BIOLOGICAL TECHNOLOGIES OFFICE

Medics Autonomously Stopping Hemorrhage (MASH)

Lt Col Adam M. Willis, MD, PhD

Proposers' Day

September 18, 2025

DARPA

Proposers’ Day objectives

- To **encourage** and **promote teaming** among organizations that have the relevant expertise, research facilities, and capabilities for executing research and development responsive to the MASH program goals

- To introduce the science and technology community (industry, academia, government, etc.) to the MASH program vision

- To facilitate information exchange between the DARPA MASH program management team and potential program investigators

Frequently Asked Questions (FAQs)

- Please **submit all your questions** about program details via **MASH Program E-mail (MASH@darpa.mil)**. The team will compile, and we'll hold a discussion session at the end of the day and run through them then.

- We will make every effort to answer your questions today. Unanswered questions will be addressed (along with every question received as determined appropriate) in the **FAQ on the opportunity website**.

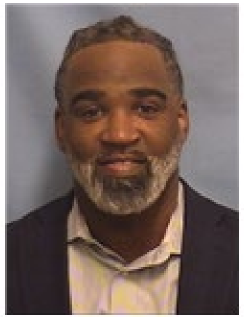
Teaming is important

- To fully address the PS, you may need to team with other entities
- Each team should submit a unified proposal under a single PI
- Foreign entities may join a team or submit as the PI
- Even if you are a member of a team, you may still join any number of other proposal teams or form your own and submit a proposal as PI
- You must find your collaborators on your own, but today is a great opportunity for networking!

MASH Team Member Introductions and Due Dates

DARPA MASH Team	
Adam Willis, MD, PhD	DARPA/BTO Program Manager
André Curlee	DARPA/BTO Chief of Staff to Adam Willis
Jason Allio	DARPA/BTO Program & Financial Support
Natasha Woods	DARPA/BTO Program Security Representative
Justin Manzo, PhD	DARPA/BTO Technical SETA
Cristina Russo, PhD	DARPA/BTO Technical SETA
Dr. Danyal Fer, MD, USAF	Government Team Member
William "Tyler" Davis, MD	Government Team Member


Adam Willis


Andre Curlee


Jason Allio


Natasha Woods


Justin Manzo


Cristina Russo


Danyal Fer


Tyler Davis

<u>Abstracts Due:</u> Wednesday, October 15, 2025

<u>OPP Due</u>: Tuesday, November 25, 2025

Opening comments

- The Proposers' Day briefing is intended to provide an orientation to the MASH Program Solicitation and is solely for information purposes
- The solicitation supersedes anything presented or said by DARPA at the Proposers' Day
- A PS has been released, please keep in mind there will be a continually updated FAQ for clarifying information
- Examples in this briefing (e.g., technologies, use cases) are chosen for ease of illustration only and do not constitute endorsement of any particular approach
- Interested performers are expected to be able to articulate a clear and compelling vision for their technology, proposed course of research, and transition potential
- Teaming is important! Today is a great opportunity for networking
- We need your help to make this program a success!

MASH program vision

DoD Problem: Without pre-hospital solutions for internal hemorrhage the DoD will have massive warfighter losses to survivable injuries.

Impacts

1. Stop lethal forms of torso hemorrhage without a surgeon via **demonstrator system**
2. Provide MIS path to **enter trauma market** and utilize **full autonomy**
3. Push standard of pre-hospital hemorrhage control to 48+ hrs

Why DARPA?

Forward-based automated trauma surgery can only be de-risked by combining novel signal exploitation coupled with the latest in robotic learning.

Program Vision: Forward medical sites with **autonomous** robotic systems to stabilize torso hemorrhage without need of a surgeon, providing 48+ hours to reach definitive care.

