



AFRIKA KOMMT! 2025-2027

An Initiative of German Industry for Future Leaders from Africa

Overall remarks: AK is a fellowship position i.e. Alongside making meaningful contributions, the primary focus is on your professional development and learning.

Profile Name: Clinical Operations Fellow

Company: ID:AK_14_BNT_02	BioNTech / Biotech	Company Logo		
Education:	Bachelors degree in a scientific field (biology, chemistry),or natural/life sciences or medical background			
Professional Experience:	<p>At least 3 years experience working in clinical trials either at a site or at a organization responsible for executing clinical trials (non-government or government, academic, industry organization).</p> <p>Familiar with the difficulties of conducting clinical trials in their country.</p>			
Maximum years' experience needed	Graduate / work experience 1-4y		Other	
	<input checked="" type="checkbox"/>		<input type="checkbox"/>	
Additional Qualifications:	<ul style="list-style-type: none"> Familiar with international guidelines ICH-GCP and ethics requirements as well as informed consent content and Good Documentation requirements. Good grasp of English both oral and written. Experience working in a laboratory or collecting samples, tracking samples, also of interest. Passionate to address unmet needs in Infectious Diseases, be highly engaging, and excited to contribute to the successful development of the first mRNA vaccines for e.g. HIV, Tuberculosis and Malaria. Exhibits consistent work practices with highest ethical standards in compliance with internal SOPs, local regulations. Project management skills preferrable. 			
This profile focuses on the indicated skill sets:	People Leadership	Expertship/ Specialist	Project/Program Management	Other
	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	
Country Focus:	<p>All nationalities from sub-Saharan Africa are welcome to apply. Nationals from the following countries are preferred: Rwanda, Mozambique, Tanzania, Uganda, Gabon and Democratic Republic of Congo.</p>			
Division / Location / Department:	Global Clinical Operations located in Mainz, Germany.			
Planned Tasks & Activities:	Be assigned to a clinical study to assist with study execution. The following tasks may be assigned:			

- Scheduling and coordinating various team meetings, preparing agendas. May draft presentations and follow up on status of open action items with team members. Summarize and present status of activities to the team.
- Supports the planning and conduct of project training as required within the study conduct such as oversight of training matrix; documents completion by team members.
- Coordination of study related documents such as TMF plan, Vendor Oversight Plan, country and site feasibility questionnaires, the Study Management Plan, Study Monitoring Plan, etc.
- Contribute to Trial Master File (TMF) set-up, maintenance, and close-out (paper or electronic) during the clinical trial; supports regular QC checks and tracking during the trial including running reports and following up with team members.
- Supports coordination and/or review of clinical trial documents (e.g., protocol synopsis, investigator's brochure (IB), patient informed consent forms (ICF), etc.).
- Monitors and updates trial information as necessary such as investigator/site status for the trial, contact information, trial insurance updates, sample collection status and supports with clinical trial registry.
- Supports the review, tracking, and management of clinical trial monitoring reports. Supports the process of investigator site selection.
- Oversees a specified vendor to make sure they are fulfilling the contract requirements – may involve helping describe the scope of work, checking the activity such as sample receipt and analysis. Reviewing activity reports, resolving issues, escalating to the team when needed.

Remarks:

None