Team finds navigators are integral to clinical research process

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A study reported in this week's *Science Translational Medicine* found that qualified investigators are more likely to respond to opportunities for clinical trials if they are contacted by an institution-specific point person, or navigator.

Jonathan M. Davis, MD, Tufts Clinical and Translational Science Institute (CTSI) Director of Regulatory Affairs and Chief of Newborn Medicine at Floating Hospital for Children at Tufts Medical Center and a multi-institution team of child health researchers instituted the Point-Person Project, a pilot study that built a national network of navigators to find investigators with the bandwidth and expertise to respond to pediatric clinical research opportunities.

Multisite clinical trials are inherently complex and time-consuming. Clinical trials involving children face even greater challenges, with small patient populations and few investigators trained in pediatric therapeutics development. The Point-Person Project seeks to find these investigators and solicit their participation in a variety of clinical research projects for industry as well as individual investigators.

"If studies can't draw enough investigators to participate, patients and industry will suffer," says Dr. Davis. "When a research opportunity presents itself, we need to rapidly assemble a team of experts who can commit to participation and patient enrollment. The navigators find and connect these experts to get things underway."

The project designated 84 navigators at 55 institutions supported by the Clinical and Translational Science Awards (CTSA) program, funded through the National Center for Advancing Translational Sciences (NCATS). Over the course of one year, 289 investigators from 40 institutions responded to research opportunities, with 16 sites involved in start-up or enrollment of at least one trial. One research group that formed as a result of the Point-Person Project published a manuscript, developed a full clinical trial protocol, and submitted an Investigational New Drug (IND) application for approval by the Food and Drug Administration (FDA).

"Overall, our pilot project increased awareness of, and conversation about, planned clinical trials," says Dr. Davis. "Unfortunately, though, many investigators who initially expressed interest chose not to participate for a variety of reasons, but the most concerning was because industry-sponsored studies - required by law - typically don't lead to academic achievement."

Despite these challenges, Dr. Davis thinks the Point-Person model should be adopted nationally and the CTSA sites function as a clinical trials network. "We still have a lot of work to do," he says. ""Going forward, initiatives like the Point-Person Project will be more successful with a national infrastructure for clinical trials, institutional investment in clinical and translational research, and investigator education about regulatory requirements and good clinical practice. With these elements, and a network of navigators across the country, we'll be better equipped to design and conduct studies that benefit children."

More information: *Science Translational Medicine*, stm.sciencemag.org/content/7/279/279fs11.full.pdf

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