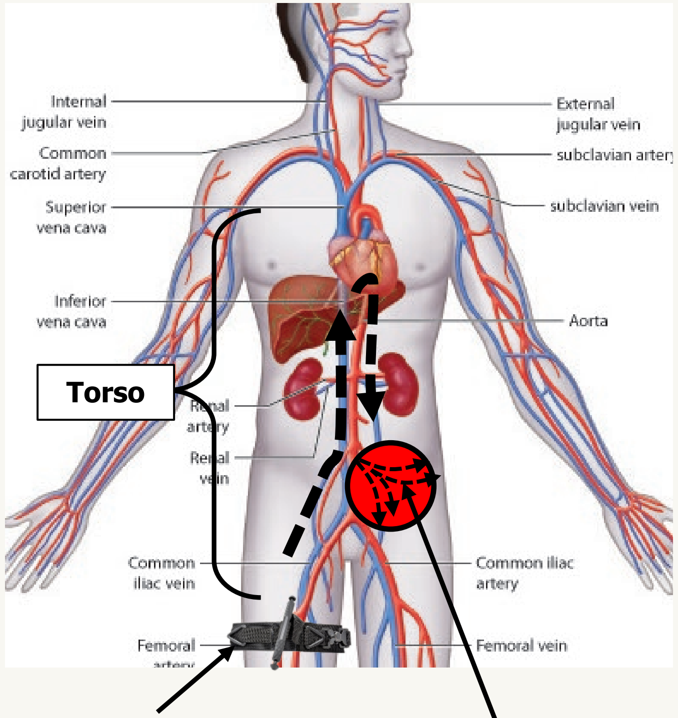
MIS: minimally-invasive surgery

Torso hemorrhage dominated survivable GWOT fatalities, will worsen in LSCO

Stopping non-compressible torso hemorrhage…

<u>Lethal Hemorrhage:</u>
= 40% x Total Blood Volume (5L) = 2L
= 15.6 cm diameter hematoma

Example: liver injury – hard to access, can present without external hemorrhage, fatal without surgery

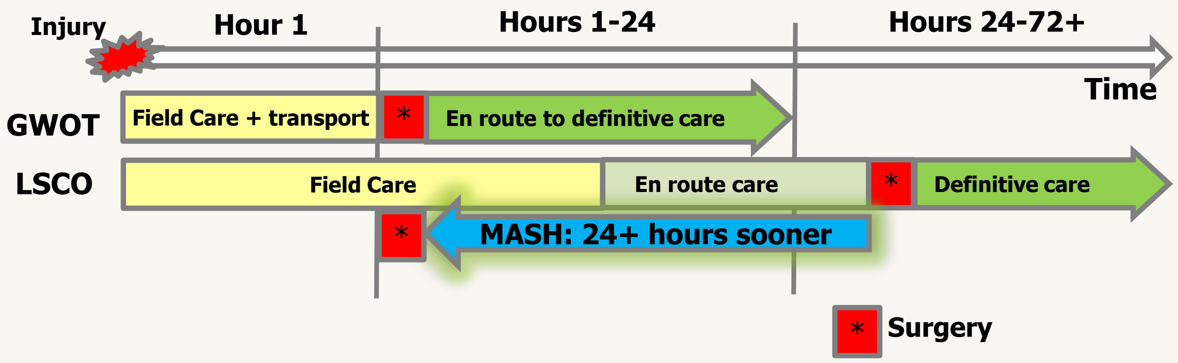


Compressible hemorrhage via tourniquet

1.8 mm/s flow (.012 mL/s) lethal in 48 hours

Base image from: https://pressbooks.ccconline.org/bio106/chapter/cardiovascular-structures-and-functions/

…is a BIG Deal.



GWOT: Global war on terror
LSCO: Large-scale combat operations
NCTH: Non-compressible torso hemorrhage

Pre-hospital intervention for NCTH will maximize lives saved in combat

SOA surgery for civilian and military use cases – a huge gap

Current treatment options for stopping the bleed at Role 2+:

