Clinical Development

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 shaping clinical trial strategies across Phases I–IV, from designing study protocols to supporting regulatory submissions. They will develop skills in designing clinical trial strategies across Phases I–IV, ensuring alignment with regulatory and ethical standards such as International Council for Harmonization - Good Clinical Practice(ICH-GCP), U.S. Food and Drug Administration (FDA), EMA (European Medicines Agency), and World Health Organization (WHO) guidelines.
Qualifications	Medical Degree with 2–3 years of experience in Infectious Diseases or emerging infections in a hospital/or academic setting, clinical setting; clinical trials experience is preferred
Planned Tasks and Activities	• Assigned to a clinical study to assist with the tasks outlined below under the supervision of an SME. • Supports the design of clinical trial strategies across Phases I–IV, including objectives, endpoints, dosing, and population selection. • Assists in the development of study protocols and ensures alignment with regulatory and ethical standards (e.g., ICH-GCP, FDA, EMA, WHO). • Monitors safety and immunogenicity, establishes data safety monitoring boards (DSMBs), and tracks adverse events. • Ensures proper clinical monitoring through site visits, data verification, and protocol compliance. • Assists in managing clinical data collection, cleaning, and analysis in collaboration with biostatistics and data management teams. • Participates in providing responses related to safety and efficacy, including IND/CTA submissions and responses to agency feedback. • Supports the coordination of cross-functional efforts with preclinical, manufacturing (CMC), regulatory, and other multidisciplinary teams. • Assists in preparing documentation for approval, including clinical study reports (CSRs) and marketing authorization dossiers.
Location	Germany , Virtual /Hybrid participation not possible