



ASPR



EZ-BAA Pre-Proposal Teleconference

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

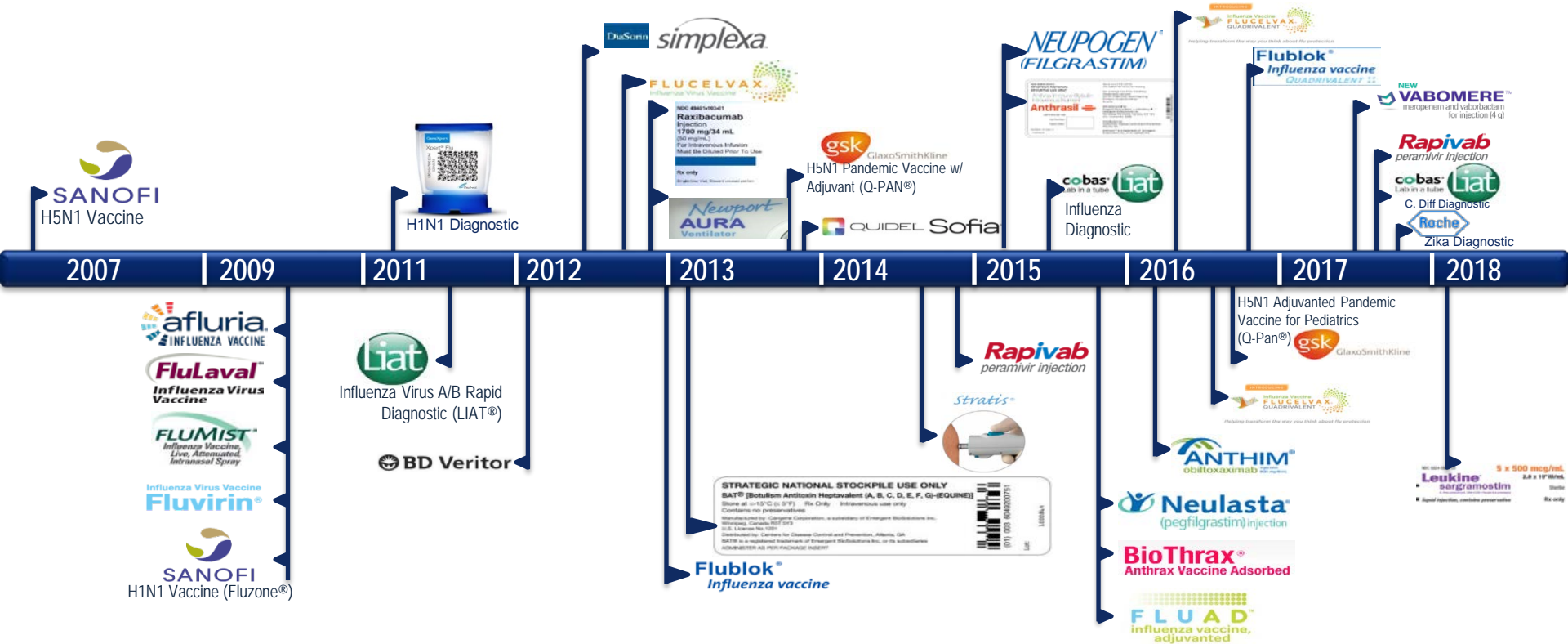
The BARDA Model



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-Ready

CAPTURE

Set targets & research agenda
Coordinate with “deep thinkers”
across USG, academia,
industry, and other
stakeholders.

SOLUTION MAPPING

Establish Integrated Solutions
for Intelligent Acceleration

DRIVE-X

ACCELERATE

Investors: BARDA, DoD

DRIVE-Launch

INITIAL SUSTAINMENT
(1-18 Months)

Investors: BARDA, MCIP

DRIVE ^{VENTURES}
Investing in National
Health Security

STRATEGIC SUSTAINMENT

Corporate Venture Capital
Model Investment in Products

PHEMCE 2.0 Industry DoD

DRIVE Response Framework

Situational Awareness/Recognize

How do we know something is happening, an agent has entered the community?



