Clinical Operations

BioNTech Industry Profile

for

sub-Saharan Africa Health Research and Innovation (SAHRI) Fellowship Program

Global Health EDCTP3

Co-funded by the European Union

Summary	Fellows will gain hands-on experience in planning and executing clinical trials from start-up to close-out. Sahri fellow will develop expertise in accelerating trial delivery, ensuring quality, compliance, and alignment with Good Clinical Practice (GCP) standards.
Qualifications	Holders of primary master's in medical field or life science (biology, chemistry, etc.) 3+ years of experience in clinical trial operations (site, academic, industry, or government)
Planned Tasks and Activities	Be assigned to a clinical study to assist with study execution. The following tasks may be assigned: • Schedule and coordinate various team meetings, prepare agendas, draft presentations, and follow up on the status of open action items with team members. Summarize and present the status of activities to the team. • Support the planning and conduct of project training as required during study execution, including oversight of the training matrix and documentation of completion by team members. • Coordinate study-related documents such as the Trial Master File (TMF) plan, Vendor Oversight Plan, country and site feasibility questionnaires, Study Management Plan, Study Monitoring Plan, and other relevant materials. • Contribute to the setup, maintenance, and close-out of the TMF (paper or electronic) during the clinical trial; support regular quality control (QC) checks and tracking throughout the trial, including running reports and following up with team members. • Assist in the coordination and/or review of clinical trial documents (e.g., protocol synopsis, investigator's brochure (IB), patient informed consent forms (ICF), etc.). • Monitor and update trial information as needed, including investigator/site status, contact information, trial insurance updates, sample collection status, and clinical trial registry support. • Support the review, tracking, and management of clinical trial monitoring reports. • Assist in the process of investigator site selection. • Oversee specified vendors to ensure they fulfill contract requirements, which may include defining the scope of work, monitoring activities such as sample receipt and analysis, reviewing activity reports, resolving issues, and escalating concerns to the team when necessary.
Location	Germany , Virtual /Hybrid participation not possible