

U.S. Department of Health and Human Services (HHS) sponsors development of portable, user-friendly burn imaging device

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Program advances next-generation technology to improve care for burn patients

An imaging device to evaluate the severity of burn injuries quickly and accurately will take the next steps in development under a contract by U.S. Department of Health and Human Services' Office of the Assistant Secretary for Preparedness and Response (<u>ASPR</u>). Fast, accurate information about burn severity is critical to provide the appropriate care for patients.

This enhanced triage ability will be particularly important in any type of mass casualty incident involving burns, including those resulting from a nuclear detonation

Triaging and treating burns effectively requires early clinical evaluations on the depth and severity of the injury. This initial clinical assessment informs a healthcare provider whether surgical procedures are necessary or if wounds will heal with other non-surgical treatment.

Under a 2-year, \$27.3 million contract, SpectralMD, Inc., of Dallas, Texas, will advance the development of this next-generation burn imaging device, DeepView. The project is part of a long-standing effort by the Biomedical Advanced Research and Development Authority (BARDA), a component of ASPR, to develop new medical products that help save lives during a radiological or nuclear emergency.

"We want to give medical providers as many modern tools as we can to help them save lives in disasters," said BARDA Director Rick Bright, Ph.D. "An emergency situation with many burn casualties could overwhelm surgical facilities and specialized burn care providers. They need fast, accurate assessments of burn injuries to provide effective medical treatment and to guide appropriate use of limited burn care resources immediately."

BARDA's extensive market research has shown that burn surgeons consider current wound imaging technologies to be cumbersome and not user-friendly. Instead of using devices, experienced burn surgeons visually evaluate burn wounds and use their experience to determine the wounds' healing potential.

However, this visual, clinical assessment requires experienced surgeons to be available, and the United States does not have enough experienced burn surgeons to evaluate the large number of burn patients anticipated in a radiological or nuclear incident.

Under a prior BARDA contract, SpectralMD demonstrated the potential of the DeepView technology in clinical study at a single burn center. This preliminary work demonstrated the potential of the DeepView technology to detect the burn depth at least as accurately as experienced burn surgeons.

The company is using advanced Artificial Intelligence (AI) algorithms to train the device's software to analyze wounds at pixel level to determine tissue damage severity, burn depth and other physiological information well beyond human capability.

Under the new agreement with BARDA, SpectralMD will conduct an expanded feasibility clinical trial across five burn centers to further develop a new easily portable hardware platform and the machine learning algorithm for faster processing and optimal performance. The contract can be extended for up to a total of 4 years and up to \$91.1 million. If extended, the contract would support algorithm training and validation (pivotal) studies as needed to seek FDA 510k clearance.

The device is part of BARDA's robust portfolio of development projects to treat mass casualties from chemical, biological, radiological or nuclear incidents. These advanced development projects include eight products to treat skin injuries from burns and radiation, as well as other treatments for thermal burns, blast injuries and acute radiation exposure, such as blood, gastrointestinal, and lung injuries.

BARDA is seeking additional proposals for products that could be used to treat illnesses and injuries caused by disasters. Visit www.medicalcountermeasures.gov or Eederal Business Opportunities (BARDA-CBRN-BAA-18-100-SOL-00003) to learn more about partnering with BARDA.

About HHS, ASPR and BARDA

HHS works to enhance and protect the health and well-being of all Americans, providing for effective health and human services and fostering advances in medicine, public health, and social services. The mission of the Office of the Assistant Secretary for Preparedness and Response (ASPR) is to save lives and protect Americans from 21st century health security threats. Within ASPR, BARDA invests in the advanced research and development, acquisition, and manufacturing of medical countermeasures – vaccines, drugs, therapeutics, diagnostic tools, and non-pharmaceutical products needed to combat health security threats. For more about ASPR and BARDA, visit www.phe.gov.