RFA-CA-17-052: *Analyzing and Interpreting Clinician and Patient Adverse Event Data to Better Understand Tolerability*

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Agenda

1. *Goals of the RFA*
2. *Important dates*
3. *Examples of*
   - *Eligible projects*
   - *Ineligible projects*
4. *Key aspects of projects*

Goals of RFA

1. Support projects that explore analytic approaches of clinical trial data that have used both the Common Terminology Criteria for Adverse Events (CTCAE) and the Patient-Reported Outcomes version of the Common Terminology Criteria for Adverse Events (PRO-CTCAE™)
2. Outcomes from these projects will allow better insights into patient tolerability of agents and regimens undergoing testing in cancer clinical trials.

Important Dates

- Application due date: ***January 17, 2018***
  - Late applications will not be accepted
- Scientific Merit Review: June-July 2018
- Advisory Council Review: August 2018
- Earliest Start Date: September 2018

Examples of:

Eligible Submissions

- Analyzing longitudinal data of CTCAE grades, PRO-CTCAE scores, other PRO scores, and dose modifications
- Employing pharmacokinetic data in conjunction with PRO-CTCAE scores and CTCAE grading
- Representing the data using different graphical techniques
- Multiple datasets, with at least one having both CTCAE grades and PRO-CTCAE scores

Ineligible Submissions

- At least one dataset lacking both CTCAE grades and PRO-CTCAE scores
- Projects proposing to prospectively collect CTCAE grades and PRO-CTCAE scores
- Data collected outside clinical trial setting
- Data collected in disease settings other than cancer

Key Aspects of Projects

- An operational definition of tolerability that relates to the patient- and clinician-reported data that will be used in the analyses.
- Address how minority health and/or health disparity populations or data will be integrated into the proposed studies.
- Have at least one clinical trial dataset with CTCAE and PRO-CTCAE data
- Must use existing data sources rather than collect new data.
- Describe the clinical trial(s) in which the data were collected.
- Describe the dataset, including sample size, demographics of the patient population, frequency of data collection, and types of data collected
- Investigators will share their analytic approaches and methods with members of the consortium and the Steering Committee.

Key Aspects (cont.)

- Each funded research team will be comprised of at least one of each of the following:
  - Biostatistician
  - Data scientist (combined expertise of biostatistician and data scientist is acceptable),
  - Clinical trialist
  - PRO measurement expert.
- Creation of a consortium of the funded research teams, academic investigators, industry sponsors, NCI and regulatory staff and patient advocates
- Establishment of a Steering Committee to:
  - Identify areas of opportunity that can best be exploited with a group effort of the awardees;
  - Encourage development of new methodologies and approaches for sharing among awardees;
  - Optimize information flow among the awardees and the NCI.

Everything You Need to Know about the RFA

https://grants.nih.gov/grants/guide/rfa-files/RFA-CA-17-052.html

Questions?

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