Clinical Research Associate II | Oncology and Rare Diseases

FIRSTNAME LASTNAME

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Profile

Clinical Research Associate with four years of independent monitoring experience at a global CRO, covering phase II and III trials in oncology and rare diseases. Manages eight to ten sites in Germany and Austria, including site selection, initiation, risk-based monitoring and close-out. Former Study Nurse with strong site relationships.

Career highlights

- Activated six sites in four months for a rare disease study, ahead of the country plan.
- Kept protocol deviations at assigned sites 30 percent below the study average.
- Rated "exceeds expectations" in two sponsor oversight visits.
- Co-trained three new CRAs on the CRO's risk-based monitoring process.

Professional experience

Clinical Research Associate II **January 2023 to present**
Global CRO (example) Munich, Germany (home-based)

- Monitor eight to ten sites in Germany and Austria on-site and remotely according to ICH-GCP and the monitoring plan.
- Perform source data review and verification and follow up on findings and protocol deviations.
- Support ethics and authority submissions and site contracts with the start-up team.

Clinical Research Associate I **November 2021 to December 2022**
Global CRO (example) Munich, Germany

- Completed the CRO's CRA training programme and co-monitored with senior CRAs.
- Ran site qualification and initiation visits in two oncology studies.
- Maintained eTMF documents in Veeva Vault.

Earlier experience

Study Nurse, university hospital oncology trials centre, Munich (April 2018 to October 2021)

Education

Bachelor of Science in Nursing, 2018 | Registered Nurse, state examination, 2015

Further training

ICH-GCP E6(R3) (2025) | EU Clinical Trials Regulation 536/2014 and CTIS (2023)

Languages

German (native) | English (business fluent)

Core competencies

Site monitoring | Risk-based monitoring | SDV and SDR | Site selection and initiation | ICH-GCP E6(R3) | EU CTR and CTIS | Veeva Vault eTMF | Medidata Rave | Oncology | Rare diseases

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