Implementation of a Clinical Trial Toolbox: Breaking Barriers for Investigators in Clinical and Translational Research

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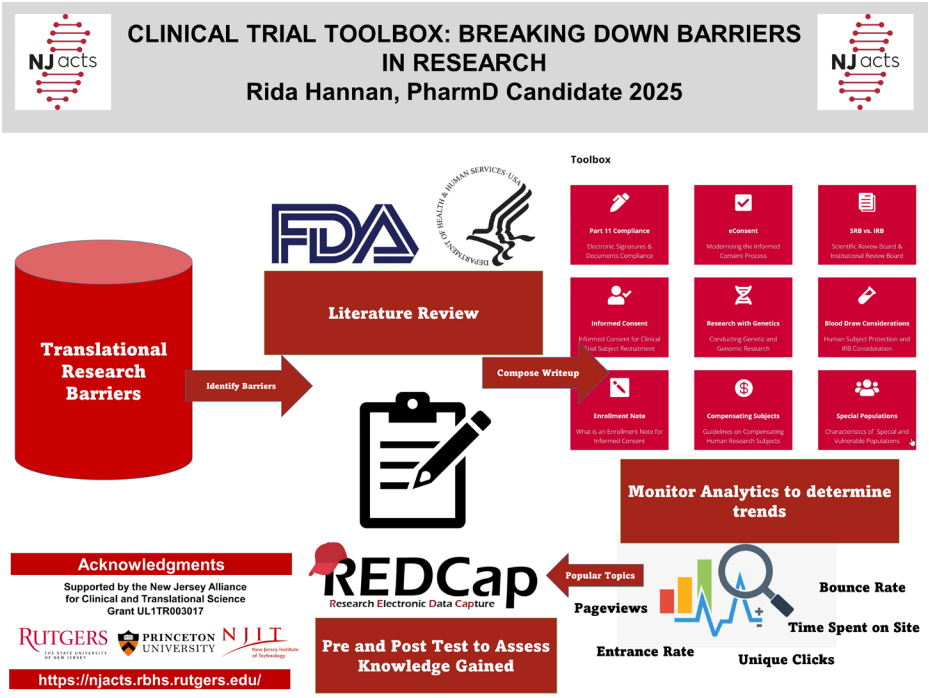
The success of clinical trials is oftentimes challenged by an investigator's ability to take their idea and progress it through different stages of translational research. The NJ ACTS Regulatory Core has implemented a Clinical Trial Toolbox that will serve as a standalone resource for Investigators to access information in order to overcome common barriers and streamline the process of preclinical to human subject trials.

Literature review of federal guidelines and regulations, IRB policies, and resources from NJ ACTS Core experts were utilized to compile information for the write ups. The write-ups were then categorized into three major categories: Regulatory Processes, Vulnerable Populations, and Quality Control of Information. In order to assess knowledge gained from the toolbox, participants will take a pre-test, read a designated section of the toolbox, and then take a post-test. Comparison of pre and post test scores will serve to quantify knowledge gained from resources within the toolbox.



The effectiveness of the toolbox was assessed using analytics from the website including pageviews, time spent on the site, entrance, and bounce rate. These metrics were used to monitor trends and popularity among common topics in order to assess knowledge gained. For example, unique click results were utilized in creation of a pre and posttest on popular topics that reflect common barriers that investigators face. An increase in score of the post-test is anticipated to reflect the knowledge gained from reading a section of the Toolbox. These tests will be a way to have quantitative evidence that establishes the toolbox as an effective resource for investigators.

A Clinical Trial Toolbox represents an educational tool that would provide investigators with supporting regulatory material as evidenced by metrics showing increased activity in the toolbox and high post test scores.