

Lifestyle Alterations

Translational Research Opportunity Information Guide

Purpose

This guide provides a structured format to gather information concerning opportunities in cancer translational research that would benefit from focused funding and dedicated management. The opportunities must address specific clinical or product development goals. This guide is not intended to be used for programs of discovery research, methodology development or infrastructure development that are not tightly linked to specific and concrete clinical or product development objectives.

The guide characterizes the information to be gathered about the opportunity in four key respects:

- Strength of its scientific rationale
- Clinical or public health importance
- Technical feasibility of the envisioned development approach
- Suitability for NCI investment

1. Informative title of opportunity

Define the opportunity concisely, identifying the modality to be created and the primary clinical target.

Example: “Exercise and Diet Intervention for Modification of Breast Cancer Risk”

2. Scientific basis of the opportunity

- Three to five key points established by prior discovery research, translational research and/or clinical research that provide the scientific basis for the opportunity.
- For each point, the nature of the evidence (epidemiologic, animal model, clinical, or other) that was used to establish the point.
- Pertinent literature references whenever possible.

3. Importance of clinical or public health need

- Annual U.S. incidence of condition addressed by this modality (comment or explain incidence estimate).
- Five-year survival rate of patients with this condition.
- Any alternative interventions for this condition that are currently available.
- Any alternative interventions for this condition that are currently in development.
- Other factors or considerations that would inform decisions about prioritizing this need relative to other public health needs.

4. Activities and resources needed to realize the opportunity

Activity / resource	Title or brief description of activity / resource	Status of activity / resource (√)				Specific individuals, laboratories, companies, etc, who can provide the required resource (if already available) or conduct the necessary studies or development activities (if not already completed).
		completed / available	minimal effort needed to complete	substantial effort needed to complete	activity or resource not necessary	
SUPPORTING TOOLS						
Identification of target population via existing databases or new studies						
Development and validation of biochemical, behavioral and/or imaging "assays" to measure effect of lifestyle alteration						
Other						
Other						
CREATION OF MODALITY						
Specification of lifestyle alteration						
Other						

Activity / resource	Title or brief description of activity / resource	Status of activity / resource (√)				Specific individuals, laboratories, companies, etc, who can provide the required resource (if already available) or conduct the necessary studies or development activities (if not already completed).
		completed / available	minimal effort needed to complete	substantial effort needed to complete	activity or resource not necessary	
Other						
PRECLINICAL DEVELOPMENT						
Evaluation of effect in animal model						
Other						
Other						
CLINICAL TRIALS						
Pilot study to assess efficacy of lifestyle alteration						
Refined specification of lifestyle alteration						
Study of efficacy in larger, more diverse population						
Other (specify)						

5. Suitability for NCI investment

- Estimate of years required to advance this modality to a study in a large population.
- Likelihood that industry, foundations, or other non-government organizations will develop the modality without NCI involvement.
- Likelihood that the modality will be widely adopted if shown to be efficacious.

Specific activities and resources in academia, government and industry that should be coordinated so as to realize the opportunity in the most timely and efficient manner.

- Collaboration among investigators in academia and/or government, including investigators from the NCI intramural research program
- Collaboration with industry- or foundation-driven research initiatives
- Access to industry financial and/or infrastructure resources
- Financial support from foundations or other philanthropic sources