Request for Proposals (RFP) for Investigator-Initiated Research examining opioid overdose reversal in Emergency Department (ED) and Emergency Medical Service (EMS) settings

The prevalence of overdoses involving synthetic opioids including illicitly manufactured fentanyl continues to increase.[1] There are limited clinical and real-world data examining long-acting opioid overdose treatments and the role they may serve for the contemporary management of known or suspected opioid overdose.

As such, proposals to be considered for this RFP must align with the following research interest:
Investigations that explore the safety and effectiveness of nalmefene[#] alone, or in sequence with naloxone, for the treatment of known or suspected opioid overdose in ED/EMS settings.

Instructions for Submission of Research Proposals

Sponsor Investigator Applicants must submit their Curriculum Vitae (CV) and a brief letter of intent that outlines the study concept (study proposal) via email to iitprogram@pharma.com by 5:00 PM ET March 31, 2022. The study proposal should include:

- Sponsor investigator CV (Applicant)
- Institutional affiliation/Study Site(s)
- Research Objective(s)
- Study design, methods
- Target population(s)
- Endpoints and intended analysis
- Estimated study duration and preliminary budget
- Anticipated drug supply required and any funding request

Proposal Review and Response

Applicant proposals will be evaluated by a medical and scientific review committee. Selection of proposals will be based on medical and scientific merit, feasibility, and investigator/site qualifications. Review focus will also be on innovation, cost-efficiency, and translatability to medical practice. Following initial review, a selected set of Applicants will be asked to submit a full study protocol which includes a line-item budget reflective of the fair market costs for executing the research and in context of any requested financial support from all sources. Both a protocol and budget are required for final approval.

Financial support and or drug supply will be issued based upon a fully executed agreement. All approved protocols are expected to result in publication of findings in a peer-reviewed journal.

Additional Information

[#]An Abbreviated New Drug Application (ANDA) has been submitted and is under review by the FDA for Nalmefene, a sterile solution 1mg/ml, 2ml vial for intravenous, intramuscular, and subcutaneous injection.

Sponsor Investigators must be willing to assume regulatory responsibility for the research including obtaining an IND or exemptions granted by FDA as applicable.

Questions regarding the process/requirements for submitting a letter of intent may be submitted to: iitprogram@pharma.com

[1] Ahmad FB, Rossen LM, Sutton P. Provisional drug overdose death counts. National Center for Health Statistics. 2021, https://www.cdc.gov/nchs/nvss/vsrr/drug-overdose-data.htm