DRIVe Type to Treat BAN VITAL Topic

2025.08.22

Program: Type to Treat: Therapeutic Efficacy through Predicting Treatment Response (TyPe)

Topic Title: Approaches for Predicting Treatment-Responsive Patients to Enable Therapeutic Efficacy of BARDA Medical Countermeasure Products for National Health Security

Eligibility, Funding Guidelines and Duration:

- We are accepting applications from academic innovators, non-profit entities and for-profit startups and companies globally
- The TyPe awards are anticipated to be multi-year awards for development activities taking approximately 1-3 years; however the exact timeline for each project will be finalized during negotiations.
- Applicants may request $750K - $1M in funding
- Applicants may propose larger dollar-value projects through cost sharing
- Awards will be structured as milestone-based, fixed price contracts

Overview

To enable therapeutic efficacy in clinical trials as well as inform use once therapies are marketed, strategies are needed to address heterogeneity of treatment effect. These strategies have supported a burgeoning field of companion and complementary diagnostics for therapeutic intervention and clinical care in chronic disease. This program aims to leverage such strategies for development of therapeutics in BARDA's mission space (Chemical, Biological, Radiological or Nuclear (CBRN) threats; pandemic influenza; and emerging infectious diseases) or for FDA-approved medical countermeasures relevant to BARDA's mission space that treat injuries, insults, infection, or severe disease from health security threats.

This topic seeks technologies and approaches that can predict treatment benefit among patients to increase the probability of demonstrating therapeutic efficacy during clinical development and to guide treatment decisions during clinical care for improved patient outcomes. These technologies may be based on phenotyping, sub-phenotyping, endotyping, genotyping, and/or other approaches to identify patients likely to benefit from specific treatments. The goal is to advance the development of platform technologies that are commercially sustainable outside of US government support (i.e., not dependent on BARDA acquisition) that have potential to be used for multiple therapeutics, indications, or use cases relevant to both national health security and everyday clinical care of Americans. These tools will help ensure that patients receive the right treatment at the right time to enable therapeutic effectiveness, while aiming to reduce development costs, accelerate development timelines, as well as enhance the efficiency and success of advancing therapeutics to approval and market.

To be considered responsive under this Topic, offerors should propose development and clinical evaluation plans for the patient subtyping platforms that meet the following requirements:

1. The platform must enable improved efficacy in the stratified treatment-responsive patient subpopulation compared to the all-comer patient population for an FDA-approved therapeutic or therapeutic candidate relevant to BARDA's mission space. That is development of a platform that just stratifies a population without tying to potential treatment(s) effects will not be prioritized.
2. Offerors should define and justify the selection of the FDA-approved therapeutic or BARDA-relevant therapeutic candidate that will be used for the use case.
    a. Please describe the relevance of the therapeutic's or candidate's proposed label indication to BARDA's mission space.
    b. Therapeutics may be pathogen-targeted or host-directed and may include a range of therapeutic and clinical management approaches including biologics, small molecules, and devices.
3. Offerors should describe the evidence (e.g., preliminary data generated by the offeror, scientific publications) to link patient characteristics being measured that are associated with treatment effect to the therapeutic mechanism(s) of action.
4. Offerors should propose clinical validation of the platform through retrospective clinical data and/or access to samples and data from prospective clinical studies of patients treated with the therapeutic product.
    a. Ideally the data and samples could be leveraged from partnership with an organization already supported by BARDA or other entities for a cost-savings.
    b. Preclinical data alone is acceptable for indications subject to the animal rule.
    c. It is anticipated that there may be some iteration on the platform as new datasets become available.
    d. Please elaborate on the clinical dataset(s) that will be used in this proposal.
5. At a minimum, a RUO (research use only) prototype of the platform capable of implementation in the clinical setting should be available to evaluate under this proposal.
    a. It is assumed that the platform will be a single component or combination of components including a device, assay, diagnostic, algorithm, etc. that can eventually seek regulatory approval to guide therapeutic use. The term Platform is used to signify the ability for the technology to pivot (e.g., transcription of different genes, algorithm modification, etc) to different use cases (e.g., different disease indications or different therapeutics).
    b. Offerors should describe how the platform could pivot: 1) to inform development of other BARDA-relevant therapeutics to treat the underlying disease biology in the same stratified patient populations, 2) to inform development of other BARDA relevant-therapeutics by leveraging the technology to identify new stratified patient populations, 3) to inform the development of the selected therapeutic for other BARDA-relevant indications with similar underlying disease biology, or 4) to develop related devices for BARDA relevant use cases (e.g., screening/early detection, prognosticating outcomes, pharmacodynamic/therapeutic response monitoring). Please describe the work and time that would be required to enable these pivots.

