JOB DESCRIPTION – Clinical Research Manager

Cognoa is a digital health company that is using AI to change the standard of care in pediatric behavioral health. By increasing access to timely developmental and behavioral health screening and diagnosis for conditions like autism spectrum disorder, Cognoa ensures children receive the right support during the critical window when interventions have the greatest chance for improved lifelong outcomes.

Cognoa's app guides parents through a clinically-validated assessment that can identify signs of delay, as well as risk for autism and ADHD. Cognoa is supporting the development of digital diagnostics and a digital therapeutic.

Cognoa is seeking a Clinical Research Manager to support clinical studies initially in autism spectrum disorder, and then in ADHD and other neurobehavioral conditions.

Please direct inquiries and resumes to Badri Rengarajan at Cognoa (badri@cognoa.com). For more information, view cognoa.com.

Responsibilities

- Clinical operations lead for managing and executing study protocols
- Act as a project manager for clinical trial operations, including crafting and maintaining study timelines, formulating budget, enabling payments, managing vendors, and monitoring study and site status (including timelines and budget)
- Assist in development of protocol
- Assist in investigator and site selection
- Negotiate study site budget and contracts
- Conduct study initiation visits
- Develop case report forms
- Build and maintain study documents (e.g., protocol (and amendments), informed consent forms, regulatory forms and reports, adverse event reporting forms, monitoring plan, data management plan, study agreements and budgets, clinical study reports, etc.)
- Work with sites and IRBs/IECs for study and study material approvals
- Assist with creation and maintenance of SOPs
- Create and maintain training materials
- Serve as primary liaison with clinical study sites, including resolving site issues
- Help review and select vendors
- Plan and execute investigator and other study meetings
- Track, catalyze, and maintain enrollment
- Ensure supply of intervention (e.g., digital therapeutic)
- Engage in trial monitoring/site audits, risk identification, and risk mitigation
- Manage quality of clinical study data collected by study sites and vendors. Issue and resolve queries. Engage in source data verification and writing monitoring visit reports.

- Engage with site staff (or parents as appropriate) to assist with video creation and transmission
- Conduct study closeout activities
- Assist in review and preparation of data and study reports
- Work with team members across functions (e.g., clinical, regulatory, statistics/data science, engineering, finance)
- Create and deliver presentations to internal and external audiences as required

Background and Experience

- 5 or more years of clinical research experience, preferably with experience in a biopharmaceutical/device/diagnostic company or CRO
- Knowledge of GCPs, ICH guidelines, regulatory guidelines and regulations
- Interest in autism and neurobehavioral health is favorable though not necessary
- Experience in digital diagnostics and digital therapeutics is favorable though not necessary
- Experience in drug and device/diagnostic arenas is useful
- Ability to work with MS Office applications and Google applications
- Bachelor's degree preferred

Desired Attributes

- Ability to work in startup/small company environment
- Proactive
- Organized and systematic
- Flexible thinker
- Good communicator
- Open to creative and unconventional solutions
- Interest in digital health

Other Information

- Preferred location: San Francisco bay area (Office is in Palo Alto, CA)
- Contract-to-hire path is available
- Travel: 25-30%
- Work hours per week: ~40

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