United States Jobs Expertini®

Senior Clinical Trial Manager

Apply Now

Company: BioPhase

Location: United States

Category: other-general

BioPhase Solutions specializes in recruiting top talented professionals for Southern California's Life Sciences community. We are currently looking for an ONSITE Sr. Clinical Trial Manager to work for a leading San Diego area biotech company.*Must be local to San Diego, CA.Key Responsibilities:· Oversee the performance of CROs and third-party vendors, including co-monitoring, to ensure compliance with study protocol and in accordance with scope of work; identify areas of concern and escalate to Clinical Operations Managers. · Perform initial review of CRO and other third-party study vendor invoices for correctness. · Develop and maintain good working relationships with CRO, investigators and study staff. · Perform clinical data review of data listings and summary tables, including query generation.· Assist with third-party vendor training on protocols and practices. Coordinate the logistics of product readiness with sites and internally. Work cross-functionally with product manufacturing, QA and supply chain management, to coordinate site training, product delivery, supply management to ensure readiness and product availability prior to patient treatment. · Ensure studies are carried out according to the study protocol, SOPs, and ICH/GCP regulations and study-specific manuals and procedures. · Ensure timely response to queries and monitoring discrepancies. · Plan and conduct investigator meetings as directed. · Manage the investigational product (IP) and non-IP study drug accountability and reconciliation process. · Review and/or approve IP release packages. · Review key study quality metrics (e.g. patient eligibility, primary endpoint data, etc.) and determine appropriate action in conjunction with study team. · Prepare and/or review study-related documents (e.g., Monitoring Plan, Laboratory Manual, Patient Diary, Pharmacy Manual, CRF

Completion Guidelines, etc.). · Track and report on current progress of the study including site activation, patient enrollment, monitoring visits and data submission backlogs. · Contribute to the preparation of clinical protocols, amendments, informed consent forms, study manuals and guides, electronic case report forms, and any other clinical research related documents. · Participate in the planning of QA activities, coordinating the resolution of applicable audit findings. · Ensure audit-ready condition of clinical trial documentation including central clinical files; review monitoring visit reports to ensure quality and resolution of site-related issues; coordinates and assist in the planning of regulatory or ethics committee activities, as appropriate. · Prepare/review site study documents (i.e., site-specific informed consent, study tools/worksheets, investigator contracts, and site payments). · Manage clinical monitoring activities (including approval of visit report templates, monitoring plan, etc.) ensuring compliance with ICH/GCP and applicable regulations, including the management through resolution (e.g. CAPA) of any site or study level issues, deviations, etc. · Participate in the selection, training, and evaluation of study personnel (contract and internal) to ensure the efficient operation of the function. · Collaborate with cross-functional teams (e.g. Medical Monitor, Regulatory Affairs, CRO, vendors and Investigators/site staff). Education/Experience Requirements:Bachelor’s in Life Sciences or equivalent. Graduate degree preferred.Therapeutic experience in autoimmunity is strongly preferred.Proven experience in early phase clinical trials.Thorough knowledge of clinical research concepts, practices, FDA regulations and ICH guidelines regarding drug development and data management methods.5 or more years' experience managing clinical trials as the sponsor is preferred; prior working experience at a site or in a CRO is a plus.Strong site management and CRO management skills required.Experience monitoring sites and conducting other site management activities.*Travel requirement up to 30%What we offer:As we work to develop innovations that take care of others, we also work to care for our teammates’ professional and personal growth and well-being.· Full support and career-development resources to help you reach your potential· A diverse and inclusive community of belonging, where teammates are empowered to bring ideas to the table and actApply now and let's make work better!www.biophaseinc.com

Apply Now

Cross References and Citations:

1. Senior Clinical Trial Manager Muscatjobs Jobs United States Muscatjobs ↗
2. Senior Clinical Trial Manager Nightshiftjobs Jobs United States Nightshiftjobs ↗
3. Senior Clinical Trial Manager Airconditioningjobs Jobs United States Airconditioningjobs ↗
4. Senior Clinical Trial Manager Thechatgptjobs Jobs United States Thechatgptjobs ↗
5. Senior Clinical Trial Manager Devopsjobs Jobs United States Devopsjobs ↗
6. Senior Clinical Trial Manager Turkeyjobs Jobs United States Turkeyjobs ↗
7. Senior Clinical Trial Manager Maxillofacialjobs Jobs United States Maxillofacialjobs ↗
8. Senior Clinical Trial Manager Finddriverjobs Jobs United States Finddriverjobs ↗
9. Senior Clinical Trial Manager Pinkcollarjobs Jobs United States Pinkcollarjobs ↗
10. Senior Clinical Trial Manager Iosjobs Jobs United States Iosjobs ↗
11. Senior Clinical Trial Manager Fresherjobs Jobs United States Fresherjobs ↗
12. Senior Clinical Trial Manager Whitecollarjobs Jobs United States Whitecollarjobs ↗
13. Senior Clinical Trial Manager Melbournejobs Jobs United States Melbournejobs ↗
14. Senior Clinical Trial Manager Blockchainjobs Jobs United States Blockchainjobs ↗
15. Senior Clinical Trial Manager Technologyjobs Jobs United States Technologyjobs ↗
16. Senior Clinical Trial Manager Physiotherapistjobs Jobs United States Physiotherapistjobs ↗
17. Senior Clinical Trial Manager Findremotejobs Jobs United States Findremotejobs ↗
18. Senior Clinical Trial Manager Realestatejobsnearme Jobs United States Realestatejobsnearme ↗
19. Senior clinical trial manager Jobs United states ↗
20. AMP Version of Senior clinical trial manager ↗
21. Senior clinical trial manager United states Jobs ↗
22. Senior clinical trial manager Jobs United states ↗
23. Senior clinical trial manager Job Search ↗
24. Senior clinical trial manager Search ↗
25. Senior clinical trial manager Find Jobs ↗