



MID-ATLANTIC REGIONAL MEETING

November 10, 2020

WELCOME TO THE 2020 FLC MID-ATLANTIC REGIONAL MEETING

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SCHEDULE AT A GLANCE

TUESDAY, NOVEMBER 10 ALL TIMES EDT

TIME	ACTIVITY	INFO
8:30 – 8:50 am	Orientation	Corin Hindenach, FLC, Regional Support Manager Nerissa Legge, FLC, Professional Development Director
8:50 – 9 am	Break	
9 – 9:10 am	Welcome from your Regional Coordinators	Vladimir Popov, Frederick National Laboratory for Cancer Research Claudia Haywood, Frederick National Laboratory for Cancer Research
9:10 – 9:15 am	Break	
9:15 – 9:45 am	Keynote: Unleashing Innovation	Mojdeh Bahar, National Institute of Standards and Technology
9:45 – 10 am	Break	

SCHEDULE AT A GLANCE

TUESDAY, NOVEMBER 10 ALL TIMES EDT

TIME	ACTIVITY	INFO
10 – 10:45 am	Becoming the Data Capital of Europe: Edinburgh’s Push to Create a World Class Innovation Ecosystem	Gordon Donald, University of Edinburgh John Lonsdale, University of Edinburgh
10:45 – 11 am	Break	
11 – 11:45 am	AI and the Patent Process	Dean Alderucci, Carnegie Mellon University Henry Wixon, National Institute of Standards and Technology
11:45 a.m. – Noon	Break	
Noon – 12:50 pm	Awards Luncheon	Moderated by: Claudia Haywood, Frederick National Laboratory for Cancer Research Carmen Krieger, Environmental Protection Agency
12:50 – 1 pm	Break	
1 – 1:45 pm	Federal Tech in the Covid-19 Response	Paul Zielinski, FLC Executive Director Jordana Bieze Foster, FLC Marketing Manager
1:45 – 2 pm	Break	
2 – 2:45 pm	Cultivating an Entrepreneurial Culture in Federal Labs	Tom Stackhouse, National Cancer Institute Andre Marshall, National Science Foundation Rob Griesbach, U.S. Department of Agriculture (retired) Laura Prestia, National Cancer Institute
2:45 – 3 pm	Break	
3 – 3:30 pm	Biaera, An Entrepreneurial Success Story	Justin Hartings, Biaera Technologies
3:30 – 3:45 pm	Break	
3:45 – 3:50 pm	Closing Remarks	Vladimir Popov, Frederick National Laboratory for Cancer Research Claudia Haywood, Frederick National Laboratory for Cancer Research
3:50 – 4 pm	Break	
4 – 5 pm	Networking Hour Room 1: Awards Recap & the Future of the FLC Mid-Atlantic Region Room 2: Can an Entrepreneurial Culture Exist in a Federal Lab?	Room 1 moderated by Vladimir Popov and Claudia Haywood, Frederick National Laboratory for Cancer Research Room 2 moderated by Tom Stackhouse, National Cancer Institute

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Patience, persistence, and creativity make USAMRDC's Body Cooling System a T2 success story

Civilians as well as warfighters can now benefit from the U.S. Army Medical Research and Development Command's (USAMRDC) system for treating exertional heat illness, thanks to T2 perseverance and a smart "reboot" for a stalled license negotiation.

The USAMRDC's Body Cooling System (BCS), called the Arm Immersion Cooling System under its original patent, is a lifesaving device that is used to treat overheating of the body. Due to a variety of factors (e.g. exertion, environmental conditions, fitness level, illness, toxins) human core body temperature can rise to levels that are harmful or fatal.

The BCS provides a simple mechanism by which the core body temperature of up to six standing individuals, or one immersed individual, can be relatively quickly and safely decreased at any time in almost any situation. A person suffering from overheating can lean into the BCS's raised basin of cool, yet relatively comfortable water, to submerge their arms from the elbows down. Blood near the skin's surface rapidly cools and circulates throughout the body, dissipating excess body heat and dropping core body temperatures in minutes.

