

# **Biospecimen-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:* “Bladder Cancer Early Detection via Microsatellite Instability Assay of Urinary Sediment”

### **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	
<b>SUPPORTING TOOLS</b>						
Research-grade reproducible assay and standard reagents for biomarker or profile						
Biospecimen repositories linked with outcomes data for relevant disease						
Other						
Other						
<b>CREATION OF MODALITY</b>						
Initial definition of patient subset with biomarker using small number of specimens in a single laboratory						

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	
Validation of assay and correlation of biomarker with outcome retrospectively across large number of specimens in different labs						
Other						
Other						
<b>PRECLINICAL DEVELOPMENT</b>						
Clinical grade biomarker assay protocol / reagent(s) / device						
Validation in prospective human study of biomarker correlation with outcome						
Other						
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	
<b>CLINICAL TRIALS</b>						
Study in humans of utility of biomarker to direct therapy or chemoprevention or predict outcome / risk						

**5. Suitability for NCI investment**

- Estimate of years required to advance this biospecimen-based assessment modality to a prospective validation study of correlation with outcome in humans.
- Likelihood that industry will develop the modality without NCI involvement.
- Likelihood that industry will commercialize the modality if NCI demonstrates preliminary efficacy in human studies.
- Likelihood that the 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