AiCuris
Anti-infective Cures

## Committed to making the difference

AiCuris – founded in 2006 – is a specialist for infectious diseases. Its focus comprises discovery, research and development of novel antiviral and antibacterial agents in the indications human cytomegalovirus, herpes simplex virus, hepatitis B virus, adenovirus, and (multi-)resistant bacterial infections treated in the hospital. With its highly innovative pipeline, AiCuris addresses specialist markets and severe, potentially life-threatening infections with high medical need. Major steps for the company were signing a license agreement with Merck & Co. (MSD) and the marketing authorization for Prevymis™ (Letermovir) in the US and Europe.

To support our development team we are looking for a

# Clinical Trial Manager (m/f/d)

*(in full-time)*

The role is to manage, coordinate and supervise all processes regarding clinical trials (Phase 1–3) in collaboration with the AiCuris project team, medical experts, service providers (CROs/ CMOs), and ethical / regulatory bodies. As experienced Clinical Trial Manager, you will take over the responsibility for the proper and high-quality execution of our clinical trial management from planning to execution and the monitoring of all processes related to the trial.

## Responsibilities

- Manage, implement, coordinate, and supervise all processes needed for clinical trial start-up, trial conduct and trial close-out from sponsor's perspective
- Support trial centre and patient recruitment, take care of the cooperation with the trial centres, being their central sponsor contact person throughout the entire project
- Contract management with trial centres and CROs as well as other external service providers
- Supervise CRO's and other external service providers' performance with respect to implemented processes, quality, timelines, milestones and costs
- Track and supervise trial budget and data quality
- Prepare data, be responsible for the trail documentation and support the creation of presentations, trial documents and publications
- Organise, support and accompany audits at trial centres and external service providers
- Work closely with internal functions such as medical affairs, regulatory affairs, pharmacovigilance, pharmacokinetics and external service providers (e.g. data management, statistics, monitoring, central laboratories)
- Identification and optimisation of processes to increase quality and effectiveness; work on the further development of the departmental internal SOP system by writing and reviewing SOPs

## Skills and qualifications

- Scientific or medical background (university degree or experience in a medical profession, e.g. as a nurse)
- Advanced knowledge in pharmaceutical business (5+ years)
- 3+ years of experience in planning and conducting international clinical trials, preferably as Clinical Trial Manager, Project Manager or in a comparable position
- Familiar with applicable local and international law and guidelines (e.g. ICH-GCP)
- Familiar with EDC systems

AiCuris Anti-infective Cures GmbH
phone: +49 202 317 63 2599

Attn.:
Mrs. Daniela Boshoven
fax: +49 202 317 63 1177

Friedrich-Ebert-Str. 475/ Building 302
email: jobs@aicuris.com

D-42117 Wuppertal
web : www.aicuris.com

- Good organisational and communication skills, team player, capable of setting priorities and to manage high workload, used to working in a proactive manner
- Positive and constructive attitude, people management competencies and trustworthiness
- Business-fluent in English; German skills would be beneficial

## What we can offer

We offer an exciting and challenging job in an innovative company with a promising R&D portfolio and a highly motivated team exhibiting many years of Big Pharma and Biotech R&D experience.

## How to apply

Interested to join our team? Then apply online using our application form. If you have any questions, please do not hesitate to contact us at +49 202 317 63 2599.

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