



 **DRIVE**

# Annual Report

10.19.20

# Table of Contents

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## About DRIVe 03

- Letter to our Stakeholders
- Investing in Innovation
- DRIVe Ecosystem

## Our Work 18

- DRIVe by the Numbers
- DRIVe Portfolio
- Accelerator Network
- Accelerator Metrics

## Special Focus 32

- COVID-19 Response
- Mitigating Racial Bias in Health Challenges

## The Team 39



# About DRIVe

## SECTION 01

# Letter to our stakeholders

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In recent decades, our nation has faced a number of challenges, including raging forest fires, destructive hurricanes, and infectious disease outbreaks. Additionally, the threat of chemical, biological, and radiological attacks large and small always loom tall. Every emergency reminds us that preparation and prevention are better investments than those we must make to respond. However, even under the best circumstances, we are never as prepared as we need to be and because there will always be elements of unpredictability, we must be prepared to respond in unexpected ways.

DRIVe was created to deliver that unexpected response. We are an innovation team, built to respond quickly, proactively, collaboratively, and with our eye towards future impact. We exist so BARDA and the U.S. government can be a little more agile, as we can identify problems that others may not, we can invest in approaches to better prepare for future health emergencies, and we can test out completely new ways to approach health security. Ideally, we'll fail early and fail fast, so BARDA and the medical countermeasure enterprise can better succeed.

The 21st century will continue to bring transformative capabilities online — synthetic biology, artificial intelligence, advanced manufacturing, behavior change, and completely new models of human organization. DRIVe is pushing the boundaries of transformation and proactively seeking opportunities to channel the advances in these fields to meet 21st-century health security challenges. In so doing, the significant impact on the health security of our nation — and the world — cannot be understated.

The two initial areas of interest for DRIVe — Solving Sepsis and ENACT — have already had an early and outsized impact on the advancement of tools for pre-symptomatic disease detection, predicting the severity of sepsis with novel, host-based detection and prediction

devices. The very existence of these programs has already begun to catalyze innovation by raising awareness among our stakeholders that these are important problems, and the technologies we've begun to support are on their way to being in the hands of people.

In response to COVID-19, DRI<sup>V</sup>e has pivoted the work of ENACT and Sepsis to testing remote monitoring and disease severity prediction tools to support patients and healthcare providers. DRI<sup>V</sup>e is working closely with our BARDA colleagues to advance alternative vaccine delivery technologies, such as skin patches, in a new program entitled "Beyond the Needle." These technologies have the potential to enable much simpler access and even self-administration of vaccines.

Challenging assumptions can also take us in new directions. Sometimes the best medical countermeasures are those that can drive the behavior change needed to fight outbreaks and improve the resiliency of the population by recognizing underlying health and social inequities. DRI<sup>V</sup>e has the tremendous opportunity to help design a 21st-century approach to prevent, prepare for, and respond to health emergencies, and to seek partnerships with a more diverse set of innovators across racial, ethnic, intellectual, and geographic boundaries. DRI<sup>V</sup>e is committed to exploring all the innovative paths required to save lives and protect Americans. We know that in partnership with you, our commitment to continually deliver unexpected responses to unpredictable challenges will become a reality.



*Sandeep Patel, PhD*  
BARDA DRI<sup>V</sup>e Director

# Did DRI<sup>V</sup>E Transform the Way the Government Invests in Innovation?

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Two years ago, BARDA launched an ambitious effort to transform the way the government invests in and drives innovation for national health security. The initiative was designed to decentralize innovation across America, disrupt the way the government invests in new approaches to health security, and empower a new generation of innovators across the country — and around the world — with the capital and resources necessary to accelerate innovative products to combat 21st-century health security threats.

From the outset, DRI<sup>V</sup>E was anything but “business as usual” within the government. Let’s start with the name: the Division of Research, Innovation, and Ventures; bringing together government research and development efforts — hyper-focused on innovation — with a venture capital mindset and investment vehicles is atypical of government. DRI<sup>V</sup>E was designed with a customer-first mindset, built on private sector principles of speed and agility, with acute acknowledgment that to be successful the government had to move faster to keep up with you and the speed of innovation characteristic of a startup.

We knew great, innovative ideas were out there, we just needed to find a new way to identify them wherever they might be, so we created our accelerator network to search for innovation outside of Washington and major biotech hubs. We needed to find a new way to invest in those ideas through business-friendly approaches, so we introduced the EZ-BAA to award contracts in less than 30 days. And we needed to find a new way to accelerate the development of those innovative products and technologies toward patients, so we assembled an internal and external network of technical experts to provide wrap-around services.

If there was one word that could explain DRI<sup>V</sup>E two years in, it would be culture. DRI<sup>V</sup>E had a unique opportunity in the government to build a team from the ground up and design a new culture for how BARDA invests in innovation. The team leveraged the principles of great innovation programs and watched our share of TED Talks together to get new ideas. We built prototypes off of lean startup principles and leveraged best practices from Clayton Christensen’s “The Innovator’s Dilemma” from day one to ensure our team was designed with

the structure, authorities, and funding necessary for innovation. We took time to get all of our restless innovators on our “Innovation Bus” in the right seat and working together, and we took even longer to complete a nationwide search for the first DRI<sup>V</sup>e Director. The result was an innovation team and culture unmatched to any team I have experienced within the government throughout my tenure at the Department of Health and Human Services.

The nimble, flexible culture has enabled DRI<sup>V</sup>e to quickly build a portfolio of XX innovative products and invest more than \$55M in our first two years. When COVID-19 arrived in early 2020, DRI<sup>V</sup>e temporarily pivoted, like a startup, to support BARDA’s and America’s new mission. BARDA benefited by leveraging DRI<sup>V</sup>e’s established team to provide surge staffing; repositioning DRI<sup>V</sup>e’s business friendly EZ-BAA to rapidly award new COVID-19 diagnostic contracts to support development and testing towards Emergency Use Authorization; and shifting its Solving Sepsis and ENACT portfolio to field and test approaches to respond to COVID-19.

However, the road to today has also been long. Looking back, and being honest, there were many skeptics of DRI<sup>V</sup>e both inside and outside the government, and they were loud. DRI<sup>V</sup>e’s unique culture, the startup communication approach, the relatively small amount of seed funding, and the radical investment ideas left many thinking BARDA’s pet project in the sub-basement — only because there was no room left in the basement — was designed to fail. But like any startup, the DRI<sup>V</sup>e team pushed forward through this adversity, and seized the opportunity to prove our skeptics wrong. The team thrived on being BARDA’s underdog, living by the motto “Keep DRI<sup>V</sup>ing.”

As you review this annual report, looking over DRI<sup>V</sup>e's investments and accomplishments, you get to be the judge of our first two years. Did we position our country to be able to better respond to tomorrow's threat? Did we transform the way the government invests in innovation?