Quick and effective treatment can help avoid the costs associated with more extensive treatment and hospital stays. The BCS can increase the overall capacity for people to work in hot, humid environments by as much as 60%. The system takes up little space, is easy to set up and transport, is adjustable and low-tech, requiring only water and ice to operate.

The true essence of the tech transfer excellence in this success story revolves around the steadfast determination of the inventor and T2 staff to get the lifesaving Body Cooling System into widespread use.

Licensing inventions sometimes requires the maturation of the technology, including field testing to reduce the level of associated risk. The T2 mechanism by which USAMRDC started the process was a Commercial Evaluation License to First Line Technology (FLT) in 2014. Those negotiations stalled, but the USAMRDC's tech transfer innovation continued.

At the 2019 Emergency Medical Services conference, USAMRDC and CrowdRX formed a cooperative research and development agreement (CRADA) to field test the BCS at five large outdoor summer concerts. For the CrowdRX staff, who regularly deal with patients with extremely high (over 107°F) body temperatures, the technology provided a much-needed new method for body cooling.



Above: The basin of the Body Cooling System holds up to 48 gallons of water and is large enough to immerse an individual suffering from exertional heat illness.

A key outcome of the CRADA relationship included the BCS being successfully used for two seriously overheated individuals who might otherwise have died. In addition, USAMRDC received proof of concept, critical feedback about product improvements, and convincing evidence of an unexplored emergency personnel market.

These factors resulted in a second-generation design and strongly contributed to breaking the impasse with the prospective licensee FLT, which designs and manufactures disaster preparedness and emergency response equipment—a perfect fit for the BCS. The CRADA with CrowdRX ended in September 2019. In 2020, FLT reopened negotiations for the BCS and entered an exclusive patent license agreement for the widespread commercialization of the BCS for sports teams and emergency personnel.

In addition to the CRADA, two internal use agreements enabled field-testing at military events and training facilities. All three of these agreements provided data and pushed improvements to the technology, leading to the execution of the patent licensing agreement between USAMRDC and FLT. ❖



NCI's partnership with Aadastra moves new brain cancer drug along the path to commercialization

A partnership between the National Cancer Institute and Aadastra Pharmaceuticals has led to an orphan drug designation for a new cancer treatment and a clinical trial to move the treatment closer to commercialization.

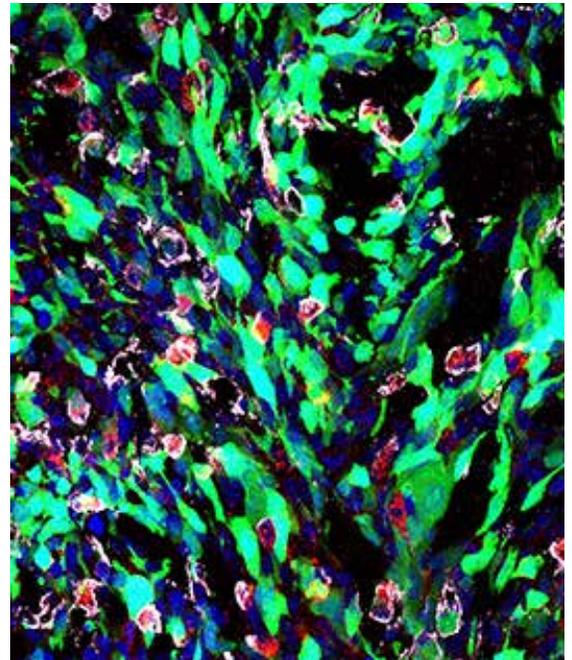
Zotiraciclib, developed by Princeton, New Jersey-based Aadastra, is an investigational cancer drug that is being evaluated for the treatment of patients with glioma, a type of brain tumor that is difficult to treat. Glioma represents 80% of all malignant primary brain tumors; types of gliomas include astrocytoma, ependymoma, and oligodendroglioma.

