From: [redacted]
To: APHIS-AnimalCare
Subject: Class R licensure
Date: Wednesday, December 30, 2020 9:56:24 AM
Attachments: LoVLETRprotocol 3.5_Post ACURO mods.pdf

Dear Sir or Madam,

We have been advised through the ACURO group in DOD that we will need to license as a Class R facility in order to perform our clinical trials. We are a veterinary biopharma C Corp developing a freeze dried plasma product for dogs which combined with our commercial freeze dried platelet product is undergoing Phase 2/3 evaluation for use in low volume lyophilized early trauma resuscitation (LoVLETR). Our preclinical development has been performed under contract research organization contract and we do not maintain animals for clinical evaluation. However, the Phase 2/3 will involve pet owned dogs presenting to clinical facilities (public, academic and private) for treatment of trauma. In review of the Blue Book and registration packet it is unclear if facilities like ours involved in clinical research should be registered. Can you provide guidance regarding the potential licensure of BodeVet as a Class R facility. I have included the DOD funded protocol in question for informational purposes.

Best regards,

Anne

[redacted]
BodeVet, Inc.
9210 Corporate Blvd
Suite 310
Rockville, MD 20850
[redacted] cell)
[redacted]@bodevet.com

Clinical Trial in Support of Trauma Indications for Lyophilized Canine Blood Products

Clinical Protocol: W81XWH-20C0067
01May2020 through 28Apr2022

CDRL A001

Protocol 2-2019-K9

Version 3.5

Principal Investigator: [redacted] DVM
[redacted]@bodevet.com

Program Manager: [redacted] DVM, DACVECC
[redacted]@bodevet.com

BodeVet, Inc.
9210 Corporate Blvd
Suite 310
Rockville, MD 20850
240-408-8060
www.bodevet.com

Table of Contents

CLINICAL RESEARCH PROTOCOL

CLINICAL TRIAL IN SUPPORT OF TRAUMA INDICATIONS FOR LYOPHILIZED CANINE BLOOD PRODUCTS

Protocol Version 3.5 Approval Signature

Protocol Number:	2-2019-K9
Version Date:	9Oct2020
Investigational Biologic:	StablePlate Rx®, StablePlas™
Study Phase:	II/III
Sponsor-Investigator:	Bodevet, Inc.
Principal Investigator:	(b) (6), (b) (7)(C) DVM BodeVet, Inc. 9210 Corporate Avenue Suite 310 Rockville, MD 20850 [redacted] bodevet.com
Site Coordinators	

Approval:

_____ _____

PI or Sponsor Signature (Name and Title) *Date*

_____

Organization

This confidential information about an investigational product is provided for the exclusive use of investigators of this product and is subject to recall at any time. The information in this document may not be disclosed unless federal or state law or regulations require such disclosure. Subject to the foregoing, this information may be disclosed only to those persons involved in the study who have a need to know, with the obligation not to further disseminate this information.

Protocol Site Investigator Signature

I have read the protocol specified below. In my formal capacity as Investigator, my duties include ensuring the safety of the study subjects enrolled under my supervision and providing BodeVet, Inc. with complete and timely information, as outlined in the protocol. It is understood that all information pertaining to the study will be held strictly confidential and that this confidentiality requirement applies to all study staff at this site. Furthermore, on behalf of the study staff and myself, I agree to maintain the procedures required to carry out the study in accordance with accepted GCP principles and to abide by the terms of this protocol.

Protocol Number: **2-2019-K9**

Protocol Title: **CLINICAL TRIAL IN SUPPORT OF TRAUMA INDICATIONS FOR LYOPHILIZED CANINE BLOOD PRODUCTS**

Protocol Date: 9 Oct 2020

_____ _____

Investigator Signature *Date*

_____

Print Name and Title

_____

Site Name

_____

Address

_____

_____

_____

_____

Phone Number

_____

List of Abbreviations

AABB	American Association of Blood Banks
ACD-A	Acid Citrate Dextrose Anticoagulant Formula A
AE	Adverse Event
ATT	Animal Trauma Triage scoring system
aPTT	Activated prothrombin time
C	Degrees Centigrade
CBC	Complete blood count
CCF	Critical Care Form
CFR	Code of Federal Regulations (US FDA)
CRF	Case report form
DEA	Dog erythrocyte antigen
DOGiBAT	A novel uniform bleeding score system involving 9 anatomical sites
FMS	FAST-Modified Score to measure abdominal and thoracic fluid based on the Focused Assessment with Sonography for Trauma technique
FDA	Food and Drug Administration
GCP	Good Clinical Practice
ICF	Informed consent form
CVM	Center of Veterinary Medicine (FDA)
HEPES	N-(2hydroxyethyl) piperazine-N'-(2 ethane sulfonic acid)
IACUC	Institutional Animal Use and Care Committee
KCl	Potassium chloride
LCP	Lyophilized canine platelets

MAP	Mean arterial pressure
NaCl	Sodium chloride
NaHCO3	Sodium bicarbonate
NHP	Nonhuman primate
NZWR	New Zealand White Rabbit
QC	Quality Control
PI	Principal Investigator
PT	Prothrombin Time
SBP	Systolic blood pressure
SI	Shock Index
TA	Test Article
TGA	Thrombin Generation Assay
UABE	Unanticipated Adverse Biologic effect
VCM	ROTEM assay by Entegrion
WFI	Sterile Water for Injection USP

TITLE	**Clinical Trial in Support of Trauma Indications for Canine Lyophilized Blood Products**
Sponsor	BodeVet, Inc.
FUNDING ORGANIZATION	USAMRAA Contract W81XWH20C0067
NUMBER OF SITES	6 -10
RATIONALE	Hemorrhagic shock is a major cause of death in veterinary patients, particularly in cases of trauma. Based on mortality data from military and civilian studies, revised resuscitation guidelines emphasize use of platelets and plasma with minimized crystalloid resuscitation to significantly increase rates of survival following trauma. Many veterinary clinics and emergency care centers have a limited supply of canine blood products for immediate transfusion to stabilize emergent critical patients. Treatment of injured military, search and rescue, and police working canines further highlight these resource constraints as stabilization of these patients relies on the current standard of crystalloid resuscitation, a practice now recognized as harmful in human medicine. Canine freeze-dried platelets have been shown to significantly reduce bleeding in dogs and could be lifesaving for the treatment of trauma. The combination of freeze-dried platelets and freeze-dried plasma could advance canine trauma resuscitation efforts to human trauma standards. This study is designed to evaluate the administration of two lyophilized blood products, StablePlate RX® Canine (lyophilized canine platelets) and StablePlas™ Canine (lyophilized canine plasma) and their effects on hemodynamic stabilization following trauma, and to determine survival benefit when compared to current veterinary standard of care for trauma resuscitation.
STUDY DESIGN	This is a multicenter, randomized safety and efficacy study.
PRIMARY OBJECTIVE	To evaluate the efficacy of StablePlate RX® and StablePlas™ in clinical canine patients for the control of life-threatening hemorrhagic and hypovolemic shock secondary to trauma.
SECONDARY OBJECTIVE	To evaluate the feasibility of use for StablePlate RX® and StablePlas™, lyophilized blood products, in clinical canine patients for the control of life-threatening hemorrhagic and hypovolemic secondary to trauma.
NUMBER OF SUBJECTS	60 *includes all study sites
SUBJECT SELECTION CRITERIA	Inclusion Criteria: Canine patients will be evaluated and selected using standardized scoring systems, DOGiBAT, FMS and Animal Trauma Triage Score. Inclusion criteria include (1) Documented trauma such as blunt force injury, bone

	fractures, internal hemorrhage, or traumatic brain injury; (2) Presence of shock secondary to acute trauma as documented by a minimum of 2 of the following abnormalities: decline in body temperature < 100°, abnormal heart rate (>140bpm or <80bpm), elevated (>35 breaths per minute) respiratory rate with or without elevated respiratory exertion, prolonged capillary refill time >2 seconds, progressively dull mentation, lactate greater than 4 mmol/L; (3) Shock index of 1.3 or greater; ; (4) DOGiBAT score of "2" or greater and/or FMS score of "1 "or greater ; (5) ATT score of "3" or greater. Exclusion Criteria: Previous administration of blood products in the last 72 hours prior to enrollment in the study including whole blood, packed red blood cells, platelet rich plasma, platelet concentrate, fresh frozen plasma, frozen plasma. One single fluid bolus of balanced isotonic crystalloid at 10 mL/kg during initial trauma evaluation is accepted. Administration of crystalloid resuscitation therapy beyond 10 mL/kg or any synthetic colloid in the last 72 hours prior to enrollment in the study is cause for exclusion. Patient weight must be greater than 5kg and less than 60kg. Patient must not be currently undergoing treatment for congestive heart failure and/or primary hypertension. Patients that have undergone surgery within the preceding 48 hours of enrollment will be excluded.
EXPERIMENTAL GROUP A	StablePlate Rx® will be administered by single intravenous bolus injection at a dose of 1.5 x 10^9/kg followed by StablePlas™ administered by rapid infusion at a dose of 6 mL/kg at time point 0. Repeated dosage to support ongoing resuscitation is discussed below.
EXPERIMENTAL GROUP B	StablePlate Rx® ,the lyophilized platelet product, will be administered by single intravenous bolus injection at a dose of 1.5 x 10^9/kg at time point 0 followed by a balanced crystalloid at a dose of 6mL/kg. Repeated dosage to support ongoing resuscitation is discussed below.
EXPERIMENTAL GROUP C	StablePlas™ ,the lyophilized plasma product, will be administered by rapid intravenous bolus at a dose of 6 mL/kg at time point 0. Repeated dosage to support ongoing resuscitation is discussed below.
CONTROL GROUP	A balanced isotonic crystalloid will be administered at a dose of 10mL/kg by single intravenous bolus injection. Repeated dosage to support ongoing resuscitation is discussed below.

