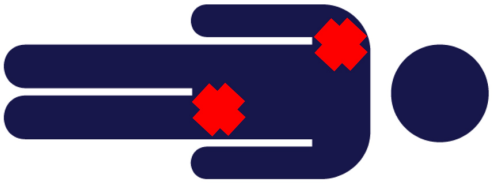
Trial Protocol



PhoXSTAT

A PILOT RANDOMIZED CLINICAL TRIAL OF THE XSTAT® HEMOSTATIC DEVICE IN THE PREHOSPITAL SETTING

VERSION HISTORY

Amendment no.	Protocol no.	Description of changes (incl. author(s) of changes)	Date of protocol
	1	New Document	Dec 20, 2018
1	1.1	Updated DSMB, Screening Cards, Stickers, other minor non-technical changes.	Apr 19, 2019
2	1.2	Updated Dr. Holcomb's affiliation	Oct 23, 2019
3	1.3	Changes requested by FDA	May 23, 2021

AWARD INFORMATION

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TRIAL REGISTRATION

Clinicaltrials.gov: [Pending]

ABBREVIATIONS

AE	Adverse Event
APTT	Activated Partial Thromboplastin Time
CIRO	Clinical Investigations Regulatory Office
CIS	Center for Injury Science
CRF	Case Report Form
DOD	Department of Defense
DSMB	Data Safety and Monitoring Board
eCRF	Electronic Case Report Form
ED	Emergency Department
EFIC	Exception From Informed Consent
EMS	Emergency Medical Services
FDA	Food and Drug Administration
GCP	Good Clinical Practice
HRPO	Human Research Protection Office
INR	International Normalized Ratio
IRB	Institutional Review Board
NIH	National Institute of Health
LAR	Legally Appointed Representative
OR	Operating Room
ORP	Office of Research Protections
PT	Prothrombin Time
REDCap	Research Electronic Data Capture
ROC	Resuscitation Outcomes Consortium

ROTEM	Rotational Thromboelastometry
RQ	Research Question
SAE	Serious Adverse Event
SOPM	Standard Operating Procedures Manual
TEG	Thromboelastography
UAB	University of Alabama at Birmingham
USAMRMC	US Army Medical Research and Materiel Command

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1. PROTOCOL SUMMARY

1.1 Questions addressed

How many patients might benefit from the XSTAT® device, in the civilian setting? How many patients could be enrolled into a trial? What are the baseline estimates of possible future primary and secondary outcomes for a full randomized clinical trial? Is the XSTAT® device easy to use, in the prehospital setting? How does the XSTAT impact operative management of penetrating junctional injuries and are the sponges easy to remove? Is the use of the XSTAT® device associated with adverse effects?

1.2 Eligible population

Patients aged 15 years and over, or with an estimated body weight of 50kg or more; who have suffered a penetrating junctional injury (femoral or axillary) with visible bleeding; who a suffering from class 3 or 4 hemorrhagic shock; and who will be taken directly to a level I trauma center participating in the PhoXSTAT trial.

1.3 Interventions

Standard prehospital care plus XSTAT®, compared with standard prehospital care.

1.4 Outcome assessment

We will assess feasibility of a future efficacy/effectiveness trial, and usability and safety of the XSTAT® device.

1.5 Coordination

Local: By investigators and research assistants in participating trial sites. Central: By Trial Office at UAB.

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3. INTRODUCTION

3.1 Background

3.1.1 Trauma is a major public health issue

Trauma is the leading cause of death for people ≤45 years of age and is the third leading cause of death in the United States (US) overall. Trauma accounts for 41 million Emergency Department (ED) visits and 2 million hospital admissions in the US each year, with an economic burden of more than $585 billion.(1)

Among the injured, hemorrhagic shock is a leading cause of early death, and is responsible for over 35% of prehospital deaths and 40% of deaths within the first 24 hours after injury.(2) Hemorrhage control is of paramount importance in preventing battlefield mortality and is the top priority of the US military.(3) In a study of injuries from Operation Iraqi Freedom and Operation Enduring Freedom, hemorrhage accounted for 82% of potentially survivable casualties.(4)

3.1.2 Junctional bleeding is particularly challenging, and currently available treatments are unsatisfactory

Junctional bleeding is hemorrhage occurring at the junction of two anatomically distinct regions. The PhoXSTAT trial will specifically investigate injuries to the axillary or femoral regions. These injuries are associated with high mortality. A National Trauma DataBank analysis of 120 isolated femoral arterial injuries revealed a mortality rate of 7.5%. (5)

Bleeding from a junctional injury is difficult to control. Currently available treatments include tourniquets, direct and indirect pressure, and hemostatic dressings. These are unsatisfactory (21 CFR 50.24(a)(1)) because

a) A tourniquet cannot be applied to these body regions: Junctional injuries are too proximal to permit the application of a tourniquet to temporarily occlude blood flow. It is not possible to occlude the iliac (for femoral arterial injuries) or subclavian (for axillary arterial injuries) arteries with a tourniquet.
b) Indirect pressure on proximal vessels is ineffective. (6) For the same reasons, it is not possible to provide effective digital compression of the iliac or subclavian arteries.

c) Direct pressure is ineffective, particularly in deep wounds. (6) Penetrating injuries to the junctional vasculature are difficult to control with direct pressure. Inserting digits into these types of wounds can also exacerbate bleeding, by causing further injury to vascular structures.
d) Existing hemostatic agents have important practical drawbacks that limit their effectiveness with junctional injuries. For example, junctional injuries often involve deep vascular structures that cannot be easily accessed from the skin surface. Hemostatic bandages inserted through small skin wounds cannot effectively compress deep vascular structures. Similarly, hemostatic powder applied through a small skin wound will not adequately coat deep vascular structures. Hemostatic powders are also difficult to remove during definitive vascular repair.

There are few effective treatment options for junctional injuries other than operative control – which is rarely available in the prehospital setting. Current body armor also does not adequately protect junctional regions. In recent US military efforts, junctional injuries contributed to >70% of potentially survivable casualties.(4)

3.2 XSTAT® – A Novel Hemostatic Approach to Junctional Injuries

XSTAT® (RevMedx™, Wilsonville, Oregon) is a novel hemostatic device with features potentially well suited to junctional hemorrhage control.(6)

3.2.1 Mechanism of action

The XSTAT® device injects small, rapidly-expanding cellulose sponges into the wound cavity using a syringe-like delivery system. In the wound, XSTAT® sponges expand and swell to fill the wound cavity, within 20 seconds of contact with blood, facilitating compression of bleeding structures. XSTAT® can be applied through skin wounds. The system can readily access deep vascular structures. While rapidly hemostatic, the hemostatic sponges are also relatively easy to remove. In the setting of junctional bleeding, XSTAT® may allow for hemostatic pressure generation from within the wound tract rather than from external compression (as with a tourniquet or manual compression).

3.2.2 Why the XSTAT 12 device may be better than existing available therapies

The XSTAT 12 device may be better than existing available therapies because of its mode of application: The device allows the delivery of the hemostatic component (the sponges) close to the site of bleeding, using the injector. This is particularly helpful for ballistic injuries, where the wound may be relatively small. The device is easily inserted into the wound tract, and directed towards the bleeding femoral or axillary artery – even if the arterial injury is out of reach of tourniquets, direct or indirect pressure, or hemostatic dressings.

3.2.3 Operational philosophy

Hemorrhage should be controlled as early as possible, ideally before reaching a trauma center or medical treatment facility. Given its small size, low weight, and ease of application, the XSTAT® device is well-suited for prehospital use, in both the civilian and military setting, and this is probably where the device's applicability lies.

There would appear to be less justification for the use of XSTAT® in the setting of a trauma center, where patients can be taken directly to an operating room, or have bleeding controlled by other means.

3.2.4 Current evidence

Although efficacious in animal studies, there have been few studies of the XSTAT device in humans. A recent ten-patient case series, eight of whom had arterial injuries, and two of whom had venous injuries or soft-tissue bleeding, showed that XSTAT appeared to control bleeding well. Overall, half were junctional injuries. XSTAT was able to stop bleeding in nine of ten patients on the first deployment, with the remaining patient requiring one repeat injection. There were no technical device failures or embolic complications.(7)

3.3 Rationale for this trial

3.3.1 The need for further study

XSTAT® is approved by the US Federal Drug Administration (FDA) for application in battlefield and civilian trauma patients. However, other than the case series described above,(7) there have been no supporting human evaluations of XSTAT®. There is an

urgent need for data to demonstrate the safety and efficacy of the device, prior to recommending its widespread use in the prehospital setting.

3.3.2 The need for a pilot trial

Before a full-scale trial can be conducted, the feasibility of conducting such a study, and the planning assumptions underlying it, will need to be confirmed. The key issues which such a pilot trial needs to address are:

a) The number of penetrating junctional zone injuries encountered in the prehospital civilian setting.
b) The feasibility of randomizing patients in the prehospital setting.
c) Usability.
d) Safety.
e) Validation of the proposed primary outcome of an efficacy trial.

4. AIM AND OBJECTIVES

4.1 Aim

The aim of the PhoXSTAT trial is to evaluate the feasibility of conducting a randomized clinical trial of the XSTAT® device, in the prehospital setting.

4.2 Objectives and research questions (RQ)

The objectives of the PhoXSTAT trial are:

4.2.1 Trial feasibility

Objective 1: To evaluate the number of patients with penetrating junctional (femoral and axillary) zone injuries that can be entered into a trial (RQ 1: "How many patients that might benefit from the XSTAT® device, in the civilian setting, can be entered into a trial?")

Objective 2: To evaluate possible future primary and secondary outcomes for a full randomized clinical trial, including admission lactate, admission base deficit, and mortality. (RQ 3: "What are the baseline estimates of possible future primary and secondary outcomes for a full randomized clinical trial?")

4.2.2 Device usability

Objective 3: To evaluate the usability of the XSTAT® device, in the prehospital setting, in patients with junctional injuries, in terms of the insertion of the device, and deployment of the sponges. (RQ 4: "Is the XSTAT® device easy to use, in the prehospital setting?")

