Welcome

• DRIVe Background and EZ-BAA - Tyler Merkeley
• ENACT - Julie Schafer
• Solving Sepsis - Kim Sciarretta
• DRIVe Contracting – Troy Francis
• Live Q&A - Tyler, Julie, Kim and Troy

Note: If there is any discrepancy between what is presented today and the EZ-BAA, the EZ-BAA takes precedence
The BARDA Model

BARDA develops and makes available medical countermeasures (MCMs) by forming unique public-private partnerships with industry partners.
35 BARDA-Driven FDA Approvals, Licensures, and Clearances

By Comparison - It takes large pharma 10 years to clear only 8-13 countermeasures
BARDA Division of Research, Innovation, and Ventures (DRIVE)

DRIVE Mission: Transforming Health Security

Accelerate the research, development, and availability of transformative countermeasures to protect Americans from natural and intentional health security threats.
DRIVE Response Framework

**Situational Awareness/Recognize**
How do we know something is happening, an agent has entered the community?

**Identification/Characteize**
What is it, is it drug resistant, are certain subpopulations more susceptible, will it become an epidemic?

**Design**
How do we stop the spread of the disease? Drugs, vaccines, PPE, social distancing?

**Validate**
Methods under design are evaluated, clinical trials, non-clinical trials, epidemiology, surveillance.

**Produce**
On demand manufacturing of X.

**Distribute**
Novel ways to get product/information to those who need it.

**Administration**
everyone who needs X is provided.

Driving Life-Saving Innovation

**DRIVE Partnering Model**

**Impact Areas**

**Driving It All Together**

<table>
<thead>
<tr>
<th>TRADITIONAL VC FUNDING</th>
<th>Friends &amp; Family</th>
<th>Angel</th>
<th>Series A</th>
<th>Series B</th>
<th>Series C</th>
<th>IPO</th>
</tr>
</thead>
<tbody>
<tr>
<td>TRADITIONAL PRODUCT DEVELOPMENT</td>
<td>Solve Sepsis</td>
<td>Hit - Lead OP Feasibility &amp; OP Development</td>
<td>Preclinical Development Product Development</td>
<td>Clinic Clinical Evaluation</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**DRIVE Accelerator Network**

- NIAID Contract
- BARDA ARD
- DTRA Contract
- BARDA PBS
- MCS Contract

Transforming the Way Government Does Business

• Decentralizing idea generation and capture
  ▪ Accelerator Network
  ▪ Incubator Network (coming soon)

• Streamlining acquisition process
  ▪ EZ Broad Agency Announcement
  ▪ DRIVe Digital Resources
  ▪ Multiple Award Options

• Multiple partnering opportunities
  ▪ DRIVe Launch and DRIVe Ventures
  ▪ DRIVe EZ Broad Agency Announcement
  ▪ DRIVe Broad Agency Announcement
  ▪ Others as needed
DRIVE-X

Easy Broad Agency Announcement (EZ-BAA)

Goal: To accelerate innovations and improve availability of transformative products and technologies to protect Americans from natural and intentional health security threats by soliciting revolutionary technologies and innovations in health security.

• Objective for EZ-BAA:
  ▪ Streamline online application, selection and award process
  ▪ Quickly provide funding to accelerate innovation
  ▪ Position successful product developers for follow-on external and internal investment
DRIVe-X
Easy Broad Agency Announcement (EZ-BAA)

• Please read the EZ-BAA carefully!
• FedBizOpps: www.fbo.gov
  ▪ Solicitation Number: BAA-18-100-SOL-00018
  ▪ EZ-BAA Announcement
  ▪ EZ-BAA Amendments
  ▪ Pre-Proposal teleconference slides
  ▪ FAQs
• DRIVe website: www.DRIVe.hhs.gov
  ▪ EZ-BAA resources including fact sheets, sample application, and a sample cost estimate
  ▪ DRIVe submission portal (to be announced)
EZ 1-Step Process: Abstract and Cost Estimate Submission

• Abstract
  ▪ No more than 2000 words
  ▪ Includes the following:
    ✓ Relevance to DRIVe Areas of Interest (AOI)
    ✓ Technical Approach with qualitative and quantitative metrics
    ✓ Ability to transition strategy and expand use of application

• Cost Estimate
  ▪ Total cost should not exceed $749k including indirect costs
  ▪ Includes the following:
    ✓ Direct Labor (name, position, annual rate, level of effort
    ✓ Materials, supplies & equipment
    ✓ Travel
    ✓ Other Direct Costs (consultants, subcontractors, etc.)
Review Criteria: Acceptable or Unacceptable

• Definition of **Acceptable**:
  ▪ The submitted abstract maps to the AOI identified in the EZ-BAA solicitation and could result in disruptive innovation, is cost realistic, and is likely to result in achievable advancements in the AOI to DRIVe. A finding of Acceptable results in the submitted abstract being considered for award and funding based on the appropriate procurement instrument to be determined by the CO, GO, OTAO and subject to the availability of funding.