DURATION OF SUBJECT PARTICIPATION AND DURATION OF STUDY	Canine patients will be hospitalized and monitored for 24 hours after enrollment to the study. **Screening:** 0 timepoint (T0), 1 hour following the initiation of resuscitation (T1), 4 hours after the initiation of the initial resuscitation period (T4), and 24 hours post-resuscitation (T24). **Treatment:** Prior to or immediately following enrollment, first-line standard of care resuscitation with balanced crystalloid is allowed at a maximum dose of 10mL/kg during patient eligibility review and consent process. No platelet or plasma containing blood products nor colloidal fluids may be administered until patient is randomized. All patients enrolled will receive the same standard of medical care through the duration of study analysis as defined prior to study initiation. Once randomized to treatment group, patients may receive two doses of the randomized therapy. **Follow-up:** 30 days The total duration of the study is expected to be 15-18 months. 12-15 months for subject recruitment and 3 months for final subject follow-up and data capture.
CONCOMMITANT MEDICATIONS	Allowed at any time: Packed red blood cells (5 mL/kg), antifibrinolytic therapy; (ie, tranexamic acid), medications to control pain, anxiety, nausea and/or infection as deemed necessary by the primary clinician. Mannitol is permitted if required for suspected increased intracranial pressure. Allowed after T4: Other platelet and/or plasma containing blood products (stored whole blood, fresh plasma, platelet concentrate), routine supportive crystalloid or colloid fluid therapy per the enrolling clinician's guidance
Efficacy Evaluations	Prior to randomized therapy administration, investigators will record baseline data including vital signs (heart rate, respiratory rate and effort, pulse quality, mucous membrane color and quality, SI, pulse oximetry), CBC, biochemistry profile, lactate , pH(measured on iSTAT CG4 cartridge or equivalent), VCM and complete physical examination documenting trauma on a standardized record sheet. The modified DOGiBAT, Animal Trauma Triage Score (ATT) and FAST- Modified Score (FMS) will be provided for standardized assessment of trauma and response to treatment. Vital parameters including heart rate, respiratory rate and effort, pulse quality, mucous membrane color and quality, and SI will be measured every 15 minutes for the first 90 minutes during resuscitation and until SI is at or below 1.1 for greater than one hour; the time taken to achieve and sustain the target SI will be documented. Samples will be taken for VCM, PCV/TS and pH/lactate at thirty minutes and one hour after the initiation of resuscitation. Baseline, one, four- and twenty-four- hours post initiation of resuscitation clinicians will repeat the DOGiBAT, ATT, FMS, vital sign measurement, and serum and plasma samples will be processed and banked for PT/aPTT, D-dimer, and markers of endotheliopathy. CBC will be run at baseline, one, and twenty-four hours and biochemistry/electrolyte profile will be run at baseline and 24 hours post-initiation of resuscitation. At all study time points, a standardized data collection sheet will be used to record patient vital signs and diagnostic data.

Primary endpoint	• 6-hour mortality after presentation for emergent treatment and resuscitation
Secondary endpoints	• Time taken to reach a shock index of less than 1.1 for greater than 1 hour, amount of product required for resuscitation, total blood product usage, VCM at 1 hour, 4 hours and 24 hours after resuscitation initiation, 24-hour mortality, and 30-day mortality
Other Evaluations	Measured hematocrit, PT, aPTT, D-dimer, blood pH, lactate, VCM, modified DOGiBAT score, ATT Score, FMS, MAP, endotheliopathy markers, number of days in the hospital, and the cost of initial resuscitation efforts.
Safety Evaluations	Observation for evidence of volume overload, transfusion reaction, and normovolemic restoration will be performed every ten minutes during product administration and for twenty minutes afterwards. If the patient fails to demonstrate adequate hemodynamic improvement 15 minutes after initial product administration with a SI persisting at or above 1.1, a second dose of the randomized treatment may be administered and monitored as before. One hour after initial product administration, patients may enter the rescue protocol if SI is still 1.1 or greater and/or at clinician's discretion.
Planned Interim Analyses	When approximately 10% of the patients have completed the study, an interim analysis for safety will be conducted by an independent data monitoring committee. A secondary interim analysis to evaluate for efficacy will be performed after 80% of the patients have been enrolled. Serious adverse events will be monitored by the study coordinator on an ongoing basis throughout the study.

Purpose of the Study

Name of investigational biologic "Test Article"

StablePlate Rx®, StablePlas™

Intended Use of the investigational biologic "Test Article"

StablePlate Rx® and StablePlas™ will be used for control of life-threatening shock secondary to hemorrhage and trauma.

Objectives of the clinical investigation

Primary objective

To evaluate the efficacy of StablePlate RX® and StablePlas™ in clinical canine patients for the control of life-threatening hemorrhagic and hypovolemic shock secondary to trauma.

Secondary objective To evaluate the feasibility of use for StablePlate RX® and StablePlas™, lyophilized blood products, in clinical canine patients for the control of life- threatening hemorrhagic and hypovolemic secondary to trauma. Anticipated duration of the clinical investigation 15-18months

Detailed Protocol 2-2019-K9

Protocol number and title

2-2019-K9 Clinical Trial In Support of Trauma Indications for Canine Lyophilized Blood Products

Protocol version number and date

Version 3.5, 9Oct2020

Study Design

General study design

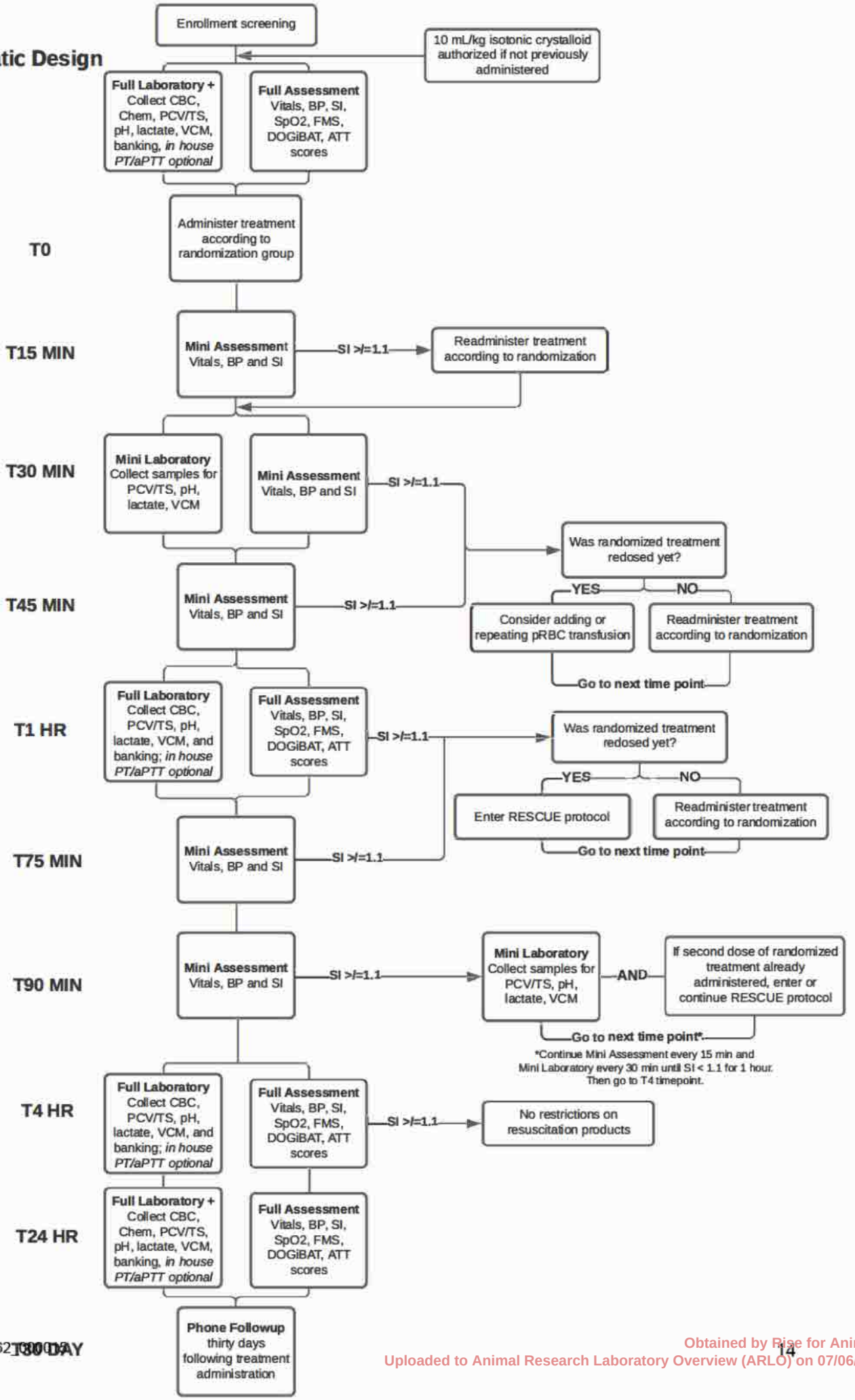
A randomized, controlled, multi-institutional clinical trial involving both private and academic veterinary practices.

Interventions

StablePlateRX® Canine: lyophilized allogeneic pooled canine platelet product

StablePlas™ Canine: lyophilized allogeneic pooled canine plasma product

Protocol Schematic Design



Subject selection

General characteristics of the proposed subject population(s)

Clinical patients presenting for acute traumatic injury such as blunt force trauma, penetrating injury, and/or traumatic brain injury with evidence of hemorrhage and shock secondary to trauma.

Anticipated number of research subjects

Fifteen (15) clinical patients will be selected for each arm of the study. This number was based on the ability to ensure an adequately powered study for efficacy determination.
The study involves 60 dogs randomized to receive one of four resuscitation strategies: StablePlate RX® and StablePlas™, StablePlas™, StablePlate RX® or veterinary standard of care resuscitation with balanced crystalloids. This sample size was selected utilizing a significance level of $p< 0.05$, an 80% chance or detecting a statistically significant difference, and a ratio of 1:1 between group assignments. Classical calculation of this sample size results in 15 dogs per group.

