial Infarction
- ☐ VOD (SOS)
- ☐ Other → Specify: [ ]

How was the thrombotic event documented?
- ☐ Chest X-ray
- ☐ Doppler/Ultrasound
- ☐ Venography
- ☐ MRI
- ☐ CT
- ☐ D-dimer → Results: [ ] (µg/L)
- ☐ Other → Specify: [ ]

11. Hemostatic assessment

Source
- ☐ Chart review
- ☐ Patient assessment by research staff
- ☐ Patient self-assessment

Any bleeding identified?
- ○ No
- ○ Yes
- ○ Unknown, patient did not complete diary

Site	No	Yes	Grade	Description
General	○	○	Grade 4	○ Any bleeding that is fatal or life threatening. For example: - Bleeding that requires transfer to intensive care/treatment unit - Bleeding that is associated with hemodynamic instability and causes inadequate tissue perfusion (for further clarification see general guideline above).

Case ID: **Site Linking ID:** [ ]

Site	No	Yes	Grade	Description
			Grade 3	Any bleeding that does not fulfil the criteria for grade 4 bleeding BUT requires: Red cell transfusion specifically related to treatment of bleeding within 24 hours of onset of bleeding. OR A significant intervention, for example: - Endoscopy to treat the bleeding - Interventional radiography to treat the bleeding - Transfer to the operating theatre/ room for treatment of bleeding
			Grade 2	Any bleeding that does not fulfil the requirements for grade 3 bleeding BUT requires an intervention or treatment: Examples of Interventions - Nasal Packing - Bladder irrigation Examples of treatments - Platelet transfusion given to treat active bleeding and NOT given only because the platelet count is below the prophylactic platelet transfusion trigger - Medications prescribed to treat bleeding
			Grade 1	Bleeding that does not fulfill the requirements for grade 2 bleeding. Please see examples in organ-specific categories below.
Oral and nasal			Grade 4	Any bleeding that requires intubation to protect the airway
			Grade 3	Any bleeding that requires a transfusion or a procedure (not including intubation)
			Grade 2	Oropharyngeal bleeding - total duration of all episodes in previous 24 hours > 30 minutes* Epistaxis - total duration of all episodes in previous 24 hours > 30 minutes* Multiple (> 5) hemorrhagic bullae or blisters
			Grade 1	Spontaneous oropharyngeal bleeding - total duration of all episodes in previous 24 hours < 30 minutes* Traumatic oropharyngeal bleeding e.g. after bites to lips and tongue lasting > 10 minutes or interfering with daily activities Epistaxis - total duration of all episodes in previous 24 hours < 30 minutes* Petechiae of oral mucosa Few (≤ 5) hemorrhagic bullae or blisters
Skin			Grade 4	
			Grade 3	Any bleeding that requires a transfusion or a procedure
			Grade 2	Multiple (> 5) spontaneous bruises (ecchymoses) each > 2.5cm or any one > 10cm Many (> 10) spontaneous bruises (ecchymoses) (> 10mm in diameter) that does not fulfil the above criteria Purpura (3mm to 10mm diameter). Many purpuric lesions (> 10). Petechiae covering > 25% of skin (1 arm = 10%; 1 leg = 25%; trunk = 44%; head = 6%).
			Grade 1	Few (≤ 5) spontaneous bruises (ecchymoses) over 2.5cm in size and none > 10cm Purpura (3mm to 10mm diameter) (Few purpuric lesions (≤ 10). Petechiae (< 3mm diameter) covering ≤ 25% of skin (1 arm = 10%; 1 leg = 25%; trunk = 44%; head = 6%)
Soft-tissue and musculoskeletal			Grade 4	Any bleeding that causes compartment syndrome
			Grade 3	Any bleeding that requires a transfusion or a procedure (not including compartment syndrome)

Case ID: **Site Linking ID:** [ ]