**Tyler Merkeley, MS, MBA**

*Former Interim DRI<sup>V</sup>e Director (2018-2019)*

*& Co-Founder of DRI<sup>V</sup>e*



# Solving Sepsis

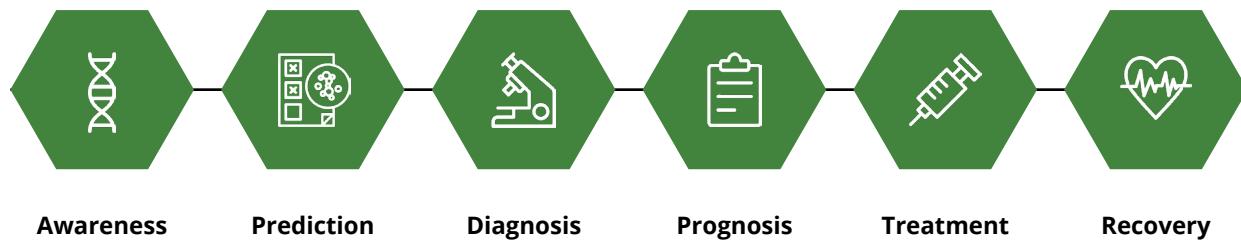
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The Solving Sepsis program catalyzes the field through a coordinated approach toward development of innovative technologies that will advance the way we recognize infection severity and combat sepsis, build resiliency in our healthcare system, improve patient outcomes, and save lives. The goal is to reduce the incidence, morbidity, mortality, and economic burden of sepsis by investing in key strategic areas through partnerships with companies, universities, not-for-profits, and government entities.

Such a coordinated systematic approach has been the focus of the program since its inception, with emphasis on strategic areas, including education and awareness; host-based diagnostics that predict, identify, or prognosticate sepsis; improved or novel clinical management or host-targeted therapeutic approaches; and technologies to improve patient care post-discharge in the recovery phase.

Generating technological approaches along the sepsis patient continuum, Solving Sepsis considers the pre-hospital space through hospital/inpatient care and discharge. By focusing on innovative technologies in advanced development through regulatory approval, the program ensures implementation and adoption of such technologies.

As there are limited host-based diagnostics FDA approved and marketed, and early detection of sepsis is critical to improve outcomes, the Solving Sepsis program has been focused on creating a comprehensive strategy to promote infection severity diagnostic tools in a number of clinical settings. In addition, the Solving Sepsis program has been heavily focused on messaging that sepsis strategies can build resilience in healthcare, as such a threat-agnostic approach can be a roadmap for a future response to any public health threat.



# ENACT

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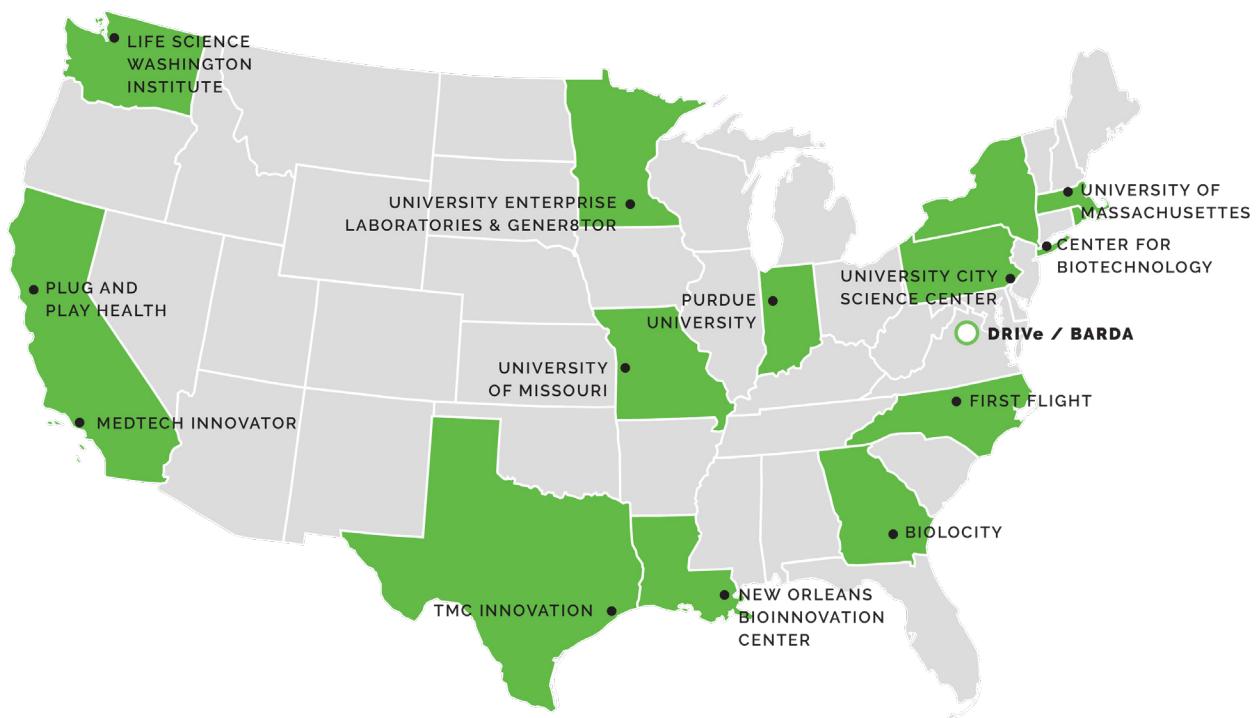
**The ENACT Program aims to protect Americans and save lives via technology enabling Early Notification to Act, Control and Treat.** ENACT seeks tools to identify, characterize, and adapt signatures — biological, biometric, behavioral, and physiological — that can inform on health security threats or exposures earlier than currently possible. Ideally, these tools will identify such health security threats prior to symptom onset in order to facilitate treatment and prevent subsequent cascading effects.

The program is currently exploring discovery and validation of biomarkers suitable for non-invasive, or minimally invasive, collection and other health signatures; tools that can enable continuous biochemical and/or biophysical monitoring over extended periods of time; and host-based (quantitative and multiplexed) diagnostics suitable for use in the home. Its portfolio comprises wearables that integrate into everyday life, novel sensors, cloud-based reporting and data analytics, and disease prediction platforms that empower individuals, medical care providers, and public health organizations with information. ENACT-supported technologies employ host response as a pre-symptomatic beacon, separating infected and healthy individuals.

The program looks to promote more rapid treatment and comprehensive prophylaxis to individuals, and will improve social distancing, reducing the spread of illness, and lead to earlier intervention. This will be accomplished by supporting telehealth-based approaches to provide real-time information on influenza and influenza-like illness activity, detect other potential epidemic illnesses, and identify new outbreaks or emerging diseases that may impact the U.S.

# Accelerator Network

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Advances in medical technology commonly take years to find their way to patients due to high costs associated with development and commercial risks. **Accelerators help to bridge that gap by providing access to stakeholders, potential investors, and access to otherwise-hard-to-obtain resources.**

The DRI<sup>V</sup>e Accelerator Network leverages key regional hubs across the U.S. where health security products and technologies in biotechnology, life science research, and medical innovations are heavily occurring. These accelerators, of which there are currently 13, provide BARDA DRI<sup>V</sup>e-funded developers with technical and business support. This enables innovators to cross the “valley of death,” allowing the progress from the laboratory bench to the basis of a commercially-successful business or product.

Companies require varying levels of support in the DRI<sup>V</sup>e portfolio — some are well-established pharmaceutical or medical technology companies, some are serial entrepreneurs with a successful track record, and some have exciting technologies, but lack in business acumen or experience. A tailored package of support is developed for each depending on the needs of the company.

The DRI<sup>V</sup>e Accelerator Network also hosts events and prize competitions that aim to stimulate awareness and innovation around BARDA areas of interest. The accelerators work together to host these coordinated challenges by assisting BARDA in the design, development, and execution on a national scale.

