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Strengthening Pharmacovigilance and Clinical Trials Oversight Capacities Through the VaccTrain Project: Achievements and Lessons Learned from LMICs in Africa

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Abstract

Background

Strengthening regulatory systems is essential for ensuring timely access to quality-assured, safe and effective medicinal products and improving preparedness for public health emergencies. The VaccTrain Project was established to strengthen clinical trials oversight (CTO) and pharmacovigilance (PV) systems in African National Regulatory Authorities (NRAs).

Objectives

To evaluate the contribution of the VaccTrain Project to strengthening WHO Global Benchmarking Tool (GBT)-aligned CTO and PV systems in partner countries in sub-Saharan Africa.

Methods

Between 2018 and 2025, VaccTrain supported partner NRAs through regulatory system assessments, development and review of legislation, guidelines and standard operating procedures, targeted capacity strengthening, implementation support, and regional collaboration with WHO, AVAREF and AUDA-NEPAD/AMRH. Project outcomes were assessed using regulatory outputs and operational key performance indicators, including regulatory documents, clinical trial application (CTA) reviews, Good Clinical Practice (GCP) inspections, adverse drug reaction (ADR) reporting, pharmacovigilance activities including pharmacovigilance inspections.

Results

The project supported the development or review of 185 pharmacovigilance-related and 79 CTO-related regulatory documents aligned with WHO GBT requirements. Progressive implementation of regulatory functions was demonstrated by increasing CTA assessments, GCP inspections, ADR reporting and other PV activities across participating countries. The project strengthened regulatory functionality, promoted regional harmonization and reliance, and enhanced preparedness for future public health emergencies.

Conclusions

The VaccTrain project demonstrates that long-term, implementation-oriented regulatory system strengthening can improve both the structural and functional maturity of CTO and PV systems in resource-constrained settings. The combination of regulatory framework development, practical implementation, mentorship and regional collaboration provides a sustainable model for strengthening regulatory preparedness and resilience in Africa.

Introduction

The World Health Organization (WHO) emphasized that during the COVID-19 pandemic, more than 22,000 COVID-19-related clinical trials were registered, of which less than 10% were well-designed and well-implemented and contributed meaningfully to policy recommendations by WHO and other bodies (WHO 2024). The vast majority comprised the “research waste” due to failure to articulate clear research questions, duplication of previous research,

use of inefficient trial processes, failure to produce scientifically robust and clinically relevant answers, among others. The COVID-19 pandemic therefore highlighted major structural weaknesses in the clinical trial ecosystem across the globe. Such inefficiencies are especially critical in low-middle-income countries (LMICs) where financial, human, and infrastructural resources are already constrained (Alemayehu et al. 2018; Abiri et al. 2022). This leads to impaired responsiveness to public health emergencies (Council for International Organizations of Medical Sciences (CIOMS) 2021). Therefore, establishing sustainable research and regulatory ecosystems is of paramount importance for the resource-limited African countries. Beyond the described need to strengthen the clinical trial ecosystem, robust vaccine safety monitoring (pharmacovigilance, PV) is essential to ensure the continued surveillance of vaccine safety, respond to potential safety signals and maintain trust in vaccination campaigns that help reduce the burden of vaccine-preventive infectious diseases. Therefore, the regulatory oversight of clinical development and PV is paramount for providing access to quality-assured, safe and efficacious innovative vaccines throughout their life-cycle.

The VaccTrain project was initiated in 2016 with a focus on NRAs from various Regional Economic Communities (RECs) in Africa, allowing them to benefit from strong collaboration with regional and international organizations. Based on their request, the following countries from the RECs of West African States (ECOWAS) were included in the project: Ghana (Food and Drugs Authority Ghana, FDA Ghana), Liberia (Liberia Medicines & Health Products Regulatory Authority, LMHRA), Sierra Leone (Pharmacy Board of Sierra Leone, PBSL), Senegal (Agence sénégalaise de Réglementation Pharmaceutique, ARP) and The Gambia (Medicines Control Agency, MCA The Gambia). In 2019, the project was extended to include the NRAs in Zimbabwe (Medicines Control Authority of Zimbabwe, MCAZ) and Rwanda (Rwanda Food and Drugs Authority, Rwanda FDA).

Since the initiation of the Global Health Protection Programme (GHPP) by the German Federal Ministry of Health (Bundesministerium für Gesundheit, BMG), the VaccTrain project at the Paul-Ehrlich-Institut (PEI) has been supporting partner agencies in sub-Saharan Africa with a focus on regulatory system strengthening and capacity development in Clinical Trials Oversight (CTO) and PV of vaccines and biologicals targeting preventing and treating infectious diseases that significantly impact public health in Africa and worldwide. Within this context, the VaccTrain project is collaborating closely with the key institutions, including African Vaccine Regulatory Forum (AVAREF) and WHO AFRO to support regulatory improvement efforts and the harmonization of standards in Africa. This is crucial for ensuring access to quality-assured, safe, and effective medicinal products and innovative technologies.

The VaccTrain project contributed to WHO, AUDA-NEPAD/ AMRH and AVAREF activities facilitating regulatory harmonization initiatives. The VaccTrain project worked with the WHO Regulatory System Strengthening (RSS) team to follow the requirement of WHO GBT and to align, implement and harmonize the approach across the partner countries.

