



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

***Presentation to NCI Board of Scientific Advisors (BSA)
March 28, 2022***

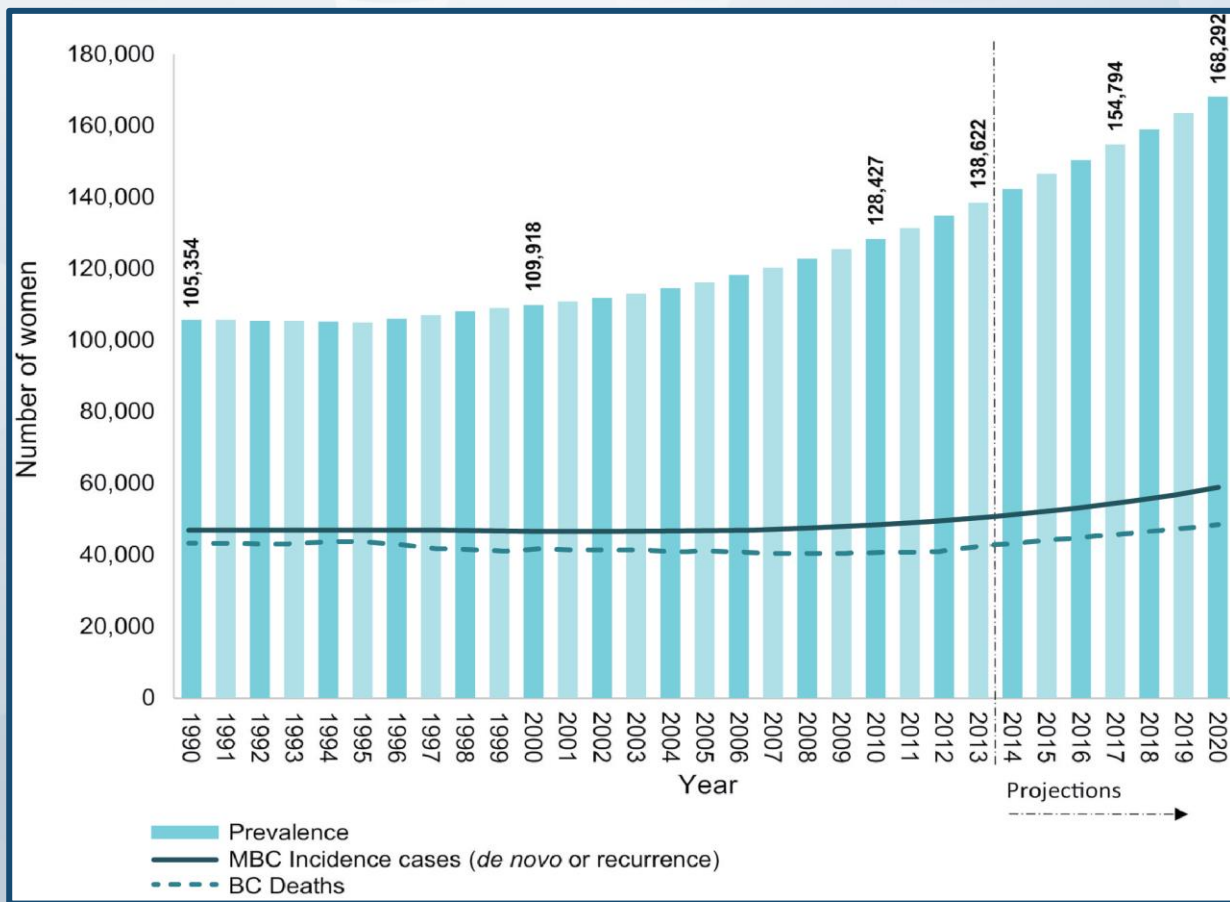
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Purpose of RFA

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

Growing Population of Advanced and Metastatic Cancer Survivors



Increasing prevalence of metastatic breast cancer survivors
Mariotto et al., 2017, CEBP