Objective 4: To evaluate the usability of the XSTAT® device, in the operating room setting, in patients with junctional injuries, in terms of the removal of the sponges. (RQ 5: "Are the XSTAT® sponges easy to remove, in the operating room?")

4.2.3 Device safety

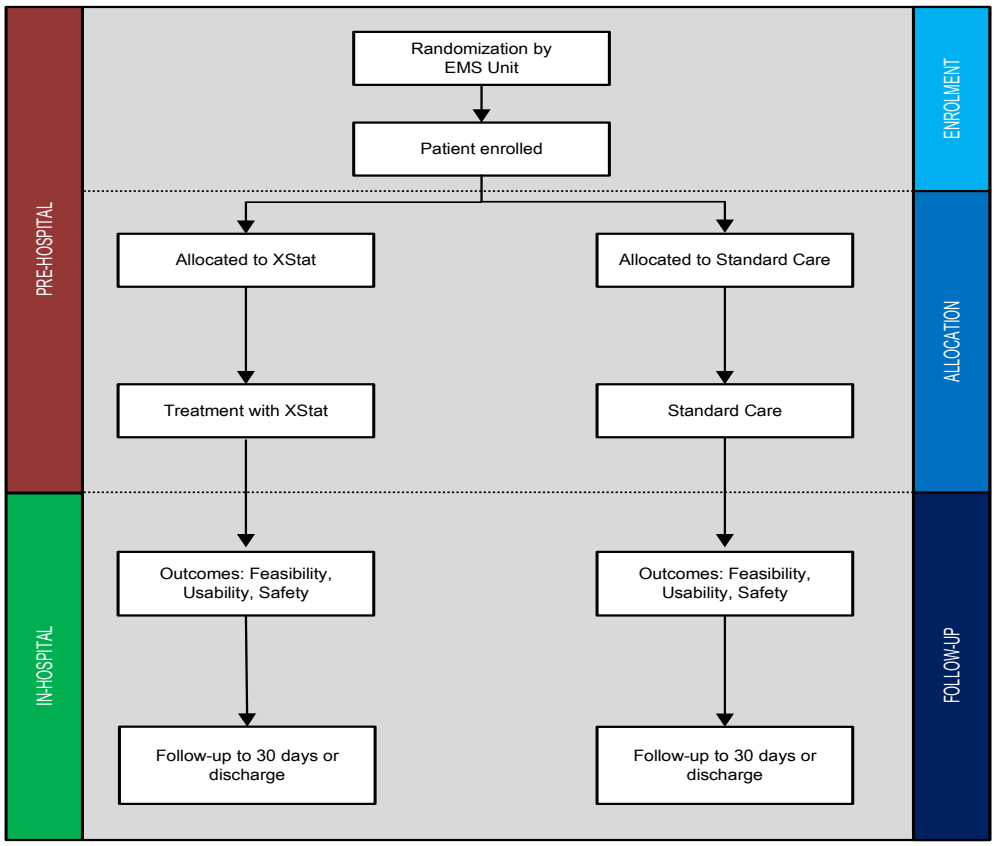
Objective 5: To evaluate the safety of the XSTAT® device, in patients with junctional injuries. (RQ 6: “Is the use of the XSTAT® device associated with adverse effects?”)

5. DESIGN AND INTERVENTION

5.1 Design

Pragmatic, prehospital, randomized, multi-site, pilot/feasibility trial.

Figure 1. Consort diagram



5.2 Intervention to be evaluated

Patients allocated to the intervention group are treated with standard prehospital care plus XSTAT®. The trial will only use the "XSTAT-12" device, which is more suited to the types of injuries seen in civilian practice. XSTAT® application will follow the manufacturer's guidance, with injection into bleeding wounds. A sufficient number of sponges are used to fill the injury void. Repeat XSTAT® application is performed in the event of persistent bleeding. (The trial packs will contain two devices.)

Figure 2. Xstat device being used to treat right groin wound

XSTAT® sponges must be removed surgically. However, all patients with junctional injuries typically undergo operative exploration and repair of vascular injuries. The radiopaque markers embedded in each sponge aid in identification of sponges retained within the body. Each XSTAT® device consists of 38 sponges. Because all sponges may not be deployed into the wound or there may be dislodgement from the wound during patient movement, a radiographic survey must be undertaken to identify any retained sponges. The recent cases series by Warriner et al identified retained sponges in two out of ten patients on initial post removal x-rays following wound exploration for definitive hemorrhage control and sponge removal.(7)

It is possible that patients who are initially (in the prehospital setting) thought to have a serious injury, and who are treated with XSTAT, then turn out not to have an injury requiring operative treatment. These patients might have been managed non-operatively, had they not been treated with XSTAT. Determining the number of “forced” or non-therapeutic explorations is a key outcome of this study. However, it is important to recognize that XSTAT is an FDA-approved device, and that this situation can therefore also arise in everyday practice, outwith the context of a trial.

5.3 Control treatment

Patients allocated to the control group receive standard prehospital care, consisting of direct pressure/dressings.

5.4 Other aspects of care

All other aspects of trauma resuscitative care take place according to local protocol, including airway management, provision of supplemental oxygen, intravenous fluid resuscitation, administration of blood products, splinting of extremities, bandaging of wounds and surgical interventions. Upon arrival at the hospital, ED/trauma center personnel perform initial patient assessment according to standard Advanced Trauma Life Support protocols. Patients receive concurrent interventions, including provision of oxygen, insertion of intravenous lines, and infusion of intravenous fluids and blood products.

6. RECRUITMENT

6.1 Setting

The PhoXSTAT trial is conducted in the prehospital setting, by participating Emergency Medicine Service (EMS) providers, and associated level I trauma centers.

6.2 Patients/Study Subjects

The study's entry criteria select patients with life-threatening injuries, as specified under 21 CFR 40.24(a)(1):

6.2.1 Inclusion criteria

a) Age ≥15 years or estimated body weight ≥50 kg.
b) Penetrating junctional injury (femoral or axillary), with
    i. visible bleeding
    ii. too proximal to be controlled with a tourniquet
c) Class 3 or 4 hemorrhagic shock
d) Patient will be taken to participating level I trauma center, directly from the scene

6.2.2 Exclusion criteria

a) Prisoners, children <15 years old, known pregnant patients.
b) Patients receiving chest compressions (prior to XSTAT® use).
c) Patients with an opt-out bracelet.

Adolescents will be included because children aged 15 and over are typically transported to, and treated, in adult trauma centers. Only children below this age are taken to specialist pediatric trauma centers (when available).

6.3 Randomization

6.3.1 Randomization by vehicle

Patients are individually randomized, albeit indirectly, by randomizing EMS vehicles. (Given the administrative and logistical difficulties of direct individual randomization in the prehospital setting, this approach is more practical.)

6.3.2 Trial intervention packs

Each EMS vehicle randomly receives a pre-packaged, sealed, numbered trial intervention pack, consisting of a durable plastic case, which either contains either two XSTAT® devices, or is empty. The pack remains on the vehicle until used or expired. When a suitable patient meeting the inclusion criteria for the trial is identified by the EMS providers, the pack is opened. If it contains the device, it is used. Once a pack has been used, it is replaced (when the vehicle returns to its base location).

6.3.3 Tracking labels

The trial intervention packs also contain a tracking label, which must be attached to the patient, to ensure that the trauma center is a) made aware of the patient's enrollment; and b) able to identify which treatment was administered. The tracking label is also used to collect a small amount of prehospital data.

This mechanism avoids having to access a randomization mechanism in real-time and having to carry multiple packs. The disadvantage is that, should a crew encounter more than one suitable patient per shift, some patients may be missed. In addition, in a small study, there is a possibility that, purely by chance, eligible patients may be preferentially encountered by EMS units randomized to either the intervention, or the control treatment. This risk will be reduced with a larger sample size.

6.4 Consent (EFIC)

PhoXSTAT is an Exception from Informed Consent (EFIC) trial. We have extensive experience conducting major trauma trials under EFIC rules. Through our activities with the national Resuscitation Outcomes Consortium (ROC), we have executed eight trials on cardiac arrest or major trauma patients using EFIC. We are experienced with all aspects of EFIC, including communicating with the targeted communities, delivering information to patients and their families, and disseminating study information and results. Examples of studies that we have successfully carried out under EFIC include: ROC Hypertonic Saline Trial, ROC Hypotensive Resuscitation Trial, PROPPR, and the ROC TXA Trial. We have also conducted EFIC for numerous cardiac arrest trials.

All patients participating in the trial, regardless of whether allocated to receiving the intervention, or control treatment, are likely to benefit. Those receiving treatment with

XSTAT® will benefit from its probable hemostatic action. Patients randomized to control treatment will also benefit, because they will be part of a carefully designed study to assess the safety of treatment and will thus receive more clinical attention than patients who are not participating in the trial. The severity of junctional injuries is often underestimated by clinicians, with serious consequences, and this benefit is therefore tangible.

The procedures outlined below are based upon procedures that have been historically approved by the UAB Institutional Review Board and other related agencies such as the US Army Medical Research and Materiel Command (USAMRMC) Human Research Protection Office (HRPO). The nature and risk/benefit profile of XSTAT® is similar to these prior trials.

Because of the time-critical nature of hemorrhage care, the trial will be carried out under "Exception from informed consent required for emergency research" (EFIC) rules outlined in the guidance document "Waiver of Informed Consent Requirements in Certain Emergency Research" (Federal Register, Vol. 61, pp. 51531-51533, November 1, 1996 - http://www.gpo.gov/fdsys/pkg/FR-1996-10-02/html/96-24968.htm), OHRP "Basic HHS Policy for Protection of Human Research Subjects" (45 CFR 46.101(i) - http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.101), and FDA regulations 21 CFR 50.24.23-25.

