

## Clinical Operations Program Director - Biotech

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Company: Proclinical

Location: Brussels

Category: computer-and-mathematical

Proclinical are representing a medium sized, global biotech who are expanding rapidly due to the significant products that are coming through in our clients pipeline. As a result, they're seeking several Clinical Operations Program Directors to strengthen our clients Global Clinical Trial Operations team. The Clinical Operations Program Directors is responsible for the oversight of clinical-related activities within a specific therapeutic indication for an asset or across all indications for an asset. The Clinical Operations Program Directors co-leads the Clinical Development department and co-owns the Clinical Development Plan. This role is crucial in driving the execution of the clinical program in collaboration with the Clinical Development department.

### Key Responsibilities:

- Accountable for all clinical-related aspects within the assigned therapeutic indication/program.
- Create the CDP in collaboration with the Medical Development Lead, Project Manager and other Clinical Development representatives.
- Act as primary point of contact for all clinical-related activities for a given indication or across asset indications.
- Lead the Clinical Development meetings, supported by the PM.
- Ensure that clinical trials are executed according to the CDP, following the company procedures and processes and conducted in compliance with ICH-GCP and other

applicable legislation.

- Identify risks of missing team goals, timelines or spend expectations, ensure that these are reflected in applicable risk registries and drive their mitigation.
- Oversee the clinical trial budgets, contribute to timeline and resource requirements and inform the PM in case the timelines or budget deviate from projected.
- Support continuous improvement processes and consistency.
- Act as line manager of Clinical Trial Managers (CTMs) and/or Clinical Trial Associates (CTAs).

#### Requirements:

- Experience with overseeing FiH programs through to commercial (Phase I-IV)
- BSc or MSc. PhD degree is a plus.
- Minimum of 10 years of leading experience in Clinical Development/ Operations within a biotech/ pharma
- Experience in working in an outsourced model, including overseeing CROs and vendors.
- Strong interpersonal and stakeholder management skills.
- Proven Clinical Operations experience in a relevant global leadership position in the pharmaceutical/biotech industry.
- Strong organisational skills, able to manage multiple and varied tasks and prioritize workload.
- Strong verbal and written English communication skills.
- Thorough knowledge of ICH GCP guidelines and other applicable regulatory requirements and guidelines.
- Rare diseases experience would be a plus.

#### About Proclinical:

Proclinical is a leading recruiter in the life sciences sector, dedicated to pairing exceptional talent with top positions globally. Want to stay updated? Follow us and check out our website for live roles and updates [www.proclinical.com](http://www.proclinical.com)

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