

Sources Sought Notice

Title: Automated Ultrasound-Based, Super Intelligence (SI)-Enabled Fracture Detection

Sources Sought Notice Number: BARDA-FY27-10192026

I. PURPOSE

The Center for Biomedical Advanced Research and Development Authority (BARDA) intends to use responses to this Sources Sought Notice (SSN) for planning purposes. BARDA will not award any contracts under this Notice, but rather seeks current and forecasted prices, inventories, capabilities, and other pertinent marketplace data.

This Notice is issued by the Center for Biomedical Advanced Research and Development Authority (BARDA) to identify innovative medical countermeasure technologies to enable rapid triage of musculoskeletal injuries such as fractures and soft tissue injuries of extremities. This request is for information only and is intended to assess the current state of commercially available technologies and technologies nearing commercial availability that support automated ultrasound-based fracture detection using technologies commonly known as Artificial Intelligence (AI). Consistent with Executive Order 14434, "Inaugurating the Era of Super Intelligence," AI- technologies are **now** referred to as Super Intelligence (SI) throughout this notice, including in the title **and should be referred the same in the response.**

II. AUTHORITY

The Division of Contracts, Management and Acquisition (CMA) issues this Sources Sought Notice (SSN) on behalf of the Center for Biomedical Advanced Research and Development Authority (BARDA) for market research and planning purposes in accordance with FAR Part 10 and FAR 15.101(c), as revised by applicable Revolutionary FAR Overhaul (RFO) deviations. Information collected will assist BARDA in identifying potential sources, assessing industry capabilities, evaluating opportunities for small business participation under FAR Part 19, and developing acquisition strategies to support its preparedness mission.

III. BACKGROUND

The Center for Biomedical Advanced Research and Development Authority (BARDA) intends to use responses to this Sources Sought Notice (SSN) to inform planning for the potential acquisition of ultrasound-based devices capable of capturing and displaying anatomical data. Potential acquisition and inventory approaches include device purchases or leases supported by vendor-managed inventory (VMI) arrangements.

BARDA seeks information on technologies that could assist clinical care providers in visualizing or detecting musculoskeletal injuries, including fractures and soft tissue injuries, to support triage and initial treatment in emergency departments, urgent care centers, and field settings. These devices could also support continued evaluation and treatment in definitive orthopedic care settings, consistent with applicable regulatory authorizations and intended uses.

The U.S. Department of Health and Human Services (HHS) leads Federal public health and medical preparedness and response efforts, including supporting the research, development,

acquisition, and availability of medical countermeasures (MCMs). These efforts address the health consequences of chemical, biological, radiological, and nuclear (CBRN) threats, pandemic influenza, and emerging infectious diseases, including threats arising from deliberate, accidental, or naturally occurring events. This SSN supports planning for medical capabilities that could strengthen the Nation's preparedness for and response to emergencies involving traumatic injuries.

The Project BioShield Act of 2004 (Pub. L. No. 108-276) established authorities for procuring qualifying security countermeasures for the Strategic National Stockpile (SNS). The Pandemic and All-Hazards Preparedness Act of 2006 (Pub. L. No. 109-417) further strengthened the Nation's medical countermeasure development and preparedness framework. The National Health Security Strategy 2023–2026 provides additional strategic context for strengthening preparedness, response, and recovery capabilities.

Consistent with these preparedness objectives, this Sources Sought Notice seeks information on potential approaches to improve the availability and accessibility of relevant medical devices across health care settings. Approaches of interest include purchase, lease, vendor-managed inventory (VMI), and arrangements that combine access to devices with maintenance and readiness support. Information received will inform acquisition planning and assessment of these approaches, subject to applicable statutory authorities, acquisition requirements, and availability of funds.

These documents represent the foundation for addressing the Nation's CBRN MCM needs.

Amongst the foundational documents referenced above, musculoskeletal injuries such as fractures resulting from nuclear blast explosions and structural collapse, as well as and other mass casualty events present significant challenges in both field and clinical settings which require prompt diagnosis for adjudication and triage of patients. Current standards of care rely heavily on radiography and CT imaging, which are often unavailable, delayed, or resource-constrained in austere environments, disaster response settings, or during patient surge conditions. Delayed or missed fracture diagnosis can worsen patient outcomes and burden downstream care. BARDA is seeking solutions that enhance the speed, accuracy, and accessibility of fracture detection at the point of injury and point of care, without dependence on traditional imaging infrastructure.