These interactions illustrate the increasingly interconnected nature of medicines regulation: global standards and WHO frameworks are translated through regional mechanisms and national institutions, while South–South collaboration, reliance, and shared regulatory learning can reduce duplication across jurisdictions. Regulatory systems strengthening in this context therefore extends beyond national capacity development and forms part of a wider global health architecture for coordinated evidence generation, regulatory oversight, and emergency preparedness.

This article is aimed to describe the VaccTrain project achievements and lessons learned in the second phase of the GHPP (2023–2025).

The objectives of this study were to evaluate the contribution of the VaccTrain project to strengthening CTO and PV systems in partner NRAs in sub-Saharan Africa by assessing regulatory system development, implementation of WHO GBT-aligned regulatory frameworks, operational functionality, regional collaboration and preparedness for public health emergencies.

Methods

The VaccTrain project launched a call for proposals in 2016, commenced in June 2018 and was implemented in two phases until December 2025. To reach its objectives, the VaccTrain project employed a combination of the following activities:

- In-person and online workshops;
- Train-the-trainer initiatives;
- Technical review sessions for regulatory documents;
- Cross-country collaboration and peer learning;
- Regulatory systems strengthening exercises aligned with WHO GBT indicators;
- Stakeholder engagement with national regulatory authorities and public health institutions.

The VaccTrain strategy consists of baseline assessment, strategic planning, capacity development, and regulatory system strengthening as well as implementation activities (Fig. 1).

Data were derived from VaccTrain training records and operational manual related CTO and PV activities conducted between 2023 and 2025 (see Annex 1). Documents initially created or reviewed by VaccTrain were counted as “newly developed” or “reviewed”, respectively. All workshops were assessed and counted as “online” if the meeting was entirely remote, or “onsite” if at least one VaccTrain member was physically participating in the event. Data on Key Performance Indicators (KPIs) are indicated as reported by partner countries.

Microsoft PowerPoint and Excel was used for creation of figures.

Results

Development and Review of Regulatory Documents

In collaboration with the partner agencies, existing regulatory documents were reviewed and updated or documents were newly developed in alignment with WHO GBT CTO and vigilance functions indicators, particularly those related to:

- Legal provisions for national clinical trials and vigilance systems;
- Medicines and related products regulations;
- Regulatory guidelines and guidance documents;
- Public health emergency policies;
- SOPs and operational templates.

Development of documents to fulfill WHO GBT criteria for maturity levels 1–3 was prioritized and scope was extended to maturity level 4 indicators whenever feasible. In total, 185 PV system-related and 79 CTO-related regulatory documents were reviewed and updated or newly developed (Table 1).

Table 1
Regulatory documents for PV and CTO developed with VaccTrain partner countries.

PV	Total		Regulations		Guidelines		SOP/Templates	
	Developed	**Reviewed**	**Developed**	**Reviewed**	**Developed**	**Reviewed**	**Developed**	**Reviewed**
	96	**89**	**2**	**4**	**28**	**10**	**66**	**75**
Total	185		6		38		141	

CTO	Total		Regulations		Guidelines		SOP/Templates	
	Developed	**Reviewed**	**Developed**	**Reviewed**	**Developed**	**Reviewed**	**Developed**	**Reviewed**
	22	57	3	4	3	7	16	46
Total	79		7		10		62	

Capacity Building and Training Activities

Between 2019 and 2025, the VaccTrain project supported PV and CTO regulatory strengthening activities in collaboration with the NRAs MCA, LMHRA, and PBSL, with regional (RCOREs, WAHO), and international partners (AVAREF, WHO HQ, WHO AFRO, AUDA-NEPAD, CEPI) (Table 2). Partner NRAs were highly involved over the entire project period. Following a decline in 2021 and 2022 due to the COVID-19 pandemic, the number of activities markedly increased from 2023 onward, alongside increased regional and global engagements. These trends reflect growing institutional engagement, strengthened partnerships, and increased regional commitment to CTO and PV system development. The detailed description of the project related activities is provided in the Annex 1.

Table 2
Number of capacity building and training activities conducted in the VaccTrain project between 2019 and 2025*.

Year	Number of activities				
	MCA	**LMHRA**	**PBSL**	**Regional**	**Global**
2019	1	2	2	3	0
2020	4	4	4	3	0
2021	2	2	2	1	0
2022	1	1	1	0	0
2023	7	7	7	0	1
2024	8	6	5	9	1
2025	6	4	5	3	3
Total	29	26	26	19	5

** Some activities were conducted jointly with multiple partner countries, so they appear twice in the table.*

***Regional - RCOREs, WHO AFRO, AVAREF, WAHO, CEPI, AUDA-NEPAD); Global – WHO HQ.*

Key training and technical activities included online and onsite workshops:

- Train-the-trainer (TTT) programs;
- Regulatory capacity-building workshops;
- Workshops on review and refinement of guidelines and SOPs;
- Workshops on PV and CTO regulatory systems strengthening;
- Regional and international collaboration meetings to support future regulatory cooperation.