1. Packing / Hemostatic agents
2. Intravascular embolization
3. Electrocautery
4. Vascular ligation

Affords 48+ hours to reach definitive surgery

Current practice in two settings

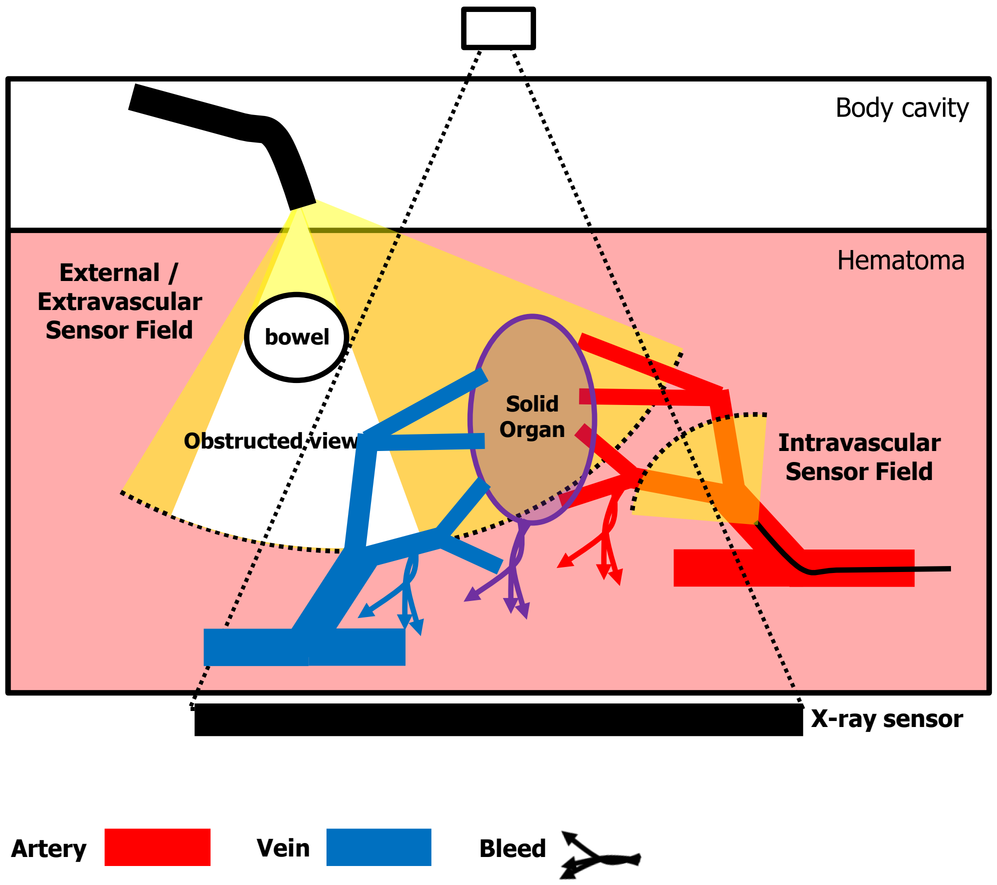
	Damage Control Surgery	**SOA Robotic Surgery**	**MASH**
Planning	None	Multiple outpatient visits, labs, imaging	None
Blood Volume	Decreasing	Stable	Decreasing
Pace	Rapid repair (< 30 minutes)	Controlled (up to 5 hours)	Rapid Repair
Location	Operating Room (Role 2- wartime)	Tertiary Care	Role 1
Resources	Surgeon	Robot + **Surgeon**	Medic + Robot
Incision	Large OPEN (18 – 35 cm)	Small MIS: 1-5 cm	Small < 5 cm
Training Availability	Starved	Robust	Starved
Autonomy	None	Limited	**Full**

MIS: minimally invasive surgery
SOA: State-of-the-art

Both surgical hemostasis and robotic surgery need advancements to achieve vision

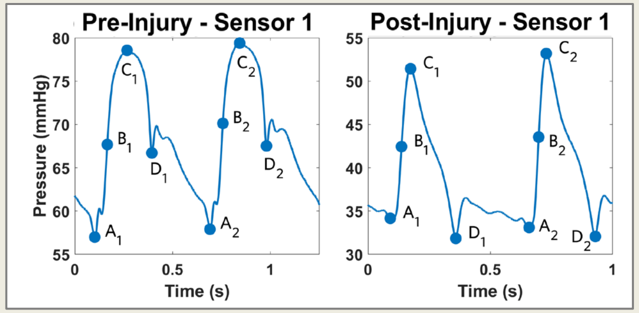
Sensors: “seeing” hemorrhage not necessary to detect and localize source

Canonical Bleed



Intravascular hemorrhage detection

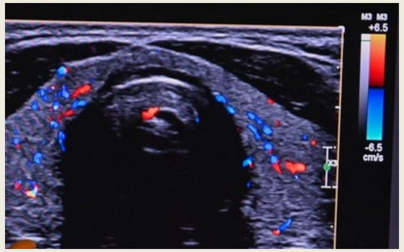
Ultrasound[1]



Pressure signal[1]

Extravascular hemorrhage detection

- X-ray (external)
- Electrocardiogram (external)
- Ultrasound (intracavitary, external)
- Fluoroscopy
- Many other existing sensors



DVIDS 250115-F-XD903-1022

Multiple approaches enable sensing to guide hemorrhage perception and treatment

[1] S. H. Arshad et al., "Endovascular Localization of Aortic Injury in a Porcine Model," in IEEE Open Journal of Engineering in Medicine and Biology (2025).

