OncoRes Medical

Inspired | Restless | Human | Visionary

Clinical Trials Manager

OncoRes Medical was founded at the intersection of medicine, science and humanity to improve the accuracy of breast-conserving surgery and eliminate the physical, psychological and economic burdens associated with repeat operations.

Our unique, informal culture champions vision, restlessness, and humanity. Knowing we have an open and supportive team means each of us has the freedom to take responsibility and ownership. We have a shared passion to work restlessly, pioneering change to re-imagine the world while remaining grounded in our commitment to science and quality.

Our passion for helping patients focuses us on the patient. We believe that all breast cancer patients deserve the opportunity to move beyond their breast cancer surgery knowing that all the cancer has been removed, the first time. In everything we do, we are thinking about how we can inch closer to a world free from re-excisions... We are going BEYOND BREAST CANCER

Overview:
The Clinical Trials Manager at OncoRes Medical is responsible for managing the successful and timely delivery of clinical trials. The successful candidate will be expected to work with a Clinical Program team and support ongoing research and development at OncoRes Medical.
If you want to use your expertise to help develop a novel, disruptive medical product that will impact the lives of millions of people around the world, get in touch! This is a unique opportunity to get involved in an early, rapidly growing company with significant growth and development opportunities for the right candidate.

Responsibilities:

- Lead all aspects of clinical trial start-up activities (*e.g.*, ethics and governance approvals).
- Support the execution of the trials, working closely with the clinical team in OncoRes and key external parties (*e.g.*, principal and clinical investigators, research nurses, and Clinical Research Organisations).
- Oversight of Trial Master File and Essential Documents.
- Proactively ensure the successful delivery of clinical trials as defined by the clinical development team including:
    - Management of timelines, budgets, and allocation of internal resources ensuring project milestones and deliverables are monitored and achieved.
    - Anticipating, identifying, and managing potential study risks, including implementing contingency plans to ensure minimal disruption throughout the study program.
- Ensure studies are conducted in accordance with applicable guidelines (*e.g.*, standard operating procedures and local; national and international regulations)
- Develop trial-related training material and run training modules.
- Prepare reports reflecting study progression.

- Serve as liaison with participating clinical research sites.
- Contribute to technical analysis of results in relation to clinical outcomes.
- Understand ICH Good Clinical Practice and regulatory guidelines.
- Provide clinical trial support for formal regulator engagements.
- Develop and maintain strong working relationships with investigators and study staff
- Serve as an ambassador to promote OncoRes Medical's core values; we are Inspired, Restless, Human and Visionary.

Qualifications:

- Bachelor's degree or equivalent required, preferably in Life Sciences (e.g., Biology, Chemistry, Biochemistry, Nursing, Pharmacy).
- Experience in successfully delivering Clinal Trials, preferably in the Medical Device sector.
- Post-graduate qualification in Project Management or Business Administration (Desirable).
- Understanding of FDA and TGA guidelines regarding clinical trials including Good Clinical Practice guidelines and ISO 14155.
- Demonstrated knowledge and ability to plan, prioritize, and coordinate the completion of deliverables and tasks, must be highly flexible, have a hands-on approach and be willing to take initiative.
- Ability to effectively communicate through written and verbal means and constructively collaborate with colleagues is required.
- Ability to remain professional and positive in all personal interactions, and work with honesty and transparency while being committed to doing what's best for our patients, customers and company.
- Qualified candidates must be legally authorized to be employed in Australia.

Benefits:

- Comprehensive and competitive remuneration packaging including access to the employee stock ownership plan and phone allowance.
- A flexible and fun workplace where we understand that your life is more than your job.
- A rare opportunity to work closely alongside world-class colleagues and mentors with many collective years' experience in all aspects of medical device development and commercialisation. All of us share a passion to work collaboratively where every voice is heard, and your personal professional development is a high priority.

OncoRes is committed to building and fostering an inclusive, diverse workplace. We believe the differing perspectives and experiences each of us brings inevitably increase innovation and teamwork, flowing into positive tangible outcomes.

To Apply:

Please submit a cover letter and CV addressed to Wes Allen (Clinical Program Manager) to apply.
careers@oncoresmedical.com