Despite recent advances in surgical techniques, radiation and chemotherapy, this disease remains incurable. Standard therapy consists of extensive surgery (if surgery is possible), followed by radiation therapy and chemotherapy. However, most patients experience relapse, and the median survival is less than 15 months. Thus, there is a large unmet need for the development of effective treatments of gliomas.

Zotiraciclib is a small molecule that inhibits multiple proteins known as kinases that regulate cellular processes such as DNA transcriptional regulation, cell cycle control, and DNA damage response, etc. Preclinical studies suggest zotiraciclib shuts down several specific pathways that glioma cells use to replicate and survive.

This novel anti-cancer agent is being studied and developed in a partnership between the National Cancer Institute and Aadastra Pharmaceuticals. NCI used several technology transfer mechanisms to initiate and advance the collaboration, starting with a Confidential Disclosure Agreement (CDA) so the parties could discuss collaborating, followed by a Material Transfer Agreement (MTA) for preclinical studies of zotiraciclib, then a Clinical Trial Agreement (CTA) for a Phase I/II clinical trial, and an MTA amendment for additional studies. Technology transfer advanced the collaboration by serving as a bridge between the development efforts and clinical priorities of Aadastra and the scientific concerns of the NCI investigators.

NCI played a key role in conducting several preclinical studies that provided the foundational data to justify a clinical trial of zotiraciclib. Based on positive data from these basic and translational preclinical studies, which were published in March 2018, NCI initiated the first clinical trial of zotiraciclib in brain tumor patients at the National Institutes of Health Clinical Center.



Above: Nanoparticles in the brain (courtesy of NCI Visuals Online).

In addition, zotiraciclib in December 2019 received orphan drug designation from the Food and Drug Administration (FDA) and the European Medicines Agency (EMA) for treatment of glioma.

One aspect of the excellence in the technology transfer effort was the speed with which the various agreements were negotiated and executed. These technology transfer efforts led zotiraciclib to be more rapidly translated from the bench (preclinical experiments done by NCI) to the bedside (first clinical trial in brain tumor patients). For example, the company's MTA template was negotiated and executed in eight days, and the CTA was negotiated and fully executed in two months. A rapid execution of the CTA allowed the NCI clinical trial to begin without delay. Data collection was completed in October 2020.

Since zotiraciclib targets multiple components of tumor cell survival and proliferation, it may enhance clinicians' ability to kill cancer cells and may reduce the potential for cancers to develop resistance to therapies – a particular challenge in treating glioblastoma. But in addition to glioblastoma, zotiraciclib has the potential to target multiple cancer indications, including hepatocellular tumors, as well as breast, ovarian, colorectal, pancreatic, and gastric cancers. ☞



NASA engineer's airborne remote-sensing innovation inspires nationwide educational network

National Aeronautics and Space Administration (NASA) engineer Geoff Bland has long been interested in simple, inexpensive devices to keep cameras and other sensors airborne. Thanks to a school project in Wayne County, Michigan, that interest has facilitated an educational partnership that has benefited thousands of students nationwide and is helping to shape the next generation of scientists.

In 2010, Wayne Regional Educational Service Agency (RESA) contacted Bland, looking for a way to monitor ponds and streams where water samples were being collected by students. Bland, who works at Goddard Space Flight Center's Wallops Flight Facility, had worked on other educational programs that incorporated remote sensing and Earth observation data.

Bland had found that the tool traditionally used to stabilize a camera on a windblown kite didn't provide the stability needed and tended to get tangled. So he and NASA technician Ted Miles developed an Aeropod device that is aerodynamically stabilized and is not attached directly to the kite but to a line that hangs from a ring suspended between ball bearing swivels on two segments of a kite string. It was patented in 2012. Aeropods can be equipped with the same sensors as drones, require far less training and never run out of power.

Wayne RESA's leadership, with Bland's collaboration, was granted a small two-year NASA Cooperative Agreement Notice (CAN) award and piloted the Investigating Climate Change and Remote Sensing (ICCARS) Project. The program used Aeropod data to help middle and high school students understand the science of climate change and its relationship to changes in land use and land cover.