• Definition of **Unacceptable**:
  ▪ The submitted abstract does not map to the AOI identified in the EZ-BAA solicitation and could not reasonably result in disruptive innovation, is not cost realistic, and could not reasonably result in achievable advancements in the AOI to DRIVe. A finding of Unacceptable will result in the abstract not being considered for award or funding.

• Offerors will be notified regarding status of abstract submitted
Areas of Interest (AOI)

• DRIVe wants to emphasize revolutionary approaches hyperfocused on the following AOIs:
  ▪ Early Notification to Act, Control, and Treat (ENACT)
  ▪ Solving Sepsis
  ▪ Other Innovative Products with potential to radically transform Health Security

Note: If addition to the general AOI descriptions in the EZ-BAA, the next few slides provide additional information on the ENACT and Solving Sepsis strategy
DRIVE AOI #1: Early Notification to Act, Control, and Treat (ENACT)

• Infectious disease agents such as influenza are a significant threat to health security
  ▪ CDC estimates that influenza infections have led to up to 710,000 hospitalizations and up to 56,000 deaths annually since 2010
  ▪ A pandemic strain could cause millions more deaths
  ▪ Novel diseases can spread in communities, undetected
• Late, or no diagnosis prevents best use of medications contributes to spread of infectious diseases in communities, and delays in public health response in an emergency
Early, Actionable Information is Needed

• Individuals need early signals to seek care, and take action to protect others
  ▪ Empower individuals, and disrupt traditional, outdated healthcare paradigm for diagnosis and treatment
  ▪ Reduce impact on health care system during times of crisis

• Public health officials rely on data to inform decision making on outbreak response

• Bringing innovation into the home and on the person will allow for early information, and early action
Traditional Healthcare Paradigm

- Waiting for symptoms to emerge
  - Leads to delayed treatment
  - Creates burden on the US healthcare system
  - Costs productivity
  - Increases risk of transmission
ENACT Vision for Early Response

Acute Respiratory Infection Symptoms → Diagnosis → Appropriate Treatment → Cloud Reporting

ENACT - Early Notification to Act, Control, and Treat

Flu +

Prompt Treatment

Leveraging the Power of a Connected Network

Data reported to cloud

Cloud warns public health officials of potential outbreak in community

Deployment of assistance on ground
Areas of Interest

Health Signatures
Discovery & Validation

Diagnostic Technology
& Development

Cloud-based reporting
& data analytics

Prediction &
Artificial Intelligence

Novel Biosensing &
Wearable Technologies

In-home, near user
deployment
BARDA’s mission is to develop MCMs against CBRN, influenza and emerging infectious disease threats, to minimize public health impact.

DRIVEe AOI #2: Solving Sepsis

Sepsis is a secondary confounder that arises from primary insults – threatens our ability to protect our Nation.

Targeting pathogen or insult is critical, but not always sufficient.
The General Problem

**Enormous healthcare impact to the US public and growing each year...**

<table>
<thead>
<tr>
<th>MORBIDITY</th>
<th>MORTALITY</th>
<th>MANAGEMENT</th>
<th>GROWING COST</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>1.5 Million</strong></td>
<td>&gt;250,000 people die each year</td>
<td><strong>1:3</strong></td>
<td>responsible for nearly <strong>$24 Billion</strong></td>
</tr>
<tr>
<td>people each year in U.S.</td>
<td>&gt;80,000 are discharged to hospice</td>
<td>patients who die in hospital have sepsis</td>
<td>Annually (6.2% of hospital costs)</td>
</tr>
</tbody>
</table>

Sepsis is a life-threatening organ dysfunction caused by a dysregulated host response to infection (Sepsis-3)
Challenges in Current Practices