Site	No	Yes	Grade	Description
			Grade 2	Asymptomatic spontaneous soft-tissue hematoma greater than 10cm in diameter Symptomatic soft-tissue hematoma (e.g. causing pain or discomfort). Spontaneous joint bleeding (confirmed by aspiration, imaging study or other accepted technique)
			Grade 1	Asymptomatic spontaneous soft-tissue hematoma less than 10cm in diameter Traumatic hematoma of any size Traumatic joint bleeding (confirmed by aspiration, imaging study or other accepted technique)
Gastrointestinal			Grade 4	
			Grade 3	Rectal Bleeding requiring a transfusion Hematemesis requiring a transfusion Any bleeding that requires a transfusion or a procedure
			Grade 2	Melena Hematochezia - visible red blood mixed in stool, not requiring a transfusion Hematemesis - Grossly visible blood in emesis (vomit) or in nasogastric drainage tube (not related or secondary to swallowed blood)
			Grade 1	Fecal occult blood Rectorrhagia- visible red blood on tissue paper/not mixed with stool
Genitourinary			Grade 4	Any bleeding that causes: increase ≥ 3 X reference serum creatinine or Serum creatinine rises by ≥ 354 µmol/L (4.0 mg/dl) or Commenced on renal replacement therapy or Urine output < 0.3 mL/kg/hr for > 24 hrs or Anuria for at least 12 hrs.
			Grade 3	Any bleeding that causes: increase ≥ 1.5 X reference serum creatinine or Serum creatinine rises by ≥ 26 µmol/L (0.3mg/dl) within 48 hours Urine output < 0.5 mL/kg/hr for > 6 consecutive hrs Any bleeding that requires a transfusion or a procedure
			Grade 2	Abnormal vaginal bleeding (Unexpected bleeding out of normal cycle OR Bleeding heavier than normal OR Breakthrough bleeding (patient on hormonal therapy to prevent bleeding)) more than spotting Gross/visible hematuria
			Grade 1	Abnormal vaginal bleeding (Unexpected bleeding out of normal cycle OR Bleeding heavier than normal OR Breakthrough bleeding (patient on hormonal therapy to prevent bleeding)) with spotting Microscopic hematuria/ dipstick positive hematuria
Pulmonary			Grade 4	Any bleeding requiring respiratory support (includes non-invasive (CPAP, BiPAP), or invasive ventilation)
			Grade 3	Any bleeding requiring supplemental oxygen to maintain oxygen saturation above 93%.
			Grade 2	Hemoptysis - Visible blood Blood in broncho-pulmonary lavage, or blood tinged sputum (excluding those with nose or oropharyngeal bleeding or mucositis).
			Grade 1	

Case ID: **Site Linking ID:** [ ]

Site	No	Yes	Grade	Description
Body cavity	○	○	Grade 4	
			Grade 3	○ Grossly visible blood in body cavity fluids AND organ dysfunction with symptoms, AND/OR need to intervene (e.g. to aspirate) ○ Any bleeding that requires a transfusion or a procedure
			Grade 2	○ Visible blood in body cavity fluid (e.g. red cells apparent in fluid aspirate) short of criteria for Grade 3 or 4
			Grade 1	
Eye	○	○	Grade 4	○ Retinal bleeding with permanent visual impairment ** (present for > 7 days) ○ Vitreous bleeding with permanent visual impairment ** (present for > 7 days)
			Grade 3	○ Retinal bleeding with temporary visual impairment ** (present for ≤ 7 days) ○ Vitreous bleeding with temporary visual impairment *** (present for ≤ 7 days)
			Grade 2	○ Diffuse sub-conjunctival hemorrhage in both eyes ○ Spontaneous retinal bleeding without visual impairment ○ Spontaneous vitreous bleeding without visual impairment
			Grade 1	○ Sub-conjunctival hemorrhage ○ Traumatic retinal bleeding without visual impairment ○ Traumatic vitreous bleeding without visual impairment
Central nervous system	○	○	Grade 4	○ CNS symptoms with non-traumatic bloody lumbar puncture ○ CNS bleeding on imaging study with neurological dysfunction
			Grade 3	○ Lumbar puncture with visible red color in absence of neurological symptoms, and non-traumatic tap ○ Spontaneous CNS bleeding on imaging study without neurological dysfunction
			Grade 2	○ Lumbar puncture with blood (> 5 RBC/µL in CSF on microscopic analysis and non-traumatic tap), no neurological symptoms and no visible red color ○ Traumatic CNS bleeding on imaging study without neurological dysfunction
			Grade 1	
Invasive sites	○	○	Grade 4	
			Grade 3	○ Any bleeding that requires a transfusion or a procedure
			Grade 2	○ Bleeding at invasive sites (venipuncture sites, intravenous lines or catheter exit sites): active oozing at site for a cumulative total of > 1 hour in the previous 24 hours.
			Grade 1	○ Bleeding at invasive sites or sites of minor trauma (e.g. venipuncture sites, intravenous lines or catheter exit sites): active oozing at site for > 10 minutes