The Goddard Strategic Partnerships Office created a new educational license that required feedback rather than monetary payment. This newly created license not only provided a way to get Aeropod technology into the hands of students and teachers and encourage citizen science, it also created a potential commercial market for companies to license the technology.

In 2016, NASA granted RESA a new five-year CAN award to expand the program into what is now the AEROKATS and ROVER Education Network (AREN). AEROKATS, or Advanced Earth Research Observation Kites and Atmospheric and Terrestrial Sensors, refers mainly to the kite-based Aeropod portion of the program. ROVER, or Remotely Operated Vehicle



Above: Aeropods (pictured) can be equipped with the same sensors as drones, require far less training and never run out of power.

for Education and Research, is a remote-controlled watercraft for collecting in-water measurement systems that was also developed by Bland and Miles, in collaboration with the University of Maryland Eastern Shore (UMES).

Multiple public and private organizations – from as far away as Fairbanks, Alaska – have joined AREN. Currently, dozens of schools in Wayne County participate, and countless students and teachers from coast to coast have also gotten involved.

Bland says he's made sure NASA's rigorous operations procedures are part of the curriculum. Like a rocket launch, each flight or mission is a team effort in which all participants have specific roles, checklists are developed and followed, risks are assessed and mitigated, and operations are preceded and followed by comprehensive briefings.

"I hope the young people participating today turn into the next generation of NASA engineers, scientists, professionals, and support staff, people who will help us continue to understand our own planet and explore the universe," Bland said. "And, hopefully, the program is fun, too." ❖



Seed funding and a start-up help NCATS-CCHMC cancer therapy cross preclinical Valley of Death

Collaborations, a spin-off company, and a creative approach to funding have helped the National Center for Advancing Translational Sciences (NCATS) navigate its new blood-cell cancer drug through the dreaded preclinical “Valley of Death.”

NCATS, part of the National Institutes of Health (NIH), and Cincinnati Children’s Hospital Medical Center (CCHMC), a teaching hospital, collaborated to develop small molecules for treating myelodysplastic syndrome (MDS) and acute myeloid leukemia (AML).

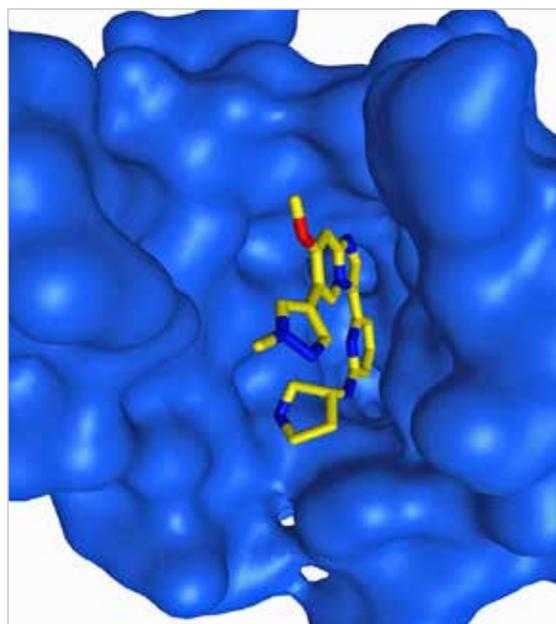
AML and MDS are blood cell cancers that urgently need improved treatments. Collectively, more than 30,000 new cases of MDS and AML are diagnosed in the United States each year. The median survival time for MDS is only 2.5 years after diagnosis, and the five-year survival rate for AML is only 27%.

Interleukin-1 receptor-associated kinase (IRAK) and FLT3 kinase enzymes play key roles in driving the progression of AML and MDS. Small-molecule inhibitors of FLT3 have shown initial promise in treating AML. However, FLT3 inhibitors have not led to long-lasting remission, since FLT3 inhibition results in increased compensatory signaling through IRAK1/4. The new treatment co-developed by NCATS and CCHMC will have potential to provide long-term benefits for MDS and AML by inhibiting both IRAK and FLT3.

