

Agents (Drugs or Biologics)

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: “Proteasome inhibitor for the treatment of multiple myeloma”

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, molecular/genomic, cell culture, 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						
Research-grade reproducible assay for effect of agent on oncogenic activity						
Clinically- or target-relevant cell culture system(s)						
Clinically- or target-relevant animal model(s)						
Validated assay and standard reagents or imaging methods to measure biomarkers of biological response						
Validated assay and standard reagents or imaging methods to measure biomarkers of endpoint in humans						

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	
Biospecimen / image repositories linked with outcomes data for relevant disease						
Research-grade reproducible assay and standard reagents or imaging methods to measure target						
Validated assay or imaging biomarker(s) that define(s) patient cohort likely to respond to agent						
Other						
Other						
CREATION OF MODALITY						
Experimental system to assess impact of perturbing target						

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	
Identification of candidate agents						
Selection of lead candidate						
Other						
Other						
PRECLINICAL DEVELOPMENT						
Preliminary toxicology screening						
Process development / pilot manufacturing						
Verification of activity / PK in pilot product						
Implementation of GLP / GMP manufacturing						
Verification of activity / PK / stability / QC in GMP/GMP product						
Definitive toxicology screening						
IND submission						

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						
Other						
CLINICAL TRIALS						
Phase I clinical trial(s)						
Phase II clinical trial(s)						

5. Suitability for NCI investment

- Estimate of years required to advance this agent to a phase II trial.
- Likelihood that industry will develop the agent without NCI involvement.
- Likelihood that industry will commercialize the agent if NCI demonstrates preliminary efficacy in phase II trials.
- Likelihood that the agent will be adopted into routine clinical practice 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