# BARDA Ventures

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**BARDA Ventures is a new initiative that will reinvigorate the way that the U.S. government invests in promising health security products and technologies.** Authorized by the “21st Century Cures Act” in 2016, BARDA will work with venture capital and nonprofit partners to invest, develop, and utilize novel technologies to improve America’s preparedness posture against known and unknown threats. Through the use of a third-party, non-profit managing entity, BARDA Ventures will provide dilutive investments into promising health security products and technologies and bring them to the marketplace.

Over the past year, BARDA has built a team of investment, biotechnology, and health experts to lead this effort. Culminating in extensive discussions with industry experts and two separate requests for information, BARDA identified how venture capital practices and methodologies could align the interests of private industry with the U.S. Government to solve our most challenging health security issues.

BARDA Ventures will be guided by the following principles to strengthen the U.S. national health security preparedness and response: establish a more nimble and agile funding mechanism that enables BARDA to act with speed and flexibility; fortify U.S. influence on health security technology development; maximize taxpayer value.

In the light of the COVID-19 pandemic, it is clear that no two public health emergencies are alike. BARDA Ventures offers a new opportunity to energize the health tech and life science industries. BARDA Ventures will work to bring critical lifesaving technologies to the market and ensure equitable distribution and access. Through this new initiative, BARDA will utilize experts in the private sector to ensure that BARDA Ventures will uniquely catalyze sustained investment in health security for generations to come.

# DRIVE Start

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The DRI<sup>V</sup>e Start Program Innovation and Alliance Management **identifies opportunities and engages with key internal and external partners in order to develop novel capabilities and products in health security innovation.** The team identifies game-changing technologies, increases productive partnerships, and develops an innovative technology pipeline that can serve to create a culture of innovation and creativity. The key to the DRI<sup>V</sup>e Start team's success is providing the right balance of expertise, time, money, and investment to address the problems effectively and efficiently.

DRI<sup>V</sup>e Start ensures successful innovative outcomes for both BARDA and partners through many key tactics, including developing an internal "think tank" to create a pipeline of near- and mid-innovative health technologies. They utilize the DRI<sup>V</sup>e Accelerator Network to develop and identify scaling partners, landscape reviews, business needs, and commercialization views to continue to support the success and increase the value of DRI<sup>V</sup>e investments. DRI<sup>V</sup>e Start identifies non-traditional partners and technologies, including dual-use and repurposed technologies, to evaluate their potential to fill BARDA and USG gaps and needs.

The program is comprised of three key components: DRI<sup>V</sup>e Start Tuesday Talk Series, a weekly speaker series that provides information about novel technologies being developed, as well as experiences and lessons learned by a variety of academia, industry, government, and nonprofits; DRI<sup>V</sup>e Start Prize Challenges, competitions that leverage DRI<sup>V</sup>e's ability to form public-private partnerships to solicit innovative ideas and develop rapid solutions through prize competitions, hack-a-thons, and grand challenges; and DRI<sup>V</sup>e Start Incubator, a pipeline designed to support the development of early-stage innovations through the provision of small amounts of seed funding and wrap-around services.

# DRIVE Catalyst Office

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DRIVE and its Catalyst Office started with the **vision of building a comprehensive, end-to-end system that can bring products to market faster than before, bridging the intersection of science and business.** In the two years since its launch, DRIVE has built a roadmap that serves as a one-stop shop for product development and commercialization for innovation. DRIVE understands that achieving success in the scientific field goes beyond having novel ideas and presence in renowned publications; it truly takes a village.

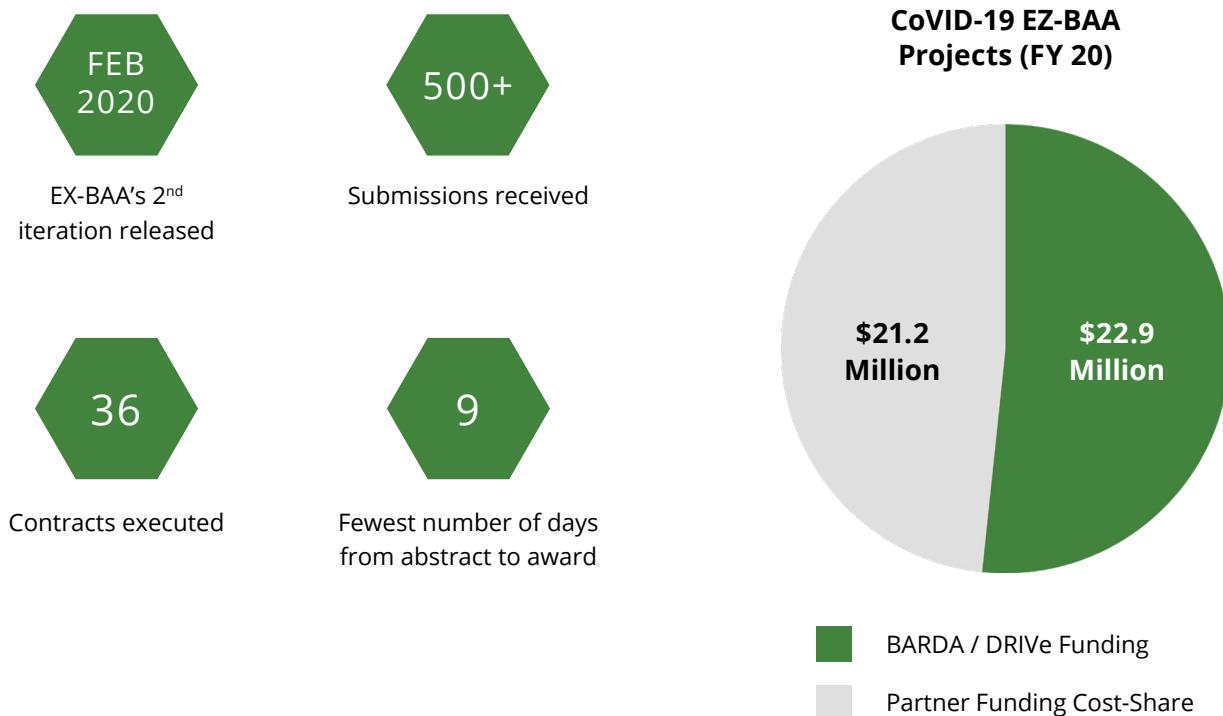
In 2020, DRIVE has taken this idea and catalyzed it. The Catalyst Office is ensuring that DRIVE's Accelerator Network is maintained and improved wherever possible, and it led the launch of BARDA Ventures, which utilizes the same approaches, strategies, and advantages employed by successful investors. The Catalyst Office believes that DRIVE must continuously change, break down, remodel, and accelerate its own thinking on what is the status quo to pandemic preparedness and health security.