The NCATS Office of Strategic Alliance worked closely with Cincinnati Children’s Innovation Ventures (CCIV), a unit of CCHMC that facilitates the translation of discoveries into improved care for children, to explore pathways to support technology development through the late preclinical development phase (i.e. “Valley of Death”). This phase of product development often fails because it is significantly more expensive than early-stage discovery; it involves lengthy process development, scale-up, and toxicology testing; and it is less likely to receive federal funding.

NCATS entered into an inter-institutional agreement (IIA) that allowed CCIV to take the lead in filing patent applications, and marketing and exclusively licensing their joint intellectual property (IP) for the new IRAK/FLT3 inhibitors. CCIV filed and secured patents for the composition of matter and the methods of use for the inhibitors.

In late January of 2020, CCIV facilitated the creation of a start-up, Kurome Therapeutics, whose mission is dedicated specifically to the preclinical and clinical



Above: The chemical structure of a prospective drug sitting inside the protein kinase IRAK4. (Image courtesy of Cincinnati Children’s Hospital Medical Center)

development of the novel IRAK/FLT3 inhibitors. CCIV facilitated series seed funding for Kurome from Cincinnati Children’s and investment funds including CincyTech. CCIV also recruited an experienced entrepreneur-in-residence to manage the project operation and to coordinate product development by NCATS and CCHMC investigators.

NCATS and CCIV worked together to enable CCHMC to enter into an exclusive license with Kurome for the IP covering novel IRAK/FLT3 inhibitors and for the treatment and diagnostic applications for AML, MDS and solid tumors. CCHMC, Kurome, and NCATS also entered into a cooperative research and development agreement (CRADA), providing Kurome with options to license future IP relevant to the inhibitors. The exclusive license agreement and the CRADA provide Kurome with a sustainable intellectual property portfolio.

Since Kurome was founded in January of 2020, it has used the proceeds from the series seed investments to fund ongoing preclinical developments by the investigators at NCATS and CCHMC, dramatically accelerating the drug development. Significant progress has already been made, as optimized drug leads have been developed and new patent applications have been filed. ☘



Three agencies collaborate to update respirator testing and ensure emergency responder safety



Scientists from three FLC Mid-Atlantic Region agencies have collaborated to update the respirator testing process used to verify the safety of the nation's emergency responders.

The collaboration included the Department of Homeland Security's (DHS) Science and Technology Directorate (S&T) Chemical Security Analysis Center (CSAC), the U.S. Army's Combat Capabilities Development Command Chemical Biological Center (CCDC CBC), and the National Institute of Safety and Occupational Health's (NIOSH) National Personal Protective Technology Laboratory (NPPTL).

Each laboratory made unique contributions to the interagency partnership: CSAC's understanding of chemical threats to the homeland and its modeling and hazard assessment capabilities; CCDC CBC's filtration science expertise; and NPPTL's outreach to industry and the responder community.

In the event of a chemical, biological, radiological, or nuclear (CBRN) hazard release, emergency responders rely on respiratory protection to prevent inhalation exposure to these hazards. NIOSH evaluates CBRN air-purifying respirator (APR) canisters by challenging the ability of the respirator filter media and carbon bed to protect against 11 test representative agents (TRAs). This approach dates back to the original 2001 CBRN hazard assessment and the hazards landscape at that time.

However, CBRN hazards are constantly evolving in type, usage, and dissemination. Therefore, there was a compelling need to re-evaluate CBRN hazards to ensure existing and future NIOSH-approved CBRN APR canisters provide adequate protection from both existing and newly emerging hazards. A preliminary analysis supported starting the reassessment process by focusing on chemical hazards.

NIOSH, working with the responder community and with CSAC scientists, generated a comprehensive list of chemical inhalation hazards relevant to emergency responders. CSAC then conducted hazard assessments using its state-of-the-art modeling tools and extensive data bases of toxicological properties. CSAC also collected data on the physical properties of these chemicals as relevant to predicting filter behavior.

With CCDC CBC, CSAC grouped the chemicals into classes. These classes formed the underlying basis for the testing methodology. CCDC CBC was responsible for applying cutting edge science relevant to filter



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behavior. The result was a determination of TRAs for each chemical class.

