Pre-Application Webinar

Research Consortium for Improving Management of Symptoms During and Following Cancer Treatment (IMPACT) (U24, UM1)

Outcomes Research Branch
Healthcare Delivery Research Program
Division of Cancer Control and Population Sciences

NIH NATIONAL CANCER INSTITUTE

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https://healthcaredelivery.cancer.gov/about/orb/

Webinar presenter

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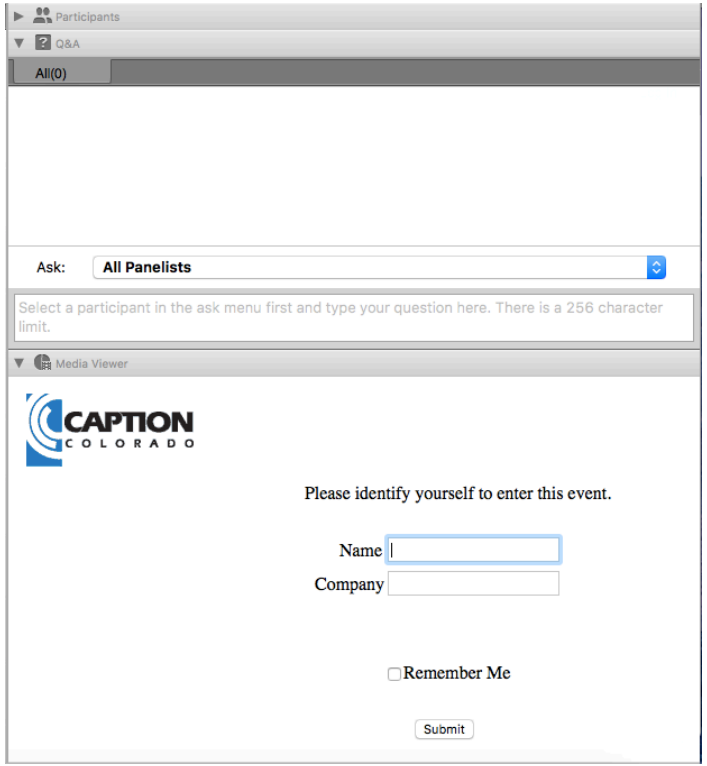
Using WebEx and webinar logistics



- Submit questions at any time during the presentation. Type into the Q&A feature on the right of the interface and press “submit”
  - Closed captioning is available by selecting the Media Viewer Panel on the right hand side of your screen
- This webinar is being recorded

Webinar Outline

I. Background and Scope of the Problem
   - Cancer Moonshot℠ Initiative
   - Cancer Symptom Management Research

II. Goals of the Requests for Applications (RFA)
   - Consortium:
     UM1 Research Centers
     U24 Coordinating Center

III. Application Requirements

IV. Questions

Background & Scope of the Problem

Beau Biden Cancer Moonshot℠ Initiative
Blue Ribbon Panel Recommendation

Beau Biden Cancer Moonshot℠ Initiative

GOAL: Accelerate progress in preventing, diagnosing, and treating cancer by accomplishing a decade's worth of work in 5 years

CANCER MOONSHOT

$1.8 billion in funding for Cancer Moonshot Initiatives over the next 7 years

RECOMMENDATION: Minimize cancer treatment's debilitating side effects

- Accelerate the development of guidelines for routine monitoring and management of patient-reported symptoms to minimize debilitating side effects of cancer and its treatment

Scope of the Problem

Cancer-related symptom burden is substantial

- Patients experience multiple symptoms concurrently
- Symptoms are often inadequately treated

Poorly controlled symptoms contribute to:

- Nonadherence, treatment delays and discontinuation
- Emergency room visits and unscheduled hospitalizations
- Impaired physical and social functioning
- Poor quality of life
- Lower rates of return to work and impaired ability to work

Major Barriers to Effective Symptom Control

Symptoms are not systematically assessed and reported

- Patient-reported outcomes (PROs) are not used in many practice settings
- When integrated, PRO reports do not always facilitate clinical decision-making

Symptoms are not adequately managed

- Providers are unfamiliar with existing clinical practice guidelines
- Resources for symptom management not identified or used

Lack of systematic efforts to translate research into practice

- RCTs show benefits of integrated symptom assessment and reporting

Goals of the RFA

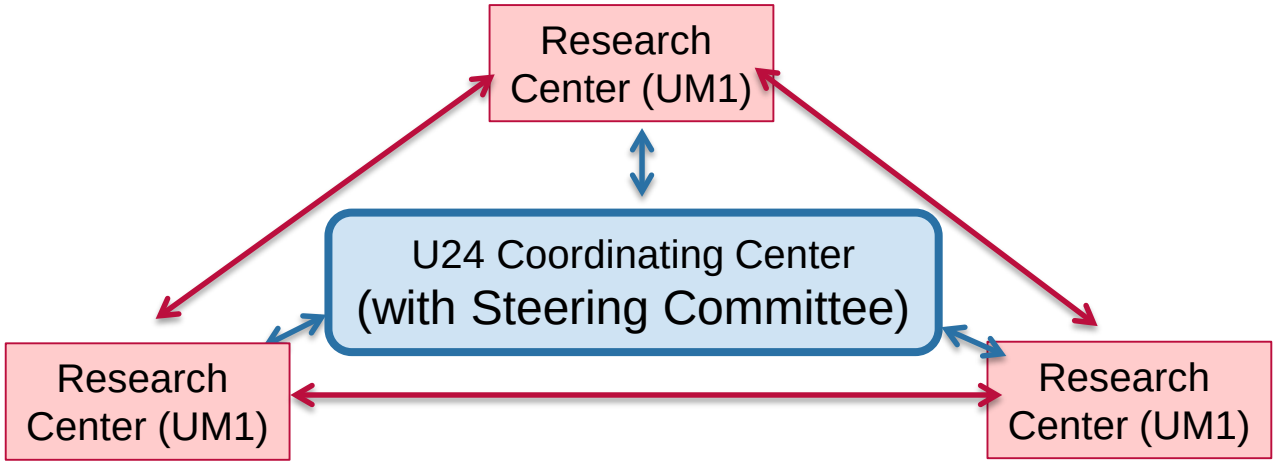
Improving Management of Symptoms During and Following Cancer Treatment (IMPACT)