6.4.1 Conditions present for conduct under 21 CFR 50.23

The use of EFIC is justified, as per FDA regulations 21 CFR 50.24.23-25, because the victims of major trauma are:

a) In a life-threatening situation that necessitates urgent intervention: Femoral and axillary arterial injuries are associated with high mortality
b) Available treatments are unproven or unsatisfactory: Available treatments include tourniquets, direct and indirect pressure, and hemostatic dressings. Section 3.1.2 contains details of why these treatments are unsatisfactory.
c) Collection of valid scientific evidence is necessary to determine the safety and effectiveness of the intervention: Preclinical and clinical studies conducted to date confirm the safety of the XSTAT device.

d) Obtaining informed consent is not feasible because the subjects are not able to give their informed consent as a result of their medical condition: The patients who will be included in this trial will be suffering from life-threatening hemorrhagic chock (class 3, 30-40% of blood volume lost; class 4, 40% of more of blood volume lost). Class 3 hemorrhagic shock is associated with “changes in mental status”. In class 4 hemorrhagic shock, “mental status becomes increasingly altered” (https://www.ncbi.nlm.nih.gov/books/NBK470382/). Patients who meet the inclusion criteria for the trial are therefore unlikely to have capacity to provide informed consent to participate.
e) The intervention must be administered before consent can be obtained from the subject’s legally authorized representative: The therapeutic window for controlling hemorrhage, before the patient exsanguinates, is small. The time required to contact a LAR could determine whether a patient who could have lived, dies.
f) There is no reasonable way to identify prospectively individuals likely to become eligible for participation: Patients do not usually expect to suffer penetrating junctional injuries.
g) Participation in the research holds out the prospect of direct benefit to the subjects: Preclinical and early clinical data suggest that there is a real possible and direct benefit to patients treated with the XSTAT device.
h) The clinical investigation could not practicably be carried out without the waiver: There is no alternative means of carrying out this type of research.

In conformance with EFIC rules, measures to protect the rights and welfare of subjects will include, at least:

a) Community consultation
b) Public disclosure
c) Independent data monitoring
d) Notification of LAR or family members of a subject’s enrollment in the trial, with opportunity to discontinue trial participation.

Community consultation and public disclosure will be performed prior to study enrollment and at the completion of the study in the form of multimedia press releases organized by the study team. Examples of communication activities may include town hall meetings, press releases, website postings, random-digit-dialing surveys, and the use of social

media (Facebook and Instagram). These communications will describe plans for the study, including potential risks and benefits, equipoise and a summary of the results of the study upon completion. Information regarding the study will also be available on the UAB website.

6.4.2 Informed consent by patient

As described above, patients who meet the inclusion criteria for the trial, including the presence of class 3 or 4 shock (which is associated with mental status changes), are very unlikely to have the capacity to provide consent. Furthermore, a detailed discussion of the risks and benefits of participation could results in life-threatening delays to treatment. However, as per 21 CFR 50.24(a)(6), if patients are deemed to have capacity, informed consent will be sought and documented.

6.4.3 Informed consent by LAR

In the rare scenario where a LAR/family member is immediately available and the opportunity for consent is present, a short script (appendix 3) providing information regarding the study will be made available to the LAR/family member, affording the opportunity to withdraw consent for the patient's participation.

If an arterial injury is present, the therapeutic window for intervention is extremely short. Depending on the severity of the injury, exsanguination can occur within minutes. Importantly, this time is measured from the time of injury, rather than the time of arrival of emergency medical services. Once present, paramedics will be working to resuscitate (with intravenous fluid or blood transfusions, and sometimes also intubation) and transport the patient to a facilitate capable of definitive hemorrhage control, as quickly as possible. Contacting a family member of LAR who is not present at the scene is therefore unlikely to be feasible – both because contact details will not be available, and because of the time required. Nevertheless, should a situation arise where this is possible, efforts will be made to contact family members and ask whether he or she objects to the subject's participation in the research, as required by 21 CFR 50.24(a)(7)(v). This discussion will also be guided by the script in appendix 3.

6.4.4 Consent for ongoing participation

Once a subject is enrolled in the study, the research team will make frequent attempts as soon as feasible to contact a LAR/family member to obtain permission for continued participation and provide an opportunity to withdraw. A verbal withdrawal will be considered binding. Attempts to contact a LAR/family member will include direct contact, telephone contact and written contact or any other contact options as approved by local IRB policy.

6.4.5 Death before consent can be obtained

In the event the subject does not survive following the traumatic injury, his/her information will be included in the data analysis. Written notification may be sent to the deceased's family regarding participation in this study, per local IRB policy. Due to the severity of the injuries incurred, it is difficult to specify the timeframe involved with obtaining the consent, however multiple attempts will be made to obtain consent prior to completion of the study.

6.4.6 Opt-out

The ability and method of "opting out" of the study will be determined by the UAB Institutional Review Board, with updating by the other two sites (USC and VUMC). Because the population eligible for enrollment includes all citizens in the study regions, it will not be possible to target specific individuals, although the UAB IRB may suggest specific age groups and ethnic groups, determined by trauma registry data. Citizens wishing to opt-out of the trial will be provided with an "opt-out" bracelet. EMS personnel will be trained to check for opt-out identifiers prior to enrolling any patient.

6.4.7 "Prospect of direct benefit"

Information from animal and preclinical studies, and early clinical use support the potential for the investigational product to provide a direct benefit to the individual subjects. Participation in this pilot trial holds out the prospect of direct benefit to the subjects because

a) The subjects are in a life-threatening situation that necessitates intervention. Specifically, the condition in question (junctional hemorrhage) is not well-

addressed with currently available treatments, and hemorrhage is frequently not controlled until the patient reaches hospital.

b) Information from appropriate animal and other preclinical studies support the potential for the intervention to provide a direct benefit to the individual subjects.
c) The risks associated with the investigation are reasonable in relation to what is known about the medical condition of the potential class of subjects, the risks and benefits of standard therapy, if any, and what is known about the risks and benefits of the proposed intervention or activity.

6.4.8 Choice of endpoints

This protocol is for a pilot trial. The FDA recognizes that it is important to obtain preliminary information on the effect of new treatments on a variety of outcomes, including biomarkers (e.g., measurement of brain infarcted area, degree and extent of acidosis) before proceeding to a study that evaluates effectiveness. This pilot trial will evaluate several possible endpoints which could be used in a future effectiveness trial, including a biomarker (lactate).

7. OUTCOMES

PhoXSTAT is a pilot trial, and consequently there is no "primary" outcome. As per the aims and objectives, the following will be evaluated:

7.1 Trial feasibility (Objectives 1-2)

We will evaluate the feasibility of a full efficacy/effectiveness trial, using the following parameters:

a) Number of patients with penetrating junctional (femoral and axillary) zone injuries who are entered into the pilot trial, and randomized. (Objective 1)
b) Ability to obtain baseline estimates of possible future primary and secondary outcomes for a full randomized clinical trial. (Objective 2)

7.2 XSTAT usability (Objectives 3 and 4)

In order to conduct a full trial, the device has to be usable. Usability will be evaluated in the prehospital and operating room setting.

7.2.1 Prehospital setting (Objective 3)

Many civilian penetrating injuries are caused by low energy transfer firearms (typically handguns). The resulting wounds can be small, which may make insertion of the XSTAT® device difficult. We will evaluate the usability of the device in the prehospital setting, by investigating the following:

a) Ease of insertion
b) Ease of deployment
c) Overall satisfaction with the device

7.2.2 Operating room (Objective 4)

Use of the XSTAT device commits the patient and medical team to operative exploration of the wound, and retrieval of the sponges. We will evaluate surgeons' views on the device, by collecting data on the following:

a) The ease of sponge removal
b) The time required to remove the sponges

c) The use of x-rays/image intensifiers to ensure complete removal of the sponges
d) Overall satisfaction with the device

7.3 XSTAT safety (Objective 5)

Although XSTAT® is thought to be a low-risk device, we will nevertheless obtain formal data on its safety profile, which will include the following:

a) Number of patients suffering allergic reactions or anaphylaxis
b) Number of patients developing wound infections
c) Number of patients developing tissue damage thought to be related to the insertion of the device or deployment of the sponges
d) Number of patients suffering embolization of the sponges
e) Number of patients who suffer inadvertent retention of sponges (beyond first operation)
f) Number of patients in whom no vascular injury is identified

8. DATA COLLECTION

8.1 Personnel

All three participating PhoXSTAT sites have research assistants available in the emergency department. Research assistants initiate, and complete, the data collection for the trial.

8.2 Case Report Form

Data is initially collected using paper Case Report Forms (CRFs, appendix 2), and then transcribed into an electronic database. The electronic CRF uses the Research Electronic Data Capture (REDCap) system, a secure research database developed by NIH. Data logic checks are used to minimize data entry errors. Data audits are performed on a randomly selected 20% of enrolled subjects. When data are complete, and all suspect entries addressed, the database will be "locked" and exported to STATA or SAS for analysis.

8.3 Patients entered into pilot trial: Prehospital data collection

The PhoXSTAT trial requires the collection of a minimal amount of prehospital data – primarily relating to the usability and safety of the device. Each trial intervention pack contains a tracking label, which must be attached to the patient, using the cable tie supplied. The tracking label contains a mini-questionnaire. If the patient was allocated to treatment with Xstat, the following details must be completed:

8.3.1 Usability

Ease of insertion of device into wound

a) Unable to insert (wound too small to accept device)
b) Reasonably easy to use (wound accepted device with some manipulation)
c) Easily inserted (wound accepted device without difficulty)

Ease of deployment of sponges

a) Unable to deploy sponges
b) Reasonably easy to deploy sponges (several sponges successfully injected)
c) Easily deployed (majority or all of sponges successfully injected)

Overall satisfaction with the device

a) Dissatisfied
b) Neither satisfied nor dissatisfied
c) Satisfied

8.3.2 Safety

a) Anaphylaxis

The tracking label is shown in appendix 1. The data on the patient's tracking label must be transferred to the electronic case report form (eCRF) (see below) at the earliest opportunity, by research assistants in the emergency department, to mitigate against data loss.

8.4 Patients entered into pilot trial: In-hospital data collection

The following data are collected in-hospital.