Inclusion criteria

Patient inclusion criteria which must be met include the following: (1) Presence of acute trauma (e.g. blunt force, penetrating. and/or traumatic brain injury and (2) Presence of shock secondary to acute trauma as documented by at least two of the following parameters: decline in body temperature < 100°, abnormal heart rate (<80bpm or >140bpm), elevated (>35 breaths per minute) respiratory rate with or without elevated respiratory exertion, prolonged capillary refill time >2 seconds, dull mentation, and/or blood lactate greater than 4 mmol/L. (3) Shock Index of 1.3 or greater is required in addition to two of the five physical parameters. (4) Hemorrhage is required for inclusion. Canine patients will be evaluated and selected using a multi-faceted standardized assessment form combining the modified DOGiBAT score, FAST modified score and the Animal Trauma Triage score. The modified DOGiBAT must be 2 or greater and/or the FMS must be 1 or greater. The ATT score evaluates the severity of trauma assessing 6 physiological systems assigning a score ranging from "0" (none) to "3" (severe), where each point increase in the score has a demonstrated decreased likelihood of survival. Dogs must score a “3” minimum overall score to be included in the study.

Exclusion criteria

Exclusion from the study is based on the criteria in Table 1.

Table 1 Exclusion Criteria for Patients

Exclusion items	Criteria for exclusion
Administration of platelet and/or plasma containing blood products	Patients may not receive platelet and/or plasma containing blood products within 72 hours of enrollment into the study –
Administration of fluid therapy outside of pre-determined volumes	Patients may not receive crystalloid fluid therapy in excess of 10 mL/kg balanced crystalloid bolus after traumatic event and prior to study enrollment. Patients may not receive any hypertonic saline nor colloidal fluid therapy prior to study enrollment.
Weight class	Patients must be greater than 5kg and less than 60 kg
Congestive heart failure, previously diagnosed hypertension, pulmonary hypertension	Patients currently treated for CHF or primary hypertension at the time of enrollment
Recent surgery	Patients may not have undergone surgery within the previous 48 hours

Study procedures

Screening procedures

PE
Shock Index
Modified DOGiBAT Bleeding
Score Animal Trauma Triage Score
FAST-Modified Score
APTT
PT
Fibrinogen
CBC
Biochemistry including electrolytes
Lactate
pH (venous)
SpO2
D-dimer
VCM
Markers of endotheliopathy

Safety guidelines allow a maximum of 12 mL/kg of blood collected from our case patients within 24 hours. Our protocol collects a standard total of 54.8 mL in 24 hours. Also allowed are additional blood draws totaling 4 mL between time points 1.5-3.5 hours of treatment for additional contingency testing (VCM, iSTAT, PCV/TP). This allows a maximum of 58.8 mL total blood volume collected within 24 hours.

Trial solution administration procedure

Administration of StablePlas™, StablePlate®, and supportive fluid therapy will occur through a patent peripheral catheter of 22 gauge or greater. See Appendix H and I for specific administration instructions.

Allocation of treatment

Subjects will be assigned to a treatment arm of the study by assignment through a Sealed Envelope

randomization scheme. However, to avoid time delay during critical resuscitation, randomization will be provided as prepared treatment packets labeled with a pre-assigned study number containing the randomization allocation from Sealed Envelope and all study forms will be provided to each study site. Upon study inclusion approval by the onsite clinical trial coordinator, treatment packets will be taken in numerical order and opened to receive randomization assignment. Additional treatment packets may not be opened to obtain a randomization to a different control arm, and the study sponsor will have a complete listing of the pre-assigned study randomizations and the coordinating randomization provided by Sealed Envelope.

Treatment adherence/Study compliance

Clinical records will be reviewed to evaluate for treatment adherence and study compliance.

Clinical patients may be removed from the study with permission from the clinical site coordinator. Clinical patients administered fluid therapy that deviates from the assigned study arm prior to the 4- hour time period data collection period will be excluded due to non-compliance.

If euthanasia occurs during the study period, the reason for euthanasia must be documented.

Follow Up Procedures

PE
Shock Index
Modified DOGiBAT Bleeding
Score Animal Trauma Triage Score
FAST-Modified Score
APTT
PT
CBC
Biochemistry including electrolytes
Lactate
pH (venous)
SpO2
D-dimer
VCM
Markers of Endotheliopathy

Procedures to assess safety

Safety will be evaluated based on incidence of adverse events associated with the administration of StablePlate Rx® and StablePlas™.

Schedule of activities (Study Table)

See Appendix A for a complete listing of study activities.

Study outcome evaluations

Study objectives

Evaluation for short-term safety and effectiveness of both StablePlate RX® and StablePlas™ will be

evaluated through a randomized, controlled evaluation comparing administration of each biologic alone, both biologics, or crystalloid fluid resuscitation following trauma and hemorrhage.

Efficacy endpoints will be based on improvement of modified DOGiBAT score and/or FMS score after administration, improvement of ATT score after administration, decrease in 6-hour mortality, decrease in time to achieve hemodynamic stability following product administration compared to control group, decrease in hospitalized stay, decrease in supplemental transfusion product administration and clinical improvement by observation.

Evaluation for long-term safety and effectiveness of both StablePlate RX® and StablePlas™ will be performed by examining 24-hour mortality and 30-day mortality.

Evaluation of feasibility as indicated by resuscitation success, cost and protocol compliance will be performed.

Study Endpoints

Primary: 1) A decrease in 6-hour mortality when compared to control. 2) A decrease in 24-hour mortality when compared to control. 3) Successful resuscitation as evidenced by improvement of Shock Index to less than 1.1.

Secondary: 1) Time taken to reach a Shock Index of less than 1.1, 2) Amount of transfusion product required for resuscitation, 3) Total blood product usage, 4) Improvement in hematocrit at 4 hours post enrollment, 5) Improvement of modified DOGiBAT score and/or FMS score at 4 hours post enrollment, 6) Improvement of ATT at 4 hours post enrollment, 7) Decrease in 6-hour mortality, 8) Decrease in time to achieve hemodynamic stability following test article administration compared to control group, 9) Decrease in hospitalized stay, 10) Decrease in supplemental transfusion product administration, 11) Clinical improvement by observation as evidenced by clinical PE, 12) Improvement of coagulation status as evidenced by VCM, PT, aPTT, D-Dimer and platelet count, and 13) The cost of initial resuscitation efforts.

Other: Improvement of endotheliopathy as indicated by markers (syndecan-1, thrombomodulin, hyaluronan)

Sample size determination

The study involves 60 dogs randomized to receive Stable Plate Rx® and StablePlas™, StablePlate RX® alone, StablePlas™ alone, or crystalloid fluid as the primary hemodynamic stabilizing fluid following trauma. This sample size was selected utilizing a significance level of $p < 0.05$, an 80% chance or detecting a statistically significant difference, and a ratio of 1:1 between group assignments. Classical calculation of this sample size results in 15 dogs per group.
Updates to the statistical plan and evaluation of the sample size will be made at the interim analysis time periods (10% enrollment and 80% enrollment)

RISK ANALYSIS

Anticipated potential risks

Incomplete restoration of hemodynamic stability due to ongoing losses.

To minimize this potential risk, a rescue protocol has been included for each group.

Possible increased risk of thrombosis secondary to administration of lyophilized platelet product.

To minimize this potential risk, the product has been evaluated prior to release for use for thrombin generation potential and microparticle formation. The results of thrombin generation and microparticle interrogations reveal an average endogenous thrombin potential (ETP) of 70 and microparticle percentage of 5% which is considered an acceptably low risk for an indication of potentially life-threatening hemorrhage.
Benefits of the lyophilized platelet product are considered: the ability to improve hemostatic competence in conjunction with resuscitation efforts in trauma.

Potential immune-mediated adverse reaction to the lyophilized plasma product.

To minimize this potential risk, the product has been produced utilizing DEA 1 negative donors that have been evaluated for plasma antibody to known DEA type. Prior to pooling for lyophilization, donors are evaluated by major and minor crossmatch utilizing all dogs in the production pool. Dogs will be closely monitored before, during and after administration of the product measuring temperature, pulse rate and quality, respiratory rate and character, mucous membrane color, and CRT for up to 6 hours after transfusion. Benefits of the lyophilized plasma product are considered to be: the ability to rapidly prepare and administer a dual-purpose product to restore both blood volume and hemostatic competence simultaneously.

Circulatory overload following administration of lyophilized plasma product, combined lyophilized platelet and plasma product, or overzealous crystalloid fluid administration.

Dogs in all treatment groups will be closely monitored for indications of circulatory overload including edema, chemosis, emesis, vocalization, and dyspnea.

Adverse event recording/reporting

Adverse event definitions

Adverse effect. Any untoward medical occurrence in a clinical study of an investigational biologic; regardless of the causal relationship of the problem with the biologic or, if applicable, other study treatment or diagnostic product(s).

Associated with the investigational biologic or, if applicable, other study treatment or diagnostic product(s). There is a reasonable possibility that the adverse effect may have been caused by the investigational biologics or, if applicable, the other study treatment or diagnostic product(s).

Disability. A substantial disruption of an animal's ability to conduct normal life functions.

Life-threatening adverse effect. Any adverse effect that places the subject, in the view of the investigator-sponsor, at immediate risk of death from the effect as it occurred (i.e., does not include an adverse effect that, had it actually occurred in a more severe form, might have caused death).

Serious adverse effect. Any adverse effect that results in any of the following outcomes: death, a life-threatening adverse effect, inpatient hospitalization or prolongation of existing hospitalization, a persistent or significant disability/incapacity.

Hospitalization. Shall include any initial admission (even if less than 24 hours) to a healthcare facility as a result of a precipitating clinical adverse effect; to include transfer within the hospital to an intensive care

unit. Hospitalization or prolongation of hospitalization in the absence of a precipitating, clinical adverse effect (e.g., for a preexisting condition not associated with a new adverse effect or with a worsening of the preexisting condition; admission for a protocol- specified procedure) is not, in itself, a serious adverse effect.

Unexpected adverse effect. Any adverse effect, the frequency, specificity or severity of which is not consistent with the risk information described in the clinical study protocol(s) or elsewhere in the current body of knowledge regarding the safety of this product.

Unanticipated adverse biologic effect. Any serious adverse effect on health or safety or any life-threatening problem or death caused by, or associated with, a biologic, if that effect, problem, or death was not previously identified in nature, severity, or degree of incidence in the investigational plan, or any other unanticipated serious problem associated with a biologic that relates to the rights, safety, or welfare of subjects.

Eliciting adverse effect information

Clinical study subjects will be routinely evaluated for adverse effects from the initial administration of randomized therapy and throughout hospitalization.