Goals of the RFA

Create a Research Consortium to:

- Develop scalable, transferable, and sustainable symptom management systems to monitor and address common cancer symptoms
- Rigorously examine impact on symptom control, functioning, treatment delivery, and healthcare utilization
- Using consortium-wide data, evaluate effects across:
  - Symptoms
  - Cancer continuum
  - Minority and medically underserved populations
- Produce findings and materials for wider implementation

Overview of the Research Consortium



Two RFAs to Support four Cooperative Agreement grants

- UM1 Research Centers
- U24 Coordinating Center

Research Centers (UM1)

GOAL: Deploy and Evaluate Integrated Symptom Management System for Cancer Care

- Implement integrated systems into routine clinical practice;
- Verify whether adoption of integrated systems can reduce the harmful effects of poorly controlled symptoms;
- Create the foundation for effective, scalable and sustainable symptom management approaches in routine cancer care.

Research Centers (UM1)

Required Components: Study Design

- Deploy integrated symptom assessment and management system in clinical practices using implementation science principles
- Use a randomized design to test system impact on **patient outcomes**, **cancer treatment delivery**, and **healthcare utilization**
- Measure extent of adoption and contributors to success
- (Conduct in a 5-year project)

Research Centers (UM1)

Required: Integrated symptom monitoring and management

- Address common symptoms
  - Include at least **pain** or **fatigue** (others relevant for cancer types proposed)
  - Provide point of care clinical decision support and care-coordination based on the presence and severity of symptoms
  - Account for patient, provider, and practice characteristics, regarding proposed changes in clinical practice

Research Centers (UM1)

Required Components: Patient Population & Healthcare Delivery

- Demonstrate in **under-resourced settings**, diverse patient populations
- Address multiple points on cancer continuum
  i. Treatment with curative intent
  ii. Treatment without curative intent
  iii. Survivorship (post-treatment)
- Measure extent of adoption and contributors to success

Research Centers (UM1)

Required: Informatics

- Symptoms must be collected via **electronic data capture**, integrated with EHRs
- **One, uniform electronic platform** must be used for all clinical practices in the Research Center, with a fully operational EHR
- Data must be collected in formats that **allow for sharing** across funded Research Centers

Coordinating Center (U24)

- **GOAL: Coordinate and support efforts of the Research Centers funded under the UM1**
- **Main responsibilities:**
  1. **Consortium coordination**
  2. **Ensure standardized, harmonized, data collection across research centers**
  3. **Establish processes for pooled analyses**
     - Capacity for data storage/security
     - Capacity for integrated databases
     - Plans for analytic approaches
     - Experience coordinating large databases

Coordinating Center (U24)

Additional Required Components

- Provide an overview of Coordinating Center's role in the Consortium
- Highlight unique approaches that show effective and innovative ways to coordinate multi-institutional, transdisciplinary research
- Describe approaches to Consortium coordination, oversight of a Steering Committee, and any relevant working groups

All Centers: Data and resource sharing

Required to comply with Resource Sharing Plan policy, specified under 21st Century Cures Act and the Beau Biden Cancer Moonshot℠ Initiative

Grant mechanisms: U24 and UM1 Cooperative Agreements

Cooperative Agreement for Resource-Related Research Projects (U24)	Cooperative Agreement for Research Project with Complex Structure (UM1)

• Support for research projects aimed at improving resources to serve biomedical research
• Substantial federal programmatic staff involvement in research activities
• Plans for 1 Award
  • Direct costs cannot exceed $375,000 per year
• Project period: maximum 5 years
	• Supports large-scale research activities with complicated structures (e.g. research consortia or clinical networks)
	• Substantial federal programmatic staff involvement in research activities
	• Plans for 3 Awards
	  • Direct costs cannot exceed $1,120,000 per year
	• Project period: 5 years

Application Requirements

Application requirements

- UM1 **Research Strategy** must cover:
  A. Overview of the Proposed Center
  B. Administrative Unit
  C. Research Design and Implementation Unit
  D. Data Management, Statistics, and Informatics Unit

- U24 **Research Strategy** must cover:
  A. Coordinating Center Overview
  B. Plans and Approaches to Basic Coordinating Center Functions

Application requirements: Review

- One-time submission
- Special emphasis panel
- Please note and address the Special Review Criteria in both RFAs
- Letter of Intent: to Ashley Wilder Smith (smithas@mail.nih.gov)
  - UM1: Required
  - U24: Recommended

Read the FOAs very carefully!

- RFA-CA-17-042 (UM1)
  RFA-CA-17-043 (U24)

- Application Due Date:

  January 17, 2018

- Letter of Intent: 30 days prior (December 17, 2017)

- Start the process early! Allow time for registration in the System for Award Management, eRA Commons, and Grants.gov

Resources

- Today's webinar and FAQ will be posted on our website: https://healthcaredelivery.cancer.gov/media
- Connect with us early!
- Check the FOA for contact information

Questions?

Please type your questions in the Q & A section on WebEx

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