INNOVATING CROSS-DOMAIN SOLUTIONS TO DETECT EMERGING BIOLOGICAL THREATS

The Synergistic Observational Research Community Of Tomorrow (SORCoT): A Deployable Network To Rapidly Establish And Administer Decentralized Trials

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Background information: Having learned lessons from our inpatient and virtual outpatient trials where poor recruitment was a major factor impacting success, the Leidos team redefined the clinical trial model to help improve the speed, efficiency and recruitment success.
Purpose: To establish affinity-based networks maintained by non-traditional strategic partners to rapidly commission and recruit participants for future decentralized clinical trials (DCTs). These networks will be used to evaluate repurposed and new targeted therapies in a compressed timeframe during future public health emergencies (PHEs).
Objective: Conduct a preliminary study with a limited number of participants and one strategic partner to demonstrate that the SORCoT model can successfully operate. Increase the number of participants ("scaled up") and additional strategic partners ("scaled out"). Initially test the agnostic SORCoT model, with its web-enabled data collection tool, focused on Post Acute Sequelae of COVID-19 (known as PASC or Long COVID) with the aim of testing hypotheses for other disease outbreaks (past, present, and future).
Rationale of the research: By adopting the SORCoT model we intend to increase the pace and efficiency of recruitment and enrollment efforts which, combined with the assessment of scientific literature and other data, will improve the down-selection process and reduce the time to identify effective therapeutics.
Relationship to other areas of study: Many organizations had difficulty enrolling participants into COVID clinical trials and are now looking at non-traditional models for future PHEs. The agnostic nature of SORCoT should support any clinical research endeavor where research needs a quick bolus of participants. Initially, we are using the model to study Long COVID, but it could be deployed for other outbreaks, novel or otherwise.
Methods: SORCoT is a combination of a recruitment model using established participant populations from partner organizations and a supportive web-enabled data collection tool which is both quick and efficient, to operate and conduct DCTs. Participants will self-report their health information via surveys and possibly Electronic Health Records (EHRs) and wearable devices. Collaboration with technical networks of subject matter experts will help inform and refine the hypothesis generation process used to create targeted survey content and guide analytical efforts. The web-enabled SORCoT platform will provide for the testing of multiple hypotheses simultaneously using retrospective and prospective data.
Preliminary results: The proposed work is in its preliminary stages of development; there are no preliminary results to share. Preliminary conclusions: The proposed work is in its preliminary stages of development; there are no preliminary conclusions to share. Impact to the JSTO mission and the Joint Force: This new approach should enhance warfighter health and effectiveness by reducing the response time for the USG to identify effective therapeutics.