Training activities included theoretical background for clinical trial authorization, safety in clinical trials, Good Clinical Practice (GCP) guideline and inspections, Adverse Drug Reaction (ADR) reporting, Good Vigilance Practice (GVP) inspections, signal management, and benefit-risk assessment. Hands-on practical activities covered the assessment of key regulatory documents, including clinical trial applications (CTAs), substantial and non-substantial amendments for clinical trials, causality assessments of ADRs and adverse events following immunization (AEFIs), periodic safety update reports (PSURs), risk management plans (RMPs), and risk minimization measures (RMMs). If feasible, training activities were conducted jointly with multiple partner agencies.

Guidelines and standard operating procedures (SOPs) were jointly developed, reviewed, harmonized, and subsequently tested in mock GCP and GVP inspections (see discussion). In the TTT program, regulatory officers of partner NRAs received a two weeks training at the PEI where insight into the European system and interaction with PEI assessors was facilitated.

The implementation of the developed regulatory framework was facilitated by VaccTrain via operationalization of the key regulatory activities in the field of PV and CTO. The key performance indicators (KPI) for CTO were selected as following: number of reviewed CTAs and GCP inspections (Annex 2). For PV system, these included the number of ADR reports received and processed, review of PSURs, assessment of RMPs, and GVP inspections (Annex 2). KPIs demonstrated the level of maturity of the system, as the most functional the number of CTA review and ADR reports are depicted in Fig. 2. Despite fluctuations over time, the data indicate increasing regulatory activity, particularly the rise in ADR/AEFI reporting in Sierra Leone in 2025. Of note, KPIs depend not only on the NRAs but also on sponsors who submit CTAs and on marketing authorization holders.

The partner NRAs showed varying but overall increasing numbers of ADRs/AEFIs reports to UMC and varying, but generally augmenting number of CTAs over the years.

Considerable differences were observed between participating countries, reflecting differences in regulatory maturity, available resources and clinical research activity. Sierra Leone demonstrated the highest level of operational functionality in both CTO and PV indicators, particularly in ADR reporting, reflecting successful implementation of reporting systems and increased stakeholder engagement. The Gambia demonstrated a stable clinical trial review function despite relatively low research activity, while Liberia showed gradual development of CTO functionality with increasing CTA assessments and GCP inspections following implementation of regulatory procedures. These findings illustrate that regulatory strengthening should primarily be assessed through longitudinal progress within individual countries rather than direct comparison between NRAs operating in different contexts.

On a regional level, VaccTrain supported training and harmonization activities coordinated by AVAREF, including trainings on clinical trial assessment, GCP including GCP inspection, as well as the development and implementation of tools to assess CTAs. The VaccTrain project supported trainings in English and in French. VaccTrain supported WHO AFRO in the field of PV including a Vaccine Safety Training Workshop for East and Southern Africa Countries. In addition, VaccTrain contributed as trainers in clinical trial authorization simulation exercises with CEPI.

On a global level, VaccTrain supported WHO HQ-led activities, exemplified by the development, review, and implementation of tools for the assessment of RMPs and algorithms for causality assessment of adverse events following maternal immunization which have been adopted and fully implemented by partner countries.

Discussion

Regulatory Maturity and Sustainability

The current situation underscores the need for regulatory strengthening capacity activities in the continent where the African Medicines Agency (AMA) is still nascent, and only few NRAs have attained sustainable or advanced regulatory status as per the WHO GBT (World Health Organization 2026). Most African NRAs operate in resource-constrained settings where sustainability of regulatory systems is a challenge. In response to this, the VaccTrain project contributed to the AUDA-NEPAD and AMA initiatives to develop a harmonized African regulatory system by strengthening national regulatory systems and Regional Centers for Regulatory Excellence (RCOREs).

The VaccTrain project demonstrated that targeted regulatory capacity-building initiatives substantially strengthen PV and CTO systems. During the program, VaccTrain successfully supported partner countries in establishment and improvement of regulatory structures and technical competencies. These revised or newly developed frameworks are aligned with international regulatory standards and harmonized with regional African guidelines and templates, thereby supporting regulatory convergence and sustainability across the region. The partner agencies moved from a reactive/ad hoc decision making, to a pro-active, risk-based system thereby enhancing preparedness for epidemic and pandemic threats.

Support provided through VaccTrain contributed to:

- Increased awareness of international standards and regulatory requirements, including alignment with ICH guidelines, EU Directives, EMA guidelines, WHO GBT requirements;
- Improved understanding of CT and PV operational system and structures;
- Enhanced technical competencies among regulatory personnel;
- Improved documentation and procedural standardization;
- Increased preparedness for public health emergencies and safety monitoring of vaccines and biologicals.

The comprehensive assessment of existing PV and CTO regulatory frameworks and their operationalization informed the development context-specific approaches, targeted to the operational reality and the requirements of the LMIC system, while maintaining alignment with international standards. The large number of newly developed and reviewed documents (185 PV system-related and 79 CTO system-related documents) demonstrates both the considerable need for regulatory system strengthening as well as the high level of engagement from the partner NRAs.

