Request for Proposal RFP_2018_3942: Seeking Healthcare Providers Interested in Conducting Clinical Studies with a Non-Pharmacologic Treatment for Neonatal Abstinence Syndrome (NAS)

RFP Title
Seeking Healthcare Providers Interested in Conducting Clinical Studies with a Non-Pharmacologic Treatment for Neonatal Abstinence Syndrome (NAS)

Due Date
03/05/2019

Opportunity
Collaboration to conduct clinical studies with a non-pharmacological treatment for neonatal abstinence syndrome.

Timeline
Activity beginning March 2019

Financials
Collaboration agreements to be negotiated.

RFP Description
NineSigma, on behalf of Prapela, Inc., seeks organizations interested in collaborating to conduct clinical studies for assessment and regulatory clearance of a non-pharmacological treatment for newborns diagnosed with neonatal abstinence syndrome.

NineSigma invites interested Ohio-based candidates to promptly submit a brief, non-confidential statement of interest.

Background
Prapela, Inc., one of the winners of the Challenge Phase of the Ohio Opioid Technology Challenge, has developed products with stochastic vibrotactile stimulation (SVS) a sub arousal, stochastic (random) vibration. In pilot studies with results published in PLOS one, SVS has been found to significantly improve relaxation and cardiorespiratory function in pharmacologically treated NAS patients. SVS is non-habit forming and does not disrupt sleep cycles as it stabilizes the brain’s pacemaker neurons responsible for cardiorespiratory function. Stabilizing these neurons can enhance healthy, rhythmic breathing and heart rate which helps babies relax. More information about Prapela and its device are available at Prapela.com.

Prapela is developing the SVS Hospital Bassinet Pad as a medical device for use in hospitals to treat NAS and is releasing its SVS Baby Box to treat irritability after hospital discharge.

Prapela seeks to conduct additional clinical studies with Ohio-based healthcare providers. They are looking for collaborators who are interested in one or more of the following projects:

Project 1. SVS Hospital Bassinet User Study: This is a 2-phase study to determine the impact of the device on the behavior of nurses and physicians treating NAS infants in hospitals. Phase 1 will identify usage and practices among nurses and physicians working in hospitals units with consumer baby products to help treat NAS infants. Phase 2 of the user testing project will focus on the SVS hospital bassinet pad usability and acceptability of the device as a non-pharmacological treatment for NAS infants. Using insights from Phase 1, this initiative will gather more detailed information using an online focus group. An online focus group is an internet-based research technique where panel members respond to questions asked by the moderator and their fellow panel members over a specific time period.

Project 2. SVS Hospital Bassinet Clinical Study: The company is searching for 2 hospitals to conduct a study with 120 newborns pharmacologically treated for NAS to
demonstrate the impact of the technology on medication use, outcomes, cost, and length of stay with a one-month follow-up. This would be followed by a regulatory submission to FDA for marketing clearance. The selected providers would bring resources of a neonatal research hospital including staff to help design and conduct the study and a biostatistician to interpret results. Prapela would contribute devices and financial support, to be negotiated.

Project 3. SVS Baby Box Experience Study: The study objective is to collect information from care providers and mothers at an extended care facility on their experience using the SVS Baby Box to calm irritable babies previously treated for prenatal opioid exposure. In this case, the collaborator would work jointly on the study design and would help collect information about use of the device and impressions about its use. For the study, Prapela would contribute SVS baby boxes, train staff and mothers on their use, and collect information through interviews with participants. No personal information will be collected from mothers or on infants.

Key Success Criteria
Collaboration partners should:
- Be located in Ohio
- Currently be treating NAS newborns in a hospital setting and/or be providing extended care for mothers and babies recovering from opioids

Hospitals interested in collaboration should:
- Have experience in designing and executing IRB review clinical studies
- Be willing to participate in a multi-center study

Area of Interest
Medical Specialties > Laboratory Medicine and Clinical Testing
Statistics and Probability > Clinical Trials

Possible Approaches

Preferred Collaboration Types
To Be Negotiated

Items to be Submitted
Your response should not contain any confidential information.

Your expression of interest should include:
- A description of your organization, resources, capabilities and relevant patient population
- A description of your relevant background and experience with neonatal abstinence syndrome and with clinical studies
- A copy of your CV or resume and other relevant publications
- Indication of which project is of interest

Appropriate responses to this Request
Responses from hospitals, extended care organizations, physicians, or clinicians are welcome. For example:
- You are a health care professional with deep interest in treating neonatal abstinence syndrome.
- You represent a company or hospital that has experience conducting clinical studies.

Award Amount

Attachments
No Files Selected

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