PARATUS Digital Health Accelerator | POWERED BY MATTER

Digital Tools for Pre-hospital TBI Assessment

OVERVIEW

BARDA supports advanced development of products that address the medical consequences of nuclear detonation and related blast injuries. Patient care after such a mass casualty event may occur for an extended time at field sites or other non-hospital settings. Providers in these settings may have limited access to the imaging and laboratory equipment normally available in a hospital or higher-acuity care setting.

Traumatic brain injury (TBI) is among the types of injuries expected from such a blast event. In resource-limited conditions, it may be difficult to quickly discern whether a patient has a TBI that requires rapid escalation to a higher level of care. Thus, novel noninvasive rapid TBI assessment capabilities are needed that can be performed at the point of need—without specialized imaging equipment or laboratory access—by first responders as well as trained clinical staff.

BARDA seeks to support the development of software that informs patient triage after a suspected head injury in the prehospital environment (for example, to rule in/out need for imaging studies) and aids in the identification of acute TBI that needs rapid escalation of care. Algorithms that use data collected with the sensors and imaging capabilities typically available on a smartphone or tablet are preferred (such as, but not limited to, quantitative pupillometry or eye tracking); however, BARDA will consider supporting development of algorithms that use multimodal digital data collected with a noninvasive device that could be used at scale in the prehospital environment (e.g. an EEG headband, portable/hand-held imaging tool, filter attached to a smartphone etc.). Ultimately, the resulting technology should provide actionable information in real-time to aid in decisions related to patient management (e.g., triage, transport, additional diagnostic tests) or treatment.

Development should advance the technology toward a commercial product. Tools intended for research use only are not responsive.

DESIRED ATTRIBUTES OF A FINAL PRODUCT

Not necessarily fully achieved through this solicitation, but envisioned as an end-goal for supported products:

1. System can be used for pediatric and adult assessment
2. Assessment conducted and results available in less than 2 minutes
3. No pre-injury baseline information needed
4. Results are not confounded by other/polytrauma
5. Ability to perform all steps and generate results without an internet connection
6. Interoperable with electronic medical record systems
7. No specialized training required for use

FUNDING LEVELS

Software Prototype Stage: $500k - $1M; approximately 12 months long projects
Applicant has established their data collection and analysis approach, but additional software development, analytical validation, and data collection from a small number of TBI patients is needed to build their algorithm and prepare for a larger-scale data collection.

Early Clinical Stage: up to $2M; approximately 12-24 months long projects
Applicant has demonstrated proof-of-concept for their indication with a small number of TBI patients but expanded clinical data collection is needed to refine and test their algorithm, and to demonstrate the value of using their technology.

REQUIRED RESPONSE ELEMENTS

1) Description of the envisioned step-by-step process for assessing a patient, including time from patient presentation to obtaining TBI output
2) Overview of the biological or clinical rationale for using the proposed data types for TBI assessment, citing references as appropriate
3) Discussion on the technical challenges to achieving the envisioned final product
4) Discussion of how the results from the assessment lead to the TBI output
5) Provision of preliminary/proof-of-concept data for the capability (must be generated by the applicant) aligned to the funding stage requested and preferably from clinical subjects
6) Presentation of the regulatory plan, including the specific indication for use, regulatory pathway, predicate device (if any) and substantial equivalence (if applicable), and regulatory timeline
7) Clinical risk management strategy
8) Technical approach to algorithm development— the R&D plan for the project
    a. Set clear objectives, milestones, and performance metrics that demonstrate the advancement and utility of the technology.
    b. State the plan for clinical data collection, including study sites and enrollment targets. A justification for the indicated enrollment target is required. Retrospective data may be allowable with justification.
    c. For early clinical-stage projects, present a clearly defined and justified comparator method.
    d. For early clinical-stage projects, present a plan for comparing the performance of the algorithm to the assessment of an end user with capabilities commonly available today (to demonstrate that the new approach would make a difference).
9) Plan for user experience studies with intended end users (such as first responders) as part of the project

ADDITIONAL CONSIDERATIONS

1) Funding is not intended for device and hardware development.
2) Inclusion of questionnaire and observation-based assessments in the protocol is acceptable, but algorithm performance without these components must be evaluated. Data from other tools a first responder would have is allowed.
3) Initial capabilities may focus on an indication for adults or pediatrics; however, capabilities that work across age groups are desired.
4) Awardees are expected to engage the FDA through the Q-submission pathway during their project, if they are not already engaged in this process.
5) Technologies intended only for wellness, performance optimization, or research-use-only applications are not responsive.