Quantifying the problem and program structure

Improvements needed (yellow)
Novel to MASH (red)

Sense blood loss → **Perceive** bleed location(s) → **Move** to bleed → **Stop** Bleed

Sense blood loss: Current sensors adequate for use

Extravascular

- Perceive bleed location(s): *Needs to work in highly deranged anatomy* (Novel to MASH)
- Move to bleed (Novel to MASH):
  - *Needs rapid path planning around soft obstacles*
  - *Needs large training sets*

Intravascular

- Perceive bleed location(s) (Novel to MASH):
  - *Needs interpretation of signal in real-time*
  - *Needs rapid inverse calculations*
- Move to bleed (Improvements needed):
  - *Needs improved path planning*
  - *Needs to work on deranged anatomy*

Stop Bleed: Current procedures adequate for use

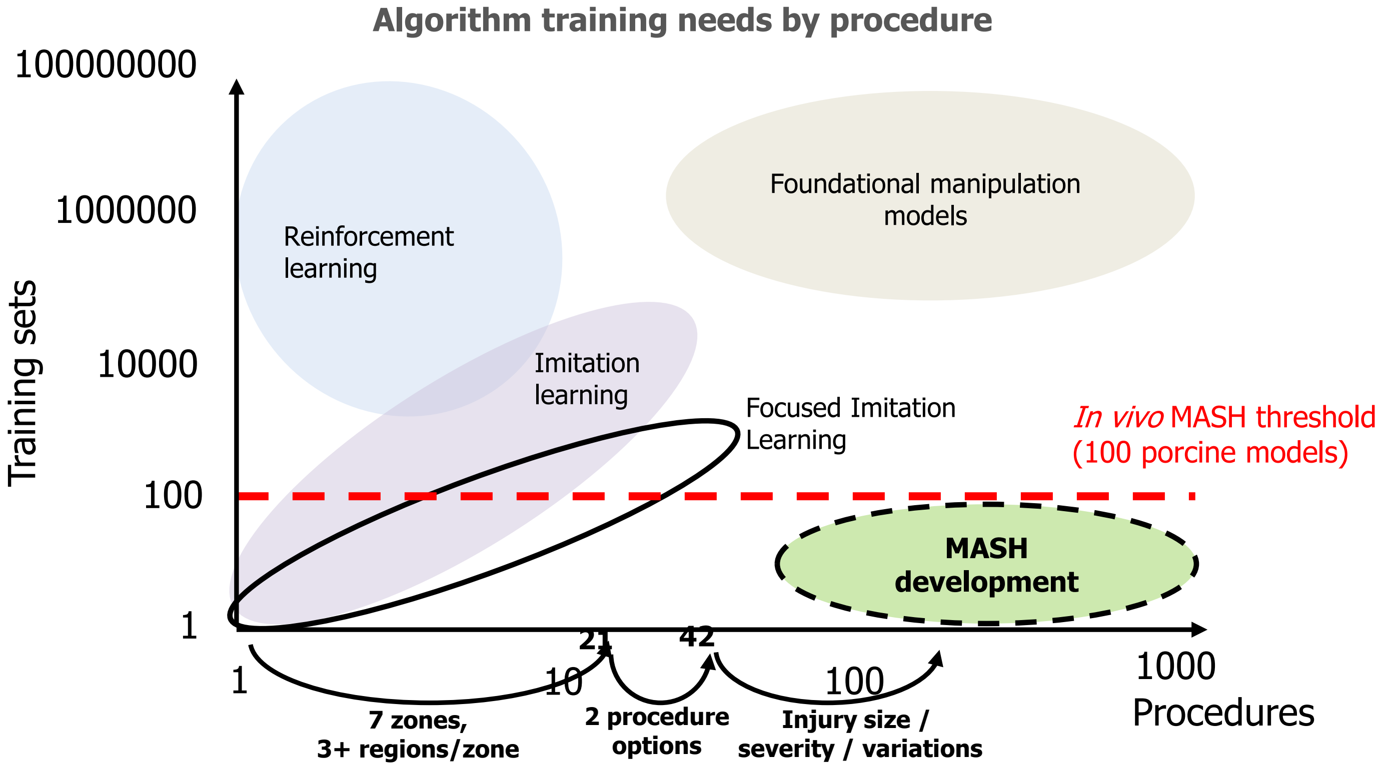
Primary factors and challenges:

1. Deranged anatomy → Large, diverse state space
2. Maneuvering in novel environments → Challenges robotic actuation and motion planning
3. Sensor data limited → Challenges localization and navigation
4. Multiple system elements → Rigorous integration