12. Adverse events

☐ No ongoing or new adverse events reviewed

Previous days reported adverse events

	Ongoing	Previous days report	Todays report	AE classification

Complete this form for: Enrolled patients

Daily Form

Reason: Daily Form
Form released: 2018-03-28
Version: 1.09.00

Case ID: **Site Linking ID:** [ ]

	Adverse Event	Grade	Seriousness	Relatedness	Still present		Grade	Seriousness	Relatedness	(DCC Only)	
					No	Yes				System Organ Class	PT

AE Grades

AE Seriousness

AE Relatedness

Todays new adverse events

☐ No new adverse events

	New Adverse Event	Todays report			AE classification (DCC Only)	
		Grade	Seriousness	Relatedness	System Organ Class	PT
1		---	---	---	[]	[]
2		---	---	---	[]	[]
3		---	---	---	[]	[]
4		---	---	---	[]	[]
5		---	---	---	[]	[]
6		---	---	---	[]	[]
7		---	---	---	[]	[]
8		---	---	---	[]	[]
9		---	---	---	[]	[]
10		---	---	---	[]	[]
11		---	---	---	[]	[]
12		---	---	---	[]	[]
13		---	---	---	[]	[]
14		---	---	---	[]	[]
15		---	---	---	[]	[]

Followup Form

Form released: 2016-10-05
Version: 1.01.00

Case ID: To be assigned **Site Linking ID:**

1. **Date of followup review:** - -

☐ No follow up completed

2. **Any thrombosis or thrombotic/occlusive events identified since last reported follow up?**

○ No
○ Not reviewed
○ Yes → Location:

Date of onset symptoms per patient: - -

Diagnosis

☐ Line occlusion
☐ DVT
☐ Central venous thrombosis
☐ PE
☐ CVA
☐ Myocardial Infarction
☐ VOD (SOS)
☐ Other → Specify:

How was the thrombotic event documented?

☐ Chest X-ray
☐ Doppler/Ultrasound
☐ Venography
☐ MRI
☐ CT
☐ D-dimer → Results: (µg/L)
☐ Other → Specify:

3. **Any adverse events identified since last reported follow up?**

Previous adverse events at last report

#	Adverse Event	Max Grade	Date of Max Grade	Seriousness	Relatedness	AE Resolved?		Date of Resolution	DCC Only	
						Yes	No		SOC	PT

New adverse events

☐ No new adverse events

Adverse Event	Max Grade	Date of Max Grade	Seriousness	Relatedness	AE Resolved?		Date of Resolution	DCC Only	
					Yes	No		SOC	PT
	---	- -	---	---	○	○	- -	[]	[]
	---	- -	---	---	○	○	- -	[]	[]

Followup Form

Form released: 2016-10-05
Version: 1.01.00

Case ID: To be assigned **Site Linking ID:**

Adverse Event	Max Grade	Date of Max Grade	Seriousness	Relatedness	AE Resolved?		Date of Resolution	DCC Only	
					Yes	No		SOC	PT
	---	- -	---	---			- -	[]	[]
	---	- -	---	---			- -	[]	[]
	---	- -	---	---			- -	[]	[]
	---	- -	---	---			- -	[]	[]
	---	- -	---	---			- -	[]	[]
	---	- -	---	---			- -	[]	[]
	---	- -	---	---			- -	[]	[]
	---	- -	---	---			- -	[]	[]
	---	- -	---	---			- -	[]	[]
	---	- -	---	---			- -	[]	[]
	---	- -	---	---			- -	[]	[]
	---	- -	---	---			- -	[]	[]
	---	- -	---	---			- -	[]	[]

Complete this form for:
• Patients who no longer meet inclusion and/or exclusion criteria prior to randomization
• Patients who stop the study and all follow up early
• Patients who have completed 120 study days

