About ITM

ITM is a privately owned biotechnology and radiopharmaceutical group of companies dedicated to the development, production and global supply of targeted diagnostic and therapeutic radiopharmaceuticals and radioisotopes for use in cancer treatment. We are developing a proprietary portfolio and growing pipeline of targeted treatments in various stages of clinical development addressing cancers such as neuroendocrine cancers or bone metastases. Our main objectives are to significantly improve treatment outcomes and quality of life for cancer patients through a new generation of Targeted Radionuclide Therapies in Precision Oncology. The headquarters are located in the heart of the research center of the Technical University of Munich (TUM).

We would like to fill the following permanent vacancy in a hybrid working model in Garching as soon as possible

Lead Clinical Research Associate (f/m/d)

Your role

Your profile

- Oversee CRO monitoring activities for clinical trials, ensuring compliance with regulatory standards, protocols, timelines, and ICH-GCP. Track performance and compliance metrics for CRO CRAs and sites
- Act as the primary contact for CRO CRA Managers and CRAs, ensuring effective communication and coordination throughout the trial
- Review and approve monitoring visit reports, metrics, protocol deviations, and corrective actions, ensuring compliance and identifying trends or issues
- Develop and implement the Clinical Monitoring Plan (CMP), including risk-based strategies, monitoring tools, and CRA training materials
- Identify, assess, and mitigate study risks throughout the trial, ensuring effective risk management strategies are in place to proactively address potential issues. Ensure alignment with risk-based monitoring models
- Contribute to the creation and maintenance of study-specific documents and systems (e.g., Protocol Deviation Plans, IRT and IRT Manuals, Data Entry Guidelines, EDC, CTMS)
- Oversee site feasibility, selection, setup, and activation, including budget reviews, feasibility questionnaires and site activation checklists
- Ensure proper site close-out, preparation for COVs, and follow-up on open items for resolution

- A bachelor's degree in a scientific/medical discipline or equivalent
- At least 3 years of clinical research or equivalent experience, with proven experience in clinical monitoring or clinical trial management
- Experience monitoring oncological clinical trials, with experience in radiopharmaceutical development being an advantage
- Deep understanding of ICH-GCP, relevant regulations, and other applicable regulatory frameworks
- Strong communication and leadership skills, including experience managing CRO relationships
- Excellent problem-solving abilities and a proactive approach to risk management
- Ability to work cross-functionally within a team environment and provide constructive feedback
- Proficiency with clinical trial management systems (CTMS), EDC, IRT systems, and eTMF
- Fluency in written and oral English

- Contribute to the development and updates of SOPs for trial monitoring and sponsor oversight processes
- Proactively participate in trial team meetings (Kick-off, Trial Team, Protocol Deviation Reviews) to provide updates and insights
- Ensure internal quality control of eTMF documents related to site, monitoring, and central trial materials
- Assist the CTM with sponsor oversight tasks, including ICF development, audit preparation, and follow-up actions
- Manage CRO vendor performance to ensure the quality of deliverables aligns with sponsor expectations. Monitor vendor activities to ensure they meet agreed-upon milestones, timelines, and quality standards
- Attend sponsor oversight visits as applicable to ensure compliance with monitoring plans.
- Provide training and mentorship to CRO CRAs, if required, ensuring alignment with sponsor expectations and regulatory guidelines (i.e. specific to radiopharmaceuticals)
- Proactively manage audit trails and ensure trial readiness for inspections. Ensure that all study-related documentation is complete, accurate, and accessible for audit purposes
- Escalate compliance and performance issues to the CRO, ensuring timely resolution and corrective actions

- For Late-Phase Studies: Ensure coordination with the central monitor, facilitating communication and support as required

Our offer

- Exciting challenges in an up-and-coming and fast-growing company with a high degree of creative freedom
- An open working atmosphere in an international corporate culture with short communication channels
- Comprehensive onboarding programme
- Flexible working hours with home office options
- Attractive special payments
- Just a good salary? Not with us! We also offer you
    - Employee participation programme
    - Job bike or subsidised job ticket
    - Above-average contribution to the company pension scheme
    - Individually tailored further training programme (including German and English courses)
    - Health promotion programmes (e.g. EGYM Wellpass, subsidy for local fitness studio, sponsorship of sporting events, various lifestyle coaching sessions)

ITM is an employer that ensures equal opportunities. Qualified applicants are encouraged to apply and will be considered during the selection process regardless of gender, age, national or ethnic origin, religion or belief, disability, sexual orientation, gender identity, or any other characteristic protected under the German General Equal Treatment Act (AGG).

If you are a qualified individual with a disability or are otherwise covered under applicable law and are unable to apply through our online application process, you may request a reasonable accommodation. Please contact career@itm-radiopharma.com.

When you apply, please let us know your earliest possible starting date and your salary expectations. You can submit your CV in German and English in docx or pdf format.

Apply now

Contact

Anastasia Dauns

career@itm-radiopharma.com

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People & Culture
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Note for recruitment agencies
Please note that we do not accept unsolicited applications or offers of assistance. The telephone number given in the advertisement is intended exclusively for applicants and should not be contacted for any other purpose. Thank you very much!

More about ITM

With us, you will have the opportunity to work in an international environment on ground-breaking projects that can have a significant impact on cancer care worldwide. We are looking for dedicated, talented and passionate professionals who share our vision and want to help shape the future of oncology. If this exciting challenge appeals to you and you would like to contribute to realising our common goal, please do not hesitate to send us your application. We look forward to hearing from you!

For more information please visit: www.itm-radiopharma.com