Position Description – Phase 1 Site Director

Company: Momentum Clinical Research / PCRN
Reports To: Chief Operating Officer
Direct Reports: Site Manager, Clinical Operations (Phase 1), Principal and Sub Investigators.
Location: Auckland (Takapuna Phase 1 Unit)
Date: April 2026

Position Summary
The Phase 1 Site Director is accountable for the end-to-end leadership, performance, and growth of the Phase 1 clinical trials unit.

This role extends beyond traditional site leadership, combining operational excellence in early phase delivery (FIH and complex protocols), direct sponsor and CRO engagement, commercial performance and growth accountability, and strong people and change leadership to stabilise and scale performance.

The Site Director is the single point of accountability for quality, delivery, and financial performance, ensuring the unit is recognised as a high-performing, audit-ready, sponsor-preferred partner.

Key Accountabilities

Site Leadership and Culture
- Lead a multidisciplinary Phase 1 team across clinical, operational, and administrative functions
- Set clear expectations, performance standards, and accountability across all roles
Build a high-performance culture focused on precision, ownership, and continuous improvement
- Lead through change, stabilising legacy practices and embedding consistent operating discipline
- Coach and uplift leadership capability across Site Manager and senior coordinators

Phase 1 Operational Delivery
- Oversee end-to-end delivery of Phase 1 trials, including FIH and complex protocols
- Ensure precision execution across participant safety and clinical oversight, protocol adherence and data integrity, sampling accuracy and timing compliance, and unit flow, scheduling, and capacity utilisation
- Drive performance across recruitment and randomisation, visit execution and protocol compliance, and data quality and query turnaround
- Maintain continuous inspection readiness with strong CAPA discipline and audit response capability

Sponsor and CRO Engagement

- Act as the senior operational lead for sponsors and CROs
- Lead site positioning in feasibility assessments, sponsor presentations and qualification visits, and issue resolution and escalation management
- Build trust and credibility through consistent delivery and transparent communication
- Partner with Business Development to convert pipeline into awarded studies

Commercial Performance and Growth

-Accountable for Phase 1 site P&L performance, including revenue delivery and cost control
-Drive optimisation of conversion rates (screening to randomisation), participant throughput and unit utilisation, and cost per visit and staffing efficiency
-Identify and execute growth opportunities, including new sponsor relationships, expansion of therapeutic capability, and increased study complexity and value
-Contribute to pricing, feasibility, and strategic positioning of Phase 1 capability

Workforce and Capacity Management

- Develop and maintain a fit-for-purpose resourcing model aligned to study complexity and demand
- Ensure appropriate mix of investigators, coordinators, and clinical staff
- Optimise rostering and scheduling to maximise utilisation and minimise bottlenecks
- Lead workforce planning aligned to pipeline and growth trajectory

Quality, Risk and Governance

- Ensure compliance with ICH-GCP, AU/NZ regulatory requirements, and internal SOPs and quality frameworks
- Drive proactive risk identification and mitigation across participant safety, protocol execution, and operations
- Embed robust CAPA processes and eliminate repeat findings
- Lead response to audits, inspections, and sponsor escalations

Change and Transformation

- Lead implementation of standardised operating models and systems
- Drive adoption of new processes, including centralised startup and shared services, and technology platforms such as CTMS, QMS, and recruitment systems
- Stabilise and uplift inconsistent or legacy practices
- Deliver measurable improvement in performance, quality, and efficiency

Key Relationships

<u>Internal</u>
COO, CMO
Research Area Managers
Site Managers and Phase 1 staff

Quality and Risk
Business Development and Start-Up
Finance, People and Capability

External
Sponsors and CROs (senior stakeholders)
Principal Investigators
Vendors and service providers

Qualifications and Experience

- 8–10+ years in clinical research operations
- Significant Phase 1 or early phase clinical trial experience is required, including delivery of complex protocols such as FIH, intensive sampling, and unit-based studies
- Proven leadership of high-control, high-throughput clinical environments
- Strong track record managing sponsor relationships and escalations
- Demonstrated accountability for operational and financial performance
- Experience leading change and performance turnaround environments
- Deep understanding of ICH-GCP and regulatory frameworks
- Tertiary qualification in health sciences, nursing, or related discipline

Personal Attributes

-Operationally precise and comfortable in high-control, high-complexity environments
-Commercially aware with a strong understanding of revenue drivers and performance levers
-Credible leader across clinical, operational, and sponsor stakeholders
-Decisive and accountable with clear ownership of outcomes
-Resilient under pressure and able to lead in high-stakes environments
-Drives change, challenges legacy practices, and delivers measurable improvement

Key Performance Indicators

-Recruitment and randomisation performance vs target
-Protocol compliance and data quality
-Audit and inspection outcomes
-Sponsor satisfaction and repeat business
-Revenue delivery and cost management
-Workforce utilisation and capacity efficiency
-CAPA effectiveness and reduction in repeat findings

Performance Expectation

The Phase 1 Site Director is expected to deliver measurable improvement in operational performance, quality, and commercial outcomes within the first 6 months, including uplift in conversion, utilisation, and sponsor confidence.