- Lack of patient education/awareness
- Sepsis not considered by physician
- Misdiagnosis
- Lack of accurate biomarkers
- Standard of care practices inadequate
- Lack of understanding of immune dysregulation
- Delayed pathogen detection & treatment (incorrect antibiotic, AMR, etc.)
- Delayed access to healthcare
- Patient comorbidities
- Patient population heterogeneity (age, background, pathogen)

Inability to restore homeostasis

Death from sepsis may occur rapidly despite medical care

Mortality rises 7% for every 1hr appropriate antibiotics are delayed

DRIVE Solving Sepsis Program Vision

**Goal:** Reduce the incidence, morbidity and mortality due to sepsis annually by investing in **target areas** throughout the patient treatment plan

- Develop decision support toolkits to empower the individual and the clinician
- Develop technologies that can restore and maintain homeostasis of the patient

![Diagram showing the Sepsis Coalition and related strategies](image)
**Solving Sepsis**

**PATIENT** → **CLINIC VISIT** → **ICU CLINICAL MANAGEMENT**

- **Education and Awareness**
- **Diagnostic// Prognostic toolkits**
- **New Therapies**
- **Diagnostic// Prognostic toolkits**

**INVESTMENT TARGET AREAS**

- Continuous Monitoring/Integrated Feedback
- Individualized Treatment capabilities
- National sepsis database
- Machine Learning/AI

**Virtual Community**

*Not expected to be funded via traditional BAA mechanism*

**PREVENT RE-ADMISSION**

*ASPR*

**Saving Lives. Protecting Americans.**

24
Enabling Technologies

Database: No central Sepsis repository exists

Continuous Monitoring: Need to monitor dynamic changes

Point-of-Care Prognostic/Diagnostic: Host vs. pathogen based

Biomarker discovery

Individualized treatment approaches to restore homeostasis

Host-pathogen pathway analysis
DRIVe AOI # 3: Other Innovative Products with potential to radically transform Health Security

What’s your moonshot idea?

DRIVe wants to hear your bold idea to radically transform Health Security
Contracting Reminders

• ALL abstracts must be submitted via the DRIVe.hhs.gov portal. This is the only accepted means.
• Submit no later than 24 May 2019
• Abstracts cannot be Classified, in part or in whole
• Contract Types (CPFF, Fixed Price, OTAs, etc.)
• If there is a Conflict of Interest concern, please send to DRIVeContracting@hhs.gov
• After submission, communication must go through contracting: DRIVeContracting@hhs.gov
## Submitted FAQs

<table>
<thead>
<tr>
<th>Questions</th>
<th>Answers</th>
</tr>
</thead>
<tbody>
<tr>
<td>May an investigator or offeror submit more than one proposal? Is there a limit to the number of proposals submitted by an individual?</td>
<td>There is currently no limit to the number of abstracts that can be submitted by an offeror or institution. Each abstract will be reviewed through the process. If the proposal is deemed Unacceptable, the offeror will have an opportunity to re-submit at a later date. It is recommended on that offer’s submit only their best products for consideration with the potential to radically transform Health Security.</td>
</tr>
<tr>
<td>What is the duration of an award?</td>
<td>Generally speaking, DRIVe anticipates that EZ-BAA awards will be short in duration. However, specific Period of Performance (POP) for awards vary by project proposed.</td>
</tr>
<tr>
<td>Questions</td>
<td>Answers</td>
</tr>
<tr>
<td>--------------------------------------------------------------------------</td>
<td>----------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Are offerors permitted to submit a list of reviewers that they expressly do not wish to be involved in the review of their Abstract (due to known or perceived conflicts of interest)?</td>
<td>DRIVe will not be managing such a list. However, all reviewers will be screened in advance for Conflict of Interests. If a prospective offeror believes a conflict of interest may exist, the situation shall be addressed with the Contracting Office via <a href="mailto:DRIVeContracting@hhs.gov">DRIVeContracting@hhs.gov</a> prior to abstract submission.</td>
</tr>
<tr>
<td>Does the combined synopsis/solicitation posted for BAA-18-100-SOL-00018 on FBO contain requirements similar to an existing contract or will this be a new requirement?</td>
<td>BAA-18-100-SOL-00018 is a new requirement.</td>
</tr>
</tbody>
</table>
Live

Q & A

Toll: 415-228-5027 | Toll-free: 888-282-1742
Passcode: 5181148
Additional Questions?

EZ-BAA Questions:
DRIVeContracting@hhs.gov

AOI-specific questions:
DRIVe@hhs.gov