6. Offerors should provide a description of the platform technology in terms of form factor, required inputs (including how the inputs will be collected), analyses that will be conducted, and stage of development of all components.

Additional considerations:

1. Offerors should propose future development plans to prospectively validate the platform in conjunction with the existing FDA-approved or BARDA-relevant therapeutic in development (Fig. 1). It is desired to conduct some initial prospective evaluation under this proposal, but if not feasible, then please describe the future approach and timeline.
2. Offerors should describe the intended use and clinical setting for the patient subtyping platform, as well as the commercialization plan.
3. Offerors should provide a regulatory plan/strategy, including FDA engagement, for the development of the platform towards regulatory approval, if relevant. FDA engagement is expected within the project period, although it is anticipated that FDA approval will not be achieved within the scope of the proposed work. Please share if there has been any initial engagement with the FDA (which is preferable) and how this has informed the proposed development plan.
    a. Provide an overview of past regulatory interactions related to the platform.
    b. Describe a regulatory plan for ultimately achieving regulatory approval for the product (as well as with the therapeutic, if relevant) and specify what part of the work would be completed under the proposed scope of work.
4. **The following are considered out-of-scope at this time:**
    a. Proposals focused only on early development of platform technology or exploratory biomarker discovery. However, this is allowable if there is sufficient justification and evidence to support the proposed development approach (i.e., there is some data available, and the idea is not just at concept stage), and the proposal ends in a prototype that is validating some clinical data (retrospective or prospective) or preclinical data if the indication is subject to the animal rule.
    b. Proposed therapeutic indications that are not relevant to BARDA's mission space (e.g., oncology)
    c. Technologies that only identify patients at risk of severe outcomes and do not plan to further inform on therapeutic interventions or collect evidence that a certain therapeutic's mechanism of action could benefit a specific patient subtype.
    d. Technologies that solely leverage pathogen-based biomarkers to inform on pathogen-targeted therapeutics (e.g., antibiotic resistance and antibiotic administration)

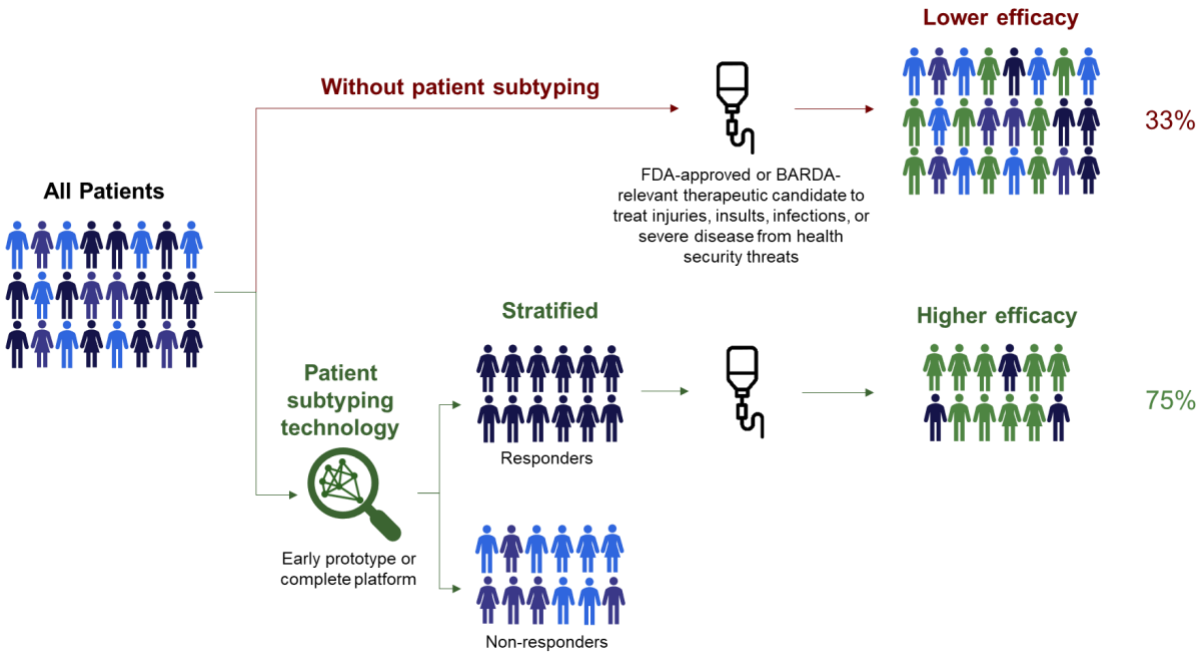

Figure 1. The proposed project must generate evidence demonstrating greater therapeutic efficacy based on use of patient subtyping technology to stratify patients by predicted treatment response.