Pre-Application Webinars for RFA-CA-17-052, "Analyzing and Interpreting Clinician and Patient Adverse Event Data to Better Understand Tolerability (U01)"
Frequently Asked Questions

Does a study need to have CTCAE and (specifically) PRO-CTCAE, or can it have CTCAE and "other" PRO measures? The application must identify available datasets that investigators will use for the development of the analytic approaches. Each dataset needs to originate from a clinical trial (Phase I-IV cancer treatment or control trials) that include CTCAE. At least one dataset must include both CTCAE grades and PRO-CTCAE scores. Other datasets may include PROs, other than PRO-CTCAE. None of the datasets need to be included with the application, but sufficient detail about the trial and the dataset needs to be described such that the reviewers can appropriately evaluate. (Part 2, Section I, Main Research Objectives and Requirements)

Are the clinical trials limited to only chemotherapy trials? No. A cancer treatment clinical trial can include one or more therapies (chemotherapy, immunotherapy, biologics, radiation therapy, surgery, etc.) aimed at improving survival. In addition, datasets from trials evaluating cancer control interventions (symptom management, supportive care) are also acceptable.

Should the budget include travel for Consortium meetings? Or will meetings be held via conference call? Yes, the budget should include travel for the co-investigators to travel to one Consortium meeting per year. Additional meetings will be held via conference calls.

Will reviewers be looking for specific aspects (toxicity grades, reports of interference) in the definitions of patient tolerability or should the definition be more conceptual? The definition may be conceptual with a set of definitions for different scenarios (interventions, diseases). Reviewers will be asked to assess the clinical relevance of the conceptual definition or set of definitions for tolerability, but not the operational characteristics of the definition.

What are the characteristics of a data scientist? The field of data science includes scientific methods, process and systems to extract knowledge from data in various forms, either structured or non-structured. This includes data mining, machine learning, and data visualization. Data scientists will show evidence of incorporating statistics, mathematics, information science, and computer science in their work.

Can the budget include activities like qualitative interview with patients? No. While applications can include activities to prospectively collect qualitative and quantitative patient data, money cannot be requested to support these activities.

Can the budget include qualitative interviews with key stakeholders (clinicians, regulators, patients) to gain their input on how the data are displayed and reported in meaningful terms? Yes. Since these data will be used to inform analytic and graphic approaches, money can be requested for these activities.

Since pediatric trials do not use PRO-CTCAE, are they excluded? Yes. At this time, PRO-CTCAE is undergoing validation in the pediatric cancer setting and has not been employed in any pediatric cancer clinical trials.

One of the requirements is having a clinical trialist on the team. What are the characteristics of this specialty. For the purposes of this RFA, a clinical trialist is a physician who has served as a study chair and evaluated adverse events.

How should the approach to collaboration across the Consortium be decribed? The Moonshot Initiative puts significant emphasis on collaboration across different disciplines. For these applications, the investigators are asked to provide a description of previous collaborative efforts with data from clinical studies, as well as how they believe they can contribute to the consortium.

Can EMR data be linked to trial data?
If the investigators have EMR data linked to the trial (or the ability to do so) and that linkage is designed to inform their conceptual definition of tolerability, then yes.

If applicants have trials trial with PRO-CTCAE and CTCAE, but they are registration trials and the primary endpoints may not be reported during the duration of the grant, would these be eligible?
Yes. Applications with datasets where the primary endpoints have not yet been reported or the trials are open and accruing are eligible. The expectation is that the proposed analyses will focus on aggregate data and not include comparisons between treatment arms.

For applications that contain multiple datasets, can the analyses be done individually or must it be done in aggregate?
It is entirely up to the investigators and acceptable to do either or both.

Is this a one-time RFA? How many awards are anticipated?
At this time, this RFA will be a one time solicitation. NCI is interested in developing the best methods to address the use of PRO-CTCAE in the context of patient tolerability. This Moonshot RFA is one means to facilitate the research. Investigators are free to submit investigator initiated awards as well. NCI intends to commit $3.25million in FY 2018 to fund three to five awards.