Frequently Asked Questions: NOT-CA-20-038

Administrative Supplements for the Development of Risk-Stratified Cancer Survivorship Care Algorithms

Is testing and implementation of a risk-stratified survivorship care pathway within the scope of this supplement notice?

No, this supplement is not intended to support projects that implement risk-stratified care pathways. Instead, this supplement is asking investigators to use available data from their parent study-alone or in conjunction with other data sources like EMR data, cancer registry data, etc., to develop and/or validate a risk-stratified algorithm.

Is collection of new data within the scope of this supplement notice?

This supplement should focus on using existing data. Collection of new data is not within the scope of this supplement notice.

How will you prioritize applications for funding?

We will be prioritizing supplements based on the scientific merit and innovation, as well as the strength of the rigor and methods to develop and/or validate a risk stratified survivorship care algorithm.

When will these supplements start?

These supplements are tentatively scheduled to begin in late summer of 2020.

For what types of cancers should the work be conducted?

Work can be conducted on any cancer type. Keep in mind that the cancer type chosen should be amenable to risk stratification and risk stratified care. If a cancer type includes only individuals at high risk for an adverse outcome, this cancer type may not be a good cancer on which to focus, as care is not likely to change with the development of an algorithm.

Is it better to focus on multiple cancer types or a single cancer type?

An application can focus on a single cancer or multiple cancers. The investigator must justify the choice of the cancer or cancers to be studied. Further, applications that propose algorithms for one cancer type should address how this approach may serve as a prototype for other types of cancer.

What variables should be included in the algorithm/model?

This is up to the investigator. We envision that variables to be included in the model <u>may</u> include, but are not limited to, patient characteristics such as sex, race and physical functioning/mobility, clinical characteristics of the cancer, and treatments that the patient received.

What is the preferred outcome for the model? If the parent study only has

mortality, is that sufficient? There is no preferred outcome for the model; the outcome proposed in the study must be justified. Outcomes could include mortality, recurrence, or longer-term adverse events.

Can I utilize SEER (or EMR) data to build or validate the algorithm/model? Yes,

Surveillance, Epidemiology, and End Results cancer registry data, electronic medical records, and other data sources can be used to build or validate the algorithm/model. Keep in mind that the supplement must support work within the scope of the parent study.

Is there a dollar limit on how much can be requested in an administrative supplement?

NCI will consider application budget requests of no more than \$150,000 in total costs and budgets must reflect the actual needs of the proposed project.

How long does the PI have to spend an administrative supplement?

Supplement project must be within the currently approved project period for the existing parent award. Note that supplement funds may be carried into future years if the investigator is not able to complete the proposed work during the one-year period. Please work with the grants management specialist assigned to the parent grant if supplement funds need to be carried into a future year.

Can the PI request an administrative supplement if their grant is in the first year of a new award?

Administrative supplements to a grant in the first year of a new award (Type-1 or Type-2) may not be considered a high priority as the PI has not had sufficient time to determine if there is a need for additional funds/aims for the study.

Are grants with carryover funds eligible for the supplement?

Grants with more than 25% carryover are eligible for administrative supplements, but may not be considered a high priority for funding unless the PI can demonstrate a bona fide need for additional funding and that adequate progress is being made on the parent grant.

Can the PI request a supplement if the grant is coming to an end and they plan to request a cost extension (NCE)?

The project and budget periods must be within the currently approved project period for the existing parent award. The application budget is limited to 1 year only. Requests for no-cost extensions on the parent grant to accommodate a supplement will not be permitted.

Can the PI request a supplement if their grant is in a cost extension (NCE)?

No, the project and budget periods must be within the currently approved project period for the existing parent award.

What costs can the PI request in the supplement?

Costs related to, and appropriate for the work proposed, can be included in the supplement request. However, PI salary, travel, and publication costs should not be included in the request, unless well justified.

Who can request an administrative supplement?

Personnel listed in the parent grant can initiate an administrative supplement request, but the request should be submitted by the awardee/recipient institution. For supplements to parent awards that include multiple PDs/PIs, the supplement may be requested by any or all of the PDs/PIs (in accordance with the existing leadership plan) and submitted by the awardee/recipient institution.

Can a co-PI on a multi-PI grant submit a separate supplement application to the grant on which s/he is a PI, for a different idea?

For supplements to parent awards that include multiple PDs/PIs, the supplement may be requested by any or all of the PDs/PIs (in accordance with the existing leadership plan) and submitted by the awardee /recipient institution of the parent award. Whether multiple supplement applications can be submitted to a single grant will depend on availability of funds.

What level of detail is needed with respect to the parent grant in the description of the proposed idea for the administrative supplement?

The level of detail will depend on the requirements outlined in the supplement announcement. In general, the PI should provide a brief description of the overall objective/scope of the parent grant, including the specific aims. The information provided should allow Program to determine if the work proposed in the supplement is within scope of the parent grant, and whether and how the supplemental work will enhance/contribute to the objective/aims of the parent grant.

The description of the scope of the overall parent grant and the anticipated contribution of the requested supplement in relation to the parent grant should not exceed five pages.

How should the investigator submit the supplement application?

The PI must submit the application through the NIH Omnibus Administrative Supplement FOA (<u>https://grants.nih.gov/grants/guide/pa-files/PA-18-591.html</u>) as directed through NOT-CA-20-038.

Can a P mechanism be the parent grant?

Applicants must hold a current NCI-funded grant that is one of the following mechanisms: R01, U01, R37, P01, U19, or UM1. P30 Cancer Center grants are not eligible for this supplement award.

Does the \$150,000 budget include indirect costs as well?

Yes, the budget limit of \$150,000 of total costs includes indirect costs.