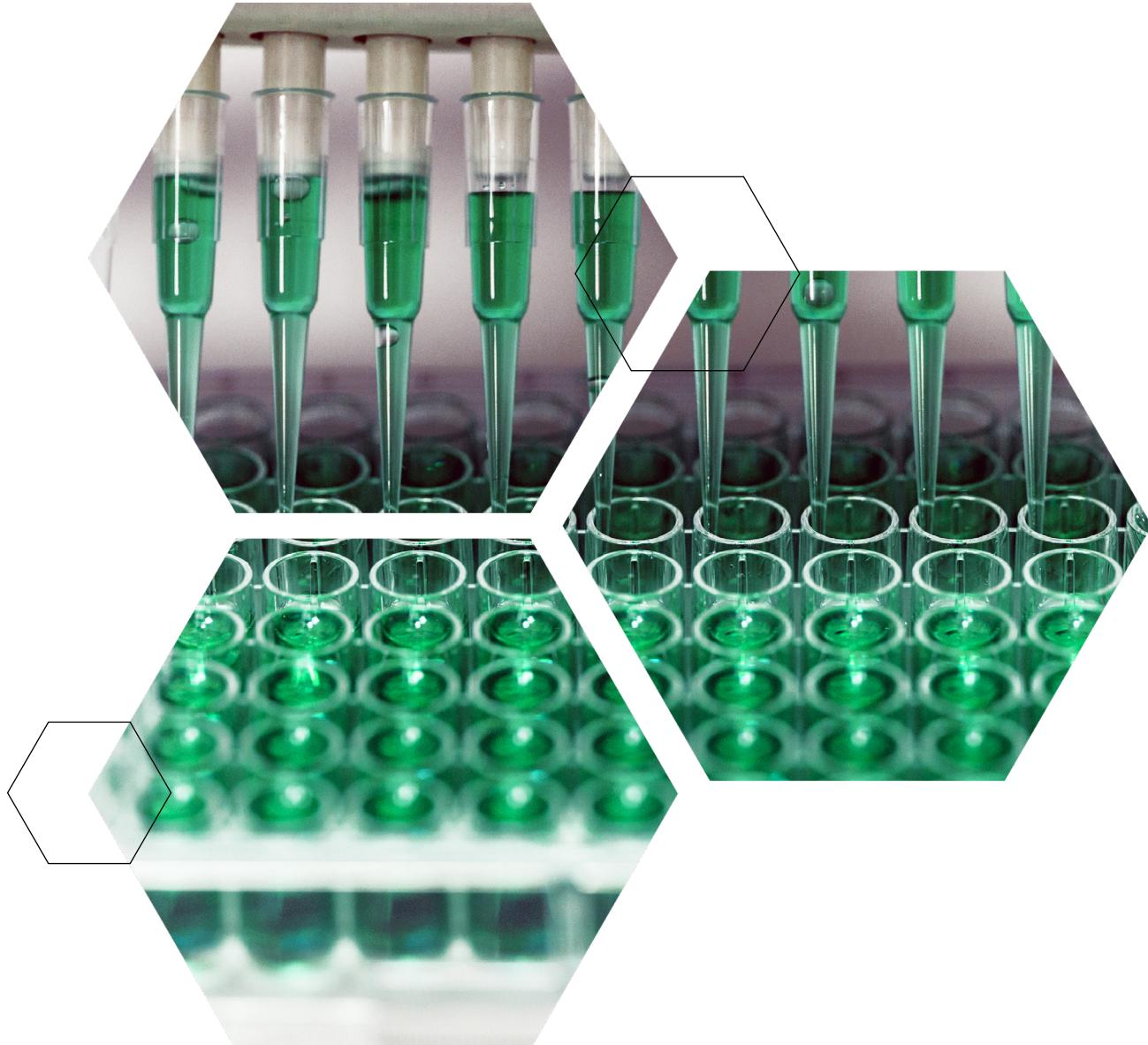
# EZ-BAA

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**The Easy Broad Agency Announcement (EZ-BAA) has advanced health security R&D by streamlining procurement processes.** The DRI<sup>V</sup>e Acquisition team has forged an integrated team that emphasizes the transformation of business practices to match the technological innovations DRI<sup>V</sup>e pursues. The goal of the team is to maximize public dollars by exploring and implementing streamlined acquisition practices, increasing industry engagement, and leveraging BARDA investments.

To date, DRI<sup>V</sup>e has awarded 54 EZ-BAA contracts, with a total funding obligated of \$36,910,293.67.





# Our Work

## SECTION 02

# DRIVE By The Numbers

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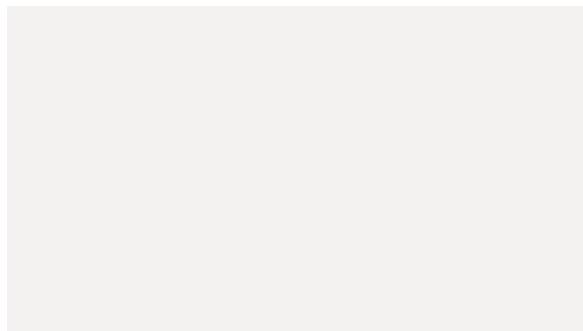
# DRIVE Portfolio

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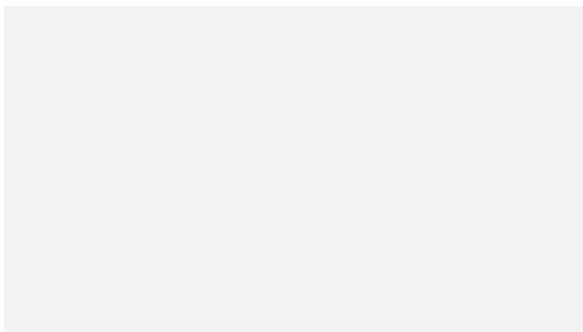
## SOLVING SEPSIS



The first marketed and FDA-cleared Early Sepsis Indicator (ESI) that will be combined with machine learning from Electronic Health Record data to create a digital diagnostic solution for more accurate sepsis alerts.

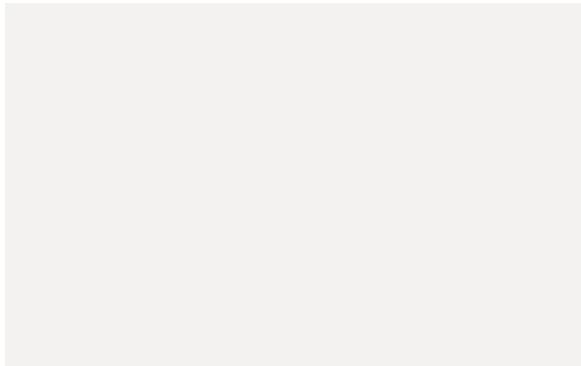


An advanced development of a rapid sepsis diagnostic to detect changes in biophysical properties of host immune cells in blood.

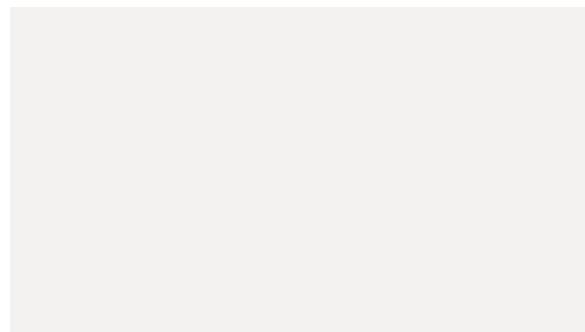




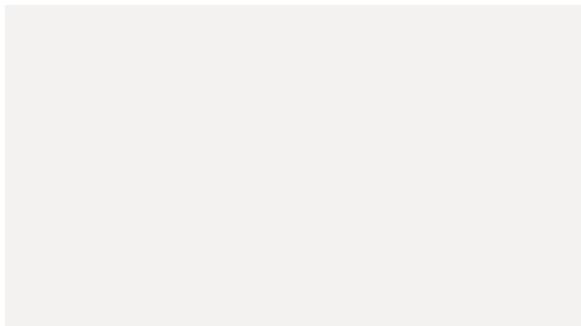
BARDA's first funded artificial intelligence technology; a predictive algorithm that uses machine learning of Electronic Health Record data to identify sepsis in the ICU.



