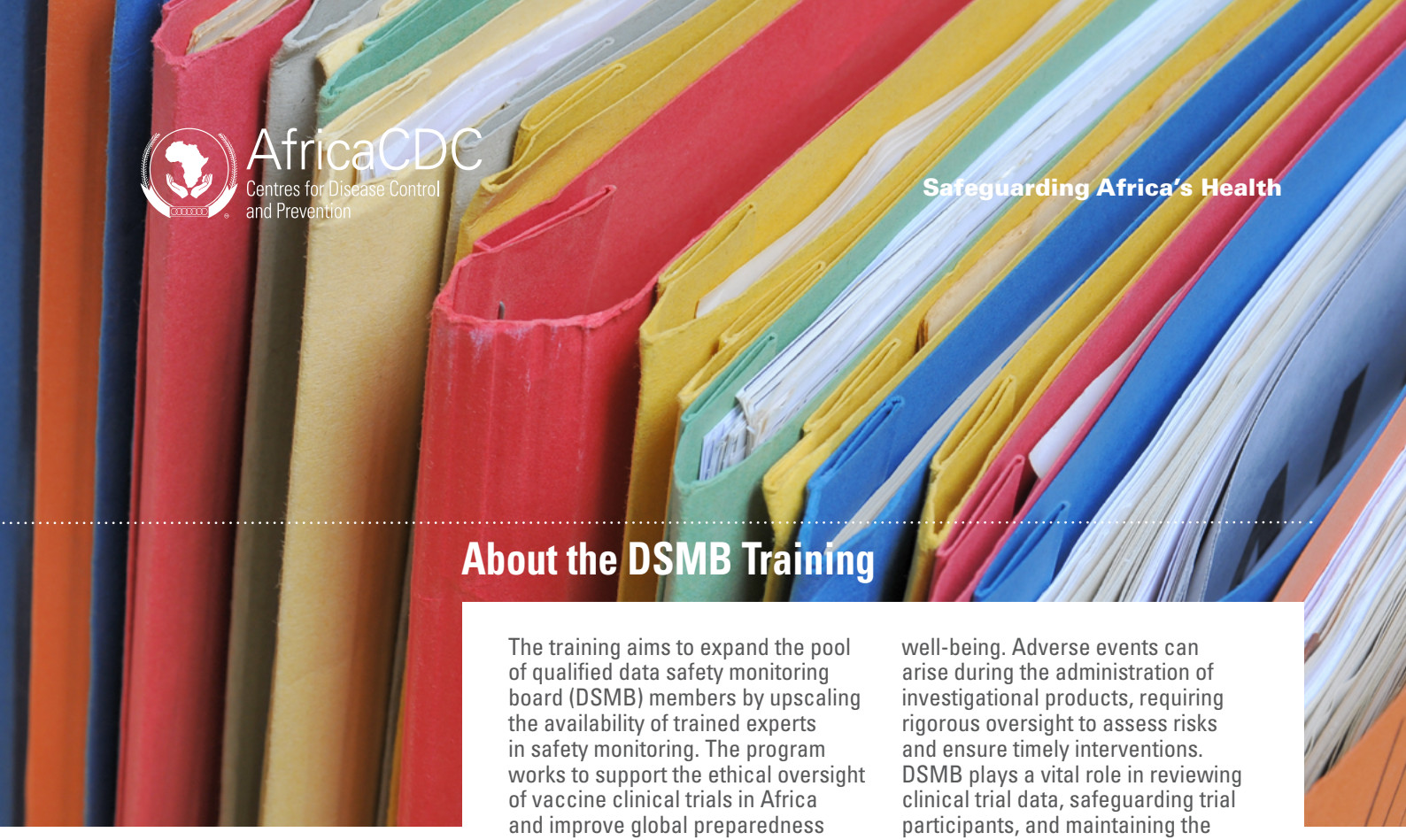

AfricaCDC
Centres for Disease Control and Prevention

Safeguarding Africa's Health

DATA AND SAFETY MONITORING BOARD (DSMB)

About the DSMB Training

The training aims to expand the pool of qualified data safety monitoring board (DSMB) members by upscaling the availability of trained experts in safety monitoring. The program works to support the ethical oversight of vaccine clinical trials in Africa and improve global preparedness for emerging health threats. The program is an 8-week training that includes self-paced learning and live virtual sessions facilitated by leading experts in vaccine safety and clinical trial monitoring. Upon successful completion, participants can then join the DSMB global pool, where they may be considered for future clinical trial oversight roles.

Safety monitoring in clinical trials is crucial to ensure ethical research practices and protecting participant's well-being. Adverse events can arise during the administration of investigational products, requiring rigorous oversight to assess risks and ensure timely interventions. DSMB plays a vital role in reviewing clinical trial data, safeguarding trial participants, and maintaining the integrity of study results. To strengthen DSMB expertise continentally, Africa CDC, in collaboration with the Safety Platform for Emergency Vaccines (SPEAC), will offer a structured DSMB training course that will robustly build the capacity of training participants to undertake the very crucial role of monitoring clinical trials for vaccines and other new treatment platforms in Africa and elsewhere to confront emerging and reemerging public health threats.