The functionality of the regulatory systems for PV and CTO was tested, confirming their effectiveness. Training programs tailored to the specific regulatory gaps and priorities of the partner agencies targeted the need for wholistic and advanced activities in regulatory functions which is highlighted in recent literature (Dehaghi et al. 2023; Menang et al. 2023). The scope of the training activities shifted from primarily knowledge-transfer to hands-on practical and more strategic and collaborative efforts. Practice-focused trainings enhanced oversight of critical regulatory tasks and facilitated a better understanding of the interconnections between related regulatory functions.

This holistic approach resulted in optimized cooperation and communication between departments within the NRAs and improved the outcomes of regulatory procedures. The efficiency of the controlled measures was tested during

mock GCP and GVP inspections, which were conducted either individually or as joint inspections. This improved quality assurance and control of the PV and CTO systems in the partner countries. These activities demonstrated advancements in reliance and recognition and fostered improved collaboration among NRAs.

Regional Collaboration and Knowledge Exchange

Regional collaboration and knowledge exchange are vital to build sustainable, efficient, and harmonized regulatory systems and ultimately to improve access to medicines, vaccines, and biologicals. VaccTrain promoted this regional collaboration by facilitating interactions between NRAs, technical experts, and partner institutions.

The project especially enabled:

- Knowledge exchange between participating countries;
- Joint workshops and technical discussions;
- Sharing of regulatory best practices;
- Strengthening of regional regulatory and ethics networks;
- Harmonisation-oriented discussions related to safety monitoring of vaccines and biologicals.

An important component of the project involved supporting the Ghana FDA and Zimbabwe MCAZ as the RCOREs in CTO and PV. This facilitated South–South collaboration, enabling African regulators to exchange practical experiences and technical expertise. The project further strengthened this approach through the implementation of a “Train-the-Trainer” (TTT) program at PEI. Regulatory officers from partner countries were exposed to German and European PV and CTO systems, including the EU reliance model and relevant regulatory guidelines and procedures. Following completion of the program, trained fellows transferred acquired knowledge within their national regulatory authorities, and extended the knowledge sharing to the countries from the respective RCORE regiones. The reach out has covered countries in the ECOWAS and SADC regions.

The expansion of the TTT model through the involvement of graduated fellows as facilitators in online assessments of PV and CTO regulatory structures represented an innovative and sustainable capacity-building strategy. This approach promoted mutual learning and strengthened cooperation between RCOREs and NRAs. The combination of African regional expertise with European regulatory experience provided context-specific solutions that contributed to the strengthening of CTO and PV regulatory systems in sub-Saharan Africa.

A major achievement of the project was its contribution to regional and international harmonization initiatives. In collaboration with the WHO HQ Regulatory Systems Strengthening team, the AVAREF, and the AUDA-NEPAD AMRH initiative, VaccTrain supported efforts toward harmonized regulatory processes within the African region. Such collaboration strengthened alignment with global best practices and facilitated greater regional cooperation in PV and CTO.

The collaborative efforts described illustrate a reciprocal approach to regulatory enhancement. By adapting WHO standards and European experiences to local contexts, we establish a more effective regulatory framework. The participation of African RCOREs and partner NRAs in promoting peer learning signifies a commitment to shared growth and expertise. This interconnected strategy minimises redundancy while leveraging established best practices, ensuring national regulatory advancements align with both African and global frameworks and contribute to a cohesive, sustainable global regulatory architecture.

Emergency Preparedness

The project has made significant contributions to enhancing emergency preparedness and response capacities in light of the COVID-19 pandemic (Owusu Sekyere et al. 2022). Through simulation exercises in clinical trial operations and regulatory support for the evaluation of protocols related to the WHO COVID-19 Solidarity Trial, the agencies have strengthened their readiness for future public health emergencies. Moreover, the measures developed and implemented during the pandemic have been thoughtfully expanded to address potential emerging public health threats. This initiative aims to establish a sustainable system and operational plans for future emergencies in resource-limited settings, carefully tailored to align with the unique needs and characteristics of NRAs in Sierra Leone, The Gambia, and Liberia.

PV and CTO system functionality

Development of regulatory documents alone does not demonstrate the maturity or effectiveness of a regulatory system. Functional implementation is reflected by the ability of an NRA to consistently perform its core regulatory functions. Therefore, VaccTrain monitored selected operational indicators of CTO, including the annual number of CTAs reviewed and authorized and the number GCP inspections conducted. Although these indicators are also influenced by the number of sponsor submissions, they provide an important measure of operational readiness and institutional functionality. Despite variations between countries, the observed increase in CTA assessments and the initiation of GCP inspections demonstrate that the newly established regulatory frameworks were translated into routine regulatory practice.

Functional implementation of PV systems was evaluated using operational indicators reflecting the routine performance of key pharmacovigilance functions: number of PSURs, RMPs, PV inspections and ADR reports. While some indicators depend on marketing authorization holder activity and product availability, increasing ADR reporting represents one of the most direct measures of the functionality of a national PV system. The progressive increase in ADR reporting observed in the partner countries indicates improved reporting pathways, increased awareness among healthcare professionals and enhanced regulatory capacity for signal detection and safety monitoring.

The VaccTrain Project achievements could be summarized as follows:

- Improved safety monitoring of vaccines and biologicals and public health emergency preparedness;
- Strengthened capacities in PV and CTO regulatory systems;
- Supported the transition from regulatory framework development to functional implementation of WHO GBT-aligned CTO and PV systems, thereby improving regulatory preparedness for future public health emergencies.