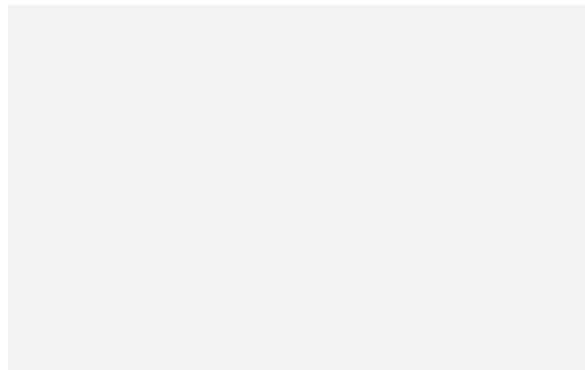
The first FDA-cleared, host-based sepsis diagnostic that will expand to a next-generation solution in order to more accurately diagnose sepsis and distinguish whether the infection is viral or bacterial.



A dual partnership with both DRIvE and BARDA's Division of Detection, Diagnostics, & Devices Infrastructure to develop a point-of-care diagnostic for sepsis, separately determining presence of an infection as bacterial or viral and 30-day risk stratifying to predict sepsis outcome.



Development of a host-based sepsis biomarker assay to complement and leverage their FAST-ID pathogen identification platform from whole blood, such that pathogen and host responses can both be detected on the same platform.

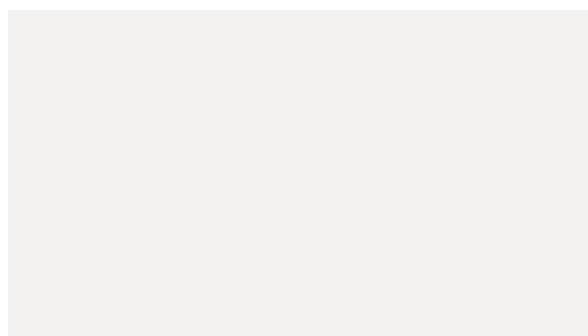
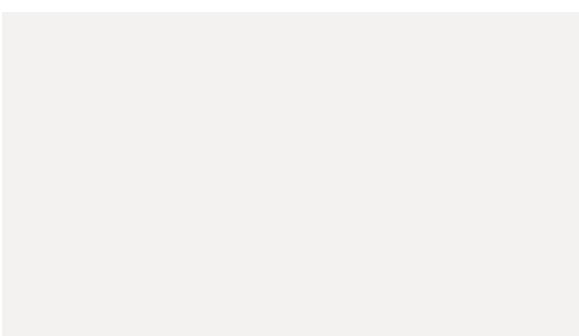




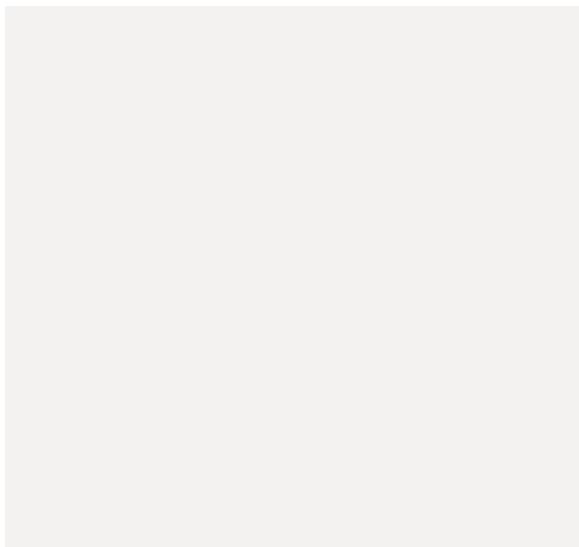
Development of sepsis educational material for special populations (i.e. pregnant women) based on establishment and analysis of NY State Department of Health's database.



High-quality, evidence-based education and training to healthcare providers on the recognition, treatment, and management of sepsis along the patient care continuum.



## RAPIDLY DEPLOYABLE CAPABILITIES



**Text-based virtual care to assess, diagnose and treat COVID-19**

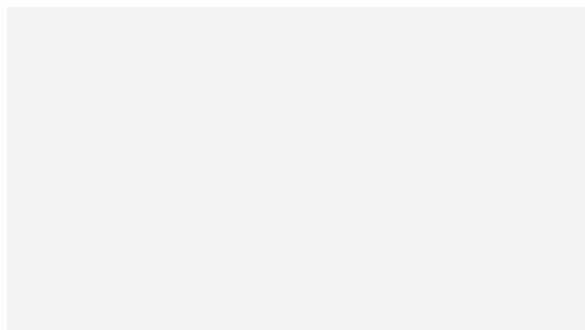
The 98point6 primary care platform combines a telehealth service with AI and machine learning to provide a comprehensive program of diagnosis, assessment, triage, reporting and tracking of SARS-CoV-2 infections to a national population of patients.

## RAPIDLY DEPLOYABLE CAPABILITIES



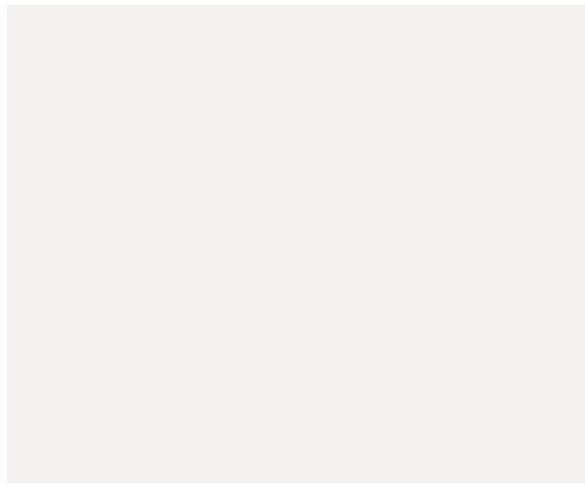
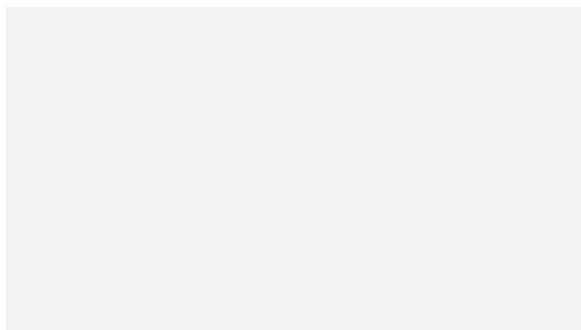
### Monocyte Distribution Width (MDW) and Algorithms for Sepsis Detection

As part of the partnership with BARDA's Solving Sepsis program, Beckman Coulter and Dascena will conduct clinical studies for validation of the sepsis prediction algorithm, including studies that enrich for COVID-19 patient subpopulations to ensure that the algorithm is trained and optimized for detecting viral-induced causes of sepsis.



### Continuous Monitoring Platform & Algorithm for COVID-19 Severity

A FDA-cleared Artificial Intelligence-powered continuous remote patient monitoring platform that utilizes a wearable vital-signs sensor, integrates with other devices, and includes symptom chatbot and video visit functionality. The platform continuously collects respiratory rate, oxygen saturation, mobility, pulse rate and body temperature data.