An entity of the African Union

CEPI SPEAC

Email us:
alemayehud@africacdc.org

www.africacdc.org
africacdc

What the Training Covers

The eight-week-long intensive training course will employ a modular format, combining recorded lectures with live virtual sessions, an approach that ensures flexibility while maintaining interactive learning environment. Expert trainers and subject matter specialists drawn from across the world will facilitate sessions, leveraging their real-world experience to provide high-quality instruction.

- Introduction to Clinical Trials & DSMB
- Vaccine Clinical Trials & Safety Monitoring
- DSMB Roles & Decision-Making
- Regulatory & Ethical Considerations
- Safety Monitoring & Risk Assessment
- Statistical Methods for DSMB
- DSMB Meetings & Case Discussions
- Practical Applications, quizzes and final assessment

At the End of the Training Participants are Expected to have Developed Core Competencies in the Following Areas

- Increased competence in detecting, assessing, and responding to adverse events in clinical trials.
- Strengthened protection of trial participants through rigorous safety monitoring practices aligned with international standards.
- Practical knowledge in epidemiology, biostatistics, clinical trial design, and ethical principles relevant to DSMB operations.
- Improved quality and consistency in DSMB deliberations and recommendations.
- Stronger Regulatory and Ethical Compliance.
- Better equipped to align clinical trial practices with Good Clinical Practice (GCP), regulatory requirements, and ethical guidelines.
- Reduction in protocol deviations or violations that compromise study integrity.
- Strengthened regional capacity to conduct high-quality trials without over-reliance on external expertise.
- Enhanced ability to analyze interim data and make informed safety decisions during clinical trials.
- ustained Capacity for Vaccine Safety Surveillance.

Our Trainers and Facilitators

The course will be led by a team of experienced and globally acclaimed trainers from the Safety Platform for Emergency Vaccines (SPEAC), a CEPI-funded initiative to enhance safety for CEPI-funded trials across various platforms for multiple priority pathogens.

Who can Apply?

- Organizations supporting vaccine safety surveillance
- Clinical trial hubs
- National Regulatory Authorities (NRAs)/National Pharmacovigilance centers
- Ethics committees
- To qualify, you must possess the following:
- Be citizens of an African Union Member State

- Have at least 3 years of professional experience in clinical research, pharmacovigilance (PV), regulatory science, public health, or related fields.
- To be eligible for the DSMB training, applicants must hold a minimum of a Bachelor's degree, with preference given to those holding a Master's (MSc) or PhD in a relevant field such as medicine, pharmacy, epidemiology, public health, biostatistics, pharmacovigilance, pharmacoepidemiology, or other related disciplines.
- Candidates should have at least three years of professional experience in clinical research, pharmacovigilance, regulatory science, public health, or similar Applicants must also be in full-time employment at a public or private institution in Africa actively involved in pharmacovigilance, clinical trials, or related research activities.
- Have a good track record or be able to demonstrate the potential for effective safety surveillance and/or clinical trials leadership where you can positively impact medicine safety and regulation outcomes in Africa and elsewhere.

Participant's Selection

Selection for the DSMB Course will be done by an independent committee comprising of experts from Africa CDC, and global partners. A total of 20 participants will be chosen for every course, considering professional background, relevant experience, and geographical representation to ensure a diverse cohort. The selection process will emphasize equal opportunity approach to secure the representation of women and underrepresented groups.

How to apply

- All applications must be submitted using the online application form. Incomplete applications will not be considered.
- All applicants must provide the following required information:
  - A support letter from the current employer to confirm employment, guaranteeing that the candidate will be allowed enough time to participate in the Fellowship program and to attend the full eight weeks of institutional residential experience.
  - Letters of recommendation from two reputable professional referees.
  - A personal statement (maximum 500 words) providing evidence of the candidate's commitment to medicine safety in Africa detailing the following: technical qualification, experience and professional attainment; vision of, and the future impact of effective medicine safety and regulation in Africa.

For Enquiries: any questions or clarifications regarding the DSMB training program? Please reach us at alemayehud@africacdc.org

Important Dates to Remember

Registration Deadline:

May 25, 2025

The course start date:

June 23, 2025

Completed applications with all supporting documents should be submitted through https://redcap.link/rb72sd0g

About Africa CDC

Africa Centers for Disease Control and Prevention (Africa CDC) is an autonomous technical institution of the African Union that supports the Member States (MS) in the planning, preparing, and responding effectively and efficiently to the continent's public health threats and outbreaks. Leadership principles of credibility, ownership, delegated authority, timely dissemination of information, transparency, accountability, and value addition guide Africa CDC.