The researchers determined that the current 11 NIOSH TRAs adequately represented all chemical hazards identified in the updated Hazard Assessment. Consequently, there was no need to change or add to the TRAs that had been instituted two decades ago. This finding generates confidence in the safety of the filtration canisters that have been used by the emergency responder community since 2001. The process also resulted in a standardized methodology upon which to evaluate future hazards—an important scientific advancement.

The project was completed in 2019, with science having been transferred into guidance. The findings and their implications are continuously being transferred to respirator stakeholders, professional societies, standard-setting organizations, and the emergency responder community.

The results are being used as the basis for updating NIOSH publications, including the NIOSH CBRN Respiratory Protection Handbook and an updated protocol for canister certification. NIOSH is also communicating the findings to the responder community - the ultimate customers and beneficiaries of the testing methodology.

In July 2020, the project team was awarded the 2020 NIOSH Bullard-Sherwood Research to Practice Science and Service Award, in the Intervention category. This award recognizes outstanding application of occupational safety and health research. ☘



NIST-TEDCO entrepreneurship program facilitates 11 new start-ups and \$2.7M in annual revenue



An entrepreneurial program created by the National Institute of Standards and Technology (NIST) and the Maryland Technology Development Corporation (TEDCO) has resulted in 11 new businesses that have generated \$2.7 million in annual revenue.

The NIST Science and Technology Entrepreneurship Program (N-STEP) is a joint effort by the NIST Technology Partnerships Office (TPO) and TEDCO designed to create collaborations resulting in new company formations by departing NIST employees and commercialization of NIST technologies, which in turn, creates jobs. Informally, two-way tech transfer is also happening as N-STEP recipients maintain relationships with their NIST contacts.

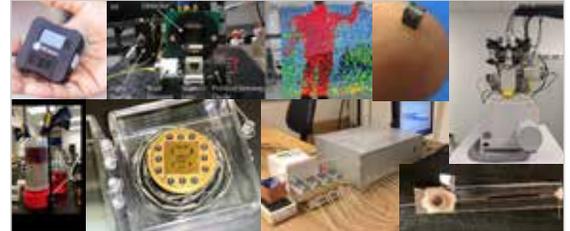
Since the start of the program in 2016, N-STEP has resulted in the creation of 11 new businesses (including eight in the state of Maryland), which have generated \$2.7 million in annual revenue, \$1.2 million in investment, an additional \$4.8 million in follow-on funding (e.g. grants), and 26 jobs reported in their required annual economic impact reports through February 2020.

Individuals who are nearing the end of their term of NIST employment are eligible for N-STEP; these include postdocs and associate researchers who are at NIST on temporary appointments and need future career options. NIST has more than 3,500 associates or visiting scientists doing research at NIST each year. Also, an average of 85 post-doctoral researchers join NIST each year. Most spend two years at NIST before moving on; NIST retains about 35% for longer-term employment.

Departing NIST employees in the N-STEP program get to launch their own companies, built on NIST research and their own skills, with the support they need for start-up success.

TEDCO is an independent instrumentality of the state of Maryland, established to facilitate the creation of businesses and support their growth in all regions of the state. TEDCO provides business assistance and funding for early-stage, technology-based businesses and fosters technology transfer and commercialization from state universities and federal labs.

N-STEP can be characterized as having “low hurdles” for its participants to clear. Participants receive mentorship and training, leading to the creation



Above: Companies and technologies that have resulted from the N-STEP program include (clockwise from top left): N5 Sensors, Inc. (“Chip-scale Hybrid Gas Sensors for Indoor Air Quality Monitoring”), Z-senz, LLC (“Resonant LIDAR Electronics for Small UAVs”), Vapor Cell Technologies, LLC (“Optimized Bonding Technology to Mass-Manufacture Chip-Scale Vapor Cells”), zeroK NanoTech, LLC (“Low Temperature Ion Source for Nanomachining and Nano-microscopy”), Parman Tech, LLC (“Analytical Nano-Particle Separation Instrumentation for Pharmaceutical Applications”), Microbial Pulse Diagnostics, LLC (“A Rapid Biophysical Diagnostic for Antimicrobial Susceptibility Testing”), Graphene Waves, LLC (“Affordable Quantum Resistance Standards Based on Graphene”), and PathOtrak, LLC (“MVP Design and Fabrication of a System for the Separation of Pathogenic Bacteria From Food Samples”).

of a business proposal that the participant presents to the TEDCO staff. If they are successful, a contingent award is made, and the participants learn how to form a company and secure a patent license.

