Project Manager

At Burning Rock Dx- Irvine, California

Burning Rock Dx LLC (NASDAQ:BNR) is searching for a Project Manager to join our team who will be responsible for supporting the Burning Rock Dx US team projects.

What you'll do:

- Manage key initiating, planning, executing, controlling, and closing processes; develop and implement project plan; build team ownership and commitment to project plan.
- Develop detailed project schedules for clinical studies utilizing a standard MS project template, manage critical path and dependencies closely, ensure schedule is maintained and communicated effectively throughout the organization.
- Use internal project management and finance systems to update project milestones, study timelines, and key project data; ensure data is up-to-date and an accurate reflection of the current state of the project.
- Drive identification of risks and issues, facilitate team in the creation of mitigation strategies to reduce overall risk profile.
- Ensure all Clinical core team members are working to meet the expectations of the team's schedule and that their functional management team is engaged when issues or exceptions occur that need to be managed at a broader level. Identify and remove barriers as needed to ensure functional teams stay on track.
- Be responsible for team and cross-functional budget, schedule, and risk related communications. Inform and present project progress and known risks to leadership. Communicate and influence resolution of cross-functional budget or capacity issues.
- Manage pharmaceutical clinical trials for precision oncology companion diagnostic devices; drive timeline and deliverables with both internal and external stakeholders.
- Work with site General Manager to develop clinical research study plan and execute accordingly.
- Support FDA regulatory submission projects for IVD products.
- Gather input from cross-functional teams and create plans to help the team produce deliverables on schedule.
- Oversee and resolve operational aspects of clinical trials in conjunction with project teams and in accordance with standard operating procedures (SOP), good clinical practice (GCP) and specific country regulations such as site and vendor selection, and prepare clinical trial budgets.
- Monitor progress and follow up with team members and line managers when issues develop.
- Influence others to achieve positive results and collaboration.
- Develop additional project management tools to improve clinical trial performance.

What you'll bring to our team:

- Bachelor's Degree in Biology, Biostatistics, Biological Sciences, Health Sciences, or related field.

- Minimum 2 years in execution and management of clinical research studies for medical products.
- Ability to work in a highly matrixed and geographically diverse business environment.
- Ability to work within a team and as an individual contributor while leveraging and/or engaging others to accomplish projects.
- Strong verbal, written communications, and interpersonal skills with ability to effectively communicate at multiple levels in the organization.
- Multitasks, prioritizes and meets deadlines in timely manner.
- Strong organizational and follow-up skills, as well as attention to detail.
- Strong sense of urgency & organizational skills;

Preferred skills:

- Master's degree
- PMP Certification
- Prior history working in an FDA and/or ISO regulated development environment; specifically, ISO 13485
- Familiarity with NGS platform strongly preferred
- Excellent knowledge of ISO and local regulations and required for clinical trials
- Strong work ethic to generate high quality work under tight deadlines
- Demonstrated leadership and self-motivation.

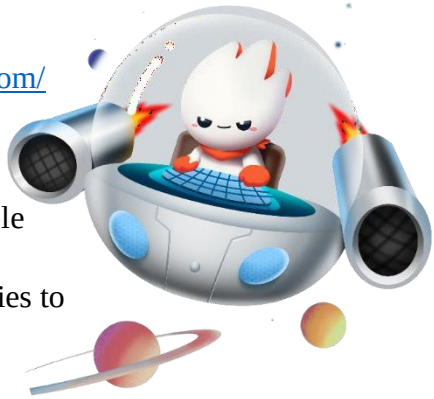
About Us:

- Our business consists of **i)** NGS-based therapy selection testing for late-stage cancer patients, with the leading market share in China and over 300,000 tissue and liquid- based tests completed cumulatively, **ii)** Global pharmaceutical services on biomarkerdetection and companion diagnostics developing, and **iii)** NGS-based cancer early detection, which has entered into commercialization stage in China.

- Founded in 2014, we have evolved from a startup into a pioneer of global cancer detection and have been constantly expanding our business layout. We focus on cancer detection services for patients, healthy people and Biopharma Partners. Our product portfolio can meet the requirements of various clinical circumstances, from detection for a specific cancer, to pan-cancer detection.

- We have four offices around the world, including Guangzhou, Shanghai, Beijing and California and over 12,000 square meter molecular pathology and NGS laboratory. In 2020, we set up the laboratory in California and received both CLIA certification and CAP accreditation.

- We have demonstrated our unique technical strength by presenting our studies in prestigious academic journals and international conference. Our oncopanel shows excellent clinical performance in FDA-led study, delivering high sensitivity and specificity.
- We have maintained close strategic cooperation with Illumina in several areas. We also cooperated with Biopharma partners to conduct global clinical studies, and provide world leading genetic testing service. Biopharma Partner Services include genomic data solutions, central lab testing, CDx Development & commercialization, and precision patient recruitment.
- Check out our website for more information! https://us.brbiotech.com/



In addition to working with a great team of smart and energetic people, we also offer a very competitive benefits package. We care about our people as they are the key to our success. We provide an open and friendly work environment where we empower people and provide them with opportunities to develop their long term career.

If you would like to learn more about this role, please contact Ying Tang at ying.tang@brbiotech.com