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FIRST FLIGHT COMPANIES

HIGH SCIENCE – HIGH IMPACT
EARLY STAGE
SCIENCE DRIVEN COMPANIES
OUT TO CHANGE THE WORLD
1983
- 1983 New Technology Jobs Act creates North Carolina Technology Development Authority

1991
- The Science and Technology Research Center in RTP [TUCC Building] transferred to NCTDA.
- NCDTA becomes NFP: spun out of Dept. of Commerce.

1991
- NCTDA becomes a self-sustaining entity; government funding ceases.

2002
- First Flight Venture Fund established: subsidiary of NCTDA.

2004
- First Flight Venture Fund closed.

2009
- NCTDA changes its name to First Flight Venture Center, Inc. [FFVC]

NCTDA was the HQ and technology hub for 24 NC incubators including Charlotte, Fayetteville, NCSU Centennial Campus and more.
FIRST FLIGHT SUCCESS

$8B ↑ Market Cap for First Flight Grads

325 ↑ Companies in 25 Years

$70.5M Investment Raised by Current Companies While at First Flight
SOLVING PROBLEMS THAT MATTER


2017 FIRST FLIGHT

CLIENT ACCOMPLISHMENTS

$24M Funding (All Sources: Debt, Equity, Grants)

150+ Total Employees (Full & Part Time)

32-38 Companies
LIFTOFF - A UNIQUE MODEL FOR WINNING EARLY STAGE FUNDING

- Innovative, cost-effective, self-sustaining solution to assist companies for grant funding.
- In this first of its kind program, science-based entrepreneurial companies are vetted for their potential to impact society and present a value proposition likely to result in grant funding.
- Grant writing experts work with LiftOff companies from the start to finish of the grant writing and submission process at a subsidized cost.
- Once a company is selected as viable for the program, a strategic plan is created, grant proposal opportunities prioritized and submitted.
- Grant awards yield a success fee that is re-invested in the LiftOff program, enabling other companies to secure non-dilutive funds.
LIFTOFF SUCCESS

YOY Comparative Data

- Grants funded: 2 (2016), 7 (2017)
- Millions received: $1.3 (2016), $10.2 (2017)
NEWEST PROGRAM: HANGAR6

ONE-OF-A-KIND ADVANCED PROTOTYPING FACILITY

- EDA i6 Award Winner in 2017
- Grand Opening February 2018
- Only existing rapid prototyping capability in RT Region
- Startups have rough ideas of what they need to make, but they need to evolve designs in real time. Hangar6 provides design expertise and synergy with like-minded entrepreneurs

Business Model
- Monthly or Annual Fee
- Members schedule use of lab’s tools
- Staff services to help develop designs and improve technical skills
- 3D large format scanner & printers
- Fusion 400 FLA 3D printer
- CO2 laser
- Metal fiber laser
- CNC full scale production milling machine
- Welding shop
- Wood working shop
- Mini CNC Router
- New equipment added regularly based on member feedback
SELECT ALUMNI

bioMASON
live gamer
PANACEA SOLUTIONS
Ridge Diagnostics
AFFINERGY
Exam Design Inc.
sciQuest
United Therapeutics Corporation
Koolbridge Solar
canymede
baebies
sageworks
Cognosci
Bloodhound Technologies
Galaxy Diagnostics
RadarFind
Saffron Technologies

HIGH SCIENCE HIGH IMPACT
FIRST FLIGHT VENTURE CENTER
First Flight Venture Center was selected as one of eight accelerators in the country by HHS to drive innovation in lifesaving medical technologies to solve challenging problems spanning modern health security threats and daily medical care.

DRIVE (Division of Research, Innovation, and Ventures) is part of the Biomedical Advanced Research and Development Authority (BARDA) in the HHS Office of the Assistant Secretary for Preparedness and Response (ASPR).
DRIVE Accelerator Network

Transforming Health Security

First Flight
High Science. High Impact.

BARD (Biomedical Advanced Research and Development Authority)
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
DRIVE Mission: Transforming Health Security

Accelerate the research, development, and availability of transformative countermeasures to protect Americans from natural and intentional health security threats.
Situational Awareness/Recognize
How do we know something is happening, an agent has entered the community?

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

Produce
On demand manufacturing of X.

Administration
everyone who needs X is provided.

