



## ***Pre-Application Webinar***

**Research to Understand and Address  
the Survivorship Needs of Individuals  
Living with Advanced Cancer**

**RFA-CA-22-027**

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# Overview

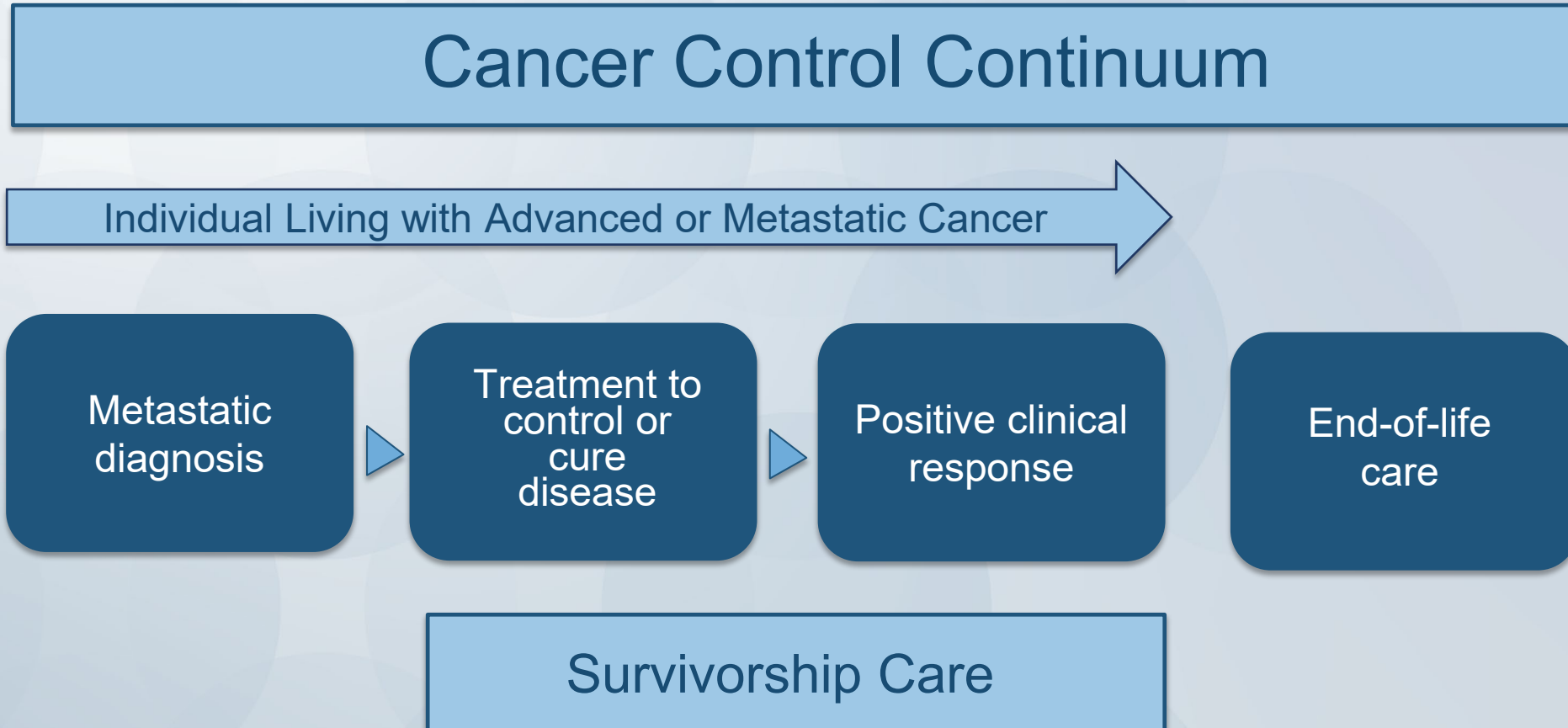


- ✓ Background
- ✓ RFA details and requirements
- ✓ Questions

# Individuals Living with Advanced or Metastatic Cancers: Describing the Population

- “Likely Incurable Cancer”
  - People diagnosed with advanced or metastatic cancer, or who progress to metastatic cancer, make up a population of survivors with what is likely incurable cancer
- Characteristics:
  - May cycle on and off treatment
  - May have periods with and without active disease
  - Includes individuals with advanced/metastatic cancer receiving targeted therapies or immunotherapies

# Survivors Living with Advanced or Metastatic Cancer



# What is Survivorship Care?

Prevention/  
surveillance of  
recurrence and  
new cancers

Surveillance/  
management of  
effects of  
cancer and its  
treatment

Health  
promotion/  
preventive care

Care Coordination

Institute of Medicine. 2005. *From cancer patient to cancer survivor: Lost in transition.*



# Goals for RFA-CA-22-027

# Purpose of RFA-CA-22-027

To support R01 applications to better understand and/or address survivorship needs for individuals living with likely incurable cancers