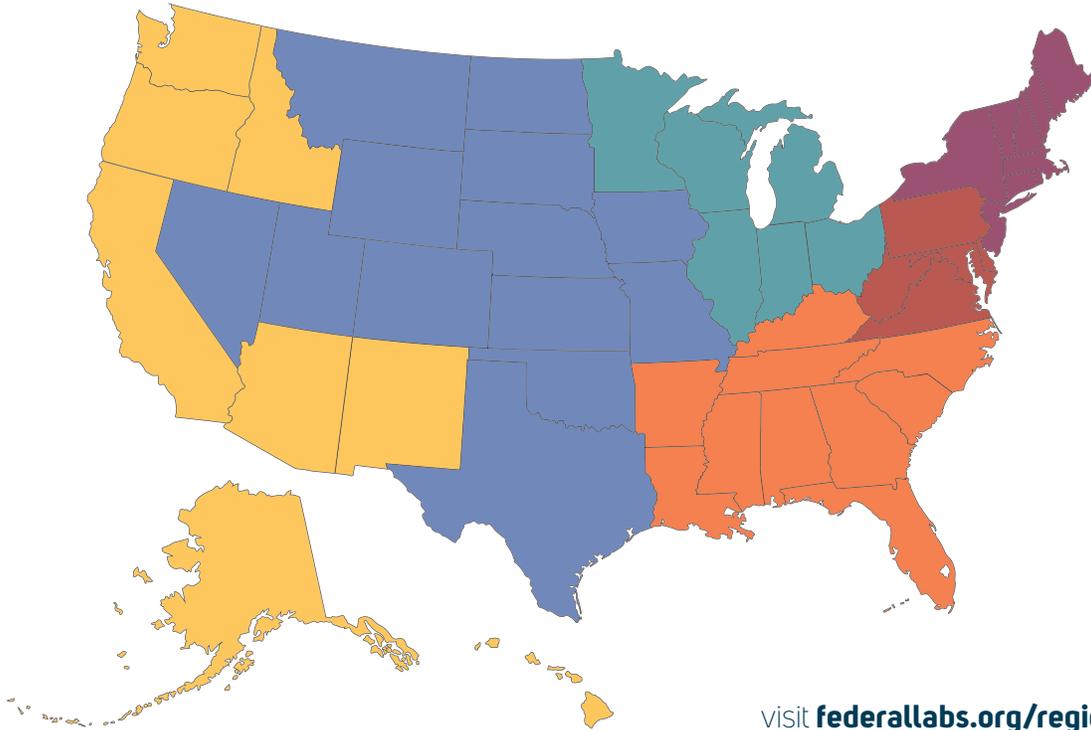
N-STEP funding is \$100K for a one-year project to advance the technology toward commercialization. An additional \$12K must be used to develop the entrepreneur’s business acumen. Companies are encouraged to pursue grant funding for much needed follow-on funds to further development and sustain the company.

The technology transfer mechanisms used by N-STEP are the standards, starting with a research license at no cost to the company, preserving the company’s cash for operations and translational development efforts. The knowledge transfer is often facilitated with a cooperative research and development agreement (CRADA), allowing access to unique facilities, equipment, etc. and lowering the cost for the startup.

There has been funding from the three NIST Small Business Innovation Research (SBIR) awards and four SBIR awards from the National Science Foundation and the Department of Energy. N-STEP companies have raised money from investors, Maryland small business funding sources (including TEDCO), and a corporate bank loan. Some start-ups have also developed strategic partnerships with international corporations. ☞

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