Enabling Tech:

1. Rapid robotic learning
2. Multi-physics modeling

Enabling technology: rapid robotic learning, layered learning strategy



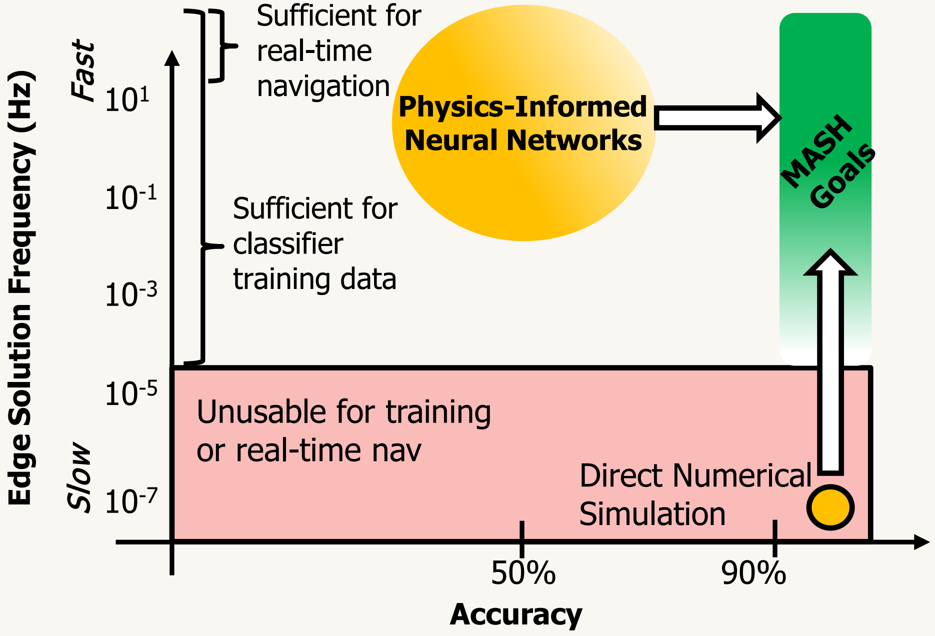
Technique	Role	Sample Reduction Impact
Transfer learning	Reuse models from prior organs/tasks	3-5 X
Imitation learning (including focusing techniques)	Sample recovery and fault-focused training	5-10 X
Synthetic simulations	Generate 1M+ diverse trajectories	100 X coverage
Ex vivo / phantoms	Many repetitions with different trauma	10-100 X
Data augmentation	Rotate / flip / mirror / adjust color	10-100 X
Multimodal training	Videos + sensors + LLM priors	Generalization boost
Layered Learning Strategy	***Effect of combined techniques***	***150K – 50M X Reduction in training size***

LLM: large language model

Combined techniques can overcome lack of training data needed to enable autonomy for trauma surgery

Enabling technology: multi-physics modeling

Conventional physics-based models lack the needed accuracy or speed



But! Fast accurate multi-physics forward modeling are available for training classifiers

- Physics informed Deep Operator hypernetworks to predict **intravascular pressure signals**
- Hyper-UNets can accelerate **tissue mechanics** for simulation 1000x

