An Example for Establishing a Clinically Translational Innovation Lab at a University Setting
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OBJECTIVES/GOALS: This poster shares a case study on how a group at The Johns Hopkins University formed a translational lab missioned to reinvent currently existing treatments for acute spinal cord injuries, implanting in humans within a five-year window. The poster showcases how a project funded by the Defense Advanced Research Projects Agency has been implemented. METHODS/STUDY POPULATION: The translational team; Holistic Electrical; ultrasonic and Physiological Interventions Unburdening those with Spinal cord injury. (HEPIUS) Lab is composed of many parts as listed below: neurosurgeons; engineers; radiologists; public health specialists; statisticians; patient advocates; ethicists; sonographers; researchers; academic collaborators; and specialized industry partners. Sometimes physically separated; the team has videoconferencing carts across locations to stay connected at every step in the process. The lab facilities were organized with several key facets in mind: research and development (R&D); prototyping; fabrication; verification; and validation (V&V); animal model testing; cadaveric testing accessibility; mock operating room for simulations; and collaboration hubs. RESULTS/ANTICIPATED RESULTS: Due to communications with the US Food and Drug Administration (FDA), DARPA, patient advocates, ethicists, internal review boards, and other bodies, the team has a clear path towards clinical translation. The team has the following stages in progress or scheduled: manufacturing devices, benchtop testing, rat and pig models, biocompatibility testing, cadaveric testing, and clinical use. The lab space was designed to achieve these core functions. For rapid, in-house manufacturing, the lab has unique capabilities including 3D metal printing. For experiments, industry collaborations and equipment acquisitions enable the highest quality research. These technologies are assembled into diagnostic, therapeutic, testing, and manufacturing hubs to drive real change in the lives of many; the patient comes first. DISCUSSION/SIGNIFICANCE: This laboratory, team, and system of operation is aimed to enable novel practices for the clinical translation of spinal cord medical solutions. For researchers interested in launching their own translational work, this poster may serve as a reference, example, and inspiration for similar hopeful university-centered hubs.

The Team Science Landscape within the National COVID Cohort Collaborative (N3C)
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OBJECTIVES/GOALS: As question complexity in science and medicine increase, the need for teams with diverse skill sets grows as well. We identify essential roles and barriers that define the team environment within the National COVID Cohort Collaborative (N3C), an initiative grounded in interdisciplinary team science. METHODS/STUDY POPULATION: This work was compiled through a combination of observations, interviews, and survey responses involving members of the N3C research community, specifically those involved in N3C workflows and clinical domain teams. Observational data was obtained through participation in N3C workflow and domain team research and meetings. The survey included five questions related to team science elements and barriers, as well as contrasting science-based teams and non-science-based teams, such as “What elements are common between both Team-Science and non-Team-Science teams?”, and was sent to members of two domain teams: Immunosuppressed and Compromised and Social Determinants of Health. RESULTS/ANTICIPATED RESULTS: Team science within N3C has a unique structure of roles and barriers that define the team environment of each project. Within each group, team and role management within team science is an ongoing process that occurs even after a team is formed. We obtained 8 survey responses that indicated communication, attribution, team management, collaboration, interdisciplinary diversity, and problem solving were key aspects to successful team science. Additionally, survey respondents identified prominent barriers to successful team science that included bandwidth constraints, lack of a shared scientific language, learning curves, funding, and lack of communication. DISCUSSION/SIGNIFICANCE: Communication was identified as a key component of team science and a prominent barrier, which indicates that successful team science relies on communication between team members. Thus, it is vital that teams identify and commit to using predefined methods of communication to function effectively.

Reframing the JTF Clinical Trial Competencies from a CRP Team Science Perspective
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OBJECTIVES/GOALS: Our goal is to explore and collaboratively identify the team science competencies essential for Clinical Research Professionals at all experience levels and how these
competencies relate to the Joint Task Force for Clinical Translational Research Professionals Competencies. METHODS/STUDY POPULATION: Team science competencies for clinical research professionals are poorly defined. The JTF Clinical Trial Competencies lack sufficient emphasis on team science, though it is briefly included in two JTF competency domains: Leadership & Professionalism, and Communication & Teamwork. The competencies primarily focus on tasks related to clinical research and basic knowledge of product development; however, a conceptual model for applying the competencies using a team science lens is needed. Currently, the JTF competency figure is often thought of as sequential, given the competencies are numbered, creating the misconception that the last competencies are less important. We support a new figure showing the permeability of team science across competencies and the connectedness and equality of the competencies. RESULTS/ANTICIPATED RESULTS: Our anticipated results are to show the integral nature of team science in clinical research professional communities of practice. Once complete, we will have identified measurable team science competency-based skills essential for clinical research professionals at various levels of expertise. Understanding the multi-dimensional team science competencies will inform targeted team science education and training for clinical research professionals. Our revised competency framework provides an improved team science conceptual model for clinical translational science. DISCUSSION/SIGNIFICANCE: Our work will define team science competencies as related to clinical research professionals at all experience levels. The interdependence of teams across clinical trial activities necessitates a consideration of an improved conceptual framework for clinical translational team science competencies.

