Scaling-up and Maintaining Evidence-based Interventions to Maximize Impact on Cancer (SUMMIT)
Questions and Answers

Scale-Up

Q: Is scale up being conceptualized as policy- or systems-level implementation strategies?

A: This depends on the research question and proposed implementation strategies that are hypothesized to impact increasing scale-up. They may include policy and/or systems level and others but nothing specific is required per se.

Q: Emerging literature suggests that the implementation strategies are different from scale-up strategies, or at the least that scale-up strategies will need to be supplemented to the implementation strategies. Are you expecting to see this difference in the proposals? Should we be considering this difference in the UG3 phase?

A: For the purposes of this RFA, we consider scale-up strategies to be implementation strategies that will effectively enable many sites to simultaneously implement the specific evidence-based interventions. There may be some strategies that will go beyond those used to support local implementation, and we expect that applicants will justify the selection of strategies that are hypothesized to support scale-up as well as sustainment of interventions.

Q: Scale-up strategies such as WHO Expand Net have been used in tobacco use treatment (TUT) overseas- Can we adapt this model to US conditions although this model has not been used here before?

A: Adaptation of scale-up models used in international settings but not used in the US is allowed. Explanations about the relevance of the model to US settings/conditions and how the model is being adapted should be included in the application.

Lung Cancer Screening (LCS)

Q: The RFA states we must address all components of the LCS continuum in our study. Can you clarify if we need to power on all outcomes or can we have one primary outcome and rest secondary/exploratory?

A: The selection of primary outcome and power analyses should be based on the research question(s) proposed as part of the study.

Q: Can we have a primary phase we are focusing on (e.g., adherence or SDM or diagnostic follow-up) while also supporting the other phases of the process?

A: It depends on the research question(s). Regardless, all components of LCS must be included as part of the study and proposed to test strategies to scale-up and sustain all LCS components specified in the RFA.

Q: When you discuss monitoring for 12 months post-implementation in the screening RFA. Does this refer to bringing in new patients at that time or bringing in patients for a second screening examination?
A: The sustainment phase may include bringing in new patients and/or follow-up screening depending on the research question.

Tobacco Use Treatment for Cancer Survivors (TUT)
Q: On the webinar, in the example provided under TUT study design, the example study uses Practice Facilitation vs. learning Collaborative. Is it possible to compare Practice Facilitation and Learning Collaborative in one arm to standard practice?
A: The example provided in the webinar is just that. Comparison to standard practice is allowed and should be appropriately reflected in the research question(s).

Q: Are surrogate measures of quitting such as linkages to Quitline, tobacco clinics acceptable vs measuring the participants' quit rate? Please clarify, is cessation (effectiveness) required as an endpoint?
A: No, referrals or linkages to services are not adequate, as the goal is to demonstrate that evidence-based interventions are being received to address the gap in care. We expect that applicants will determine whether a cessation endpoint is required, and this may depend on the degree to which the study examines individual intervention outcomes if there are questions or concerns about intervention effectiveness as the intervention is scaled to broader populations. It will be important to justify whether the scaled-up, sustainable program is able to retain effectiveness in promoting cessation. In addition, the services provided may include the Quitline but would likely not be limited to that; a more intensive intervention should be considered. It will also be a strength to include a motivational component for those patients not yet motivated to quit.
Resources for cessation in cancer care settings are available here:
https://cancercontrol.cancer.gov/brp/tcrb/treating-tobacco-use-cancer-care-settings

Q: How should 'offered' tobacco use treatment be measured?
A: The approach should be determined by the applicants. It may be viewed as a strength to assess both the provider and patient report that treatment was offered. Note also that there will be working groups of funded investigators, which may include a measurement working group. The approach to measuring the offer of treatment could be discussed and revised in such a group.

Q: Could you please clarify more about cancer survivors and its definitions? Patients with cancer in any stage?
A: An individual is considered a cancer survivor from the time of diagnosis, through the balance of life. This includes patients with cancer in any stage.

Study Design
Q: Do we need to use RCT to design the intervention? Does other design such as cross-over or stepped wedge designs acceptable?