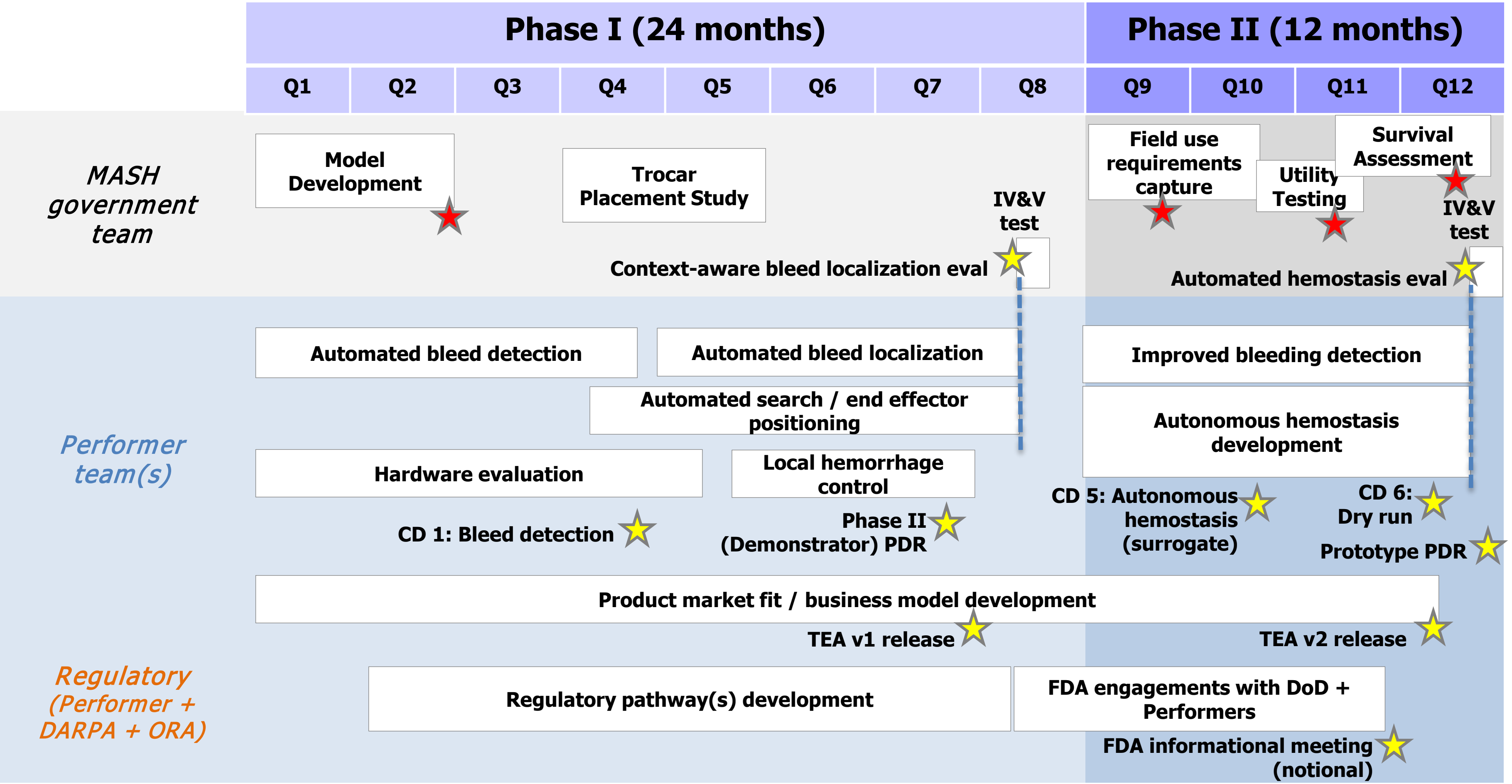
Inverse physics modeling from observed data (flow, pressure) can pinpoint bleed source

To support inverse problem, can employ AI tools:

- Neuronal networks for contact mechanics
- AI velocimetry for fluid dynamics
- Physics-informed Deep Operator Networks for flow prediction

Fast and accurate models can enable robotic training and localization of bleeding source

MASH program structure and gantt



★ Government-furnished information

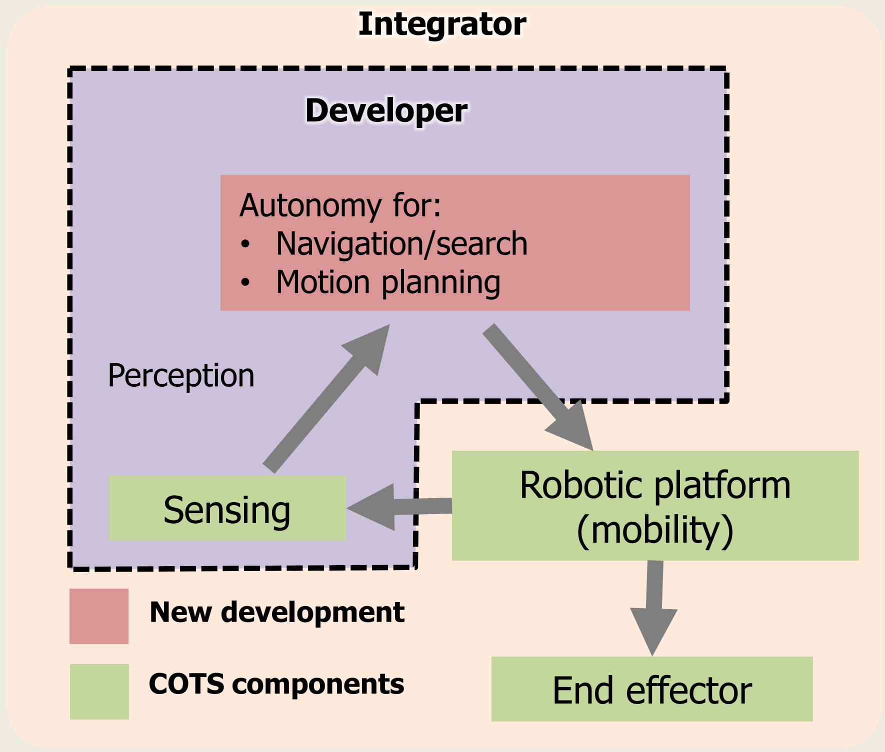
☆ Performer key milestone (not exhaustive)