8.4.1 Physiological parameters

The following measurements are collected on admission:

a) Systolic, diastolic, and mean blood pressure
b) Heart rate
c) Shock index

8.4.2 Usability

The ease of sponge removal

a) Unable to remove all sponges
b) Reasonably easy to remove all sponges
c) Sponges easily removed

The time required to remove the sponges

a) 1 hour or longer
b) Between 5 and 59 minutes
c) Less than 5 minutes

The use of x-rays/image intensifiers to ensure complete removal of the sponges

a) Imaging not used due to patient's clinical condition
b) Imaging not used as not available
c) Imaging deemed unnecessary
d) Imaging used

Outcome of imaging:

a) Additional sponges seen on imaging
b) No additional sponges seen on imaging

Overall satisfaction with the device

a) Dissatisfied
b) Neither satisfied nor dissatisfied
c) Satisfied

8.4.3 Blood tests

The following blood tests, which are all measured routinely as part of the clinical assessment of trauma patients, are collected, as soon as possible after admission:

a) Blood lactate level (from arterial or venous blood gas measurement)
b) Blood base deficit (from arterial or venous blood gas measurement)
c) Hemoglobin/hematocrit, platelet count
d) Prothrombin time (PT)/international normalized ratio (INR), activated partial thromboplastin time (APTT)/ratio
e) Thromboelastograph (TEG) or thromboelastogram (ROTEM), if available

8.4.4 Survival

Time of death (if applicable)

8.4.5 Blood product/adjunct use

The amount of blood products used, over the first 24h since injury, are collected:

a) Red cell concentrate (units)
b) Plasma (units)
c) Platelets (pools)
d) Whole blood (units)
e) Cryoprecipitate (units)

f) Tranexamic acid (grams)

8.4.6 Length of stay

a) Intensive care (days)
b) Hospital (days)

8.4.7 Safety

PhoXSTAT collects data on a number of prespecified safety events, over the first 7 days following injury, unless discharged earlier, including:

a) Allergic reactions or anaphylaxis
b) Wound infections (clinical diagnosis)
c) Tissue damage thought to be related to the insertion of the device or deployment of the sponges (clinical diagnosis)
d) Embolization of the sponges
e) Inadvertent retention of sponges (beyond first operation)
f) Non-therapeutic exploration

The above data are also to be entered into the eCRF as it becomes available.

8.5 Data collection schedule

The data collection schedule is summarized in table 1.

Table 1: Data collection

Data	Pre-hospital	On admission	OR	6 hrs	24 hrs	7 days*	30 days*	Discharge
Feasibility								
Lactate		✓						
Blood pressure		✓						
Heart rate		✓						
Base deficit		✓						
Hemoglobin		✓						
Hematocrit		✓						
Platelet count		✓						
PT/INR		✓						
APTT/ratio		✓						
TEG / ROTEM		✓						

Blood products					✓			
Survival		✓		✓	✓		✓	✓
Length of stay								✓
Safety	✓	✓				✓		
Usability	✓		✓					

*if still in hospital

9. RECRUITMENT TARGETS

As PhoXSTAT is a feasibility trial, part of the rationale for which is to ascertain the number of eligible and recruitable subjects, there are no formal recruitment targets. An analysis of registry data from UAB suggests that there are around 10 patients per year who might benefit from XSTAT® application. On this basis, we anticipate enrolling a maximum of 50 patients, across the three PhoXSTAT sites, over two years.

10. STATISTICAL ANALYSIS

10.1 Feasibility

We will report the number of patients meeting the inclusion criteria, and the number of patients enrolled and randomized into the pilot trial.

10.2 Usability

This analysis will also be performed on intervention (XSTAT®) subjects only. We will report details for both categories.

10.3 Safety

We will identify and report the individual and composite incidence of each of the a priori defined adverse events.

10.4 Efficacy

We will compare the intervention (XSTAT®) and control groups, with regards to outcomes specified. As this is a pilot/feasibility study, no power or sample size calculation is required.

11. TRIAL MANAGEMENT

11.1 Trial office

The PhoXSTAT Trial Office is in the Center for Injury Science, University of Alabama at Birmingham, and provides support for the trial sites.

11.2 Project Management Group

The Program Manager takes responsibility for the day to day transaction of trial activities, such as site set-up and training, oversight of recruitment, etc. The PhoXSTAT Project Management Team meets at least weekly during the course of the trial to ensure smooth running and trouble-shooting.

11.3 Local organization in sites

Local PIs and research assistants are responsible for all aspects of local organization including identification of participants, data collection, and notification of any problems or unexpected developments for the duration of the trial. Specifically, participating sites will also be responsible for liaising with EMS agencies and providers, and for supplying and tracking trial intervention packs, including withdrawing packs which have expired.

Research assistants are responsible for ensuring that study data is collected and logged onto the remote web-based data capture system in a timely manner. The site agreement documents the full list of responsibilities for sites. Appropriate members of the local team must be fully conversant with the trial protocol and have Good Clinical Practice training. A delegation log is prepared for each site, detailing the responsibilities of each member of staff working on the study. This delegation log is kept at each site and at the Clinical Trial Center.

12. RESEARCH GOVERNANCE

12.1 Lead site

The Center for Injury Science at the University of Alabama at Birmingham is a Clinical Trial Center with expertise in running multicenter EFIC clinical trials in the prehospital and emergency department setting. The trial is run under the auspices of CIS aiding compliance with research governance and the principles of GCP and providing centralized trial administration.

12.2 Monitoring

The Principal Investigators ensure that adequate systems are in place for monitoring the quality of the trial and appropriate expedited and routine reports, to a level appropriate to the risk assessment of the trial. CIS's Standard Operating Procedures will be followed.

12.3 Relationship with the manufacturer of the XSTAT® device

The manufacturers of the XSTAT® device (RevMedx™) have no role in the design, conduct, analysis, or reporting of the trial. The relationship between XSTAT® and the trial staff is governed by a Clinical Supply Agreement. We have developed a close working relationship with RevMedx™ and will liaise with the company regarding any safety issues.

12.4 Data protection

Data collected during the course of the research will be kept strictly confidential and accessed only by members of the trial team. Participant's details are stored on a secure database and regular checks and monitoring are in place to ensure compliance. The data manager (in collaboration with the Principal Investigators) manages access rights to the data set. Participants are allocated an individual specific trial number and their details are anonymized on the secure database.

13. HUMAN SUBJECTS RESEARCH

13.1 FDA Requirements

This study will enroll approximately 50 patients with Penetrating junctional injuries. The study intervention (XSTAT® 12) is approved by the Food and Drug Administration (FDA) as a Class II nonsignificant risk medical device under 21 CFR 878.4452 “Non-absorbable expandable hemostatic sponge for temporary internal use.” Although it is a nonsignificant risk device being used in accordance with its defined indications, we are required to seek an FDA Investigational Device Exemption (IDE) because it is used in this setting in accordance with the regulations for exception from informed consent.

13.2 Potential risks

The patients in the feasibility trial will be randomized to one of two treatment arms – XSTAT or standard care. Eligible patients for this trial will have been identified as having non-compressible (and therefore life-threatening) junctional injuries. As the randomization will take place at EMS unit level (rather than patient level), the risk of delaying treatment is negligible.

There is a possibility of some of the sponges, which form part of the device, being retained. This could occur because the sponges are not seen (at operation or on x-ray), or because they could not be located. Sponge retention could result in problems such as infection and pain.

There is also a theoretical possibility that the wound which the sponges are injected into is in continuity with the pleural or peritoneal cavities. This may result in the patient requiring an additional procedure or operation, to remove these sponges.

Lastly, it is possible that, despite the paramedics’ best belief, the bleeding originated from tissue, rather than a vascular injury, and might have stopped, or did stop, without surgical exploration and repair. In this case, patients might require an operation which they might otherwise not have needed.

Overall, the risks of this study are deemed low.

13.3 Protection of human subjects

The reasons for conducting an EFIC trial are outlined in section 6.4. A detailed explanation of each criterion stipulated in the regulations for this exception and how our trial design applies to these criteria is outlined in Appendix 3.

14. ADVERSE EVENT/EFFECT REPORTING

The XSTAT device is FDA approved, has been in use for some time, and its safety profile is well established.(7) Nevertheless, it is possible that adverse events may occur, and the trial will collect data on adverse events that may be associated with the use of XSTAT. Adverse events will be reviewed by the sponsor, which is the Department of Defense.

14.1 Definitions and classification

All untoward medical occurrences will be classified by:

a) Whether they involved a trial participant
b) Were related to the use of the device
c) Seriousness
d) Whether anticipated/unanticipated.

Note that adverse *events* are non-device-related medical occurrences, whereas adverse *effects* are caused by the investigational device or procedure.

14.1.1 Untoward medical occurrence

An untoward medical occurrence is an unintended disease or injury or untoward clinical sign in a trial participant caused by or related to the investigational device, device-related procedure, or comparator. Not all complaints about investigational devices have to do with untoward medical occurrences. If a complaint does not involve a trial participant or other person, it is not medical and is called a “non-medical complaint.” Non-medical complaints do not need to be logged.

14.1.2 Adverse events

If the untoward medical occurrence did involve a trial participant, but was not related to the device, it is an adverse event. These events are further classified as serious adverse events (SAE) or non-serious adverse events (AE).

14.1.3 Serious adverse events

Serious adverse events are untoward medical occurrences in a subject that are not related to the investigational device, comparator, or trial procedures, but that meet the criteria of “serious.” A serious adverse event is one that:

a) Led to a death
b) Led to a serious deterioration in the health of the subject that:
    i. Resulted in a life-threatening illness or injury, or
    ii. Resulted in a permanent impairment of a body structure or a body function, or
    iii. Required in-patient hospitalization or prolongation of existing hospitalization, or
    iv. Resulted in medical or surgical intervention to prevent life threatening illness or injury or permanent impairment to a body structure or a body function
    v. Led to fetal distress, fetal death, or a congenital abnormality or birth defect.

A planned hospitalization for a pre-existing condition or a condition required by the protocol, without serious deterioration in health, is not considered serious.