## NIH Research Project Grant (R01)

- Supports a discrete, specified, and circumscribed research project
- Most commonly used grant program
- 3-5 years of funding
- PIs strongly encouraged to present preliminary data to support proposed aims

# Example Research Topics

- Examination of factors associated with physical and psychological symptoms, adverse effects, and other survivorship outcomes
- Determining components of survivorship care to optimize outcomes
- Understanding the impact of living longer with likely incurable cancer on employment and financial concerns



## Example Research Topics (continued)

- Development and testing of models of survivorship care tailored based on the needs of the survivor and health system resources
- Development of interventions to address shared decision-making in the context of prognostic uncertainty among individuals with likely incurable cancers

# Key Considerations

- Population: Any group of individuals living with likely incurable cancer
  - Diagnosed at any age
  - Single or multiple primary cancer types
  - Treatments received
- Studies must focus on survivors and measure outcomes at the survivor level, but can also include caregiver, provider, and health system-level targets

# Additional Considerations

- Applications strongly encouraged (but not required) to:
  - collect clinical data including biomarker and radiologic data to characterize treatment response, toxicities, and disease status as appropriate
  - focus on individuals treated with newer therapies
  - include diverse populations: race/ethnicity, geography, socioeconomic factors

# Applications not considered responsive

- Focus on populations other than individuals living with likely incurable cancers
- Development and/or testing of cancer-directed therapies
- Focused exclusively on end-of-life care
- Focus on caregivers only (without a focus on survivors)
- Applications proposing a non-randomized program evaluation of an existing model of survivorship care



# RFA Details

# Application Dates

	1 <sup>st</sup> Receipt	2 <sup>nd</sup> Receipt
<b>Application Due Date</b>	September 30, 2022	September 29, 2023
<b>Letter of Intent Due Date</b>	30 days prior to application due date	30 days prior to application due date
<b>Scientific Merit Review</b>	~March 2023	~March 2024
<b>Advisory Council</b>	~May 2023	~May 2024
<b>Earliest Start Date</b>	July 2023	July 2024

# Application Details: Letter of Intent

- Due 30 days prior to the application due date
- Send by email to [michelle.mollica@nih.gov](mailto:michelle.mollica@nih.gov)
- Should include:
  - Title of proposed study
  - Contact information for the Principal Investigators
  - Names of other key personnel
  - Participating institutions
  - Number and title of this RFA

# Application Details

- Applications proposing clinical trials should follow NIH Clinical Trials guidelines: <https://grants.nih.gov/policy/clinical-trials.htm>
- Application budgets should reflect the needs of the proposed project but must not exceed \$500K in direct costs per year



# Specific Application Requirements: Significance

- Justification of proposed study population
- Justification explaining how proposed research addresses pressing need or evidence gap
- Explanation of how study findings will inform future strategies to improve outcomes

# Specific Application Requirements: Approach

- Plan for survivor stakeholder engagement during the development, planning, and conduct of proposed project
  - Proposed list of stakeholders and justification
  - Goals for working with stakeholders
  - Description of plan for collaboration
- Justification of the approach to include information, where appropriate, on disease characteristics and cancer treatment, individual characteristics, and socioenvironmental context
- Justification of the collection of biomarker and/or radiologic data where appropriate

# Requirements: Resource Sharing Plan

- Detailed data/resource sharing plan that is consistent with NIH policy and follow Findable, Accessible, Interoperable, Reusable (FAIR) principles for Resource Sharing Plans
- Plan must describe:
  - Type of data to be shared
  - Data repository to which the data will be submitted for sharing
  - Timeline for the data to be shared

# Application Review

- Applications reviewed by NCI Special Emphasis Panel
- Please note and address special review criteria included in the RFA

# Resources

- Read the RFA carefully:  
<https://grants.nih.gov/grants/guide/rfa-files/RFA-CA-22-027.html>
- Webinar and FAQ will be posted on our website:  
<https://healthcaredelivery.cancer.gov/funding/opportunities.html>
- Contact us early with questions

# Expected Impact

Address gap areas identified by stakeholders

Enhance understanding of symptoms, care patterns, and unmet needs

Increase effective strategies to improve care delivery

Improve outcomes for this growing population

# Pre-submitted and other FAQs

- How will ESI status be incorporated into the review process and funding decision, if at all?
  - ESI-submitted applications will not be reviewed separately from the EI applications in the SEP. We will consider ESI status as a factor in our funding decisions.
- Can you please provide additional guidance on expectations and examples for the stakeholder engagement plan?
  - NIH does not have a template for survivor stakeholder engagement. We encourage investigators to include a clear plan for how they will integrate survivor stakeholders as part of the design, conduct, and dissemination of the study and its findings.

# Pre-submitted and other FAQs

- Are foreign institutions allowed to apply? What about foreign partners and/or subcontracts?
  - Foreign institutions are not eligible to apply for grants under this FOA. However, foreign components to domestic institution applicants are allowed, with justification.
- Will most grants be funded in the first round?
  - We plan to balance how many grants we fund between the first and second receipt dates.





# Questions?

## Contact Information:

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