Lessons Learned

The project’s achievements illustrate several important lessons:

1. Long-term partnerships are essential for sustainable regulatory strengthening.
2. Regional collaboration accelerates learning and promotes harmonization.
3. Practical workshops and hands-on document review exercises are highly effective in building technical competence.
4. Alignment with WHO GBT indicators provides a structured pathway for regulatory system development.
5. Continuous investment in the regulatory frameworks and it´s operationalization under routine and emergency condition is critical for institutional sustainability.

The increase in training activities observed from 2023 onward may reflect growing national ownership, increased technical confidence, and expanding regional collaboration.

Collaboration with other international stakeholders active in the region, including EMA, and GIZ, as well as AUDA-NEPAD/ AMRH, WHO and AVAREF was essential in supporting the establishment and operationalization of AMA. Coordinated engagement helped to avoid fragmented and duplicated capacity strengthening activities and promoted the efficient use of limited resources.

Challenges

Despite these achievements, the implementation of the project encountered several important challenges. Establishing trustful and productive collaboration with partner countries required considerable time and continuous engagement. Technical barriers, including unstable internet connectivity and limitations in virtual communication infrastructure, significantly affected online interactions and delayed implementation of some activities. In addition, variable levels of engagement by NRAs in the development of regulatory structures raised concerns regarding long-term sustainability and institutional ownership.

The COVID-19 pandemic had a substantial impact on project implementation. Travel restrictions and lockdown measures prevented in-person training activities, including the second edition of the TTT program at the PEI. Regulatory authorities in partner countries faced increased workloads related to pandemic response activities, limiting their ability to fully engage in project activities. These challenges highlighted the importance of adaptive implementation strategies and resilient collaboration mechanisms in international capacity-building projects. In response, the project adopted a more collaborative and regionally integrated approach. This approach emphasized stronger involvement from partner countries, enhanced exchanges between NRAs and RCOREs, and further implementation of reliance on and recognition of decisions not only from NRAs within the African Union (AU) but also from regulatory authorities in the European Union/European Economic Area (EU/EEA) and international organizations such as the WHO and the Pharmaceutical Inspection Co-operation Scheme (PIC/S). These efforts improved awareness, kept stakeholders updated with global regulatory decisions, maintained effective oversight of dynamic changes in regulatory processes, and enabled the prompt implementation of necessary regulatory measures.

This revised strategy of strengthened international cooperation optimized the capacities of resource-limited NRAs, ensured effective oversight, and facilitated the timely implementation of required regulatory measures. It also promoted confidence and sustainable ownership of regulatory decisions made in alignment with international partners.

The regulatory framework developed and improved by NRAs and RCOREs jointly during their years of cooperation with the VaccTrain project has resulted in a well-structured and functional system. This system has demonstrated its effectiveness both during routine operations and under stress tests during public health emergencies. It has enabled harmonized yet locally adaptable implementation approaches across various contexts and requirements of regulatory agencies in LMICs in Africa.

Despite the progress achieved, several challenges remained:

- Limited human, infrastructural, and financial resources;
- Limited sustainability of training and retention of expertise due to high staff turnover;
- Need for continuous improvement of system and structures for developing resilient and sustainable regulatory systems for CTO and PV;

- Variable levels of institutional maturity across countries;
- Competing public health priorities;
- Legal limitations.

Addressing these challenges will require continued international collaboration, political commitment, and investment in regulatory systems strengthening.

Conclusion

The achievements and progress over the years leave us hopeful for the establishment of a resilient and well-functioning regulatory system with enhanced capacities for further development. Such a system could achieve better operability and provide the possibility for a proactive approach in regulating CTO and PV functions with further investment in regulation and continuous development in the field. Overall, the VaccTrain experience illustrates the value of combining international technical expertise, regional collaboration, and sustainable training models in strengthening PV and CTO systems. Continued investment in regulatory systems strengthening, digital learning infrastructure, and regional partnerships will be critical for maintaining and expanding these achievements in the future.

We believe that the dissemination of the acquired experience and extending the approach to other NRAs and RCOREs will enhance overall maturity of the regulatory systems, will improve cooperation and reliance and regulatory preparedness for emergencies throughout the African continent and beyond that would ultimately increase access to high-quality, safe, efficacious, and affordable medicinal products for all.