CD: capability demonstration
IV&V: independent verification & validation
ORA: DHA Office of Regulated Activities
PDR: preliminary design review
TEA: techno-economic assessment

Teaming considerations: capabilities and expertise

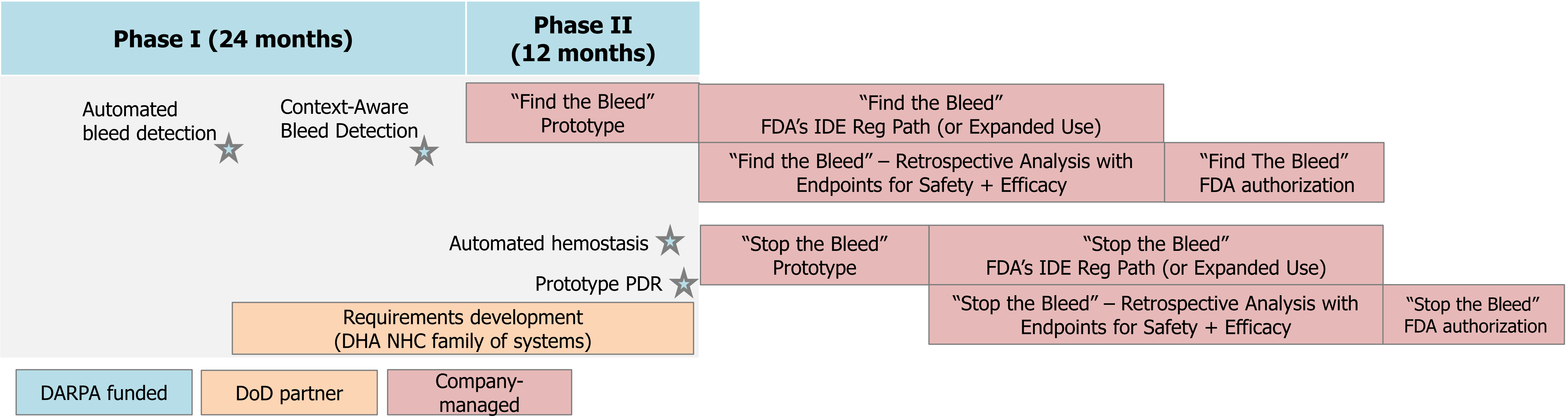
1. Trauma / vascular surgery
2. Large animal models
3. Surgical robotic devices
4. Autonomy and perception
5. AI / ML
6. Physics and physiology modeling
7. Anatomy segmentation
8. Systems engineering
9. FDA/Regulatory product development

Notional example of a teaming configuration



MASH transition and regulatory plan

Strategy: Efficiently pivot DARPA wins to MIS partners to incorporate trauma care and aggressively pursue regulatory pathways that ensure DoD access to MASH technologies.



IDE: investigational device exemption
MIS: minimally invasive surgery
NHC: non-compressible hemorrhage control
PDR: preliminary design review

Areas out of scope

1. Human subjects research (efforts should leverage large animal models)
2. Cell salvage technologies
3. Approaches that require manual surgical techniques for hemostasis as performed by the medic, or require medics to perform medical decision making
4. Approaches not pursuing full (Level 5) surgical autonomy
5. Approaches proposing novel end effectors, sensors, or robotic platforms
6. Autonomy not capable of understanding underlying physics (of movement, obstacles, blood flow patterns, etc.)
7. Approaches proposing the use of pharmacological solutions as the sole means of performing hemostasis. No pharmacologic dosing experiments will be supported, however pharmacologic agents with an approved FDA indication (even if off-label) or with Investigational New Drug (IND) approval can be proposed if in support of hemostasis.
8. Approaches requiring continuous monitoring by the medic following the hemostasis procedure
9. Approaches with no viable path to a prototype design suitable for use in a field-forward, Role 1 military treatment facility
10. Approaches for obtaining initial access to the vasculature or abdomen (e.g. trocar placement) for the robotic platform, or studies to train medics to obtain such access
11. A proposed robotic platform with no current, in-process, or anticipated near-term clinical indication for a related use by a recognized (though not explicitly domestic) medical device regulatory authority. Note: the clinical indication does not have to be for the exact use proposed to support the MASH program.