14.1.4 Adverse device effects

An untoward medical occurrence that happened in a subject and is related to the device or device procedure (but not the comparator) is an adverse device effect. If the occurrence does not meet the definition of serious, it is classified as an adverse device effect (ADE). Adverse device effects are a subset of adverse events.

14.1.5 Serious adverse device effects

An untoward medical occurrence that happens in a subject, is related to the investigational device, comparator, or procedure, and is serious, but is not unanticipated is a serious adverse device effect (SADE). Untoward medical occurrences that are not unanticipated, i.e. are unsurprising, are identified in the investigator’s brochure or protocol and informed consent form.

As with serious adverse events, a serious adverse device effect is one which

a) Led to a death
b) Led to a serious deterioration in the health of the subject that:
    i. Resulted in a life-threatening illness or injury, or
    ii. Resulted in a permanent impairment of a body structure or a body function, or
    iii. Required in-patient hospitalization or prolongation of existing hospitalization, or
    iv. Resulted in medical or surgical intervention to prevent life threatening illness or injury or permanent impairment to a body structure or a body function
    v. Led to fetal distress, fetal death, or a congenital abnormality or birth defect.

A planned hospitalization for a pre-existing condition or a condition required by the protocol, without serious deterioration in health, is not considered serious.

14.1.6 Unanticipated serious adverse device effect

An untoward medical occurrence that happens in a subject; is related to the investigational device, device procedure, or comparator; is serious; and was unanticipated is classified as an unanticipated serious adverse device effect (USADE). Serious adverse device effect which are *anticipated* are listed below.

14.2 Reporting period

The reporting period includes any adverse events which occurred between randomization and discharge.

14.3 Reporting procedure

All members of the patient management teams will be instructed as to the possible adverse events prior to the start of the trial and will be given an emergency contact number to immediately report any suspected adverse event to the site investigators.

Any possible untoward medical occurrence is identified will be evaluated and classified by the site PI, as follows:

a) Relation to XSTAT device: “Effect” (device-related) vs “event” (device-unrelated)

b) Seriousness: Serious (meeting the criteria listed above) or not
c) Anticipated: Anticipated (matching the conditions shown in the list below) or unanticipated

14.3.1 Adverse events (AE)/adverse device effects (ADE)

Adverse events and adverse device effects which are not deemed serious will be recorded using the “PHOXSTAT Adverse Event Recording Form”.

14.3.2 Anticipated serious adverse events (SAE)/serious adverse device effects (SADE)

Anticipated adverse device effects include:

a) XSTAT sponges left in situ after the index operation (either because they cannot be located, or because they were overlooked)
b) XSTAT sponges which entered the peritoneal or pleural cavities
c) XSTAT sponge embolization

Anticipated serious adverse events include:

a) Need for surgical procedure to remove sponges, in the absence of a vascular injury requiring ligation or repair
b) Death unrelated to XSTAT device
c) Acute Kidney Injury
d) Acute Lung Injury/Acute Respiratory Distress Syndrome
e) Cardiac arrest
f) Pulmonary embolus
g) Extremity arterial thrombosis
h) Multi-organ Failure
i) Myocardial infarction
j) Ventilator-Associated Pneumonia

Anticipated serious adverse events and adverse device effects will also be recorded using the “PHOXSTAT Adverse Event Recording Form”. In addition, a “PHOXSTAT Serious Adverse Event/Serious Adverse Device Effect” form must be completed, and emailed to the PHOXSTAT Trial Office (swstephens@uabmc.edu) within 48 hours. All reports of anticipated SAE/SADE will be forwarded to the medical monitor.

14.3.3 Unanticipated serious adverse events/serious adverse device effects (USADE)

Unanticipated serious adverse events and adverse device effects will also be recorded using the “PHOXSTAT Adverse Event Recording Form”. In addition, a “PHOXSTAT Unanticipated Serious Adverse Event/Serious Adverse Device Effect” form must be completed, and emailed to the PHOXSTAT Trial Office (swstephens@uabmc.edu) within 48 hours. In addition, the Study PI must be notified, by telephone (205-757-9418) within 48 hours.

On notification of a USAE/USADE report, the PHOXSTAT Trial Office will, within 3 business days:

a) Forward the report to the medical monitor
b) Notify the PHOXSTAT DSMB
c) Notify the UAB IRB
d) Notify the reporting site’s IRB
e) Notify the DoD (ORP/HRPO, and USAMRMC)

In addition, the PHOXSTAT Trial Office will, within 7 days, notify the FDA, using the MedWatch form.

14.4 Role and responsibility of the Independent Medical Monitor

An independent medical monitor will review all adverse events/effects and provide an unbiased written report of the events. At a minimum, the medical monitor must comment on the outcomes of the event or problem and in case of a serious adverse event/serious adverse device effect, comment on the relationship to participation in the trial. Because a moderate number of deaths are expected due to the nature of the injuries, individual reports to the PHOXSTAT DSMB will be aggregated and reported on a timely schedule acceptable to the DSMB.

If the death is considered unexpected and is either suspected or probably due to treatment, this event will be promptly reported to the DSMB. The medical monitor must also indicate whether he/she concurs with the details of the report provided by the principal investigator.

Dr. Patrick Bosarge is the independent medical monitor for this study. He has committed to comply with the following statements:

The monitor:

a) Is independent of the research team.
b) Possesses sufficient educational and professional experience to serve as a subject advocate.
c) Will promptly report discrepancies or problems to the IRB.

14.5 Role and responsibility of the Data and Safety Monitoring Board

The PHOXSTAT DSMB is a distinct and separate entity and functions independently from the sponsor, and the Trial Office. It will be comprised of the following:

a) Dr. Henry Wang (chairman)
b) Dr. Stacia DeSantis (statistician)
c) Dr. John Holcomb (methodologist)

The DSMB has the authority to stop the research in progress, remove individual subjects from the research, and take whatever steps are necessary to protect the safety and well-being of the subjects until the IRB can assess its reports.

In addition to reviewing individual reports forwarded by the Independent Medical Monitor, the DSMB will, in conjunction with the trial's biostatistician, conduct interim analyses of the data, at intervals of its choosing. The DSMB will meet at least annually, or more frequently if deemed necessary.

15. QUALITY ASSURANCE

15.1 Training

15.1.1 Clinical staff

All clinical personnel (EMS and hospital-based) undergo initial and continuing training in XSTAT® application, which reviews indications, methods of deployment, and removal of the sponges. The training also covers the design and objectives of the trial, and data collection procedures.

15.1.2 Research staff

A Standard Operating Procedure Manual (SOPM) developed by the UAB research team provides standard definitions of all study variables (i.e., data elements) and describes all data collection and data entry procedures in detail. Copies of the SOPM will be distributed to all sites to be used in training each site‘s research team and will be available on the study website through UAB CIS.

Initial training for research assistants and study coordinators is conducted on site. Training includes completing the case report forms, obtaining the laboratory data, and other procedures described in the SPOM. Training of other study staff is the responsibility of trial site coordinators. Training activities will be monitored by the clinical and/or data monitoring team through records of training sessions submitted.

Awareness of the trial protocol in the ED and OR among all staff members is important. Sites will be responsible for orientation and education of all ED personnel on the study to ensure that those designated to collect data are notified of eligible patients upon arrival. Sites may wish to take advantage of staff meetings and in-services to inform and educate the ED staff. Also, the support and collaboration of hospital administrators and physicians can facilitate recruitment and data collection in the ED and OR. The additional tasks required of a research protocol may be taxing in a busy ED setting and, without a show of support from management, procedures outside patient treatment may be inconsistent. The trial sites are responsible for establishing and maintaining coalitions with physicians and hospital administrators to ensure they become stakeholders and receive recognition for their part in the trial.

15.2 Study Monitors

The study monitors will report to UAB. Monitors will be trained in trial procedures, trained to identify source documentation, to assess regulatory compliance, to review source documents for agreement with study records, to identify possible unreported adverse events, and to look for protocol violations. Sites will be visited periodically to assess data quality, review training logs, and monitor study enrollment.

16. PROJECT TIMELINE

16.1 Summary/Gantt Chart

YEAR 1												
	PLANNING AND PREPARATION PHASE											
	2018			2019								
	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep
Finalize RevMedx Contract												
Execute CTA with Sites												
Develop Protocol												
Develop Randomization Mechanism												
Develop & test database												
Conduct community consultation & public disclosure												
Obtain HARPO approval												
Obtain IRB approval												
Investigator's Meeting (kick-off meeting)												
Train study personnel												
Site 1 set-up (UAB)												
Site 1 Enrollment Begins (UAB)												
Site 2 set-up (USC)												
Site 2 Enrollment Begins (USC)												
Site 3 set-up (Vandy)												
Site 3 Enrollment Begins (Vandy)												
YEAR 2												
	EXECUTION PHASE											
				2020								
	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep
Enrollment												
YEAR 3												
	EXECUTION PHASE (cont'd)											
				2021								
	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep
Enrollment												
YEAR 4												
	EXECUTION PHASE (cont'd)						ANALYSIS PHASE					
				2022								
	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep
Enrollment												
Analysis												
Report/Publication												

16.2 Detailed description/Milestones

16.2.1 Year 1: Planning Phase

Task & Timeline	*Notes*
Develop and document industry partnerships necessary for conduct of the clinical trial (Months 0-3)	We will formalize a contractual agreement between UAB and RevMedx™, Inc., to include at a minimum, intellectual property rights, and data ownership.