End of Study Form

Form released: 2016-10-26
Version: 1.04.00

Case ID: To be assigned **Site Linking ID:**

1. **Date of study end:** - -

2. **Patient stage of study**

- Pre-randomization
- Randomization/pre-activation
- Post activation

3. **Reason for stopping study**

- Lost eligibility prior to randomization → Explain:
- Withdrew consent (including all follow up) → Explain:
- Other → Explain:
- Death *(question 4 is required)*

  Presumed cause of death
  - Bleeding → Location:
  - Graft versus host disease
  - Disease progression
  - Thrombosis → Location:
  - Infection
  - Other → Specify:

  Site PI letter required

  Date received or uploaded - -

  (no site letter attached)
- Completed 120 study days *(question 4 is required)*

  Patient status
  - Alive
  - Deceased

4. **Any thrombosis or thrombotic/occlusive events identified**

Date of review: - -

- No
- Not reviewed

Complete this form for:
• Patients who no longer meet inclusion and/or exclusion criteria prior to randomization
• Patients who stop the study and all follow up early
• Patients who have completed 120 study days

End of Study Form

Form released: 2016-10-26
Version: 1.04.00

Case ID: To be assigned **Site Linking ID:**

○ Yes → Location:

Date of onset symptoms per patient: - -

Diagnosis

- ☐ Line occlusion
- ☐ DVT
- ☐ Central venous thrombosis
- ☐ PE
- ☐ CVA
- ☐ Myocardial Infarction
- ☐ VOD (SOS)
- ☐ Other → Specify:

How was the thrombotic event documented?

- ☐ Chest X-ray
- ☐ Doppler/Ultrasound
- ☐ Venography
- ☐ MRI
- ☐ CT
- ☐ D-dimer → Results: (µg/L)
- ☐ Other → Specify:

ALERT Form

Form released: 2018-03-28
Version: 1.05.00

Case ID: **Site Linking ID:** [ ]

1. ## Event dates:

Date of event: [ ]-[ ]-[ ] *(yyyy-mm-dd)*
Date site aware of event: [ ]-[ ]-[ ] *(yyyy-mm-dd)*
Date reported to CCC/DCC: [ ]-[ ]-[ ] *(yyyy-mm-dd)*

2. ## Did you report to your IRB (outside of annual review reporting)?

- ○ No
- ○ Yes → Date reported to local IRB: [ ]-[ ]-[ ] *(yyyy-mm-dd)*

3. ## Patient stage of study at time of event:

- ○ Pre-randomization
- ○ Randomization/pre-activation
- ○ Treatment/Activation
- ○ Follow-up
- ○ End of treatment

4. ## Select only 1 situation from below

Ineligible patient

- ○ Inclusion/Exclusion not met and patient randomized or study drug given
- ○ Consent not signed appropriately
- ○ No longer eligible/lost eligibility

Pharmacy related issues

- ○ Pharmacy dispensing error
- ○ Inventory issue (including lack of drug availability or lost bottles)

Randomization issues

- ○ Randomization information changed (i.e. diagnosis on randomization form incorrect)
- ○ Incorrect patient randomized
- ○ Randomized too early

Dosing Issues

- ○ Dose greater than expected
- ○ Drug not stopped within 24 hours of event requiring drug to stop (Protocol section 6.3)
- ○ Renal insufficiency identified and drug dose was not modified accordingly
- ○ Dose less than expected — patient chose to take less than ordered dose or patient chose to skip dose

Expeditable adverse events

Thrombosis or thrombotic/occlusive event occurred

- ○ Line occlusion
- ○ DVT
- ○ Central venous thrombosis
- ○ PE
- ○ CVA
- ○ Myocardial Infarction
- ○ VOD (SOS)
- ○ Other → Specify: [ ]

Other expeditable adverse events

- ○ Ocular changes identified
- ○ Patient became pregnant
- ○ Death

Case ID: **Site Linking ID:** [ ]

- Serious adverse event

Other events

- Study therapy unblinded - DO NOT REPORT ANY UNBLINDING RESULTS HERE
  Name of authorized person who unblinded (enter text here - 100 char limit)
- Patient modified follow up schedule
- Chemotherapy after study drug is permanently discontinued
- tPA given for
  - Venous catheter line issue (sluggish line, difficulty accessing, less than all lumens occluded)
  - Venous catheter line occlusion
  - Other → Specify: *(250)*
- Superficial Venous Thrombosis/ Superficial Venous Thrombophlebitis/SVT
- Other event

5. **Explain circumstances**

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