Abbreviations

ADR, Adverse Drug Reaction; AEFI, Adverse Event Following Immunization; AMA, African Medicines Agency; AMRH, African Medicines Regulatory Harmonisation; AVAREF, African Vaccine Regulatory Forum; ARP, Agence sénégalaise de Réglementation Pharmaceutique; AU, African Union; AUDA-NEPAD, African Union Development Agency-New Partnership for Africa's Development; CEPI, Coalition for Epidemic Preparedness Innovations; CTA, Clinical Trial Application; CTO, Clinical Trials Oversight; ECOWAS, Economic Community of West African States; EU, European Union; FDA Ghana, Food and Drugs Authority Ghana; GBT, Global Benchmarking Tool; GCP, Good Clinical Practice; KPI, Key Performance Indicator; LMIC, low-middle-income country; LMHRA, Liberia Medicines & Health Products Regulatory Authority; MCA The Gambia; Medicines Control Agency The Gambia; MCAZ, Medicines Control Authority of Zimbabwe; NRA; National Regulatory Authority; PEI, Paul-Ehrlich-Institut; PSUR, Periodic Safety Update Report; PIC/S, Pharmaceutical Inspection Co-operation Scheme; PBSL, Pharmacy Board of Sierra Leone; PV, Pharmacovigilance; RCORE, Regional Centre of Regulatory Excellence; RECs, Regional Economic Communities; RMP, Risk Management Plan; RMM, Risk Minimization Measure; Rwanda FDA, Rwanda Food and Drugs Authority; SOP, Standard Operating Procedure; TTT, Train-the-Trainer; WAHO, West African Health Organization; WHO, World Health Organization

Declarations

Clinical trial number

not applicable.

Ethics declaration

not applicable.

Financial Declaration

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Author Contribution

OR: conceptualization, planning, lead writing, first draft, editing, review of literature, supervising;OR, LAR, EYND, OA, JDKG, JDK, FN, HM: acquisition of data; data validation; LAR, EYND: writing, editing, review of literature; OR, LAR, EYN: table and figure creation; OA, JDKG, JDK, FN, HM: review and further editing; HM: supervising;OR: communication, submission.All Authors read and approved the final manuscript.

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Data Availability

The datasets generated and/or analysed during the current study are not publicly available due confidentiality and data protection rights but are available from the corresponding author on reasonable request.

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Annexes

Annex 1 Activities during VaccTrain

Year	Activity Title	CT or PV	MCA	LMHRA	PBSL	Regional*	Global**
2019	Opportunities for future collaboration (FDA Ghana)	CT and PV	-	-	-	X	-
2019	Kick-off meeting: Marketing Authorization and Pharmacovigilance	PV	X	X	X	X	-
2019	Train-the-Trainer (MCAZ, FDA Ghana)	CT and PV	-	-	-	X	-
2019	Regulatory capacity building: Clinical Trials Oversight (Liberia)	CT	-	X	-	-	-
2019	Regulatory capacity building: Clinical Trials Oversight (Sierra Leone)	CT	-	-	X	-	-
2020	Regulatory capacity building: Pharmacovigilance (Sierra Leone)	PV	-	-	X	-	-
2020	Regulatory capacity building: Pharmacovigilance (Liberia)	PV	-	X	-	-	-
2020	Regulatory capacity building: Pharmacovigilance (The Gambia)	PV	X	-	-	-	-
2020	Pharmacovigilance Workshop (online)	PV	X	X	X	X	-
2020	PV regulatory workshop: Guidelines and SOPs - review and refinement (1/2)	PV	X	X	X	X	-
2020	PV regulatory workshop: Guidelines and SOPs - review and refinement (2/2)	PV	X	X	X	X	-
2021	Workshop on Pharmacovigilance Regulatory Systems Strengthening (online)	PV	X	X	X	-	-
2021	Workshop on COVID-19 Vaccination Campaign (online)	PV	X	X	X	X	-
2022	Satellite meeting with partner countries on VaccTrain 2.0 project	CT and PV	X	X	X	-	-
2023	Workshop on PV training, review of current status of PV and CT system at PBSL	CT and PV	X	X	X	-	-
2023	Informal Benchmarking and Workplan development	CT and PV	-	X	-	-	-
2023	UMC Training	PV	-	-	X	-	X
2023	Scientific Advisory Committee training on CTA Assessment	CT	-	X	-	-	-
2023	Joint online workshop on risk-based GCP Inspection	CT	X	X	X	-	-
2023	Joint GCP Inspection	CT	X	X	X	-	-

Year	Activity Title	CT or PV	MCA	LMHRA	PBSL	Regional*	Global**
2023	Informal Benchmarking and PV Training	CT and PV	X	-	-	-	-
2023	CTO and PV training workshop	CT and PV	X	X	X	-	-
2023	Joint online Workshop GCP inspection technique	CT	X	X	X	-	-
2023	GCP Inspection	CT	X	-	-	-	-
2023	Informal Benchmarking and monitoring progress in PV and CT regulation (online)	CT and PV	-	-	X	-	-
2024	Scientific Advisory Committee PV Workshop on Causality Assessment, Review of PV Guidelines, and Regulation	PV	-	X	-	-	-
2024	CT and PV Workshop (Zimbabwe)	CT and PV	-	-	-	X	-
2024	GVP Training (BoMRA at MCAZ)	PV	-	-	-	X	-
2024	GCP Training (BoMRA at MCAZ)	CT	-	-	-	X	-
2024	UMC Training	PV	X	-	X	-	X
2024	Train-the-Trainer at PEI (Gambia, Liberia, Sierra Leone)	CT and PV	X	X	X	-	-
2024	Inaugural Meeting For Members Of The Medicines Safety Experts Committee & Online Training	CT and PV	X	-	-	-	-
2024	CTO Training Workshop (with AVAREF)	CT	X	X	X	X	-
2024	WAPCP Symposium	PV and CT	X	X	X	X	-
2024	Training workshop on Assessments of Clinical Trials Applications (Namibia)	CT	-	-	-	X	-
2024	Pharmacovigilance Training of Health Care Professionals (online)	PV	X	-	-	-	-
2024	CTO and PV training For the Medicines Safety Expert Committee (online)	CT and PV	X	-	-	-	-
2024	Training on the Roles of the Scientific Advisory Committee	CT and PV	-	X	-	-	-