MASH program metrics

	Phase I	Phase II
Detect bleeding	• Positive predictive value > 90% (correctly identifying that an active bleed is in any listed target (artery, organ, vein) from the MASH Vessel and Organ list) • Negative predictive value > 90%	• PPV > 95% • NPV > 95%
Localize bleeding	• Correct target > 90% accurate (from possible MASH Vessel and Organ list, see attachment) • Distance to nearest upstream branch point accurate to +0/-1 cm (location can't be downstream from true site)	N/A
Time to complete inspection[*,‡]	< 1 hour	N/A
Position end effector	End-effector moved to all key abdominal regions in < 1 hour (to within region of effect of Phase II end effector at correct target from MASH Vessel and Organ list)	N/A
Hemostasis	With manual positioning of end-effector, demonstrate ability to stop bleeding (arterial, solid organ, venous)	Stop bleeding[*] within 1 hour (hematoma<30% total blood volume for 48 hours[Ψ])
Product Market Fit	Profitability and time to profitability of MASH Phase I capabilities across civilian, DoD markets and in different geographies	• Profitability and time to profitability of MASH Phase II capabilities across civilian, DoD markets and in different geographies • FDA regulatory submission roadmap

** With animal baseline survival of 50% and approximately 20% blood volume loss at 1 hour*
‡ From insertion to anatomic localization of all bleeds and positioning of end effector
Ψ Independent of any fluid resuscitation protocolized during IV&V testing and studied under government survival assessment

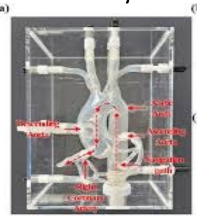
MASH government-led testing

IV&V

Phase I

Modeling

Mockup



Large animal – find hemorrhage

Phase II

Large animal – find and stop hemorrhage

- Final testing against program metrics for each performer team
- Performers required to transport Demonstrator System to IV&V site
- Test methods document provided in advance as GFI

Utility Testing

Field medic utility study – gather usage insights at simulated Role 1, casualty collection point (possible)

Army medic evaluations

18D medic evaluations

- Study to enhance portable prototype design in support of Month 36 Objective System PDR
- Performers required to bring Demonstrator System or prototype <u>mockup</u>
- Government team to provide outcomes report as GFI

Survival Assessment

What treatments beyond hemostasis are required to ensure survival?

- Study to provide insights beyond hemostasis outcomes (protocolized resuscitation) necessary for 48+ hour survival
- Performed in parallel with Phase II IV&V testing
- Government team to provide outcomes report as GFI

GFI: government-furnished information
IV&V: independent verification & validation
PDR: preliminary design review

Who cares, and will this make an impact?

DoD Stakeholders

DHA: Reducing mortality increases resilience of the Joint Force to sustain joint-domain formations
Precise, fast, agile solution to control internal bleeding and decrease dying from wounds
- CDD for non-compressible hemorrhage control

USA MRDC: Conduct R&D to treat intracavitary hemorrhage in an austere environment
- ICD for Combat Casualty Care Support for Future Operations

Develop robotic solution sets to enhance pre-hospital capability in future operations
- ICD for Autonomous Care and Evacuation

USINDOPACOM: SECDEF shall… [reduce] the movement and distance associated with patient care - 2025 NDAA

USAFRICOM: Mobile damage control surgery was a top recommendation to improve survivability - RAND Report

Per NATO Chiefs Medical Services Advisory Board

Care Far Forward is a **Top 3 priority** for capability development

Dual-use community interests

- MIS elective surgery – autonomous fault recovery
- Stateside austere medicine
  - Paramedic support / upskilling
  - Remote ERs – efficient trauma management
- International markets (AUS, ROK, UK, others)

CDD: Capability Development Document
DHA: Defense Health Agency
ICD: Initial Capabilities Document
MIS: Minimally invasive surgery
MRDC: Medical Research & Development Command
NCTH: Non-compressible torso hemorrhage