Identification/Characterize

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

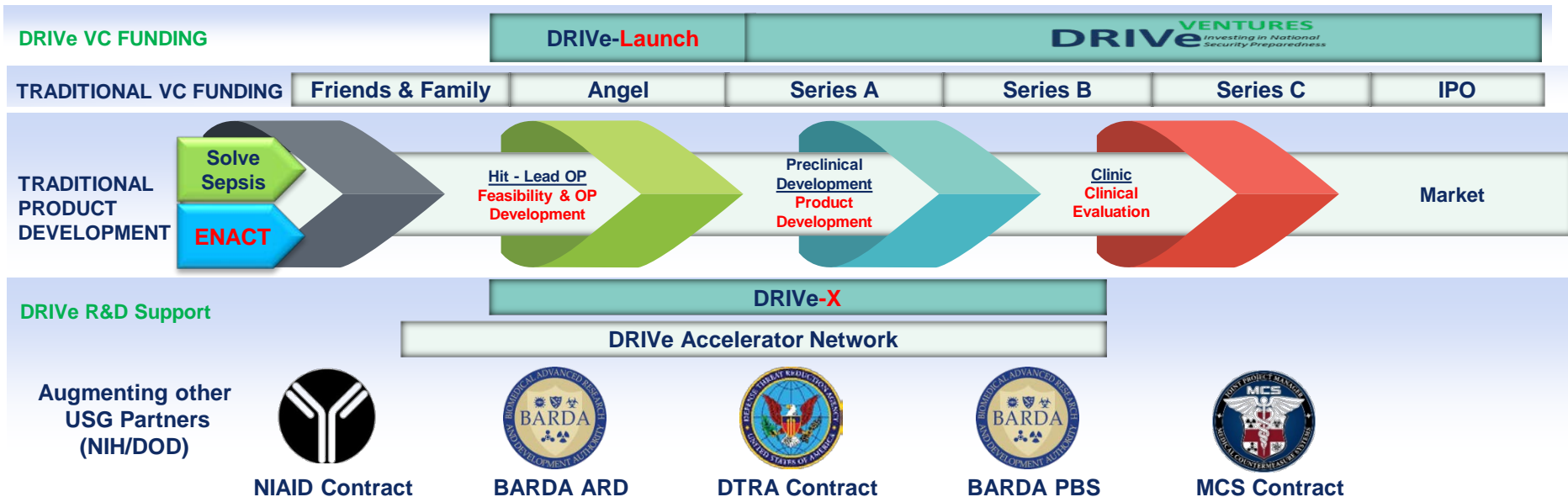
novel ways to get product/information to those who need it.



Administration

everyone who needs X is provided.

Bringing It All Together



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, OTA0 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

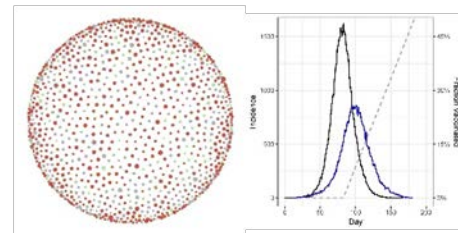
Note: In addition to the general AOI descriptions in the EZ-BAA, the next few slides provide additional information on the ENACT and Solving Sepsis strategy

DRIVE AOI #1: Early Notification to Act, Control, and Treat (ENACT)

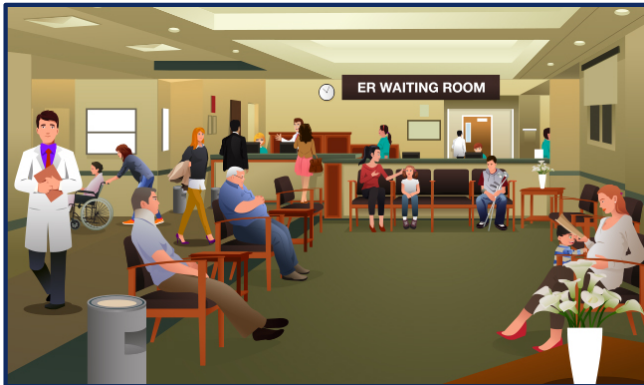
- Infectious disease agents such as influenza are a significant threat to health security
 - CDC estimates that influenza infections have led to up to 710,000 hospitalizations and up to 56,000 deaths annually since 2010
 - A pandemic strain could cause millions more deaths
 - Novel diseases can spread 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

