

## Study Start Up Specialist

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Company: DM Clinical Research

Location: Karachi

Category: business-and-financial-operations

Study Start-Up Specialist Study Start-Up Specialist will be an integral part of the project management team and help manage the portfolio of active and future studies Business Development has in the pipeline, to include but not limited to bringing pipeline opportunities to activation within defined timelines. They will also be involved in the process improvement strategies for DM Clinical Research for all stakeholders. DUTIES & RESPONSIBILITIES Develop/maintain positive relationships with Sponsors/CRO's & Key Stakeholders for study start up activities. Prepare and prioritize correspondence via email to sponsor level. Maintaining a working knowledge of current FDA regulations, GCP/ICH guidelines, organizational SOPs, guidance documents and study protocols. Handle sensitive and confidential information with discretion. Prepare, participate and/or lead study start up team meetings as appropriate. Utilize Study Start Up platforms to track activities and develop reports. Support the on site clinical operations team with start up activities and provide study startup updates to management and site staff. Observe, disseminate & promote Study Start Up Timelines, monitoring all startup milestones, and meeting deadlines, and drive outcomes follow-up with applicable stakeholders to ensure resolution. Reporting project status and issues to Senior Project Manager on a regular basis. Assist in Sponsor/CRO vendor management for site readiness. Act as a subject matter expert on all SSU related activities, overseeing and leading activation activities. KNOWLEDGE & EXPERIENCE Education: High School Diploma or equivalent required. Experience: 3+ years of clinical research experience Experience with ICH/GCP documentation and process preferred. Experience working in the clinical research industry and knowledge of the clinical trials process required. Experience

in Study Start-Up activities, activation, supplies & accesses delivering high quality work in a dynamic environment. Credentials: N/A Knowledge and Skills: Flexible and willing to provide cross-functional support. Ability to manage multiple tasks simultaneously and meet deliverables deadlines in accordance with Study Start-Up timelines. Be detail-oriented and demonstrate attention to detail with ability to use critical thinking skills to proactively identify and solve problems. Excellent oral and written communications skills. Strong presentation, documentation and interpersonal skills. Proficient computer skills including Word, Excel (Advanced), Power Point, Adobe Software and Google Sheets. Strong prioritization and time management skills Powered by JazzHR

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