Liaison with additional sites (Months 3-6)	Liaise with two additional trauma centers/EMS providers willing to participate in the trial.
Develop protocol, case report forms, and study database (Months 0-6)	We will develop and finalize the clinical trial protocol including a manual of procedures. We will test and finalize case report forms (CRF) for the study. (Sample data collection form in Appendix 2)
Obtain HRPO approval (Months 0-12)	All US Army Medical Research and Materiel Command (USAMRMC) supported research involving humans, human data, human specimens, or cadavers must be reviewed for compliance with Federal and Department of Defense (DoD) human subjects protection requirements and approved by the Office of Research Protections (ORP). The ORP has two human subjects protection review and compliance oversight offices, the Human Research Protections Office (HRPO) and the Clinical Investigations Regulatory Office (CIRO). Our research team has considerable experience obtaining HRPO approval.
Obtain IRB approval (Months 4-9)	Once the protocol is finalized, we will obtain appropriate Institutional Review Board (IRB) approvals.
Conduct Exception From Informed Consent Community Consultation and Public Disclosure Activities (Month 6-12)	The study will be carried out under federal Exception from Informed Consent (EFIC) regulations. We will conduct all required EFIC community consultation and public disclosure activities.

Training (Months 11-12)	Once the protocol is approved by HRPO and the UAB IRB, we will coordinate prehospital protocol training. The study team will provide training for all prehospital care providers, and additional training for trauma surgeons for the removal of XSTAT® devices.

16.2.2 Year 2/3: Trial Execution Phase

Task & Timeline	*Notes*
Enrollment (Months 13-36)	Subject recruitment

16.2.3 Year 3/4: Data Analysis Phase

Task & Timeline	*Notes*
Data Analysis (Months 25-42)	While data analysis will be ongoing throughout the trial, detailed final analyses will be commenced during the last year of trial enrollment. We will require 6 months after trial completion to complete final data cleaning and analysis.

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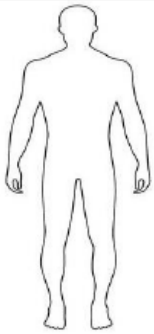
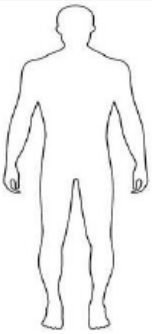
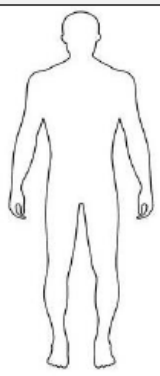
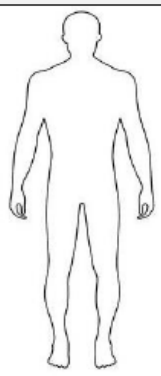
18. APPENDICES

Appendix 1: Sample tracking label

The tracking labels are found inside the study packs. They are printed on stiff, waterproof card, are hole-punched, and be supplied with a tie. The label should be completed as directed, and then attached to the patient's wrist or ankle. Labels are specific to trial sites.

PhoXSTAT	**Prehospital XSTAT Trial**	**Kit Number:**	
YOUR PATIENT HAS BEEN RANDOMIZED TO STANDARD CARE. USE THE DIAGRAMS BELOW TO INDICATE THE LOCATION OF THE WOUND(S) THAT MADE YOU ENTER THE PATIENT INTO THE TRIAL.			
 Front	Comments	 Back	Comments
Date:		**Vehicle ID:**	

PhoXSTAT	**Prehospital XSTAT Trial**	**Kit Number:**	
FIRST WOUND TREATED		**SECOND WOUND TREATED (IF APPLICABLE)**	
 Mark Location	**How many devices used on this wound?** ☐ Only one XSTAT used on this wound ☐ Both XSTATs used on this wound **Ease of insertion of device into wound:** ☐ Unable to insert ☐ Reasonably easy to use ☐ Easily inserted **Ease of deployment of sponges:** ☐ Unable to deploy sponges ☐ Reasonably easy to deploy sponges ☐ Easily deployed **Time device used:**	 Mark Location	**How many devices used on this wound?** ☐ Only one XSTAT used on this wound **Ease of insertion of device into wound:** ☐ Unable to insert ☐ Reasonably easy to use ☐ Easily inserted **Ease of deployment of sponges:** ☐ Unable to deploy sponges ☐ Reasonably easy to deploy sponges ☐ Easily deployed **Time device used:**
Date:		**Vehicle ID:**	

Appendix 2: Data Dictionary Codebook

The University of Alabama
Ophthalmology Services Foundation

PhoXSTAT

Codebook

Data Dictionary Codebook 04/19/2019 1:29pm

Collapse all instruments

#	Variable / Field Name	Field Label *Field Note*	Field Attributes (Field Type, Validation, Choices, Calculations, etc.)
Instrument: **Form 5: Randomized to XSTAT** (form_5_randomized_to_xstat)			Collapse
1	kit_number	Kit label #	text, Identifier
2	vehicle_id	Vehicle ID #	text
3	header_f6		descriptive
4	num_wounds Show the field ONLY if: [vehicle_id] <> ""	Section Header: *Describe the wounds treated with XSTAT:* How many wounds were treated with XSTAT?	radio 1, 1 2, 2
5	wound_1_loc Show the field ONLY if: [num_wounds] = '1' or [num_wounds] = '2'	Where was the anatomical location of wound #1?	radio 1, Axilla 2, Groin
6	wound_1_side Show the field ONLY if: [num_wounds] = '1' or [num_wounds] = '2'	On which side of the body was the wound #1?	radio 1, Left 2, Right
7	wound_1_orientation Show the field ONLY if: [num_wounds] = '1' or [num_wounds] = '2'	What was the anatomical orientation of wound #1 (Choose all that apply)?	checkbox 1, wound_1_orientation___1, Anterior 2, wound_1_orientation___2, Posterior 3, wound_1_orientation___3, Medial 4, wound_1_orientation___4, Lateral
8	wound_2_loc Show the field ONLY if: [num_wounds] = '2'	Where was the anatomical location of wound #2?	radio 1, Axilla 2, Groin
9	wound_2_side Show the field ONLY if: [num_wounds] = '2'	On which side of the body was wound #2?	radio 1, Left 2, Right
10	wound_2_orientation Show the field ONLY if: [num_wounds] = '2'	What was the anatomical orientation of wound #2 (Choose all that apply)?	checkbox 1, wound_2_orientation___1, Anterior 2, wound_2_orientation___2, Posterior 3, wound_2_orientation___3, Medial 4, wound_2_orientation___4, Lateral
11	kit_opened_yn Show the field ONLY if: [num_wounds] = '1' or [num_wounds] = '2'	Section Header: *Describe the use of the study protocol:* Was kit opened?	yesno, Required 1, Yes 0, No
12	randomized_yn Show the field ONLY if: [kit_opened_yn] = '1'	Was the patient randomized to treatment with XSTAT syringe?	yesno, Required 1, Yes 0, No

13	xstat_attempted Show the field ONLY if: [randomized_yn] = '1'	Was treatment with XSTAT attempted?	yesno, Required 1 Yes 0 No
14	violation_reason Show the field ONLY if: [xstat_attempted] = '0' and [randomized_yn] = '1'	Please state reason(s) for protocol violation	notes
15	num_devices Show the field ONLY if: [randomized_yn] = '1' and [xstat_attempted] = '1'	Section Header: *DATA FROM PREHOSPITAL TRACKING LABEL* Number of XSTAT devices used	radio 1 1 2 2
16	xstat_used_wound_1 Show the field ONLY if: [xstat_attempted] = '1'	Was an XSTAT device used for the wound to the [wound_1_side], [wound_1_orientation] [wound_1_loc]?	yesno 1 Yes 0 No
17	xstat_used_wound_2 Show the field ONLY if: [xstat_attempted] = '1' and [num_wounds] = '2'	Was an XSTAT device used for the wound to the [wound_2_side], [wound_2_orientation] [wound_2_loc]?	yesno 1 Yes 0 No
18	sponge_insert_dt_tm_1 Show the field ONLY if: [xstat_used_wound_1] = '1'	Section Header: *Provide information on the XSTAT use for the wound to the [wound_1_side], [wound_1_orientation] [wound_1_loc]* What was the date and time at which the sponges were inserted into the wound to the [wound_1_side], [wound_1_orientation] [wound_1_loc]? (M-D-Y H:M)	text (datetime_mdy)
19	ease_of_insertion_wound_1 Show the field ONLY if: [xstat_used_wound_1] = '1'	Ease of insertion of device into the wound to the [wound_1_side], [wound_1_orientation] [wound_1_loc]	radio 1 Unable to insert 2 Reasonably easy to use 3 Easily inserted
20	ease_sponge_deploy_wound_1 Show the field ONLY if: [xstat_used_wound_1] = '1'	Ease of deployment of sponges into the wound to the [wound_1_side], [wound_1_orientation] [wound_1_loc]	radio 1 Unable to deploy sponges 2 Reasonably easy to use 3 Easily deployed
21	sponge_insert_dt_tm_2 Show the field ONLY if: [xstat_used_wound_2] = '1'	Section Header: *Provide information on the XSTAT use for the wound to the [wound_2_side], [wound_2_orientation] [wound_2_loc]* What was the date and time at which the sponges were inserted into the wound to the [wound_2_side], [wound_2_orientation] [wound_2_loc]?? (M-D-Y H:M)	text (datetime_mdy)
22	ease_sponge_deploy_wound_2 Show the field ONLY if: [xstat_used_wound_2] = '1'	Ease of deployment of sponges into the wound to the [wound_2_side], [wound_2_orientation] [wound_2_loc]	radio 1 Unable to deploy sponges 2 Reasonably easy to use 3 Easily deployed
23	ease_of_insertion_wound_2 Show the field ONLY if: [xstat_used_wound_2] = '1'	Ease of insertion of device into the wound to the [wound_2_side], [wound_2_orientation] [wound_2_loc]	radio 1 Unable to insert 2 Reasonably easy to use 3 Easily inserted
24	form_5_randomized_to_xstat_complete	Section Header: *Form Status* Complete?	dropdown 0 Incomplete 1 Unverified 2 Complete
Instrument: **Form 1 Arrival In ED** (form_1_arrival_in_ed)			Collapse