Recording and assessment of adverse effects

All observed or volunteered adverse effects (serious or non-serious) and abnormal test findings, regardless of treatment group, if applicable, or suspected causal relationship to the investigational biologic or, if applicable, other study treatment or diagnostic product(s) will be recorded in the subjects' case histories. For all adverse effects, sufficient information will be pursued and/or obtained so as to permit 1) an adequate determination of the outcome of the effect (i.e., whether the effect should be classified as a *serious adverse effect*) and; 2) an assessment of the casual relationship between the adverse effect and the investigational biologic or, if applicable, the other study treatment or diagnostic product(s).

Adverse effects or abnormal test findings felt to be associated with the investigational biologic or, if applicable, other study treatment or diagnostic product(s) will be followed until the effect (or its sequelae) or the abnormal test finding resolves or stabilizes at a level acceptable to the investigator-sponsor.

Abnormal test findings

An abnormal test finding will be classified as an *adverse effect* if one or more of the following criteria are met:

- The test finding is accompanied by clinical symptoms
- The test finding necessitates additional diagnostic evaluation(s) or medical/surgical intervention including significant additional concomitant drug or other therapy. (Note: simply repeating a test finding, in the absence of any of the other listed criteria, does not constitute an adverse effect.) The test finding leads to a change in study dosing or exposure or discontinuation of subject participation in the clinical study.

- The test finding leads to a change in study dosing or exposure or discontinuation of subject participation in the clinical study.
- The test finding is considered an adverse effect by the investigator- sponsor.

Causality and severity assessment

The investigator-sponsor will promptly review documented adverse effects (see Appendix L) and abnormal test findings to determine 1) if the abnormal test finding should be classified as an adverse effect; 2) if there is a reasonable possibility that the adverse effect was caused by the investigational biologic or if applicable other study treatment or diagnostic product(s); and 3) if the adverse effect meets the criteria for a *serious adverse effect*.

If the investigator-sponsor's final determination of causality is "unknown and of questionable relationship to the investigational biologic or, if applicable, other study treatment or diagnostic product(s)", the adverse effect will be classified as associated with the use of the investigational biologic or study treatment or diagnostic drug product(s) for reporting purposes. If the investigator-sponsor's final determination of causality is "unknown but not related to the investigational biologic or, if applicable, other study treatment or diagnostic product(s)", this determination and the rationale for the determination will be documented in the respective subject's case history.

Reporting of adverse effects to the FDA

The investigator-sponsor will submit a completed Adverse Effect Form (Appendix L) to the FDA for any observed or volunteered adverse effect that is determined to be an *unanticipated adverse biologic effect*. A copy of this completed form will be provided to all participating clinical site coordinators.

The completed form will be submitted to the FDA as soon as possible and, in no event, later than 30 working days after the investigator-sponsor first receives notice of the adverse effect.

If the results of the sponsor-investigator's follow-up evaluation show that an adverse effect that was initially determined to not constitute an *unanticipated adverse biologic effect* does, in fact, meet the requirements for reporting; the investigator-sponsor will submit a completed form as soon as possible, but in no event later than 10 working days, after the determination was made.

For each submitted form, the sponsor-investigator will identify all previously submitted reports that that addressed a similar adverse effect experience and will provide an analysis of the significance of newly reported adverse effect in light of the previous, similar report(s).

Subsequent to the initial submission of a completed form the investigator-sponsor will submit additional information concerning the reported adverse effect as requested by the FDA.

Reporting of adverse effects to the responsible IACUC

In accordance with applicable policies of the Institutional Animal Care and Use Committee (IACUC) for the clinical sites, the investigator-sponsor will report, to the IACUC, any observed or volunteered adverse effect that is determined to meet all of the following criteria: 1) associated with the investigational biologic or, if applicable, other study treatment or diagnostic product(s); 2) a serious adverse effect; and 3) an unexpected adverse effect. Adverse event reports will be submitted to the IACUC in accordance with the respective IACUC procedures.

Applicable adverse effects will be reported to the IACUC as soon as possible and, in no event, later than 30 calendar days following the investigator-sponsor's receipt of the respective information. Adverse effects which are 1) associated with the investigational drug or, if applicable, other study treatment or diagnostic product(s); 2) fatal or life-threatening; and 3) unexpected will be reported to the IACUC within 24 hours of

the investigator-sponsor's receipt of the respective information.

Follow-up information to reported adverse effects will be submitted to the IACUC as soon as the relevant information is available. If the results of the sponsor-investigator's follow-up investigation show that an adverse effect that was initially determined to not require reporting to the IACUC does, in fact, meet the requirements for reporting; the investigator-sponsor will report the adverse effect to the IACUC as soon as possible, but in no event later than 10 calendar days, after the determination was made.

Withdrawal of subjects for treatment failure

This study design allows for multiple administrations of StablePlate Rx®, StablePlas™, or crystalloid fluid resuscitation based on clinical evaluation of patients for the first 24 hours of the study. Clinical patients may be transfused with platelet and plasma containing products including whole blood, stored blood, plasma and fresh platelet concentrate after T1 (one-hour post administration of randomized therapy) if the clinician determines hemorrhage control to be inadequate or ongoing (see Appendix L, Rescue Protocols). This does not exclude the subjects from the data set.

Administration of packed red blood cell units is allowed at any time point of the study based on clinician evaluation. Surgical intervention for hemorrhage control (i.e. exploratory laparotomy/thoracotomy) may be performed after T1 data collection and will not exclude subjects from the data set.

DESCRIPTION OF THE INVESTIGATIONAL BIOLOGIC

StablePlate RX® is a dry white powder composed of canine polled platelets and trehalose/polysucrose buffer. See Appendix H.

StablePlas™ is a dry white powder composed of canine pooled plasma. See Appendix I.

MONITORING PROCEDURES

Monitoring of the clinical study for clinical protocol compliance will be conducted periodically by the qualified staff of the study sponsor (BodeVet Inc.).

The clinical site coordinators will permit direct access to the study monitors and appropriate regulatory authorities to the study data and the corresponding source data and documents to verify the accuracy of these data.

LABELING

Refer to Labeling detail in Appendix B.

CONSENT MATERIALS

Refer to Form for Client Consent in Appendix C.

ANIMAL WELFARE INFORMATION

Refer to individual clinical sites for specific IACUC (animal welfare and ethics) information. Appendix D includes the approved protocols from each institutional review.

ADDITIONAL RECORDS AND REPORTS

Data handling and record-keeping

A Case Report Form (CRF, see Appendix K) will be completed for each subject enrolled into the clinical study. The investigator-sponsor will review, approve and sign/date each completed CRF; the investigator-sponsor's signature serving as attestation of the investigator-sponsor's responsibility for ensuring that all clinical and laboratory data entered on the CRF are complete, accurate and authentic.

A Critical Care Form (CCF, see Appendix F) will be completed for each subject enrolled into the clinical study during the initial resuscitation period. The investigator-sponsor will review, approve and sign/date each completed CCF; the investigator-sponsor's signature serving as attestation of the investigator-sponsor's responsibility for ensuring that all clinical and laboratory data entered on the CCF are complete, accurate and authentic.

The sponsor's internal quality assurance department will evaluate records for completeness. Clinical site project coordinators will be responsible for providing a complete record on each study subject for review.

Record maintenance and retention

The investigator-sponsor will maintain records in accordance with Good Clinical Practice guidelines; to include:

- FDA correspondence related to the transfusion biologic and investigational Plan; including copies of current investigator lists, progress reports, notice of biologic recall or disposition, and failure to obtain informed consent reports;
- IACUC or animal welfare correspondence (including approval notifications) related to the clinical protocol; including copies of adverse event reports and annual or interim reports;
- Current and past versions of the -approved clinical protocol and corresponding approved consent form(s) and, if applicable, subject recruitment advertisements.
- Signed Investigator's Agreements and Certifications of Financial Interests of Clinical Investigators;
- Curriculum vitae (investigator-sponsor and clinical site coordinators) Certificates of required training (e.g. DOGiBAT) for investigator-sponsor and listed clinical site coordinators;
- Normal value(s)/range(s) for medical/laboratory/technical procedures or tests included

in the clinical protocol;

- Laboratory certification information if available
- Instructions for on-site preparation and handling of the investigational biologics and/or study treatment or diagnostic product(s), and other study-related materials (i.e., if not addressed in the clinical protocol);
- Master randomization list
- Signed informed consent forms (see Appendix C)
- Completed Case Report Forms; signed and dated by investigator-sponsor (Appendix K)
- Completed Critical Care Forms; signed and dated by investigator-sponsor (Appendix F)
- Copies of investigator-sponsor correspondence to clinical site coordinators, including notifications of adverse effect information;
- Subject screening and enrollment logs;
- Investigational biologic accountability records, including documentation of biologic disposal
- Retained biological specimen log;
- Final clinical study report

The investigator-sponsor will retain the specified records and reports for up to 2 years.

APPENDICES

Appendix A: STUDY ACTIVITIES

Physical examination

The physical examination will include a general body score, mental status, temperature, blood pressure, pulse and respiration with pulse oximetry. Weight in kilograms will also be included.

Modified DOGiBAT bleeding score modified

The bleeding score assessment will be performed using the standard scoring card provided.

Animal Trauma Triage score

The trauma score assessment will be performed using the standard scoring card provided.

CBC

A complete blood count will be performed using the standard in-house analyzer.

Biochemistry

A standard biochemistry including electrolytes using the standard in house analyzer

FAST Modified Score

The fluid score assessment will be performed using ultrasonography measuring the presence/absence of abdominal and thoracic fluid using the generated scoring card provided.

PT

Evaluation of prothrombin time using standard in house methodology.

pOX

Evaluation of pO2 as determined by pulse oximetry.

APTT

Evaluation of activated prothrombin time using standard in house methodology.

VCM

A standard thromboelastography will be performed using dry viscoelastic methodology (VCM by Entegrion).

