

Image-Based Assessment Modalities

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: “New Imaging Biomarker for Assessment of Colon Cancer Disease Progression”

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 assessment modalities for this condition that are currently available.
- Any alternative assessment modalities 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						
Assays (specify)						
Assays (specify)						
Other supporting tools (specify)						
Other supporting tools (specify)						
CREATION OF MODALITY						
Imaging platform						
Imaging agent						
Dosimetry and other tests of radiolabeling						
Optimization of acquisition and analytic parameters in Phase 0 setting						
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						
Testing and refinement of imaging performance, PK/PD, toxicology, etc. in preclinical setting						
GMP production for agent						
IND submission						
Testing/refinement of imaging performance, PK/PD, toxicology, etc. in Phase I/II setting						
Pre-IDE meeting for platform						
GMP manufacturing for platform						
Availability of optimized platform for clinical testing / 510(k) filing						
File IDE						

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 II+ trials for specific clinical utilities						

5. Suitability for NCI investment

- Estimate of years required to advance this imaging modality to a phase II trial.
- Likelihood that industry will develop the imaging modality without NCI involvement.
- Likelihood that industry will commercialize the imaging modality if NCI demonstrates preliminary efficacy in phase II trials.
- Likelihood that the imaging modality 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