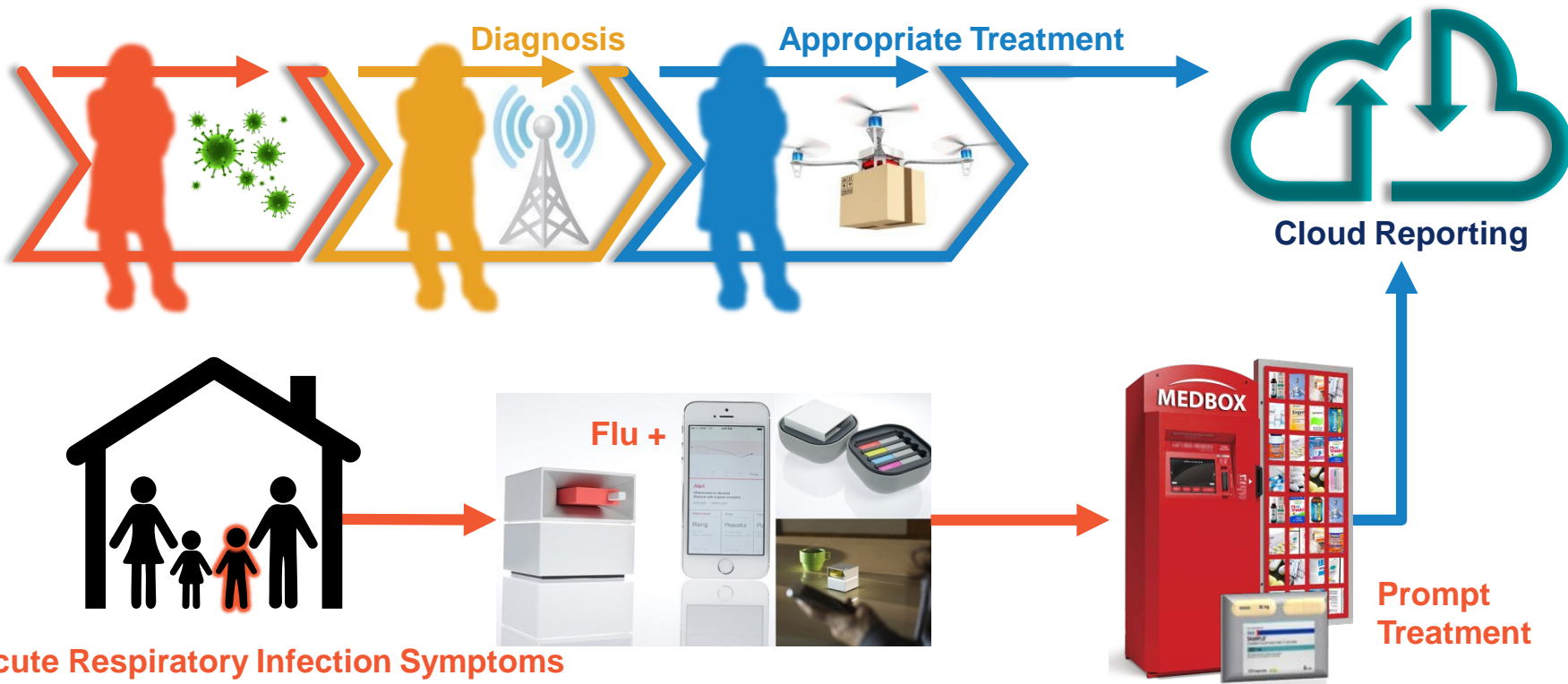


Traditional Healthcare Paradigm

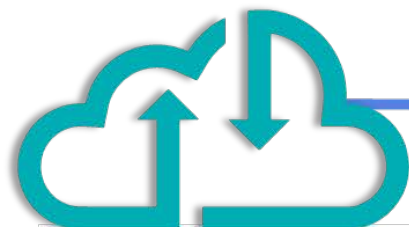


- Waiting for symptoms to emerge
 - Leads to delayed treatment
 - Creates burden on the US healthcare system
 - Costs productivity
 - Increases risk of transmission

ENACT Vision for Early Response



Leveraging the Power of a Connected Network



Data reported to cloud



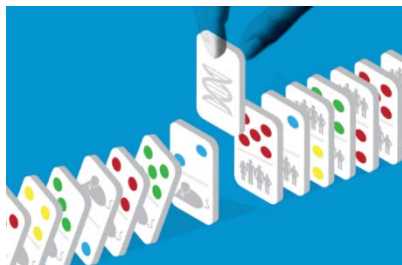
Cloud warns public health officials of potential outbreak in community