A: To clarify, the trials proposed as part of the SUMMIT initiative should be focused on testing strategies to scale-up and sustain the specified interventions (LCS or TUT for cancer survivors), and not focused on designing a new intervention. Any design proposed in the trial to test strategies to increase scale-up and sustainment must use a randomized controlled trial (RCT) design. This may include but is not limited to variations of RCTs, such as stepped-wedge cluster RCT or cluster RCT, and others, so long as the design is a type of randomized controlled trial.

Q: Should randomization occur at the clinic level or patient level?
A: This depends on the research questions.

Common Data Element
Q: Are patient outcomes required for data collection?
A: This should depend on your research question(s).

Q: How are you defining and measuring scale-up?
A: The definition is shown in the presentation on slide 14 of the presentation. How you measure scale-up depends on the research questions. There are multiple ways to measure scale and as part of this initiative, we hope to capture some common data elements that can help inform this as well.

Q: Can you share more about the process for selecting common data elements?
A: We anticipate one of several SUMMIT initiative working groups to focus on common measures and common data elements. There are no requirements for using a specific measure or data element in the RFAs; however, applicants should demonstrate that they have the expertise in measurement in implementation science and propose to use validated measure(s) as part of their study. The decision around common measures and data elements to use across trials in the SUMMIT initiative will be made among the investigator teams post-award during the UG3 phase of the grant.

Sites
Q: What are examples of individual sites?
A: Any clinic where LCS or TUT services are/could be provided is acceptable sites. Sites may include (but are not limited to) primary care clinics, specialty care clinics, community cancer centers, and Federally Qualified Health Center (FQHC) clinics. A single clinic is considered 1 site. An example of a single site could be a single FQHC clinic that is part of a larger FQHC network.

Q: Can we mix and match different sites?
A: You can mix and match different sites as appropriate for your research question.

Q: With regards to 60 partnering sites for accrual for LCS proposal, how many patients are expected to come from each site for RCT design?
A: It depends on the research question(s).

Q: Are Letters of Support required for all participating sites (60+)?
A: Reviewers will be looking to see if there is sufficient commitment of 60+ sites. If an organization has multiple sites participating, a single letter of support from the organization indicating the number of sites participating would be sufficient.

Q: If one site dropped out during the study, can we replace with another site?
A: Yes

NCORP
Q: Are NCORP Research bases currently funded through UG grants eligible to apply, and are we allowed to use the NCORP grants for some components
A: If one is considering using the NCORP network for their proposed study, they **must** contact the NCI NCORP leads, Dr. Ann Geiger and Kate Castro, before applying to discuss the potential fit and requirements for proposing to use the NCORP network. Please see the contact information below. NCORP: NCI Community Oncology Research Program (NCORP)

- Ann Geiger: geigeram@mail.nih.gov
- Kate Castro: castrok@mail.nih.gov

PI/Institutional Eligibility
Q: Can a contact PI on one of the SUMMIT applications serve as an MPI (non-contact) on another?
A: There is no specific limitation on serving as MPI on multiple grant applications for each RFA, if the lead institution applying for the grants is different. Each would clearly need to be a separate study, as one can't submit identical applications to the same call, and it would make sense to avoid overlap in expected trial participants as that could threaten feasibility of each project as a stand-alone.

Q: Is there a minimum FTE % effort required for MPI structure?
A: While there isn't a minimum percent effort required if using an MPI structure, applicants are expected to propose a percent effort that is commensurate with their expected leadership on activities and responsibilities outlined as part of the MPI structure.

Q: Can one institution submit multiple applications to one RFA?
A: No

Q: What qualifies as one institution?
A: An institution must have a unique DUNS number or NIH IPF number.

Q: Can we apply to both RFAs from one institution?
A: Each RFA is unique, and institutions may apply to both RFAs.

Evidence-based interventions (EBIs)
Q: How do you define an EBI? How much evidence is required?
A: Evidence-based interventions are programs or practices that are shown to be effective at producing results through peer-reviewed publications or systematic reviews.

Q: Can a commercially available evidence-based program be included in the budget to support and confirm quitting?
A: Yes, but considerations should be made concerning health equity and the impact this may have on health disparities.

Q: Will digital interventions be an important aspect of proposals?
A: This depends on the research questions.

Budget:
Q: What percentage cut is expected for the budget? if there are budget cuts, would the number of sites go down?
A: Funding for these grants are dependent on the availability of funds.

Submission Information
Q: Will there be additional submission dates later on or will this December be the only?
A: We do not currently anticipate an additional submission date.