Pre-Application Webinar Research Consortium for Improving Management of Symptoms During and Following Cancer Treatment (IMPACT) (U24, UM1)
Frequently Asked Questions

What is the appropriate study design to evaluate the topics in the RFA? What would be an appropriate comparison group? Would stepped-wedge designs be acceptable for the design?
Yes, we anticipate that applicants will employ stepped wedge designs or other alternative randomization schemes such as cluster randomization, that are typically employed in pragmatic trials, where the unit of randomization is at the practice level rather than the patient level. (Section 4, Subsection 2C, printed page 13).

Is the expectation that additional outcomes will be actively (vs. passively) collected via the EHR, beyond the symptom PROs that are integral to the intervention?
Different proposed designs may require collection of distinct outcome elements, some of which will be available in the EHR and some of which may only be available via additional data collection.

Can you explain more about what is meant by an integrated cancer symptom monitoring and management system?
The integrated system must include regular assessment of cancer patient symptoms, including pain or fatigue (with a preference for pain AND fatigue) as well as other symptoms relevant for the patient population based on cancer type, stage of disease and treatment modalities. Symptom management strategies must be based on current clinical guidelines. The system must provide decision support, typically at the point of care. Deployment of the system in the practices must be based on implementation science principles, that address barriers and facilitators at the patient, provider and practice levels.

What about inclusion of symptoms for which there are no guidelines?
There are guidelines now available for most common cancer symptoms, from organizations that include National Comprehensive Cancer Network (NCCN), Oncology Nursing Society (ONS), American Psychosocial Oncology Society (APOS), American Society of Clinical Oncology (ASCO), and American Cancer Society (ACS), as well as from other specialty organizations such as the American Urologic Association.

Does NCI have any special priority focus by phase in the cancer continuum (i.e., active treatment with palliative intent, survivorship), cancer type or by stage of disease (e.g. advanced or metastatic disease vs. early stage disease)?
There is no priority focus in terms of clinical populations. Patients included in the proposed study should vary by cancer type and may vary by age group (e.g. children, adults and older adults). It is required to include patients in at *least two places on the cancer care continuum*, specifically (1) treatment with curative intent, (2) treatment with palliative intent and (3) during cancer survivorship. More information about patient populations and care delivery settings is available on printed page 6, Section 1 of the RFA.

Will my application be considered responsive if I have a diverse sample with respect to SES, age and ethnicity, but focus on only one cancer type such as leukemia or breast cancer?
Patients in the proposed study should vary by cancer type and stage of disease, in addition to being diverse with respect to age, ethnicity and SES.

Can you provide more detail about what is meant by 'addressing health disparities'?
The scope of the proposed project needs to include diverse populations including underserved patient populations. Each Research Center is required to address disparities in access to and use of symptom assessment and management. There should be a clear focus on inclusion of community-based practices that serve diverse patient populations and have limited on-site professional resources for symptom management. Clinical practices must include those that provide care to patients who are undeserved based on geographic location, race/ethnicity, income, or socioeconomic status based on the cancer type being studied. Symptom monitoring and management systems may be tailored for underserved populations, including those with low digital literacy, low educational attainment and non-English speakers. More information about this may be found in Section 4, Subsection 2, printed page 12.

While pain and fatigue are required to be measured, are they sufficient? Must I use an NIH-sponsored PRO measure such as PROMIS?
The symptom requirement is pain or fatigue, along with others relevant to the cancer types being studied. The preference is for pain AND fatigue. There is no requirement that applicants use an NIH-sponsored PRO measure, though the use of common, rigorous assessment tools should be considered to maximize cross-Center analysis. Symptom domains to be assessed should reflect the cancer type, stage of disease, and place along the treatment continuum. The measures selected should have well-demonstrated measurement properties, be feasible for use in a pragmatic trial, be easily implemented into clinical workflow, and be interpretable by clinicians and actionable to improve symptom management. Information about the use of Common Data Elements can be founded in Section 4, subsection 7, printed page 16.

