# Job Description

**Position**: Associate Director/Director, Global Trial Lead
**Edition:** 1.0
**Department**: Development Operations, Trial Strategy & Delivery
**Reports to**: Head of Program Leadership

## Overview

The Global Trial Lead (GTL) is accountable for the end-to-end delivery of one or more clinical trials, from initial strategy to Clinical Study Report (CSR) completion. This includes leading cross-functional Clinical Trial Teams (CTT), managing budgets, and leveraging matrix leadership to align internal and external stakeholders in achieving trial goals efficiently and to high-quality standards.

## Roles & Responsibilities

### Trial Leadership and Management

- Lead the cross functional Clinical Trial Team (CTT) including roles such as Medical, Biostatistics, Programming, and Data Management.
- Lead the operational Trial Team, including functions such as Start-up Specialists, Clinical Trial Associates (CTA), and Clinical Trial Managers (CTM).
- Manages CTT resources/membership, assign tasks, and ensure deadlines are met.
- Make tactical decisions within scope to ensure that CTT work aligns with program objectives.
- Define and manage CTT goals in collaboration with team members.
- Provide regular updates, reports, and escalations to the Program Lead regarding progress, challenges, risks, and resource needs.
- Review and approve key trial documents, including protocols, amendments, plans, and manuals.
- Oversee vendor selection and manage trial-related contracts and amendments.
- Drive country selection and coordinate responses to IEC/IRB comments.
- Maintain trial integrity by ensuring protocol adherence and addressing data trends.
- Collaborate with the Program Lead on cross-functional clinical development team activities and escalate issues as needed.
- Execute strategies for drug supply, regulatory submissions, and patient recruitment.

### Budget and Planning

- Assist in the development and management of the trial budget.
- Plan and maintain integrated trial timelines from study outline through CSR.
- Develop recruitment projections and approve adjustments as needed with the Project Lead.
- Act as counterpart to the CRO Project Lead/Manager.

**Risk Management**

- Identify and manage trial risks with the CTT + Project Team.
- Oversee maintenance of CTT issue, action and decision logs.
- Assist in audit preparation and ensure corrective and preventive actions (CAPAs) are implemented.
- Act as Subject Matter Expert (SME) for processes within Clinical Operations

| **Core Skills and Competencies** | Associate Director | Director |
|---|---|---|
| Pharmaceutical industry experience with knowledge of ICH/GCP Regulations | Required | Required |
| CNS or TA specific drug development experience and various phases of development | Required | Required |
| Proven leadership experience with a strong focus on people management and developing others | Preferred | Required |
| Matrix leadership experience (ability to lead without authority) | Required | Required |
| Experience mentoring others | Required | Required |
| Program and Project management skills and knowledge of tools and processes | Learning | Developing |
| End-to-end trial planning and execution | Advanced | Expert |
| Regulatory submission knowledge | Proficient | Advanced |
| Develop and monitor key performance metrics | Proficient | Advanced |
| Excellent written and verbal communication skills | Proficient | Advanced |
| Excellent negotiation, collaboration and interpersonal skills with ability to work effectively with others at all levels of the organization | Proficient | Advanced |
| Proven ability to lead and collaborate with cross-functional teams. | Proficient | Advanced |
| Strong trial planning and budget management skills. | Proficient | Advanced |

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|---|---|---|
| Strong program planning and budget management skills. | Learning | Developing |
| Experience in outsourcing and vendor management. | Advanced | Advanced |
| Ability to drive working groups and lead process improvements, champion more efficient and effective methods/processes | Developing | Proficient |
| Strong understanding of clinical trial processes, ICH-GCP regulations, and the clinical drug development lifecycle | Proficient | Advanced |
| Ability to proactively identify risks, develop mitigation strategies, and resolve issues effectively. | Proficient | Advanced |
| Experience managing trials in global settings, with the ability to oversee complex, multi-regional operations. | Proficient | Advanced |
| Stakeholder management skills. | Proficient | Advanced |

Learning – Acquiring knowledge by exploring concepts, practicing fundamentals, and may require guidance or structured instruction.

Developing – Actively improving skills and gaining experience. Knowledge can be applied but may still need support or refinement.

Proficient – Solid, reliable competence. Ability to perform task independently, solve problems effectively, and demonstrate efficiency in using the skill

Advanced – High level of competence. Able to handle complex tasks independently, troubleshoot effectively, and apply best practices.

Signature

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Employee Date (DD-Mmm-YYYY)

Signature

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Manager Date (DD-Mmm-YYYY)