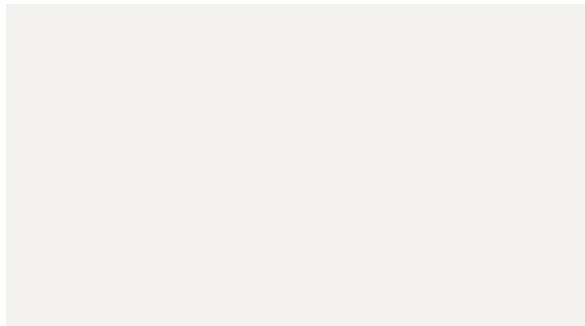
### Rapid Sepsis Diagnostic

As part of the partnership through BARDA's Solving Sepsis program for the advanced development of Cytovale's rapid sepsis diagnostic, the company will perform a pre-analytical and pre-clinical pilot validation of the sepsis diagnostic at emergency department sites with patients suspected of respiratory infections including SARS-CoV-2.

## empatica

### Aura

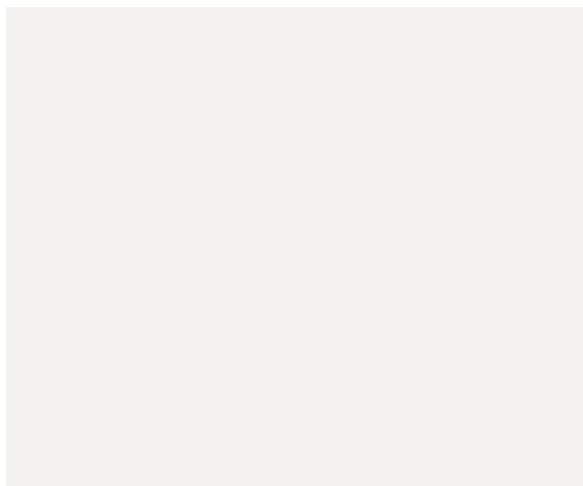
Aura is an early warning platform for COVID-19 infection. This diagnostics platform enables continuous and real-time insight into infection likelihood before symptoms present through the use of a wearable device and an algorithm that can continuously monitor physiological health markers and produce an output.



## evidation

### COVID-19 Detection & Forecasting Model Pilot

Evidation seeks to develop a model that can detect whether an individual has likely been infected with COVID-19 and understand an individual's susceptibility to infection.



## ImmuneXpress

### SeptiCyte RAPID Host-Based Sepsis In Vitro Diagnostic

SeptiCyte® RAPID is a host response gene expression, blood-based diagnostic for rapid identification of sepsis that will be evaluated to triage COVID-19 patients for severe outcomes (sepsis) in the ICU and ED.



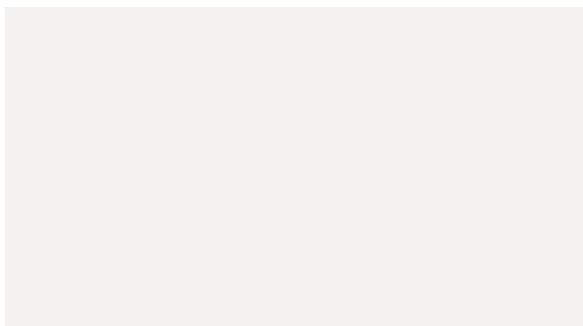
### Sepsis COVID-19 webinars

The Sepsis Institute provides educational content to support healthcare providers in the recognition and management of sepsis along the entire continuum of care. Two new webinars will provide sepsis education for healthcare providers caring for COVID-19 patients.



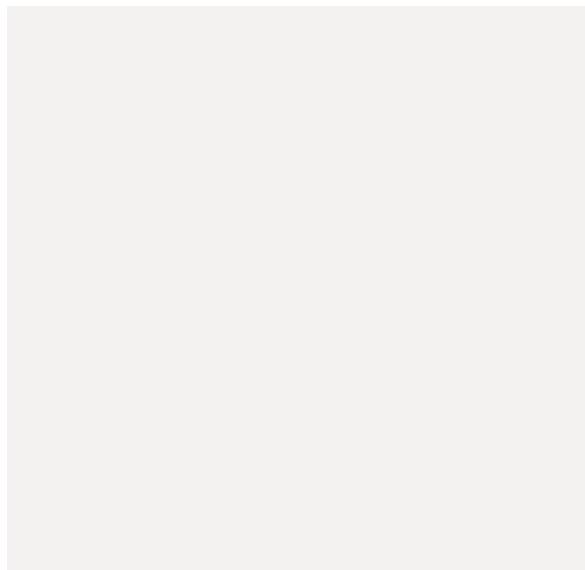
### Sonica's Bio-Integrated, Wireless Sensor System (ADAM) System

Sonica Health developed the ADAM Monitoring System for COVID-19. The soft, conformable, wireless device softly adheres to the suprasternal notch at the base of the throat for continuous monitoring. This project establishes the sensor's ability to identify early respiratory infections, including COVID-19, in a high-risk clinical population.



### Vista Solution

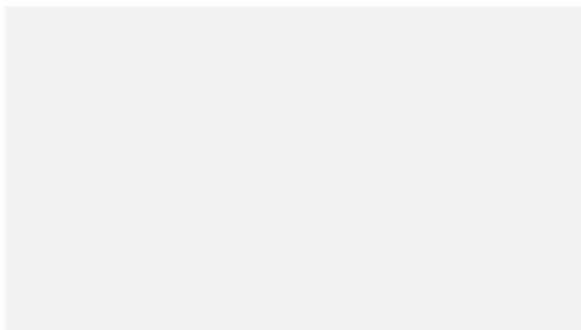
Vista Solution is an FDA-cleared remote patient monitoring system for use within hospital, nursing home facilities, and homes. Vista Solution is comprised of the VitalPatch biosensor, a tablet where vital signs are viewed and transmitted to a central cloud, a secure cloud, and a central monitoring hub.



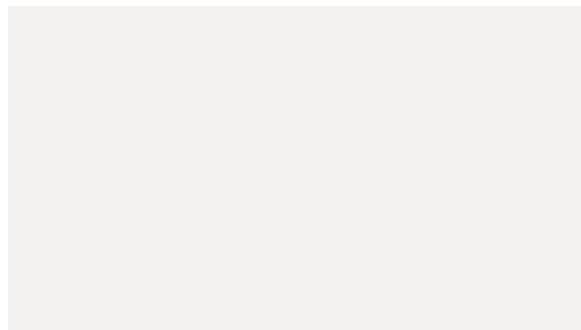
## BEYOND THE NEEDLE



A solid dose implantable vaccine for pandemic influenza.

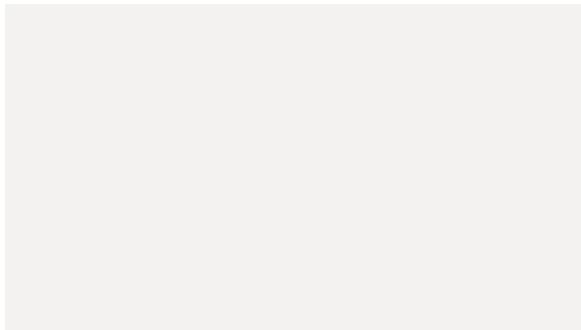


An EGRESS rapid deployment oral vaccine for COVID-19.

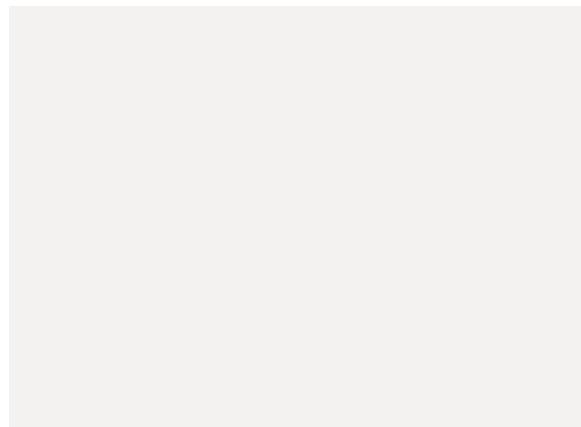


Massachusetts  
Institute of  
Technology

A 3D-printer automated, integrated microneedle fabricator system designed to enable distributed manufacturing of vaccine/drug patches.

