INNOVATING CROSS-DOMAIN SOLUTIONS TO DETECT EMERGING BIOLOGICAL THREATS

Acceleration Of Clinical Trials Under Pandemic Conditions: Lessons Learned

Tilly Lawrence Leidos

Background information:
Leidos responded to DTRA's request to research the safety and efficacy of pre-existing FDA-approved therapeutics and conduct clinical trials with a repurposed drug(s) as an intervention to the novel COVID virus. Leidos utilized its Leidos-Enabled Adaptive Protocol for Clinical Trials (LEAP-CT) platform to test the safety and efficacy of repurposed drugs. There were many obstacles and lessons learned; recruitment being a major factor.
Purpose:
To offer DTRA a new capability for managing time-sensitive clinical trials under the most stressful conditions, providing national command authorities an agility of response that was lacking.
Objective:
To identify and test the safety and efficacy of an FDA-approved drug alone or in combination with others.
Rationale of the research:
In the early, most uncertain moments, it is essential to get contracts in place, identify the most promising interventions from the existing set of options, select the most qualified vendors, and initiate and execute the protocols.
Relationship to Other Areas of Study:
This work adds to the body of knowledge of clinical trial best practices; shaping policy, balancing safety and speed, and executing under public health crises.
Methods:
We developed an adaptive protocol design with two addenda. One addendum was a virtual outpatient trial to treat post-exposure, the other was an inpatient trial to prevent exacerbation of mild to moderate COVID symptoms. Leidos subject matter experts and DTRA program management reviewed the literature to identify the most promising drugs to repurpose, eventually selecting famotidine and celecoxib. Our approach included early engagement with FDA. We chose Contract Research Organizations (CROs) and instantiated a prototype software platform with the ability to provide patient-reported outcomes (ePRO) in real-time. We recruited participants through traditional treatment facilities, radio/TV advertising and social media.
Results:
We encountered delays in almost every area of the project, from getting our government contract in place to recruiting sites and patients, severely impacting our mission. Though our famotidine-celecoxib protocols were solidly grounded in data that were available at the time, we encountered resistance from FDA and potential clinicians, as well as potential participants who were living in a climate of fear and distrust. Despite a significant expenditure in outreach, we achieved only a fraction of the enrollment goal. The ePRO system and the CROs we selected had difficulty aligning the data systems. We learned several lessons about the challenges of recruiting and managing clinical trials under pandemic conditions and are using what we've learned to develop a new platform community for the future.
Conclusions:
Taking these lessons learned, Leidos is merging its life sciences, data analytics and AI capabilities to prepare and validate new processes, systems and organizational support (i.e., Synergistic Observational Research Community of Tomorrow [SORCoT]) to help ensure successful completion of future clinical trials under the most severe conditions.
Impact to JSTO Mission and Joint Force (if known):
For the sake of the warfighter and field level leadership, our team's experience is a lesson for the future.