Clinical Trial Manager

Reports to: Associate Director, Clinical Operations

Classification: Exempt

Company:
CymaBay Therapeutics, Inc. (NASDAQ: CBAY) is a clinical-stage biopharmaceutical company focused on developing therapies for liver and other chronic disease with high unmet medical need. The Company's lead program is seladelpar, a potent, selective, orally active PPARδ agonist currently in clinical development for the treatment of patients with the liver diseases primary biliary cholangitis (PBC), NonAlcoholic SteatoHepatitus (NASH), and Primary Sclerosing Cholangitis (PSC).

CymaBay has previously announced positive data from its Phase 2 study of seladelpar in patients with PBC and following successful discussion with the FDA and EMA has advanced into a global Phase 3 registration program. CymaBay is committed to bring this program to successful global approvals and to retain full global rights to launch and commercialize seladelpar for the treatment of PBC. In addition, the unmet medical need and the significant market size of NASH represents a unique opportunity for CymaBay and the Company commenced a Phase 2b Proof of Concept Study in 2018 in that indication. This study was fully enrolled ahead of time and first results are expected in the second quarter of this year. PSC represents a third exciting opportunity for seladelpar in an additional orphan liver disease with a very high unmet medical need.

CymaBay is well funded and has the financial strength to meet its ambitious programs. For more information, please visit www.cymabay.com.

Summary:
The Clinical Trial Manager (CTM) will provide collaborative leadership for their assigned clinical studies. The CTM will work with other CymaBay functional area leads including Data Management, Medical Safety, Biostatistics, Finance and Regulatory. This role will oversee management of full service CROs and specialty vendors.

Essential Functions and Job Responsibilities:

- Oversees all operational aspects of assigned clinical studies from site selection, start-up, enrollment, study maintenance and close-out
- Works cross functionally with other departments such as Regulatory, Medical Safety, Data Management and Finance
- Primary contact to manage full service CRO and specialty vendors to conduct clinical studies
- Identify risks to the study timelines and/or conduct, propose mitigations and implement mitigations with team and manager support
- Ensure proper site training and management, provides ongoing oversight of compliance with study protocols
- Responsible for keeping studies on time and within budget
- Prepare or work with CRO to prepare reports, data summaries and study status metrics
- Monitors compliance with SOPs, FDA regulations and ICH/GCP guidelines

- Organize and lead study meetings including weekly cross functional meetings and Investigator Meetings
- Track study progress, provide status reports weekly and represent the study in program level meetings
- Collaborate with and mentor other clinical operations team members
- Review and revise Standard Operating Procedures (SOPs)
- Prepares and reviews study related plans and documents including informed consents, monitoring plans, laboratory manuals and clinical site procedures manual with a low level of supervision
- Participate in EDC and IWRS set-up, case report form design, user acceptance testing, completion guidelines development and other related activities
- Monitor clinical data entry progress and follow up on incomplete data entry and/or outstanding queries
- Work closely with CRO team to oversee clinical sites
- Establish and maintain communication with clinical investigators and study teams
- Monitor clinical site protocol deviations, clinical data entry and other activities to identify areas for improvement
- Ensure compliance with protocol, overall clinical objectives and regulatory requirements
- Complete other responsibilities as assigned

Minimum Qualifications:

- BA/BS or equivalent training and/or experience in life sciences or related technical degree
- 8+ years of clinical study experience with 4+ years at a sponsor company preferred
- 3+ years of team mentorship and/or line management experience
- Experience in global multi-site trials preferred
- Clinical trial management experience in phase 2 and/or 3 clinical setting
- CRO and vendor management experience
- Excellent written, oral and listening skills with the ability to operate well in a team environment