Title

Administrative Supplements for National Cancer Institute (NCI) Support of the electronic collection of PRO-CTCAE using Patient Cloud ePRO in the Experimental Therapeutics Clinical Trials Network (ETCTN)

Key Dates

Application Receipt Date: 01/08/2017
Anticipated Award Date: 03/01/2018

Purpose

The importance of assessing tolerability and toxicity of new agents and new combinations of therapies in the ETCTN trials continues to increase. NCI has developed a new patient-reported outcome (PRO) measurement system, PRO-CTCAE™, designed to be used as a companion to the CTCAE to directly capture symptomatic AEs by patient self-report in cancer clinical trials. NCI is piloting its use on electronic tablets and/or personal smart phones in several ETCTN trials via the Patient Cloud ePRO application. The purpose of this notice is to announce that NCI will consider administrative supplement requests to support the expanded involvement of ETCTN sites in the coordination and implementation of ETCTN clinical trials with the ePRO pilot. This funding is expected to lead to enhanced participation and training of the site research staff to implement the electronic collection of patient's self-reporting of their symptomatic adverse events during the conduct of at least three ETCTN trials in 2017 and 2018.

Background of the Patient Cloud ePRO Pilot

The NCI recently procured Medidata Patient Cloud ePRO (electronic Patient Reported Outcomes) for use in a 2-year pilot in ETCTN and NCTN trials. This mobile application will be used on patients' personal cell phones and tablets and/or clinic tablets to collect patient responses to patient reported outcome tools, such as PRO-CTCAE, and patient diaries, and transfers these data to the same Medidata Rave database as the ETCTN or NCTN clinical trial. This allows all the patient reported data and clinical trials data to reside in the same clinical trials database. The goals of the Patient Cloud ePRO include: elimination of the collection of paper surveys and manual data entry; real-time, seamless electronic entry of PROs into the clinical trial database; and enhanced ability to more efficiently analyze data. The implementation of ePRO will require training of research staff in the use of the ePRO module. This training will be provided by NCI through conference calls and online training modules and videos.

Three ETCTN trials have initially been selected for the ePRO pilot and will include PRO-CTCAE items that will provide exploratory data to better assess tolerability of the treatment regimens. This will allow investigators and the NCI to have both the CTCAE and corresponding PRO-CTCAE items collected at the same timepoints and these data will be available for analysis in the same Medidata Rave database. **While the selected awardees are encouraged to participate in all 3 ETCTN trials, a minimum of 2 are required, and include:**

1. NCI Protocol: 10020 – "A Phase II Multiple-Arm, Open-Label, Randomized Study of PARP Inhibition (Veliparib; ABT-888) and Anti-PD-L1 Therapy (Atezolizumab; MPDL3280A) Either Alone or in Combination in Homologous DNA Repair (HDR) Deficient Triple Negative Breast Cancer (TNBC)"
    - Adding an amendment to add ePRO PRO-CTCAE pilot

2. NCI Protocol: 10021 – "A Phase 2 Study of Durvalumab and Tremelimumab Alone or in Combination with High or Low-Dose Radiation in Metastatic Colorectal and NSCLC"
    - Will be adding an amendment to add ePRO PRO-CTCAE pilot

3. NCI Protocol: 10107 – "Phase 2 Randomized Clinical Trial of Anetumab Ravtansine and Pembrolizumab Compared to Pembrolizumab for Mesothelin-Positive Malignant Pleural Mesothelioma"
    - Not active yet (protocol is approved on hold) and has plans to activate with ePRO PRO-CTCAE pilot.

This supplemental funding provides for partial salary support of research staff, such as a CRA or a research nurse, to:

- lead implementation of ePRO at an ETCTN Lead Academic Organization (LAO) or Affiliated Organization (AO);
- participate in a working group with the NCI and CTSU to create best practices for the site implementation of ePRO and PRO-CTCAE in ETCTN trials.

Eligible Institutions and Number of Applications

Each participating ETCTN LAO and AO may be awarded up to a maximum of $20,000 in direct costs. Each ETCTN UM1 LAO grantee institution may submit a supplement request for a maximum of $60,000 direct costs for a maximum of 3 sites (LAO and AO sites) within the LAO grant package.

Allowable Costs

- Increased salary support for one research team staff already involved on the UM1 parent grant or its affiliated organizations;
- Travel costs for research team staff to attend one ETCTN investigator meeting/year.

Application Procedures

1. Applications must be submitted electronically through the following **Funding Opportunity Announcement PA-16-287 mechanism**:
    a. https://grants.nih.gov/grants/guide/pa-files/PA-16-287.html

2. **Cover Letter**
   A cover letter should accompany each application and include:
    a. Request for an administrative supplement to support the project
    b. Title of the supplement
    c. UM1 grant number
    d. Contact information for the Contact PI of the UM1
    e. Signatures of the Contact PI of the UM1 and the authorized institutional official

3. **Applications should include**

    a. NIH Biosketch for the ETCTN research team staff to be supported through this supplement

b. Approach (1-2 pages maximum and if submitting for more than one site, label each site and describe each criterion for each site):

   i. Describe how the implementation of the electronic collection of patient reporting of symptomatic adverse events using patient's personal smart phones and/or clinic tablets in several ETCTN trials will be integrated into their clinics.

   ii. Discuss the roles of the key research team member involved in this pilot and how he/she will ensure patient enrollment into these specific trials and maintain patient engagement in self-reporting using their own smart phones and/or clinic tablets.

   iii. Discuss the commitment from the sites to actively participate in an ETCTN-wide working group of the ePRO pilot. Describe any experience of staff in leading efforts to improve site clinical trial practices that may help contribute to the success of this pilot including the recruitment of patients into this optional PRO component of the trials and ensure high quality data with minimal missing data reports.

Review Criteria

All requests will undergo administrative review by NCI staff.

Awards

Awards will be based on responsiveness to the aims of this announcement and the availability of funds.

Reporting Requirements

A separate supplement Progress Report must be submitted in conjunction with the parent award Annual Progress Report, https://grants.nih.gov/grants/rppr/index.htm. The progress report should include the work to implement this pilot at sites, including the work to recruit and enroll patients in the parent trial and the e-PRO pilot, tracked reasons why patients decline participation in the ePRO pilot, and any challenges with patients enrolled and how they were addressed.

Questions

- **Programmatic:** Please contact S. Percy Ivy (ivyp@ctep.nci.nih.gov) or Jeff Moscow, MD (jeffrey.moscow@nih.gov) for questions related to ETCTN.
- **PRO-CTCAE:** Please contact Lori Minasian, MD, FACP (minasilo@mail.nih.gov) for ePRO pilot and PRO-CTCAE questions.
- **Budget:** Please contact Shane Woodward (woodwars@mail.nih.gov) at the NCI Office of Grants Administration for assistance regarding the budget.