Rationale and Specific Aims

Cancer clinical trials are vital to the advancement of cancer treatment. Attaining the full benefit of cancer research requires the participation of informed and willing cancer patients that represent the diversity of the U.S. population; yet, accrual to cancer clinical trials is low overall, at about 5-8%.[1] There are many reasons for low CCT enrollment. Patient barriers include lack of awareness,[2-5] degree of self-efficacy,[6-8] fear, distrust, cost concerns,[9] and/or logistical concerns. **These barriers may be even more acute for patients from underrepresented groups,**[10,11] including patients without insurance and/or with low income; Black, Indigenous, and People of Color; patients from rural areas; and patients in certain age groups (such as young adults and seniors), which results in even lower trial participation rates.[1] The literature also cites numerous institutional and provider barriers to clinical trial accrual. In fact, one major barrier is that treating oncologists often do not communicate the possibility of trial participation with patients who appear to be eligible.[1] A meta-analysis showed that even among institutions that participate in clinical trials, up to 27% of eligible patients are *not* offered the opportunity to participate in a trial.[1] This lack of provider communication about the possibility of trial participation may be even more pronounced among underrepresented patients,[1,12-16] who often have higher cancer mortality rates than the population as a whole.[17] Low accrual rates to CCTs for these and other populations have a significant effect on both the quality of research and the rate at which new scientific discoveries are made.[18] Enrollment among racial/ethnic minorities, older adults, adolescents, and young adults in particular has not been adequate to understand aspects of care and treatment response unique to these populations.[19-21] The low accrual rate also affects the quality of care provided to these patients.[22]

Given that even eligible patients may not be informed about the option of receiving treatment through a clinical trial, it is critical to encourage and normalize patient inquiry about trials prior to beginning treatment, especially for underrepresented groups. In order to effectively inquire about clinical trials, patients need to understand that such inquiry is encouraged and supported, that there is an expectation that they will be involved in making decisions about their treatment,[23,24] and that they are able to take on this role.[6-8] Several studies have suggested that education before the first oncologist visit improves knowledge, attitudes, and preparation for treatment decision making, and can increase patients' willingness to ask about and consider receiving treatment through a clinical trial.[25] This education, and the normalization of patient inquiries about clinical trials, can begin with the patient's trusted primary care provider.

PCPs are a potential gateway to clinical trial access because they interact with patients at the time of their cancer diagnosis, often provide ongoing care, and are a trusted source of information.[26,27] **Several studies have shown that a trusted physician's recommendation was the primary factor influencing patients' decisions to enroll in a clinical trial.** [3,8,28-34] **Therefore, PCPs' attitudes, beliefs and behaviors about clinical trials may have considerable implications for patient participation in clinical trials.**[19,35-37] PCPs should be knowledgeable about, comfortable with, and able to effectively communicate to patients the importance of asking about and considering participation in clinical research. Although PCPs have reported that they would like more of their patients who are diagnosed with cancer to participate in clinical trials, they feel that they cannot adequately talk about trials with patients, due in part to their own lack of understanding about clinical trials as a high quality option for treatment.[38,39] Moreover, PCPs need guidance about how to effectively communicate with patients about trial participation. This gap in knowledge and skills represents a significant opportunity to educate PCPs about cancer clinical trials in order to improve trial accrual and patients' access – particularly access of underrepresented patients – to the full range of treatment options. Enhancing PCPs' understanding of CCTs, improving their capacity to inform patients about the possibility of trial participation, and strengthening their referral patterns to oncologists already participating in clinical trials may serve to diminish key patient barriers to trial participation.

In fact, previous research, including our own, has demonstrated that conducting outreach and education with PCPs who serve underrepresented populations may break down key barriers to trial participation.[40-42] This can be done through improving PCPs' capacity to effectively 1) educate recently diagnosed patients about the possibility of trial participation at the time of treatment referral *for all types of cancer*; and 2) provide positive reinforcement to patients if advice is sought about trial participation. **Here we propose to study the effectiveness of an innovative, tailored online cancer clinical trials training for PCPs, with a particular emphasis on those who treat primarily patients who are underrepresented on clinical trials,** especially Black, Indigenous, and People of Color; young adults and the elderly; those who are

of low-socioeconomic status; and those who reside in rural areas. **There is no other evidence-based training available, of which we are aware, that is designed to provide this kind of capacity building to PCPs.** This study, while focused on oncology, is intended to be proof of concept for an intervention that can be adapted for other disease areas, such cardiology, rheumatology, and gastroenterology.

The overarching goal of the proposed study is, in partnership with LLS, to implement a training intervention to increase PCPs' capacity to encourage patients, particularly those from groups that are underrepresented on trials, to inquire about cancer clinical trials at the point of treatment decision making, which will demonstrate to the oncologist that the patient is receptive to and potentially interested in trial participation. The training will also encourage PCPs to reflect on their referral patterns, and modify them as needed to enhance patients' access to clinical trials. In order to achieve this, we will conduct a single-arm, longitudinal, national study of an innovative online cancer clinical trial training intervention with PCPs whose patient panels are predominantly from underrepresented groups. Our specific aims follow:

1. *Develop two training intervention delivery modes.* Based on feedback we have received from our organizational partners and from *CCT Link* participants, we determined that multiple modes of delivery would optimize implementation of the training in a real-world setting, given that individuals have a range of learning-style preferences. Consequently, we will use a bi-modal strategy, offering the intervention in two online formats: a self-directed version and a facilitator-guided version.

2. *Use a tailored and interactive approach.* We will enhance our previous pilot online intervention used in *CCT Link* by adding interactive and tailored elements, based on the attitudes and beliefs that participants report in the pre-intervention survey, to maximize participant engagement and increase learning.

3. *Collect longitudinal data.* Although our *CCT Link* pilot study found positive outcomes at three months post training, we do not know the more distal impact of the intervention on PCPs. In the proposed study, we will conduct brief follow-up surveys with participants at three and six months, which will allow us to demonstrate and describe the lasting impact of the intervention.

4. *Recruit a large, national sample.* Our *CCT Link* pilot study focused only on one geographical area (New York City) and included a relatively small sample. The proposed study will be implemented nationally, emphasizing recruitment of PCPs who serve underrepresented patients.