What kinds of technologies are you anticipating will be employed by applicants, (for example tablets, smart phones, etc.)?
We anticipate that applicants will employ a range of technologies. The plan for data collection should include electronic data capture using a platform that is either integrated within the EHR or a stand-alone system with interface capabilities within the EHR. Applicants may choose whatever mode of administration is most feasible and effective, but should also consider sample size and power to account for potential differences by mode.

Can grant funds be used to purchase dataplans or hardware?
Yes, funds may be used to purchase dataplans or hardware if those purchases fit both within the research plan and the budget. If an applicant proposes use of grant funds to purchase dataplans or hardware, the research plan should address considerations of sustainability and scalability once the funding period is over.

The RFA request and components of it are very broad with multiple levels, yet the budget (350K) is quite small for these grand aims.
The budget of $350K direct costs per year is for the coordinating center not for the research centers, direct costs for the research centers is $1.12 million per year.

Are study sites required to have a shared electronic health record and a portal for electronic PRO data collection
Because data will be pooled across study sites there should be an inter-operable symptom assessment and management across sites. The electronic system should possess functionality for collecting PROs and providing scored information to clinicians. Data must be collected in formats that allow for data sharing across funded Research Centers. The electronic platform must be either embedded within the

EHR or able to seamlessly interface with the EHR such as with online tools, apps or software with application programming interface (API) capabilities. Awardees may use the early stages of the project for final refinement of the platform, refinement of the process of delivering scored information to clinicians and providing the decision support, and scaling the system for full implementation across all study sites/practices. More information about this may be found on printed page 7, Section 1.

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Can the symptom management intervention address caregivers?
The main focus should be on development of a system for symptom monitoring and guideline-concordant symptom management. As such, caregiver participation in a symptom management intervention might be one feature of the system for symptom assessment and management, particularly for certain populations such as pediatrics. However, consideration of sample size, power, and budget should be considered if including caregivers.

Would offering the system for symptom surveillance and management in another language such as Spanish be of value?
Yes, it would, particularly since barriers to symptom monitoring and management often exist because of limitations in patient-provider communication. It would also be of value to address access for underserved, Spanish-speaking cancer patients.

May an institution apply for both the U24 and the UM1 (coordinating center)?
Yes, an institution may apply to both announcements. Please note that the UM1 and U24 applications must have different PIs.

Is a letter of intent required and by what deadline?
A letter of intent is required for the UM1 and recommended for the U24. Those letters of intent are due by December 17, 2017.

Will you accept international collaborators as subcontractors?
Non-domestic (non-U.S.) Entities (Foreign Institutions) are not eligible to apply. Non-domestic (non-U.S.) components of U.S. Organizations are not eligible to apply. Foreign components, as defined in the NIH Grants Policy Statement, are allowed. For more information, please see Section 3, subsection 1, printed page 9.

Will the new NIH clinical trials policies being implemented in 2018 apply to these submissions?
As the application due date is before the date for implementation of the new clinical trials policies, those policies will not apply to these submissions.

Can you say more about what should be included in the data sharing plan?
The Cancer Moonshot public access and data sharing plan requires that applicants describe their proposed process for making resulting publications and the underlying primary data immediately and broadly available to the public. More information and a link to the full policy is available in Section 4, subsection2 A, printed page 14.

Can my application include a demonstration of technology to the reviewers?
No, unfortunately there is no capacity for inclusion of multimedia materials in the application. Should you wish, screen shots could be included, if they can be accommodated within the page limits of the application. The section on preliminary studies can be used to describe the technology for symptom evaluation and management that will be employed in the study, and to provide data from pilot studies.

Can IMPACT studies be conducted within the NCI Community Oncology Research Program (NCORP)?
No. Institutions holding NCORP grants are welcome to apply or participate as sub-contractors, but may not use NCORP funds to support IMPACT activities. The IMPACT Coordinating and Research Center funding is intended to cover all study-related activities without the need to rely on other funds to support the proposed work.

Will there be another set of solicitations issued?
No