CLINICAL TRIALS TRANSFORMATION INITIATIVE

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Clinical Trials Transformation Initiative Releases New Recommendations and Tools for Improving Patient Recruitment in Clinical Trials

Durham, NC - The Clinical Trials Transformation Initiative (CTTI) has released new recommendations and tools for enhancing the efficiency of clinical trial recruitment. Patient recruitment is a leading challenge in the efficient completion of clinical trials, which can result in wasted resources and delays in bringing new therapies to market. The foundational principle for this new approach is that recruitment planning should be started earlier in the clinical trial development process and continue throughout the implementation.

“The Recruitment Project recommendations are the result of an in-depth study evaluating why too often clinical trial recruitment efforts fail,” said Jonca Bull, M.D., the FDA’s Assistant Commissioner for Minority Health. Bull served as a team lead for the project. “These recommendations have the potential to catalyze greater efficiencies in diverse patient recruitment – women, minorities and older adults-- by focusing on the earliest stages in protocol development”.

The recommendations and tools were developed with input from a diverse team of stakeholders, including clinical researchers, patient advocates, and representatives from academia, industry, and the FDA. “What we found was that, to truly make a difference, we need a comprehensive solution that covers all areas of clinical research, from making sure the study is asking the right questions—questions that matter to patients and providers—to shaping study design and feasibility, to budget and implementation,” said Kelly McKee, a project team member from Eli Lilly and Company. Among the released tools, a new framework outlines considerations for strategic recruitment planning throughout all stages of a clinical trial.

According to the recommendations, recruitment planning should also be more inclusive of all relevant stakeholders. “Too often important feedback from patients, study coordinators, and health care providers is not obtained when their insights can make or break a trial and prevent avoidable amendments,” said Bray Patrick-Lake, Director of Patient Engagement for the Duke Clinical and Translational Science Award. “CTTI’s evidence-based recommendations and toolkits provide practical guidance for successful clinical trial recruitment planning that will help ensure stakeholders are appropriately engaged and the right questions are asked during study design, feasibility, and recruitment planning activities.”

A thoughtful approach to recruitment planning before study activation is expected to alleviate downstream recruitment challenges and ensure trial viability. The work builds on CTTI’s previous advancements in the areas of engaging patient groups in clinical trials and a quality by design approach to improving clinical trials.

Established by Duke University and the FDA as a public-private partnership in 2007, CTTI comprises over 70 member organizations working to identify and promote practices that will improve the quality and efficiency of clinical trials. More information about CTTI and its project is available at http://www.ctti-clinicaltrials.org.

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