Appendix B: Labelling Test Article

STABLEPLATE RX CANINE

StablePlate RX® Canine

Lyophilized Canine Platelets for Intravenous Administration

1.5 x 10^{10} particle count/vial

Rehydration concentration 1.8 x 10^{9} particle count/mL

CAUTION: This drug is to be used by or on the order of a licensed veterinarian. Not for use in human

LOT#: _____ Date of Expiration: _____

--001

STABLEPLAS CANINE

StablePlas™ Canine

Lyophilized Canine Plasma for Intravenous Administration

250ml

CAUTION: This drug is to be used by or on the order of a licensed veterinarian

DOSING INSTRUCTIONS: 6 mL/kg by IV administration

LOT#: _____ Date of Expiration: _____

--001

APPENDIX C Example patient consent form

Title of clinical study: EVALUATION OF STABLE PLATE RX® AND STABLEPLAS™ IN CANINE TRAUMA PATIENTS: A MULTICENTER CLINICAL TRIAL

1. Title of clinical study: EVALUATION OF STABLE PLATE RX® AND STABLEPLAS™ IN CANINE TRAUMA PATIENTS: A MULTICENTER CLINICAL TRIAL

2. Investigator(s) Name and Contact Information: INSERT CLINICIAN AND HOSPITAL

3. Why is this clinical study being done and why is my dog being invited to takepart?

   Your dog has presented with significant trauma requiring emergency care and stabilization. While our hospital staff is already diligently working to stabilize your pet, trauma in dogs can be life-threatening when there is severe bleeding or significant head trauma. Obtaining sufficient blood products to treat trauma on an emergency basis can be challenging in veterinary hospitals due to the short shelf life and specialized storage needed to accommodate traditional dog blood products, including platelets and plasma. We are therefore interested in finding platelet and plasma products that can be stored for extended periods of time at room temperature and will quickly and efficiently stabilize dogs suffering from traumatic injury to improve the care offered in veterinary hospitals.

   This clinical trial will evaluate the early application of a novel commercial freeze-dried platelet product (StablePlate RX®) and freeze-dried plasma product (StablePlas™) against the current standard of care for trauma management and stabilization. These new products are derived from dog platelets or plasma donated by healthy canine donors. The products have undergone extensive pre-clinical testing on healthy dogs and are deemed safe to administer. These are the SAME blood products that your dog would likely receive for severe bleeding in trauma, only in a freeze-dried, readily available form. We are testing the use of these products to determine if they are superior to the current standard of care in canine trauma in an effort to improve survival outcomes and decrease the time and cost to stabilize canine patients following significant trauma.

4. If I choose to enroll my dog in this clinical study, what will happen to my dog, what will my time commitment be, and what are my responsibilities?

   We will perform diagnostic tests and administer treatments as for any other dog suffering from significant trauma in accordance with the current standards of care for canine trauma stabilization.

   Your dog will be randomly assigned to one of three treatment arms of the study or a CONTROL group. Group A will receive StablePlate RX and StablePlas. Group B will receive StablePlate RX and a balanced isotonic crystalloid and Group C will receive StablePlas. The CONTROL group will received balanced isotonic crystalloid considered the current standard of care.

   Your dog will continue to receive supportive care of trauma management in the form of fluid support, pain control and primary injury management in accordance with the study protocol.

We will perform standardized evaluation of your dog before administering the products, monitor your dog every 15 minutes for the first 90 minutes during and after product administration to check for response to treatment, and then repeat the standardized evaluation 1 hour, 4 hours, 24 hours post-product administration (in addition to any other necessary evaluations as determined by the doctor in charge). These assessments will involve physical examination, focused ultrasound assessment, bleeding time tests and collection of blood samples for laboratory analysis.

- Your dog may receive multiple transfusions of the StablePlate RX® or StablePlas™ product. Your dog's doctor will know which products are being administered but will not be able to change the group to which your dog has been randomly assigned. Your dog's doctor has also been provided with a "rescue" protocol to ensure that if you dog fails to respond to the treatments specified by the group assignment, other resuscitation options will be available to ensure the best level of care.

- Your time commitment will be limited to answering some questions about your dog during a follow-up telephone call at 30-days post-administration.

5. What happens if I do not want to enroll my dog, or I enroll my dog, but I change my mind later?

- Participation in this study is voluntary. If you decide not to participate, your choice will not affect your dog's current or future medical care. We fully understand and support your decision.

- If you choose to participate, we will communicate with you throughout the study and tell you about any significant findings that may affect your willingness to continue participating.

- You can remove your dog from the study at any time. Please let us know if you decide to remove your dog from the study. Data we have already collected to that point may be included in the study.

6. What are the benefits for my dog or other dogs?

Your dog may benefit through the administration of platelet and/or plasma transfusion products that can limit ongoing bleeding and help your dog to stabilize following the trauma suffered, with potentially life-saving benefits. These products will be provided at no cost to you. In addition, the results of the additional diagnostic testing conducted as part of the study, at no cost to you, will be made available to your dog's doctor, which may aid in the management of your dog's condition. Other dogs may benefit from the results of this study through the generation of new knowledge and evaluation of new products for use in dogs. If the study demonstrates that the novel StablePlate RX® and StablePlas™ have superior results in patient response to treatment following trauma compared to the current standard of practice, this new treatment is likely to become available for the management of all dogs with bleeding secondary to severe trauma. This may prove lifesaving for other dogs including military and police working dogs that are at high risk of trauma. .

7. Are there any risks in participating in this clinical study?

The novel products have undergone pre-clinical testing on healthy dogs. In addition, the platelet product, StablePlate RX®, has been commercially available for use in dogs since September 2017. Your dog will be receiving the current standard of care for trauma management through the duration of the study, and the administration of life-saving medications or procedures will not be withheld in favor of the study outside of safe application guidelines provided for use of these new products.

These new products have demonstrated efficacy in reducing bleeding in pre-clinical models and clinical patients. If your dog fails to respond to the new treatment, then your dog's doctor can administer supplemental alternative treatments such as fresh whole blood to reduce bleeding. The principal potential risk is those associated with bleeding time assessments and blood sampling (bruising, discomfort at the sampling site, skin irritation). Every effort will be taken to minimize these risks. If you believe your dog becomes injured, ill or appears uncomfortable while participating in the study, please contact the investigator listed on the first page of this form. Emergency medical advice and therapy will be provided for your dog according to the hospital's standard procedures and fee structures.

8. Can my dog be removed from the study without my permission?

   Yes. If it is in the best interest of your dog or the study, investigators may prevent your dog from continuing to participate. Study investigators will explain why your dog was removed from the study. Compensation until the point of study removal is not compromised by this action.

9. What happens to the information collected for the clinical study?

   All information collected will become part of the medical record and may be used by the veterinary clinician to direct clinical care. All identifying client and animal details will be confidential for the study. Data resulting from the study will become the property of the veterinary hospital, but will be shared with BodeVet Inc., the study sponsor, with the exception of financial data. Specimens collected may be used in future research and may be shared with other organizations or commercial entities.

10. What about costs? What about benefits?

    Your involvement in the study will not cost you anything additional. The following study costs are supported by BodeVet Inc., study sponsor:
    - StablePlate RX®, StablePlas™, packed red blood cells (up to 2 doses), crystalloid
    - Blood tests including complete blood count, serum chemistry panel, and coagulation testing, up to 3 times
    - A $500.00 credit applied to your total veterinary bill associated with the first 24 hours of care..

    The following costs are <u>not</u> covered by the study: any additional blood testing recommended by the doctor treating your dog on any day of hospitalization, the cost of hospitalization, surgery, general anesthesia, sedation, supportive care beyond the initial 12 hour stabilization period (including oxygen therapy, fluid therapy, other blood transfusions, etc.), drugs such as pain medications and antibiotics, imaging (including radiographs, ultrasound, CT, MRI), microbiological tests, histological or clinicopathological testing. Any tests or procedures unrelated to the study are your responsibility.

11. Is there anything else I should know?

    This study is sponsored by: BodeVet, Inc.
    9210 Corporate Blvd.
    Suite 310
    Rockville, MD 20850
    240-408-8060 (phone)
    support@bodevet.com

12. Who can I talk to if I have questions?

If you have any questions or concerns, please contact the clinical investigator as stated above. If your dog needs medical assistance, please contact the investigator or your attending clinician. Seek emergency medical advice as needed.

CONSENT:

By signing below, I certify that I am the legal owner or owner's agent of the dog described below. I understand that I will receive no compensation other than that described above. I agree that I am financially responsible for all other costs associated with my dog's treatment and care. I further agree to hold the named Clinical Investigator and associated facility, the study sponsor, and their representatives, harmless for liability during study participation. have been given the opportunity to ask all questions that Icurrently have regarding this study and they have been answered to my satisfaction. I agree to permit my dog to participate in this clinical study and undergo the procedures described to me above. I understand the statements in this informed consent document and that a signed and dated copy of the consent form will be given to me. I recognize that StablePlate RX® and StablePlas™ are experimental products and that efficacy has not been defined.

Signature of Owner	Printed Name of Owner	Date

Contact Investigator Use Only:

1st Witness Signature	Printed Name	Date

This work is supported by the U.S. Army Medical Research and Development Command under Contract No. W81XWH20C0067.

APPENDIX D IACUC Approvals from Clinical Sites

Protocol 2-2019-K9

Complications since discharge:

CRITICAL CARE FORM

PATIENT NAME								**OWNER NAME**										
PATIENT ID								**PROBLEM LIST**										
DVM NAME								**INSTRUCTIONS:** Highlighted areas are mandatory evaluations/tests. The shaded "C" indicates contingency – *ONLY perform these tasks if SI is >/=1.1* . For laboratory tests, please simply initial that the sample was collected and enter data on CRF.										
TIME (clinician insert times)																		
Assessment	**0**	**0.25 HR**	**0.5 HR**	**0.75 HR**	**1 HR**	**1.25 HR**	**1.5 HR**	**1.75HR**	**2 HR**	**2.25 HR**	**2.5 HR**	**2.75HR**	**3 HR**	**3.25 HR**	**3.5 HR**	**3.75 HR**	**4 HR**	**24 HR**
Weight (kg)																		
Temp									C				C					
HR/PQ								C	C	C	C	C	C	C	C	C		
RR/RE								C	C	C	C	C	C	C	C	C		
MM/CRT								C	C	C	C	C	C	C	C	C		
SBP								C	C	C	C	C	C	C	C	C		
SI (HR/SBP)								C	C	C	C	C	C	C	C	C		
SpO2																		
FMS									C				C					
DOGiBAT									C				C					
ATT									C				C					
Laboratory (in order of tube fill)																		
Banked Patient Plasma 2x 2.7 mL BTT																		
Banked Patient Serum 4 mL RTT																		
Chemistry (Use RTT above)																		
CBC 2 mL LTT																		
VCM 0.3 mL WB							C		C		C		C		C			
iSTAT CG4+ 0.3 mL WB							C		C		C		C		C			
PCV/TS 0.2 mL WB							C		C		C		C		C			
PT/aPTT (optional) 1.8 mL BTT																		
TOTAL DRAW VOLUME (mL)	14		0.8		14		0.8		0.8		0.8		0.8		0.8		12	14