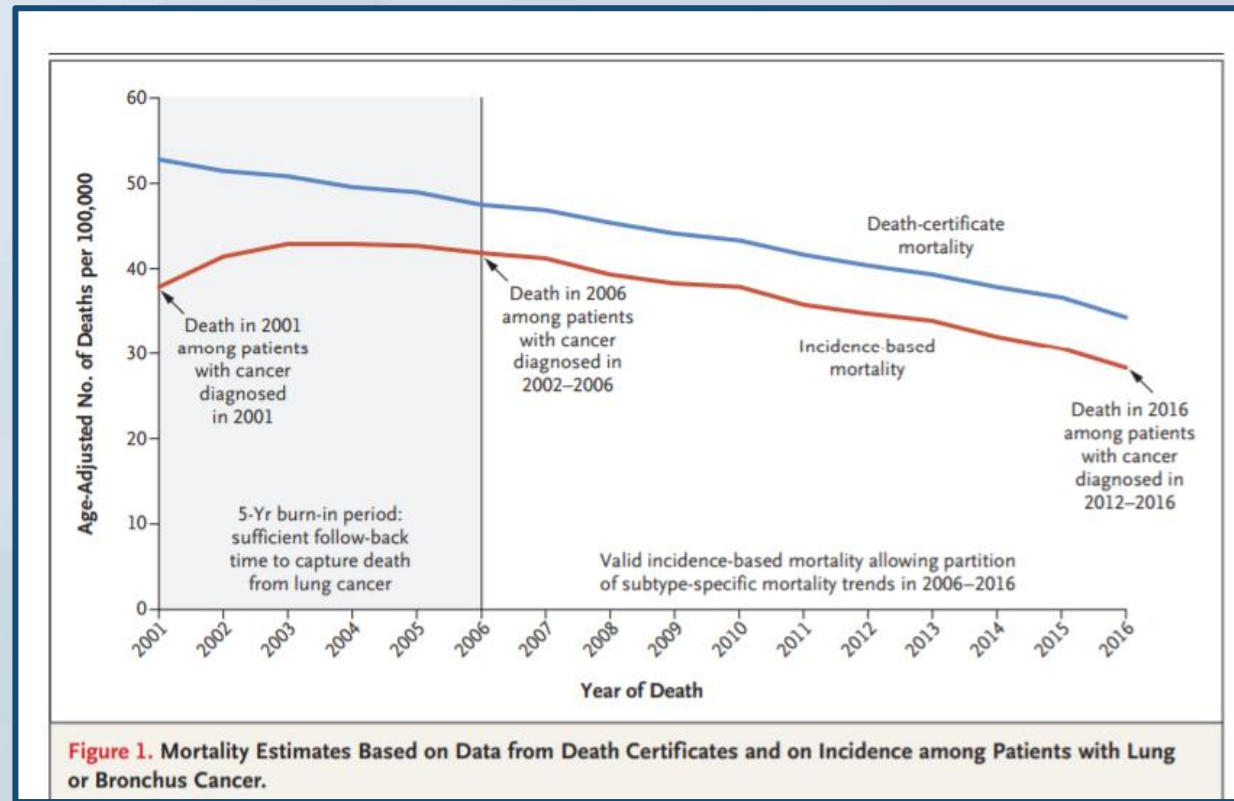


Figure 1. Mortality Estimates Based on Data from Death Certificates and on Incidence among Patients with Lung or Bronchus Cancer.

Decreasing mortality of lung cancer survivors
Howlader et al., 2020, NEJM

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

Example Survivor Profile: John Smith

- 2010: diagnosed with stage 4 non-small cell lung cancer at age 71; predicted to survive less than 3 years
 - Originally treated with four cycles of chemotherapy but experienced tumor growth; initiated re-challenge chemotherapy with disease control
 - Tumor growth after 6 years; treated with cycles of erlotinib for 3 years after treatment break to reduce side effects
 - After disease progression, EGFR mutation analysis detected T790M mutation; treated with osimertinib for over 1 year with disease control

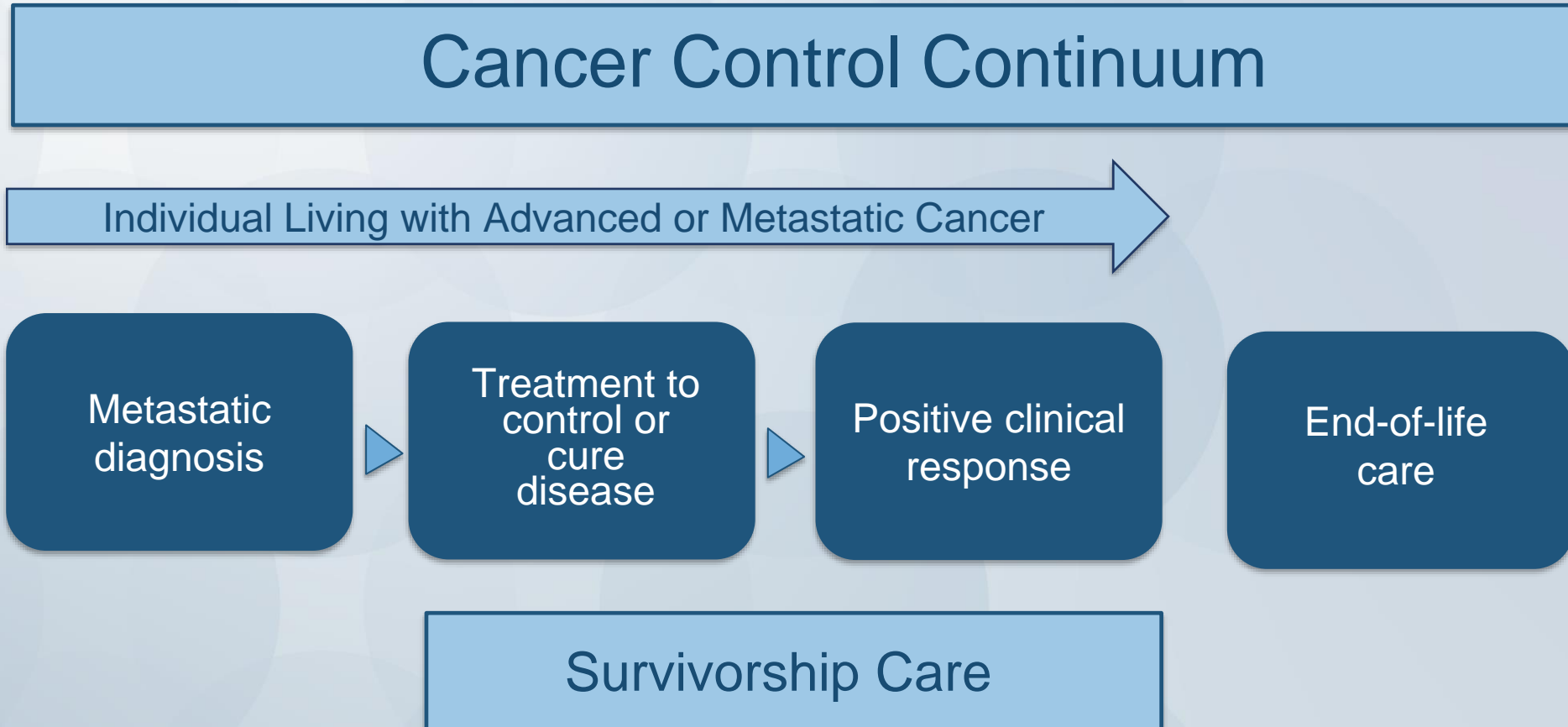
Adapted from: Matsuzaki et al., 2019; *Medicine*

