Job Title: **Clinical Research Associate**
Reports to: **Senior Director, Clinical Operations**
Location: **Airway Therapeutics Spain SL;** Madrid, Spain

About Airway Therapeutics, Inc. ("Airway"):

Airway is an emerging biopharmaceutical company developing a novel recombinant human protein to break the cycle of injury and inflammation for patients with respiratory and inflammatory diseases. We have successfully completed a Phase 1b study for the prevention of bronchopulmonary dysplasia ("BPD") in very early preterm born babies and are currently conducting a global Phase 2b/3 trial with clinical operations in the US, Europe, Israel and South America.

Position Summary:

We are recruiting for several CRA positions responsible for guiding and monitoring execution of the clinical protocol and data review for the clinical trial at multiple sites in (1) Spain and (2) Belgium/France, ensuring compliance with all regulatory, GCP/ICH guidelines and contractual requirements, and establishing and maintaining sound clinical and data collection practices. This position will be a Sponsor position while interfacing with Sponsor's CRO and following CRO SOPs.

Key Accountabilities:

- Conduct site qualification visits, presenting the study to the sites, and prepare evaluative reports necessary for the final selection of investigators and study sites
- Collect site documentation required for regulatory submissions and during study execution.
- Conduct clinical trial site initiation visits and prepare reports; advise and train site personnel on sponsor and regulatory requirements for study conduct; participate in site meetings and multicenter investigator meetings
    - Implement study-specific monitoring and reporting procedures, methods, guidelines, and tools
- Working with Sponsor Clinical Operations leadership, proactively encourage and facilitate site enrollment, helping to implement tailored recruitment action plans, and providing feedback to site staff and sponsor Clinical Operations leadership to maintain engagement and momentum in reaching enrollment targets.

- Conduct site monitoring visits and follow-up to ensure that all clinical aspects of the study are being carried out in accordance with state and federal regulations, GCP/ICH guidelines and policies, and identify any deficiencies; prepare on-site monitoring visit reports.
    - Review on-site files and records, case report forms, and source documents for completeness, accuracy, consistency, and compliance; identify deficiencies, and provide remedial training and/or initiate corrective action as required
    - Ensure site documentation is properly maintained and filed in the Trial Master File (TMF) and Investigator Site File (ISF) per GCP and local regulations.

    - Confirm appropriate transmission of SAEs to pharmacovigilance, review case report form queries and problems
- Track study progress including regulatory submissions, subject enrollment, case report form (CRF) completion, and data query resolution.

- Participate in the closeout process of the clinical study and conduct site visits; prepare study closeout visit reports
    - Collect all required investigator/site study documents from selection of site through closeout and ensure they are filed appropriately in the TMF
- Perform miscellaneous job-related duties as assigned

Education and Experience:

- Bachelor's degree, preferably in pharmacy, nursing or biological sciences
- Minimum of 3 years in-patient pharmaceutical CRA experience directly related to the duties and responsibilities specified
- Experience in neonatology and/or pediatrics would be valued
- Strong understanding of clinical research regulations including GCP and ICH guidelines.
- Languages:
    - Required: Spanish, English (written and spoken)
    - French, English (written and spoken)

Work Environment:

- Fast-paced, small organization with large collaborating network
- Offices in Madrid, Spain, Cincinnati, OH and Marietta, GA
- Requirement for participation in conferences and prompt responsiveness to email and phone calls
- Ability to be productive and successful in an intense work environment is critical
- Ability to travel domestically to sites on routine basis