# Job Title : Clinical Program Manager

OCTIMET Oncology NV is a company that acts as a translational accelerator, focusing on creating value for investors and patients by providing rapid clinical proof of concept for cancer therapies through innovative clinical development strategies and patient centered biomarker approaches. The current focus is on its clinical stage asset OMO-1, a highly selective small molecule MET inhibitor that will be developed with specific biomarkers.

In order to strengthen our team, we are currently looking for a **Clinical Program Manager**.

## Minimum Requirements

- Master in Life Sciences (Biomedical Sciences, Pharmacy, Biology, Chemistry, Bioengineering or equivalent)
- 5 years of clinical research experience as Clinical Program/Study Manager within pharmaceutical industry (Sponsor/CRO)
- Solid expertise in vendor/project management and experience with clinical study/project-related systems & tools
- Excellent oral and written communication in English
- Strong organisational skills, result-oriented and solution-driven
- Proven teamwork and collaboration skills
- Flexible and dynamic, dealing with change as an opportunity
- Based in Beerse office, Belgium, at least 4 days a week
- Ability to travel nationally and internationally
- Background in oncology clinical studies is a plus
- Experience in (start-up) biotech environment is a plus
- Broader understanding of the drug development process is a plus

## Internal and External Contacts/Customers

- Primary contact for CRO and other vendors related to the assigned clinical studies to ensure high quality oversight
- Primary contact internally for all operational clinical study-related activities
- A key member of the Clinical Project Team

## Reporting Relationship

Reports directly to COO

## Key responsibilities

The Clinical Program Manager is responsible for all clinical operational aspects related to the assigned global clinical studies from initial setup until study closure and final reporting. Clinical-study-related responsibilities include:

- Operational management within scope, timelines and budget of different clinical studies, aligned with the overall drug development program
- Risk management of the assigned clinical studies including risk identification, risk assessment and risk mitigation strategies
- Selection, management and oversight of the CRO and other directly managed vendors assigned to the clinical studies
- Ensure clinical studies are conducted in compliance with ICH-GCP and other applicable regulations and guidelines, as well as with OCTIMET quality procedures

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- Review and/or approval of study-related documents and operational plans, including regular revisions during study conduct
- Review of study-related operational reports and data listings during conduct of clinical study to ensure reliable data quality and pro-active issue identification and resolution
- Ensure proper and timely filing and archiving of clinical study-related documents including oversight of TMF maintenance
- Proactively track patient recruitment including identification and implementations of measures preventing recruitment delays
- Ensure timely availability of study drug on site through cross-functional interaction with CMC experts and clinical supply vendor
- Report internally on all operational aspects of the assigned clinical studies
- Involvement in further development of clinical-related procedural documents and setup of process improvement initiatives

**OCTIMET Oncology NV offers**

- A competitive salary package including benefits
- A dynamic work environment in a growing biotech company

To apply, please send your motivation letter and CV to:

OCTIMET Oncology NV
JLABS - Turnhoutseweg 30
2340 Beerse – Belgium
info@octimet.com