Appendix F DOGiBAT, ATT and FAST-modified Score Cards

Modified CANINE DAILY BLEEDING ASSESSMENT TOOL (DOGiBAT)

CASE ID:_____

Site	Bleeding Grade			Score given Enter Grade OR X = not collected			
	0	1	2	T0	T1H	T4H	T24H
Skin	No	Petechiae/ecchymosis single site	Petechiae/ecchymosis >1 site				
Catheter/venipuncture/ other cutaneous	No	Self-limiting/<5 min	>5 min and/or intervention to control				
Oral mucosa	No	Petechiae	Frank hemorrhage				
Intraocular	No	Fundoscopic	Hyphema				
Epistaxis	No	Unilateral and <5 min	Bilateral or >5 min				
GI	No		Hematemesis, hematochezia, melena				
Urinary	No		Macroscopic				
Pulmonary (suspected/observed)	No	N/A	Yes				
Intracranial hemorrhage (suspected/observed)	No	N/A	Yes				
Total score (max = 18)							

_____

_____

_____

_____

_____

ANIMAL TRAUMA TRIAGE SCORE

CASE ID: _____

Site	Trauma Grade				Score Given			
	0	**1**	**2**	**3**	T0	T1H	T4H	T24H
Perfusion	MM pink/moist, CRT 2 sec, T ≥100F, strong or bounding femoral pulse quality	MM hyperemic or pale pink, MM tacky, T ≥ 100F, CRT 0-2 sec, fair remoral pulses	MM very pale pink and tacky, CRT 2-3 sec, T < 100F, non-palpable femoral pulses	MM gray/blue/white, CRT >3 sec, T <100F, non-palpable femoral pulses				
Cardiac	HR 60-140 bpm, normal sinus rhythm	HR 140-180 bpm, NSR or VPC < 20/min	HR >180, consistent arrhythmia	HR <60, erratic arrhythmia				
Respiratory	Regular resp rate with no stridor, no abdominal component	Mild inc resp rate and eff, ±abd comp, mild upper airway sounds	Mod inc resp rate and effort, some abd comp, elbow abduct, mod inc upper airway	Marked resp effort or gasping/agonal resp, little/no air passage				
Eye/Muscle /Integ	Abrasion/laceration – none or partial thickness, no ocular fluorescein uptake	Abrasion/laceration – full thickness No deep tissue Eye – corneal lac not perf	Abrasion/laceration – full thickness, deep tissue inv, art/nerve/muscle intact Eye: corneal perf, punctured globe or proptosis	Penetration of abdomen/thorax Abrasion/laceration full thickness, deep tissue inv, artery/nerve/muscle compromised				
Skeletal	Wt bearing 3 or 4 limbs No palpable fx/jt laxity	Closed limb fx/rib fx or any mandibular fx Single jt laxity/lux (including SI) Pelvic fx with unilateral intact SI-ilium-acetabulum Single limb open/closed fx at or below carpus/tarsus	Multiple grade 1 conditions, single long bone open fx above carpus/tarsus with cortical bone preserved Non-mandibular skull fx	Vertebral body fx/luxation except coccygeal, multiple long bone open fx above tarsus/carpus, single long bone open fx above tarsus/carpus with loss of cortical bone				
Neurologic	C: conscious, alert to sl dull, interest in surrounding P: normal spinal reflexes, purposeful mvmt and nociception in all limbs	C: dull/depressed/withdrawn P: abn spinal reflexes with purposeful mvmt and nociception intact in all 4limbs	C: unconscious, respond to noxious stimuli P: absent purposeful mvmt with intact nociception in 2 or more limbs or nociception absent in 1 limb, decr anal or tail tone	C: non-responsive to all stimuli, refractory seizures P: absent nociception in 2 or more limbs, absent tail or perianal nociception				

Score 0-3 (3=most severe) for each of the listed categories. Add all scores together for total ATT score.
Journal of Veterinary Emergency and Critical Care. 2007;4(2)77-83.

FAST-Modified Score

Case ID: _____

Site	Fluid Grade (0 = negative, 1 = positive)			
	T0	T1h	T4h	T24h
Diaphragmatic-hepatic				
Spleno-renal				
Cysto-colic				
Hepato-renal				
Pleural fluid				
Pericardial fluid				
Total Score				

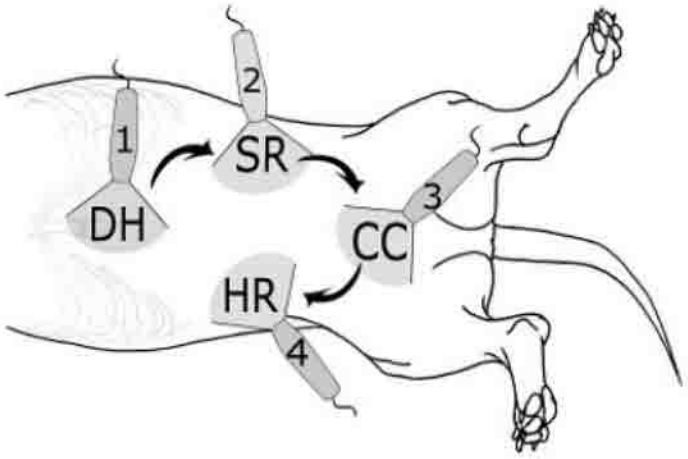


Figure 2: Depiction of the 4-point abdominal focused assessment with sonography for trauma, triage and tracking (AFAST), protocol performed in right lateral recumbency beginning at the diaphragmatico-hepatic (DH) view, followed by the spleno-renal view (SR), the cysto-colic view (CC), and completed at the hepato-renal view (HR). Direction (arrows) and order of AFAST exam (numbered ultrasound probes) are illustrated.

Journal of Veterinary Emergency and Critical Care 21(2) 2011, pp 104–122

Appendix G Administration of StablePlate RX

ADMINISTRATION OF STABLEPLATE RX®

DESCRIPTION: A sterile non-pyrogenic white to off-white freeze-dried powdered cake containing a derivative of canine platelets. When reconstituted according to label instructions the resulting white suspension has a final particulate concentration of 1.5 x 10^{10} particles per 8ml vial. Rehydrated material contains HEPES, NaCl, KCl, Dextrose, NaHCO3, trehalose, ethanol and polysucrose.

INDICATION: An intravenous administration developed for the treatment of acute uncontrolled hemorrhage in bleeding patients secondary to thrombocytopenia.

REHYDRATION INSTRUCTIONS:

1. Draw 8ml of sterile water for injection (WFI) into a sterile syringe and needle.
2. Insert the supplied sterile clave in a clean manner via the rubber seal of the dehydrated product vial.
3. Remove the needle used to draw up the WFI and attach the syringe of WFI to the sterile clave
4. Inject the sterile water slowly directing the stream of liquid against the glass side of the vial rather than directly into the cake, allowing the cake to become immersed in the solution.
5. Gently mix by swirling the vial for 5 seconds to rehydrate the cake. Do not SHAKE or FOAM.
6. Allow the rehydrated solution to sit for approximately 3 minutes before use.
7. Ensure the product does not have large particles or aggregates.
8. If large particles or aggregates are observed, swirl for another 5 seconds and allow to sit for 5 minutes before use
9. Draw calculated dose into a sterile syringe using the needle-free sterile clave port.
10. DO NOT USE HYPERTONIC SOLUTIONS for rehydration.

DOSING INSTRUCTIONS:

The dose is 1.5 x 10^9 particles per kg bodyweight (0.8ml of reconstituted solution per kg).

1. Administer through a catheter system greater than or equal to 22 gauge.
2. Give as a slow intravenous bolus at 1 mL/min.
3. Do not mix with other products or solutions.
4. Do not use a blood filter for administration
5. Flush catheter with an appropriate amount of saline after administration.
6. A syringe driver can be used for administration.

CONTRAINDICATIONS, WARNINGS etc.

For Use only in Dogs. Not for use in humans. Keep out of Reach of Children. Only to be administered to animals under the care of a veterinary surgeon.

The safe use of StablePlate RX® has not been evaluated for use in animals under 9 months of age or during pregnancy. Good Laboratory Practice (GLP) acute toxicity studies in New Zealand White rabbits (NZWR) and canines have found no definitive product related toxicities.

Any potential suspected adverse event associated with administration of the product acute or delayed should be reported as soon as possible to [redacted] DVM, [redacted]@bodevet.com or [redacted] Do not use after the expiry date on the carton. Unopened vials should be stored at room temperature (18°- 30°C). This product should be utilized immediately after rehydration. The rehydrated product is not considered active beyond 4-hour post-rehydration.

DO NOT REFRIGERATE OR FREEZE. Any unused product should be disposed of as clinical waste.

PACKAGING QUANTITES:

8ml vial, in a single carton.

APPENDIX H Administration of StablePlas CANINE

ADMINISTRATION OF STABLEPLAS™ CANINE

DESCRIPTION: A sterile non-pyrogenic white to off-white freeze-dried powder containing canine plasma. When reconstituted according to label instructions the resulting white suspension. Rehydrated material contains canine plasma.

INDICATION: StablePlas, a pooled allogeneic plasma product, may be used to supplement coagulation factors in dogs or replace lost or nonfunctional clotting factors in dogs.

REHYDRATION INSTRUCTIONS (120ml):

1. Draw 112 ml of sterile water for injection (WFI) into a sterile syringe and needle.
2. Insert needle in a clean manner via the rubber seal on the injection port of the dehydrated product vial.
3. Inject the sterile water slowly directing the stream of liquid against the wall of the container rather than directly into the powder, allowing the powder to become immersed in the solution.
4. Gently mix by swirling the container for 5 seconds to rehydrate the powder. Do not SHAKE or FOAM.
5. Allow the rehydrated solution to sit for approximately 5 minutes before use.
6. Ensure the product does not have large particles or aggregates.
7. If large particles or aggregates are observed, swirl for another 5 seconds and allow to sit for 5 minutes before use.
8. Break the seal on the infusion line, and allow the line to fill with plasma.
9. DO NOT USE HYPERTONIC SOLUTIONS for rehydration.

