# Taiwan Jobs Expertini®

**Associate Clinical Research Associate (CRA) / Clinical Research Associate (CRA)**

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Company: MSD France

Location: Taiwan

Category: other-general

**Job Requirements**

The opportunities

As a ACRA or CRA, you will be accountable for performance and compliance for assigned protocols and sites in a country. Under the oversight of the CRA manager, you will ensure compliance of study conduct with ICH/GCP and country regulations, Company policies and procedures, quality standards and adverse event reporting requirements internally and externally. You will act as primary site contact and site manager throughout all phases of a clinical research study, taking overall responsibility of allocated sites. You will also actively develop and expands the territory for clinical research, finding and developing new sites. Participates in internal meetings and workstreams as SME for monitoring processes and systems.

Responsibilities include, but are not limited to:

•Develops strong site relationships and ensures continuity of site relationships through all phases of the trial.

•Performs clinical study site management/monitoring activities in compliance with ICH-GCP, Sponsor SOPs, Local Laws & Regulations, Protocol, Site Monitoring Plan and associated documents.

•Gains an in-depth understanding of the study protocol and related procedures.

•Coordinates & manages various tasks in collaboration with other sponsor roles to achieve Site Ready.

•Participates & provides inputs on site selection and validation activities.
•Performs remote and on-site monitoring & oversight activities using various tools to ensure data generated at site are complete, accurate and unbiased and the Subjects' right, safety and well-being are protected.
•Conducts site visits including but not limited to validation visits, initiation visits, monitoring visits, close-out visits and records clear, comprehensive and accurate visit & non-visit contact reports appropriately in a timely manner.
•Collects, reviews, and monitors required regulatory documentation for study start-up, study maintenance and study close-out.
•Communicates with Investigators and site staff on issues related to protocol conduct, recruitment, retention, protocol deviations, regulatory documentation, site audits/inspections and overall site performance.
•Identifies, assesses and resolves site performance, quality or compliance problems and escalates per defined CRA Escalation Pathway as appropriate in collaboration with CRA Manager, CRM, TA Head and CRD as needed.
•Works in partnership with GCTO country operations, finance, regulatory affairs, pharmacovigilance, legal and regional operations, HQ functional areas and externally with vendors and IRB/IECs and Regulatory Authorities in support of assigned sites.
•Manages and maintains information and documentation in CTMS, eTMF and various other systems as appropriate and per timelines.
•Contributes to CRA team knowledge by acting as process Subject Matter Expert (SME), buddy/mentor and sharing best practices as appropriate/required.
•Supports and/or leads audit/inspection activities as needed.
•Performs co-monitoring visits where appropriate.
•Following the country strategy defined by CRD and/or CRA manager, contributes to the identification of new potential sites and works closely with them to develop strong clinical research capabilities.

What you must have:
•Min. 1 year of direct site monitoring experience in a bio/pharma/CRO for Associate CRA role
•Min. 2 years of direct site monitoring experience in a bio/pharma/CRO for CRA role
•Preferred: B.A./B.S. with strong emphasis in science and/or biology

•Fluent in Local Languages and English (verbal and written) and excellent communication skills, including the ability to understand and present technical information effectively.
•Good understanding and working knowledge of clinical research, phases of clinical trials, current GCP/ICH & country clinical research law & guidelines.
•Good understanding of Global, Country/Regional Clinical Research Guidelines and ability to work within these guidelines.
•Demonstrated high level of monitoring skill with independent professional judgment.
•Good IT skills (Use of MS office, use of various clinical IT applications on computer, tablet and mobile devices) and ability to adapt to new IT applications on various devices.

We are proud to be a company that embraces the value of bringing diverse, talented, and committed people together. The fastest way to breakthrough innovation is when diverse ideas come together in an inclusive environment. We encourage our colleagues to respectfully challenge one another's thinking and approach problems collectively for the common good. We are an equal opportunity employer, committed to fostering an inclusive and diverse workplace.

This posting has been created to pipeline talent for prospective roles that we anticipate will be needed soon in our organization. By applying to this Pipeline Advertisement you will be submitting your interest to be contacted for roles similar to what is described in the Pipeline Advertisement.

**Requisition ID:** 100781

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