Pacific Clinical Research
NETWORK NEW ZEALAND

Clinical Director

At PCRN we are experienced professionals dedicated to improving the health and well-being of our patients. Together, we conduct high-quality clinical trials and pave the way for global availability of innovative medicines and treatments.

REPORTING TO: Chief Executive Officer

DIRECT REPORTS: Investigators (as assigned)

LOCATION: Auckland

1. Why the role exists:

As a skilled and experienced Clinical Director you will lead and oversee the medical team and work closely with the Chief Operations Officer to deliver clinical trials within PCRN. The Clinical Director is responsible for strategic planning, execution, and management of clinical research studies, ensuring they are compliant with the protocol, the International Council for Harmonisation - Good Clinical Practice (ICH-GCP) and local regulations.

The Clinical Director is the technical or division lead of the medical team and will also be assigned as Principal Investigator (PI) on specific studies. **When acting as Principal Investigator, please refer to the Investigator JD for role summary.**

Clinical Director: Maximum of 1.5-2 days per week
Principal Investigator: Balance

2. What you will do:

Responsibilities
General • Provide leadership within the organisation or at assigned sites. • Contribute as a member of the SLT to the development and implementation of the strategic direction of the business. • Be responsible for the resource planning for the medical team. • Support Investigators in the development of recruitment plans, review of CVs and interviews. • Contribute to feasibilities in a timely manner. • Act as Country Lead (CL) on studies and support any Investigators acting in the role of CL on a study. • Own materials and processes for Investigator team. • Onboard Investigators. • Lead the monthly Investigator meetings, including preparing the agenda and providing content. Actively follow-up on action items.

- Conduct 121 meetings with direct reports.
- Develop goals for the Investigator team in line with corporate strategy. Track performance across the Investigator team.
- Develop and lead training of Investigator / Senior Investigator and other staff on medical topics, as required.
- Attend client meetings and conferences as required, to support business development activities.
- Be able to present PCRN network expertise and service offering.
- Support the development of case studies as required.
- Lead process improvement and training depending on findings.
- Identify trends across sites and develop new processes / training. Address training needs within team as they arise.
- Complete all other tasks assigned.

Study Start-up

- Work with stakeholders for oversight of all sites to develop additional relationships that would support recruitment.
- Maintains and expands the PCRN Specialist Network.
- Attend the Start Up meetings to provide medical input to the recruitment strategy and other areas relevant to the efficient delivery of the study. Providing medical input to re-align recruitment for studies tracking behind targets.
- May attend SSVs.
- May attend the SIV for a study if the PI is new to the role or in other circumstances as required.

Study Conduct

- Hold oversight of consent processes and QC across sites.
- Check Investigators are meeting regularly with monitors and all action items are followed up in a timely manner.
- Provide oversight of issues identified during monitoring visits looking for trends that need to be shared with other sites or Investigators, particularly where there may be a safety issue or where additional training, or process improvement may be required.

Study Close Out

- Leads lessons learnt discussions from a medical perspective at the end of studies.

Budget

- Work closely with Finance team to ensure justifications for hiring are within

budget and appropriately approved. • Provide input to budgeting of medical team activities, review and manage medical team utilisation and study realisation across all sites.
Regulatory • Overall accountability for medical team adherence at all PCRN sites to ICH GCP, local regulations, study protocols and PCRN Policies and Procedures, thereby ensuring participant safety and data integrity. • Provide support during preparation and conduct of audits/inspections, and during follow-up. • Ensure PCRN sites provide adequate medical care for participants for any adverse events. • Maintain an overview of Health and Disability Ethics Committee and local Regulatory processes.
Continuous Improvement • Identify and discuss with the PCRN Leadership team any areas in the business where processes and systems can be streamlined, whilst ensuring high quality delivery of products and services. • Make recommendations and initiate team training to ensure continual improvement. • Participate in ongoing training and continuing medical education activities sufficient to maintain NZ medical registration and competency of practice
Health, Safety and Compliance • Fully comply with PCRN Health and Safety Policies and Procedures. • Comply with Health and Safety Policy and Procedures for visitors when on customer premises. • Champion health and safety policy, implementation, and safety culture. • Remain current with any legislative or procedural changes to ensure the business remains compliant. • Identify hazards and work with management to eliminate them. • Regularly review health and safety practices and oversee Health and Safety Representatives.

3. What you will bring to the role

Experience (Essential)

- Significant experience working as a Clinical Trial Investigator.
- Excellent leadership and organisational capability.
- Knowledge of ICH GCP.
- Current Indemnity Insurance.

- Current ACLS certificate.
- Demonstrated ability in the use of the following technology: Computers, Microsoft Office software, copier, and multi-line telephone.
- Fluent in written and spoken English.

Qualifications

- A recognised Batchelor of Medicine Degree if not obtained in New Zealand.
- Registered with the New Zealand Medical Council (MCNZ) – Te Kaunihera Rata o Aotearoa and approved to practice medicine in New Zealand under either a General, Vocational or Special (Clinical Research) scope of practice.

Attributes and Competencies

- Demonstrated capabilities as a leader
- Demonstrated ability to multitask
- Demonstrated ability to be flexible/adapt as daily schedule may change rapidly
- Demonstrated ability to work in a fast-paced environment
- Demonstrated verbal, written, and organisational skills
- Demonstrated interpersonal and communication skills
- Demonstrated problem solving and strategic decision-making ability
- Demonstrated ability to work as a team player

4.Who you will regularly collaborate with

Chief Executive Officer
Investigators
Senior Leadership Team
Clinical Teams
Sponsors & CROs

5. Our expectations

At PCRN we have a clear set of behaviours that we recruit, measure, reward and develop our people against:

I AM Adaptable

I AM Proactive

I AM Curious and Communicative

I AM a Team Player

☐ I have read and understand the job description for my position. I am able to perform all the essential functions of this position.

I agree to comply with the corporate compliance policy and all laws, rules, regulations, and standards of conduct relating to my position. As an employee, I understand my duty to report any suspected violations of the law or the standards to my immediate supervisor.

As an employee, I will strive to uphold the mission and vision of the organisation. All employees are required to adhere to the values in all their interactions with customers and fellow employees.

Employee Name:	
Employee Signature:	
Date:	

The intent of this position description and person specification is to provide a representative summary of the major duties and responsibilities performed by staff in this job classification. You may be requested to perform job related tasks other than those specified.