

Clinical Research Associate

Project description

Bloomlife is seeking to hire a freelancer or contractor to take the role of Clinical Research Associate and contribute to the successful clinical validation of its latest medical device product.

Your Role

You are central to the success of our clinical studies. You operate hand in hand with our clinical studies manager to oversee the design, planning, recruitment, and execution of clinical studies to assess the safety and effectiveness of our products.

Your responsibilities include:

- You contribute to the development of study-related documents, including study protocols, Informed Consent Forms, Case Report Forms, study manuals, and coordinate distribution to investigational sites and review committees
- You coordinate activities associated with study start-up, site initiation, follow-up, and execution for all US-based clinical sites
- You manage the interaction with US clinical sites to ensure successful execution of the studies; you organize weekly progress calls and visit clinical sites in the US when necessary and where possible
- You coordinate all study logistics to make sure the studies have the equipment and consumables necessary for successful study execution; you provide first-line technical support to the clinical study teams in case of issues with the equipment
- You monitor, on a daily basis, the integrity of the data (sensor and clinical) collected during the studies, identify possible data issues, and escalate to the technical and engineering team as quickly as possible

Your experience

We're looking for a contractor or a freelancer eager to contribute to a product that impacts the lives of pregnant women globally.

To succeed with this assignment, it will help to have:

- 3+ year experience running clinical trials for medical devices
- Experience designing, setting up, executing, and managing multi-site clinical studies
- Experience interfacing with ethics committees, IRBs, and regulatory bodies
- Working knowledge of Good Clinical Practice for Medical Devices (ISO 14155)
- Familiar with digital health products and connected devices
- Working knowledge of data visualization and scientific software is a plus
- Experience designing and running clinical trials for FDA certification is a plus

- Good communication and interpersonal skills

Timeline & location

The project will start on February 8th, 2021. It will run for 3 months, with a possible extension to a follow-up project for another 3 months.

The assignment is primarily remote with frequent visits (twice per week) to Bloomlife's clinical partner in Phoenix, AZ.