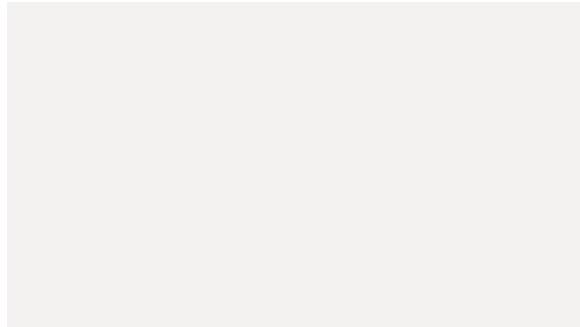


A shelf-stable, dissolvable, microneedle skin patch with a timed-release vaccine.

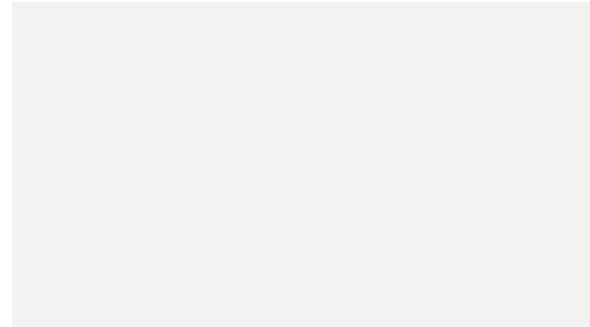




A MIMIX™ COVID-19 single-dose, shelf-stable, self-applied SARS-CoV-2 skin patch vaccine.



A COVID-19 skin patch VaxiPatch™ vaccination kit designed for shelter-in-place use.



# Accelerator Network

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**DRIVe's Accelerator Network identifies and accelerates health security products and technologies to market. The primary areas of support the accelerators provide BARDA are:**

## TECHNOLOGY SOURCING

The DRIVe accelerators are an innovation engagement platform that works to support all of BARDA. While the DRIVe accelerators have supported the traditional programs at DRIVe, they also support the divisions across BARDA with a program called "the BARDA Reverse Pitch." The BARDA Reverse Pitch is a series of monthly events where a leader from a BARDA division will present an innovation need to our accelerators, who then source market research and introductions to the presenter.

In the past year, we have done reverse pitches for RFI's (e.g. Alternative Blood Products for CBRN division), landscape reviews (e.g. Chlorine Therapeutics for CBRN division), and raised awareness of new BARDA partnerships (e.g. Blue Knight program). In addition, these BARDA Reverse Pitches reflect quick pivots and reactions to the pandemic market, such as for COVID-19, where the BARDA IMT leadership team presented the technology and innovation needs in order for BARDA to swiftly respond to the COVID-19 pandemic.

## WRAP-AROUND SUPPORT

The DRIVe Accelerator Network provides product and business support to the overall health security industry. The DRIVe accelerators leverage their connections with various stakeholders in the healthcare ecosystem to accelerate business and product development. In addition to helping innovators with BARDA relevant technologies to mature their product or business, the DRIVe Accelerator Network provides DRIVe-funded companies with targeted support to help ensure the company's success.

For example, the Sepsis Alliance, which is an organization that provides educational content and awareness on the best practices and latest treatment options to address sepsis in the health system, holds an annual conference that attracts thousands of clinicians who are trying to address the burden of sepsis. The DRIvE accelerators provided relevant sepsis technologies to the Sepsis Alliance team to review and select three to four sepsis-relevant startups that they would showcase on their panel. This ability for the DRIvE Accelerators to leverage their network and provide relevant companies to initiatives such as this ensures that there is a multiplying impact from the deployed BARDA capital.

Beyond leveraging their network, the DRIvE accelerators have subject matter expertise when it comes to company and product development. Many of the DRIvE portfolio companies have worked with various accelerators to receive regulatory or clinical expertise and feedback on their product or regulatory pathway.

## EVENTS & OUTREACH

The DRIvE Accelerator Networks conducts outreach and networking through the use of hosting and attending events on behalf of BARDA. The Accelerator Network hosted a total of 331 events where BARDA was discussed or presented to the 13 innovation clusters across the nation. In addition to hosting events to spread the message of BARDA DRIvE, each accelerator in the DRIvE Accelerator Network hosted remote 2019 BARDA Industry Day (BID) local events at their accelerator facility. These distributed events across the network allowed innovators that could not physically access Washington, DC for BID to be able to participate and connect with BARDA experts via one of the DRIvE accelerator satellite locations.

## MARKET RESEARCH

The DRIvE Accelerator Network is uniquely positioned to provide BARDA insights into the innovation landscape for various technologies of interest. BARDA has leveraged these market research capabilities and conducted reviews on a number of topic areas from Host Based Tx to Anti Fungals to ECMO. Most recently, the DRIvE accelerators completed a landscape review for Chorine Therapeutics, which was leveraged by our CBRN and DRIvE teams in the development and launch of the ReDIRECT EZ-BAA topic area.

Along with landscape reviews to increase BARDA business and market intelligence, the DRIvE accelerators provide various program managers with product and customer discovery insights

as they shape their funding and program strategies. For example, our DRI<sup>V</sup>e accelerators used their deep industry networks to provide the Rapidly Deployable Capabilities team with introductions to key healthcare stakeholders that provided feedback on challenges and trends they see in the adoption of disease severity detection technologies within various care settings. This level of insight allows our program teams to make more informed decisions when scoping their program strategies and constructing their technology portfolio's.

Additionally, the DRI<sup>V</sup>e accelerators assisted with our COVID-19 Response:

- Sourcing for the COVID-19 IMT EZ-BAA topic areas
- COVID-19 specific events & awareness
- Health security industry support (COVID-focused cohort)

# BARDA DRI<sup>V</sup>e Accelerator Metrics

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331	12,510	327
Events where BARDA is discussed/presented	Innovators Engaged Directly on behalf of BARDA	Innovators referred to DRI <sup>V</sup> e for market research
154	18%	
Wrap Around Support provided to Health Security companies	% of companies referred / funded from Accelerators	





# Special Focus

SECTION 03

# COVID-19 Response

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## RAPIDLY DEPLOYABLE CAPABILITIES

COVID-19 created a vital need to rapidly field technologies that could have an immediate impact in BARDA's response to the pandemic. DRI<sup>V</sup>e was able to pivot the development of several pathogen agnostic technologies in its ENACT and Solving Sepsis portfolios and issued two EZ-BAA topics to create the COVID-19 Rapidly Deployable Capabilities (RDC) program.

The goal was to pilot clinical validation studies of technologies in advanced development (or those that are FDA cleared) that could provide adjunctive support to the traditional medical countermeasure response of vaccines, diagnostics, and therapeutics. The RDC program aims to empower individuals with self-monitoring to stratify risk of infection, even in asymptomatic patients. Healthcare providers are at the forefront of detection through remote patient monitoring to identify patient deterioration and determine when a patient may need escalated care. They are also entrusted with triage tools in hospital settings to identify patients that need hospital or ICU care, and to assist in the allocation of hospital resources.