Year	Activity Title	CT or PV	MCA	LMHRA	PBSL	Regional*	Global**
2024	Train-the-Trainer at PEI (MCAZ)	CT and PV	-	-	-	X	-
2024	Technical support for the development of the Terms of Reference for the Vigilance Technical Committee AMRH-AMA	PV	-	-	-	X	-
2024	WHO AFRO Vaccine Safety Training Workshop for East and Southern Africa Countries	PV	-	-	-	X	-
2024	Study Tour (Sierra Leone)	CT and PV	-	-	X	-	-
2024	Study Tour (Liberia)	CT and PV	-	X	-	-	-
2024	Study Tour (The Gambia)	CT and PV	X	-	-	-	-
2025	AVAREF Training workshop on Assessments of Clinical Trials Applications	CT	X	X	X	X	-
2025	GVP Inspection Training (Ghana)	PV	X	X	X	X	-
2025	WHO RMP Workshop (WHO HQ)	PV	-	-	X	-	X
2025	LMHRA Stakeholder Meeting and GVP inspection	CT and PV	X	X	X	X	X
2025	CTO and PV training workshop	CT and PV	X	-	-	-	-
2025	Public Sensitization Campaign	PV	X	-	-	-	-
2025	Signal Management Training (online)	PV	X	X	X	-	-
2025	WHO RMP Workshop (Uganda)	PV	-	-	-	-	X

**Regional - RCOREs, WHO AFRO, AVAREF, WAHO, CEPI, AUDA-NEPAD); **Global – WHO HQ.*

Abbr. AMA, African Medicines Agency ; AMRH, African Medicines Regulatory Harmonisation; AUDA-NEPAD, African Union Development Agency-New Partnership for Africa's Development; AVAREF, African Vaccine Regulatory Forum; BoMRA, Botswana Medicines Regulatory Authority; CEPI, Coalition for Epidemic Preparedness Innovations; CTA, Clinical Trial Application; CTO, Clinical Trials Oversight; FDA Ghana, Food and Drugs Authority Ghana; GCP, Good Clinical Practice; GVP, Good Vigilance Practice; LMHRA, Liberia Medicines & Health Products Regulatory Authority; MCA, Medicines Control Agency The Gambia; MCAZ, Medicines Control Authority of Zimbabwe; PV, Pharmacovigilance; PBSL, Pharmacy Board of Sierra Leone; PEI, Paul-Ehrlich-Institut; RCORE, Regional Centre of Regulatory Excellence; RECs, Regional Economic Communities; RMP, Risk Management Plan; SOP, Standard Operating Procedure; UMC, Uppsala Monitoring Center;

WAPCP, West African Postgraduates College of Pharmacists; WAHO, West African Health Organization; WHO HQ, World Health Organization Headquarters

Annex 2 Key Performance Indicators (KPIs)

The Gambia

	Number	2017	2018	2019	2020	2021	2022	2023	2024	2025
CTO	CTAs	0	4	7	4	6	3	3	3	3
	GCP inspections	0	0	0	0	0	0	1	0	0
PV	RMPs		0	0	0	0	0	0	0	0
	PSURs	0	0	0	0		0	0	0	6
	PV inspections	0	0	0	0	0	0	0	0	0
	ADR/AEFI reports	-	-	-	-	45	8	51	61	44

Liberia

	Number	2017	2018	2019	2020	2021	2022	2023	2024	2025
CTO	CTAs	0	0	0	0	1	2	1	0	0
	GCP inspections	0	0	0	1	2	1	2	0	0
PV	RMPs	0	0	0	0	0	0	0	0	0
	PSURs	0	0	0	0	0	0	0	0	0
	PV inspections	0	0	0	0	0	0	0	0	2
	ADR/AEFI reports	0	0	0	0	170	0	0	1525	24

Sierra Leone

	Number	2017	2018	2019	2020	2021	2022	2023	2024	2025
CTO	CTAs	2	2	3	1	2	2	4	2	2
	GCP inspections	2	2	1	1	0	1	1	0	1
PV	RMPs	0	0	1	1	0	1	0	2	2
	PSURs	1	2	1	1	2	3	2	2	2
	PV inspections	0	0	0	0	0		0	10	5
	ADR/AEFI reports	287	484	41	1	560	399	896	7	1739

Abbr. ADR, Adverse Drug Reaction; AEFI, Adverse Event Following Immunization; CTA, Clinical Trial Application; CTO, Clinical Trial Oversight; GCP, Good Clinical Practice; PSUR, Periodic Safety Update Report; PV, Pharmacovigilance; RMP, Risk Management Plan.