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

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

Distribute
novel ways to get product/information to those who need it.
BRINGING IT ALL TOGETHER

DRIVE Transforming Health Security

Driving Life-Saving Innovation

Impact Areas

DRIVE Partnering Model

DRIVE-VC FUNDING

TRADITIONAL VC FUNDING
Friends & Family
Angel
Series A
Series B
Series C
IPO

TRADITIONAL PRODUCT DEVELOPMENT
Solve Sepsis
ENACT

Hit - Lead OP Feasibility & OP Development
Preclinical Development
Product Development
Clinic Clinical Evaluation

Market

DRIVE Launch

DRIVE-X

DRIVE Accelerator Network

DRIVE R&D Support
Augmenting other USG Partners (NIH/DOD)

NIAID Contract
BARDA ARD
DTRA Contract
BARDA PBS
MCS Contract

HIGH SCIENCE HIGH IMPACT
FIRST FLIGHT VENTURE CENTER
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
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
EZ 1-STEP PROCESS: ABSTRACT AND COST ESTIMATE SUBMISSION

- **Abstract**
  - No more than 12,500 characters (~2000-2500 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.)
HIGHLIGHTS: EZ-BAA PROCESS

- Submit a proposal **NOW** for funding of up to $749k.
- Funding decisions: **AS SHORT AS 30 DAYS**
- Current guidelines: **MAY SUBMIT MULTIPLE PROPOSALS.**
- This funding opportunity ends May 24, 2019.
- You may ask questions until you submit your abstract. Email your EZ-BAA Questions to **DRIVEContracting@hhs.gov.** Email Areas of Interest (AOI)-specific questions to **DRIVE@hhs.gov.**
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 emphasizes revolutionary approaches hyperfocused on the following AOIs:
  - Early Notification to Act, Control, and Treat (ENACT) Infectious disease agents
  - Solving Sepsis
  - Innovative Products to radically transform Health Security
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

Prompt Treatment

HIGHEST SCIENCE HIGH IMPACT FIRST FLIGHT VENTURE CENTER
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
Targeting pathogen or insult is critical, but not always sufficient.

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

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.
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>
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<tbody>
<tr>
<td>1.5 Million</td>
<td>&gt;250,000 people die each year</td>
<td>1:3 patients who die in hospital have sepsis</td>
<td>responsible for nearly $24 Billion Annually (6.2% of hospital costs)</td>
</tr>
<tr>
<td>people each year in U.S.</td>
<td>&gt;80,000 are discharged to hospice</td>
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Sepsis is a life-threatening organ dysfunction caused by a dysregulated host response to infection (Sepsis-3)
CHALLENGES IN CURRENT PRACTICES

**Infection**
- Lack of patient education/awareness
- Sepsis not considered by physician
- Delayed pathogen detection & treatment (incorrect antibiotic, AMR, etc.)

**Diagnosis**
- Lack of accurate biomarkers
- Misdiagnosis
- Delayed access to healthcare

**Intensive Care**
- Standard of care practices inadequate
- Lack of understanding of immune dysregulation
- Patient comorbidities
- Patient population heterogeneity (age, background, pathogen)

**Inability to restore homeostasis**

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

**Death from sepsis may occur rapidly despite medical care**
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

Sepsis Coalition
National Sepsis Database
Public-private partnerships in “virtual community”
SOLVING SEPSIS

PATIENT ➔ CLINIC VISIT ➔ ICU CLINICAL MANAGEMENT ➔ PREVENT RE-ADMISSION

- Education and Awareness*
- Diagnostic//Prognostic toolkits

ICU CLINICAL MANAGEMENT:
- New Therapies
- Diagnostic//Prognostic toolkits

INVESTMENT TARGET AREAS:
- Continuous Monitoring/Integrated Feedback
- Individualized Treatment capabilities
- Machine Learning/AI
- National sepsis database

*Virtual Community

*Not expected to be funded via traditional BAA mechanism

HIGH SCIENCE HIGH IMPACT
FIRST FLIGHT VENTURE CENTER
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
ADDITIONAL QUESTIONS?

EZ-BAA Questions: DRIVeContracting@hhs.gov

AOI-specific questions: DRIVe@hhs.gov
First Flight’s BARDA DRIVe Accelerator is identifying promising health security innovations in the early stages of development.

The goal is to accelerate R&D and business activities to position them for investment and commercialization and foster the community of health security innovators and entrepreneurs.

First Flight will perform outreach activities, evaluate emerging innovations, provide business mentoring, technical support, and grant writing services.
Emil Runge
Program Manager,
First Flight DRIVE Accelerator
www.firstflightventure.org