Category: Trial Recruitment & Community Outreach and Engagement – Work in Progress

Study Consent Rates and Decline Reasons at the University of Illinois Cancer Center

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1. Background
To address barriers to clinical trial participation, we want to understand clinical trial participation rates and reasons patients decline participation by time (pre/post-COVID pandemic), gender, and race/ethnicity.

2. Goals
The University of Illinois clinical trials office (UICC CTO) analyzed treatment clinical trial participation acceptance rates and reasons for declining clinical trial participation by time, gender, and race/ethnicity.

3. Solutions and Methods
In May 2018, the UICC CTO began collecting demographics and reasons for declining study participation for patients approached for treatment trials. Interim findings from May 2018 through December 2021 were analyzed using 1 logistic regression and 1 multivariable regression model to examine participation and reasons for declining by year (pre/post-COVID), gender, and race/ethnicity.

4. Outcomes
Five-hundred seventy-nine patients were approached to consent to a treatment clinical trial. Sixty-one percent were female, 39 percent were male, 21 percent were Hispanic, 51 percent were Black, 44 percent were white, and the remaining 4 percent were a mix of other races.

The overall acceptance rate was 75 percent (435 patients agreed to participate). Compared with pre-pandemic rates, there was a decline in acceptance rates, post-pandemic, 78% vs. 72%, OR = 0.66, 95%CI [0.44, 0.98], p = .04. Gender and racial/ethnic differences were not statistically significant (ps = 0.15-0.81) across gender (female = 77%, male = 73%), race (white = 79%, black = 74%, other = 60%), and ethnicity (non-Hispanic = 74%, Hispanic = 82%).

Among the 144 patients who declined participation, 52 percent had clinical concerns (e.g., preferred standard treatment, fear of side effects); 27 percent had concerns of experimentation; and 21 percent had logistic/unknown concerns (e.g., transportation, time, insurance). Patients were more likely to decline participation due to mistrust post-pandemic relative to pre-pandemic, 30% vs. 23%, OR = 0.47, 95%CI [0.22, 1.00], p = .05. Male patients were more likely to decline participation due to logistic and unknown concerns, 30% vs. 13%, OR = 0.65, 95%CI [0.28, 1.50], p = 0.31.

5. Lessons Learned and Future Directions
The UICC CTO treatment clinical trial acceptance rate was relatively high, similar across patient gender, race, and ethnicity, though these rates dipped since the COVID-19 pandemic. Burden of participation was not a significant reason for declining trial participation in this study, perhaps due to providing transportation for any clinical trial participants in need of it and UICC's broad financial assistance policy. New interventions need to be developed to address fears of experimentation and clinical concerns in the post COVID-19 pandemic era.

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UICC CTO plans to repeat this analysis annually to assure clinical trial participation barriers are minimized and to monitor the success of efforts to address existing barriers. In the short term, together with community members, we are developing and implementing clinical trial educational modules targeting our patients and the community. These interventions will address concerns about clinical trial participation.