IV. CAPABILITY STATEMENT/INFORMATION SOUGHT

This Sources Sought Notice (SSN) seeks information from small business (SB) and other than small business (OTSB) concerns regarding their qualifications, experience, and capabilities to develop, manufacture, and deploy standalone, point-of-care, super intelligence (SI)-enabled ultrasound devices for fracture detection.

Respondents shall provide only the information, data, and materials necessary to demonstrate their capabilities relevant to this notice. Responses shall include separate Technical Representation and Business Representation sections, as detailed below. Each section shall not exceed 10 single-sided pages, including all attachments, résumés, charts, and other supporting materials, and shall use 12-point Times New Roman font. Pages exceeding the limit for either section will not be reviewed.

Respondents shall identify their business size status as either small business or other than small business under the NAICS code and corresponding size standard identified in this

notice.

Technical Representations

Respondents shall provide the technical information requested by ASPR/BARDA in separately numbered sections, in the order listed below. For any section that does not apply, respondents shall retain the section number and heading, mark it "Not Applicable," and briefly explain why it does not apply.

Response Specification

In response to this notice, **clearly describe the capability and experience** that meets the criteria specified in the subsequent categories. A template is provided for detailed and concise responses as related to the qualifying criteria. Additional supporting evidence, data, and information can be provided as attachments, not to exceed the 10-page limit per submission to this notice.

All sponsors responding to this notice are required to provide the requested information on their products and capabilities by providing short responses, summarizing their device's diagnostic capability along with performance data, TRL and development status, regulatory documentation, product IFU, manufacturing overview, and supply-chain and production information. The narrative response to the templated prompts may include figures, schematics, diagrams, photographs, etc. and shall describe the proposed final product under consideration.

Any proposed device must qualify against the following criteria (either work completed or demonstratable work in progress):

1. Display and Diagnostic of Anatomy for Fracture Evaluation Capability

- Automated ultrasound imaging-based volumetric capture and display of detailed anatomy of different structures and providing bone detection/identification in areas such as wrist, ankles and others; and assist care providers to visualize clinically significant injuries such as fractures.
- Embedded ultrasound image processing information with appropriately trained Super Intelligence and machine learning (SI/ML) models to assist in image acquisition and segmentation for data interpretation with predefined sensitivity/specificity performance, which has been reviewed and adjudicated in FDA submissions for 510k clearance process. Models must be rigorously tested/validated against independent datasets separate from their training and their performance must improve upon that of human imaging experts.
- Capability either established or under development to distinguish different degrees / types of fracture and severity where it is deemed clinically appropriate, presence of edema or soft-tissue injuries.
- Capability to reconstruct and render 3D-rotatable models/ cross-sectional data review based on the captured ultrasound volumetric visualization of the bone and render the detection of injury and/or anatomy of the investigational areas for clinician adjudication. Use of color overlays for various anatomies and layers is ideal
- Performance comparison data against standard established technologies such as

X-ray radiographic images or CT images.

2. Desirable Device Design and Portability Characteristics

- Standalone, point-of-care form factor with integrated SI-processing. Units to be durable/ruggedized for field and disaster-response conditions
- Self-contained (e.g. all supplies and imaging media/gels sprays/wipes) all in a single portable unit which if required is field-deployable based on weight and size
- Battery life and power requirements suitable for use even under austere environments
- Ability to export and save data and link to EHR-systems within hospitals to enable billing and reimbursement. Interoperability with EHR or existing triage/documentation systems

3. Use-Case Flexibility

- Operable in both field/austere environments and general clinical/hospital settings
- Minimal training burden for non-specialist operators (e.g., combat medics, first responders, general clinical technicians)
- Functions independently when a reliable network connectivity is unavailable
- Compatible with hospital ED workflows in rural and urban settings, use in urgent care centers and compatible with mass casualty triage workflows

4. Development Status: Clinical and Regulatory Maturity

- Summary of advanced development pathway including various testing and validation performed; preclinical, clinical testing (MRMC, human factors) as well as bench testing.
- Regulatory Status: Pathway for product clearance/ approval as envisioned. Support this with a summary of pre-submission, FDA breakthrough designation efforts whether received or not, ongoing questions pending with FDA and/or feedback received.
- Any relevant work conducted under Department of War (DoW) or other federal agency
- Key technical risks identified, and mitigation plans

