Clinical Trial Manager
Predicine Inc., Hayward, California
Job ID: 000036

Predicine Inc. is an international precision medicine organization that is committed to developing the first- and best-in-class precision diagnostics products to enable precision medicine and to address the unmet medical needs in US, China, and worldwide. At Predicine, we believe that people are our most vital assets and we are dedicated to creating a great place to work. We value a culture of innovation, integrity, responsibility, productivity, and teamwork, and invite people who share the same values to join us.

The position

We seek a highly motivated and talented individual to lead the capacity building effort of clinical trail management at Predicine. The incumbent will be responsible for coordinating the operational aspects of study operated at Predicine, closely working with internal R&D and operation team and customer PI to ensure studies are carried out according to technic/Quality/Timeline guide. The successful candidate is expected to effectively develop and execute on innovative projects, publish exciting research in high quality scientific, technical or medical journals, present at professional meetings and promote collaborative efforts to push precision translational sciences forward. This individual is expected to be, or develop into, externally recognized expert in precision diagnostics and medicine.

As a Clinical Trial Manager, you are expected to:

- Coordinate all operational aspects of a study; including development of study timelines and metrics
- Prepare study-related documents (e.g., site-specific informed consent, investigator contracts, and site payments, study tools/worksheets, monitoring plan, laboratory and sample processing manual, CRF completion guidelines, site monitoring report, etc.).
- Ensure studies are carried out according to the study protocol, SOPs, and ICH/GCP regulations and study specific manuals and procedures.
- Develops and manages study budget and maintains it within financial goals.
- Develop and maintain strong working relationships with investigators and study staff
- Be a subject matter expert on clinical operations and assist in the training of CRAs, CTAs and CRO personnel on protocols and practices

- Work with customer to provide timely project update and address questions and requests
- Generate study report and deliver to customer

Who you are

In adding new members to our team, we look for people who are also inspired by our mission and who would fit in well with the collaborative, rigorous and entrepreneurial spirit of the company culture. Because we know that people are critical to our success in bringing novel diagnostics and medicines to patients, we are dedicated to creating a great place to work and to providing our people with programs, services and benefits that would allow them to bring the best to the business and to their personal and professional growth.

- Bachelor's degree or equivalent combination of education/experience in science or health-related discipline
- Minimum 3 years of clinical trial Industry experience within in vitro diagnostics (IVD) highly preferred; pharmaceutical, biologics or medical device experience also acceptable.
- Minimum of 2 years direct trial management experience.
- Thorough knowledge of GCP, ICH guidelines and other US and international clinical regulatory requirements.
- Working experience with an electronic data capture system and CTMS/LIMS system
- Demonstrated ability to develop positive working relationships with individuals and teams internally and externally
- Ability to work independently as well as part of a cross functional team
- Excellent problem solving ability necessary
- Excellent written and verbal communication skills
- Flexible attitude to adjust to changing client and regional needs
- Ability and willingness to international travel 25% of the time.

This is an exciting opportunity to participate in, and to enable, our vision of transforming healthcare through development of innovative technologies. If you are looking for opportunities to accelerate your growth and the growth of a company, and to make a positive and immediate impact on the society, please submit cover letter and resume to: hr “at” predicine “dot” com.

Predicine is an Equal Opportunity Employer.