Workforce Development

Analyzing the NJ ACTS Education and Offering Inventory to Assess Training across the CTSA Consortium

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OBJECTIVES/GOALS: The New Jersey Alliance for Clinical and Translational Science (NJ ACTS) interest in developing a comprehensive education and training program for enhancing the quality, efficacy, and safety of the clinical research enterprise led to the release of a survey distributed nationwide to assess initiatives in the translational science workforce. METHODS/STUDY POPULATION: Twenty-one hubs responded to the survey and data was exported from REDCap to Excel. Respondent demographics were categorized to formalize roles and data was categorically divided into sections based on training type (engagement, basic, postgraduate etc.) utilizing conditional formatting. The limitation in this survey was a branching logic defect aligned with questions on competency tool usage and the roles that they play which led to only six hubs having the advantage to respond to all questions. RESULTS/ANTICIPATED RESULTS: Summary findings showed that the majority of respondents for the survey (30%) were the Director of Operations. Further; the Joint Task Force (JTF) domain Scientific Concepts and Research Design was the most preferred Hard Skill (81%) while the least preferred was Investigational Product Development and Regulation (29%). In spite of only six hubs receiving the short competency assessment; 50% of those hubs stated they would utilize ‘In House Assessment Tools’ and 83% stated they used the tools to ‘Develop Personalized Training Plans’. The assessment of this Inventory was indeed necessary to identify trends in available trainings across the CTSA consortium. DISCUSSION/SIGNIFICANCE: The internal cross training catalogue will help to develop an infrastructure for the NJ ACTS community to work along with other CTSA hubs while creating comprehensive clinical research training initiatives and programs.

Valued Approaches

Biostatistics, Epidemiology, and Research Design

Ends of Endemics: Capturing Viral UTRs in Clinically Relevant Arbovirus Samples

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OBJECTIVES/GOALS: Whole-genome viral sequencing is vital to inform public health and study evolution. Arboviruses evolve in vectors, reservoir hosts, and humans, and require surveillance at all points. We developed a new rigorous method of sequencing that captures whole viral genomes in field-collected and clinical samples. METHODS/STUDY POPULATION: ClickSeq is a novel method of Next Generation Sequencing (NGS) library synthesis using azido-nucleotides to terminate reverse transcription. The cDNA generated can be ligated to sequencing and indexing primers at room temperature using copper (Cu I) and vitamin C. With this approach, we designed primers located ~250 bp apart along the genomes of the arboviruses Chikungunya 37797, Zika Dakar, Yellow Fever Asibi, Dengue serotype 2, West Nile 385-99, and St. Louis Encephalitis Virus (SLEV) clade II. We tested this method with varying viral titers: lab-infected mosquito pools, field-collected mosquito pools from a Texas West Nile and SLEV outbreak, and patient isolates from a Pakistani CHIKV outbreak. The cDNA was sequenced in the UTMB NGS Core and aligned using bowtie. RESULTS/ANTICIPATED RESULTS: The use of a single protocol to capture whole viral genomes including UTRs for multiple viruses from different sample collection styles is ideal for arboviruses. Primers for multiple viruses were pooled and used to sequence mosquito pools. The Tiled ClickSeq method captured whole viral genomes without the need for host depletion. UTRs were captured even when the viral strain used for primer design differed from the resulting strain. Discrete variants were captured in both the hypervariable nsP3 region and the UTR in the patient isolates from the CHIKV outbreak compared to the 2017 outbreak. Texas WNV and SLEV outbreaks are now defined from the 2020 outbreak and can be further tracked to update public health measures and understand viral evolution. DISCUSSION/SIGNIFICANCE: UTRs impact both human and mosquito fitness, leading to further outbreaks. Tiled ClickSeq aims to capture whole viral genomes with a method and cost that can be implemented by public health researchers to understand disease evolution as it happens to update both public health and basic virology to the effects of evolution on arboviruses.