

NCATS Advisory Council June 2015

Concept Clearance

NCATS EXPLORATORY CLINICAL TRIALS FOR SMALL BUSINESS

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Description of the Goal

- The purpose of this proposed FOA is to support applications from Small Business Concerns (SBCs) for clinical trials (i.e., Phase I and II clinical studies) of drugs, biologics, devices, or diagnostics, as well as surgical, behavioral or rehabilitation therapies, that contribute to the justification for and provide the data required to design a future trial to confirm efficacy.

Description of the Outcome

- **Potential Impact?**
 - Applications must aim to generate data that inform a decision whether to continue further clinical development of the proposed intervention or diagnostic.
- **Criteria for evaluating success?**
 - NCATS will keep track of the number of applications that are submitted and funded under this FOA.
 - Analyze the quality of Clinical Trials that are submitted under the FOA.

Description of the Initiative

- **What is the major obstacle/opportunity to address?**
 - This FOA proposal is important as it will address improving the quality of human subject research that is conducted by SBCs under the SBIR/STTR grant program.
 - Applications under this FOA must aim to generate data that inform a decision whether to continue further clinical development of the proposed intervention or diagnostic.
- **Relevance to the NCATS' mission?**
 - This FOA is very relevant as it would address getting more treatments to patients.
- **Brief summary of ongoing research/activity in this area?**
 - NCATS currently accepts SBC clinical trial projects through SBIR/STTR omnibus solicitation and wishes to use this FOA to improve human subjects research for this Small Business program.