REHYDRATION INSTRUCTIONS (250ml):

1. Draw 224 ml of sterile water for injection (WFI) into a sterile syringe and needle.
2. Insert needle in a clean manner via the rubber seal on the injection port of the dehydrated product vial.
3. Inject the sterile water slowly directing the stream of liquid against the wall of the container rather than directly into the powder, allowing the powder to become immersed in the solution.
4. Gently mix by swirling the container for 5 seconds to rehydrate the powder. Do not SHAKE or FOAM.
5. Allow the rehydrated solution to sit for approximately 5 minutes before use.
6. Ensure the product does not have large particles or aggregates.
7. If large particles or aggregates are observed, swirl for another 5 seconds and allow to sit for 5 minutes before use.
8. Break the seal on the infusion line, and allow the line to fill with plasma.
9. DO NOT USE HYPERTONIC SOLUTIONS for rehydration.

DOSING INSTRUCTIONS:

The dose is 6 mL of reconstituted solution per kg bodyweight.

1. Administer through a catheter system greater than or equal to 22 gauge.
2. Give as a rapid infusion.
3. Do not mix with other products or fluid solutions.
4. Use only the in-line provided blood filter for administration; do not attach additional blood filters to the infusion set.
5. Flush catheter with an appropriate amount of saline after administration.

6. A syringe driver can be used for administration.

CONTRAINDICATIONS, WARNINGS etc.

For Use only in Dogs. Not for use in humans. Keep out of Reach of Children. Only to be administered to animals under the care of a veterinary surgeon.

The safe use of StablePlas™ has not been evaluated for use in animals under 9 months of age or during pregnancy.

Good Laboratory Practice (GLP) acute toxicity studies in New Zealand White rabbits (NZWR) and canines have found no definitive product related toxicities.

Any potential suspected adverse event associated with administration of the product acute or delayed should be reported as soon as possible to [redacted] DVM a [redacted]@bodevet.com or [redacted]

Do not use after the expiration date on the carton. Unopened product should be stored at refrigerated temperature (0°- 8°C). This product should be utilized immediately after rehydration. The rehydrated product should be refrigerated if not utilized within 4 hours of rehydration. Product once rehydrated and stored in refrigerated temperature has an expiration of 7 days.

Any unused product should be disposed of as clinical waste.

PACKAGING QUANTITES:

250 mL bag, in a single carton.

APPENDIX I Rescue Protocols

GROUP A RESCUE PROTOCOL

The patient should be monitored in 15-minute increments; should the patient fail to respond with an improvement in Shock Index (SI remaining >/=1.1) and vital parameters 15 minutes following completion of the first administration of product, repeated dosing is indicated per the study protocol. Packed red blood cells (pRBC) may be administered at any point during the study via a second intravenous catheter per clinician assessment of patient need.

If the patient continues to display indications of hemorrhagic and/or hypovolemic shock (SI remaining >/=1.1) **one hour** after initiation of Group A dosing and despite repeated administration of test products/pRBC as clinically indicated, the rescue protocol for study group A may be initiated.

1. Repeat standardized assessment of the patient utilizing DOGiBAT, ATT, and FMS if surgical exploration of the patient is warranted to address uncontrolled hemorrhage, surgery may be performed at this time.
2. The patient may receive stored whole blood or fresh whole blood with ongoing access to lyophilized plasma and lyophilized platelets for one additional dose.
3. The patient may receive standard of care including isotonic or hypertonic crystalloids or colloid (natural or synthetic) at the clinician's discretion.

After the T4 timepoint (4 hours after enrollment), all patients are eligible for standard of care transfusion therapy as directed by the clinician.

GROUP B RESCUE PROTOCOL

The patient should be monitored in 15-minute increments; should the patient fail to respond with an improvement in Shock Index (SI remaining >/=1.1) and vital parameters 15 minutes following completion of the first administration of product, repeated dosing is indicated per the study protocol. Packed red blood cells (pRBC) may be administered at any point during the study via a second intravenous catheter per clinician assessment of patient need.

If the patient continues to display indications of shock (SI remaining >/=1.1) **one hour** after the initiation of Group B protocol and despite repeated administration of test product and pRBC as clinically indicated, the rescue protocol for study group B may be initiated.

1. Repeat standardized assessment of the patient utilizing DOGiBAT, ATT, and FMS if surgical exploration of the patient is warranted to address uncontrolled hemorrhage, surgery may be performed at this time.
2. The patient may receive stored whole blood or fresh whole blood along with one additional dose of lyophilized platelets
3. The patient may receive one dose of StablePlas.
4. The patient may receive standard of care including isotonic or hypertonic crystalloids or colloid (natural or synthetic) at the clinician's discretion.

After the T4 timepoint (4 hours after enrollment), all patients are eligible for standard of care transfusion therapy as directed by the clinician.

GROUP C RESCUE PROTOCOL

The patient should be monitored in 15-minute increments; should the patient fail to respond with an improvement in Shock Index (SI remaining >/=1.1) and vital parameters 15 minutes following completion of the first administration of product, repeated dosing is indicated per the study protocol. Packed red blood cells (pRBC) may be administered at any point during the study via a second intravenous catheter per clinician assessment of patient need.

If the patient continues to display indications of shock (SI remaining >/=1.1) **one hour** after the initiation of Group C protocol and despite repeated administration of test product and pRBC as indicated, the rescue protocol for study group C may be initiated.

1. Repeat standardized assessment of the patient utilizing DOGiBAT, ATT, and FMS if surgical exploration of the patient is warranted to address uncontrolled hemorrhage, surgery may be performed at this time.
2. The patient may receive stored whole blood, fresh whole blood, and a single additional dose of lyophilized plasma as clinically indicated.
3. At the discretion of the clinician, a single dose of lyophilized platelets may be added at this time.
4. The patient may receive standard of care including isotonic or hypertonic crystalloids or colloid (natural or synthetic) at the clinician's discretion.

After the T4 timepoint (4 hours after enrollment), all patients are eligible for standard of care transfusion therapy as directed by the clinician.

CONTROL RESCUE PROTOCOL

The patient should be monitored in 15-minute increments; should the patient fail to respond with an improvement in Shock Index (SI remaining >/=1.1) and vital parameters 15 minutes following completion of the first administration of product, repeated dosing is indicated per the study protocol. Packed red blood cells (pRBC) may be administered at any point during the study via a second intravenous catheterper clinician assessment of patient need.

If the patient continues to display indications of shock (SI remaining >/=1.1) **one hour** after the initiation of Group D protocol and despite repeated administration of test product and pRBC as indicated, the rescue protocol for study group D may be initiated.

1. Repeat standardized assessment of the patient utilizing DOGiBAT, ATT, and AFS; if surgical exploration of the patient is warranted to address uncontrolled hemorrhage, surgery may be performed at this time.
2. The patient may receive stored whole blood, fresh whole blood, or stored plasma as clinically indicated.
3. The patient may receive standard of care including isotonic or hypertonic crystalloids or colloid (natural or synthetic) at the clinician's discretion.

After the T4 timepoint (4 hours after enrollment), all patients are eligible for standard of care transfusion therapy as directed by the clinician.

APPENDIX J Adverse Reaction Form

BodeVet
9210 Corporate Blvd Suite 310 Rockville, MD 20850
240-408-8060 www.bodevet.com

REPORTING A POTENTIAL REACTION TO BODEVET PRODUCTS

In order to investigate any potential reaction to our products please complete FORM BodeVet Transfusion Adverse Reaction Form Online or Print and email to [redacted]@bodevet.com.

In order to undertake a thorough investigation for any serious reaction please provide:

1. Full Temperature Storage log for the product
2. Acceptance and Preparation Information for the product from arrival to time of use
3. Product Batch Number (or photo of the label)
4. Transfusion Monitoring Form showing temperature, pulse and respiration during the transfusion with any observations
5. Pre and Post transfusion Packed cell Volume (PCV) or Hematocrit (Hct) and Platelet count
6. Gram Stain smear made from any remaining product – please state the time the smear was made relating to the time of the transfusion. If gram stain not available provide a unstained slide.
7. Used product in a Sealed Zip Lock Bag

Recipient samples – preferably 1ml of EDTA and 1ml of separated serum. Full Clinical History of recipient relating to their current condition and treatment Please keep all samples refrigerated until shipping – and ship in controlled temperature packaging as promptly as possible following the transfusion. We suggest you use protective lab packaging with coolant (protect samples from direct contact with coolant using bubble wrap) to obtain the most representative results from our analysis of samples

During the trial 2-2019-K9 please return samples to: BodeVet Inc., 9210 Corporate Blvd. Suite 310, Rockville MD 20850. Email [redacted]@bodevet.com to advise of their shipping.

INSTRUCTIONS: Send the form to BodeVet, Inc. For US attention [redacted]DVM [redacted]@BodeVet.com). Timely reporting is important to BodeVet, Inc. [Complete areas which are not included in your internal hospital work-up and attach work-up.]

Do you suspect this reaction is the result of an attribute specific to the donor or the blood product?

Yes or suspected:

Reaction did not result in fatality: Complete this form and forward to the blood center(s)

Reaction resulted in fatality: Complete this form, forward to the blood center(s), AND report fatality to FDA/VMD

☐ **No:** Stop, do not report

Other: Consult with the BodeVet – contacts as above

For blood center use only:	Case Identification #	Date received / / (mm/dd/yy)

BodeVet, Inc. Specific Instructions:

REPORTING FACILITY INFORMATION

Date Submitted / / (mm/dd/yy)	
Name of person filling out	
Title of person filling out form	
Telephone Number	Fax #
Email Address	
Reporting Facility	
Address	
Reporting Veterinarian	Phone/Email:

PATIENT/RECIPIENT INFORMATION

Medical record #	Name *(optional)*
Age	Date of Birth / / (mm/dd/yy) *(optional)*
Weight	Sex
Attending Veterinarian	Attending's Phone #

Admitting or Primary diagnosis	
Indication for transfusion	
Relevant Severe Diagnosis (if applicable)	
Current Medications	
Current Respiratory Status	
List transfusion history **BEFORE** reaction (attach additional sheets if necessary	
List transfusion history **AFTER** reaction	
Any history of transfusion reactions (type and date)	

Current Status

ϒ Returned to pre-transfusion status	ϒ Expired (Transfusion related fatality) *
ϒ Still requires support related to transfusion	ϒ Other/Unknown

** Report to FDA/VMD within 24 hours*

BLOOD COMPONENT(S) INFORMATION

*Please list all components that were transfused **within the 24 hours prior to the transfusion reactions.** (Attach additional sheets if necessary)

*For transfusion under massive transfusion protocol or rapid multiple transfusions, please give best estimate of date and time of each unit (Request anesthesiology record if possible).