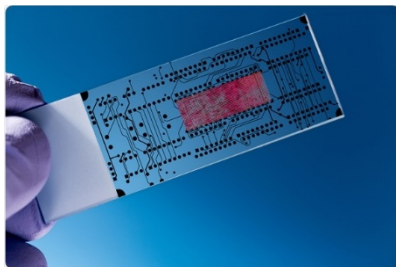
Deployment of assistance on ground



Areas of Interest



**Health Signatures
Discovery & Validation**



**Diagnostic Technology
& Development**



**Novel Biosensing &
Wearable Technologies**



**Cloud-based reporting
& data analytics**



**Prediction &
Artificial Intelligence**



**In-home, near user
deployment**

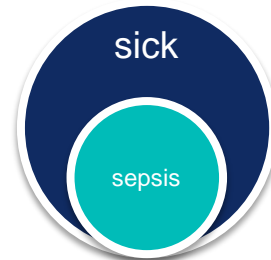


DRIVE AOI #2: Solving Sepsis

BARDA's mission is to develop MCMs against CBRN, influenza and emerging infectious disease threats, to minimize public health impact

DRIVE WILL SAVE LIVES BY 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...

MORBIDITY

**1.5
Million**

people each
year in U.S.

MORTALITY

>250,000
people die
each year

>80,000
are discharged
to hospice

MANAGEMENT

1:3
patients who
die in hospital
have sepsis



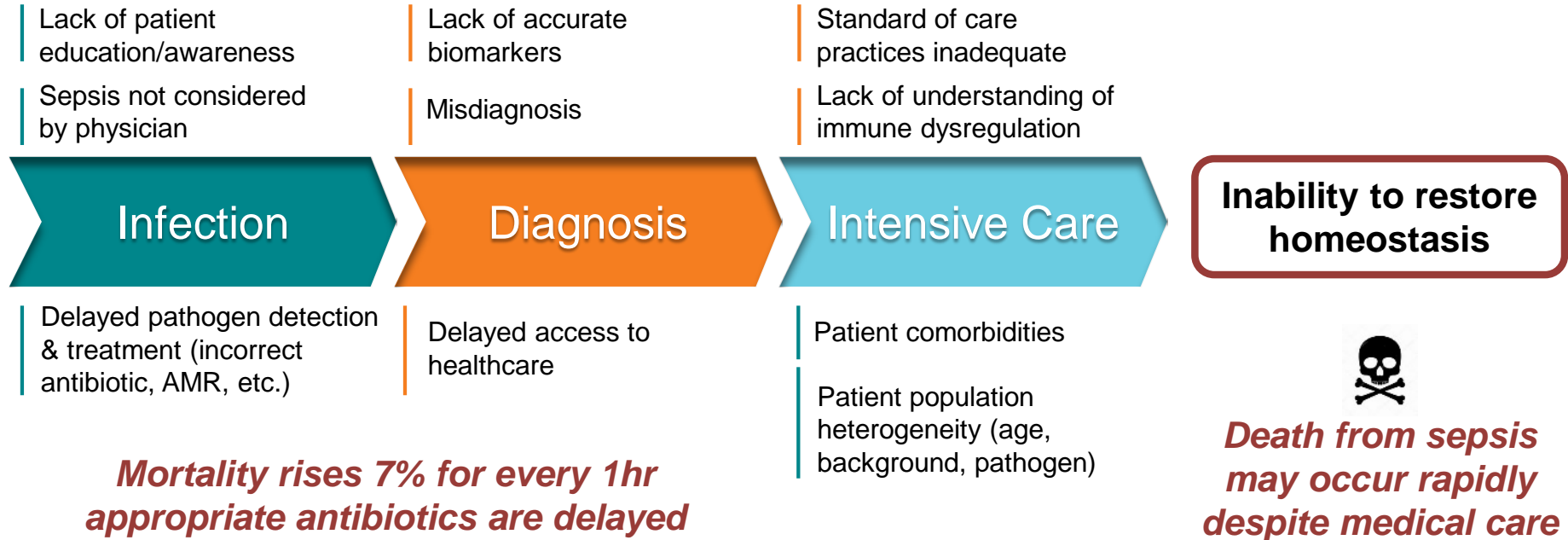
GROWING COST

responsible
for nearly
**\$24
Billion**
Annually
(6.2% of hospital costs)

