ALung Technologies, Inc. Investigator-Sponsored Research

ALung Technologies, Inc. (ALung) offers a regulatory-compliant program for Investigator-Sponsored Research (ISR) based upon good clinical practices (GCPs) and our global corporate code of ethics and compliance policy. ALung promotes the safe and ethical use of the Hemolung Respiratory Assist System (RAS) for scientifically rigorous research by experienced researchers.

Types of Research Supported

ALung reviews proposals for the following types of research that expand our scientific knowledge for the purpose of strengthening the practice of evidence-based medicine:

- Prospective or retrospective study
- Single-center study
- Multi-center study provided a Lead Principal Investigator is appointed study Sponsor and adequate infrastructure is in place for the overall conduct, coordination, and compliance with regulations
- Study measuring economic impact
- Study measuring quality of life including mobilization
- Study with a reasonable rationale, study design, patient population, size, scope, enrollment rate, duration, and statistical plan that demonstrate a high likelihood of completion and publication by the Investigator
- Study conducted on-label under applicable regulatory guidelines and authorities
- Study conducted for off-label purposes under applicable regulatory guidelines and authorities
- Study with a budget that is fair market value (FMV)

Responsibilities of Investigator

The Investigator leads the development, planning, budget, operational and data analysis facets of the research plan. Governing laws, patient privacy, and GCPs must be adhered to at all times. An Institutional Review Board (IRB) or Ethics Committee (EC) must review and approve the research. Informed consent must be obtained in accordance with local institutional policies. Study milestones should be described to ensure levels of commitment are achieved. Periodic updates of the study progress to ALung will be required. Conflicts of interest must be disclosed. Serious complications associated with the Hemolung RAS must be reported to ALung and regulatory authorities. Ensuring quality data, proper data analysis, and statistical reporting on all study endpoints is essential. Upon completion of the study, it is expected that a manuscript, abstract or poster of the study results is drafted in accordance with International Committee of Medical Journal Editors (ICMJE) guidelines and provided to ALung for prior review and comment with reasonable time for feedback.

Responsibilities of the Sponsor

In many cases, the Investigator may also assume the responsibilities of the Sponsor and the same responsibilities above apply. In addition to these responsibilities, the Sponsor:

1) registers the study on www.clinicaltrials.gov (or similar clinical trials registration website)
2) maintains proper staffing to complete the study as defined by the study schedule
3) monitors the data for quality assurance
4) ensures that neither patients nor payers are charged for the Hemolung RAS provided by ALung
5) returns all unused product and loaned equipment provided by ALung
6) manages the reporting of serious complications associated with the Hemolung RAS to ALung, regulatory authorities, and data safety monitoring board (DSMB) or clinical events committee (CEC) *when applicable*

ALung's Role as Manufacturer

ALung is not the Sponsor of an ISR. ALung does not provide resources for study design and protocol development, monitoring or data query for quality assurance, managing the conduct of the study, or performing statistical analysis or medical writing.

ALung may provide funding or equipment to support a portion of the study at fair market value (FMV) rates. ALung may provide comments on the study design but only when requested. ALung commits to provide training on the Hemolung RAS. ALung also has an obligation to report conflicts of interest and funding to meet regulatory requirements.

ALung sales personnel may not be involved in designing, conducting, or contracting any study.

Method for Submitting an ISR Proposal

Research proposals can be submitted to Alethea Wieland, Director of Clinical Affairs, by email: awieland@alung.com. Include the following documents in the submission:

- A completed application form
- A current signed CV
- A separate budget when not included in the application form *(if applicable)*

Upon receipt of the proposal materials, confirmation of the committee review date will be communicated to the Investigator. Results of the committee review will be sent to the Investigator and/or Sponsor. All proposals and accompanying materials will be kept confidential.

If ALung agrees to support the study, the following must be in place prior to study initiation:

1) IRB/EC review and approval
2) Execution of contract including details of milestone payments
3) Certification of device training
4) Listing in www.clinicaltrials.gov or similar website by Sponsor

The executed contract ensures that the roles and responsibilities for developing, executing, and publishing the results of the study are defined as the Investigator's / Sponsor's responsibilities.

ISR Program Questions

Contact Alethea Wieland at awieland@alung.com to address specific questions.