Blood Supplier	Unit Number	Component Type or Code	Volume Transfused	Date/Time Transfusion Start	Date/Time Transfusion Stop	Was Product Modified by Hospital?
				(mm/dd/yy) (hh:mm) ϒam ϒpm	(mm/dd/yy) (hh:mm) ϒam ϒpm	ϒ No ϒYes; specify
				(mm/dd/yy) (hh mm) ϒam ϒpm	(mm/dd/yy) (hh:mm) ϒam ϒpm	ϒ No ϒYes; specify
				(mm/dd/yy) (hh:mm) ϒam ϒpm	(mm/dd/yy) (hh:mm) ϒam ϒpm	ϒ No ϒYes; specify
				(mm/dd/yy) (hh:mm) ϒam ϒpm	(mm/dd/yy) (hh:mm) ϒam ϒpm	ϒ No ϒYes; specify
				(mm/dd/yy) (hh:mm) ϒam ϒpm	(mm/dd/yy) (hh:mm) ϒam ϒpm	ϒ No ϒYes; specify
				(mm/dd/yy) (hh:mm) ϒam ϒpm	(mm/dd/yy) (hh:mm) ϒam ϒpm	ϒ No ϒYes; specify

Blood Supplier	Unit Number	Component Type or Code	Volume Transfused	Date/Time Transfusion Start	Date/Time Transfusion Stop	Was Product Modified by Hospital?
				(mm/dd/yy) (hh:mm) ϒam ϒpm	(mm/dd/yy) (hh:mm) ϒam ϒpm	ϒ No ϒYes; specify
				(mm/dd/yy) (hh:mm) ϒam ϒpm	(mm/dd/yy) (hh:mm) ϒam ϒpm	ϒ No ϒYes; specify
				(mm/dd/yy) (hh:mm) ϒam ϒpm	(mm/dd/yy) (hh:mm) ϒam ϒpm	ϒ No ϒYes; specify
				(mm/dd/yy) (hh:mm) ϒam ϒpm	(mm/dd/yy) (hh:mm) ϒam ϒpm	ϒ No ϒYes; specify
				(mm/dd/yy) (hh:mm) ϒam ϒpm	(mm/dd/yy) (hh:mm) ϒam ϒpm	ϒ No ϒYes; specify
				(mm/dd/yy) (hh:mm) ϒam ϒpm	(mm/dd/yy) (hh:mm) ϒam ϒpm	ϒ No ϒYes; specify

REACTION INFORMATION
(please include copy of transfusion record)

Date of reaction (mm/dd/yy)	Time reaction started (hh:mm) ☐am ☐pm Time transfusion started (hh:mm) ☐am ☐pm Time transfusion stopped (hh:mm) ☐am ☐pm

Reaction Vital Signs

	Pre-Transfusion	During Reaction	Post Reaction
Date/Time	(mm/dd/yy) (hh:mm) ☐am ☐pm	(mm/dd/yy) (hh mm) ☐am ☐pm	(mm/dd/yy) (hh mm) ☐am ☐pm
Temperature	°C/°F	°C/°F	°C/°F
Blood Pressure (Mean)	Mm Hg	Mm Hg	Mm Hg
Pules	bpm	bpm	bpm
Respiratory Rate	bpm	bpm	bpm
O_2 Sat	%	%	%

Symptoms/Signs at time of reaction – Check all that apply

☐ Abdominalpain/cramps[1,4]	☐	☐ Loss of consciousness[1]
☐ Angioedema [1]	☐ Edema – pulmonary [2,3]	☐ Nausea/Vomiting [1, 4]
☐ Anxiety[1]	☐ Edema – Pedal [3]	☐ Oliguria [4]
☐ Arrythmia [1]	☐ Edema – conjunctival	☐ Dyspnea [3]
	☐ Erythema [1]	☐ Pain at infusion site [4]
☐ Cardiac arrest [1]	☐ Fever [2, 4]	☐ Pruritis [1]
☐ Chest pain [4]		☐ Shock [1, 4]
	☐ Stridor [1]	☐ Tachycardia [1, 2, 3, 4]
☐ Cough [3, 4]	☐ Hypertension [2, 3]	☐ Tachypnea [2,3]
☐ Cyanosis [1, 2, 3]	☐ Hypotension [1, 2, 4]	☐ Urticaria [1]
☐ Diarrhea [1]	☐ Hypoxemia [2, 3]	☐ Wheezing [1, 4]
	☐ Jugular venous distension [3]	

Allergic/Anaphylactic [1] | TRALI [2] | TACO [3] | Septic Transfusion

Suspected Adverse Reaction: Assign priority if more than one possibility*			
☐ Allergic/Anaphylaxis	☐ Transfusion-related acute lung injury (TRALI)	☐ Septic transfusion reaction	☐ Other, Specify:

Additional information:

PULMONARY-ALLERGIC-ANAPHYLACTIC REACTION INFORMATION		
Risk factors for Acute Lung Injury – Check all that apply		
☐ Acute Respiratory Distress Syndrome (ARDS) ☐ Aspiration ☐ Pneumonia ☐ Toxic inhalation ☐ Lung contusion ☐ Near drowning	☐ Severe sepsis ☐ Shock ☐ Multiple trauma ☐ Burn ☐ Acute pancreatitis ☐ Cardiopulmonary bypass ☐ Drug overdose ☐ Volume overload ☐ Renal failure	☐ Upper airway obstruction ☐ Diffuse alveolar damage ☐ Chemotherapy ☐ Amiodarone ☐ Disseminated intravascular coagulation ☐ Radiation to thorax ☐ Massive blood transfusion

Additional comments *(Other risk factors)*

Diagnostics – Check or write values								
	Pre-Transfusion			Pre-Tx	Post-Transfusion			Post-Tx
Evidence of **hypoxemia**								
O_2 sat ≤ 90% on room air	☐ Yes	☐ No	☐ Not Done		☐ Yes	☐ No	☐ Not Done	
Chest X-ray: Bilateral infiltrates	☐ Yes	☐ No	☐ Not Done		☐ Yes	☐ No	☐ Not Done	
Chest X-ray: Widened cardiac silhouette (cardiomegaly)	☐ Yes	☐ No	☐ Not Done		☐ Yes	☐ No	☐ Not Done	
Positive fluid balance ☐No ☐Yes, value +_____ml								
Elevated **Central venous pressure** greater than 12 mm Hg	☐ Yes	☐ No	☐ Not Done		☐ Yes	☐ No	☐ Not Done	
Elevated **Pulmonary artery Pressure** greater than 18 mm Hg	☐ Yes	☐ No	☐ Not Done		☐ Yes	☐ No	☐ Not Done	
Transient decrease **White blood cell count**	☐ Yes	☐ No	☐ Not Done		☐ Yes	☐ No	☐ Not Done	

Treatment and Clinical Course		
	Treatment *(Mark those treatments that are known to have been administered and check if yes.)*	**Response to treatment** *(Indicate when patient responds to administered treatment and check if yes.)*
Antihistamines	☐ Yes	☐ Yes
Bronchodilators	☐ Yes	☐ Yes
Diuretics	☐ Yes	☐ Yes
Epinephrine	☐ Yes	☐ Yes
Intubation/Ventilatory support	☐ Yes	☐ Yes
Oxygensupplementation	☐ Yes	☐ Yes
Steroids	☐ Yes	☐ Yes
Other (specify):	☐ Yes	☐ Yes

Additional comments *(Attach additional clinical information if available)*

If TRALI is suspected, please save an EDTA (purple-top) patient sample

Recipient DEA type:

Recipient plasma antibody status:

Donor plasma antibody result (if performed on unit):

Donor DEA type (if available):

SUSPECTED BACTERIAL CONTAMINATION

Were the suspect components returned to BodeVet, Inc.? ϒ No ϒ Yes

---

On reinspection doesthecomponent present any abnormalities *(e.g. clumps, discoloration, hemolysis)*?

ϒ No ϒ Yes: Describe: ϒ Unevaluable

Suspect component – Source used: ϒ Vial ϒ Not done

Gram stain performed: ϒ Negative ϒ Positive ϒ Not Done	**Result (organism):**
Culture performed: ϒ Negative ϒ Positive ϒ Not Done	**Result (organism):**

15.7

15.8 Was a secondary test performed by the hospital for this component?

ϒ No ϒ Yes, Specify:

Patient's pre-transfusion blood culture ϒ Negative ϒ Positive ϒ Pending ϒ Not done

Date/Time	(mm/dd/yy) (hh:mm) ϒ am ϒ pm	Result (organism):

Patient's post-transfusion blood culture result ϒ Negative ϒ Positive ϒ Pending ϒ Not done

Date/Time	(mm/dd/yy) (hh:mm) ϒ am ϒ pm	Result (organism identified if positive):

15.9 Does the patient have history of fever or of other infection related to his/her underlying medical condition? ϒYes ϒNo

---

Was the patient on antibiotics at the time of transfusion? ϒ Yes ϒ No Name:

Is the patient currently being treated with antibiotics? ϒ Yes ϒ No Name:

15.10 *Did the patient have an absolute neutropenia (neutrophil less than 500 per µl)* **prior to transfusion?** ϒ Yes ϒ No

Comments:

FOR BodeVet Use	
Suspected transfusionreaction categorization*	
Reaction	☐ Allergic/Anaphylactic ϒ TRALI ϒ Septic Transfusion Reaction ϒ Other:
Case definition criteria	☐ Definitive ϒ Probable ϒ Possible
Severity	☐ Non-severe ϒ Severe ϒ Life Threatening ϒ Death
Imputability	☐ Definite ϒ Probable ϒ Possible ϒ Ruled out ϒ Not Determined
Notes	

APPENDIX K Case Report Form