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



Challenges in Current Practices

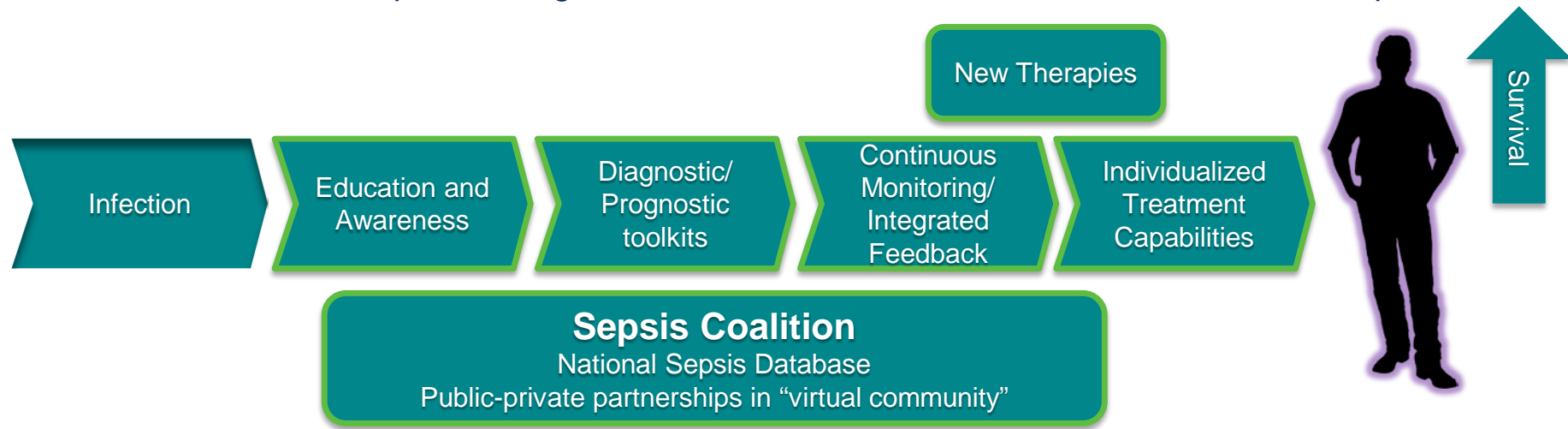




DRIVE Solving Sepsis Program Vision

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





Solving Sepsis

PREVENT
RE-ADMISSION

PATIENT



CLINIC VISIT



ICU CLINICAL
MANAGEMENT



Education and
Awareness*

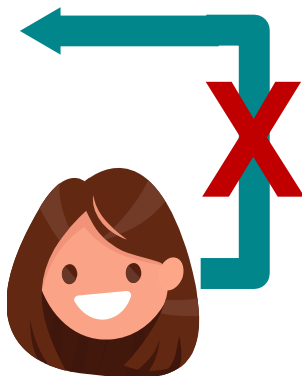


Diagnostic//
Prognostic
toolkits



New
Therapies

Diagnostic//
Prognostic
toolkits



*Virtual
Community

**Not expected to be funded via
traditional BAA mechanism*

Integrated
Feedback



Continuous
Monitoring/
Integrated Feedback

Individualized
Treatment
capabilities

National sepsis
database

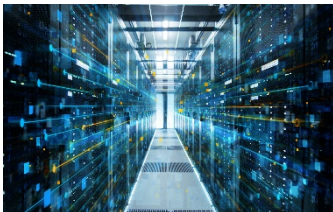
Machine
Learning/AI





Enabling Technologies

Database:
No central Sepsis
repository exists



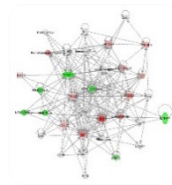
Continuous Monitoring: Need
to monitor dynamic changes



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



**Biomarker
discovery**



**Host-pathogen
pathway
analysis**

Individualized treatment approaches to restore homeostasis

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

Questions	Answers
May an investigator or offeror submit more than one proposal? Is there a limit to the number of proposals submitted by an individual?	<i>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.</i>
What is the duration of an award?	<i>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.</i>

Submitted FAQs Continued

Questions	Answers
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)?	<i>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 DRIVeContracting@hhs.gov prior to abstract submission.</i>
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?	<i>BAA-18-100-SOL-00018 is a new requirement.</i>

Live



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