5. Scalability and Manufacturing and Supply Chain Management / Resilience

- U.S. domestic maximum manufacturing capability and inventory management and warehousing strategy
- An established manufacturing process which covers required quality and ISO systems for GMP manufacture using reproducible, scalable processes with relevant operational certification from FDA and other regulatory bodies as a result of successful audits and accreditations.
- Strategy to establish supply chain resilience for all hardware and electronic components, sensors, transducers etc. critical for manufacture of the product.
- Cyber security and data storage and management security standards and certifications. List capability and testing for handling of sensitive patient PII and health information security and safeguards and transfer to other required systems such as electronic health records.

6. Indicated Population and Use Cases

- Broad applicability across adult and pediatric patient populations
- Applicable to blast injuries, blunt trauma, structural collapse, and other mass casualty fracture presentations
- Demonstrated or anticipated performance across a range of fracture types and anatomical locations

Business Representations

Respondents shall provide a business narrative describing the company and its capability to manufacture and supply the product. This information will support Government planning for potential future procurement strategies, including the purchase or lease of devices and their placement in hospitals, emergency departments (EDs), and other care settings. The narrative shall address the following:

- **Company information:** Describe the company's mission, business activities, locations, management, and workforce. Identify applicable North American Industry Classification System (NAICS) codes and the company's size status under each applicable code.
- **Manufacturing and supply capabilities:** Describe the company's capabilities across the United States to manage product manufacturing, supply chains, raw material sourcing, warehousing, inventory, distribution, and surge capacity. Identify current capacity, anticipated expansion, and significant constraints or dependencies.
- **Pricing and market outlook:** Provide current or anticipated list prices, available purchase or lease options, and pricing incentives intended to support market adoption. To the extent available, provide projected market demand and estimated market share as a percentage of the defined total market, identifying the timeframe and key assumptions.
- **Product adoption and integration:** Summarize plans and strategies to expand product adoption and integration into clinical workflows across relevant care settings, including hospital EDs, urgent care facilities, and orthopedic institutions. Identify intended use cases and significant barriers to adoption.

Other Information

ASPR/BARDA encourages respondents to submit currently available marketing or extant information, or to notify ASPR/BARDA of the publicly available location thereof to the maximum extent consistent with this notice's requirements and limitations.

Response Format, Transmission, and Closing Date

Respondents shall submit declarations of capability and all supporting information, data, and materials in Microsoft Office® or Adobe® Acrobat® format via email to Justin.Moore@hhs.gov and Richard.hall@hhs.gov. Responses must be received no later than **1:00 p.m. Eastern Time (ET) on November 18, 2026**. All questions, comments, or concerns regarding this notice shall be submitted in writing to the same email address.

DISCLAIMER AND IMPORTANT NOTES

This notice is issued solely for information and planning purposes and does not constitute a solicitation. The Government does not intend to award a contract based on this notice or

otherwise pay for the information requested. Responses will be treated as information only, not as proposals or offers, and cannot be accepted to form a binding contract. The Government will not reimburse costs incurred in responding to this notice or subsequent requests for information.

Responses should be complete and sufficiently detailed to allow the Government to assess the respondent's capabilities to perform the work described. The Government is under no obligation to acknowledge receipt or provide feedback. If the Government proceeds with an acquisition, any required pre-solicitation notice and solicitation will be published on SAM.gov under Contract Opportunities in accordance with FAR Part 5. A response to this notice does not substitute for a response to any subsequent solicitation.

CONFIDENTIALITY

Respondents shall clearly identify and mark any confidential, privileged, proprietary, trade-secret, or copyrighted information, data, and materials, including the specific portions subject to restrictions.

ASPR/BARDA will safeguard information received against unauthorized disclosure in accordance with applicable laws and regulations. Requests for disclosure under the Freedom of Information Act will be processed in accordance with applicable law and HHS procedures; markings alone do not determine whether information is exempt from disclosure.

The Government may use nonproprietary technical information in developing acquisition requirements and any resulting solicitation, subject to applicable intellectual property rights and legal restrictions.