25	site	Site	radio, Required 1 LAC+USC 2 UAB 3 VUMC
26	header_f1		descriptive
27	inj_mechanism	Section Header: *ARRIVAL* Mechanism of Injury	radio, Required 1 Gunshot wound 2 Shotgun wound 3 Stabbing/Knife wound 4 Impalement
28	arrdate	Date of arrival (M-D-Y)	text (date_mdy)
29	arrtime	Time of arrival (24h clock HH:MM)	text (time)
30	sysbp	Section Header: *FIRST AVAILABLE VITAL SIGNS AND GCS* Systolic blood pressure (mmHg)	text (integer, Min: 0, Max: 220)
31	dbp	Diastolic blood pressure (mmHg)	text (integer, Min: 0, Max: 150)
32	heart_rate	Heart rate (bpm)	text (integer, Min: 0, Max: 120)
33	gcs	Glasgow Coma Scale score (total)	text (integer, Min: 3, Max: 999)
34	gcs_eye	Glasgow Coma Scale - Eye	radio 1 1 2 2 3 3 4 4
35	gcs_verbal	Glasgow Coma Scale - Verbal	radio 1 1 2 2 3 3 4 4 5 5 9 T (Intubated)
36	gcs_motor	Glasgow Coma Scale - Motor	radio 1 1 2 2 3 3 4 4 5 5 6 6
37	gender	Section Header: *DEMOGRAPHICS* Gender	radio 1 Male 2 Female 3 Unknown
38	birthyear	Year of Birth	text (integer, Min: 1905, Max: 2010)
39	birthyr_unk	Check if birth year is unknown	radio 1 Unknown

40	age_estimate Show the field ONLY if: [birthyr_unk] = '1'	Estimated age (years)	radio 1 < 15 2 15-19 3 20-34 4 35-49 5 50-65 6 >65
41	weight_kg	Weight (kg)	text (number)
42	height_cm	Height (cm)	text (number)
43	ethnicity	Ethnicity (Check all that apply)	checkbox 1 ethnicity___1 White/non-Hispanic/non-Latino 2 ethnicity___2 American Indian/Alaskan Native/Aboriginal 3 ethnicity___3 Asian 4 ethnicity___4 Black/African-American 5 ethnicity___5 Hispanic/Latino 6 ethnicity___6 Native Hawaiian/Other Pacific Islander 7 ethnicity___7 Other-Specify 8 ethnicity___8 Not noted/Unknown
44	ethnicity_other Show the field ONLY if: [ethnicity(7)] = '1'	Ethnicity, other specify:	text
45	form_1_arrival_in_ed_complete	Section Header: *Form Status* Complete?	dropdown 0 Incomplete 1 Unverified 2 Complete
Instrument: **Form 2: Verification of Eligibility** (form_2_verification_of_eligibility) Collapse			
46	header_f2		descriptive
47	incl_age	Section Header: *Inclusion Criteria Met: To be eligible, all questions must be answered "Yes"* Age (Est. 18+ years or weight 50+kg if age unknown)	radio (Matrix) 1 Yes 0 No
48	incl_direct_scene	Received directly from injury scene	radio (Matrix) 1 Yes 0 No
49	incl_jctl_injury	Penetrating junctional injury (groin or axilla)	radio (Matrix) 1 Yes 0 No
50	excl_prisoner	Section Header: *Exclusion Criteria Present: To be eligible, all questions must be answered "No"* Prisoner, defined as those directly admitted from a correctional facility	radio (Matrix) 1 Yes 0 No
51	excl_age	Children under the age of 18 years or under 50kg if age unknown	radio (Matrix) 1 Yes 0 No
52	excl_pregnancy	Known pregnancy	radio (Matrix) 1 Yes 0 No

84	inj_named_vein_1 Show the field ONLY if: ([surg_proc_wound(1)] = '1' or ([num_wounds] = '1' and [operation_junction_site] = '1')) and [current-instance] = 1	Injury to named vein?	radio (Matrix) 1 Yes 0 No
85	inj_unnamed_vessel_1 Show the field ONLY if: ([surg_proc_wound(1)] = '1' or ([num_wounds] = '1' and [operation_junction_site] = '1')) and [current-instance] = 1	Injury to un-named vessel?	radio (Matrix) 1 Yes 0 No
86	inj_tissue_bleed_1 Show the field ONLY if: ([surg_proc_wound(1)] = '1' or ([num_wounds] = '1' and [operation_junction_site] = '1')) and [current-instance] = 1	Tissue bleeding?	radio (Matrix) 1 Yes 0 No
87	inj_pleural_violation_1 Show the field ONLY if: ([wound_1_loc] = '1' and ([surg_proc_wound(1)] = '1' or ([num_wounds] = '1' and [operation_junction_site] = '1'))) and [current-instance] = 1	Pleural violation?	radio (Matrix) 1 Yes 0 No
88	inj_peritoneal_violation_1 Show the field ONLY if: ([wound_1_loc] = '2' and ([surg_proc_wound(1)] = '1' or ([num_wounds] = '1' and [operation_junction_site] = '1'))) and [current-instance] = 1	Peritoneal violation?	radio (Matrix) 1 Yes 0 No
89	op_arterial_ligation_1 Show the field ONLY if: [surg_proc_wound(1)] = '1' or ([num_wounds] = '1' and [operation_junction_site] = '1')	Section Header: *Please describe the operative treatment on the wound to the [wound_1_side], [wound_1_orientation] [wound_1_loc]:* Ligation of arterial injury	radio (Matrix) 1 Yes 0 No
90	op_venous_ligation_1 Show the field ONLY if: [surg_proc_wound(1)] = '1' or ([num_wounds] = '1' and [operation_junction_site] = '1')	Ligation of venous injury	radio (Matrix) 1 Yes 0 No
91	op_arterial_repair_1 Show the field ONLY if: [surg_proc_wound(1)] = '1' or ([num_wounds] = '1' and [operation_junction_site] = '1')	Patch angioplasty, interposition grafting, or direct repair of arterial injury	radio (Matrix) 1 Yes 0 No
92	op_venous_repair_1 Show the field ONLY if: [surg_proc_wound(1)] = '1' or ([num_wounds] = '1' and [operation_junction_site] = '1')	Patch angioplasty, interposition grafting, or direct repair of venous injury	radio (Matrix) 1 Yes 0 No
93	op_other_details Show the field ONLY if: [surg_proc_wound(1)] = '1' or ([num_wounds] = '1' and [operation_junction_site] = '1')	Other operative treatment/additional details:	notes

94	sponges_removed_dt_tm_1 Show the field ONLY if: [randomized_yn] = '1' and [xstat_attempted] = '1' and ([surg_proc_wound(1)] = '1' or ([num_wounds] = '1' and [operation_junction_site] = '1')) and [xstat_used_wound_1] = '1'	**Section Header:** *Please describe the experience removing the XSTAT sponges from the wound to the [wound_1_side], [wound_1_orientation] [wound_1_loc]:* What was the date and time at which the sponges were finally removed (or when decision was made that they could not be removed? (M-D-Y H:M)	text (datetime_mdy)
95	ease_sponge_remove_1 Show the field ONLY if: [randomized_yn] = '1' and [xstat_attempted] = '1' and ([surg_proc_wound(1)] = '1' or ([num_wounds] = '1' and [operation_junction_site] = '1')) and [xstat_used_wound_1] = '1'	Please describe the ease of sponge removal	radio 1 Failed to remove all sponges 2 Reasonably easy to remove all sponges 3 Sponges easily removed
96	time_sponge_removal_1 Show the field ONLY if: [randomized_yn] = '1' and [xstat_attempted] = '1' and ([surg_proc_wound(1)] = '1' or ([num_wounds] = '1' and [operation_junction_site] = '1')) and [xstat_used_wound_1] = '1'	Please estimate the time required to remove the sponges	radio 1 31 minutes or longer 2 Between 5 and 30 minutes 3 Less than 5 minutes
97	imaging_sponge_removal_1 Show the field ONLY if: [randomized_yn] = '1' and [xstat_attempted] = '1' and ([surg_proc_wound(1)] = '1' or ([num_wounds] = '1' and [operation_junction_site] = '1')) and [xstat_used_wound_1] = '1'	Please describe what intraoperative imaging was used to ensure removal of the sponges	radio 1 Imaging not used due to patient's condition 2 Imaging not used, as not available 3 Imaging not used, as deemed unnecessary 4 Imaging used
98	imaging_outcome_1 Show the field ONLY if: [randomized_yn] = '1' and [xstat_attempted] = '1' and [imaging_sponge_removal_1] = '4' and ([surg_proc_wound(1)] = '1' or ([num_wounds] = '1' and [operation_junction_site] = '1')) and [xstat_used_wound_1] = '1'	Describe the outcome	radio 1 Additional sponges were seen on imaging 2 No additional sponges were seen on imaging
99	xstat_satisfaction_1 Show the field ONLY if: [randomized_yn] = '1' and [xstat_attempted] = '1' and ([surg_proc_wound(1)] = '1' or ([num_wounds] = '1' and [operation_junction_site] = '1')) and [xstat_used_wound_1] = '1'	Please describe your overall satisfaction with the XSTAT device	radio 1 Dissatisfied 2 Neither satisfied nor dissatisfied 3 Satisfied
100	inj_named_artery_2 Show the field ONLY if: [surg_proc_wound(2)] = '1'	**Section Header:** *Please describe the findings for the wound to the [wound_2_side], [wound_2_orientation] [wound_2_loc]:* Injury to named artery?	radio (Matrix) 1 Yes 0 No
101	inj_named_vein_2 Show the field ONLY if: [surg_proc_wound(2)] = '1'	Injury to named vein?	radio (Matrix) 1 Yes 0 No
102	inj_unnamed_vessel_2 Show the field ONLY if: [surg_proc_wound(2)] = '1'	Injury to un-named vessel?	radio (Matrix) 1 Yes 0 No