Figures

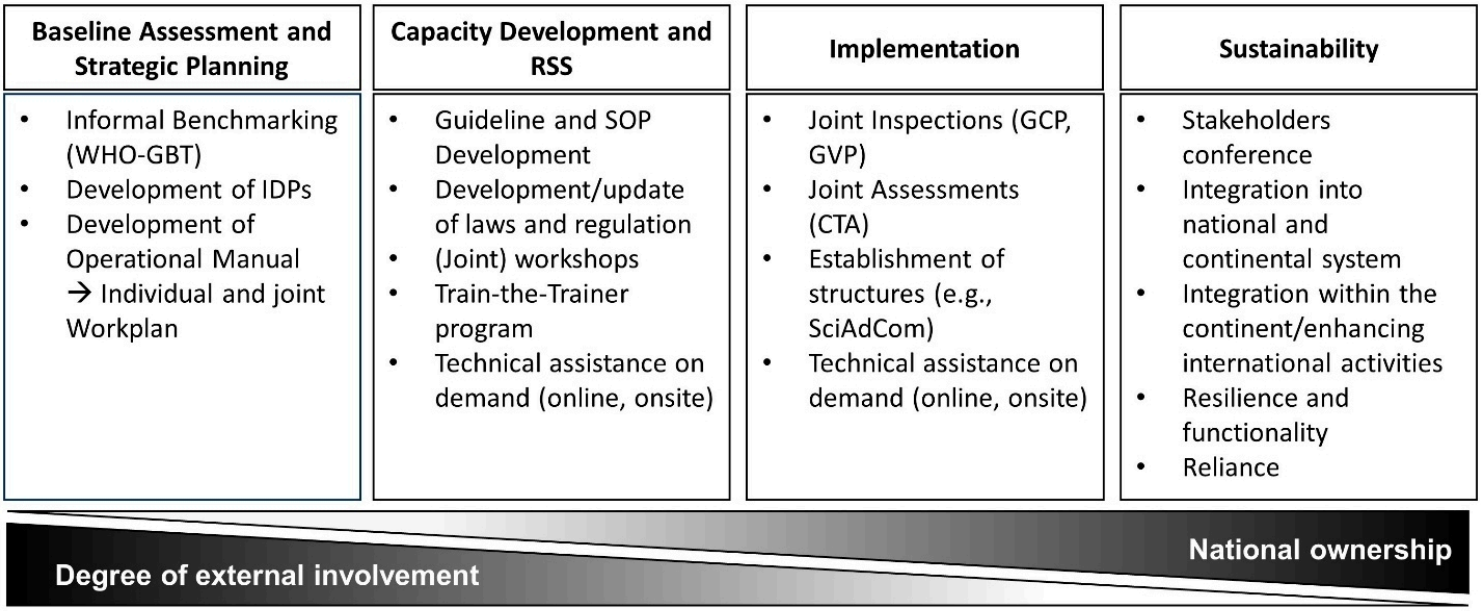


Figure 1

VaccTrain model for regulatory capacity strengthening. Abbr. CTA, Clinical Trial Application; GBT, Global Benchmarking Tool; GCP, Good Clinical Practice; GVP, Good Vigilance Practice; IDPs, Institutional Development Plans; SciAdCom, Scientific Advisory Committee.

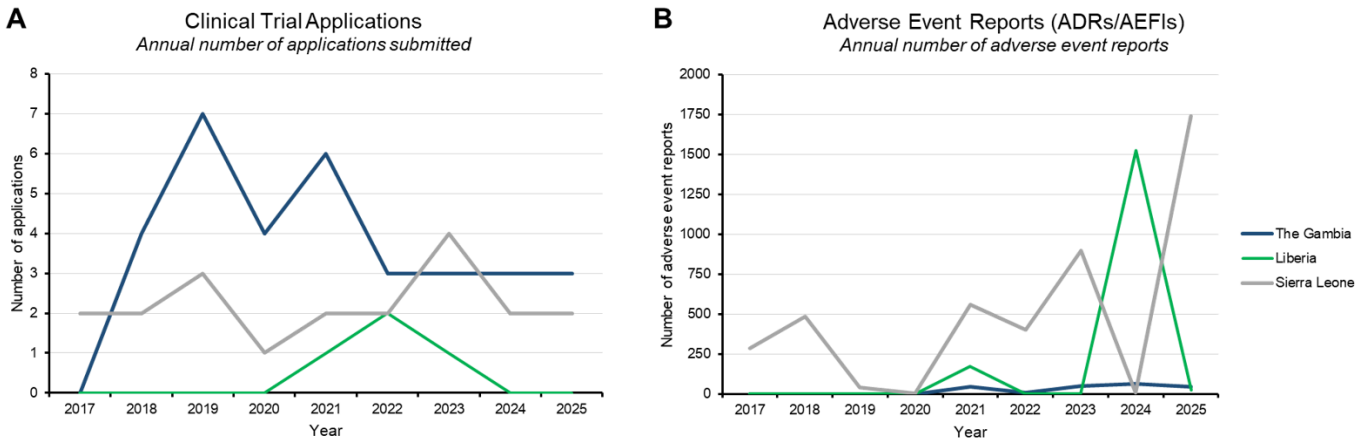


Figure 2

Selected Key Performance Indicators for VaccTrain Partner Countries. Abbr. ADR, Adverse Drug Reaction, AEFI, Adverse Event Following Immunization.