Example Survivor Profile (continued)

- 2021: John Smith has survived over 11 years since his lung cancer diagnosis
- Continues to experience:
 - Long-term physical symptoms and psychological concerns- scan anxiety, uncertainty, fear of cancer progression
 - Financial hardship related to costly treatments
 - Waning caregiver support given long cancer trajectory
 - Substantial issues coordinating care among multiple providers

Adapted from: Matsuzaki et al., 2019; *Medicine*

Survivors Living with Advanced or Metastatic Cancer



Evidence Gaps Identified at NCI-led Meeting and Portfolio Analysis

- Clinical, genomic, and lifestyle factors associated with improved outcomes and better quality of life
- Types and trajectories of physical and psychological symptoms
- Prognostic awareness for patients and caregivers, and strategies to enhance communication of prognosis between patients and providers
- Optimal models of health care delivery
- Research to improve care quality and quality of life for individuals living with likely incurable cancers



RFA: Example Observational Research Topics

- Identifying factors associated with physical and psychological symptoms (including symptom trajectories) and other survivorship outcomes (e.g., quality of life, functional status)
- Determining components of survivorship care to reduce barriers and optimize survivorship outcomes
- Understanding the impact of living longer with incurable cancer on employment, financial concerns, and patient and caregiver well-being

RFA: Example Interventional Research Topics

- Development and testing of models of survivorship care that address:
 - Care coordination
 - Management of comorbid conditions
 - Management of changing symptom trajectories
 - Psychological needs (e.g., scan anxiety, depression)
 - Financial concerns
 - Support for the survivor/caregiver dyad
- Interventions to address shared decision-making and patient-provider communication in the context of prognostic awareness

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 caregivers, providers, and health system-level targets
- Studies must collect clinical data including biomarker and radiologic data to characterize treatment response, toxicities, and disease status as appropriate
- Strong interest in proposals that:
 - Focus on individuals treated with newer therapies
 - Include diverse populations: race/ethnicity, geography, socioeconomic factors

Justification for RFA

- NIH does not have a robust portfolio focused on survivorship for this population
- Previous FOAs have focused on end-of-life care exclusively
- Incentivize simultaneous work to provide foundation to effectively understand and improve outcomes for survivors living with likely incurable cancers

Proposed Budget

- 2 receipt dates/rounds proposed, with funding in FY23 and FY24
- Round 1 funding: \$3M in FY23, approx. 3 awards, total costs are \$15M over 5 years
- Round 2 funding: \$3.5M in FY24, approx. 4 awards, total costs are \$17.5M over 5 years
- Total funding across both rounds = \$32.5M (FY23 – FY28)

Clarifications in Response to BSA Subcommittee Feedback

- **Palliative Care:** emphasize the importance of palliative and supportive care in survivorship for this population
- **Evidence gap:** need to understand the impact of social and environmental factors on survivorship outcomes
- **Example Interventional Research Topics**
 - **Models of care:** include attention to access to care and telehealth
 - **Psychosocial support:** include focus on social isolation
- **Inclusion of clinical and biomarker data:** clarify that this is not as a primary endpoint but rather collected as appropriate to inform study findings

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



Questions?

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