RDC includes solutions for pediatric patients through interest in diagnostic tools that are able to distinguish mild COVID-19 from severe COVID-19 (including sepsis), as well as any complications, such as Multisystem Inflammatory Syndrome in children (MIS-c).

RDC proactively established a network across USG for those agencies and organizations that have an interest in remote monitoring and telemedicine in order to coordinate approaches and identify challenges that may affect implementation.

These efforts were able to pivot these technologies to aid in triaging severe COVID-19 patients for care and validating for use in viral (e.g. SARS-COV2) sepsis cases, respectively.<sup>23</sup> Also the end of FY19, with launch in FY20 an award was made to the the Rory Staunton Foundation (now, End Sepsis).to partner to combat maternal sepsis. This expands to two partners focused on sepsis education and training.

## SOLVING SEPSIS

Almost any infection can lead to sepsis and SARS-COV2 is no exception, as sepsis and septic shock are one of the severe outcomes of COVID-19. Sepsis is a dysregulated response to infection leading to organ dysfunction that is seen with SARS-COV2 positive patients, described early on as “cytokine release syndrome” and multi-system organ damage/dysfunction.

In order to develop adjunctive solutions to the traditional medical countermeasure response for COVID-19, several sepsis technologies were pivoted, and capability will be validated in clinical studies to determine if they can aid in triaging patients for care. In situations where hospital resources are limited and emergency departments are becoming overwhelmed, as has been seen in several host spots across the country to date, having a tool that can aid in identifying those patients that need escalated care (e.g. ICU) versus those that have mild illness and can recover at home could greatly change our preparedness posture.

In addition, the Solving Sepsis program remains interested in any infection severity technologies that can inform and prognosticate outcomes or identify early health deterioration in order to improve patient outcomes. Wearable and other algorithm-based technologies that may be applicable were the subject of market research calls as part of BARDA's RDC program. Two topics were issued under the BARDA DRIVe EZ-BAA special instructions for COVID-19. Topic 4.1D, which focuses on remote monitoring and remote diagnostic tools along the care continuum, including infection severity tools, and Topic 4.1E, which focuses on Pediatric Diagnostic Tools for severe COVID-19 disease (including sepsis) and MIS-C. Remote physiological monitoring wearable technologies were awarded to Vital Connect and Current Health to monitor COVID-19 patients for severe outcomes. In addition, an award was made to Beckman Coulter to validate a technology to detect pediatric MIS-C patients.

## EZBAA (4.1D AND 4.1E)

The Rapidly Deployable Capabilities program has made six new awards under the DRIVe EZ-BAA COVID-19 special instructions to maximize impact in the COVID-19 response as well as expand existing partnerships with an additional five organizations.

### **Topic EZ-BAA 4.1D - Remote Patient Monitoring/ Remote Diagnostic Tools**

Development of adjunctive diagnostic technologies with near-term impact that are critical to improving the efficiency and effectiveness of our health infrastructure during the COVID-19 outbreak. These technologies should be in advanced stages of development and after clinical

validation must be scaled and deployed in less than 90 days. More information can be found here: [XXX](#)

### **Topic EZ-BAA 4.1E- Pediatric Diagnostic Tools for Severe COVID-19 Disease and MIS-C**

The clinical presentation of COVID-19 in children is not fully understood and remains challenging to address. Diagnostic tools that can specifically identify and distinguish severe COVID- 19 disease from mild illness in children and/or predict the onset of Multisystem Inflammatory Syndrome in Children (MIS-C) are needed to aid in clinical management of these patients. More information on this topic can be found here: [XXX](#)

## **BEYOND THE NEEDLE**

DRIVe also created a new program, Beyond the Needle, in response to the COVID-19 pandemic. Born out of the BARDA Vaccine groups' background work in both the Institute of Epidemiology and Infectious Diseases (IEID) and Chemical, Biological, Radiological, and Nuclear (CBRN) divisions, Beyond the Needle is focused on developing technologies for that offer alternative routes of administering vaccines than needles.

Beyond the Needle will ease the enormous burden on healthcare staff, resources, supply chain, storage, and distribution by reducing or eliminating the need for hundreds of millions of ancillary supplies needed for traditional needle-and-syringe vaccination, especially in a pandemic. This will make vaccination more accessible to a greater number of people, and more quickly, in a greater range of settings.

Six projects have been awarded so far under Beyond the Needle. Included in the four awarded and being developed in 2020 are microneedle skin patches and an oral formulation. And even after COVID-19, DRIVe intends to keep this program as an area of focus, hoping to expand it even further.

# Mitigating Racial Bias in Health Challenges

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**DRIVe was founded on the principle of transformation and innovation; transforming the way the government invests in and supports innovation for national health security.** Our broad and deep relationships with scientists, investors, entrepreneurs, and startups set us apart from our peers. DRIVe, as an agent of change, is in a position to address racial and other health disparities in the identification, design, development, and use of medical countermeasures.

The nation remains gripped in the COVID-19 pandemic causing leaders to highlight the need to tackle the significantly disproportionate impact that the pandemic has had on Black, Hispanic, and American Indian and Alaska Native communities as reported in studies recently published in the mainstream press and peer-reviewed journals.[1] Promises have been made to target resources — funding, testing assets, and more — to those communities hardest hit by the virus.

DRIVe's partnerships within its accelerator network are just a few of the ways we're advancing new types of medical countermeasures. The following are examples of how three of our health accelerators are aspiring to be more inclusive and responsive to systemically underserved communities.

## PLUG AND PLAY

- Donated \$20,000 to each of the following organizations: Black Girls Code, The Hidden Genius Project, and the Equal Justice Initiative, and are planning for deeper partnership with the first two organizations.
- Matched donations from employees up to \$50,000 to any non-profit fighting racial injustice.

- Initiated a Diversity and Inclusion Task Force to take action towards including more Black leaders in our events and bringing more diversity onto Plug and Play's team.
- Our Fall Batch 11 program accepted 15 health startups total, with 7 (roughly half) of those startups having female founders and/or co-founders.

## THE CENTER FOR BIOTECHNOLOGY AT STONY BROOK UNIVERSITY

**The Center for Biotechnology at Stony Brook University is a NYS-designated Center for Advanced Technology (NYS-CAT)**

Cultural and socioeconomic circumstances often preclude some student populations from equally participating in the innovation economy. To address this inequity, the Center for Biotechnology has launched several unique initiatives supporting engagement of underrepresented student populations in entrepreneurial roles within the life sciences. These initiatives include conscious recruitment of a diversity of students as "Commercialization Fellows," a 1-3 year temporary appointment that supports the Center for Biotechnology's economic development mission, and the opportunity for female graduate students to participate in a four-day "Women in STEM Leadership" program.

## GBETA MEDTECH

**gBETA Medtech (a program of University Enterprise Laboratories and gener8tor) selected two startup companies for the Fall cohort, whose missions focus on inclusion and eliminating barriers.**

- DrugViu is making medical research more accessible and inclusive by making it easier for people with autoimmune diseases to participate in drug development trials.
- Hued, described as a social impact organization, has a technology-enabled platform that gives Black and Latino communities access to culturally competent healthcare providers.
- In addition to their drive to improve access and inclusion, both companies were founded by African American leaders.



## Health Security

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The necessity for ensuring equal and equitable access to prevention, diagnostic, and treatment technologies has been made plain by this pandemic, but the disproportionate burden on communities of color long predates this disease outbreak. DRI<sup>V</sup>e's arrival is the harbinger of the approach to health security that does not shy away from the challenges created by years of racism in our society.



# The Team

SECTION 04

# DRIVE Team

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