103	inj_tissue_bleed_2 Show the field ONLY if: [surg_proc_wound(2)] = '1'	Tissue bleeding?	radio (Matrix) 1 Yes 0 No
104	inj_pleural_violation_2 Show the field ONLY if: [surg_proc_wound(2)] = '1' and [wound_2_loc] = '1'	Pleural violation?	radio (Matrix) 1 Yes 0 No
105	inj_preitoneal_violation_2 Show the field ONLY if: [surg_proc_wound(2)] = '1' and [wound_2_loc] = '2'	Peritoneal violation?	radio (Matrix) 1 Yes 0 No
106	op_arterial_ligation_2 Show the field ONLY if: [surg_proc_wound(2)] = '1'	**Section Header:** *Please describe the operative treatment on the wound to the [wound_2_side], [wound_2_orientation] [wound_2_loc]:* Ligation of arterial injury	radio (Matrix) 1 Yes 0 No
107	op_venous_ligation_2 Show the field ONLY if: [surg_proc_wound(2)] = '1'	Ligation of venous injury	radio (Matrix) 1 Yes 0 No
108	op_arterial_repair_2 Show the field ONLY if: [surg_proc_wound(2)] = '1'	Patch angioplasty, interposition, grafting, or direct repair of arterial injury	radio (Matrix) 1 Yes 0 No
109	op_venous_repair_2 Show the field ONLY if: [surg_proc_wound(2)] = '1'	Patch angioplasty, interposition, grafting, or direct repair of venous injury	radio (Matrix) 1 Yes 0 No
110	sponges_removed_dt_tm_2 Show the field ONLY if: [randomized_yn] = '1' and [xstat_attempted] = '1' and [surg_proc_wound(2)] = '1' and [xstat_used_wound_2] = '1'	**Section Header:** *Please describe the experience removing the XSTAT sponges from the wound to the [wound_2_side], [wound_2_orientation] [wound_2_loc]:* What was the date and time at which the sponges were finally removed (or when decision was made that they could not be removed? (M-D-Y H:M)	text (datetime_mdy)
111	ease_sponge_remove_2 Show the field ONLY if: [randomized_yn] = '1' and [xstat_attempted] = '1' and [surg_proc_wound(2)] = '1' and [xstat_used_wound_2] = '1'	Please describe the ease of sponge removal	radio 1 Failed to remove all sponges 2 Reasonably easy to remove all sponges 3 Sponges easily removed
112	time_sponge_removal_2 Show the field ONLY if: [randomized_yn] = '1' and [xstat_attempted] = '1' and [surg_proc_wound(2)] = '1' and [xstat_used_wound_2] = '1'	Please estimate the time required to remove the sponges	radio 1 31 minutes or longer 2 Between 5 and 30 minutes 3 Less than 5 minutes
113	imaging_sponge_removal_2 Show the field ONLY if: [randomized_yn] = '1' and [xstat_attempted] = '1' and [surg_proc_wound(2)] = '1' and [xstat_used_wound_2] = '1'	Please describe what intraoperative imaging was used to ensure removal of the sponges	radio 1 Imaging not used due to patient's condition 2 Imaging not used, as not available 3 Imaging not used, as deemed unnecessary 4 Imaging used
114	imaging_outcome_2 Show the field ONLY if: [randomized_yn] = '1' and [xstat_attempted] = '1' and [surg_proc_wound(2)] = '1' and [imaging_sponge_removal_2] = '4' and [xstat_used_wound_2] = '1'	Describe the outcome	radio 1 Additional sponges were seen on imaging 2 No additional sponges were seen on imaging

115	xstat_satisfaction_2 Show the field ONLY if: [randomized_yn] = '1' and [xstat_attempted] = '1' and [surg_proc_wound(2)] = '1' and [xstat_used_wound_2] = '1'	Please describe your overall satisfaction with the XSTAT device	radio 1 Dissatisfied 2 Neither satisfied nor dissatisfied 3 Satisfied
116	form_7_operative_treatment_complete	Section Header: *Form Status* Complete?	dropdown 0 Incomplete 1 Unverified 2 Complete
Instrument: **Form 8: Blood/Blood Product Transfusion Record** (form_8_bloodblood_product_transfusion_record) Collapse			
117	header_f8		descriptive
118	red_cell_units	Red cell concentrate (units)	text (integer) Field Annotation: @DEFAULT="0"
119	plasma_units	Plasma (units)	text (integer) Field Annotation: @DEFAULT="0"
120	platelet_units	Platelets (units)	text (integer) Field Annotation: @DEFAULT="0"
121	cryo_units	Cryoprecipitate (units)	text (integer) Field Annotation: @DEFAULT="0"
122	whole_blood_units	Whole blood (units)	text (integer) Field Annotation: @DEFAULT="0"
123	form_8_bloodblood_product_transfusion_record_complete	Section Header: *Form Status* Complete?	dropdown 0 Incomplete 1 Unverified 2 Complete
Instrument: **Form 9: Procoagulant medication** (form_9_procoagulant_medication) Collapse			
124	header_f9		descriptive
125	txa_mg	Tranexamic acid (mg)	text (number) Field Annotation: @DEFAULT="0"
126	fibrinogen_mg	Fibrinogen concentrate (mg)	text (number) Field Annotation: @DEFAULT="0"
127	octaplex_mg	Octaplex (mg)	text (number) Field Annotation: @DEFAULT="0"
128	prothrombin_complex	Prothrombin complex concentrate	text (number) Field Annotation: @DEFAULT="0"
129	vitamin_k	Vitamin K	text (number) Field Annotation: @DEFAULT="0"
130	other_procoag_med	Other (specify, including amount)	notes
131	form_9_procoagulant_medication_complete	Section Header: *Form Status* Complete?	dropdown 0 Incomplete 1 Unverified 2 Complete
Instrument: **Form 10: Admission Blood Work** (form_10_admission_blood_work) Collapse			
132	header_f10		descriptive
133	blood_gas_source	Section Header: *From blood gas analysis:* Source	radio 1 Arterial 2 Venous
134	lactate	Lactate (mmol/L)	text (number)
135	basedef	Base deficit (mmol/L)	text (number)
136	hgb	Section Header: *From routine lab work:* Hemoglobin (g/dl)	text (number)

137	hct	Hematocrit (%)	text (number, Min: 0, Max: 100)
138	platelet_count	Platelet count	text (integer)
139	pt	Prothrombin time (s)	text (number)
140	inr	International Normalized Ratio	text (number)
141	aptt	Activated Partial Thromboplastin Time (s)	text (number)
142	teg_r	Section Header: *Thromboelastography:* R (mins)	text (integer)
143	teg_k	K (mins)	text (integer)
144	teg_alpha_angle	Alpha angle (degrees)	text (number)
145	teg_ma	MA (mm)	text (number)
146	teg_la30	LY30 (%)	text (number, Min: 0, Max: 100)
147	form_10_admission_blood_work_complete	Section Header: *Form Status* Complete?	dropdown 0, Incomplete 1, Unverified 2, Complete
Instrument: **Form 11: Outcomes** (form_11_outcomes)			Collapse
148	header_f11		descriptive
149	injury_iss	Injury Severity Score	text (integer, Min: 1, Max: 75)
150	patient_outcome	Patient	radio, Required 1, Discharged from acute care 2, Died
151	dc_date Show the field ONLY if: [patient_outcome] = '1'	Discharge date (M-D-Y)	text (date_mdy)
152	death_date Show the field ONLY if: [patient_outcome] = '2'	Date of death (M-D-Y)	text (date_mdy)
153	icu_ever Show the field ONLY if: [patient_outcome] = '1' or [patient_outcome] = '2'	Ever in ICU?	yesno 1, Yes 0, No
154	icu_days Show the field ONLY if: [icu_ever] = '1'	Days spent in the ICU	text (number)
155	place_of_death Show the field ONLY if: [patient_outcome] = '2'	Where did the patient die?	radio 1, Prehospital (prior to arrival in the ED) 2, Emergency Department 3, Operating Room 4, Intensive Care Unit 5, Floor 6, Palliative Care Unit
156	form_11_outcomes_complete	Section Header: *Form Status* Complete?	dropdown 0, Incomplete 1, Unverified 2, Complete
Instrument: **Form 12: Adverse Events/Effect Recording Form** (form_12_adverse_eventseffect_recording_form)			Collapse
157	header_f12		descriptive
158	event_code	Event/effect code (Choose from list above; leave blank if not listed)	text (integer, Min: 1, Max: 19)

159	event_desc	Description of event	notes
160	event_start_date	Start date (M-D-Y)	text (date_mdy)
161	event_end_date	End date (M-D-Y), leave blank if ongoing	text (date_mdy)
162	event_xstat_related	Relationship to use of XSTAT device?	radio, Required 1 Related ("effect") 2 Unrelated("event")
163	event_serious	Serious adverse event/device effect?	radio, Required 1 Yes ("serious") 0 No ("not serious")
164	event_anticipated	Anticipated?	radio, Required 1 Yes ("anticipated") 0 No ("unanticipated")
165	form_12_adverse_eventseffect_recording_form_complete	Section Header: *Form Status* Complete?	dropdown 0 Incomplete 1 Unverified 2 Complete
Instrument: **Form 13: Subject/LAR Consent** (form_13_subjectlar_consent) Collapse			
166	header_f13		descriptive
167	died_before_lar	Please check this box if the patient died before contact was made with the LAR	checkbox 1 died_before_lar___1
168	contact_date_time	Contact Date and Time (M-D-Y H:M)	text (datetime_mdy)
169	contact_purpose	Purpose of contact	radio 1 Contacting LAR for consent 2 Contacting participant for consent
170	contact_type	Type of contact	radio 1 Phone 2 In person 3 Other
171	contact_type_other Show the field ONLY if: [contact_type] = '3'	Specify	text
172	contact_outcome	Outcome	radio 1 Made contact, consent given 2 Made contact, consent not given 3 No reply, did not make contact 4 Note additional information on Form 14
173	form_13_subjectlar_consent_complete	Section Header: *Form Status* Complete?	dropdown 0 Incomplete 1 Unverified 2 Complete
Instrument: **Form 14: Additional Information** (form_14_additional_information) Collapse			
174	header_f14		descriptive
175	form_no	Form Number	text (integer, Min: 1, Max: 13)
176	additional_details	Additional details	notes

177	form_14_additional_information_complete	Section Header: *Form Status* Complete?	dropdown 0 Incomplete 1 Unverified 2 Complete